

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-001**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Food Recovery Committee (FRC) Report

**Issue you would like the Conference to consider:**

At the 2018 biennial meeting a Food Recovery Committee was formed to address the unresolved questions related to the practice of food donations posed during the Council I debate on issue 2018-1-24. The Conference charges included reviewing current practices and guidance and determining if a modification of the FDA Food Code was needed for food donation as an allowed practice.

Specifically, the charges were:

1. Evaluate existing materials including the AFDO guidance, Comprehensive Resource for Food Recovery Programs, and any other relevant guidance and documents pertaining to donated food; update the CFP guidance as needed; and evaluate opportunities to better disseminate existing guidance.
2. Identify best practices for handling, storage, and labeling of food for donation.
3. Examine existing state regulations that address food safety procedures for donation.
4. Recommend any necessary language changes to the FDA Food Code to ensure the safety of donated food.
5. Report back to the 2020 Biennial Meeting.

**Public Health Significance:**

Food donation is a safe practice that can reduce food waste and provide food assistance to those in need. The confusion that surrounds what foods can be safely donated and which sections of the Food Code apply to food donation can be addressed by providing easy-to-use guidance for food donations and modifying the FDA Food Code by adding a definition and sections acknowledging the practice.

The need for food assistance is documented by the US Department of Agriculture (USDA). On September 4, 2019, the USDA released its annual study measuring food security

entitled Household Food Security in the United States in 2018. This report is based on data from the December 2018 food security supplement to the U.S. Census Bureau Current Population Survey (CPS), that provides the most recent statistics on the food security of U.S. households, including how much households spent on food, and the extent to which food-insecure households participated in federal programs.

Key findings in the 2018 study report:

- 37.2 million (11.5%) individuals lived in food-insecure households.
- 14.3 million (11.1%) households were food insecure.
- 5.6 million (4.3%) households had very low food security.
- 11.2 million (15.2%) children lived in food-insecure households.
- 2.9 million (7.5%) households with seniors were food insecure.
- 1.3 million (8.9%) households with seniors living alone were food insecure.

The exact number of organizations and food establishments that donate food to food banks and food pantries for distribution to those need is unknown. Feeding America is made up of 200 food banks that work alongside an estimated 60,000 partner agencies. An estimated 20,000 grocery stores donate food to Feeding America-affiliated food banks or their partner agencies. There are numerous other retailers outside of the Feeding America network that donate directly to local food banks and food pantries. The Feeding America network also includes nearly 5,000 food service establishments that donate food to local food recovery operations; there are assumed to be many other food service donations happening outside of the Feeding America network.

<https://www.feedingamerica.org/sites/default/files/research/hunger-in-america/hia-2014-executive-summary.pdf>

Food Donation Connection reports on their website, "In 2017, an estimated 1,400 business entities through 19,300+ foodservice locations (restaurants, airports, travel plazas, retailers, hotels, universities, hospitals, distribution centers) donated 50 million pounds of prepared surplus food to 11,000 hunger relief organizations."

Food donation supports the reduction of food waste. In the United States, an estimated 30-40 percent of the food supply is wasted. The USDA's Economic Research Service estimates that 31 percent of food loss occurs at the retail and consumer levels; a percentage that corresponds to approximately 133 billion pounds of wasted food each year, worth nearly \$161 billion in 2010. [https://foodwastealliance.org/wp-content/uploads/2014/11/FWRA\\_BSR\\_Tier3\\_FINAL.pdf](https://foodwastealliance.org/wp-content/uploads/2014/11/FWRA_BSR_Tier3_FINAL.pdf) This amount of food and economic waste has far-reaching impacts on society. Wholesome food that could have helped feed families in need is sent to landfills. Land, water, labor, energy and other inputs are used in producing, processing, transporting, preparing, storing, and disposing of discarded food.

For food donation to be accomplished in a manner that provides safe food to those in need, this practice must be conducted under the same conditions as food offered for sale. It must come from commercial suppliers under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food and are not acceptable sources of donated food. Controlled processing and post processing handling are required for the safe distribution of donated food.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends acknowledgment of the 2018-1-24 Food Recovery (FR) Committee Report, with thanks to the members of the Committee for their work and dissolution of the FR committee.*

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**Content Documents:**

- "FR Committee Final Report"
- "CFP - FRC- Committee Roster"
- "1 A Handout Draft - How Food Establishments Can Donate Food"
- "1 B Handout Draft - How to Transport Donated Food"
- "1 C Handout Draft - How to Serve Donated Food"
- "1 D Handout Draft - Serving Highly Susceptible Populations"

**Supporting Attachments:**

- "Supporting Attachments Available Online\_CFP"
- "Supporting Attachments Unavailable Online\_CFP"
- "Claire Cummings - Bon Appetit"
- "Example Checklist"
- "Food Recovery Network Accept Foods"
- "Donating Unsold Foods"
- "Sara Gassman - Food Recovery Network II"
- "Syd Mandelbaum - Rock and Wrap it Up"
- "TX Survey Responses"
- "Wayne Melichar - Feeding America"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

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

**COMMITTEE NAME:** Food Recovery

**DATE OF FINAL REPORT:** 11/1/2019

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

**REPORT SUBMITTED BY:** Co-Chairs, Sandra Craig and Mitzi Baum

**COMMITTEE CHARGE(S):**

**Issue #2018-I-024**

1. Evaluate existing materials including the AFDO guidance, Comprehensive Resource for Food Recovery, and any other relevant guidance and documents pertaining to donated food; update the CFP guidance as needed; and evaluate opportunities to better disseminate existing guidance.
2. Identify best practices for handling, storage, and labeling of food for donation.
3. Examine existing state regulations that address food safety procedures for donation.
4. Recommend any necessary language changes to the FDA Food Code to ensure the safety of donated food.
5. Report back to the 2020 Biennial Meeting.

**COMMITTEE WORK PLAN AND TIMELINE:**

1. The Food Recovery committee charges were broad and far reaching but fortunately the interest in the committee was robust and the committee has a large diverse roster. The committee co-chairs immediately recognized that it would be beneficial to have the entire committee review the existing materials and state regulations as a first step. This review was accomplished and discussed on the October 25, 2018 conference call. On the November 29, 2018 call the remaining tasks were broken down for subcommittees to complete.
2. Three initial subcommittees were formed, designated as tasks 1a, 1b and 1c, which were related to charge number 2. The work of the first three subcommittees provided support and insights to subcommittees 2 and 3 which developed guidance fact sheets. The full committee has reviewed and approved the deliverables of the first three subcommittees. One and two-page informational fact sheets (infographics) have been developed by the task 1 groups and then further refined by the task 2 and 3 groups. An additional subcommittee was formed to address the 4<sup>th</sup> charge after the work was completed on the infographics as they have completed their task of proposing language changes to the FDA Food Code to address Food Donation.
3. The committee has extensive diversity; therefore, it was not necessary to reach outside of the committee for consultation. We had a subject matter expert from all segments affected by food donations.
4. There were challenges related to the timelines imposed by the report deadlines, the time on the front end in selecting committee members and establishing the initial work plan. We were extremely fortunate to have committee members who had the ability to devote large amounts of time to committee work to allow us to meet the deadlines.

**COMMITTEE ACTIVITIES:**

Dates of committee meetings or conference calls: The full committee has met on the last Thursday of each month at 1:00 CST.

1. 9/2/18, 10/25/18, 11/29/18, 1/31/19, 2/28/19, 3/28/19, 4/24/19, 5/30/19, 6/27/19, 8/29/19, 9/26/19 & 10/24/19.
2. **Overview of committee activities:**

We reviewed the charges and began to review literature.

Existing regulations were identified in several states and local jurisdictions. Those that we have reviewed were Texas, Vermont, Washington and California.

The full committee was charged with reviewing documents prior to the formation of the subcommittee work groups. The full committee conference calls were used to discuss what has been gleaned from review of these documents. It was from this review that the committee felt that the existing guidance documents are sound, provide the appropriate food safety guidance but that due to the size and scope of these documents that they needed to be broken down into manageable, teachable segments. It was then determined that developing one- and two-page fact sheets from the materials in the guidance documents would be the best way to achieve the goals set out for the committee.

The members studied many documents that have formed the basis of the work of the committee. By reviewing what already exists, the committee gleaned information from existing regulations and was able to form opinions and create the final documents to be submitted. The first need that was identified is the need to uniformly address terms in a manner that the lay person will understand. Can we simplify the terms and yet address the food safety need?

The committee decided that it would be more efficient to break into subcommittees. The first subcommittee groups (1a, 1b & 1c) completed the work on charge #1, developing ways to better disseminate existing guidance. They met by phone every 2-3 weeks between full committee calls.

Subcommittee 1a - They had multiple conference calls and interacted online. They sent out a survey to this group. This group dealt more with creating documents for permitted food establishments, so the simplification was not as critical. They developed tools to sort out donation questions.

Subcommittee 1b - This group used email communications and multiple conference calls. They sent out a survey to the larger group to assist in developing the guidance and then developed guidance documents for their target audience.

Subcommittee 1c - Multiple meetings (calls) This group managed the issue of charitable organizations and how to define them. They sent out two (2) surveys: 1) to the members of Subcommittee 1c and 2) another survey to the larger committee. This help to ensure that they were aligned and there was no duplication of effort in the overlapping areas.

Subcommittee 4 had several conference calls and shared drafts of the proposed FDA Food Code revision as members made edits. Subcommittee members were each assigned a subsection of the proposed Food Code section to develop/improve. This group reported back to the full committee on the monthly call.

The work of subcommittee 3 was delegated back to the full committee and was discussed on the monthly full committee calls.

When the full committee met, we reviewed charges and timeline to complete the work, provide updates on progress for projects - each subcommittee reported on their progress, we discussed how to avoid duplicative work and next steps. The full committee has reviewed the following documents - which are the documents the subcommittees used to develop the infographics fact sheet guidance tools. These documents are listed in our supporting attachments.

CFP Comprehensive Guidance for Food Recovery

Starbucks Food Safety Management System for Food Donation

California Retail Food Code for Food Donations

Texas Food Establishment Rules

Washington State Department of Health Food Rescue - donation guide for businesses; school food donation guidelines

Washington Retail Food code

Vermont Guidance for Food Donation - businesses

AFDO Model Consumer Commodity Salvage Code

Guidance for Indiana schools

FSIS Directive 7020.1

Guidance and Documents pertaining to donated foods

IFPTI - Kansas legislators' opinions about food safety regulation of hunger relief organizations

Food Safety Regulations and Guidance for Food Donations - a 50 State Survey of State Practices (Harvard)

Plus many links to food safety and donation resources

The committee is submitting an issue for conference approval to add the infographic fact sheets to the current CFP Comprehensive Guidance for Food Recovery.

The subcommittee charged with developing any necessary changes to the FDA Food Code has reviewed the issue previously submitted to CFP (issue 2018-I-24) and the discussions which occurred in council during the conference in 2018. It was the opinion of the subcommittee that the code needs to acknowledge food donation as a practice and provide some general guidance regarding which parts of the code should apply to the practice. The committee is submitting an issue proposing these changes to the food code.

In addition to these committee activities, Mitzi Baum of Stop Foodborne Illness (co-chair) and several other CFP members, including Shana Davis of The Kroger Company, and Dr. Ernie Julian of the Rhode Island Department of Health, participated in the session "Reducing Food Waste: Industry and Regulatory Perspectives on Food Recovery Systems." at the Association of Food and Drug Officials (AFDO) annual educational conference in Atlanta, GA, June 22 - 26, 2019. Mitzi has also presented at the MCAFDO (Mid Continental Association of Food and Drug Officials) conference in February on food waste and recovery. Mitzi and Wayne Melichar (voting committee member) are participating on a newly created Food Recovery standing committee of AFDO. All of these events are outstanding examples of the MOU established between CFP and AFDO in an effort to work on issues in a mutually collaborative effort and our committee is pleased to play a part in this effort.

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

- A.a.** Evaluate existing materials including the AFDO guidance, Comprehensive Resource for Food Recovery, and any other relevant guidance materials and documents pertaining to donated food; update the CFP guidance as needed; and evaluate opportunities to better disseminate existing guidance. The review has been completed, we did not find a need to update the CFP guidance document as the recommendations in it are sound, science based and relevant. We evaluated the opportunities to better disseminate guidance and came to the conclusion that creating simple, easy to follow one- and two-page fact sheets on specific food safety topics related to the handling and preparation of donated food would be our focus.
- A.b.** Examine existing state regulations that address food safety procedures for donation. This review has been completed.
- A.c.** Identify best practices for handling, storage, and labeling of food for donation. This review has been completed and has been used to create the fact sheets.
- A.d.** Recommend any necessary language changes to the FDA Food Code to ensure the safety of donated food. This charge has been completed, a subcommittee took the proposed FDA Food Code recommendations that were submitted in the 2018 issue and refined it based on the discussion of the group and the research completed by the committee on existing state or local laws that have been reviewed.
- A.e.** Report back to the 2020 Biennial Meeting. The committee is prepared to report to the 2020 conference.

**4. Charges INCOMPLETE and to be continued to next biennium:**

**None**

**COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:**

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

**LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:**

**1. Issue #1: Food Recovery Committee (FRC) Report**

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

- (a.1) Committee Final Report (see attached PDF)**
- (a.2) Committee Member Roster (see attached PDF)**
- (a.3) 1 A Handout (see attached PDF)**
- (a.4) 1 B Handout (see attached PDF)**
- (a.5) 1 C Handout (see attached PDF)**
- (a.6) 1 D Handout (see attached PDF)**

**b. List of supporting attachments:**

- 1. Supporting Attachments Available by Links
- 2. Supporting Attachments Unavailable by Links
- 3. Claire Cummings - Bon Appetit (2019)
- 4. Example Checklist (2015)
- 5. Food Recovery Network Accept Foods (2019)
- 6. Donating Unsold Foods (2019)
- 7. Sara Gassman - Food Recovery Network II (2014)
- 8. Syd Mandelbaum - Rock and Wrap It Up (2014)
- 9. TX Survey Responses (2019)
- 10. Wayne Melichar - Feeding America (2014)

## **2. Committee Issue #2: FRC Food Code Amendment**

- a. List of content documents submitted with this Issue:** None
- b. List of supporting attachments:** See supporting attachments to Issue #1, Food Recovery Committee (FRC) Report.

## **3. Committee Issue #3: FRC Infographic Handouts Acceptance for Approval and Posting**

- a. List of content documents submitted with this Issue:** Infographics handouts submitted with Issue #1, Food Recovery Committee (FRC) Report
- b. List of supporting attachments:** See supporting attachments to Issue #1, Food Recovery Committee (FRC) Report.

Committee Roster

Committee Name: Food Recovery									
First Name	Last Name	Email	Constituency	Organization	City	State	CFP Region	Phone	Position (Chair/ Member)
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Susan	Algeo	susan@savvyfs.com	Food Industry Support	Savvy Food Safety, Inc.	Hagerstown	MD	Mid-Atlantic	855-644-3787	At-Large Non-Voting Member
Rance	Baker	rbaker@neha.org	Food Industry Support	National Environmental Health Association	Denver	CO	Southwest	303.756.9090	At-Large Non-Voting Member

## Committee Roster

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## Committee Roster

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## How Food Establishments Can Donate Food

Businesses that donate food are protected from liability by the Bill Emerson Good Samaritan Food Donation Act and may be eligible for federal tax deductions or state tax incentives.

### Follow this process when donating surplus food:



#### Partner with a charity. Decide together:

- What can be donated?
- How much? How often?
- How will it be transported?

1



#### Prepare food according to local health regulations.

- Only donate foods that have been handled and stored safely.
- If foods have been cross-contacted with a major food allergen, label them "**NOT Allergen-Free**" before donating.

2

3

#### Package food in clean, food-grade packaging.

- Some charitable feeding organizations may provide you with reusable food-grade containers.
- Unopened food items should be donated in their original commercial packaging.



4

#### Label food with:

- Name of the food;
- Date the food was prepared;
- Any major allergens in the food;
- Your establishment's contact information.



5

#### Store food according to these guidelines:

- Dry food should be stored at least six inches off the floor, separated from foods containing major allergens, and kept away from chemical products.
- Refrigerated food must be stored at 41°F or below. Store food according to cooking temperature, with foods requiring the highest cooking temperature on the bottom.
- Cover food to prevent cross-contamination.
- Store all foods separately from unsafe, spoiled, or recalled foods.



## How to Hand Off Food

Before handing off donated food to a delivery driver, take these steps.

1. Ensure that the transporting vehicle has special equipment to keep hot foods hot and cold foods cold. Insulated coolers, insulated blankets, frozen ice packs, hot boxes, or refrigerated compartments can all be used to provide temperature control.

2. Keep the following records:

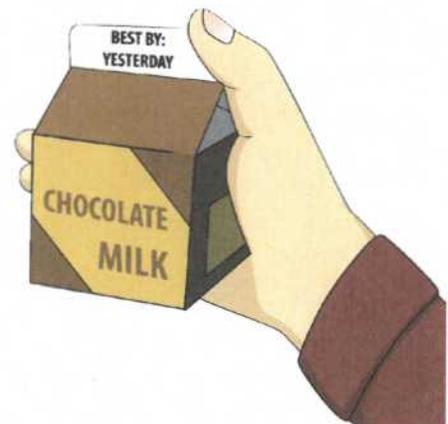
- > Name and location of food donor
- > Date the food was prepared/harvested
- > Type of food donated
- > Food temperature at pickup
- > Name of the person who transported the food



## Additional Donation Information

### “Best by” Dates

Food packaging dates (“best by,” “use by,” and “sell by”) are meant to tell consumers how long the product will be at peak quality. They do not indicate when the food is safe to eat. If handled properly, most foods will be safe to eat well after the “best by” date and could potentially be donated. Before donating foods that are past their “best by” date, confirm with the charitable feeding organization that it will accept them.



### Food Recalls

Contact the charitable feeding organization if a food recall is issued that you know affects donated food. The recipient organization is also responsible to help track food recalls.



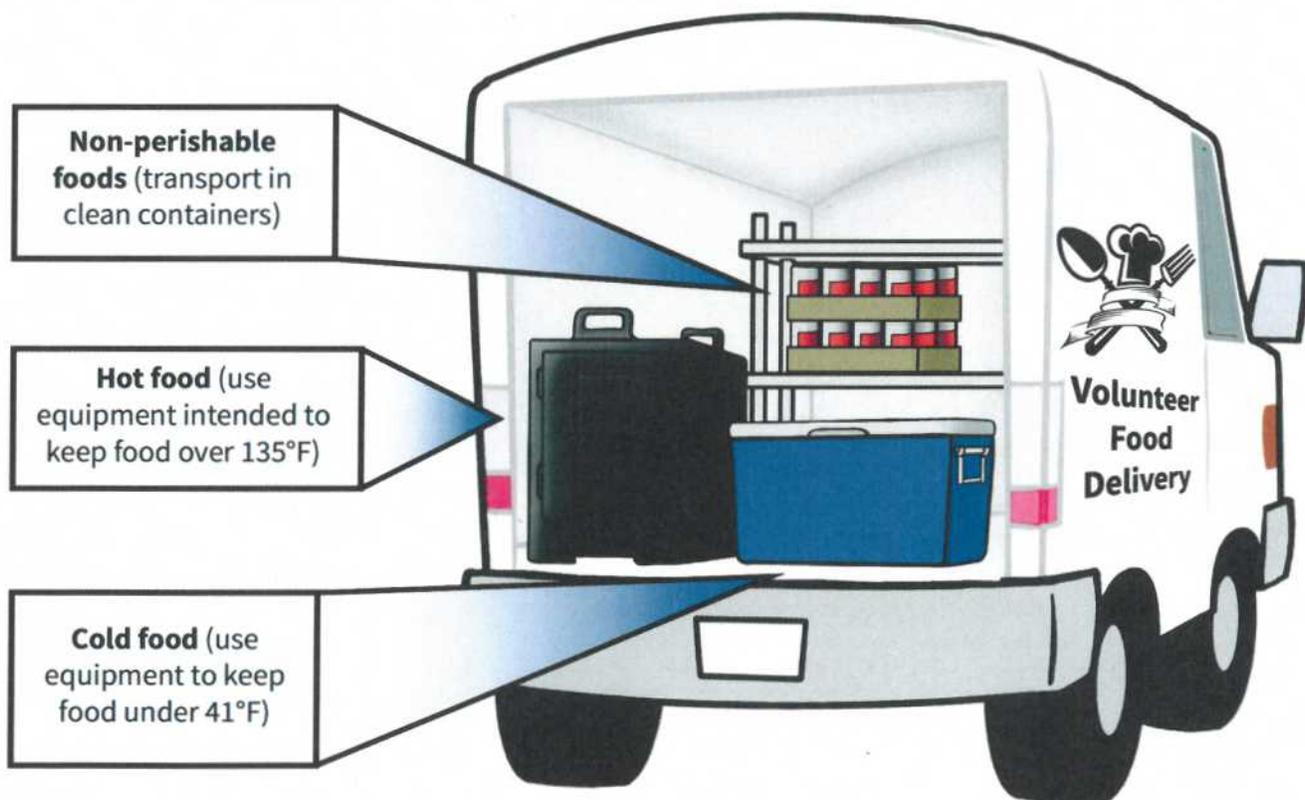


## How to Transport Donated Food

**When transporting donated food in any vehicle, make sure to follow these principles.**

- Use an insulated cooler, insulated blanket, frozen ice packs, hot box, or refrigerated compartment to control food temperatures. Each container should be cleaned and sanitized after every use.
- Store foods with lower cooking temperatures above foods with higher cooking temperatures (i.e. store salad above raw chicken).
- Keep hot foods hotter than 135°F and cold foods colder than 41°F.

**You may handle three types of food: Non-perishable foods, hot foods and cold foods.**



Consult your local regulatory authority if you have questions about safely transporting hot or cold food.



## Personal Health and Hygiene

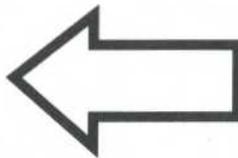
When volunteering to transport donated food, remember to use good hygiene practices.



## Keep Records for Donated Food

If you are volunteering with an established charitable feeding organization, make sure to follow their procedures. If the organization does not have any record-keeping procedures, follow the template below.

- > Name and location of food donor
- > Date the food was prepared/harvested
- > Type of food donated
- > Food temperature at pickup
- > Name of the person who transported the food
- > Name and location of delivery destination
- > Name of person accepting the delivery
- > Food temperature at delivery



Keep records for at least the past two years. Some charitable feeding organizations may need you to provide records when you deliver donated food.



## How to Serve Donated Food

As a volunteer for a charitable feeding organization, you should follow these basic food safety principles.

### When receiving new food donations, make sure:

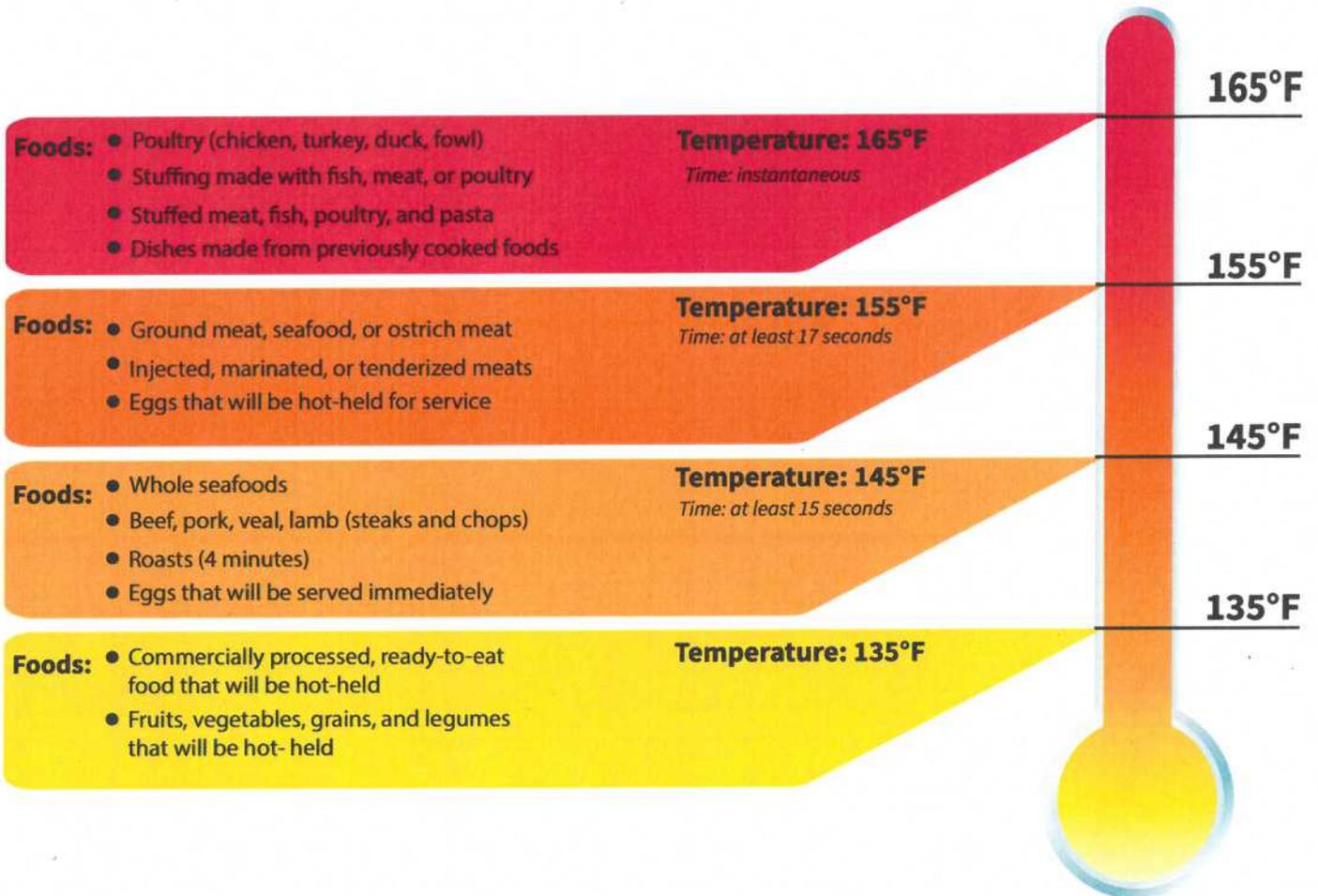
- > All food is from approved suppliers.
- > Manufactured food is in original, sealed, and undamaged packages.
- > Food prepared at retail establishments is labeled with food name, date prepared, major allergens, and the establishment's contact information.

Food Type	Receiving Requirements	Foods to Avoid
Prepared Foods	Cold - 41° or below Hot - 135° F or above Frozen solid	<ul style="list-style-type: none"> <li>● Foods that are in the danger zone (41°F - 135°F)</li> <li>● Previously reheated foods</li> <li>● Previously served foods</li> </ul>
Chilled Prepackaged Perishables	41° F or below	<ul style="list-style-type: none"> <li>● Foods that are above 41° F</li> <li>● Damaged or bulging packaging</li> <li>● Raw or unpasteurized dairy products and juices</li> </ul>
Raw Meat Poultry, Fish	41° F or below (Unfrozen) Frozen solid	<ul style="list-style-type: none"> <li>● Raw meat products that are above 41° F</li> <li>● Frozen foods that are thawed (defrosted)</li> </ul>
Whole Produce	Good Condition	<ul style="list-style-type: none"> <li>● Food that is dirty or has significant decay</li> <li>● Foods grown without good agricultural practices (Exposed to contamination)</li> </ul>
Cut Produce	41° F or below	<ul style="list-style-type: none"> <li>● Cut produce that is above 41° F</li> <li>● Color change or decay</li> </ul>
Baked Goods	Good Condition	<ul style="list-style-type: none"> <li>● Moldy or stale products</li> <li>● Evidence of damaged packaging (mice, rats)</li> </ul>
Canned/Boxed Foods	Good Condition	<ul style="list-style-type: none"> <li>● Leaking, damaged, or bulging packaging</li> <li>● Open packages</li> <li>● Home-canned products</li> <li>● Packaged products that show evidence of insect or rodent damage or infestation</li> </ul>



## Preparing and Serving Food

- > Don't handle food if you're feeling sick.
- > Wash hands frequently & always use gloves.
- > Keep your facility clean.
- > Only use potable (drinkable) water.



## Reheating and Holding Food

- > Keep cold food at 41°F or colder.
- > Keep hot food at 135°F or hotter.
- > Only reheat food one time using a microwave, oven, or stove.
- > Discard food that's been held without temperature control after four hours.

## OLDER ADULTS

Disaster Victims

## Infants and toddlers

People from food-insecure households

## People who are homeless or transient

People with behavioral health or substance abuse issues

People with chronic illness and weakened immune systems

## Pregnant women

## SERVING HIGHLY SUSCEPTIBLE POPULATIONS

Take extra care when preparing and serving donated food. Many guests at charitable organizations may be from highly susceptible populations (HSPs). HSPs have an increased risk of foodborne illness and resulting complications. HSPs may include:



## FEELING SICK?

If you have any of the symptoms on the right, notify your manager, go home, and rest! Come back when you've been symptom-free for at least 24 hours.



## VOMITING

INFECTED SORES

## DIARRHEA

YELLOWING OF EYES

## SORE THROAT FEVER

If you have a sore throat and fever or jaundice, or have been diagnosed with norovirus, hepatitis A, E. coli, Shigella, or Salmonella infection, talk to a doctor before volunteering again.

## Supporting Attachments Available Online

<b>Selected Legislation</b>			
Document	Source	Summary	Link:
Texas Food Establishment Rules	Texas Department of State Health Services	Comprehensive food safety regulations for donated food (pg. 84-85)	<a href="https://www.dshs.texas.gov/WorkArea/linkit.aspx?LinkIdentifier=id&amp;ItemID=8590002102">https://www.dshs.texas.gov/WorkArea/linkit.aspx?LinkIdentifier=id&amp;ItemID=8590002102</a>
California Retail Food Code, Article 7: Food Facility Food Donations	California Department of Public Health	Comprehensive food safety regulations for donated food (pg. 138-139)	<a href="https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/MEHKO/CALIFORNIA%20RETAIL%20FOOD%20CODE%202019.pdf">https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/MEHKO/CALIFORNIA%20RETAIL%20FOOD%20CODE%202019.pdf</a>
California Assembly Bill 2178: Limited Service Charitable Feeding Operation	California Legislative Information	A bill, signed into law in 2018, detailing exemptions from being a food facility by limited service charitable feeding operations in California	<a href="https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB2178">https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB2178</a>

<b>Guidance Documents and Directives</b>			
Document	Source	Summary	Link:
Food Rescue – Donation Guide for Businesses; School Food Donation Guidelines	Washington State Department of Health	Guidance for business and school food donation programs	<a href="https://www.doh.wa.gov/CommunityandEnvironment/Food/FoodWorkerandIndustry/SchoolFoodDonations">https://www.doh.wa.gov/CommunityandEnvironment/Food/FoodWorkerandIndustry/SchoolFoodDonations</a>
Model Consumer Commodity Salvage Code	Association of Food and Drug Officials (AFDO)	Guidance for food safety with donated food	<a href="http://www.afdo.org/resources/Documents/Committee%20Reports%202016-2017/Model%20Sorting%20and%20Salvage%203.28.18.pdf">http://www.afdo.org/resources/Documents/Committee%20Reports%202016-2017/Model%20Sorting%20and%20Salvage%203.28.18.pdf</a>
Guidance for Indiana Schools	Indiana State Department of Health	Guidance for school food donation programs	<a href="https://www.in.gov/isdh/files/School_Sharing_Tables_and_Food_Recovery_12-23-2015_(2).pdf">https://www.in.gov/isdh/files/School_Sharing_Tables_and_Food_Recovery_12-23-2015_(2).pdf</a>
Food Safety Inspection Service (FSIS) Directive 7020.1	United States Department of Agriculture (USDA) FSIS	Directive for Donation of Misbranded and Economically Adulterated Meat and Poultry Products to Non-Profit Organizations	<a href="https://www.fsis.usda.gov/wps/wcm/connect/25e1becc-4201-4cc0-a707-c9ed38a2f01c/7020.1.pdf?MOD=AJPERES">https://www.fsis.usda.gov/wps/wcm/connect/25e1becc-4201-4cc0-a707-c9ed38a2f01c/7020.1.pdf?MOD=AJPERES</a>

Guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from the Inspection Requirements of the Federal Meat Inspection Act	USDA FSIS	Directive detailing exemptions from meat inspection requirements	<a href="https://www.fsis.usda.gov/wps/wcm/connect/16a88254-adc5-48fb-b24c-3ea0b133c939/Compliance-Guideline-Livestock-Exemptions.pdf?MOD=AJPERES">https://www.fsis.usda.gov/wps/wcm/connect/16a88254-adc5-48fb-b24c-3ea0b133c939/Compliance-Guideline-Livestock-Exemptions.pdf?MOD=AJPERES</a>
Vermont Guidance for Food Donation	Vermont Agency of Natural Resources; Vermont Department of Health	Guidance for businesses and institutions on donating food safely	<a href="http://www.healthvermont.gov/sites/default/files/documents/2016/11/ENV_FL_DonatingFoodSafely.pdf">http://www.healthvermont.gov/sites/default/files/documents/2016/11/ENV_FL_DonatingFoodSafely.pdf</a>
Comprehensive Resource for Food Recovery Programs	Conference for Food Protection	Guidance for food recovery programs detailing safe practices	<a href="http://www.foodprotect.org/media/guide/comprehensive-resource-for-food-recovery-2016-version.pdf">http://www.foodprotect.org/media/guide/comprehensive-resource-for-food-recovery-2016-version.pdf</a>
Safe Surplus Food Donation Toolkit: Guidance for Food Facilities	Public Health Alliance of Southern California	Guidance detailing best practices for safely recovering food	<a href="https://phasocal.org/wp-content/uploads/2018/02/Safe-Surplus-Food-Donation-Toolkit-Version-2-Jan-2018.pdf">https://phasocal.org/wp-content/uploads/2018/02/Safe-Surplus-Food-Donation-Toolkit-Version-2-Jan-2018.pdf</a>
Food Recovery Checklist	Food Recovery Network	General checklist for food recovery programs	<a href="https://static1.squarespace.com/static/555b5cf1e4b0864ccf1a0156/t/5c98ef9d971a187c49629390/1553526685917/Food+Recovery+Checklist.pdf">https://static1.squarespace.com/static/555b5cf1e4b0864ccf1a0156/t/5c98ef9d971a187c49629390/1553526685917/Food+Recovery+Checklist.pdf</a>
Food Safety Guidelines	Food Recovery Network	Food safety information specific to food recovery programs	<a href="https://static1.squarespace.com/static/555b5cf1e4b0864ccf1a0156/t/5c98efbe4966bff81ea4424/1553526719256/Food+Safety+Guidelines.pdf">https://static1.squarespace.com/static/555b5cf1e4b0864ccf1a0156/t/5c98efbe4966bff81ea4424/1553526719256/Food+Safety+Guidelines.pdf</a>
Donating Retail Exempt Meat or Poultry Product	USDA FSIS	A Q&A log detailing the response to a question pertaining to the donation of meat and poultry products	<a href="https://askfsis.custhelp.com/app/answers/detail/a_id/2025/~/-/donating-retail-exempt-meat-or-poultry-product">https://askfsis.custhelp.com/app/answers/detail/a_id/2025/~/-/donating-retail-exempt-meat-or-poultry-product</a>
Guidance on the Food Donation Program in Child Nutrition Programs	USDA Food and Nutrition Service (FNS)	Guidance detailing the donation of food through Child Nutrition Programs	<a href="https://fns-prod.azureedge.net/sites/default/files/cn/SP11_CAC_FP05_SFSP07-2012os.pdf">https://fns-prod.azureedge.net/sites/default/files/cn/SP11_CAC_FP05_SFSP07-2012os.pdf</a>

## Research and Reports

Document	Source	Summary	Link:
Food Safety Regulations and Guidance for Food Donations – a 50 State Survey of State Practices	Harvard Center for Health Law and Policy Innovation	A report detailing the regulations and guidance documents that exist through state regulatory agencies	<a href="https://www.chlpi.org/wp-content/uploads/2013/12/50-State-Food-Regs_March-2018_V2.pdf">https://www.chlpi.org/wp-content/uploads/2013/12/50-State-Food-Regs_March-2018_V2.pdf</a>
Kansas Legislators' Opinions About Food Safety Regulation of Hunger Relief Organizations	International Food Protection Training Institute	A research project detailing the perceptions and opinions of state legislators as it relates to hunger relief	<a href="https://ifpti.org/fellowship-program/published-works/kansas-legislators-opinions-about-food-safety-regulation-of-hunger-relief-organizations/">https://ifpti.org/fellowship-program/published-works/kansas-legislators-opinions-about-food-safety-regulation-of-hunger-relief-organizations/</a>
Does Food Safety Training for Non-Profit Food Service Volunteers Improve Food Safety Knowledge and Behavior?	Food Protection Trends	A research project detailing the change in knowledge of volunteers after participating in a food safety educational program	<a href="http://www.foodprotection.org/files/food-protection-trends/May-Jun-14-Smith.pdf">http://www.foodprotection.org/files/food-protection-trends/May-Jun-14-Smith.pdf</a>
Food Safety Legislation 2018	National Conference of State Legislatures	A report detailing acts of legislation by states in 2018, including those related to	<a href="http://www.ncsl.org/research/agriculture-and-rural-development/food-safety-legislation-2018.aspx">http://www.ncsl.org/research/agriculture-and-rural-development/food-safety-legislation-2018.aspx</a>
A Place at the Table: Prohibitions on Sharing Food with People Experiencing Homelessness	The National Coalition for the Homeless and The National Law Center on Homelessness and Poverty	A report detailing the ways that organizations and people who serve other people experiencing homelessness can be penalized and criminalized for their service	<a href="https://nlchp.org/wp-content/uploads/2018/10/A_Place_at_the_Table.pdf">https://nlchp.org/wp-content/uploads/2018/10/A_Place_at_the_Table.pdf</a>
Share No More: The Criminalization of Efforts to Feed People in Need	National Coalition for the Homeless	A report detailing the criminalization of efforts to feed people experiencing hunger and food insecurity	<a href="http://nationalhomeless.org/wp-content/uploads/2014/10/Food-Sharing2014.pdf">http://nationalhomeless.org/wp-content/uploads/2014/10/Food-Sharing2014.pdf</a>
Food Loss and Waste	Council for Agricultural Science and Technology	A report detailing the need for innovative approaches and technologies for addressing food waste	<a href="https://www.cast-science.org/wp-content/uploads/2018/12/CAST_IP62_Food_Loss_and_Waste_5BA7C2603929F.pdf">https://www.cast-science.org/wp-content/uploads/2018/12/CAST_IP62_Food_Loss_and_Waste_5BA7C2603929F.pdf</a>
The Occurrence and Prevention of Foodborne Disease in Vulnerable People	Foodborne Pathogens and Disease	A research publication detailing the prevalence of foodborne diseases in vulnerable populations, including people	<a href="https://dx.doi.org/10.1089%2Ffpd.2011.0860">https://dx.doi.org/10.1089%2Ffpd.2011.0860</a>

		experiencing food insecurity	
Food Insecurity – Key Statistics and Graphics	USDA Economic Research Service (ERS)	A compilation of data and graphs detailing the prevalence of food insecurity in the United States	<a href="https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/key-statistics-graphics/">https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/key-statistics-graphics/</a>
Analysis of U.S. Food Waste Among Food Manufacturers, Retailers, and Restaurants	Food Waste Reduction Alliance	A report detailing the assessment and analysis of food waste in the United States. food industry.	<a href="https://foodwastealliance.org/wp-content/uploads/2014/11/FWRA_BSR_Tier3_FIN_AL.pdf">https://foodwastealliance.org/wp-content/uploads/2014/11/FWRA_BSR_Tier3_FIN_AL.pdf</a>
Hunger in America in 2014: Executive Summary	Feeding America	A report detailing the prevalence of hunger in the United States, the experiences of people who are food insecure, and the work supported through Feeding America to address it.	<a href="https://www.feedingamerica.org/sites/default/files/research/hunger-in-america/hia-2014-executive-summary.pdf">https://www.feedingamerica.org/sites/default/files/research/hunger-in-america/hia-2014-executive-summary.pdf</a>

### Media/Press

Document	Source	Summary	Link:
Food Banks Across the Country Increasingly Focusing on Food Safety	Food Safety News	An article detailing the ways in which food banks place emphasis on food safety in their work	<a href="https://www.foodsafetynews.com/2018/10/food-banks-across-the-country-increasingly-focusing-on-food-safety/">https://www.foodsafetynews.com/2018/10/food-banks-across-the-country-increasingly-focusing-on-food-safety/</a>
GAO Report Examines How Date Label Confusion Contributes to Food Waste	Food Safety News	An article detailing the findings of a GAO report detailing the connection between date labeling and food waste	<a href="https://www.foodsafetynews.com/2019/09/gao-report-examines-how-date-label-confusion-contributes-to-food-waste/">https://www.foodsafetynews.com/2019/09/gao-report-examines-how-date-label-confusion-contributes-to-food-waste/</a>

## Supporting Attachments Unavailable Online

<b>Guidance Documents and Directives</b>			
Document	Source	Summary	PDF File Name
Food Safety Management System for Food Donation	Starbucks	Guidelines for Starbucks employees who engage in food donation	N/A
Example TOOL: Donation Quick Checklist	Unknown	A checklist and sample labels that can be used when donating foods	ExampleChecklist201510261
Acceptable Foods to Donate	Food Recovery Network	A list of foods that are and are not acceptable for donation	FoodReoveryNetwrk_Accept_Foods_to_Donate

<b>Presentations</b>			
Document	Source	Summary	PDF File Name
Donating Unsold Food: Reducing the Poverty Footprint	United States Department of Agriculture (USDA) Webinar: Donating Unsold Food	A presentation detailing the work of Rock and Wrap It Up	Syd Mandelbaum – Rock and Wrap It Up
Tips on Food Recovery from Food Recovery Network	USDA Webinar: Donating Unsold Food	A presentation detailing the work of the Food Recovery Network	Sara Gassman – Food Recovery Network II
Q&A Transcript	USDA Webinar: Donating Unsold Food	A transcript record of the Q&A session that was incorporated into the USDA webinar	Q&As from Donating Unsold Food webinar
Donating Unsold Food – A Primer on Liability, Food Safety, and the Good Samaritan Act	USDA Webinar: Donating Unsold Food	A presentation detailing the intersections of liability, food safety, and the Good Samaritan Act by Feeding America	Wayne Melichar – Feeding America
Feeding People and Fighting Food Waste: Leadership in Food Recovery	USDA Webinar: Donating Unsold Food	A presentation detailing the work of the Bon Appetit Management Company in addressing food insecurity	Claire Cummings – Bon Appetit Management Co

<b>Data</b>			
Document	Source	Summary	PDF File Name
2019 Survey Data	Harris County Public Health; Pasadena, Texas	Selected responses from a 2019 survey of food businesses to document their food donation practices	TX Survey Responses



# FEEDING PEOPLE AND FIGHTING WASTE

LEADERSHIP IN FOOD RECOVERY

**BON APPÉTIT**  
MANAGEMENT COMPANY

*food service for a sustainable future®*

# BON APPÉTIT MANAGEMENT COMPANY



# BON APPÉTIT MANAGEMENT COMPANY



# BON APPÉTIT MANAGEMENT COMPANY

## **We're proud to be the first food service company to commit to:**

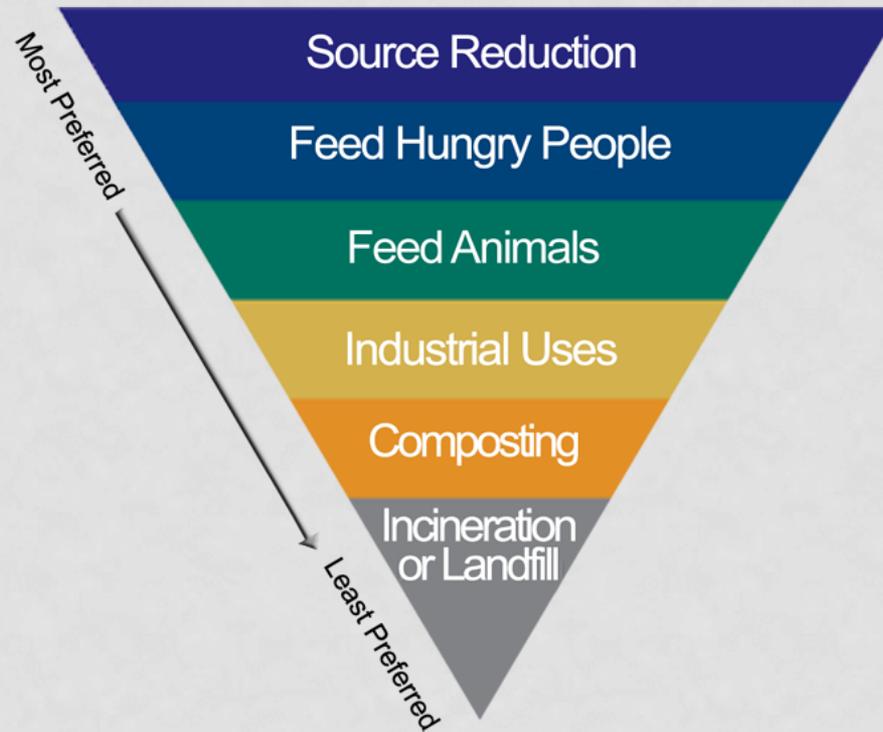
- Supporting local agriculture companywide, since 1999
- Serving only seafood that meets Seafood Watch sustainability guidelines, since 2002
- Reducing antibiotic use in farm animals, since 2003
- Serving only rBGH-free milk, since 2003
- Offering 100% café-free shell eggs, since 2005
- Tackling food's role in climate change, since 2007
- Upholding farmworkers' rights, since 2009
- Serving only humanely raised ground beef, since 2012
- Phasing out all pork raised with gestation crates, by 2015

# WASTE SPECIALIST



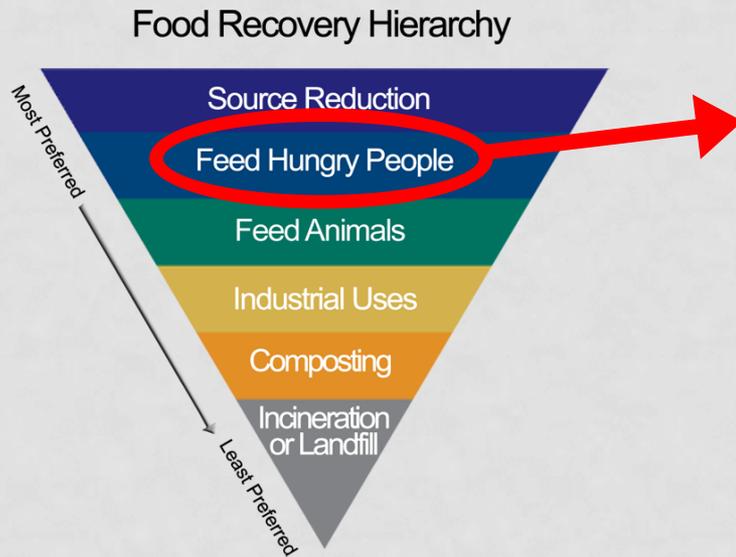
# OUR APPROACH

## Food Recovery Hierarchy



# FEED HUNGRY PEOPLE

There is no reason to compost wholesome, excess food when it could feed someone in need!



- We have over 100 food recovery programs in which excess food from our cafés is donated to people in need in our community
- We helped the Food Recovery Network develop their national guide to food recovery for chefs and managers
- We were the first business in the country to get Food Recovery Certified and now have over 30 cafes certified
- We are supporting the development of resources on gleaning which is the process of harvesting produce that would otherwise go to waste, to donate to people in need

# TRAINING

**BON APPÉTIT**  
MANAGEMENT COMPANY

*food services for a sustainable future®*

## A Guide to Food Recovery for Chefs and General Managers

May 14, 2013

Authored by Claire Cummings, West Coast Fellow

### Tables of Contents

- I. Purpose
- II. Process
- III. Foods to Donate
- IV. How to Find an Organization
- V. Tips for Success
- VI. Frequently Asked Questions and Concerns
- VII. Contact Information
- VIII. Appendix
  - i. Feeding America
  - ii. Chefs to End Hunger
  - iii. The Food Recovery Network
  - iv. The Bill Emerson Good Samaritan Food Donation Act
  - v. Works Cited

May 2013 | Bon Appétit Management Company | [www.BAMCO.com](http://www.BAMCO.com)



**webcast**  
EDUCATION SERIES

To hear the audio please call:

XXX-XXX-XXXX

Participant code: XXXX

**BON APPÉTIT**  
MANAGEMENT COMPANY

*food service for a sustainable future®*

# PARTNERSHIPS

We have worked with hundreds of organizations around the country to launch food recovery programs to rescue food from going to waste.



urban gleaners



reducing waste and want



zero percent



# RECOGNIZE AND REWARD



Food Recovery Certified!



Food Lifeline's Donor of the Year!

# TIPS FOR SUCCESS



- Approach the right people
- Bring everyone to the table
- Be knowledgeable and prepared to address concerns
- Be flexible
- Ensure longevity of program
- Make it as easy as possible

# LEARN MORE

Claire.Cummings@BAMCO.com  
www.BAMCO.com  
www.cafebonappetit.com  
@WasteAce

# Example TOOL: Donation Quick Checklist

If donating temperature sensitive food, be sure to verify temperature prior to donation

## Acceptable Prepared Food:

- Foods  $\leq 41^{\circ}\text{F}$  and  $\geq 135^{\circ}\text{F}$
- Food in range of  $41\text{--}135^{\circ}\text{F}$  only if time food entered into that range is marked on the container and temperature of food reaches  $70^{\circ}\text{F}$  or below within 2 hours and reaches  $41^{\circ}\text{F}$  or below within additional 4 hours. (Must consult with your local Health Department if you check this box.)
- Food that is consumed within 4 hrs from time food fell into range of  $41\text{--}135^{\circ}\text{F}$ . (Must consult local Health Department if you check this box)
- Unserved food from monitored, protected, and temp. controlled buffet lines.
- Food marked with description, source, allergen disclaimer, time/date of preparation.

## Unacceptable Prepared Food:

- Foods in opened or torn containers
- Food that won't properly cool from the time food entered the range of  $41\text{--}135^{\circ}\text{F}$ . Proper Cooling: food must be cooled to reach  $70^{\circ}\text{F}$  in 2 hours and  $41^{\circ}\text{F}$  in an additional 4 hours.
- Shell eggs more than 7 days past exp. date or not transported at  $45^{\circ}\text{F}$  or below
- Food stored in fridge longer than 5 days. (recipient must use within 2 more days)
- Food that is not donated in food grade packaging/containers.
- Previously served or reheated food.
- Food not marked with name, source, allergen disclaimer, time/date of preparation.

## Acceptable Manufactured Dry Goods:

- Can meat: recommend up to 2 yrs past code date
- Can fruit/veg: up to 18 months past code date
- Self-serve items from grocery dispensers

## Unacceptable Manufactured Dry Goods:

- Does not have original label
- Severely dented or rusted cans
- Seal broken or torn/open package

## Acceptable Manufactured Cold Goods:

- Refrigerated food: kept  $41^{\circ}\text{F}$  or below and not more than 1 day past code date unless frozen.
- Frozen food: kept at  $0^{\circ}\text{F}$  or below.

## Unacceptable Manufactured Cold Goods:

- Not in original packaging
- Not coded with code date
- Seal broken or torn/open package

## Acceptable Raw Meat:

- Frozen solid or  $\leq 41^{\circ}\text{F}$
- Meat marked with type, source, donation date

## Unacceptable Raw Meat:

- Meat  $> 41$
- Damaged packaging or not marked with type, source, donation date

**Acceptable Produce:** Not moldy/decayed

**Unacceptable Produce:** Moldy/decayed

**NOTE:** Shelf stable foods with manufacturer's label are acceptable passed the expiration date except for infant formula. Assume food has allergens unless marked otherwise. **For more info:** \_\_\_\_\_

DONOR NAME AND LOCATION	
TIME AND TEMPERATURE IF TEMPERATURE SENSITIVE (tcs) FOOD	
COMMON NAME OF FOOD:	
DATE OF DONATION:	
<p><b>WARNING! DO NOT SERVE THIS FOOD TO PEOPLE WITH FOOD ALLERGIES.</b> This container holds rescued food!  This food may contain one of the big 8 major allergens such as milk, eggs, peanuts, tree nuts, fish, shellfish, wheat, soy.</p>	

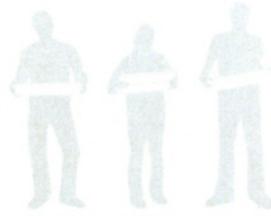
DONOR NAME AND LOCATION	
TIME AND TEMPERATURE IF TEMPERATURE SENSITIVE (tcs) FOOD	
COMMON NAME OF FOOD:	
DATE OF DONATION:	
<p><b>WARNING! DO NOT SERVE THIS FOOD TO PEOPLE WITH FOOD ALLERGIES.</b> This container holds rescued food!  This food may contain one of the big 8 major allergens such as milk, eggs, peanuts, tree nuts, fish, shellfish, wheat, soy.</p>	

DONOR NAME AND LOCATION	
TIME AND TEMPERATURE IF TEMPERATURE SENSITIVE (tcs) FOOD	
COMMON NAME OF FOOD:	
DATE OF DONATION:	
<p><b>WARNING! DO NOT SERVE THIS FOOD TO PEOPLE WITH FOOD ALLERGIES.</b> This container holds rescued food!  This food may contain one of the big 8 major allergens such as milk, eggs, peanuts, tree nuts, fish, shellfish, wheat, soy.</p>	

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## ACCEPTABLE FOODS TO DONATE

### PRODUCTS ACCEPTABLE FOR DONATION:

- Unserved prepared entrees, side dishes, and desserts
- Self-serve items from a buffet if approved by your food donor
- Unopened containers of food, beverages, condiments, sauces, and spices
- Fresh produce
- Dairy products
- Fresh chilled or frozen meat



### PRODUCTS NOT ACCEPTABLE FOR DONATION:

- Food that will not make it to the recipient organization's refrigeration within less than two hours in the Temperature Danger Zone (41-135 F)
- Home canned, vacuum-packed or pickled foods
- Perishable foods past a "use by" date, unless frozen
- Foods in sharply dented or rusty cans
- Foods in opened or torn containers exposing the food to potential contamination
- Unpasteurized milk
- Foods with an "off" odor or color
- Foods prepared, cooked, cooled, or reheated at home (except for baked goods that do not need refrigeration)
- Donations from a donor that has experienced a power outage
- Foods that have been in fridge for over 5 days

The best rule of thumb is to ask yourself if you would eat the food...if the answer is no then you shouldn't donate it!



#### Presenters:

- Syd Mandelbaum, [Rock and Wrap It Up!](#) – 1-877-691-FOOD
- Nicole Civita, [University of Arkansas School of Law](#) - [nmcivita@uark.edu](mailto:nmcivita@uark.edu)
- Claire Cummings, [Bon Appétit Management Company Foundation](#) [Claire.Cummings@BAMCO.com](mailto:Claire.Cummings@BAMCO.com)
- Wayne Melichar, [Feeding America](#) - [wmelichar@feedingamerica.org](mailto:wmelichar@feedingamerica.org)
- Sara Gassman, [Food Recover Network](#) - [sara.gassman@foodrecoverynetwork.org](mailto:sara.gassman@foodrecoverynetwork.org)

#### Moderators:

- Elise Golan, USDA – [egolan@oce.usda.gov](mailto:egolan@oce.usda.gov)
- Jimmy Nguyen, USDA – [jimmy.nguyen@fns.usda.gov](mailto:jimmy.nguyen@fns.usda.gov)

#### Questions & Answers from Webinar

- **Q: Can food be donated from school cafeterias to a local food pantry? If so, is it limited to certain foods? If a student takes a milk and doesn't drink it, can it go back into the cooler?**

**Jimmy Nguyen:** Yes. Many schools donate wholesome uneaten food to local food pantries and soup kitchens. Kathleen Weil, founder of the Food Bus, helps schools setup food recovery programs in their cafeterias. You can contact her at [kathleen.weil@gmail.com](mailto:kathleen.weil@gmail.com). For more information check out this blog: <http://blogs.usda.gov/2014/08/26/creative-solutions-to-ending-school-food-waste/>

The types of foods schools can donate are very diverse but depend on what the local health department advises. Typically, schools can donate milk, yogurt, fruit cups, granola bars, juice packs, fresh produce, string cheese, etc. Also, sometimes you can donate products that the local health department bans if you get a waiver signed by the food pantry or soup kitchen you work with.

- **Q: More specific question about school K-12 cafeterias. Can whole fruit that was placed on tray and not eaten be donated?**

**Jimmy Nguyen:** Yes, but you have to check with your local health department to see what rules they have around that. Sometimes if there are rules against donating some fresh produce, you can work around it by getting the organization you are donating to sign a waiver. I would like to add that milk is always in high demand at food pantries and food banks. Donated milk from schools would help too. You just have to make sure recovered food is refrigerated quickly and properly. But food recovery programs in schools are always great especially if they involve students. It is a great teaching

opportunity showing students how food waste impacts environment and hunger. Kathleen Weil, founder of the Food Bus, helps schools setup food recovery programs in their cafeterias. You can contact her at [kathleen.weil@gmail.com](mailto:kathleen.weil@gmail.com). For more information check out this blog: <http://blogs.usda.gov/2014/08/26/creative-solutions-to-ending-school-food-waste/>

**Wayne Melichar:** Feeding America has successful school donation program. Feel free to reach out to [pthukral@feedingamerica.org](mailto:pthukral@feedingamerica.org) to learn more.

- **Q: Does the Good Samaritan Act cover food education, for example taste testing and cooking education, done with or in connection with donated food?**

**Jimmy Nguyen:** The Good Samaritan Act (aka Bill Emerson Act) covers recipient organizations of donated food as well as donors. But make sure good safety practices are in place when you receive the donated food.

- **Q: I own a prepared foods startup and am working to source ingredients from farmer, supermarket and food distributor surplus. Do you know if these groups are generally willing to work with businesses or are they only willing to donate to non-profits?**

**Nicole Civita:** From the legal perspective, note that the Bill Emerson Act (BEA) will not provide liability protection in the situation described — the BEA requires donation not sale of the surplus food item - but certain state liability protections might. (This seems unlikely, but possible).

- **Q: Does "first-use food grade packaging" include reusable containers or disposable only? Using disposable containers seems counter to sustainability efforts.**

**Claire Cummings:** Bon Appétit Management Company does everything we can to prevent waste from happening in the first place and one way we do this is by launching reusable to-go container programs on our campuses. Eco clamshells (as they are often referred to) are a type of reusable container that replaces the need for a single-use disposable. Food is served in a reusable to-go container, the guests take their food with them, and when they return to campus they trade in their dirty container for a new one. There are many variations to this model, including the OZZI system which incorporates a vending machine into the reusable to-go container collection system. To learn more visit: <http://www.cafebonappetit.com/wellness/sustainability/disposables>.

**Wayne Melichar:** Reusable containers are allowed as long as they are dishwasher safe and are properly washed, rinsed and sanitized between uses.

- **Q: I work with Rock and Wrap it Up! and we donate healthy food safely to less fortunate families. If you freeze food is there a time limit to when it can be served?**

**Jimmy Nguyen:** Food stored at 0 degrees Fahrenheit will always be safe. Only the quality suffers with lengthy freezer storage. Check out USDA's Food Safety and Inspection Service website for more info: [http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/freezing-and-food-safety/ct\\_index](http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/freezing-and-food-safety/ct_index)

- **Q: I work in CA. Has anyone heard of an impending regulation limiting the amount of time food can be stored in sealed plastic bags? This could have impacts to food donation.**

**Nicole Civita:** This has not crossed my radar. I believe that California recently became the first state to enact a ban on single use plastic bags for grocery & convenience store checkout. "Under SB270, plastic bags will be phased out of checkout counters at large grocery stores and supermarkets such as Wal-Mart and Target starting next summer, and convenience stores and pharmacies in 2016. The law does not apply to bags used for fruits, vegetables or meats, or to shopping bags used at other retailers. It allows grocers to charge a fee of at least 10 cents for using paper bags."

[http://www.huffingtonpost.com/2014/09/30/california-plastic-bag-ban\\_n\\_5904766.html](http://www.huffingtonpost.com/2014/09/30/california-plastic-bag-ban_n_5904766.html)

See [http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill\\_id=201320140SB270](http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140SB270) for the complete text of the law. After a quick scan of the California Retail Food Code and agency press releases, I did not find anything else on point.

- **Q: What about fruits/vegetables grown in a school community garden. Can they be donated?**

**Jimmy Nguyen** Most food as long as it's properly handled and stored can be donated! Work with your local food pantry (<http://www.ampleharvest.org/find-pantry.php>) and local health department to see what they say.

- **Q: How are the foods weighed to get an accurate weight for data tracking (waste diversion and GHG reductions)? With a scale by the organization donating or by the recipient organization?**

**Claire Cummings:** It is not a perfect science and varies greatly from organization to organization. Some don't even weigh donations and instead measure by number of cases or number of hotel pans.

**Wayne Melichar:** When partnering with Feeding America, our receiving food banks and agencies weigh the product and report all donations through our reporting platform. Depending on the sophistication of the receiving party, a wide spectrum of weighing scales are used, from the highly sophisticated, commercial scales to common bathroom scales.

- **Q: What about cities who have adopted laws that it is illegal to feed the homeless?**

**Nicole Civita:** Criminalizing feeding of the homeless is in my opinion a terribly misguided, short-sighted trend that ought to spread no further. It is designed to obscure homelessness, push it out of sight, and "address" the problem by pretending it does not exist.

(See <http://www.motherjones.com/politics/2014/11/90-year-old-florida-veteran-arrested-feeding-homeless-bans> for excellent coverage & infographics on this topic.) That said, of the [71 \(and counting\) cities](#) with these bans in place, it seems that most merely prohibit "food sharing" on public property — these laws are mostly aimed at prohibiting or controlling feeding homeless people in impromptu and outdoor feeding events and efforts. Other cities "have imposed food safety

precautions, like requiring charities to get a food handler's permit, or mandating that they only serve hot food prepared in approved locations or in the form of pre-packaged meals." If you are in such a city, to remain within the bounds of the law & the protections of the Bill Emerson Act, it is advisable to make sure that you fully understand the law & comply with it even if you do not agree with it or are part of a group trying to challenge it.

- **Q: So if K12 schools have a "share table" of food served to students do food banks accept this food?**

**Jimmy Nguyen:** For people that don't know, share tables are tables setup in school cafeterias during meal service to allow students to leave food that they don't want and take foods that they do. It's a table that encourages exchange and helps to reduce food waste. To answer the question, yes, food from share tables can be donated as long as it is quickly and safely cooled according to food safety recommendations.

- **Q: So many great food recovery programs. There are several where I live in Cambridge, MA. What seems to be lacking is a good database/clearinghouse of programs, food banks, local initiatives, etc. Does anything like this exist on a national level? So important that good organizations do not unintentionally encroach on established relationships with donors, vendors, etc.**

**Jimmy Nguyen:** Indeed there are some places where you can find a lot of these groups in one place. [AmpleHarvest.org](http://AmpleHarvest.org) is an innovative nationwide non-profit that links food donors (especially home and community growers with excess fresh food) to more than 7,000 food pantries across all 50 states. Instead of collecting and redistributing food, they use technology to enable the food donor to work directly with a nearby food pantry or soup kitchen on a sustainable basis.

Also, you can check on our U.S. Food Waste Challenge website for a list of food recovery organizations that can help you setup a food recovery program: <http://www.usda.gov/oce/foodwaste/resources/donations.htm>

- **Q: Is there a place we can find rules of engagement by state?**

**Claire Cummings:** Nope, unfortunately it is not a clean and simple easy system. Start by contacting your local Department of Health. I have also found information from the local Department of Agriculture, our health inspectors, and our nonprofit partners, who are sometimes more knowledgeable about local rules and regulations.

- **Q: Do programs generally accept food that has been served out to children but not consumed from schools?**

**Jimmy Nguyen:** Yes, many schools donate wholesome uneaten food to local food pantries and soup kitchens. Kathleen Weil, founder of the Food Bus, helps schools setup food recovery programs in their cafeterias. You can contact her at [kathleen.weil@gmail.com](mailto:kathleen.weil@gmail.com). For more information check out this blog: <http://blogs.usda.gov/2014/08/26/creative-solutions-to-ending-school-food-waste/>.

You can also find local food pantries using [Ample Harvest's food pantry finder](#). One issue that schools may have to deal with is possible rules that prevent food that leaves the kitchen from reentering the

kitchen, which includes refrigerators and freezers back there. Schools will have to find a way to have a dedicated refrigerator for food donation in the cafeteria area or area outside of the official kitchen area.

- **Q: Do you have protocols for companies to track food donations?**

**Wayne Melichar:** Feeding America uses a very sophisticated tracking system to allow for all donations to any of Feeding America's 200 food banks and 60,000 agencies to be tracked nationwide, which then get compiled into 1 national tax receipt for our donors. We also provide each donor with a monthly report that track all donations made to us through all their locations nationwide. Along with the assurance of maintaining the highest food safety standards, getting that 1 national receipt is another advantage to partnering with Feeding America. We also offer guidance to our donors on what metrics they can use internally to measure the impact of their food rescue programs they set up with us.

**Syd Mandelbaum:** Yes we use Rock and Wrap It Up! spreadsheets, which are formula-embedded to record pounds of food which is converted in to USDA meal equivalents and GHG emission reduction stats.

- **Q: Where do we find more information on the Bill Emerson Act (aka Good Samaritan Act)?**

Here is a good summary of the Bill Emerson Act:

<http://media.law.uark.edu/arklawnotes/2013/08/08/the-legal-guide-to-the-bill-emerson-good-samaritan-food-donation-act/>

Also, Nicole Civita's presentation provides a good overview:

<https://prezi.com/uh-ddvay0ag/food-recovery-the-law/>

- **Q: Do any states offer tax benefits beyond the federal tax benefits for donations?**

**Nicole Civita:** Yes, many do. Some historically did, but have repealed these beneficial incentives in recent years. Off the top of my head, I know that Missouri (<http://dor.mo.gov/taxcredit/fpt.php>), California (<http://www.gleanslo.org/documents/AB%20152%20Food%20Bank%20Fact%20Sheet.pdf>), Colorado

(<http://yourhub.denverpost.com/blog/2014/06/new-state-tax-credit-to-boost-fresh-food-donations-increase-access-for-struggling-coloradans/45552/>) and Oregon

(<http://www.statesmanjournal.com/story/news/politics/2014/04/24/governor-signs-crop-donation-tax-credit/8124925/>) all have some form of state-level tax incentive related to food donation. These vary widely in what types of donations qualify. This is another area ripe for a 50 state survey to reveal the lay of the land and provide detailed information on how to claim the deduction. The Food Recovery Project welcomes project partners and support to complete this work, as well.

- **Q: How would you recommend getting local sustainability plans to include food recovery?**

**Claire Cummings:** Not sure what “local sustainability plans” is in reference to but if they are referring to a college or corporate campus then the first thing should be having food recovery written into the food service provider’s contract with the college or corporation.

**Wayne Melichar:** Feeding America often works with national donors in this capacity. Please feel free to reach out to Parul Thukral, Director of Product Sourcing Innovation at Feeding America ([pthukral@feedingamerica.org](mailto:pthukral@feedingamerica.org)) to learn more. We also have food rescue operations in college campuses as well as in schools. Feel free to contact Parul if you’d like to learn more.

- **Q: I understand that the Bill Emerson Good Samaritan Act (BEA) unified states’ laws so that organizations operating in more than one state could establish org/company-wide policy and procedure regarding food donation/recovery. Is this true?**

**Claire Cummings:** Sort of...it unifies the protections but doesn’t unify the “how” piece of food recovery. As Nicole Civita mentioned in her presentation, each state has different rules and policies around what they think it means to “safely” donate food so despite the BEA protections, donors will still need to abide by local rules and regulations for safe food donation, which unfortunately vary from place to place.

**Wayne Melichar:** Many of Feeding America’s donors have set up company-wide policies to donating food. We also work with their internal teams and provide supporting material to develop such programs and the internal communication they might need to help guide them through the process as well. . Please feel free to reach out to Parul Thukral, director of Product Sourcing Innovation at Feeding America ([pthukral@feedingamerica.org](mailto:pthukral@feedingamerica.org)) to learn more.

# TIPS ON FOOD RECOVERY

*from Food Recovery Network*



Sara Gassman  
Director of Member Support and Communications  
Food Recovery Network  
*November 2014*

**FOOD**  
RECOVERY  
NETWORK

[www.foodrecoverynetwork.org](http://www.foodrecoverynetwork.org)  
FIGHTING WASTE. FEEDING PEOPLE.

**Food Recovery Network** unites students at colleges and universities to fight **food waste** and **hunger** by recovering perishable food that would otherwise go to waste from their campuses and the surrounding communities and donating it to local hunger-fighting agencies.



**FOOD**  
RECOVERY  
NETWORK

**FIGHTING WASTE. FEEDING PEOPLE.**



# WHAT DOES IT TAKE TO GET FRN UP AND RUNNING?

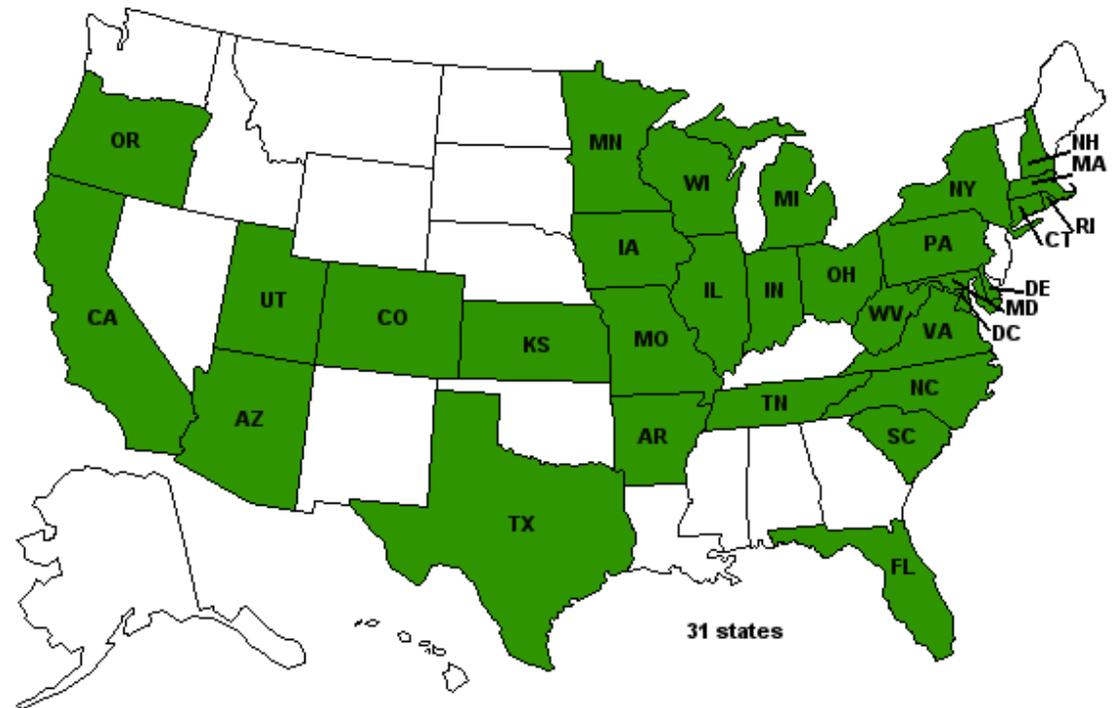


**FOOD**  
RECOVERY  
NETWORK

**FIGHTING WASTE. FEEDING PEOPLE.**

# FORM YOUR VOLUNTEER BASE

- Find your local FRN chapter
  - [Bit.ly/FRNbyU](http://Bit.ly/FRNbyU)
- Work with existing organizations



**FOOD**  
RECOVERY  
NETWORK

FIGHTING WASTE. FEEDING PEOPLE.

# COMMUNITY PARTNERSHIPS

- Consider:
  - Open hours
  - Food storage/distribution capacity
  - Who in your community does the agency serve?



**FOOD**  
RECOVERY  
NETWORK

FIGHTING WASTE. FEEDING PEOPLE.

# GET DINING ON BOARD

- Be prepared!
- Be knowledgeable
  - What need will the food recovered fill in your community?
  - Draft a protocol for recovering the food
  - How will this help dining services?



**FOOD**  
RECOVERY  
NETWORK

FIGHTING WASTE. FEEDING PEOPLE.



**@FoodRecovery**



**FoodRecoveryNetwork**



**Sara Gassman**

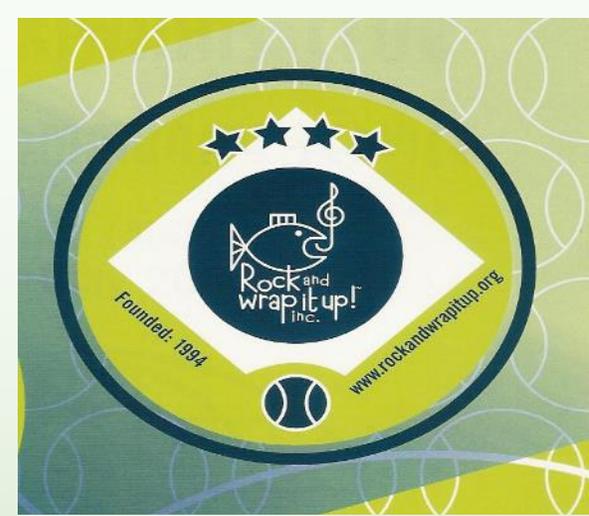
**[sara.gassman@foodrecoverynetwork.org](mailto:sara.gassman@foodrecoverynetwork.org)**

**FOOD  
RECOVERY  
NETWORK**

**FIGHTING WASTE. FEEDING PEOPLE.**

**[www.foodrecoverynetwork.org](http://www.foodrecoverynetwork.org)**

**[www.foodrecoverycertified.org](http://www.foodrecoverycertified.org)**

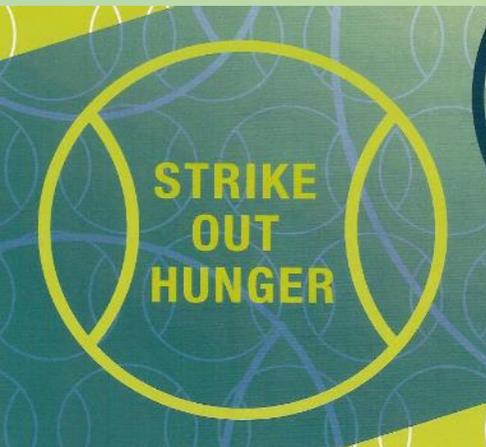


# Donating Unsold Food

Reducing the Poverty Footprint

USDA Webinar

11/12/14



# Who is Rock and Wrap It Up!



- Award winning anti-poverty think tank
- Founded in 1991: 25 years and still learning
- 5,000 unpaid volunteers, 501 C (3) charity
- Recovering food and assets in 500+ N.A. cities
- Recognized by two White House administrations
  - 1998 Point of Light recipient
  - 2014 Climate Data Initiative recognition



We have helped feed over one billion who hunger in the United States of America & Canada!

# RWU and Music: Our first love



## DONATION AGREEMENT

This Donation Agreement (“Agreement”) is made by and between [insert Tim McGraw’s entity], a company affiliated with musician Tim McGraw (“McGraw”), and Rock and Wrap It Up!, a charitable, not-for-profit company (“Recipient”), dated as of April \_\_, 2011 (“Effective Date”).

WHEREAS, in connection with its concert touring activities, McGraw has leftover foodstuffs and other consumables (the “Goods”), more particularly described as follows:

Surplus catered meals at Tim McGraw concerts

McGraw wishes to donate such Goods to Recipient, pursuant to the terms of this Agreement.

**DONATION; FREE DISTRIBUTION.** McGraw hereby donates the Goods from each concert on the “Tim McGraw Emotional Traffic Tour” to Recipient. Recipient represents and warrants that the Goods will be distributed for free to Recipient's clients.

Sharon Osbourne

9292 CIVIC CENTER DRIVE, BEVERLY HILLS, CA 90211  
PHONE: (310)859-7761 FAX: (310)859-2897

April 4, 2003

RE: OZZFEST 2003 -W- ROCK AND WRAP IT UP

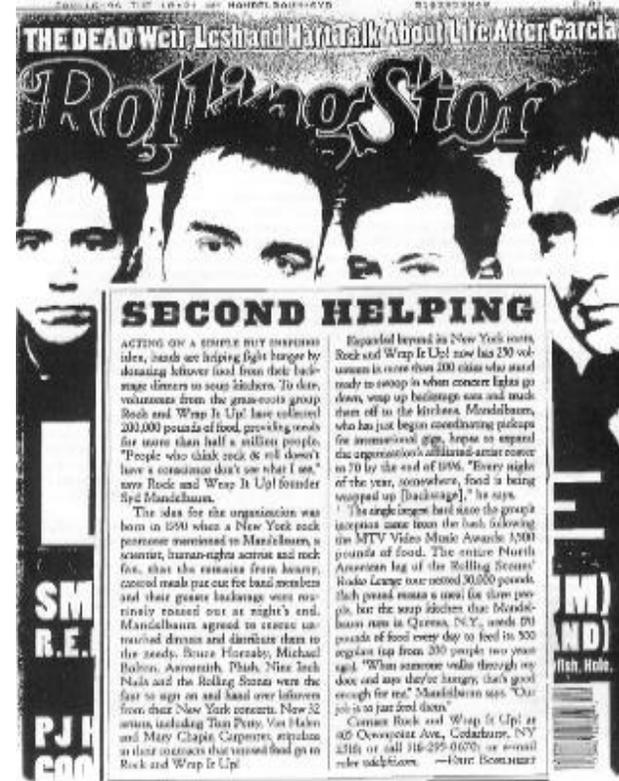
To Whom It May Concern:

Please be advised that the all of the bands and crew on “OZZfest 2003” U.S. tour would like to donate any leftover food to local soup kitchens and shelters. A representative from ROCK AND WRAP IT UP will be in contact with you to arrange for pickup and distribution of these items.

Sincerely,

Sharon Osbourne

SHARON OSBOURNE



# Increasing Agency Operating Budgets is Key



- Enables agencies to invest money elsewhere
- Potential to provide more resources & services
  - Tutors for students
  - Social Workers
  - Job placement counselors
  - Mental health counselors
  - Green collar job training
- Helps attack the root cause of poverty



Using this strategy, we have helped serve hundreds of millions who are indigent in North America



# Government Protection from liability from Liability

- 1996 - **The Bill Emerson Good Samaritan Act**
  - Passed to protect all donors of edible leftover food from liability as long as safe food handling is used
- 2008 - **Federal Food Donation Act** –  
Researched, written and sponsored by RWU!



122 STAT. 2314 PUBLIC LAW 110-247—JUNE 20, 2008

Public Law 110-247  
110th Congress  
An Act

To encourage the donation of excess food to nonprofit organizations that provide assistance to food-insecure people in the United States in contracts entered into by executive agencies for the provision, service, or sale of food.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**  
This Act may be cited as the “Federal Food Donation Act of 2008”.

**SEC. 2. PURPOSE.**  
The purpose of this Act is to encourage executive agencies and contractors of executive agencies, to the maximum extent practicable and safe, to donate excess, apparently wholesome food to feed food-insecure people in the United States.

**SEC. 3. DEFINITIONS.**  
In this Act:  
(1) APPARENTLY WHOLESOME FOOD.—The term “apparently wholesome food” has the meaning given the term in section 2(b) of the Bill Emerson Good Samaritan Food Donation Act (42 U.S.C. 1791(b)).  
(2) EXCESS.—The term “excess”, when applied to food, means food that—  
(A) is not required to meet the needs of executive agencies; and  
(B) would otherwise be discarded.  
(3) FOOD-INSECURE.—The term “food-insecure” means inconsistent access to sufficient, safe, and nutritious food.  
(4) NONPROFIT ORGANIZATION.—The term “nonprofit organization” means any organization that is—  
(A) described in section 501(c) of the Internal Revenue Code of 1986; and  
(B) exempt from tax under section 501(a) of that Code.

**SEC. 4. PROMOTING FEDERAL FOOD DONATION.**  
(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Federal Acquisition Regulation issued in accordance with section 25 of the Office of Federal Procurement Policy Act (41 U.S.C. 421) shall be revised to provide that all contracts above \$25,000 for the provision, service, or sale of food in the United States, or for the lease or rental of Federal property to a private entity for events at which food is provided in the United States, shall include a clause that—

# Using Federal Food Donation Act to Feed Hungry Americans



- Obtain more partnerships to expand food recovery; 43.5 million still food insecure
- If the Federal Government is recommending food recovery, every state, city and town agency is a candidate for food recovery
- Donors protected by the Bill Emerson Good Samaritan law
- All food-generating corporations in America need to be approached



# Everyone Wins on Election Night!



DEMOCRATIC NATIONAL COMMITTEE

TO: State Chairs  
Executive Directors

FROM: DNC Chairman Terry McAuliffe

DATE: October 4, 2002

RE: Election Night Festivities

I am writing to ask you to participate in a worthwhile effort. By now you undoubtedly have someone working on plans for your election night party. I am asking you to add something to your plans: feeding the hungry with leftovers from your party.

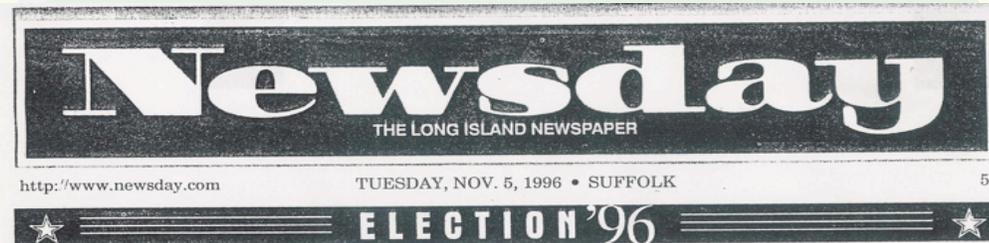
A hunger relief organization called "Rock and Wrap It Up!" (RWU) has volunteers in most cities that collect leftover food following music concerts and other events, and then distribute the unused recovered items to local soup kitchens. Over 130 artists and entertainers specify in their contracts that their leftovers go to this particular organization.

We have the opportunity to do the same with our election night leftovers. Since 1996, the DNC has participated in RWU's, Everyone Wins on Election Night, a coordinated election night effort to donate food. Over 75,000 Americans have been fed as a result. This is a wonderful way to help a great number of people across the nation. When you sign your catering contract, just include a provision that "Rock and Wrap It Up" will recovery the edible leftover food and bring it to a place of need.

Before Election Day, someone from Rock and Wrap It Up! will be in contact with you. If you would like to talk with them before then, you can call the founder, Syd Mandelbaum, at 516.295.0670. You should also feel free to contact Julie Eddy at the DNC with any questions, at 202.863.8121.

Thank you for helping with this effort.

Democratic Party Headquarters ■ 430 South Capitol Street, SE ■ Washington, DC, 20003 ■ (202) 863-8000 ■ Fax (202) 863-8174  
Paid for by the Democratic National Committee. Contributions to the Democratic National Committee are not tax deductible.  
Visit our website at [www.democrats.org](http://www.democrats.org)



By Stuart Vincent  
STAFF WRITER

Supporters of Bill Clinton and Bob Dole have finally found common ground — and it's already occupied by the likes of Nine Inch Nails, Def Leppard and Hootie & the Blowfish.

Like those musical acts, Clinton and Dole campaign headquarters in New York and other states have agreed to donate leftover catered food to soup kitchens as part of a nationwide program coordinated by a Cedarhurst man who has made feeding the hungry his cause.

Over the past three years, Syd Mandelbaum, 46, blood research scientist, Lawrence Board of Education member and rock fan, has persuaded dozens of rock and pop acts in the United States, Canada and Great Britain to donate leftover food to his Rock and Wrap It Up! organization. The food is included in the performers' contracts with concert arenas.

On this Election Day, Rock and Wrap It Up! enters the political arena with plans to collect leftovers from the political parties' parties.

"Election night is nothing more than a big rock concert anyway," Mandelbaum said. "There's the same type of hoopla, the same type of anticipation and people are on stage."

And, as at rock concerts, a huge amount of food is ordered for the main acts and their crews. Much of the food is thrown away at the end of the night.

Mandelbaum contacted the national committees of the two major parties, which asked state political leaders to designate their leftovers to Rock and Wrap It Up!

"How could you disagree on feeding needy people?" said Stanley Nussbaum, Democratic committeeman for the 20th Assembly District in Nassau County. Nussbaum said he arranged for food from Democratic headquarters and victory parties to be donated.

Andy Paris, mayor of Cedarhurst and Republican committee leader for Lawrence, Cedarhurst, Atlantic Beach and Meadowmere Park, said he thought it was a great idea and gave Mandelbaum state and national GOP contacts. He and a spokesman at Nassau GOP headquarters said they didn't know if arrangements had been made to collect food on Long Island.

Even if the group doesn't get a lot of food from the political parties this year, Mandelbaum said, it has made important contacts for future food donations.

It's that kind of planning that has taken Mandelbaum from roles as a volunteer at the Claddagh INN soup kitchen in Arverne, Queens, and board member



Syd Mandelbaum  
File Photo

of the Long Island Cares regional food bank to the head of an international hunger relief program. In 1990, he learned from concert promoter Ron Delsener that huge amounts of food ordered for performers and their crews were discarded after each concert at the Jones Beach Theater. Mandelbaum began "rescuing" the food, taking it to the Claddagh INN and other soup kitchens run by the Interfaith Nutrition Network.

"By the end of 1993, I just realized if there was good food left over like this after every concert, there had to be food like this left over at every arena in the world," Mandelbaum said.

The group went national in 1994, international in 1995. The Hard Rock Cafe chain pays for the group's monthly mailings, Mandelbaum said, and musician Bruce Hornsby is the national spokesman.

Rock and Wrap It Up! has been profiled by Rolling Stone magazine and MTV, and has its own page on the Internet at <http://members.aol.com/rockwrap>.

"It's worked so well I now have fifty-eight bands, and we've fed in [the past] two years over 1.5 million plates of food rescued that I know of," said Mandelbaum.



Republican  
National  
Committee

its Office

## MEMORANDUM

TO: EXECUTIVE DIRECTORS

FROM: TOM JOSEFIAK, CHIEF COUNSEL

DATE: SEPTEMBER 20, 2002

SUBJECT: ELECTION NIGHT FESTIVITIES

On behalf of Governor Marc Racicot, I would like to ask you to participate in a very worthwhile effort. I am sure, by now, you have someone working on plans for your election night victory celebration. As part of those plans, the RNC is asking you to assist in feeding the hungry with leftovers from your event.

A group called "Rock and Wrap It Up, Inc." has once again requested our assistance in using all the leftover food generated from our Election Night events to feed the hungry, nationwide. In 1996, 1998, and 2000, the Republican and the Democratic National Committees contributed 35,000 pounds of food from election night galas across the country to feed nearly 25,000 hungry Americans. Rock and Wrap It Up, Inc. also has volunteers in most cities who collect leftover food from backstage after rock concerts, and then take the food to soup kitchens. One hundred and thirty bands, including Fleetwood Mac, U2, James Taylor and the Rolling Stones have participated in Rock and Wrap It Up, Inc.

They have asked that we do the same, and the RNC has agreed to assist them by not only arranging for our own "Election Night Watch 2002" leftovers to be picked up but also by asking all of you to participate. This is a terrific and simple way for all of us to help a great number of people on a nationwide basis. When you sign your contract for catering for your event, just include a provision that "Rock and Wrap It Up, Inc." is to pick up whatever food is left. Rock and Wrap It Up, Inc. will arrange for everything else.

Before election day, someone from Rock and Wrap It Up, Inc. will be in touch with you. If you would like to talk with them before then, you can call Syd Mandelbaum at (516) 295-0670.

Thank you for helping with this worthwhile effort.

Dwight D. Eisenhower Republican Center • 210 First Street Southeast • Washington, D.C. 20003 • (202) 863-8636  
FAX: (202) 863-8654 • <http://www.rrc.org> • TDD: (202) 863-8726

# Vetting Partners is the Key...Must Haves!



- Health certificate or ServSafe certificate
- On-going program
- Transportation
- Refrigeration
- Communication
- Storage
- Internet savvy for recording pickup via Google Docs\*



\* Used for our GHG reduction analysis program and USDA and EPA Food Waste Challenge

# Why We Do What We Do:



	2012	2013	2014
Attendance	43,724	40,488	42,520
Lbs food recovered	20,625	30,655	21,655
Avg./Game	255 lbs	378 lbs	267 lbs
Attendance	28,035	26,295	26,860
Lbs food recovered	13,410	14,330	9,480
Avg./Game	166 lbs	177 lbs	117 lbs



Yankees fed 56,103 who hunger and saved 72,935 lbs from entering landfill  
 Mets fed 28,631 who hunger and saved 37,220 lbs from entering landfill.

Aramark prepares approx. 20,000\* pounds of food for each game at Citi Field. Over three years they averaged 153 pounds of food leftover per game.  $153/20,000 = .0083$  efficiency.



Legends prepares about 31,200\* pounds of food at each game Yankee Stadium. They average 300 food leftover per game.  $300/31,200 = .0096$  efficiency.

**We have found that a RWU ZFW acceptable coefficient for stadiums and arenas is under .001**

# The Whole Earth Calculators



## Paper & Plastic Calculator

WEIGHT OF PAPER (IN POUNDS)  
0 lbs.

+

WEIGHT OF PLASTIC (IN POUNDS)  
0 lbs.

CONVERTS TO

0  
LBS OF CO2e

## Share the Result

Add Thanks  
Donating Organization Twitter Handle

@ username

Add an Event Name  
What hashtag is your event using?

# hashtag

Message Preview  
Preview your message before you share. (You will have the option to change the wording after clicking "Share".)

Thanks for donating 0 lbs of paper and 0 lbs of plastics saving 0 lbs CO2e from landfills @WholeEarthCalc



## Food Recovery Calculator

INPUT WEIGHT OF FOOD (IN POUNDS)  
0 lbs.

CONVERTS TO

0  
MEALS

0  
LBS OF CO2e

## Share the Result

Add Thanks  
Donating Organization Twitter Handle

@username

Add an Event Name  
What hashtag is your event using?

Message Preview  
Preview your message before you share. (You will have the option to change the wording after clicking "Share".)

Thanks to @username for donating 0lbs of food, creating 0 meals saving 0lbs CO2e from landfills @WholeEarthCalc

28

- Mobile app for statistical analysis
- Two conversions
  - Pounds of food (USDA) into meals
  - Landfill reduced (EPA guidelines)
- Direct sharing on Twitter through app
- Version 2 – Paper & Plastics calculator!

# Calculator Designed for Super Bowl 48



- 50,736 pounds of food recovered
- 39,027 meals
- 38,509 pounds of CO<sub>2</sub>e reduced



# Why School and Snack Wrap Now



- Collects healthy unopened snacks
- Encourages youth charity
  - Generation Y (Born 1980-2000) out number Boomers (1946-64)
  - 70% of America is under 30
  - Cultivate team loyalty at a younger age



People, Planet and Profit= 21st Century Business Ethics

# RWU and the NHL



Since the NHL partnered with Rock and Wrap it Up! in October of 2010, the League's Food Recovery Initiative has diverted

- More than **211 tons** of waste from landfill has been diverted
- Providing ~ 324,000 meals,
- The NHL reduced the equivalent of approximately **160 Metric Tons** of Carbon Dioxide from the environment.

“The NHL doesn't only want to be environmentally responsible and set an example for others, it also wants to be socially responsible.”

NHL Commissioner Gary Bettman,  
Beyond Sports Summit, September 2011





Ensuring  
food safety:  
Freezer  
chests



# USDA and EPA Programs

- Works with Rock and Wrap It Up! to calculate green house gas emissions reduction numbers for programs such as Food Recovery Challenge and WasteWise



**EPA's Food Recovery Challenge**

The graphic shows a plate with three circles: a green circle for "Cost Savings", a red circle for "Feeding Hungry People", and an orange circle for "Reducing Environmental Harm". To the left is a fork labeled "Technical Assistance/Tools", and to the right is a knife and spoon labeled "Recognition & Awards" and "Waste Tracking System" respectively.

<http://www.epa.gov/foodrecoverychallenge>

**Rethink**

EPA United States Environmental Protection Agency

[www.epa.gov/smm](http://www.epa.gov/smm)

# Future Platforms



- Piloting food and asset recovery from Military bases
- Re-introduction of Federal Food Donation Act through US Department of Agriculture
- Program expansion in hospitals
- Whole Earth Calculator for hotels with additional waste streams statistics
- Whole Earth Calculator Lesson Plan Expansion
- Green job training (Building Analyst) at CCNY



# Our Vision



“Grassroots efforts such as these can provide an immeasurable boost to our eventual goal of ending hunger in the United States. There are over 95 billion pounds of food wasted by Americans each year in this country. Rock and Wrap it Up! has the answer.”

The Honorable Dan Glickman, President  
Motion Picture Association of America  
Former Secretary of Agriculture  
RWU Tribute Dinner at World Trade Center, NY  
(Windows on the World)  
June 18, 2001



# Learn More About Us



- [www.RockandWrapItUp.org](http://www.RockandWrapItUp.org)
- (877) 691-FOOD
- Twitter @rockywrap  
@WholeEarthCalc
- [Facebook.com/RockandWrap](https://www.facebook.com/RockandWrap)
- [YouTube.com/sydmandelbaum](https://www.youtube.com/sydmandelbaum)



Reducing our Planet's Poverty Footprint by Reducing Society's Carbon Footprint

# #28

**COMPLETE**

**Collector:** Web Link 1 (Web Link)  
**Started:** Monday, February 18, 2019 1:47:37 PM  
**Last Modified:** Monday, February 18, 2019 2:01:11 PM  
**Time Spent:** 00:13:34  
**IP Address:** 96.76.185.241

Page 1: Tell us about your food donation practices

**Q1** What type of food establishment are you? **Grocery Store**

**Q2** In the last 12 months, did your establishment donate any excess, prepared food to a charitable food assistance program (e.g. food pantry)? **Yes**

Page 2: My food establishment does donate or has donated food to charitable feeding sites.

**Q3** In the last 12 months, how frequently did your establishment donate food? **1 - 5 times**

**Q4** Did your establishment face any of these challenges when donating food? (Check all that apply) **Finding organizations that accept food donations**, **Keeping documentation for food donations**

**Q5** What, if any, are your concerns about donating excess, prepared food to charitable organizations?

Not being sued. A concern that was expressed by receiving organisations in case of reaction to spices used in food

**Q6** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important)

Claiming the federal tax deduction for food donations to charitable organizations	<b>4</b>
Reducing waste collection costs	<b>2</b>
Receiving recognition for donating to a charitable organization	<b>3</b>
Increasing staff morale for donating excess foods to a good cause	<b>1</b>

Page 3: My food establishment has not donated food to charitable feeding sites.

## Food Donation Practices

**Q7** Which reason(s) best describes why your establishment has not donated food? (Check all that apply)

---

**Respondent skipped this question**

**Q8** Is your establishment interested in donating excess prepared food?

---

**Respondent skipped this question**

**Q9** If provided with food safety training specific to donations, how likely would it be for your establishment to start donating?

---

**Respondent skipped this question**

**Q10** What, if any, are your concerns about donating excess, prepared foods to charitable organizations?

---

**Respondent skipped this question**

**Q11** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important)

---

**Respondent skipped this question**

## #43

**COMPLETE**

**Collector:** Web Link 1 (Web Link)  
**Started:** Tuesday, February 19, 2019 8:14:50 PM  
**Last Modified:** Tuesday, February 19, 2019 8:17:02 PM  
**Time Spent:** 00:02:12  
**IP Address:** 108.237.58.197

Page 1: Tell us about your food donation practices

**Q1** What type of food establishment are you? **Grocery Store**

**Q2** In the last 12 months, did your establishment donate any excess, prepared food to a charitable food assistance program (e.g. food pantry)? **No**

Page 2: My food establishment does donate or has donated food to charitable feeding sites.

**Q3** In the last 12 months, how frequently did your establishment donate food? **Respondent skipped this question**

**Q4** Did your establishment face any of these challenges when donating food? (Check all that apply) **Respondent skipped this question**

**Q5** What, if any, are your concerns about donating excess, prepared food to charitable organizations? **Respondent skipped this question**

**Q6** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important) **Respondent skipped this question**

Page 3: My food establishment has not donated food to charitable feeding sites.

**Q7** Which reason(s) best describes why your establishment has not donated food? (Check all that apply) **Concern about the liability**

**Q8** Is your establishment interested in donating excess prepared food? **Yes**

**Q9** If provided with food safety training specific to donations, how likely would it be for your establishment to start donating? **Somewhat likely**

## Food Donation Practices

**Q10** What, if any, are your concerns about donating excess, prepared foods to charitable organizations?

Someone gets sick and tries to say it's because we gave them "bad" food just because it's leftovers

---

**Q11** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important)

Claiming the federal tax deduction for food donations to charitable organizations	<b>2</b>
Reducing waste collection costs	<b>3</b>
Receiving recognition for donating to a charitable organization	<b>1</b>
Increasing staff morale for donating excess foods to a good cause	<b>4</b>

---

# #57

**COMPLETE**

**Collector:** Web Link 1 (Web Link)  
**Started:** Tuesday, March 12, 2019 3:30:03 PM  
**Last Modified:** Tuesday, March 12, 2019 3:34:07 PM  
**Time Spent:** 00:04:03  
**IP Address:** 73.255.24.205

Page 1: Tell us about your food donation practices

**Q1** What type of food establishment are you? **Restaurant - Sit Down**

**Q2** In the last 12 months, did your establishment donate any excess, prepared food to a charitable food assistance program (e.g. food pantry)? **No**

Page 2: My food establishment does donate or has donated food to charitable feeding sites.

**Q3** In the last 12 months, how frequently did your establishment donate food? **Respondent skipped this question**

**Q4** Did your establishment face any of these challenges when donating food? (Check all that apply) **Respondent skipped this question**

**Q5** What, if any, are your concerns about donating excess, prepared food to charitable organizations? **Respondent skipped this question**

**Q6** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important) **Respondent skipped this question**

Page 3: My food establishment has not donated food to charitable feeding sites.

**Q7** Which reason(s) best describes why your establishment has not donated food? (Check all that apply)

**Concern about the liability** ,

**Donating food is time-consuming,**

Other (please specify):

Too much red tape with Health Dept rules and regulations

## Food Donation Practices

**Q8** Is your establishment interested in donating excess prepared food? **Yes**

---

**Q9** If provided with food safety training specific to donations, how likely would it be for your establishment to start donating? **Somewhat likely**

---

**Q10** What, if any, are your concerns about donating excess, prepared foods to charitable organizations?

We have vegetables that can be used to make soups and sometimes the specs are off we have to discard chicken items.

---

**Q11** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important)

Claiming the federal tax deduction for food donations to charitable organizations	<b>4</b>
Reducing waste collection costs	<b>1</b>
Receiving recognition for donating to a charitable organization	<b>3</b>
Increasing staff morale for donating excess foods to a good cause	<b>2</b>

---

# #60

**COMPLETE**

**Collector:** Web Link 1 (Web Link)  
**Started:** Tuesday, March 12, 2019 4:12:11 PM  
**Last Modified:** Tuesday, March 12, 2019 4:14:13 PM  
**Time Spent:** 00:02:01  
**IP Address:** 73.206.94.237

Page 1: Tell us about your food donation practices

**Q1** What type of food establishment are you? **Restaurant - Fast Food**

**Q2** In the last 12 months, did your establishment donate any excess, prepared food to a charitable food assistance program (e.g. food pantry)? **No**

Page 2: My food establishment does donate or has donated food to charitable feeding sites.

**Q3** In the last 12 months, how frequently did your establishment donate food? **Respondent skipped this question**

**Q4** Did your establishment face any of these challenges when donating food? (Check all that apply) **Respondent skipped this question**

**Q5** What, if any, are your concerns about donating excess, prepared food to charitable organizations? **Respondent skipped this question**

**Q6** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important) **Respondent skipped this question**

Page 3: My food establishment has not donated food to charitable feeding sites.

**Q7** Which reason(s) best describes why your establishment has not donated food? (Check all that apply) **Other (please specify):  
Didnt know we could do that**

**Q8** Is your establishment interested in donating excess prepared food? **Yes**

## Food Donation Practices

**Q9** If provided with food safety training specific to donations, how likely would it be for your establishment to start donating? **Very likely**

---

**Q10** What, if any, are your concerns about donating excess, prepared foods to charitable organizations?

Someone picking it up

---

**Q11** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important)

Claiming the federal tax deduction for food donations to charitable organizations	<b>2</b>
Reducing waste collection costs	<b>1</b>
Receiving recognition for donating to a charitable organization	<b>4</b>
Increasing staff morale for donating excess foods to a good cause	<b>3</b>

---

# #64

**COMPLETE**

**Collector:** Web Link 1 (Web Link)  
**Started:** Tuesday, March 12, 2019 9:32:21 PM  
**Last Modified:** Tuesday, March 12, 2019 9:37:24 PM  
**Time Spent:** 00:05:03  
**IP Address:** 73.77.142.161

Page 1: Tell us about your food donation practices

**Q1** What type of food establishment are you? **Restaurant - Fast Food**

**Q2** In the last 12 months, did your establishment donate any excess, prepared food to a charitable food assistance program (e.g. food pantry)? **Yes**

Page 2: My food establishment does donate or has donated food to charitable feeding sites.

**Q3** In the last 12 months, how frequently did your establishment donate food? **Weekly**

**Q4** Did your establishment face any of these challenges when donating food? (Check all that apply) **How to package/store food donations**

**Q5** What, if any, are your concerns about donating excess, prepared food to charitable organizations?

Company rules

**Q6** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important)

Claiming the federal tax deduction for food donations to charitable organizations	<b>4</b>
Reducing waste collection costs	<b>3</b>
Receiving recognition for donating to a charitable organization	<b>2</b>
Increasing staff morale for donating excess foods to a good cause	<b>1</b>

Page 3: My food establishment has not donated food to charitable feeding sites.

## Food Donation Practices

**Q7** Which reason(s) best describes why your establishment has not donated food? (Check all that apply)

---

**Respondent skipped this question**

**Q8** Is your establishment interested in donating excess prepared food?

---

**Respondent skipped this question**

**Q9** If provided with food safety training specific to donations, how likely would it be for your establishment to start donating?

---

**Respondent skipped this question**

**Q10** What, if any, are your concerns about donating excess, prepared foods to charitable organizations?

---

**Respondent skipped this question**

**Q11** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important)

---

**Respondent skipped this question**

# #67

**COMPLETE**

**Collector:** Web Link 1 (Web Link)  
**Started:** Wednesday, March 13, 2019 2:40:15 PM  
**Last Modified:** Wednesday, March 13, 2019 2:44:02 PM  
**Time Spent:** 00:03:46  
**IP Address:** 73.77.36.117

---

Page 1: Tell us about your food donation practices

**Q1** What type of food establishment are you? **Restaurant - Sit Down**

---

**Q2** In the last 12 months, did your establishment donate any excess, prepared food to a charitable food assistance program (e.g. food pantry)? **No**

---

Page 2: My food establishment does donate or has donated food to charitable feeding sites.

**Q3** In the last 12 months, how frequently did your establishment donate food? **Respondent skipped this question**

---

**Q4** Did your establishment face any of these challenges when donating food? (Check all that apply) **Respondent skipped this question**

---

**Q5** What, if any, are your concerns about donating excess, prepared food to charitable organizations? **Respondent skipped this question**

---

**Q6** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important) **Respondent skipped this question**

---

Page 3: My food establishment has not donated food to charitable feeding sites.

## Food Donation Practices

**Q7** Which reason(s) best describes why your establishment has not donated food? (Check all that apply)

**Concern about the liability** ,

**Don't know who accepts food donations** ,

**Don't have the staff/resources to donate food** ,

Other (please specify):

generally not enough leftovers

---

**Q8** Is your establishment interested in donating excess prepared food?

**No**

---

**Q9** If provided with food safety training specific to donations, how likely would it be for your establishment to start donating?

**Not enough excess, prepared food to donate**

---

**Q10** What, if any, are your concerns about donating excess, prepared foods to charitable organizations?

liability

---

**Q11** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important)

Receiving recognition for donating to a charitable organization **4**

Increasing staff morale for donating excess foods to a good cause **3**

---

# #70

**COMPLETE**

**Collector:** Web Link 1 (Web Link)  
**Started:** Sunday, March 17, 2019 5:51:23 PM  
**Last Modified:** Sunday, March 17, 2019 6:04:31 PM  
**Time Spent:** 00:13:07  
**IP Address:** 73.155.133.165

Page 1: Tell us about your food donation practices

**Q1** What type of food establishment are you? **Restaurant - Fast Food**

**Q2** In the last 12 months, did your establishment donate any excess, prepared food to a charitable food assistance program (e.g. food pantry)? **No**

Page 2: My food establishment does donate or has donated food to charitable feeding sites.

**Q3** In the last 12 months, how frequently did your establishment donate food? **Respondent skipped this question**

**Q4** Did your establishment face any of these challenges when donating food? (Check all that apply) **Respondent skipped this question**

**Q5** What, if any, are your concerns about donating excess, prepared food to charitable organizations? **Respondent skipped this question**

**Q6** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important) **Respondent skipped this question**

Page 3: My food establishment has not donated food to charitable feeding sites.

**Q7** Which reason(s) best describes why your establishment has not donated food? (Check all that apply) **Don't know who accepts food donations**, **Don't have the staff/resources to donate food**

**Q8** Is your establishment interested in donating excess prepared food? **Yes**

## Food Donation Practices

**Q9** If provided with food safety training specific to donations, how likely would it be for your establishment to start donating?

**Somewhat likely**

---

**Q10** What, if any, are your concerns about donating excess, prepared foods to charitable organizations?

Don't know

---

**Q11** Food donations can provide certain business benefits. Please rank the importance of these benefits to your food establishment? (1 being most important)

Claiming the federal tax deduction for food donations to charitable organizations	<b>3</b>
Reducing waste collection costs	<b>1</b>
Receiving recognition for donating to a charitable organization	<b>4</b>
Increasing staff morale for donating excess foods to a good cause	<b>2</b>

---



# Donating Unsold Food - A Primer on Liability, Food Safety & the Good Samaritan Act

November, 2014

## Feeding America Food Bank Network

- Founded in 1979
- Mission: To feed America's hungry through a nationwide network of member food banks and engage our country in the fight to end hunger
- 47 million Americans served annually, including 14 million children and 7 million seniors
- Securing and distributing 3.3 billion meals annually
- Network of 200 food banks
- Approximately 58,000 local charitable agencies



## Food Safety Focus

- A foundational component of our business
- Food banks are the end of the supply chain
- Serving the most vulnerable populations



# Handling Donations from Retail and Hospitality Establishments- Perishable Foods

Donations must meet the following requirements:

- 1 • Be provided by a licensed food establishment
- 2 • Be in compliance with state & local food handling laws
- 3 • Be stored and held at appropriate temps: 41 °F or below (cold foods), 0°F or below (frozen), and 135°F or higher (hot foods)
- 4 • Be protected from air and environmental contaminants during display and/or service
- 5 • Not include foods previously served to the public (e.g. self-service buffets or on bulk display exposed to the public)
- 6 • Be first generation surplus foods (e.g. not previously reheated for the second time)
- 7 • Be packaged in first-use food grade packaging

# Handling Donations from Retail and Hospitality Establishments- Perishable Foods

## Retail and Hospitality Program Guidelines

1

- Be transported, received, stored and held at appropriate temps: 41°F or below (cold foods), 0°F or below (frozen), 135°F or above (hot foods)

2

- Use a passive device(e.g. thermal blanket, cooler w/ ice packs) or visibly active temperature retention system to maintain proper temps (e.g. refrigeration unit/truck)

3

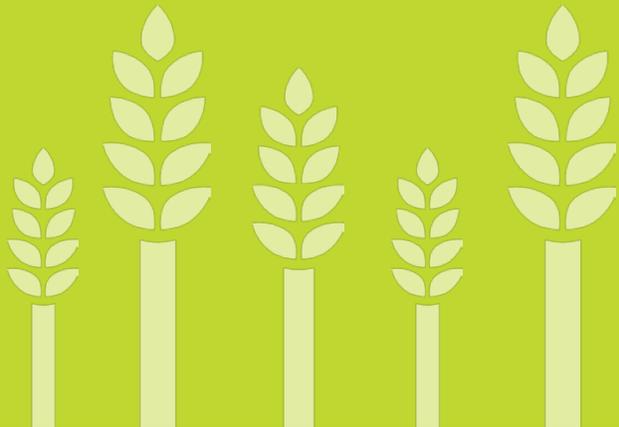
- Sample temps must be taken and documented by the Member or Agency at the time of pickup or delivery

4

- Ensure that food is properly labeled prior to distribution per Feeding America labeling guidelines

# Food Safety Training

Members must comply with the following food safety training requirements:



## Member Staff and Volunteers

Minimum of one staff member who is certified ServSafe Manager

All key food handling staff and volunteers must receive training such as ServSafe Food Handler for Food Banking

If regularly handling retail or hospitality foods, all key staff and drivers are required to maintain a current safe food handler qualification

## Agencies

The Member must provide food safety training to at least one representative from each Agency, such as ServSafe Food Handler for Food Banking

If Agencies utilize food provided by Member to make meals, their key food service program staff are required to meet local commercial food safety training requirements

## Items To Consider

- **Never** assume that a product cannot be donated
- Contact your local food bank by using our food bank locator @ [www.feedingamerica.org](http://www.feedingamerica.org)
- Food banks can turn short coded perishable products very quickly
- Food banks adhere to the same food safety standards as the food industry

# Contact us if you have further questions

For more information contact:

Wayne Melichar  
Manager of Food Safety  
[wmelichar@feedingamerica.org](mailto:wmelichar@feedingamerica.org)  
312-629-7263

Food Bank Locator  
[www.feedingamerica.org/find-your-local-foodbank/](http://www.feedingamerica.org/find-your-local-foodbank/)



**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-002**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

---

**Issue History:**

This is a brand new Issue.

**Title:**

FRC Infographic Handouts Acceptance for Approval and Posting

**Issue you would like the Conference to consider:**

We respectfully request that the Conference consider adding four (4) info graphic sheets submitted in the Food Recovery Committee (FRC) Report to the CFP's 2016 revision of the Comprehensive Resource for Food Recovery Programs.

**Public Health Significance:**

The info graphic sheets support the Conference for Food Protection's 2016 revision of the Comprehensive Resource for Food Recovery Programs by providing easy to understand info graphics on how to properly handle donated foods. By including these info graphics, individuals of all ages and learning abilities will have accurate information to safely handle donated foods.

Topics covered in the info graphic sheets are: (1) How food establishments can donate food; (2) How to properly transport donated food; (3) How to serve donated food; and, (4) Serving highly susceptible populations.

**Recommended Solution: The Conference recommends...:**

addition of the four (4) info graphic sheets (attached to Issue Titled: Food Recovery Committee (FRC) Report) to the CFP's 2016 revision of the Comprehensive Resource for Food Recovery Programs.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-003**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

FRC Food Code Amendment

**Issue you would like the Conference to consider:**

The Food Recovery Committee suggests the Conference recommend that FDA 1) modify the most current version of the FDA Model Food Code to include a definition of food donation and 2) issue interpretive guidance of existing Food Code requirements addressing the donation of food to individuals in need.

**Public Health Significance:**

Donation of food by regulated retail foodservice establishments can reduce food waste and provide food assistance to those in need. However, the current FDA Food Code, and preceding versions, do not clearly address this practice. As food donation, rescue, and recovery practices have expanded in recent years, so too has the need for knowledge and guidance in the Food Code to address these practices. A report by the Harvard Law School "Food Safety Regulations & Guidance for Food Donations: A Fifty-State Survey of State Practices" (March 2018) [https://www.chlpi.org/wp-content/uploads/2013/12/50-State-Food-Regs\\_March-2018\\_V2.pdf](https://www.chlpi.org/wp-content/uploads/2013/12/50-State-Food-Regs_March-2018_V2.pdf), notes that 12 states have added provisions for food donation into their Food Codes, with 39 states having no relevant legislation. The report further noted that even in the 12 states where relevant laws or regulations exist, the scope varies widely, and most are quite narrow. Food assistance organizations help individuals and families meet emergency food needs and, increasingly, provide 11.1% of U.S. households with their daily food needs. USDA Economic Research Service. 2018. Food Security Status of U.S. Households in 2018. <https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/key-statistics-graphics/>

Specifically, addressing food donation in the FDA Food Code and providing guidance will help ensure safe food donations and provide for consistent regulation of the donation process. The lack of uniformity among public health officials in applying food safety preventive controls to food donation practices has created a disincentive among potential food donors. Food establishments may be reluctant to donate food in the absence of clear

guidance on topics such as time/temperature controls, and packaging and labeling of food that is offered to organizations for distribution to those in need. Without guidance clarifying the process for safe food donation within the Food Code, food establishments may opt not to donate food due to concern over the risks associated with civil liability. The 2014 report "Analysis of U.S. Food Waste Among Food Manufacturers, Retailers, and Restaurants" [https://foodwastealliance.org/wp-content/uploads/2014/11/FWRA\\_BSR\\_Tier3\\_FINAL.pdf](https://foodwastealliance.org/wp-content/uploads/2014/11/FWRA_BSR_Tier3_FINAL.pdf) , notes that in a survey of 1000 restaurants, only 22 percent donated food. Two of the barriers that survey respondents listed to donating food were liability (67 percent small operators, 56 percent of retailers with 10 or more locations) and regulatory constraints (56 percent both sectors). A 2019 survey conducted by Harris County Public Health, Pasadena, Texas on food donation practices found that barriers to donation included liability concerns and lack of knowledge that food donation was an allowed practice. The Harris County survey further concluded that respondents would be more likely to donate food if clear guidance was available on how to safely offer food to those in need.

Individuals seeking assistance from food pantries or emergency feeding operations are at higher risk for serious complications resulting from a foodborne illness. A study published in 2011 (B.M. Lund, S.J. O'Brien. 2011. Foodborne Path. Dis. 8:961-973 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4555333>), indicated that individuals eligible for food assistance were at heightened risk of contracting a foodborne illness compared to the general population. Food insecurity has been tied to a myriad of negative health outcomes, particularly in children, including poorer overall physical health, cognitive problems, and anemia. Heart disease, food allergies, mental health problems, obesity, and poor self-reported health, especially symptoms linked to psychological suffering, were found to be more prevalent in food insecure populations than food secure populations.

For non-shelf stable food donation to be accomplished in a manner that provides safe food, the foods must be obtained from regulated food establishments and the conditions for preparation and handling of the food must be the same as for any food offered to the consumer from the regulated establishment. Controlled processing and post-processing handling are required for the safe distribution of donated food.

The proposals in this Issue address the lack of clarity that confronts both operators and regulators around the concern of food donated by regulated food establishments to help feed those in need. Adding a definition and providing guidance to support the practice of food donation(s) will help to address the confusion surrounding what food(s) can be safely donated and address/resolve the applicable sections of the Food Code supporting the safe practice of food donation with the goal of protecting public health.

A primary line of defense in ensuring that food meets the requirements of the proposed 3-101.12 is to obtain, transport and hold food in a manner that complies with Chapter 3. It is also critical to monitor food products to ensure that, during the donation process, food items do not become unsafe or adulterated. The regulatory community, industry, distributors and consumers should exercise vigilance in controlling the conditions to which foods are subjected and remain alert to signs of abuse.

### **Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting the following:

1. Amendment of the most current version of the Food Code to include:

a) Add general provision as section 3-101.12 Donation of Food, acknowledging that it is appropriate for licensed retail and foodservice establishments to donate food to organizations provided that the food has been stored, held, prepared or displayed in a manner that is in accordance with the applicable food safety requirements contained in the Food Code. Text to be considered for inclusion in the CFP Issue submission could be as follows: "FOOD that has not been received, stored, held, prepared, displayed, or labeled in accordance with Chapter 3 shall not be offered for FOOD DONATION."

b) Add a definition of the term "FOOD DONATION" to section 1-201.10 (B) to establish a recognized definition for that term so that when it is used in the Food Code, its meaning is widely understood as distributing food to another organization for charitable purposes with the intention that it be consumed by humans. Text to be considered for inclusion in the CFP Issue submission could be as follows: "FOOD DONATION: Practice by which a FOOD ESTABLISHMENT offers FOOD at no cost to an organization for distribution to, and consumption by, individuals in need. The donated FOOD is not offered for sale to the end consumer."

c) Furthermore that section 8-101.10 (A) be modified to reflect that it also applies to food that is donated with the following modification: "The REGULATORY AUTHORITY shall apply this Code to promote its underlying purpose, as specified in § 1-102.10, of safeguarding public health and ensuring that FOOD is safe, unADULTERATED, and honestly presented when offered to the CONSUMER or for FOOD DONATION."

2. That FDA publish supplemental guidance or interpretive language that addresses safe food donation practices and its relationship to current Food Code provisions, where appropriate. Among other issues, the FDA guidance should specifically address donation of the following:

a) FOOD requiring a VARIANCE as specified in 3-502.11 and 3-502.12 without a VARIANCE.

b) Exposed FOOD that has been on display to CONSUMERS or that has been offered for customer self-service.

c) TCS FOOD that has been held or displayed for sale or service using time alone without temperature control as specified in 3-501.19

d) FOODS packaged in the FOOD ESTABLISHMENT and that may or may not be required to be labeled when offered for sale or service in the FOOD ESTABLISHMENT

e) FOODS that are offered for sale or service in an unPACKAGED form in the FOOD ESTABLISHMENT.

f) JUICE PACKAGED in a FOOD ESTABLISHMENT that has not been treated to yield a 5-log reduction of the most resistant microorganism of public health significance.

g) Animal-derived foods that is FOOD offered, served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT and for which FOOD ESTABLISHMENTS are required to inform CONSUMERS of the increased risk of consuming such FOOD by way of a DISCLOSURE and REMINDER, as specified in 3-603.11.

h) Refrigerated, READY-TO-EAT TCS FOOD that is subject to the date marking requirements in 3-501.17

- i) FOOD that bears a quality-based or safety-based date label that was applied by the manufacturer or the FOOD ESTABLISHMENT and for which the date has passed.
- j) FOOD donated in bulk packaging, with or without a label.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-004**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: Issue 2016 I-023; new or additional information has been included or attached.

**Title:**

CFP- ISSC: Report and Recreate CFP- ISSC Joint Committee on Shellfish.

**Issue you would like the Conference to consider:**

Report from the CFP- ISSC Joint Committee on Shellfish investigating opportunities and activities to improve compliance with the Food Code Section 3-203.12. Issue :2016 I-023.

**Public Health Significance:**

The incidence of *Vibrio parahaemolyticus* (Vp) illness associated with molluscan shellfish consumption is on the increase and continues to be a significant challenge to state and federal health authorities. Increased efficiency in investigation could potentially decrease preliminary growing area closures. Timely investigation of Vp cases by State and local health officials are impeded by unsuccessful efforts to determine product source. In many cases, investigation is complicated by inadequate record keeping as required by Section 3-203.12 of the 2017 FDA Food Code.

**Recommended Solution: The Conference recommends...:**

1. Please see attached committee report (CFP- ISSC Joint Committee on Shellfish; Issue :2016 I-023).
2. The Co-Chairs would like the conference to acknowledge and thank the committee members for their work.
3. The Conference recommends CFP- ISSC Joint Committee on Shellfish be recreated. The attached annual report identifies the Committees work regarding a lack of resources available for State and Local retail food inspectors and retail food establishments. Therefore the Committee recommends the following charges
  1. Continue work to develop guidance documents for State and Local retail food inspectors and retail food establishments.

2. Report the committee's findings and recommendations at the 2022 CFP Biennial Meeting.

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**Content Documents:**

- "CFP- ISSC Joint Committee on Shellfish Final Report"
- "CFP-ISSC Shellfish Committee Member Roster"

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## Conference for Food Protection – Committee

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

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

**COMMITTEE NAME: CFP–ISSC Shellfish Committee**

**DATE OF FINAL REPORT: 12/31/2019**

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

**REPORT SUBMITTED BY: Julie Henderson**

### COMMITTEE CHARGE(S):

#### **Issue #2016 I-023**

1. The CFP- ISSC Shellfish Ad hoc Committee has been requested to address recommendation #2 by investigating opportunities and activities that will educate and advise State and Local retail food inspectors and retail food establishments of the importance of compliance with Food Code Section 3-203.12.
2. The Conference for Food Protection Executive Board voted during the August 14, 2019 meeting for the CFP- ISSC Shellfish Ad hoc Committee to draft two Issues for Board review: 1) amend the Food Code to mirror ISSC requirements; and establish a committee for the 2020 -2022 biennium to develop educational materials.

### COMMITTEE WORK PLAN AND TIMELINE:

N/A

### COMMITTEE ACTIVITIES:

1. **Dates of committee meetings or conference calls: 4/16/19, 5/21/19, 7/16/19, 8/07/19, 9/10/19, 10/15/19, and 11/19/19**
2. **Overview of committee activities:**

In 2016, the Interstate Shellfish Sanitation Conference (ISSC) submitted Issue 2016-I-023 to the Conference for Food Protection (CFP) for consideration. The CFP adopted the Issue as submitted. Recommendation #2 of the issue requested the FDA begin discussions with the ISSC and the CFP to identify steps that can be taken to enhance implementation and enforcement of shellfish record keeping at retail establishments. This committee has been requested to address recommendation #2 by investigating opportunities and activities that will educate and advise State and Local retail food inspectors and retail food establishments of the importance of compliance with Food Code Section 3-203.12. These efforts would explain how source information associated with record keeping requirements is used by Shellfish Control Authorities and the FDA in illness investigations can subsequently result in shellfish growing area closures and recalls. The purpose of this effort would be to enhance compliance of record keeping requirements to improve the ability of retail food establishments to provide complete and accurate source information in illness investigations.

The CFP ISSC Shellfish Committee first met on April 16, 2019 to discuss the committee charges. The Committee has met on the third Tuesday of each month, excepting the month of June, since then. Several members on the Committee stated that their agencies provide training to the shellfish industry and shellfish specialists (inspectors) on shellstock traceback and the importance of maintaining shellstock identification and recordkeeping. A few states educate retail food inspectors and provide educational opportunities to retail establishments. There is a gap however in the regulatory requirements for retail establishments as well as the educational opportunities to both retail food inspectors and retail establishments. Not all local and state jurisdictions adopt the most recent version of the FDA Food Code.

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

- a. Investigating opportunities and activities that will educate and advise State and Local retail food inspectors and retail food establishments of the importance of compliance with Food Code Section 3-203.12.

#### Findings and Recommendation Rationale:

The Committee reviewed guidance documents and trainings; reviewed relevant FDA Food Code sections and related Annexes as well as the FDA Model Ordinance sections. The Committee, based on the review of the existing documents and trainings, identified a gap in the availability of documents that will educate and advise State and Local retail food inspectors and retail food establishments of the importance of compliance with Food Code Section 3-203.12. The Committee concluded that there are some discrepancies in terminology, definitions, and requirements for shellstock tagging in the Food Code and the Model Ordinance that may inhibit compliance with Food Code Section 3-203.12.

**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. Issue #1: Report: CFP- ISSC Joint Committee on Shellfish; Amend Food Code**

List of content documents submitted with this Issue:

- (1) *Committee Final Report (this document)*
- (2) *Committee Member Roster (see attached PDF CFP- ISSC Joint Committee on Shellfish)*
- (3) *Proposed amendments*

List of supporting attachments: x *No supporting attachments submitted*

**2. Issue #2: CFP- ISSC 2: Recreate CFP- ISSC Joint Committee on Shellfish.**

List of content documents submitted with this Issue:

- (1) *Committee Final Report (this document)*

List of supporting attachments: x *No supporting attachments submitted*

## CFP-ISSC Shellfish Committee Roster

RE: CFP Issue 2016-I-023

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### **CFP Representatives:**

Regulator 1: Julie Henderson - Virginia Department of Health, 804-864-7463,  
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Industry 1: Barry Parsons – Paster Training, 866-394-1776, [barry.parsons@pastertraining.com](mailto:barry.parsons@pastertraining.com)

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Consumer: David Plunkett, [dvp426721@verizon.net](mailto:dvp426721@verizon.net)

CFP Executive Director, David McSwane, [dmcswane.cfp@gmail.com](mailto:dmcswane.cfp@gmail.com)

### **ISSC Representatives:**

Regulator 1: Johnathan Gerhardt - New Mexico Department of the Environment,  
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Regulator 2: Kim Stryker - Alaska Department of Environmental Conservation -  
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Regulator 3: Eric Hickey - Massachusetts Department of Public Health - [eric.hickey@state.ma.us](mailto:eric.hickey@state.ma.us)

Industry: Bill Dewey – Taylor Shellfish Company - [billd@taylorshellfish.com](mailto:billd@taylorshellfish.com)

ISSC Executive Director, Ken Moore, [issc@issc.org](mailto:issc@issc.org)

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### **FDA Consultants from its Shellfish and Retail Programs:**

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FDA Retail Consultant: FDA consultant to the CFP Board – Glenda R. Lewis, 240-402-2150,  
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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-005**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: Issue 2016 I-023; new or additional information has been included or attached.

**Title:**

CFP- ISSC Joint Committee on Shellfish; Amend Food Code

**Issue you would like the Conference to consider:**

Proposed amendments to the most current edition of the FDA Food Code based on the CFP- ISSC Joint Committee on Shellfish investigating opportunities and activities to improve compliance with the Food Code Section 3-203.12. Issue :2016 I-023. These amendments will remove discrepancies in terminology, definitions, and requirements for shellstock tagging in the Food Code and the Model Ordinance that may inhibit compliance with the Food Code, increasing the ability of retail food establishments to provide complete and accurate source information

**Public Health Significance:**

The incidence of *Vibrio parahaemolyticus* (Vp) illness associated with molluscan shellfish consumption is on the increase and continues to be a significant challenge to state and federal health authorities. Increased efficiency in investigation could potentially decrease preliminary growing area closures. Timely investigation of Vp cases by State and local health officials are impeded by unsuccessful efforts to determine product source. In many cases, investigation is complicated by inadequate record keeping as required by Section 3-203.12 of the 2013 FDA Food Code.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting that Sections 1-201.10 (B), 3-202.18, and 3-203.12 be amended to incorporate requirements from the Interstate Shellfish Sanitation Conference 2017 Model Ordinance. Specific proposed language is found below:

1-201.10 (B)

"Certification number" means ~~a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.~~ the unique identification number issued by the

SHELLFISH CONTROL AUTHORITY to each dealer for each location. Each certification number shall consist of a one to five digit Arabic number preceded by the two letter State abbreviation and followed by a two letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with this provision of the National Shellfish Sanitation Program using the following terms: shellstock shipper (SS), shucker-packer (SP), repacker (RP), and Depuration Processor(DP).

"Commingle" means:

1. To combine shellstock harvested on different days or from different growing areas as identified on the tag or label; or
2. To combine shucked shellfish from containers with different container codes or different shucking dates; and
3. To combine in-shell product harvested on different days or from different growing areas as identified on the tag or label.

Add Definition "In-shell Product" means non-living, processed shellfish with one or both shells present.

"Molluscan shellfish" means ~~any edible~~ all species of fresh or frozen oysters, clams, mussels, whether shucked or in the shell, raw, including post-harvest processed, frozen or unfrozen, whole or in part; and scallops or edible portions thereof in any form, except when the scallop final product form consists only of the shucked is the adductor muscle only.

"Shellstock" means ~~raw, in-shell~~ live molluscan shellfish in the shell.

"Shucked shellfish" means molluscan shellfish that have ~~one or~~ both shells removed.

### 3-202.18. Shellstock and In-shell Product Identification.

(A) Shellstock shall be obtained in containers bearing legible source identification tags or labels

that are affixed by a dealer that depurates, ships, or reships the shellstock, as specified in the

National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, and

~~that list are listed in the Interstate Certified Shellfish Shippers List.~~ <sup>Pf</sup>

~~(1) Except as specified under (C) of this section, on the harvester's tag or label, the following~~

~~information in the following order:~~ <sup>Pf</sup>

~~(a) The harvester's identification number that is assigned by the SHELLFISH CONTROL AUTHORITY,~~

~~(b) The date of harvesting,~~ <sup>Pf</sup>

~~(c) most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the SHELLFISH CONTROL AUTHORITY and including the abbreviation of the name of the state or country in which the shellfish are harvested,~~ <sup>Pf</sup>

~~(d) The type and quantity of shellfish,~~ <sup>Pf</sup>

~~(e) 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;,"~~ <sup>Pf</sup> and

~~(2)(1) Except as specified in (D) of this section, on each DEALER'S tag or label, the following~~

information in the following order. <sup>Pf</sup>

(a) The dealer's name and address, and the certification number assigned by the SHELLFISH CONTROL AUTHORITY.;<sup>Pf</sup>

(b) The original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested. If depurated the original shellstock shipper's certification number is not required. <sup>Pf</sup>

~~(c) The same information as specified for a harvester's tag under Subparagraphs (A)(1)(b)-(d) of this section, The harvest date; or if depurated, the date of depuration processing, or if wet stored, the original harvest date, and the final harvest date which is the date removed from wet storage.~~ <sup>Pf</sup> and

~~(d) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days. If wet stored or depurated, the wet storage or depuration cycle or lot number. The wet storage lot number shall begin with the letter "w".~~ <sup>Pf</sup>

~~(e) The most precise identification of the harvest location as is practicable including the initials of the State of harvest, and the SHELLFISH CONTROL AUTHORITY'S designation of the growing area.~~ <sup>Pf</sup>

~~(f) The type and quantity of shellstock.~~ <sup>Pf</sup>

~~(g) The following statement in bold, capitalized type: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE) \_\_\_\_\_" <sup>Pf</sup>~~

~~(h) The statement "Keep Refrigerated" or an equivalent statement.~~ <sup>Pf</sup>

(B) A container of shellstock and in-shell product that does not bear a tag or label or that bears

a tag or label that does not contain all the information as specified under subsection A of this

section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate

Shipments, Section 1240.60(d).<sup>Pf</sup>

~~(C) If a place is provided on the harvester's tag or label for a DEALER'S name, address, and~~

~~CERTIFICATION NUMBER, the DEALER'S information shall be listed first.~~

~~(C) (D) If the harvester's tag or label is designed to accommodate each DEALER'S identification~~

~~as specified in Subparagraph's (A)(2)(a) and (b) of this section, individual DEALER tags or labels need not be provided. When both the dealer and the harvester tags appear on the container, the dealer's tag is not required to duplicate the information on the harvester's tag.~~

<sup>Pf</sup>

~~(D) (E) In-shell product shall be obtained in containers bearing legible source identification tags or labels that are affixed by a dealer that depurates, ships, or reships the in-shell product, as~~

~~specified in the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, and that list:that are listed in the Interstate Certified Shellfish Shippers List.~~ <sup>P</sup>

(1) The dealer tag or label on in-shell product shall contain the following indelible, legible

information in the order specified below: <sup>Pf</sup>

(a) The dealer's name and address: <sup>Pf</sup>

(b) The dealer's certification number as assigned by the SHELLFISH CONTROL AUTHORITY: <sup>Pf</sup>

(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required. <sup>Pf</sup>

(d) A "SELL BY DATE" or the words "BEST IF USED BY" followed by a date when the product is expected to reach its shelf life. The date shall include month, day, and year. <sup>Pf</sup>

(e) If depurated, the depuration cycle number or lot number. <sup>Pf</sup>

(f) The most precise identification of the harvest location as is practicable including the initials of the State of harvest, and the SHELLFISH CONTROL AUTHORITY'S designation of the growing area.

(g) The type and quantity of in-shell product: <sup>Pf</sup>

(h) The following statement in bold, capitalized type: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE) \_\_\_\_\_." OR "THIS LABEL IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS" RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE) \_\_\_\_\_. <sup>Pf</sup>

(i) The statement "Keep Refrigerated" or an equivalent statement. <sup>Pf</sup>

3-203.12 Shellstock and in-shell product; maintaining identification.

A. Except as specified under subdivision (C) (2) of this section, shellstock and in-shell product

tags or labels shall remain attached to the container in which the shellstock and in-shell product

are received until the container is empty. <sup>Pf</sup>

B. The date when the last shellstock and in-shell product from the container is sold or served

shall be recorded on the tag or label. <sup>Pf</sup>

C. The identity of the source of shellstock and in-shell product that are sold or served shall be

maintained by retaining shellstock and in-shell product tags or labels for 90 calendar days

from the date that is recorded on the tag or label as specified in subsection B of this section, by: <sup>Pf</sup>

1. Using an approved recordkeeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under subsection B of this section; <sup>Pf</sup> and

2. If shellstock and in-shell product are removed from its tagged or labeled container:

a. Preserving source identification by using a recordkeeping system as specified under subdivision C 1 of this section, <sup>Pf</sup> and

b. Ensuring that shellstock, in-shell product, or shucked shellfish from one tagged or labeled container are not commingled with shellstock, in-shell product, or shucked shellfish from another container with different certification numbers, different harvest

dates, or different growing areas as identified on the tag or label before being ordered by the consumer.<sup>Pf</sup>

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-006**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code and Annex references to 21 CFR 110 with 21 CFR 117.

**Issue you would like the Conference to consider:**

In the Supplement to the 2017 Food Code, Section 3-501.17 Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking should be updated to strike the phrase "21 CFR 110 Current food manufacturing practice in manufacturing, packing, or holding human food" and replaced with "21 CFR 117 Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food".

Annex 2 of the above referenced document should be updated to strike references to 21 CFR 110 and replaced with 21 CFR 117.

Annex 3 of the above referenced document should be updated to strike the reference to 21 CFR 110 and replaced with 21 CFR 117.

**Public Health Significance:**

FDA has updated and replaced 21 CFR 110 with 21 CFR 117.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting that Section 3-501.17, Annex 2 and Annex 3 of the Supplement to the 2017 Food Code be amended to remove all references to 21 CFR 110 and replaced with 21 CFR 117.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-007**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code 1-201.10 replace Fruits and Vegetables with term Plant Food

**Issue you would like the Conference to consider:**

In the Supplement to the 2017 Food Code, section (2)(c) of the definition of ready-to-eat foods should be updated to strike the phrase "Fruits and vegetables" and replaced with "Plant foods".

**Public Health Significance:**

Currently, section (2)(c) of the definition of ready-to-eat foods and 3-401.13 do not use consistent terminology. The term "fruits and vegetables" was replaced with "plant foods" in section 3-401.13. Therefore, for continuity, the same change should be made in section (2) (c) of the definition of ready-to-eat foods.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting that Section 1-201.10 Statement of Application and Listing of Terms of the Supplement to the 2017 Food Code be amended as follows (language to be removed is stricken and new language is underlined):

(2) "Ready-to-eat food" includes:

(a) Raw animal FOOD that is cooked as specified under § 3-401.11 or 3-401.12, or frozen as specified under § 3-402.11;

(b) Raw fruits and vegetables that are washed as specified under § 3-302.15;

(c) ~~Fruits and vegetables~~ Plant foods that are cooked for hot holding, as specified under § 3-401.13;

(d) All TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked to the temperature and time required for the specific FOOD under Subpart 3-401 and cooled as specified under § 3-501.14;

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-008**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code 1-201.10 Statement of Application & Listing of Terms (PHF)

**Issue you would like the Conference to consider:**

The definition of Time/Temperature Control for Safety Food in the Supplement to the 2017 Food Code includes unnecessary qualification by including the phrase "(formerly "potentially hazardous food" (PHF))".

**Public Health Significance:**

The term "potentially hazardous food" is obsolete, as the term "time/temperature control for safety food" was introduced in the 2005 Food Code. In addition, the term "potentially hazardous food" does not appear elsewhere in the Supplement to the 2017 Food Code.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting that Section 1-201.10 Statement of Application and Listing of Terms of the Supplement to the 2017 Food Code be amended as follows (language to be removed is stricken):

Time/Temperature Control for Safety Food (~~formerly "potentially hazardous food" (PHF)~~).

(1) "Time/temperature control for safety food" means a FOOD that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

(2) "Time/temperature control for safety food" includes:

(a) An animal FOOD that is raw or heat-treated; a plant FOOD that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-009**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Condition Control Food

**Issue you would like the Conference to consider:**

The term "Condition Control Food" or "CCF" to be used as an equivalent or replacement term for describing "Time/temperature control for safety food" or "TCS."

**Public Health Significance:**

Improved communications.

Communicating the importance and differences between CCF and non-CCF is improved based on anecdotal field reports in Montana. Our agency believes these reports could be duplicated on a larger scale if the term is adopted. CCF represents the many conditions needed to ensure safe food by controlling pH level to water activity, cold-hold storage and any other relevant condition required to produce safe food.

**Recommended Solution: The Conference recommends...:**

The Conference recommends a letter be sent to FDA requesting that the term "Condition Control Food" or "CCF" to be used as an equivalent or replacement term for describing "Time/temperature control for safety food" or "TCS."

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-010**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code – Clarify “Equipment” definition

**Issue you would like the Conference to consider:**

Recommend Conference for Food Protection to consider an amendment to the definition of "Equipment" (see page 7 of the 2017 Food Code) provided in *1.201.10 Statement of Application and Listing of Terms*. The "Equipment" definition should also consider any physical structure, surface or accessory attached to, or in the vicinity of an actual equipment, which may directly influence an equipment's capability of producing safe food. Such a significant change should further clarify the associated definition of "Food-contact surface" (see page 8 of the 2017 Food Code) that also includes: the surface of equipment - with which food normally comes into contact, (or) - from which food may drain, drip or splash into a food, or, onto a surface normally in contact with food. For more information, see content document attached: *Proposal to Review the Definitions of "Utensil" and "Equipment" provided in the 2017 Food Code and ensuring their relation with the "Food-contact surface" Definition*.

**Public Health Significance:**

According to the CDC, over 60% of the food-related outbreaks occur in food service establishments such as restaurants, and that contaminated equipment and utensils are one of the top 5 factors contributing to food-borne illnesses. Hence, equipment surfaces that are identified as food-contact surfaces must be cleaned as specified under Part 4-6 of the 2017 Food Code, and sanitized as specified under Part 4-7 of the Code in order to control cross-contamination of food and to prevent food-borne disease occurrences. For more information, see content document attached: *Proposal to Review the Definitions of "Utensil" and "Equipment" provided in the 2017 Food Code and ensuring their relation with the "Food-contact surface" Definition*.

**Recommended Solution: The Conference recommends...:**

... a letter be sent to the FDA requesting that the definition for "Equipment" listed under 1-201.10 [see page 7 of the 2017 Food Code] be amended as follows (language to be deleted is in strike-through format, new language to be added is underlined):

Equipment.

(1) "Equipment" means an article that is used in the operation of a FOOD ESTABLISHMENT such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, TEMPERATURE MEASURING DEVICE for ambient air, VENDING MACHINE, or WAREWASHING machine.

(2) "Equipment" includes any physical structure, surface or accessory (e.g. ball bearings, overhead covers etc.) attached to, or in the vicinity of the actual EQUIPMENT which may directly influence an EQUIPMENT's capability for the production of SAFE FOOD.

~~(2)~~ (3) "Equipment" does not include apparatuses used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

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For more information, see content document attached: *Proposal to Review the Definitions of "Utensil" and "Equipment" provided in the 2017 Food Code and ensuring their relation with the "Food-contact surface" Definition.*

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**Content Documents:**

- "Proposal to Review the Definitions of "Utensil" and "Equipment""

**Supporting Attachments:**

- "Key References"

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# **Proposal to Review the Definitions of “Utensil” and “Equipment” provided in the 2017 Food Code and ensuring their relation with the “Food-contact surface” Definition**

**Presented by:**

**Amit M. Kheradia**

**Content Document created in support of Issues submitted to CFP:**

- Amend Food Code – Clarify “Equipment” definition
- Amend Food Code – Clarify “Utensil” definition

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## **Acknowledgement**

This Content Document has been developed to provide supporting information to the following proposed Issues for CFP 2020:

- *Amend Food Code – Clarify “Equipment” definition*
- *Amend Food Code – Clarify “Utensil” definition*

An appreciable level of thought and effort has been put into creating this clarification document, and there may be some limitations in the proposal as I am a first-time submitter to CFP. Whereas the Content Document closely references the “**Key references**” provided in this document, any other views expressed in this document should be that of the submitter unless they might implicitly refer to the “**Key references**” provided.

I look forward to any feedback.

Thank you for the opportunity,

**Submitter: Amit M. Kheradia**

## **Structure of this Proposal**

This content document proposal supports the following Issues submitted to CFP 2020:

- *Amend Food Code – Clarify “Equipment” definition*
- *Amend Food Code – Clarify “Utensil” definition*

The **objective** of the proposal, and hence its structure, is to explain why there is a significant need to change the definitions of “Equipment” and “Utensil” in the 2017 Food Code, so that they are consistent with the associated definition of “Food-contact surface”

The rationale or basis of the proposed recommendations in these Issues are expressed in the “**Background Information and Opinions**” section. This is the most important section of the document.

The “**Recommendations to CFP**” section shall repeat the Issues submission details that were derived from analyzing the rationale discussed in the previous section. The Recommendations for both Issues are highlighted in **blue**.

The “**Proposed Summary Chart**” provides a chart that summarizes the proposed classification of “Food-Contact Surface” with respect to the definitions of “Equipment and Utensils.” This takes into account the previous two sections i.e. “Background Information and Opinions” and “Recommendations to CFP.”

The **Key References** are the links or information sources used for obtaining background information for this proposal.

## **Background Information and Opinions**

According to the CDC, over 60% of the foodborne illness outbreaks may be sourced to food-service establishments, such as restaurants. <sup>(i)</sup> Furthermore, use of contaminated equipment and utensils has been listed as one of the top 5 CDC factors contributing to foodborne illnesses. <sup>(ii)</sup> These essential pieces of inter-linked information basically explain why the management of food-contact surfaces of equipment and utensils (through the instrument of the Food Code provisions) are important in controlling contamination incidences in establishments and in the prevention of foodborne diseases. <sup>(iii)</sup>. **Note:** Please see the “**key references**” section on superscripts <sup>(i)</sup>, <sup>(ii)</sup>, <sup>(iii)</sup>.

2017 Food Code defines “**food-contact surface**” [see page 8 of the Code] as:

- (1) A surface of EQUIPMENT or a UTENSIL with which FOOD normally comes into contact; or
- (2) A surface of EQUIPMENT or a UTENSIL from which FOOD may drain, drip or splash:
  - (a) Into a FOOD, or
  - (b) Onto a surface normally in contact with FOOD.

This definition closely aligns with 21 CFR 110.3 (g) which states that “food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations.” The section further states that “food-contact surfaces include utensils and food-contact surfaces of equipment.”

It therefore becomes clear that it is not practical to amend the definition of the “food-contact surface” in 2017 Food Code. However, the problem lies with the definitions of “Equipment” and “Utensil” as referenced below:

See page 7 of the 2017 Food Code on “**Equipment**” definition -

- (1) “**Equipment**” means an article that is used in the operation of a FOOD ESTABLISHMENT such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, TEMPERATURE MEASURING DEVICE for ambient air, VENDING MACHINE, or WAREWASHING machine.
- (2) “**Equipment**” does not include apparatuses used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

The fundamental concern with the “**Equipment**” definition is that it does not take into account any other physical structure, surface or accessory attached to, or in the vicinity of an actual equipment, which may directly influence an equipment’s capability of producing safe food. An example is a vicinity surface above the cooking vat equipment from which condensation drips back into food – such as surface needs to be called out as part of an equipment, and hence a food-contact surface. Furthermore, equipment can undergo surface modifications, and any accessory extensions (that directly influence an equipment’s capability to produce safe food) need to be called out as part

of an equipment, and hence a food-contact surface (FCS). It is important to call out these additional surfaces as “food-contact” because unlike nonfood-contact surfaces (NFCS), they need to have properties that are required to follow applicable sections of Part 4-6 and Part 4-7 of the Code, as such FCS need to be cleaned and sanitized after cleaning and before use.

See page 24 of the 2017 Food Code on “**Utensil**” definition -

**"Utensil"** means a FOOD-CONTACT implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE that is multiuse, SINGLE-SERVICE, or SINGLE-USE; gloves used in contact with FOOD; temperature sensing probes of FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD.

In a nutshell, by looking at the definition, we may classify utensils into:

- (a) **Multi-use Utensils** that normally undergo warewashing (i.e. they are cleaned and sanitized after cleaning and before use), generally according to applicable sections of Part 4-6 and Part 4-7 of the Code. Examples of such utensils include scoops, stainless steel knives, silver spoons etc.
- (b) **Single-use or Single Service Utensils** that do not undergo warewashing. Rather, they are normally for one-time use only, and then discarded. However, such items must be made of SAFE MATERIAL, and are required to be inspected for conformance to proper specifications, prior to their use. Examples of single-use utensils include disposable plates and spoons, disposable clothes and even single-use packaging for storing exposed food.

Clearly, it becomes important to distinguish between single-use and multi-use utensils, because by reading the Food Code in context, it may mean that all utensils must be cleaned and sanitized as per applicable sections of Part 4-6 and Part 4-7 of the Code, which is not the case. For instance, disposable gloves are single-use, since they are used one-time and then discarded, while, multiuse gloves may be cleaned and sanitized before use and after cleaning.

Additionally, the Code should also clearly state the exclusion (from “utensils” definition) for secondary cartons or containers that store packaged foods (where food is not exposed to the environment).

In summary, the given amendment proposals to the definitions of “Equipment” (see page 7 of the 2017 Food Code) and “Utensil” (see page 24 of the 2017 Food Code) provided in 1.201.10 Statement of Application and Listing of Terms should further clarify that definition of “Food-contact Surface” (see page 8 of the Code), and further bring it into better alignment with the rest of the Food Code, and also the 21 CFR 110.3 (g) definition that has already been stated in this section.

## **Recommendations to CFP**

**Recommendations for both Issue Titles are Highlighted in blue under Recommended**

### **Solution**

*New or additional information has been included or attached.*

**Title:** Amend Food Code – Clarify “Equipment” definition

### **Issue you would like the Conference to consider:**

Recommend CFP to consider an amendment to the definition of “Equipment” (see page 7 of the 2017 Food Code) provided in 1.201.10 Statement of Application and Listing of Terms. The “Equipment” definition should also consider any physical structure, surface or accessory attached to, or in the vicinity of an actual equipment, which may directly influence an equipment’s capability of producing safe food. Such a significant change should further clarify the associated definition of “Food-contact surface” (see page 8 of the 2017 Food Code) that also includes the surface of equipment with which food normally comes into contact, or, from which food may drain, drip, or splash into a food or onto a surface normally in contact with food. For more information, see content document attached: *Proposal to Review the Definitions of “Utensil” and “Equipment” provided in the 2017 Food Code and ensuring their relation with the “Food-contact surface” Definition.*

### **Public Health Significance:**

According to the CDC, over 60% of the food-related outbreaks occur in foodservice establishments such as restaurants, and that contaminated equipment and utensils are one of the top 5 factors contributing to foodborne illnesses. Hence, equipment surfaces that are identified as food-contact surfaces must be cleaned as specified under Part 4-6 of the 2017 Food Code, and sanitized as specified under Part 4-7 of the Code in order to control cross-contamination of food and to prevent foodborne disease occurrences. For more information, see content document attached: *Proposal to Review the Definitions of “Utensil” and “Equipment” provided in the 2017 Food Code and ensuring their relation with the “Food-contact surface” Definition.*

### **Recommended Solution:**

*The Conference recommends....*

... that a letter be sent to the FDA requesting that the definition for “**Equipment**” listed under 1-201.10 [see page 7 of the 2017 Food Code] be amended as follows (language to be deleted is in strikethrough format, new language to be added is underlined):

### **Equipment.**

(1) "**Equipment**" means an article that is used in the operation of a FOOD ESTABLISHMENT such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer,

stove, table, TEMPERATURE MEASURING DEVICE for ambient air, VENDING MACHINE, or WAREWASHING machine.

(2) "Equipment" includes any physical structure, surface or accessory (e.g. ball bearings, overhead covers etc.) attached to, or in the vicinity of the actual EQUIPMENT which may directly influence an EQUIPMENT's capability for the production of SAFE FOOD.

*(2) (3) "Equipment" does not include apparatuses used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.*

For more information, see content document attached: *Proposal to Review the Definitions of "Utensil" and "Equipment" provided in the 2017 Food Code and ensuring their relation with the "Food-contact surface" Definition.*

...

<input checked="" type="checkbox"/> <i>New or additional information has been included or attached.</i>
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**Title:** Amend Food Code – Clarify “Utensil” Definition

**Issue you would like the Conference to consider:**

Recommend CFP to consider an amendment to the definition of “Utensil” (see page 24 of the 2017 Food Code) provided in 1.201.10 Statement of Application and Listing of Terms. The “Utensil” definition should clarify on the differences between multiuse articles (that normally undergo suitable WAREWASHING) and single-use or single-service articles (that are normally discarded after one-time use), and should also clearly state the exclusion (from “utensils” definition) for secondary cartons or containers that store packaged foods (where food is not exposed to the environment). Such significant changes should further clarify the associated definition of “Food-contact surface” (see page 8 of the 2017 Food Code) that also includes the utensils with which food normally comes into contact, or, from which food may drain, drip, or splash into a food or onto a surface normally in contact with food. For more information, see content document attached: *Proposal to Review the Definitions of “Utensil” and “Equipment” provided in the 2017 Food Code and ensuring their relation with the “Food-contact surface” Definition.*

**Public Health Significance:**

According to the CDC, over 60% of the food-related outbreaks occur in foodservice establishments such as restaurants, and that contaminated equipment and utensils are one of the top 5 factors contributing to foodborne illnesses. Utensils are identified as food-contact surfaces. However, not all utensils undergo WAREWASHING, since single-service or single-use articles are discarded after one-time use. Hence, only the multiuse utensils that are identified as food-contact surfaces must be cleaned as specified under Part 4-6 of the 2017 Food Code, and sanitized as specified under Part 4-7 of the Code in order to control cross-contamination of food and to prevent foodborne disease occurrences. For more information, see content document attached: *Proposal to Review the Definitions of “Utensil” and “Equipment” provided in the 2017 Food Code and ensuring their relation with the “Food-contact surface” Definition.*

**Recommended Solution:**

*The Conference recommends....*

that a letter be sent to the FDA requesting the definition for “**Utensil**” listed under 1-201.10 [see page 24 of the Food Code 2017] be amended as follows (language to be deleted is in strikethrough format, new language to be added is underlined):

**“Utensil”**

(1) means a FOOD-CONTACT implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE ~~that is multiuse, SINGLE SERVICE, or SINGLE USE; gloves used in contact with FOOD; multiuse gloves;~~ temperature sensing probes of FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD. These multiuse articles normally undergo suitable WAREWASHING.

(2) includes SINGLE-SERVICE, or SINGLE-USE ARTICLES; packaging; and disposable gloves in contact with food. These items are normally for one-time use only, and do not undergo WAREWASHING. However, such items shall be made of SAFE MATERIAL, and are required to be inspected for conformance to proper specifications, prior to their use.

(3) does not include any secondary package, implement or container used for storing large quantities of PACKAGED FOODS.

For more information, see content document attached: *Proposal to Review the Definitions of “Utensil” and “Equipment” provided in the 2017 Food Code and ensuring their relation with the “Food-contact surface” Definition.*

...

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...

**Attachments:**

**Content Documents:** *(documents requiring Council review; approval or acknowledgement is requested in the recommended solution above)*

<See this Proposal: *Proposal to Review the Definitions of “Equipment” and “Utensil” provided in the 2017 Food Code and ensuring their relation with “Food-contact surface” Definition*>

**Supporting Attachments:** *(documents submitted to provide background information to Council)*

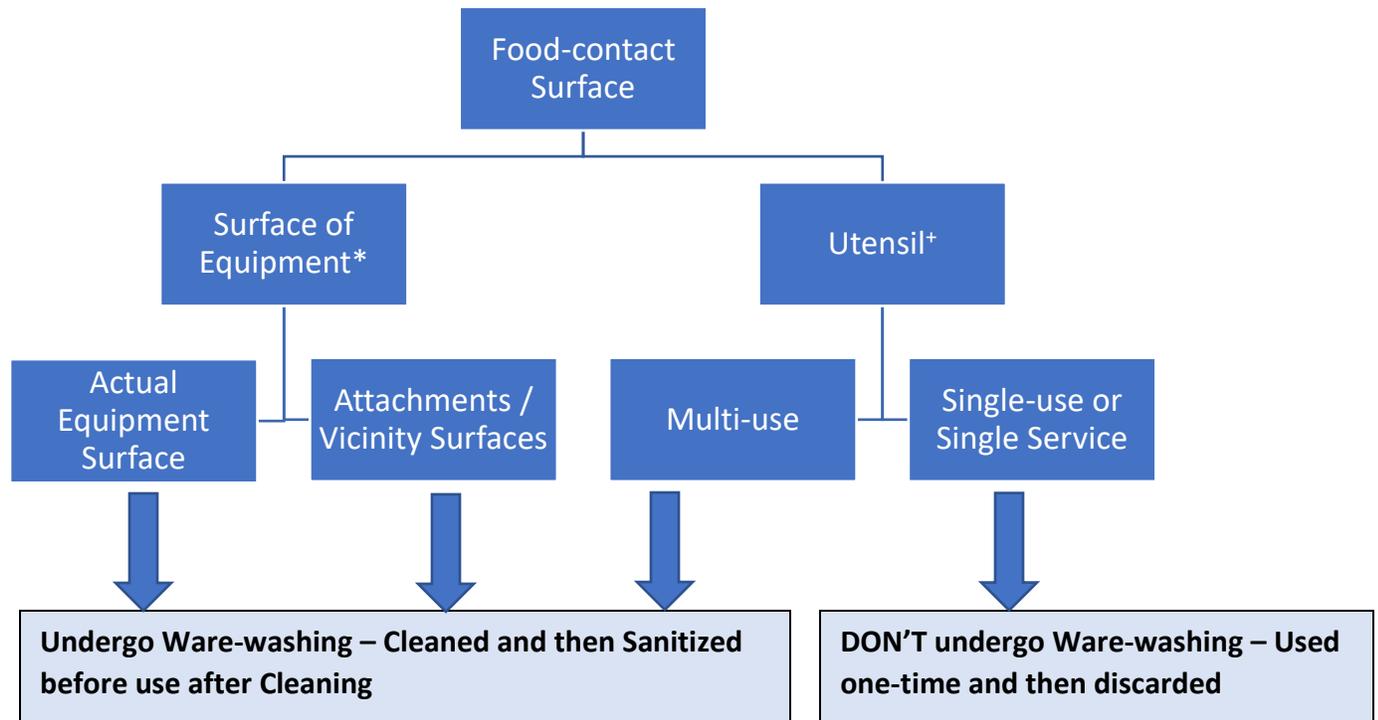
<See **Key References** in this document>

...

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## Proposed Summary Chart

The chart (illustrated below) shows the intended classification of “Food-contact surface” after taking the proposed changes (put forward in the Issues, and as described in the preceding sections of this Content Document) into account:



**\*Surface of Equipment** with which food normally comes into contact (or) from which food may drain drip or splash into a food or onto a surface normally in contact with food. Equipment does NOT include apparatuses for handling large quantities of packaged foods.

**\*Utensil** with which food normally comes into contact (or) from which food may drain drip or splash into a food or onto a surface normally in contact with food. Utensil does NOT include any secondary package, implement or container used for storing large quantities of packaged foods.

## Key References

- i. 2017 Food Code: <https://www.fda.gov/food/fda-food-code/food-code-2017>
- ii. Top 5 CDC Risk Factors: <http://www.sbcounty.gov/uploads/dph/dehs/Depts/EnvironmentalHealth/FormsPublications/Top5CDCRiskFactorsContributingFoodborneIllness.pdf>
- iii. CDC Infographic Preventing Foodborne Illness Outbreaks: <https://www.cdc.gov/nceh/ehs/publications/pfio-infographic.html>

Submitted by: Amit M Kheradia

Organization: Remco

For New CFP 2020 Issues Proposed:

- Amend Food Code – Clarify “Equipment” definition
- Amend Food Code – Clarify “Utensil” definition

### **Key References**

- i. 2017 Food Code: <https://www.fda.gov/food/fda-food-code/food-code-2017>
- ii. Top 5 CDC Risk Factors:  
<http://www.sbcounty.gov/uploads/dph/dehs/Depts/EnvironmentalHealth/FormsPublications/Top5CDCRiskFactorsContributingFoodbornellness.pdf>
- iii. CDC Infographic Preventing Foodborne Illness Outbreaks:  
<https://www.cdc.gov/nceh/ehs/publications/pfio-infographic.html>

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-011**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code – Clarify “Utensil” Definition

**Issue you would like the Conference to consider:**

Recommend the Conference for Food Protection to consider an amendment to the definition of "Utensil" (see page 24 of the 2017 Food Code) provided in 1.201.10 Statement of Application and Listing of Terms. The "Utensil" definition should clarify on the differences between multi-use articles (that normally undergo suitable ware-washing) and single-use or single-service articles (that are normally discarded after one-time use), and should also clearly state the exclusion (from "utensils" definition) for secondary cartons or containers that store packaged foods (where food is not exposed to the environment). Such significant changes should further clarify the associated definition of "Food-contact surface" (see page 8 of the 2017 Food Code) that also includes: - the utensils with which food normally comes into contact, (or) - from which food may drain, drip, or splash into a food ,or, onto a surface normally in contact with food. For more information, see content document attached: *Proposal to Review the Definitions of "Utensil" and "Equipment" provided in the 2017 Food Code and ensuring their relation with the "Food-contact surface" Definition.*

**Public Health Significance:**

According to the CDC, over 60% of the food-related outbreaks occur in food service establishments such as restaurants, and that contaminated equipment and utensils are one of the top 5 factors contributing to food borne illnesses. Utensils are identified as food-contact surfaces. However, not all utensils undergo ware-washing, since single-service or single-use articles are discarded after one-time use. Hence, only the multi-use utensils that are identified as food-contact surfaces that must be cleaned as specified under Part 4-6 of the 2017 Food Code, and sanitized as specified under Part 4-7 of the Code in order to control cross-contamination of food and to prevent food-borne disease occurrences. For more information, see content document attached: *Proposal to Review the Definitions of "Utensil" and "Equipment" provided in the 2017 Food Code and ensuring their relation with the "Food-contact surface" Definition.*

### **Recommended Solution: The Conference recommends...:**

... that a letter be sent to the FDA requesting the definition for "Utensil" listed under 1-201.10 [see page 24 of the Food Code 2017] be amended as follows (language to be deleted is in strike-through format, new language to be added is underlined):

"Utensil"

(1) means a FOOD-CONTACT implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE that is multiuse, SINGLE-SERVICE, or SINGLE-USE; gloves used in contact with FOOD; multiuse gloves; temperature sensing probes of FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD. These multiuse articles normally undergo suitable WAREWASHING.

(2) includes SINGLE-SERVICE, or SINGLE-USE ARTICLES; packaging; and disposable gloves in contact with food. These items are normally for one-time use only, and do not undergo WAREWASHING. However, such items shall be made of SAFE MATERIAL, and are required to be inspected for conformance to proper specifications, prior to their use.

(3) does not include any secondary package, implement or container used for storing large quantities of PACKAGED FOODS.

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For more information, see content document attached: *Proposal to Review the Definitions of "Utensil" and "Equipment" provided in the 2017 Food Code and ensuring their relation with the "Food-contact surface" Definition.*

### **Submitter Information:**

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### **Content Documents:**

- "Proposal to Review the Definitions of "Utensil" and "Equipment""

### **Supporting Attachments:**

- "Key References"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

# **Proposal to Review the Definitions of “Utensil” and “Equipment” provided in the 2017 Food Code and ensuring their relation with the “Food-contact surface” Definition**

**Presented by:**

**Amit M. Kheradia**

**Content Document created in support of Issues submitted to CFP:**

- Amend Food Code – Clarify “Equipment” definition
- Amend Food Code – Clarify “Utensil” definition

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## **Acknowledgement**

This Content Document has been developed to provide supporting information to the following proposed Issues for CFP 2020:

- *Amend Food Code – Clarify “Equipment” definition*
- *Amend Food Code – Clarify “Utensil” definition*

An appreciable level of thought and effort has been put into creating this clarification document, and there may be some limitations in the proposal as I am a first-time submitter to CFP. Whereas the Content Document closely references the “**Key references**” provided in this document, any other views expressed in this document should be that of the submitter unless they might implicitly refer to the “**Key references**” provided.

I look forward to any feedback.

Thank you for the opportunity,

**Submitter: Amit M. Kheradia**

## **Structure of this Proposal**

This content document proposal supports the following Issues submitted to CFP 2020:

- *Amend Food Code – Clarify “Equipment” definition*
- *Amend Food Code – Clarify “Utensil” definition*

The **objective** of the proposal, and hence its structure, is to explain why there is a significant need to change the definitions of “Equipment” and “Utensil” in the 2017 Food Code, so that they are consistent with the associated definition of “Food-contact surface”

The rationale or basis of the proposed recommendations in these Issues are expressed in the “**Background Information and Opinions**” section. This is the most important section of the document.

The “**Recommendations to CFP**” section shall repeat the Issues submission details that were derived from analyzing the rationale discussed in the previous section. The Recommendations for both Issues are highlighted in **blue**.

The “**Proposed Summary Chart**” provides a chart that summarizes the proposed classification of “Food-Contact Surface” with respect to the definitions of “Equipment and Utensils.” This takes into account the previous two sections i.e. “Background Information and Opinions” and “Recommendations to CFP.”

The **Key References** are the links or information sources used for obtaining background information for this proposal.

## **Background Information and Opinions**

According to the CDC, over 60% of the foodborne illness outbreaks may be sourced to food-service establishments, such as restaurants. <sup>(i)</sup> Furthermore, use of contaminated equipment and utensils has been listed as one of the top 5 CDC factors contributing to foodborne illnesses. <sup>(ii)</sup> These essential pieces of inter-linked information basically explain why the management of food-contact surfaces of equipment and utensils (through the instrument of the Food Code provisions) are important in controlling contamination incidences in establishments and in the prevention of foodborne diseases. <sup>(iii)</sup>. **Note:** Please see the “**key references**” section on superscripts <sup>(i)</sup>, <sup>(ii)</sup>, <sup>(iii)</sup>.

2017 Food Code defines “**food-contact surface**” [see page 8 of the Code] as:

- (1) A surface of EQUIPMENT or a UTENSIL with which FOOD normally comes into contact; or
- (2) A surface of EQUIPMENT or a UTENSIL from which FOOD may drain, drip or splash:
  - (a) Into a FOOD, or
  - (b) Onto a surface normally in contact with FOOD.

This definition closely aligns with 21 CFR 110.3 (g) which states that “food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations.” The section further states that “food-contact surfaces include utensils and food-contact surfaces of equipment.”

It therefore becomes clear that it is not practical to amend the definition of the “food-contact surface” in 2017 Food Code. However, the problem lies with the definitions of “Equipment” and “Utensil” as referenced below:

See page 7 of the 2017 Food Code on “**Equipment**” definition -

- (1) “**Equipment**” means an article that is used in the operation of a FOOD ESTABLISHMENT such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, TEMPERATURE MEASURING DEVICE for ambient air, VENDING MACHINE, or WAREWASHING machine.
- (2) “**Equipment**” does not include apparatuses used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

The fundamental concern with the “**Equipment**” definition is that it does not take into account any other physical structure, surface or accessory attached to, or in the vicinity of an actual equipment, which may directly influence an equipment’s capability of producing safe food. An example is a vicinity surface above the cooking vat equipment from which condensation drips back into food – such as surface needs to be called out as part of an equipment, and hence a food-contact surface. Furthermore, equipment can undergo surface modifications, and any accessory extensions (that directly influence an equipment’s capability to produce safe food) need to be called out as part

of an equipment, and hence a food-contact surface (FCS). It is important to call out these additional surfaces as “food-contact” because unlike nonfood-contact surfaces (NFCS), they need to have properties that are required to follow applicable sections of Part 4-6 and Part 4-7 of the Code, as such FCS need to be cleaned and sanitized after cleaning and before use.

See page 24 of the 2017 Food Code on “**Utensil**” definition -

**"Utensil"** means a FOOD-CONTACT implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE that is multiuse, SINGLE-SERVICE, or SINGLE-USE; gloves used in contact with FOOD; temperature sensing probes of FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD.

In a nutshell, by looking at the definition, we may classify utensils into:

- (a) **Multi-use Utensils** that normally undergo warewashing (i.e. they are cleaned and sanitized after cleaning and before use), generally according to applicable sections of Part 4-6 and Part 4-7 of the Code. Examples of such utensils include scoops, stainless steel knives, silver spoons etc.
- (b) **Single-use or Single Service Utensils** that do not undergo warewashing. Rather, they are normally for one-time use only, and then discarded. However, such items must be made of SAFE MATERIAL, and are required to be inspected for conformance to proper specifications, prior to their use. Examples of single-use utensils include disposable plates and spoons, disposable clothes and even single-use packaging for storing exposed food.

Clearly, it becomes important to distinguish between single-use and multi-use utensils, because by reading the Food Code in context, it may mean that all utensils must be cleaned and sanitized as per applicable sections of Part 4-6 and Part 4-7 of the Code, which is not the case. For instance, disposable gloves are single-use, since they are used one-time and then discarded, while, multiuse gloves may be cleaned and sanitized before use and after cleaning.

Additionally, the Code should also clearly state the exclusion (from “utensils” definition) for secondary cartons or containers that store packaged foods (where food is not exposed to the environment).

In summary, the given amendment proposals to the definitions of “Equipment” (see page 7 of the 2017 Food Code) and “Utensil” (see page 24 of the 2017 Food Code) provided in 1.201.10 Statement of Application and Listing of Terms should further clarify that definition of “Food-contact Surface” (see page 8 of the Code), and further bring it into better alignment with the rest of the Food Code, and also the 21 CFR 110.3 (g) definition that has already been stated in this section.

## **Recommendations to CFP**

**Recommendations for both Issue Titles are **Highlighted in blue** under Recommended**

### **Solution**

<input checked="" type="checkbox"/> <i>New or additional information has been included or attached.</i>
---

**Title:** Amend Food Code – Clarify “Equipment” definition

### **Issue you would like the Conference to consider:**

Recommend CFP to consider an amendment to the definition of “Equipment” (see page 7 of the 2017 Food Code) provided in 1.201.10 Statement of Application and Listing of Terms. The “Equipment” definition should also consider any physical structure, surface or accessory attached to, or in the vicinity of an actual equipment, which may directly influence an equipment’s capability of producing safe food. Such a significant change should further clarify the associated definition of “Food-contact surface” (see page 8 of the 2017 Food Code) that also includes the surface of equipment with which food normally comes into contact, or, from which food may drain, drip, or splash into a food or onto a surface normally in contact with food. For more information, see content document attached: *Proposal to Review the Definitions of “Utensil” and “Equipment” provided in the 2017 Food Code and ensuring their relation with the “Food-contact surface” Definition.*

### **Public Health Significance:**

According to the CDC, over 60% of the food-related outbreaks occur in foodservice establishments such as restaurants, and that contaminated equipment and utensils are one of the top 5 factors contributing to foodborne illnesses. Hence, equipment surfaces that are identified as food-contact surfaces must be cleaned as specified under Part 4-6 of the 2017 Food Code, and sanitized as specified under Part 4-7 of the Code in order to control cross-contamination of food and to prevent foodborne disease occurrences. For more information, see content document attached: *Proposal to Review the Definitions of “Utensil” and “Equipment” provided in the 2017 Food Code and ensuring their relation with the “Food-contact surface” Definition.*

### **Recommended Solution:**

*The Conference recommends....*

... that a letter be sent to the FDA requesting that the definition for “**Equipment**” listed under 1-201.10 [see page 7 of the 2017 Food Code] be amended as follows (language to be deleted is in strikethrough format, new language to be added is underlined):

### **Equipment.**

(1) "**Equipment**" means an article that is used in the operation of a FOOD ESTABLISHMENT such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer,

stove, table, TEMPERATURE MEASURING DEVICE for ambient air, VENDING MACHINE, or WAREWASHING machine.

(2) "Equipment" includes any physical structure, surface or accessory (e.g. ball bearings, overhead covers etc.) attached to, or in the vicinity of the actual EQUIPMENT which may directly influence an EQUIPMENT's capability for the production of SAFE FOOD.

*(2) (3) "Equipment" does not include apparatuses used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.*

For more information, see content document attached: *Proposal to Review the Definitions of "Utensil" and "Equipment" provided in the 2017 Food Code and ensuring their relation with the "Food-contact surface" Definition.*

...

<input checked="" type="checkbox"/> <i>New or additional information has been included or attached.</i>
---

**Title:** Amend Food Code – Clarify “Utensil” Definition

**Issue you would like the Conference to consider:**

Recommend CFP to consider an amendment to the definition of “Utensil” (see page 24 of the 2017 Food Code) provided in 1.201.10 Statement of Application and Listing of Terms. The “Utensil” definition should clarify on the differences between multiuse articles (that normally undergo suitable WAREWASHING) and single-use or single-service articles (that are normally discarded after one-time use), and should also clearly state the exclusion (from “utensils” definition) for secondary cartons or containers that store packaged foods (where food is not exposed to the environment). Such significant changes should further clarify the associated definition of “Food-contact surface” (see page 8 of the 2017 Food Code) that also includes the utensils with which food normally comes into contact, or, from which food may drain, drip, or splash into a food or onto a surface normally in contact with food. For more information, see content document attached: *Proposal to Review the Definitions of "Utensil" and "Equipment" provided in the 2017 Food Code and ensuring their relation with the "Food-contact surface" Definition.*

**Public Health Significance:**

According to the CDC, over 60% of the food-related outbreaks occur in foodservice establishments such as restaurants, and that contaminated equipment and utensils are one of the top 5 factors contributing to foodborne illnesses. Utensils are identified as food-contact surfaces. However, not all utensils undergo WAREWASHING, since single-service or single-use articles are discarded after one-time use. Hence, only the multiuse utensils that are identified as food-contact surfaces must be cleaned as specified under Part 4-6 of the 2017 Food Code, and sanitized as specified under Part 4-7 of the Code in order to control cross-contamination of food and to prevent foodborne disease occurrences. For more information, see content document attached: *Proposal to Review the Definitions of "Utensil" and "Equipment" provided in the 2017 Food Code and ensuring their relation with the "Food-contact surface" Definition.*

**Recommended Solution:**

*The Conference recommends....*

that a letter be sent to the FDA requesting the definition for “**Utensil**” listed under 1-201.10 [see page 24 of the Food Code 2017] be amended as follows (language to be deleted is in strikethrough format, new language to be added is underlined):

**“Utensil”**

(1) means a FOOD-CONTACT implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE ~~that is multiuse, SINGLE SERVICE, or SINGLE USE; gloves used in contact with FOOD; multiuse gloves;~~ temperature sensing probes of FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD. These multiuse articles normally undergo suitable WAREWASHING.

(2) includes SINGLE-SERVICE, or SINGLE-USE ARTICLES; packaging; and disposable gloves in contact with food. These items are normally for one-time use only, and do not undergo WAREWASHING. However, such items shall be made of SAFE MATERIAL, and are required to be inspected for conformance to proper specifications, prior to their use.

(3) does not include any secondary package, implement or container used for storing large quantities of PACKAGED FOODS.

For more information, see content document attached: *Proposal to Review the Definitions of “Utensil” and “Equipment” provided in the 2017 Food Code and ensuring their relation with the “Food-contact surface” Definition.*

...

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...

**Attachments:**

**Content Documents:** *(documents requiring Council review; approval or acknowledgement is requested in the recommended solution above)*

<See this Proposal: *Proposal to Review the Definitions of “Equipment” and “Utensil” provided in the 2017 Food Code and ensuring their relation with “Food-contact surface” Definition*>

**Supporting Attachments:** *(documents submitted to provide background information to Council)*

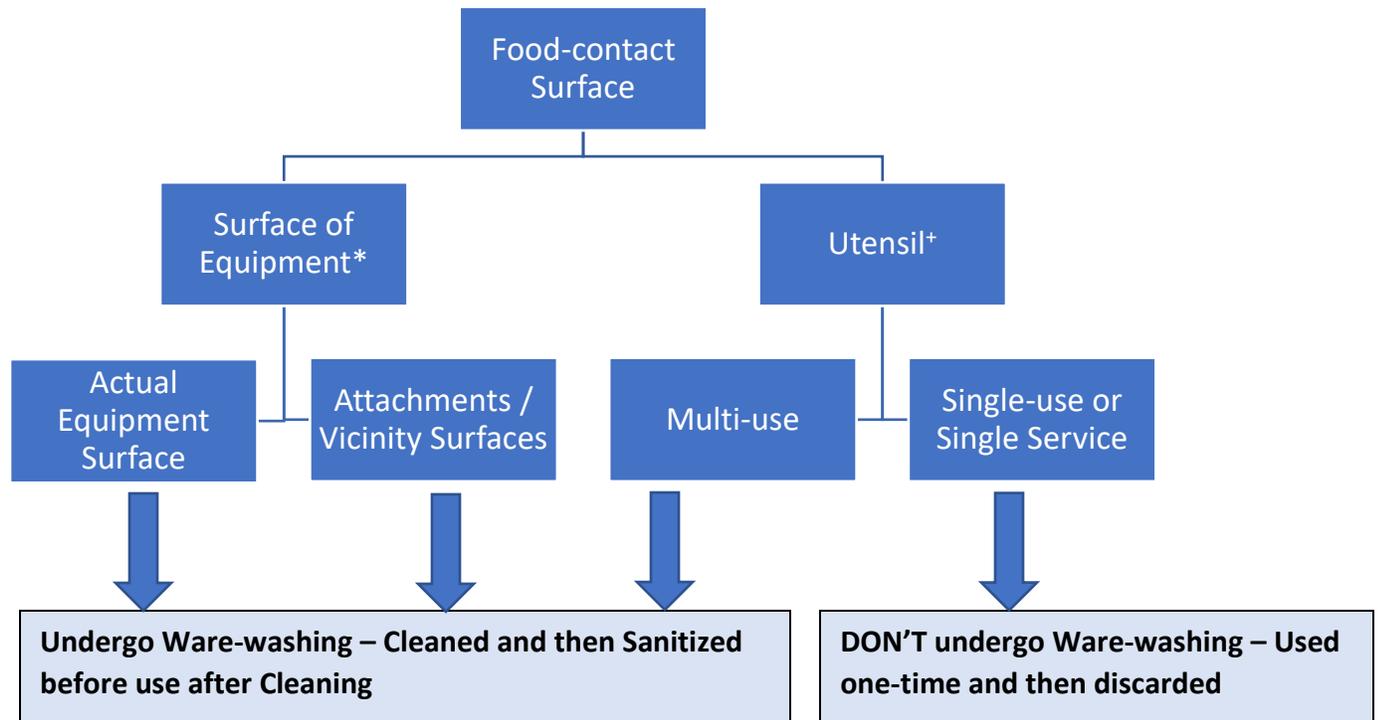
<See **Key References** in this document>

...

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## Proposed Summary Chart

The chart (illustrated below) shows the intended classification of “Food-contact surface” after taking the proposed changes (put forward in the Issues, and as described in the preceding sections of this Content Document) into account:



**\*Surface of Equipment** with which food normally comes into contact (or) from which food may drain drip or splash into a food or onto a surface normally in contact with food. Equipment does NOT include apparatuses for handling large quantities of packaged foods.

**\*Utensil** with which food normally comes into contact (or) from which food may drain drip or splash into a food or onto a surface normally in contact with food. Utensil does NOT include any secondary package, implement or container used for storing large quantities of packaged foods.

## Key References

- i. 2017 Food Code: <https://www.fda.gov/food/fda-food-code/food-code-2017>
- ii. Top 5 CDC Risk Factors: <http://www.sbcounty.gov/uploads/dph/dehs/Depts/EnvironmentalHealth/FormsPublications/Top5CDCRiskFactorsContributingFoodborneIllness.pdf>
- iii. CDC Infographic Preventing Foodborne Illness Outbreaks: <https://www.cdc.gov/nceh/ehs/publications/pfio-infographic.html>

Submitted by: Amit M Kheradia

Organization: Remco

For New CFP 2020 Issues Proposed:

- Amend Food Code – Clarify “Equipment” definition
- Amend Food Code – Clarify “Utensil” definition

### **Key References**

- i. 2017 Food Code: <https://www.fda.gov/food/fda-food-code/food-code-2017>
- ii. Top 5 CDC Risk Factors:  
<http://www.sbcounty.gov/uploads/dph/dehs/Depts/EnvironmentalHealth/FormsPublications/Top5CDCRiskFactorsContributingFoodbornellness.pdf>
- iii. CDC Infographic Preventing Foodborne Illness Outbreaks:  
<https://www.cdc.gov/nceh/ehs/publications/pfio-infographic.html>

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-012**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018-I-032; new or additional information has been included or attached and the recommended solution has been revised.

**Title:**

Use Limitation of Untreated Wood for Cooking Surface

**Issue you would like the Conference to consider:**

Revision of 4-101.17 Wood, Use limitations... to include single use cedar planks.

**Public Health Significance:**

None. To date, there is no record of a foodborne illness linked to the use of cedar planks. In addition, the FDA has recognized Cedar (*T. occidentalis*) as GRAS under 21 CFR part 172. (1)

Approved for use in manufacturing under the previous mentioned CFR, approved for use in Seafood HACCP in manufacturing, and CDC has granted variances to cruise ships for use on the ship as a cooking and serving utensil. (2)

**Recommended Solution: The Conference recommends...:**

Section 4-101.17 Wood, Use Limitations...

(A) Except as specified in paragraphs (B), (C), ~~and~~ (D), and (E) of this section, wood and wood wicker may not be used as a FOOD-CONTACT SURFACE.

(E) Untreated cedar wood planks that are intended to be a food contact surface may be used as a single-use cooking utensil and may subsequently be used as the serving food contact surface. if used as cooking utensil may then be used to serve on.

**Submitter Information:**

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**Supporting Attachments:**

- "21 CFR"
- "CDC Variances"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

## CFR - Code of Federal Regulations Title 21

**The information on this page is current as of April 1 2019.**

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).<sup>6</sup>

### New Search

[Help](#)<sup>7</sup> | [More About 21CFR](#)<sup>8</sup>

[Code of Federal Regulations]  
[Title 21, Volume 3]  
[Revised as of April 1, 2019]  
[CITE: 21CFR172.510]

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)  
PART 172 -- FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

#### Subpart F--Flavoring Agents and Related Substances

Sec. 172.510 Natural flavoring substances and natural substances used in conjunction with flavors.

Natural flavoring substances and natural adjuvants may be safely used in food in accordance with the following conditions.

(a) They are used in the minimum quantity required to produce their intended physical or technical effect and in accordance with all the principles of good manufacturing practice.

(b) In the appropriate forms (plant parts, fluid and solid extracts, concentrates, absolutes, oils, gums, balsams, resins, oleoresins, waxes, and distillates) they consist of one or more of the following, used alone or in combination with flavoring substances and adjuvants generally recognized as safe in food, previously sanctioned for such use, or regulated in any section of this part.

Common name	Scientific name	Limitations
<b>aloe</b>	<b>aloe</b> perryi Baker, A. barbadensis Mill., A. ferox Mill., and hybrids of this sp. with A. africana Mill. and A. spicata Baker	
Althea root and flowers	Althea officinalis L	
Amyris (West Indian sandalwood)	Amyris balsamifera L	
Angola weed	Roccella fuciformis Ach	In alcoholic beverages only
Arnica flowers	Arnica montana L., A. fulgens Pursh, A. sororia Greene, or A. cordifolia Hooker	Do.
Artemisia (wormwood)	Artemisia spp	Finished food thujone free <sup>1</sup>
Artichoke leaves	Cynara scolymus L	In alcoholic beverages only
Benzoin resin	Styrax benzoin Dryander, S. paralleloneurus	

	Perkins, <i>S. tonkinensis</i> (Pierre) Craib ex Hartwich, or other spp. of the Section Anthostyrax of the genus <i>Styrax</i>	
Blackberry bark	<i>Rubus</i> , Section <i>Eubatus</i>	
Boldus (boldo) leaves	<i>Peumus boldus</i> Mol	Do.
Boronia flowers	<i>Boronia megastigma</i> Nees	
Bryonia root	<i>Bryonia alba</i> L., or <i>B. diocia</i> Jacq	Do.
Buchu leaves	<i>Barosma betulina</i> Bartl. et Wendl., <i>B. crenulata</i> (L.) Hook. or <i>B. serratifolia</i> Willd	
Buckbean leaves	<i>Menyanthes trifoliata</i> L	Do.
Cajeput	<i>Melaleuca leucadendron</i> L. and other <i>Melaleuca</i> spp	
Calumba root	<i>Jateorhiza palmata</i> (Lam.) Miers	Do.
Camphor tree	<i>Cinnamomum camphora</i> (L.) Nees et Eberm	Safrole free
Cascara sagrada	<i>Rhamnus purshiana</i> DC	
Cassie flowers	<i>Acacia farnesiana</i> (L.) Willd	
Castor oil	<i>Ricinus communis</i> L	
Catechu, black	<i>Acacia catechu</i> Willd	
Cedar, white (aborvitae), leaves and twigs	<i>Thuja occidentalis</i> L	Finished food thujone free <sup>1</sup>
Centuary	<i>Centaureum umbellatum</i> Gilib	In alcoholic beverages only
Cherry pits	<i>Prunus avium</i> L. or <i>P. cerasus</i> L	Not to exceed 25 p.p.m. prussic acid
Cherry-laurel leaves	<i>Prunus laurocerasus</i> L	Do.
Chestnut leaves	<i>Castanea dentata</i> (Marsh.) Borkh	
Chirata	<i>Swertia chirata</i> Buch.-Ham	In alcoholic beverages only In beverages only; not more than 83 p.p.m. total cinchona alkaloids in finished beverage
Cinchona, red, bark	<i>Cinchona succirubra</i> Pav. or its hybrids	
Cinchona, yellow, bark	<i>Cinchona ledgeriana</i> Moens, <i>C. calisaya</i> Wedd., or hybrids of these with other spp. of <i>Cinchona</i> .	Do.
Copaiba	South American spp. of <i>Copaifera</i> L	
Cork, oak	<i>Quercus suber</i> L., or <i>Q. occidentalis</i> F. Gay	In alcoholic beverages only
Costmary	<i>Chrysanthemum balsamita</i> L	Do.
Costus root	<i>Saussurea lappa</i> Clarke	
Cubeb	<i>Piper cubeba</i> L. f	
Currant, black, buds and leaves	<i>Ribes nigrum</i> L	
Damiana leaves	<i>Turnera diffusa</i> Willd	
Davana	<i>Artemisia pallens</i> Wall	
Dill, Indian	<i>Anethum sowa</i> Roxb. ( <i>Peucedanum graveolens</i> Benth et Hook., <i>Anethum graveolens</i> L.)	
Dittany (fraxinella) roots	<i>Dictamnus albus</i> L	Do.
Dittany of	<i>Origanum dictamnus</i> L	

Crete		
Dragon's blood (dracorubin)	Daemonorops spp	
Elder tree leaves	Sambucus nigra L	In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor
Elecampane rhizome and roots	Inula helenium L	In alcoholic beverages only
Elemi	Canarium commune L. or C. luzonicum Miq	
Erigeron	Erigeron canadensis L	
Eucalyptus globulus leaves	Eucalyptus globulus Labill	
Fir ("pine") needles and twigs	Abies sibirica Ledeb., A. alba Mill., A. sachalinesis Masters or A. mayriana Miyabe et Kudo	
Fir, balsam, needles and twigs	Abies balsamea (L.) Mill	
Galanga, greater	Alpinia galanga Willd	Do.
Galbanum	Ferula galbaniflua Boiss. et Buhse and other Ferula spp	
Gambir (catechu, pale)	Uncaria gambir Roxb	
Genet flowers	Spartium junceum L	
Gentian rhizome and roots	Gentiana lutea L	
Gentian, stemless	Gentiana acaulis L	Do.
Germander, chamaedrys	Teucrium chamaedrys L	Do.
Germander, golden	Teucrium polium L	Do.
Guaiac	Guaiacum officinale L., G. santum L., Bulnesia sarmienti Lor	
Guarana	Paullinia cupana HBK	
Haw, black, bark	Viburnum prunifolium L	
Hemlock needles and twigs	Tsuga canadensis (L.) Carr. or T. heterophylla (Raf.) Sarg	
Hyacinth flowers	Hyacinthus orientalis L	
Iceland moss	Cetraria islandica Ach	Do.
Imperatoria	Peucedanum ostruthium (L.). Koch (Imperatoria ostruthium L.)	
Iva	Achillea moschata Jacq	Do.
Labdanum	Cistus spp	
Lemon-verbena	Lippia citriodora HBK	Do.
Lin <b>aloe</b> wood	Bursera delpechiana Poiss. and other Bursera spp	
Linden leaves	Tillia spp	Do.
Lovage	Levisticum officinale Koch	
Lungmoss (lungwort)	Sticta pulmonacea Ach	
Maidenhair	Adiantum capillus-veneris L	Do.

fern		
Maple, mountain	<i>Acer spicatum</i> Lam	
Mimosa (black wattle) flowers	<i>Acacia decurrens</i> Willd. var. <i>dealbata</i>	
Mullein flowers	<i>Verbascum phlomoides</i> L. or <i>V. thapsiforme</i> Schrad	Do.
Myrrh	<i>Commiphora molmol</i> Engl., <i>C. abyssinica</i> (Berg) Engl., or other <i>Commiphora</i> spp	
Myrtle leaves	<i>Myrtus communis</i> L	Do.
Oak, English, wood	<i>Quercus robur</i> L	Do.
Oak, white, chips	<i>Quercus alba</i> L	
Oak moss	<i>Evernia prunastri</i> (L.) Ach., <i>E. furfuracea</i> (L.) Mann, and other lichens	Finished food thujone free <sup>1</sup>
Olibanum	<i>Boswellia carteri</i> Birdw. and other <i>Boswellia</i> spp	
Opopanax (bisabolmyrrh)	<i>Opopanax chironium</i> Koch (true opopanax) of <i>Commiphora erythraea</i> Engl. var. <i>llabrescens</i>	
Orris root	<i>Iris germanica</i> L. (including its variety <i>florentina</i> Dykes) and <i>I. pallida</i> Lam	
Pansy	<i>Viola tricolor</i> L	In alcoholic beverages only
Passion flower	<i>Passiflora incarnata</i> L	
Patchouly	<i>Pogostemon cablin</i> Benth. and <i>P. heyneanus</i> Benth	In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor
Peach leaves	<i>Prunus persica</i> (L.) Batsch	
Pennyroyal, American	<i>Hedeoma pulegioides</i> (L.) Pers	
Pennyroyal, European	<i>Mentha pulegium</i> L	
Pine, dwarf, needles and twigs	<i>Pinus mugo</i> Turra var. <i>pumilio</i> (Haenke) Zenari	
Pine, Scotch, needles and twigs	<i>Pinus sylvestris</i> L	
Pine, white, bark	<i>Pinus strobus</i> L	In alcoholic beverages only
Pine, white oil	<i>Pinus palustris</i> Mill., and other <i>Pinus</i> spp	
Poplar buds	<i>Populus balsamifera</i> L. ( <i>P. tacamahacca</i> Mill.), <i>P.</i> <i>candicans</i> Ait., or <i>P. nigra</i> L	Do.
Quassia	<i>Picrasma excelsa</i> (Sw.) Planch, or <i>Quassia amara</i> L	
Quebracho bark	<i>Aspidosperma quebracho-blanco</i> Schlecht, or ( <i>Quebrachia lorentzii</i> (Griseb))	Schinopsis <i>lorentzii</i> (Griseb.) Engl.
Quillaia (soapbark)	<i>Quillaja saponaria</i> Mol	
Red saunders (red sandalwood)	<i>Pterocarpus san alinus</i> L	In alcoholic beverages only
Rhatany root	<i>Krameria triandra</i> Ruiz et Pav. or <i>K. argentea</i> Mart	
Rhubarb, garden root	<i>Rheum rhaponticum</i> L	Do.
Rhubarb root	<i>Rheum officinale</i> Baill., <i>R. palmatum</i> L., or other	

	spp. (excepting <i>R. rhaponticum</i> L.) or hybrids of Rheum grown in China	
Roselle	<i>Hibiscus sabdariffa</i> L	Do.
Rosin (colophony)	<i>Pinus palustris</i> Mill., and other <i>Pinus</i> spp	Do.
St. Johnswort leaves, flowers, and caulis	<i>Hypericum perforatum</i> L	Hypericin-free alcohol distillate form only; in alcoholic beverages only
Sandalwood, white (yellow, or East Indian)	<i>Santalum album</i> L	
Sandarac	<i>Tetraclinis articulata</i> (Vahl.), Mast	In alcoholic beverages only
Sarsaparilla	<i>Smilax aristolochiaefolia</i> Mill., (Mexican sarsaparilla), <i>S. regelii</i> Killip et Morton (Honduras sarsaparilla), <i>S. febrifuga</i> Kunth (Ecuadorean sarsaparilla), or undetermined <i>Smilax</i> spp. (Ecuadorean or Central American sarsaparilla)	
Sassafras leaves	<i>Sassafras albidum</i> (Nutt.) Nees	Safrole free
Senna, Alexandria	<i>Cassia acutifolia</i> Delile	
Serpentaria (Virginia snakeroot)	<i>Aristolochia serpentaria</i> L	In alcoholic beverages only
Simaruba bark Snakeroot, Canadian (wild ginger)	<i>Simaruba amara</i> Aubl <i>Asarum canadense</i> L	Do.
Spruce needles and twigs	<i>Picea glauca</i> (Moench) Voss or <i>P. mariana</i> (Mill.) BSP	
Storax (styrax)	<i>Liquidambar orientalis</i> Mill. or <i>L. styraciflua</i> L	
Tagetes (marigold)	<i>Tagetes patula</i> L., <i>T. erecta</i> L., or <i>T. minuta</i> L. ( <i>T. glandulifera</i> Schrank)	As oil only
Tansy	<i>Tanacetum vulgare</i> L	In alcoholic beverages only; finished alcoholic beverage thujone free <sup>1</sup>
Thistle, blessed (holy thistle)	<i>Onicus benedictus</i> L	In alcoholic beverages only
Thymus capitatus (Spanish "origanum")	<i>Thymus capitatus</i> Hoffmg. et Link	
Tolu	<i>Myroxylon balsamum</i> (L.) Harms	
Turpentine	<i>Pinus palustris</i> Mill. and other <i>Pinus</i> spp. which yield terpene oils exclusively	
Valerian rhizome and roots	<i>Valeriana officinalis</i> L	
Veronica	<i>Veronica officinalis</i> L	Do.
Vervain, European	<i>Verbena officinalis</i> L	Do.
Vetiver	<i>Vetiveria zizanioides</i> Stapf	Do.

Violet, Swiss Viola calcarata L		
Walnut husks (hulls), leaves, and green nuts	Juglans nigra L. or J. regia L	
Woodruff, sweet	Asperula odorata L	In alcoholic beverages only
Yarrow	Achillea millefolium L	In beverages only; finished beverage thujone free <sup>1</sup>
Yerba santa	Eriodictyon californicum (Hook, et Arn.) Torr	
Yucca, Joshua- tree	Yucca brevifolia Engelm	
Yucca, Mohave	Yucca schidigera Roez l ex Ortgies (Y. mohavensis Sarg.)	

<sup>1</sup>As determined by using the method (or, in other than alcoholic beverages, a suitable adaptation thereof) in section 9.129 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

<http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html>.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 14644, Apr. 7, 1978; 49 FR 10104, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 69 FR 24511, May 4, 2004; 72 FR 10357, Mar. 8, 2007]

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## Variances by Cruise Ships

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**Cruise Ship:** Celebrity Constellation

**Cruise Line:** Celebrity Cruises

### VSP Operations Manual Section: 7.3.2.1.7

**Manual Requirement:** Fish and Molluscan Shellfish Sources: (1) Fish that are received for service shall be commercially and legally caught or harvested or otherwise approved for service by the VSP. (2) Molluscan shellfish that are recreationally caught may not be received for service. (3) Molluscan shellfish shall be obtained from sources according to law and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish or equivalent standards; and received in interstate commerce shall be from sources that are listed in the FDA Interstate Certified Shellfish Shippers List or equivalent foreign certified shellfish listing.

**Request:** Variance to receive, prepare and serve recreationally caught fish, following a strict protocol detailing critical control points, and documenting compliance by person catching fish, guide, and ship's staff.

**Status:** Approved

**Summary:** Variance to receive, prepare and serve recreationally caught fish, following a strict protocol detailing critical control points, and documenting compliance by person catching fish, guide, and ship's staff.

### VSP Operations Manual Section: 7.4.1.1.7

**Manual Requirement:** Ensure that wood and wood wicker is not used as a food-contact surface.

**Request:** To use a cedar planks for cooking salmon and halibut. Only cedar planks intended for food contact will be used and the planks will be stored protected just as clean utensils. The planks will not be reused.

**Status:** Approved

**Summary:** Approval to use a cedar planks for cooking salmon and halibut. Only cedar planks intended for food contact will be used and the planks will be stored protected just

as clean utensils. The planks will not be reused.

**VSP Operations Manual Section: 7.2.1.2.1**

**Manual Requirement:** Ensure the supervisor or person in charge of food operations on the vessel monitors that: (1) Food operations are not conducted in a room used as living or sleeping quarters; (2) Persons unnecessary to the food operation are not allowed in the food preparation, food storage, or warewashing areas. (3) Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, or warewashing areas comply with the guidelines in this manual; (4) Food employees are effectively cleaning their hands; (5) Employees are observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented; (6) Employees are properly cooking potentially hazardous food, being particularly careful in cooking foods known to cause severe foodborne illness and death, such as eggs and comminuted meats; (7) Employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within 4 hours; (8) Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed that the food is not cooked sufficiently to ensure its safety; (9) Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused; (10) Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets; (11) Employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment; (12) Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties; (13) Food employees are informed of their responsibility to report to the supervisor or person in charge information about their health and activities as they relate to diseases that are transmissible through food.

**Request:** Variance to conduct interactive experiences onboard (Pizza Making, Sushi Making, Cookie Decorating, and/or Lawn Club Grill), in compliance with monitored hygiene, handwashing, and food preparation procedures.

**Status:** Approved

**Summary:** Variance to conduct interactive experiences onboard (Pizza Making, Sushi Making, Cookie Decorating, and/or Lawn Club Grill), in compliance with monitored hygiene, handwashing, and food preparation procedures.

**VSP Operations Manual Section: 7.7.1.1.1**

**Manual Requirement:** Ensure each food preparation area, bar, warewashing area, and garbage-processing area has at least one handwashing facility located in it.

**Request:** Prepare Lobster Murano tableside at the guest's table in the restaurant. Precautions taken include handwashing prior to preparation, not wearing jewelry on

hands or arms, food and food equipment protected during transport from the galley to the table, all potentially hazardous foods placed on 4-hour time control, and lobster will be fully cooked in the galley prior to final preparation at the table.

**Status:** Pending

**Summary:**

**VSP Operations Manual Section:** 7.2.1.2.1

**Manual Requirement:** Ensure the supervisor or person in charge of food operations on the vessel monitors that: (1) Food operations are not conducted in a room used as living or sleeping quarters; (2) Persons unnecessary to the food operation are not allowed in the food preparation, food storage, or warewashing areas. (3) Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, or warewashing areas comply with the guidelines in this manual; (4) Food employees are effectively cleaning their hands; (5) Employees are observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented; (6) Employees are properly cooking potentially hazardous food, being particularly careful in cooking foods known to cause severe foodborne illness and death, such as eggs and comminuted meats; (7) Employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within 4 hours; (8) Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed that the food is not cooked sufficiently to ensure its safety; (9) Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused; (10) Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets; (11) Employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment; (12) Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties; (13) Food employees are informed of their responsibility to report to the supervisor or person in charge information about their health and activities as they relate to diseases that are transmissible through food.

**Request:** Request to conduct a cookie or cupcake decorating class as part of the youth program. Participants must complete the Public Health and Safety Agreement prior to the activity. Anyone with AGE symptoms or sharing a cabin with someone with AGE symptoms will be excluded. No sharing of food will occur.

**Status:** Approved

**Summary:** Request to conduct a cookie or cupcake decorating class as part of the youth program. Participants must complete the Public Health and Safety Agreement prior to the activity. Anyone with AGE symptoms or sharing a cabin with someone with AGE symptoms will be excluded. No sharing of food will occur.

**VSP Operations Manual Section: 7.7.1.1.2**

**Manual Requirement:** Ensure a handwashing facility is within 8 meters (26 feet) of all parts of the area and is not located in an adjacent area that requires passage through a closed door where the user makes hand contact with the door. Ensure handwash sinks are at least 750 millimeters (30 inches) above the deck so that employees do not have to reach excessively to wash their hands.

**Request:** Prepare Lobster Murano tableside at the guests' table in the restaurant. Precautions taken include handwashing prior to preparation, not wearing jewelry on hands or arms, food and food equipment protected during transport from the galley to the table, all potentially hazardous foods placed on 4-hour time control, and lobster will be fully cooked in the galley prior to final preparation at the table.

**Status:** Approved

**Summary:** Prepare Lobster Murano tableside at the guests' table in the restaurant. Precautions taken include handwashing prior to preparation, not wearing jewelry on hands or arms, food and food equipment protected during transport from the galley to the table, all potentially hazardous foods placed on 4-hour time control, and lobster will be fully cooked in the galley prior to final preparation at the table.

**VSP Operations Manual Section: 7.2.1.2.1**

**Manual Requirement:** Ensure the supervisor or person in charge of food operations on the vessel monitors that: (1) Food operations are not conducted in a room used as living or sleeping quarters; (2) Persons unnecessary to the food operation are not allowed in the food preparation, food storage, or warewashing areas. (3) Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, or warewashing areas comply with the guidelines in this manual; (4) Food employees are effectively cleaning their hands; (5) Employees are observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented; (6) Employees are properly cooking potentially hazardous food, being particularly careful in cooking foods known to cause severe foodborne illness and death, such as eggs and comminuted meats; (7) Employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within 4 hours; (8) Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed that the food is not cooked sufficiently to ensure its safety; (9) Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused; (10) Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets; (11) Employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment; (12) Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties; (13) Food employees are informed of their responsibility to report to the supervisor or person in charge

information about their health and activities as they relate to diseases that are transmissible through food.

**Request:** Conduct cooking class inside the Murano galley where passengers prepare and consume their own food. Participants will be asked about gastrointestinal illness symptoms for 48 hours prior to the class and the participant list checked with medical. Participants will be required to wear proper attire and will be instructed in proper handwashing.

**Status:** Approved

**Summary:** Conduct cooking class inside the Murano galley where passengers prepare and consume their own food. Participants will be asked about gastrointestinal illness symptoms for 48 hours prior to the class and the participant list checked with medical. Participants will be required to wear proper attire and will be instructed in proper handwashing.

**VSP Operations Manual Section: 7.2.1.2.1**

**Manual Requirement:** Ensure the supervisor or person in charge of food operations on the vessel monitors that: (1) Food operations are not conducted in a room used as living or sleeping quarters; (2) Persons unnecessary to the food operation are not allowed in the food preparation, food storage, or warewashing areas. (3) Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, or warewashing areas comply with the guidelines in this manual; (4) Food employees are effectively cleaning their hands; (5) Employees are observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented; (6) Employees are properly cooking potentially hazardous food, being particularly careful in cooking foods known to cause severe foodborne illness and death, such as eggs and comminuted meats; (7) Employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within 4 hours; (8) Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed that the food is not cooked sufficiently to ensure its safety; (9) Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused; (10) Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets; (11) Employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment; (12) Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties; (13) Food employees are informed of their responsibility to report to the supervisor or person in charge information about their health and activities as they relate to diseases that are transmissible through food.

**Request:** Conduct mixology classes where passengers prepare and consume their own beverages. Participants will be asked about gastrointestinal illness symptoms for 48 hours prior to the class and the participant list checked with medical. Participants will be

required to wear proper attire and will be instructed in proper handwashing.

**Status:** Approved

**Summary:** Conduct mixology classes where passengers prepare and consume their own beverages. Participants will be asked about gastrointestinal illness symptoms for 48 hours prior to the class and the participant list checked with medical. Participants will be required to wear proper attire and will be instructed in proper handwashing.

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Page last reviewed: March 28, 2018

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-013**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Adding Utensils and other Food Contact Items to 7-203.11

**Issue you would like the Conference to consider:**

Section 7-203.11 of the 2017 Food Code prohibits FOOD from being stored or transported in, or dispensed from, "A container previously used to store POISONOUS OR TOXIC MATERIALS...". The same prohibition should also explicitly apply to EQUIPMENT, UTENSILS, LINENS, SINGLE-SERVICE, or SINGLE-USE ARTICLES.

**Public Health Significance:**

UTENSILS that contact containers previously used with POISONOUS OR TOXIC MATERIALS could pick up residues of the POISONOUS OR TOXIC MATERIALS. The 2017 Food Code prohibits the use of such containers with FOOD but does not explicitly extend that prohibition to EQUIPMENT, UTENSILS, LINENS, SINGLE-SERVICE, or SINGLE-USE ARTICLES. The addition of EQUIPMENT, UTENSILS, LINENS, SINGLE-SERVICE, or SINGLE-USE ARTICLES to 7-203.11 will add clarity and help protect public health by making it clear that EQUIPMENT, UTENSILS, LINENS, SINGLE-SERVICE, or SINGLE-USE ARTICLES could also be contaminated if they contact containers that have previously been used to store POISONOUS OR TOXIC MATERIALS.

**Recommended Solution: The Conference recommends...:**

The Conference recommends that a letter be sent to the FDA requesting that Section 7-203.11 of the most current edition of the Food Code be amended as follows (new language is underlined; existing language to be deleted is in strikethrough format):

A container previously used to store POISONOUS OR TOXIC MATERIALS may not be used to store, transport, or dispense FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES.<sup>P</sup>

**Submitter Information 1:**

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-014**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Enhancing Protection of Food Contact Surfaces - Section 3-304.11

**Issue you would like the Conference to consider:**

Section 3-304.11 of the Food Code would be enhanced by adding explicit requirements that food contact surfaces may not be used if they have been contaminated.

**Public Health Significance:**

Explicitly prohibiting food contact surfaces from being used if they have not been handled or stored in a way that prevents contamination would protect food and prevent foodborne illnesses.

**Recommended Solution: The Conference recommends...:**

The Conference recommends that a letter be sent to FDA recommending that Sections 3-304.11 and 4-502.13 of the Food Code be amended as follows:

3-304.11 Food Contact with Equipment and Utensils.

FOOD shall only contact surfaces of:

(A) EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code, and SANITIZED as specified under Part 4-7 of this Code, and handled as specified under Part 4-9 of this Code; <sup>P</sup>

(B) SINGLE-SERVICE and SINGLE-USE ARTICLES that are handled as specified under Part 4-9 of this Code; <sup>P</sup> or

(C) LINENS, such as cloth napkins, as specified under § 3-304.13 that are laundered as specified under Part 4-8 of this Code and handled as specified under Part 4-9 of this Code. <sup>P</sup>

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-015**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Code to Include authority to conduct foodborne illness investigations

**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.

Currently, the Food Code does not provide an explicit authority for regulatory/health authorities to gather information for a foodborne illness investigation. It contains authorities to gather information on code compliance (what is currently occurring) for plan review (what will occur in the future) but lacks the explicit authority to look at what happened in the past (which is the primary focus of a foodborne illness investigation).

Furthermore, FDA Voluntary National Retail Food Program Standards (VNRFPS) standard 5 assesses whether a regulatory program has developed policies to investigate foodborne illness. These policies implicitly rely on States' public health authorities for preventing disease transmission. Creating this explicit authority in the Food Code will ensure that all jurisdictions that adopt the Food Code will have the same baseline authority to investigate foodborne illness.

**Public Health Significance:**

Every year in the United States there are millions of cases of foodborne illness (Scallan et al., 2011), and a majority of these cases are attributable to food establishments (Jones & Angulo, 2006). Investigation of these reports of illness is of paramount importance to: a) stop additional people from being exposed and becoming ill; b) understand the system failure within a food establishment that led people to become ill; and c) identify a source of contaminated food that may have entered the food establishment.

The Food Code appendix 2's supporting documents reference the Voluntary National Retail Food Program Standards along with the Council to Improve Foodborne Outbreak Response's Guidelines for Foodborne Outbreak Response. Both documents include the need for investigating foodborne illness outbreaks.

Conducting investigations into how people became sick is an integral part of a food safety program. By understanding the system failures that resulted in a foodborne outbreak, practices can be changed to prevent the failure from happening in the future. Because of the investigation's importance, FDA includes this subject matter in VNRFPS standard 2 under the epidemiology construct and IFPTI includes this as a foundational element for the basic competency level. Additionally, the important nature of this work has developed additional advanced courses (e.g., FDA ER324 Epi-Ready for Response Teams, and CDC's Environmental Assessment Training Series).

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

### **Recommended Solution: The Conference recommends...:**

*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:

8-102.10 (C)

The REGULATORY AUTHORITY shall be provided access to all facilities, EQUIPMENT, FOOD, personnel, and existing records when needed during a foodborne illness investigation.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-016**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This is a brand new Issue.

**Title:**

Interpretation of Food Code for obtaining consumer purchase records

**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 8-304.11(H) provides sufficient authority to the regulatory authority to obtain existing consumer food product purchase records from food establishments during foodborne illness investigations.

Food Code section 8-304.11(H) states that the permit holder shall:

Comply with directives of the REGULATORY AUTHORITY including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the REGULATORY AUTHORITY in regard to the PERMIT HOLDER'S FOOD ESTABLISHMENT or in response to community emergencies; Section 8-304.11(H) provides sufficient authority to the regulatory authority to gather information (including existing records) to identify a contaminated food ingredient that may have entered the establishment and initiate a traceback to the supplier of the product.

**Public Health Significance:**

Every year in the United States there are millions of cases of foodborne illness (Scallan et al., 2011), and a majority of these cases are attributable to food establishments (Jones & Angulo, 2006). Investigation of these reports of illness is of paramount importance to: a) stop additional people from being exposed and becoming ill; b) understand the system failure within a food establishment that led people to become ill; and c) identify a source of contaminated food that may have entered the food establishment. In addition, quickly identifying the source of outbreaks through consumer purchase records is crucial to identify the specific product so that public health advisories can warn consumers to avoid certain implicated products instead of broad categories (such as Romaine, tomatoes or papayas). Such advisories have an enormous economic impact on the food sector and retail food establishments. Solving outbreaks quickly using consumer purchase records also reduces the number of people that may become ill and subsequent industry liability. Some

regulatory authorities have been denied access to consumer food product purchase information, and clarification that the Food Code provides authority to access these records will reduce illnesses and associated economic impacts.

The Food Code appendix 2's supporting documents reference the Voluntary National Retail Food Program Standards (VNRFPS) along with the Council to Improve Foodborne Outbreak Response's Guidelines for Foodborne Outbreak Response. Both documents include the need for investigating foodborne illness outbreaks and having the ability to trace food back to its source.

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

### **Recommended Solution: The Conference recommends...:**

*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 provide sufficient authority for a regulatory authority to conduct a foodborne illness investigation and obtain access to existing consumer food purchase data.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-017**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018-I-027; new or additional information has been included or attached and the recommended solution has been revised.

**Title:**

Obtain Purchase Information as part of a Foodborne Outbreak Investigation

**Issue you would like the Conference to consider:**

We would like for the U.S. Food and Drug Administration (FDA) to add 8-304.11(L) to include providing available consumer purchase records to facilitate quicker identification of a food product that may be causing illness.

This will codify an existing practice and provide uniformity to both regulatory and industry segments about expectations, processes, and use of data. Many retailers already provide consumer purchase information; however, variations exist in the processes that retailers use to share this information, and the timeliness with which they provide it.

**Public Health Significance:**

Every year in the United States there are millions of cases of foodborne illness (Scallan et al., 2011). The U.S. Centers for Disease Control and Prevention's (CDC) Foodborne Disease Outbreak Surveillance System has identified an increase in multistate outbreaks from 2010-2014 (the most recent years available). While these multistate outbreaks comprise 3% of all reported outbreaks they account for 11% of the reported illnesses, 34% of the reported hospitalizations, and 56% of the reported deaths attributable to foodborne outbreaks (Crowe, Mahon, Vieira, Gould, & Report, 2015).

Quick and efficient identification of hazardous food products and their removal from commerce is critically important to minimize the number of people that become ill. Challenges to solving foodborne outbreaks include delays in reporting illnesses and consumer recall of potential exposures (such as brand and variety of food purchased). During multistate outbreaks, when people are geographically dispersed, purchase information is critical to identify a common source. Using consumer purchase data has assisted in the identification of contaminated product in outbreaks and allowed for its

removal from commerce (Barret et al., 2013; Miller, Rigdon, Robinson, Hedberg, & Smith, 2013; Møller, Mølbak, & Ethelberg, 2018).

A recent Association of Food and Drug Officials (AFDO) survey of state health and agriculture departments found that 41% of the responding jurisdictions already have authority to collect consumer food purchase information (personal communication). However, the structure and language of the authorizing legislation varies tremendously between States. By harmonizing the language in the Food Code, it will provide a uniform standard for industry to address requests for consumer purchase information.

Once an individual is diagnosed with a foodborne illness, they typically are interviewed about potential exposures by the public health program. During this interview, the patient may be asked where they have shopped for food, if investigators can access their purchase records, and for the account number or last several digits of their credit card. Provision of the account number or last several digits of the credit card number by the patient to investigators should suffice as evidence of consent.

During the 2018 biennial meeting, a concern was raised that some industry members also have stores in the European Union (EU) and that this may violate the EU's General Data Protection Regulation (GDPR). We believe that this would meet the intent of explicit consent within the GDPR regulations and would also at a minimum meet the standard for implied consent within the United States. The GDPR standard for explicit consent requires the information to be: 1) freely given; 2) specific and informed; and, 3) an unambiguous indication (by statement or clear affirmative action). Once an individual is diagnosed with a foodborne illness, public health officials may interview them about potential exposures including their food history and where they have shopped. During this interview, the patient may be asked if investigators can access their purchase records, and for the account number or last several digits of their credit/debit card. Provision of the account number or last several digits of the credit/debit card by the patient to investigators should suffice as evidence of consent. Additionally, any information obtained by the regulatory/health authorities would be covered under the same data protection laws that public health jurisdictions use to protect all investigation data (e.g., all other exposure/food consumption information provided by the patient during an interview).

Another concern voiced at the 2018 biennial meeting is that food establishments may be subject to the Health Insurance Portability and Accountability Act (HIPAA) regulations and that releasing any information may violate those requirements. 45CFR164.512(b) provides an exception for public health activities which allows disclosure of protected health information to prevent or control disease.

An additional concern was raised that some existing terms of service for industry incentive programs would not allow for this type of data sharing. However, by including this provision in the Food Code, the legal requirement would have precedent over the terms of service and would allow for data sharing.

A comprehensive best practices document is being finalized by 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. The document, titled "Shopper History: Best Practices for use during Foodborne Illness Investigations", addresses the concerns that surfaced during the 2018

biennial meeting including data maintenance and confidentiality considerations. The finalized version will be posted at <http://www.afdo.org/shopper-cards> [afdo.org].

By adding these provisions to the Food Code, we will be able to: 1) more frequently and more quickly identify and remove food items that may be causing illness and, 2) provide a uniform standard for industry to address purchase history requests.

Barret, A. S., Charron, M., Mariani-Kurkdjian, P., Gouali, M., Loukiadis, E., Poinet-Leroux, B., . . . Mailles, A. (2013). Shopper cards data and storage practices for the investigation of an outbreak of Shiga-toxin producing *Escherichia coli* O157 infections. *Médecine et Maladies Infectieuses*, 43(9), 368-373. doi:<https://doi.org/10.1016/j.medmal.2013.05.004>

Crowe, S. J., Mahon, B. E., Vieira, A. R., Gould, L. H. J. M., & Report, M. W. (2015). Vital signs: multistate foodborne outbreaks-United States, 2010-2014. *64*(43), 1221-1225.

Miller, B. D., Rigdon, C. E., Robinson, T. J., Hedberg, C., & Smith, K. E. J. J. o. f. p. (2013). Use of global trade item numbers in the investigation of a *Salmonella* Newport outbreak associated with blueberries in Minnesota, 2010. *76*(5), 762-769.

Møller, F. T., Mølbak, K., & Ethelberg, S. (2018). Analysis of consumer food purchase data used for outbreak investigations, a review. *Eurosurveillance*, 23(24), 1700503. doi:<https://doi.org/10.2807/1560-7917.ES.2018.23.24.1700503>

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

### **Recommended Solution: The Conference recommends...:**

*The Conference recommends...*

that a letter be sent to the FDA requesting that the most current published version of the Food Code be amended as follows:

Add new section 8-304.11(L)

(L) Provide existing customer food purchase records as rapidly as possible with customer consent to the REGULATORY AUTHORITY during a foodborne illness investigation.

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**Supporting Attachments:**

- "Analysis of consumer food purchase data used for outbreak investigations"

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# Analysis of consumer food purchase data used for outbreak investigations, a review

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Article submitted on 21 Jul 2017 / accepted on 04 Jan 2018 / published on 14 June 2018

**Background:** Investigations of food-borne outbreaks are frequently unsuccessful and new investigation methods should be welcomed. **Aim:** Describe the use of consumer purchase datasets in outbreak investigations and consider methodological and practical difficulties. **Methods:** We reviewed published papers describing the use of consumer purchase datasets, where electronic data on the foods that case-patients had purchased before onset of symptoms were obtained and analysed as part of outbreak investigations. **Results:** For the period 2006–17, scientific articles were found describing 20 outbreak investigations. Most outbreaks involved salmonella or Shiga toxin-producing *Escherichia coli* and were performed in eight different countries. The consumer purchase datasets were most frequently used to generate hypotheses about the outbreak vehicle where case-interviews had not been fruitful. Secondly, they were used to aid trace-back investigation, where a vehicle was already suspected. A number of methodological as well as (in some countries) legal and practical impediments exist. **Conclusions:** Several of the outbreaks were unlikely to have been solved without the use of consumer purchase datasets. The method is potentially powerful and with future improved access to big data purchase information, may become a widely applicable tool for outbreak investigations, enabling investigators to quickly find hypotheses and at the same time estimate odds ratios or relative risks hereof. We suggest using the term ‘consumer purchase data’ to refer to the approach in the future.

## Introduction

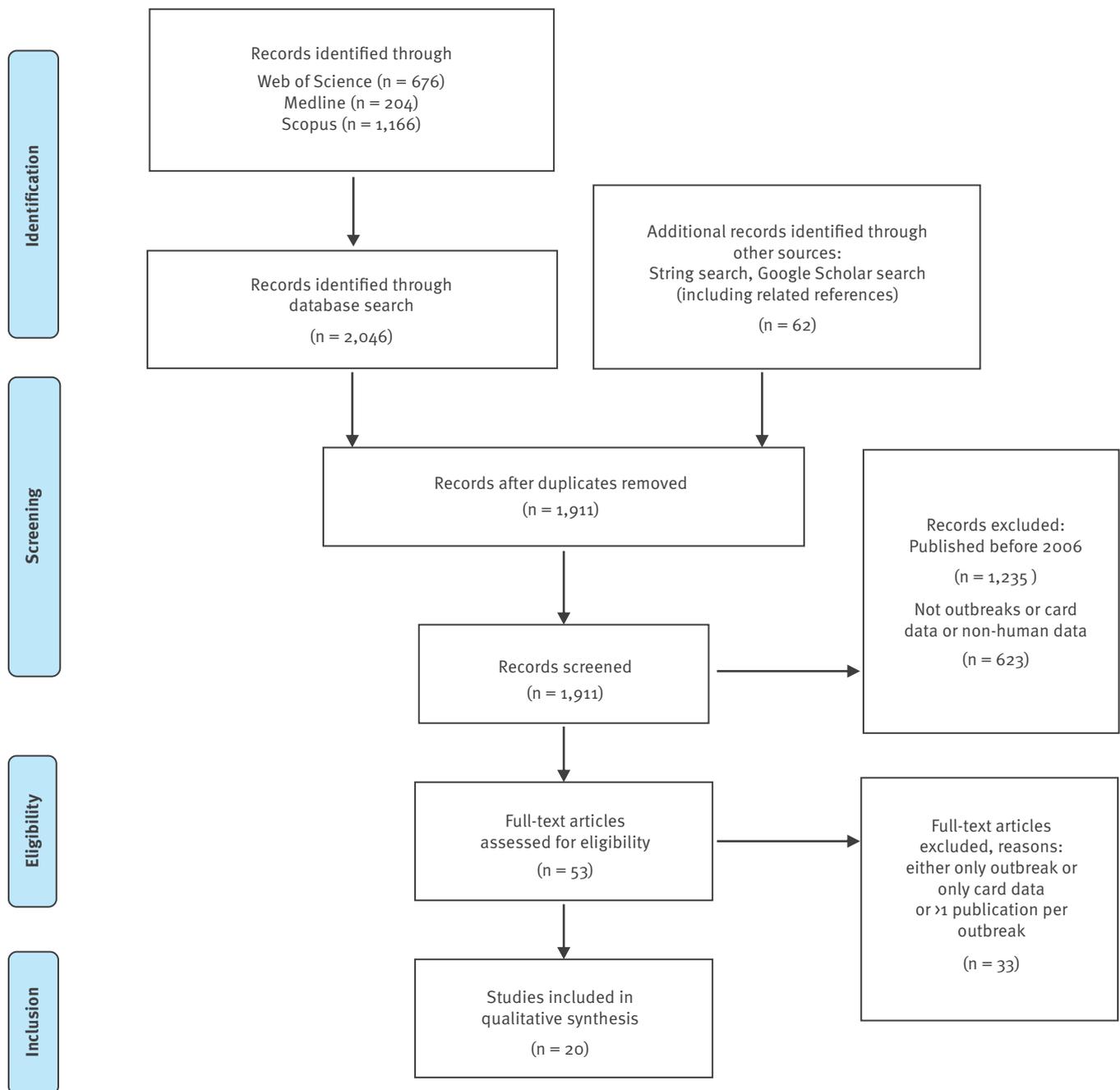
Food-borne illnesses are a considerable cause of mortality, in particular among children, in the developing world and an important cause of morbidity in the developed world. Work from the World Health Organization (WHO) Food-borne Disease Burden Epidemiology Reference Group has estimated that 600 million food-borne illnesses occurred worldwide in the year 2010,

leading to 420,000 deaths. In the WHO European Region, an estimated annual 23 million illnesses occur [1]. In the United States (US), it has been estimated that food-borne illness that can be specifically attributed to the major pathogens affects more than 48 million citizens annually [2] and amounts to an economic burden of several billion US dollars [3].

In the European Union (EU), food-borne disease outbreaks occur also frequently. In 2015, 4,362 outbreaks were of such relevance that they were reported to the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA) [4], and the control of outbreaks lies at the heart of the effort to reduce food-borne illnesses. Investigations of outbreaks help stop disease transmission, contribute to our understanding of the underlying outbreak drivers, and help to improve food safety. However, investigating food-borne outbreaks is often not a straightforward task. For dispersed outbreaks where microbiological proof often cannot readily be obtained, the steps of finding hypotheses, generally done via extensive interviews with outbreak cases – and proving/disproving hypotheses, generally done by use of analytical epidemiology, are difficult but critical factors for the success of the investigation. Outbreaks caused by agents with a long incubation time or by several different products, products with long shelf lives, low brand recognition, or representing subsets of foods that are very commonly consumed are especially hard to resolve through patient interviews. Thus alternative methods for their investigation should be considered. One such method utilises individualised consumer purchase data to resolve outbreaks, taking advantage of the fact that many retailers collect and store this information in searchable databases. The method has been used irregularly over the past decade with heterogeneous reporting and methodology and more wide-scale, systematic implementation has not ensued.

**FIGURE**

Flowchart of publication search results, 20 October 2017



In this article, we review the literature on consumer purchase data use in outbreak investigations. We classify different categories of usage in the literature and address methodological difficulties and further outline some future perspectives.

**Methods**

We searched for and included published studies in English involving food-borne outbreaks where consumer purchase data (e.g. loyalty card or credit/debit card data) were applied in outbreak investigations. The search was conducted in August 2016 using the PubMed database and Google Scholar and was repeated in October 2017 with the additional inclusion

of the Scopus and Web of Science databases. The latter search combined the search terms ('disease outbreak\*' AND 'food\*') OR 'food contamination\*' OR 'foodborne disease' with the search terms 'card\*' OR 'receipt\*' OR 'loyalty\*' OR 'till\*' or 'membership\*'. MeSH terms were used in Medline. In addition, further studies cited within the papers or already known to the author group or collaborators were also included. The search included papers published from January 2006 to 20 October 2017. Papers describing simulated outbreaks were excluded, as were papers where consumer purchase data were not applied in relation to food-borne outbreak investigations. The search was done by one author. Papers selected for narrative synthesis

**TABLE 1**

Overview of published papers of food-borne outbreak investigations using consumer purchase data (CPD) for investigations, 1 January 2006–20 October 2017

Agent causing outbreak	No of cases	Country	Source or vehicle	Duration (weeks)	Year of outbreak	Reference and year of publication
<i>Cyclospora cayetanensis</i>	29	Canada	Organic basil	13	2007	[5] Shah et al., 2009
<b>Hepatitis A virus</b>						
Hepatitis A virus	103	Denmark, Sweden, Norway, Finland	Frozen strawberries produced in Belgium	35	2013	[6] Gillesberg Lassen et al., 2013
Hepatitis A virus	165	United States	Frozen pomegranate arils produced in Turkey	19	2013	[7] Collier et al., 2014
Hepatitis A virus	9	Canada	Frozen fruit blend	10	2012	[8] Swinkels et al., 2014
<i>Listeria monocytogenes</i>	6	Switzerland	Cooked ham	14	2011	[9] Hächler et al., 2013
<b>Salmonella spp</b>						
<i>Salmonella</i> Chester	33	Canada	Pork product	9	2010	[10] Taylor et al., 2012
<i>S. Enteritidis</i>	66	United Kingdom (London)	Rotisserie chicken	1	2009	[11] Zenner et al., 2014
<i>S. Enteritidis</i>	43	United States (5 states)	Pine nuts produced in Turkey	12	2011	[12] Bedard et al., 2014
<i>S. Heidelberg</i>	134	United States (13 states)	Chicken meat	46	2012	[13] Grinnell et al., 2013
<i>S. Heidelberg</i>	136	United States (34 states)	Ground turkey	37	2011	[14] Routh, et al., 2015
<i>S. Montevideo</i> and <i>S. Senftenberg</i>	283	United States (44 states)	Pepper (spice), produced in Asia	41	2009	[15] Gieraltowski et al., 2012
<i>S. Newport</i>	42	United States	Ground beef	10	2007	[16] Schneider et al., 2011
<i>S. Newport</i>	6	United States (1 state)	Fresh blueberries	3	2010	[17] Miller et al., 2013
<i>S. Strathcona</i>	71	Denmark (plus Germany, Italy, Austria, Belgium)	Tomatoes produced in Italy	23	2011	[18] Müller et al., 2016
<i>S. Typhimurium</i>	1,054	Denmark	Unknown	29	2008	[19] Ethelberg et al., 2008
<i>S. Typhimurium</i> , monophasic	110	France	Dried pork sausage	18	2010	[20] Bone et al., 2010
<i>S. Typhimurium</i> , monophasic	337	France	Dried pork sausage	7	2011	[21] Gossner et al., 2012
<b>Shiga toxin-producing <i>Escherichia coli</i></b>						
STEC O104	60	Germany	Sprouts	9	2011	[22] Wilking et al., 2012
STEC O157	15	France	Beef burgers	6	2012	[23] Barret et al., 2013
STEC O26	20	Denmark	Organic beef salami	9	2007	[24] Ethelberg et al., 2009

STEC: Shiga toxin-producing *Escherichia coli*.

were assessed by two authors and discussed within the author group to reach consensus on methodology. A classification of use was made within the categories: hypothesis generation, trace back, corroboration of hypothesis, analytical usage.

References in papers found through the above-described search showed that, in each study, only a few other studies using the consumer card method were cited, possibly due to a marked heterogeneity in the nomenclature regarding the use of consumer

purchase data. The terms used in the found studies [5-24] included: household shopping receipts [18], consumer loyalty cards [8], shopper cards data [23], customer loyalty cards [10], supermarket loyalty cards [21], warehouse store membership card [15], loyalty card [20], grocery store loyalty card [5], credit card information [24], shopper-card information [13,14,18] and till receipts [11].

In this paper we have used the term ‘consumer purchase data’ to cover different sources of information

TABLE 2A

Category of use of consumer purchase data (CPD) for food-borne outbreak investigations, 1 January 2006–20 October 2017

Reference	Purchase data source	Category of use of CPD	Description of use of CPD	Type of outbreak	Type of vehicle
[5] Shah et al., 2009	Loyalty card; 8 cases.	Hypothesis generation and trace-back investigation	CPD used for hypothesis generation/ support of hypothesis and aid in trace back	Dispersed one-province cyclosporiasis outbreak	Organic basil was the most likely vehicle
[6] Gillesberg Lassen et al., 2013	Debit card information, several supermarkets; no. of cases not stated (<10).	Trace back	Vehicle (frozen berries) found by case-control study; CPD used to identify type and identity of product.	National, later international (4 countries) hepatitis A outbreak	Brand of frozen strawberries sold in (internationally operating) supermarket chain
[7] Collier et al., 2014	Data from membership/ loyalty cards from a retailer; no. of cases not stated.	Case finding, trace back, targeted intervention of exposed (information, post-exposure vaccination)	CPD Improved validity of initial hypothesis and targeted post exposure prophylaxis with both hepatitis A virus vaccine and immunoglobulin.	Dispersed national hepatitis A outbreak	Frozen pomegranate arils
[8] Swinkels et al., 2014	Loyalty card purchases in 3-month period; 6 cases.	Trace back	Vehicle identified in part using classical epidemiology, CPD used to locate particular producer and confirm the source. No case-control study done.	Dispersed province-wide hepatitis A outbreak	Frozen berry blend
[9] Hächler et al., 2013	Shopper cards/loyalty cards; 4 cases.	CPD support existing evidence	Supported existing evidence, use delayed by legal clarification. Consent from the patients and the retail company.	Dispersed local listeria outbreak	Cooked ham
[10] Taylor et al., 2012	Loyalty card purchases; 4 cases.	Assists hypothesis generation, trace back	Epidemiological investigation points to vehicle. CPD in subset of cases corroborates and leads to fast trace back.	Dispersed multi-province salmonella outbreak	Ready-to-eat pork product, known as head cheese
[11] Zenner et al., 2014	Till entries and receipts from single restaurant; 41 cases.	Hypothesis generation, analytical study	Helps locate dish on menu in take-away restaurant + makes analytical argument by comparing sale over different time periods.	Point-source (geographical) outbreak associated with single restaurant	Chicken dish, one item of many on a restaurant menu
[12] Bedard et al., 2014	Shopper card purchases, no of cases not stated (<10)	Hypothesis generation	CPD gives 3 distinct hypotheses, leads to source identification by microbiological testing.	Local county investigation and multi-state cluster	Pine nuts sold in supermarket/stores
[13] Grinnell et al., 2013	Shopper card purchases; 9 cases.	Trace back	Standard epidemiological methods identify vehicle, CPD used to zoom in on producer and exact product.	Dispersed multi-state salmonella outbreak	Industrial chicken products sold in supermarket chain(s)
[14] Routh et al., 2015	Loyalty card purchases; 3 cases.	Trace back	Trace back (helping to identify the vehicle, combined with traditional methods).	Dispersed national salmonella outbreak	Ground turkey
[15] Gieraltowski et al., 2012	Store membership card purchases; 7 cases initially, 19 cases at late stage.	Hypothesis generation (and trace back)	CPD information points to specific hypothesis. Also strongly aids trace back.	Dispersed multi-state salmonella outbreak, 2 serotypes and several vehicles	Salamis made with contaminated black and red pepper (dried spices)
[16] Schneider et al., 2011	Loyalty cards; 11 cases.	Aided trace back	CPD improves validity of questionnaire findings. CPD used to target trace back combined with records of beef processing.	National, multistate salmonella outbreak	Ground beef
[17] Miller et al., 2013	Shopper card purchases; 3 cases.	Trace back	Vehicle suspected by epidemiological methods, small outbreak, evidence in-conclusive. CPD gives GTIN numbers which leads to precise trace back, identifying product.	Dispersed, but small, salmonella outbreak in part of 1 state	Fresh berries, sold in supermarket chain, traced back to specific producer

CPD: consumer purchase data; GTIN: global trade item number; STEC: Shiga toxin-producing *Escherichia coli*.

**TABLE 2B**

Category of use of consumer purchase data (CPD) for food-borne outbreak investigations, 1 January 2006–20 October 2017

Reference	Purchase data source	Category of use of CPD	Description of use of CPD	Type of outbreak	Type of vehicle
[18] Müller et al., 2016	Digital receipts from cashier systems from 2 supermarket chains of purchases in 6-week period; 15 cases.	Hypothesis generation	Initial hypothesis-generating interviews are inconclusive, but points to 2 supermarkets. CPD leads to quite specific hypothesis. Followed by traditional case-control study.	Dispersed national salmonella outbreak	Particular type of tomatoes, hidden among all tomatoes in interviews
[19] Ethelberg et al., 2008	Debit cards; digital receipts from several supermarket chains purchases in 6 week period; no. of cases not stated (ca 25).	Hypothesis generation	Many different investigation methods in use. CPD applied on several supermarkets/shops. No common pattern was identified.	Large and prolonged nation-wide salmonella outbreak	Vehicle/source never identified
[20] Bone et al., 2010	Loyalty card purchases three weeks before onset; 9 cases.	Trace back and corroboration of hypothesis	Epidemiological investigation points to vehicle. CPD corroborates (9/9 cases bought product) and points to single brand. Recall without case-control study or microbiological proof.	Dispersed national salmonella outbreak	Dried salami, distributed nationwide, sold in single supermarket chain
[21] Gossner et al., 2012	Loyalty card purchases; 39 cases.	Trace back and semi-analytical use	Epidemiological investigation points to vehicle. Focused CPD corroborates and points to single brand. Proportions used for likelihood argument. Recall without case-control study or microbiological proof.	Dispersed national salmonella outbreak	Dried salami, distributed nationwide, sold in supermarket chain
[22] Wilking et al., 2012	Employee cards used for cafeteria sales; 23 cases and 30 controls.	Analytical study	CPD data used for nested case-control study within cohort of company workers	Point-source outbreak, sub-outbreak within large national STEC outbreak	Raw sprouts served as part of lunch meals
[23] Barret et al., 2013	Shopper card purchases; 5 cases (though not clearly stated).	Trace back	Find the exact brand of product after vehicle has been identified using epidemiological methods	Regional (sub-national) STEC outbreak	Fresh ground beef (burgers) sold in supermarket chain.
[24] Ethelberg et al., 2009	Debit cards; digital receipts from purchases from 2 supermarket chains in 6-week period; 7 cases.	Hypothesis generation.	Initial hypothesis-generating interviews are inconclusive, but points to single supermarket. CPD leads to specific hypothesis. Further proof from case-control study and microbiological testing.	Dispersed national STEC outbreak among children	Organic, fermented salami made of beef, distributed nationwide, sold in single supermarket chain

CPD: consumer purchase data; GTIN: global trade item number; STEC: Shiga toxin-producing *Escherichia coli*.

for purchases of food, e.g. a credit card or a loyalty card, to cover the entire process of using the data as a method for outbreak investigations.

## Results

The results of the publication search strategy are shown in the Figure. Over the study period, 20 papers published in international peer-reviewed journals were identified describing outbreaks where consumer purchase data were collected and used for food-borne outbreak investigations [5-24].

### Outbreak characteristics

Table 1 gives an overview of the outbreaks. The outbreaks were primarily caused by *Salmonella enterica* of different serotypes and subtypes (12 outbreaks) [10-21], followed by Shiga-toxin producing *Escherichia coli* (STEC) of different O-groups (3 outbreaks) [22-24], hepatitis A virus (3 outbreaks) [6-8], as well as *Listeria monocytogenes* [5] and *Cyclospora cayetanensis* [9]

(1 outbreak each). The outbreaks took place in North America [5,7,8,10,12-17] or Europe [6,9,11,18-24] and, except for two, were dispersed outbreaks, extended over time and geographical area. They were mostly nationwide outbreaks, although two outbreaks were international. Two outbreaks were point-source outbreaks examined using a cohort set-up [11,22]. The outbreaks were of varying size, the number of outbreak cases ranged from six to more than 1,000, with a median of 63 cases. The duration of the outbreaks ranged from 1 week to more than 1 year. The outbreak source was identified, with varying degrees of supporting evidence presented, for all but one [19] of the 20 investigated outbreaks.

Table 2 lists further details about each publication, categorising purchase data source and the general use of the method into categories. For the dispersed outbreaks, the purchase data were accessed from supermarket or similar type of store databases. The

databases holding the cash register information were searched for specific purchase transactions. These were based on the case/consumer loyalty card number, credit/debit card number or simply the amount paid coupled with date and branch of store, information that was derived from cases' (web) bank statements following purchases with payment cards. Consumer purchase data were used for two major purposes: source hypothesis-generation [5,9-12,18-21,24] and food trace-back investigations [5-8,10,13-17,20,21,23]. A few papers described further types of application of the methodology [7,11,21,22]. Below, the use of consumer purchase data are described in more detail including examples.

### Hypothesis generation

In all reports of dispersed outbreaks, the investigators followed the standard approach of aiming to generate a hypothesis as to the vehicle of the outbreak, using hypothesis-generating interviews with standardised questionnaires. Consumer purchase data were used in situations where the initial hypothesis-generating activities did not lead to a hypothesis or where the product category suggested was unspecific. Case-patients gave permission to the outbreak investigation teams to access sources of information that could be used to perform a search. This involved loyalty or 'shopper' card numbers, credit or debit card numbers or (online) bank statements detailing supermarket purchases. This information was then taken to the retailers to search for computerised data on all specific products bought during each particular transaction done before onset of symptoms. The time window of purchases was defined as 3 weeks [18,20], 6 weeks [24] or 3 months [8] before onset of symptoms or was not mentioned. Some investigators performed the search manually, others in a semi-automated manner by retrieving the data from a central supermarket computer system.

In seven studies (Table 2), the use of the method gave a narrower range of candidate products (often only one) than the range of products initially identified using hypothesis-generating interviews [5,10,12,15,18,20,24]. In one outbreak, no hypotheses were found [19]. The number of cases from whom consumer purchase information was obtained ranged from four to 43 in the reviewed studies. Following use of the method, testing of hypotheses was generally performed using standard methods, such as case-control studies or microbiological analysis of foods.

In one example, a local cluster of *Salmonella* Enteritidis cases detected by routine surveillance was investigated. Use of the methods on a subset of cases identified three possible hypotheses, tomatoes, avocado and pine nuts. Further investigation, including microbiological examination of products collected from cases' homes identified pine nuts as the source of the outbreak [12]. In a second example of STEC O26 infections affecting primarily children under the age of 3 years, interviews with parents failed to produce workable hypotheses. Comparison of purchase data from

seven families revealed that six of these had bought a specific brand of organic beef salami before onset, a product that none of the parents had reported during the interviews. A subsequent case-control study corroborated this product as the source of infections and the outbreak strain was later also isolated from the product [24].

### Analytical epidemiology

None of the studies of dispersed outbreaks used consumer purchase data for a regular analytical study, i.e. to produce a measure of association, such as an odds ratio. However, in several instances, the results obtained from use of the method were of sufficient specificity to produce convincing evidence as to the outbreak source. In an outbreak of salmonellosis in France, epidemiological investigations led to the hypothesis that salami-style pork sausage was the vehicle. Of 39 cases whose shopping data in one supermarket chain were retrieved, 22 had bought such sausages and 15 had bought exactly the same product from a single producer. Using overall sales data from the supermarket chain, this product was found to constitute only 3% of all salami sales. Based on this, a recall of the sausage was undertaken [21].

Two reports concerned analytical usage in a point-source outbreak setting. Following an *S. Enteritidis* outbreak found to be associated with a take-away restaurant in London, sales data were used to point to a particular chicken meal. This was done by comparing sales made by cases with sales made by other customers at the same hour the day before [11]. The second report concerned an outbreak within the outbreak of the larger German O104 STEC outbreak in 2011 [25]. It occurred among employees of a company and was linked to the company canteen where employees paid for lunch meals using their employee access cards. This meant that the employees' lunch choices were being electronically registered. This way, in a retrospective nested case-control study within the cohort, the strength of an association between cases and sprout-containing salad meals could be estimated [22].

### Trace back or trace forward

In 13 studies, trace-back and/or trace-forward investigation was performed by use of consumer purchase data, once a probable source of the infections had been identified (Table 2) [5-8,10,13-17,20,21,23]. The source of the infections in the studies ranged from vegetables, fruits and nuts (raw tomatoes, organic basil, blueberries, frozen fruit blend, pine nuts), to meat products (including beef burgers, poultry, delicatessen sausages and meat as well as ground turkey, dried pork sausages, fermented sausage, and rotisserie chicken (Table 1). In some studies, this trace back formed part of the evidence for what constituted the source of the outbreak.

In one outbreak, hypothesis generation was guided by loyalty card-derived purchase data, which revealed a

specific type of salami as a common food purchase. The purchase data therefore also facilitated locating the distributor. The resulting trace-back investigation indicated that dried pepper, used as an ingredient in the salamis, was the probable source of the outbreak. Trace forward led to further identification of tainted products including human cases affected by a second *Salmonella* serotype found in a red pepper storage facility, thereby extending the understanding of the outbreak [15]. In hepatitis A virus outbreaks in Canada and Scandinavia, frozen fruit/berries were identified as sources. The long incubation period and the fact that multiple similar product categories existed made trace back a challenge. Analysis of purchase data records allowed investigators to pinpoint the precise products via the food product identification codes without which trace back would most likely not have been possible [6,8,17].

Finally, in one outbreak [7] consumer purchase data was used to directly target exposed individuals. In this hepatitis A virus outbreak in the US, purchase data was used to define cases (purchase/exposure being part of the case definition) and further to warn customers who had purchased the product by use of automated voice-message phone calls and to target post-exposure immunisation to exposed customers. This was carried out by the affected retail chain, and not through data sharing with public health officials.

## Discussion

In this review, we found that consumer purchase data have been applied successfully in several phases of outbreak investigations. In the studies reviewed, the method was used for forming or assisting in forming hypotheses for the source/vehicle of the outbreaks where prior interviews had proven insufficient. Additionally, purchase data often aided source finding, providing a product subtype and sometimes even a lot or batch number. In some outbreaks, time to product recall was reduced, in others it was unlikely that the source would have been found, had it not been for the purchase data. The low number of documented purchase events needed in many of the studies to identify a probable source is a promising finding. Conversely, 20 papers published over the last decade represents a rather low number, suggesting the existence of obstacles to widespread use. We suggest using the term 'consumer purchase data' in future to refer to the approach as we think this term better captures the different aspects of the approach that we encountered than terms using the word 'card'.

Critical steps in the investigation of food-borne outbreaks concern identification of suspect food products and providing proof of the source beyond reasonable doubt. We believe the evidence available from the papers reviewed here suggests that the use of purchase data may be a generalisable investigation method that could be very attractive for the investigation of challenging food-borne outbreaks. As some of the papers

showed, searching through datasets across households with case-patients for common purchases may often be a more powerful method than the standard methods of interviewing case-patients, which are subject to incomplete recall. Interviews are less efficient in situations where, for instance, the period between interview and exposure is long [26] or the food is of a kind that is unlikely to be reported on, such as foods that are hard to remember (e.g. sprouts), food ingredients or sub-batches of common foods.

Establishing proof is generally possible using one of three strategies: microbiological evidence (finding the disease agent in the food using a specific typing method), epidemiological evidence (showing that a strong association between case status and a specific food consumption is present) or food supply evidence (showing a correlation between cases exposure and the presence of the incriminated foods). The papers we found generally did not use the purchase data method with the purpose of establishing proof. Potentially, however, strong evidence could be established by use of the purchase data method. If large purchase datasets from retailers were to become routinely available to outbreak investigators, comparisons could be made between case and non-case consumers. Thus, odds ratios for purchase could be calculated immediately and the process of searching for candidate foods (hypothesis generation) and the subsequent step of assessing their likelihood as outbreak vehicles (analytical epidemiology) could be performed in a single step. In addition, the methods may be a powerful tool for product identification, trace-back/trace-forward investigation and assessing likelihood of a food being an outbreak vehicle through comparisons of distribution and intensity of sales. A purchase data analysis could provide codes identifying the foods uniquely, such as European/International Article Numbering (EAN) or Global Trade Item Number (GTIN). This may potentially lead to efficient and fast comparative analyses using food databases. The latter is important, because trace-back investigations for larger outbreaks may reach levels of complexity where they become impossible to perform with traditional methods in addition to being lengthy and labour-intensive.

Such a framework would be strengthened by the increased penetration of card or mobile phone-based payments, expected to occur in the coming years. Combined with the foreseen increased application of whole-genome sequencing for routine surveillance of food-borne infections, it might also be valuable for the investigation of small or protracted outbreaks from continuous sources where cases are currently regarded as sporadic. Likewise, it may also be valuable for source attribution purposes, i.e. to describe the relative distribution of the sources which give rise to sporadic cases. Finally, as seen in one outbreak [7], it may be used to find and warn customers who have bought a product found to be contaminated and may thereby also help stop further cases [27].

Importantly, however, a number of requirements of a structural nature would need to be resolved before widespread use of the method could take place. These requirements include legal frameworks for ensuring consumer protection and patients' privacy and the need to establish and maintain agreements between public health institutions and retailers securing data access. Data protection regulations and other obstacles for data access differ between countries and this may be the reason for why application of the method was geographically skewed. Adding to that, a number of more general methodological obstacles exist. First, purchase does not equal consumption and cases may often be part of families or households so that food purchases by several persons may need to be collected. Secondly, capturing foods consumed in restaurants or smaller retailers including convenience food remains a challenge, and thirdly, purchases made without the use of loyalty or payment cards will go unnoticed with current coverage and payments systems. Finally, not all retailers may wish to share data, affecting the coverage of the purchasing data. However, even if only imperfect data can be retrieved, the method may still produce results. An analogy can be drawn with standard disease surveillance, which often also captures only a fraction of all cases, but nonetheless is useful for finding and solving outbreaks. Hence, incompleteness in exposure assessment should not preclude efficient use of the method.

Overall, the papers we found and included contained little detail on how purchase data analysis was applied. The handling of data was most often not described in detail. With few exceptions [18,21], the total number of receipts retrieved, the period and the fraction of total purchases these receipts covered were not accounted for. Also, restrictions or obstacles of a legal, cultural or habitual nature were generally not mentioned and we could therefore not extract data on such matters. The papers did in general mention good working relationships between public health authorities and food retailers. Efforts to protect citizen privacy were not described in detail. Secure systems to handle potentially sensitive purchase data, systems to obtain consent, and share data are prerequisites of a wider implementation of consumer purchase datasets, and descriptions hereof in future studies would be beneficial.

This review has several limitations. A broader literature search including more search terms, languages other than English or including unpublished outbreak reports might have revealed more studies. We also limited our search to after the year 2005, but we note that studies taking advantage of shopping receipts in paper form also exist from before this time [28]. The papers generally report successful use of consumer purchase data; however, this could be partly due to publication bias, which is known to affect reporting of food-borne outbreaks [29]. We found one example where consumer purchase data were used for investigation of a large

outbreak without finding the source [19], but it is possible that more unresolved and unpublished outbreaks using the consumer data method exist.

In conclusion, the reviewed papers describe a powerful outbreak investigation method. It holds promise of developing into a routinely applied tool provided that more automated procedures reducing labour for retailers as well as epidemiologists and ways of making data more available could be found. We envision a near future where food purchase information in some countries can be automatically collected from cases of food-borne infections and compared with that of a large panel of non-cases. Such a system would significantly improve source-identification and risk-assessment efforts, facilitate efficient trace back enabling timely interventions and reduce illness caused by food-borne pathogens.

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### Conflict of interest

None declared.

### Authors' contributions

Frederik T Møller performed the publication database search. Frederik T Møller and Steen Ethelberg reached a conclusion on each reviewed paper and drafted the manuscript while Kåre Mølbak revised it critically. All authors made substantial contributions to the conception or design of the work and interpretation of data for the work.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-018**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend the Food Code to Require Consumer Notification of Food Recalls

**Issue you would like the Conference to consider:**

This Issue helps to ensure that consumers are notified by food retailers after adulterated food has been offered for sale. During a recall, retailers have a unique role in notifying consumers who have purchased contaminated food. Consumers often return to the same grocery store week after week, affording opportunity to see in-store notices for recalled food purchased on a prior visit. Moreover, grocery stores frequently maintain purchase information through customer loyalty programs, which enables targeted communications directly to affected consumers via email, telephone text, or register printout.

Consumer notification of recalls is recommended as an industry best practice, and the majority of large food retailers have already adopted policies requiring such notice. Unfortunately, the scope and effectiveness of these policies vary, and there are no federal, state, or local standards to ensure effectiveness or appropriate implementation.

Section 211 of the Food Safety Modernization Act aimed to address this problem by authorizing the Food and Drug Administration (FDA) to publish one-page notices for recalled foods online, which grocery stores would then be required to download and post in-store. Unfortunately this authority, which has not been implemented, would be narrower, less efficient, and less informative than alternative methods of communication that could be developed directly by food retailers and their suppliers.

Amending the Food Code to require consumer notification of food recalls offers a more effective means to ensure that consumers are notified of recalls, while also providing flexibility for food retailers in identifying means to achieve that end.

**Public Health Significance:**

Between 2013 and 2018, the Food and Drug Administration (FDA) and US Department of Agriculture (USDA) together oversaw nearly 4500 food recalls, averaging more than 700 recalls annually. About half of which were Class I recalls, meaning they involved a

reasonable probability of serious adverse health consequences or death.

[https://uspirg.org/sites/pirg/files/reports/WEB\\_USP\\_Safe-Food-Report\\_Jan19.pdf](https://uspirg.org/sites/pirg/files/reports/WEB_USP_Safe-Food-Report_Jan19.pdf).

An important priority during such recall events is ensuring that affected consumers receive timely and actionable information about the recall. Such notices are essential to enable consumers to identify and discard food that may be contaminated, as well as seek out appropriate medical care (e.g. prophylaxis for Hepatitis A exposure).

Consumer notification is especially important when product may be frozen or has a long storage life, meaning purchased food can remain a risk to consumers for weeks or even months after the recall. For example, ground beef tied to a *Salmonella* outbreak recalled in October and December of 2018 continued to sicken dozens of patients for months after. The last case of illness in that outbreak was reported in February 2019, more than four months after the initial recall was initiated. <https://www.cdc.gov/salmonella/newport-10-18/epi.html>. Similarly, flour tied to an *E coli* outbreak was recalled three times between May and July of 2016, yet illnesses from that outbreak continued into September of that year, more than three months after the initial recall. <https://www.cdc.gov/ecoli/2016/o121-06-16/epi.html>. Such long delays between initiation of a recall and onset of illness suggests that contaminated product has the potential remain in consumers' homes for a substantial period, placing unknowing consumers at risk.

When a recall is initiated, the responsible firm generally ensures notice is communicated to customers and retail consignees, providing the information needed to carry out the recall. The federal agencies responsible for overseeing food recalls also conduct audit checks (FDA) and effectiveness checks (USDA) to verify that the recall has been effectively communicated to consignees and affected product is removed from commerce.

Yet the same obligation to communicate food recall information has not been extended to the end purchaser: the consumer. Instead, if consumers learn of recalls at all, the notice is typically relayed through mass media, often now amplified through posting on the FDA or USDA website, media lists, and social media. Consumers surveyed for the 2015 U.S. Grocery Shopper Trends report, issued by the Food Marketing Institute, reported learning about food recalls primarily through television (73 percent), print media (27 percent), or radio (25 percent), with only a small minority reporting having received recall notices from a grocer through in-store postings (12 percent) or email alerts (7 percent). (See Supporting Attachment: 2015 Shopper Trends).

A system driven by media communications is extremely limited: neither the news media nor consumers can reasonably be expected to take notice of hundreds of recalls announced publicly each year, many for products distributed nationwide only to select retailers or food service providers. In contrast to mass announcements, notices issued by grocery stores have the potential to be more effective, because they target information towards the population of shoppers most likely to have purchased the affected food. The average consumer visits the store for groceries 1.6 times per week, often returning to the same store more than once within a few days. <https://stores.org/2019/08/05/are-retailers-prepared-for-the-changing-grocery-shopper/>. This presents an opportunity for shoppers to identify recalled food from a prior visit and dispose of it before it is consumed. In some cases, grocery stores even retain purchase history information, enabling them to send messages via phone, email, and print mail directly to affected consumers.

Consumers have expressed a strong preference for receiving notice in this manner: the 2015 Shopper Trends report cited above found that if given the option, most consumers (58 percent) would prefer to receive recall notifications via email, and many would also like to see notices posted where the product is sold (40 percent) or at the checkout register (26 percent). (See Supporting Attachment: 2015 Shopper Trends).

Many grocery stores have already responded to this interest by adopting policies requiring consumer notification of recalls. A 2010 study commissioned by FMI and the Grocery Manufacturers Association (GMA) showed that 69 percent of major food retail companies surveyed reported posting signage in-store as part of the recall notification process.

[https://www.gmaonline.org/downloads/research-and-reports/WP\\_RecallExecution.pdf](https://www.gmaonline.org/downloads/research-and-reports/WP_RecallExecution.pdf).

Another survey published in 2016 by the Center for Science in the Public Interest (CSPI) (the organization submitting this Issue) found that 15 out of 16 respondents posted recall notices in-store. <https://cspinet.org/resource/building-food-recall-system-really-protects-consumers>. Moreover, CSPI found that 8 of 9 respondents with customer loyalty programs used the information from those programs to alert customers to food recalls affecting products they purchased.

In-store notification of recalls is recommended as a retailer best practice: The Food Marketing Institute (FMI) provides guidance recommending that consumer notifications be posted in the store, directly to the consumer (e.g. via email, phone, or mail), or other means for at least two weeks following the recall. <https://www.fmi.org/docs/default-source/food-safety/guidance-for-food-retail-product-recall.pdf?sfvrsn=2>.

In spite of this declared progress, many recall notices are still not effectively reaching consumers. As noted above, the FMI's 2015 Shopper Trends report showed that only a small minority of consumers report receiving recall notices from their grocers through in-store postings (12 percent) or email alerts (7 percent). This may be attributable to the fact that the design, coverage and consistency of the postings varies by store. The 2016 survey by CSPI found that the location, prominence, and information provided in recall postings varied substantially. Some store had no store-wide policy for posting location, leaving discretion to managers in determining where to post notices. Others limited the postings to certain foods, such as produce or products made on the premises.

Section 211 of the Food Safety Modernization Act (FSMA) aimed to remedy this problem by authorizing the FDA to publish one-page notices for foods listed in the Reportable Food Registry (RFR), and requiring grocery stores to post such notices. Yet Section 211, which has not been implemented by the FDA, is by its nature limited to FDA-regulated foods, meaning it would fail to cover meat and poultry. It is important for recall notification policies to cover such products, which are often a source of illness and can be frozen, posing a threat long after a recall.

Section 211 also hinges on a cumbersome process: first, the recalling firm must submit consumer-oriented information to the RFR within 24 hours of learning of an issue. Then the agency must generate and post a one-page summary of the information on the government's website. Grocery stores with more than 15 locations who sold the food are obligated to post either the one-page summary "or the information from such summary" within 24 hours of posting. Yet relying on such notices conveyed through the RFR and FDA's website could substantially slow notification, as food retailers have report they often receive information from suppliers well before it is posted in the RFR.

<https://www.federalregister.gov/documents/2014/03/26/2014-06614/implementation-of-the-food-and-drug-administration-food-safety-modernization-act-amendments-to-the>.

In addition, Section 211 does not require the standardized information from such notices to include the reason for the recall, a key piece of information in light of the fact that many recalls involve undeclared allergens that pose a health hazard to only a subset of consumers.

The notification system laid out under Section 211 is therefore potentially slower and less informative than an alternative system under which consumer-targeted information is transmitted directly to stores by the recalling firm.

Such a system could be required directly under the Food Code, which could fill a key gap in the current system by ensuring that recall communications delivered through the supply chain reach all the way to the end user: the consumer. Such a policy would re-enforce existing voluntary practices by creating additional incentives for retailers and their suppliers to improve the quality and consistency of consumer-directed recall communications.

Any Food Code requirement could also be harmonized with Section 211, by ensuring that notices required under the Food Code include all of the consumer-oriented information that would be submitted to the RFR were the agency to implement Section 211. Notices generated to satisfy the requirements of the Food Code would then also be compliant with the requirements of Section 211 in the event that the agency moves forward with this authority.

### **Recommended Solution: The Conference recommends...:**

*The Conference recommends* that a letter be sent to the FDA requesting that the Food Code be amended to add, after Section 3-603.11 (Consumer Advisory), a section requiring that food establishments post notification to consumers when food sold for consumption off the premises is later subject to a recall. This new section should be harmonized with the requirements of Section 211 of the Food Safety Modernization Act and generally conform to the following criteria:

Consumer-oriented recall notices should be developed in conformance with the FDA's guidance on Public Warning and Notification of Recalls, which generally recommends a public warning be issued for recalls that are likely to be classified as Class I recalls unless specific circumstances indicate that the warning would not be beneficial to the public.

<https://www.fda.gov/media/110457/download>.

Such notices should be posted for a minimum of two weeks and should be prominently and conspicuously located at the primary point of display for the recalled food, at the register, or other such locations and manners as will provide comparable notification to consumers.

If the food establishment maintains purchase history information for individual consumers, the notices may also be directed to such consumers via email, phone, mail, print-out at the register, or other such methods as will provide comparable notification to consumers.

The content for such notices should include a product description, identification code such as a UPC or sell by/use by date, contact information for the party responsible for the recall, as well as the reason for the recall, if known (such as undeclared allergen, specific pathogen, or foreign material contamination).

Instructions for enforcement of this section should be added to Annex 5 after 3.G.12. (Assessing Compliance with Consumer Advisory). The instructions should establish a process whereby the inspector may verify compliance with the requirement using either records provided by the Food and Drug Administration or records requested from the person in charge at the food establishment.

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**Supporting Attachments:**

- "U.S. Grocery Shopper Trends 2015"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*



U . S . G R O C E R Y S H O P P E R

# TRENDS 2015



THE VOICE OF FOOD RETAIL

Feeding Families  Enriching Lives



For questions or comments, please contact:

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Food Marketing Institute proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost \$770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit [www.fmi.org](http://www.fmi.org) and for information regarding the FMI foundation, visit [www.fmifoundation.org](http://www.fmifoundation.org).

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U . S . G R O C E R Y S H O P P E R  
**TRENDS 2015**

U.S. Grocery Shopper Trends

Published by:  
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## Executive Summary

### *Introduction*

The dynamic process of how we in the U.S. get our food continues to be shaped and reshaped by modern lifestyles, changing families, digital technologies and heightened awareness of the health and environmental consequences of food. With fewer traditional rules to discipline consumer choices and routines today, the relationship between shopping and eating has been changing: Americans increasingly shop without planning and eat without shopping. They devote their loyalty to products with stories, but divide their loyalties across channels and stores. Food retailers increasingly must bend and flex within the shifting shopper landscape to align supply and demand realities with product, service and merchandising opportunities.



**T**he Food Marketing Institute has long supported U.S. food retailers through annual surveys of shopper behaviors and attitudes, providing consistent metrics to evaluate the changing market landscape. In recent years, FMI has supplemented its year-over-year survey research perspective with a cultural lens, interviewing Americans in their homes and while shopping, and drawing upon ethnographic research into U.S. food consumption and consumers.

As we seek to illuminate how evolving shopper attitudes and behaviors translate into large-scale shifts that affect supermarket revenues and growth, we must also feel out places where the light of our assumptions doesn't reach. In fact, careful attention to shopper data and shopper stories has revealed some changes so fundamental that they warrant new ways to collect data and listen to stories, as well as new strategies to succeed by meeting eating needs.

This year's study focuses on a deep shift in shopping and important mealtime distinctions, and provides updates along the way about long- and short-term trends for food retailers to watch. This includes:

- Status check on current trends influencing shoppers and shopping
- How trends are coalescing into a new Shared Shopper Paradigm
- Mealtime distinctions and the case for Family Meals
- Updates to shopper values and trends, including the convergence of personal health and community wellness ideals

## *Methodology*

The report that follows draws on the extensive database of past FMI annual surveys while highlighting new insights through a combination of quantitative and qualitative research conducted in the first quarter of 2015. New survey data was collected in the U.S. from a total of 2,265 regular shoppers of groceries, 18 years and older, through a 25-minute online survey. For deeper context, a mix of qualitative approaches including in-home and in-store interviews and online journaling was used to capture insights from a total of 15 additional consumers from 10 multi-shopper households. Additional analysis was conducted with U.S. Census and USDA data sets on consumer spending, health, and eating, and 2013-2015 Hartman Group ethnographic and survey research into eating and shopping.



## Shoppers utilize multiple sources for information on food safety standards and recalls

The Internet (65%) and friends and family (58%) are the primary sources shoppers cite for learning about food safety standards and practices (see Table 4.5). However, when it comes to food recalls, television remains the most widely used information source (see Chart 4.10).

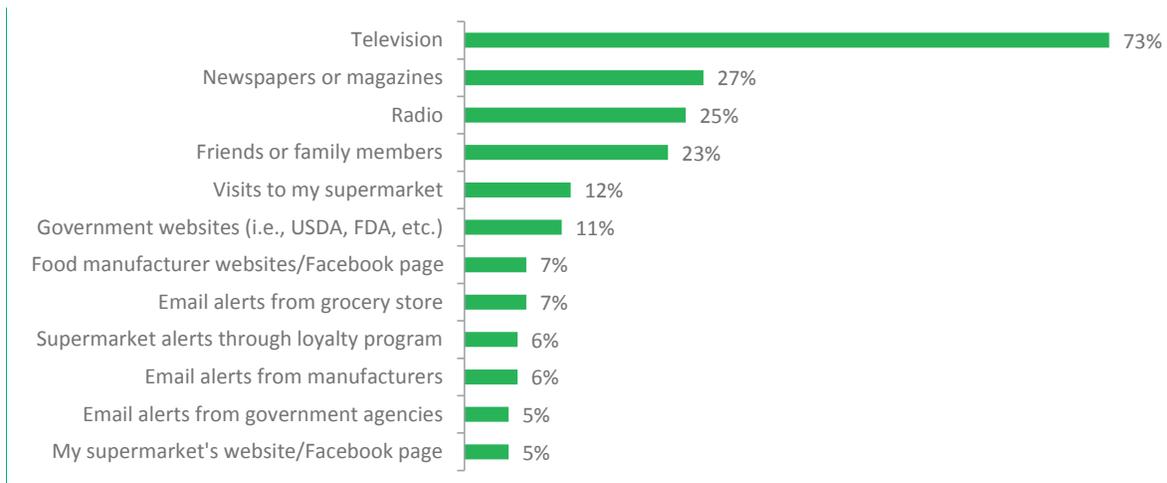
Shoppers accept a proactive recall-communications strategy from retailers, as they assign retailers an active role in ensuring food safety standards. However, while 58% of consumers would prefer email notifications, only 7% report they actually receive recall notifications from grocery stores via this method (see Charts 4.10 and 4.11). This suggests that expanded or enhanced email outreach regarding recalls would help retailers better align with shopper communications preferences. Additionally, shoppers want to see recall notifications within the store at the shelf (40%) and at checkout registers (26%).

**TABLE 4.5: WHO CONSUMERS CONSULT WITH TO LEARN ABOUT SAFE HANDLING OF FOOD**

Number of Shoppers: n=1,164	Total	Gender		Age cohort			
		Male	Female	Matures 70+	Boomers 51-69	Gen X 37-50	Millennials 18-36
Internet	65%	64%	66%	46%	58%	66%	77%
Friends and family	58%	56%	60%	52%	53%	58%	66%
Grocery store	48%	50%	48%	60%	50%	47%	44%
Doctor	47%	49%	45%	56%	46%	41%	49%
Nutritionist/Dietician	45%	45%	45%	39%	42%	44%	50%
Books	42%	41%	42%	36%	40%	40%	47%
Television	31%	32%	31%	28%	30%	32%	33%
Pharmacist	28%	32%	25%	32%	30%	26%	27%
Magazines	28%	27%	28%	24%	30%	27%	28%
Newspaper	26%	28%	25%	32%	28%	23%	25%
Radio	14%	14%	13%	12%	16%	14%	12%

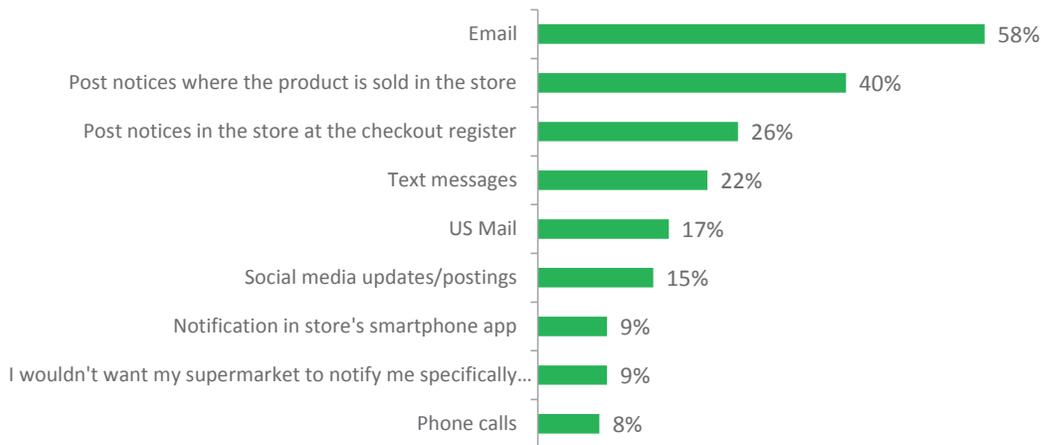
Source: FMI U.S. Grocery Shopper Trends, 2015. Q: "How likely are you to consult the following to learn about the safe handling of food?" top-2 box (somewhat/very likely). n=1,164. (See Appendix: Table A.55)

#### CHART 4.10: HOW SHOPPERS LEARN ABOUT FOOD PRODUCT RECALLS



Source: FMI U.S. Grocery Shopper Trends, 2015. Q: "How likely are you to consult the following to learn about the safe handling of food?" Q: "From which of the following sources do you typically hear about food product recalls?" n=1,164. (See Appendix: Table A.57 and A.58)

#### CHART 4.11: PREFERRED COMMUNICATION ABOUT RECALLS FROM SUPERMARKET



Source: FMI U.S. Grocery Shopper Trends, 2015. Q: "If you had your choice, how would you prefer to receive these food safety recall alerts?" n=1,164. (See Appendix: Table A.57 and A.58)

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-019**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

---

**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018-I-031; new or additional information has been included or attached.

**Title:**

Storage in Toilet Rooms

**Issue you would like the Conference to consider:**

Amend Food Code 3-305.12(B), 4-401.12(A)(2), and 4-903.12(A)(2) from Core to the appropriate Priority Foundation designation.

**Public Health Significance:**

Currently, storing food in a toilet room has the designation as a 'Core' violation. We have the opportunity to address potential contamination from the top source of Food borne illness in a more proactive manner. By changing the way food and single-service items are stored, we are shutting down a major pathway of pathogenic contamination.

Norovirus, which as you know is the leading cause of Foodborne illness (58% of cases) in the United States. CDC states that by 5 years of age, an estimated 1 in 287 of children will be hospitalized, 1 in 14 will visit an emergency room, and 1 in 6 will receive outpatient care for norovirus illness; costing an average of \$2 billion per year.

(<https://www.cdc.gov/norovirus/trends-outbreaks/burden-US.html>) 22% of those are directly tied to a commercial kitchen. (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6361381/>) It is a highly contagious virus that requires as few as 10-18 particles to get a person sick. It has the ability to re-infect by remaining on hard surfaces, many weeks after initial contamination. It states directly from the Food Code Annex : "A recent study has also shown that the bathroom environment was identified as a major reservoir of human Norovirus, even in the absence of an ill individual on site. Studies have shown that Norovirus can survive on fomite surfaces for up to at least 5 days at room temperature and that routine cleaning, without a disinfectant specifically to address Norovirus, may be ineffective in eliminating its presence on fomite surfaces and can even serve as a means of spreading the virus to other fomites."

The first place a sick person will retreat to (if they are so lucky) will be the toilet room. If this bathroom is a shared bathroom with customers and employees, management might not be

privity to outside use by customers who are sick. Research shows that asymptomatic individuals may play more of a role in the transmission than previously thought. ([https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(18\)30026-9/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(18)30026-9/fulltext))

Employees may not know they have the virus initially, as most do not have sick time pay. Should disinfection of the contaminated area not occur immediately, one study show that the virus particles associated with "toilet plume" be spread even after 6 flushes. (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4692156/>) Storing food, sanitized equipment, linens, single-service and single-use articles in these areas would be directly affected.

A proactive approach to preventing further contamination would be designating the aforementioned violations as Priority Foundation. This will accomplish two objectives directly related to food safety. It communicates the importance of minimizing risk to managers and employees. Also, it gives regulators leverage to have these violations corrected sooner than 90 days, although realistically most cores will be addressed during the next routine inspection. If the issue still isn't fixed, it can take up to 3 repeats, which is up to 1.5 years after the initial time it was observed and noted during inspection. A Priority Foundation designation will require a fix within 10 days.

2-501.11 Clean-up of Vomiting and Diarrheal Events requires establishments to have written procedures to address vomiting or diarrheal events. If having the mere written documentation to minimize exposure of consumers, food, and surfaces is a Priority Foundation, then minimizing risk of initial exposure surely would be the same.

The following are priority violations that would be supported:

2-201.11 Responsibility of Permit Holder, Person in Charge, and Conditional Employees.

3-101.11 Safe, Unadulterated and Honestly Presented

3-301.11 Preventing contamination from Hands

3-307.11(C)(D) Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food

### **Recommended Solution: The Conference recommends...:**

A letter be sent to FDA requesting amending the following sections of the most current addition of the Food Code from Core designation to Priority foundation (Pf) designation:

3-305.12(B), Food Storage, Prohibited Areas to (B) In toilet rooms <sup>Pf.</sup>

4-401.11 Equipment, Clothes Washers and Dryers and Storage Cabinets, Contamination Prevention (A)(2) In toilet rooms <sup>Pf.</sup>;

4-903.12 Prohibitions (A)(2) In toilet rooms <sup>Pf.</sup>

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**Supporting Attachments:**

- "Quantitative Risk Assessment of Norovirus Transmission"

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# Quantitative Risk Assessment of Norovirus Transmission in Food Establishments: Evaluating the Impact of Intervention Strategies and Food Employee Behavior on the Risk Associated with Norovirus in Foods

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We developed a quantitative risk assessment model using a discrete event framework to quantify and study the risk associated with norovirus transmission to consumers through food contaminated by infected food employees in a retail food setting. This study focused on the impact of ill food workers experiencing symptoms of diarrhea and vomiting and potential control measures for the transmission of norovirus to foods. The model examined the behavior of food employees regarding exclusion from work while ill and after symptom resolution and preventive measures limiting food contamination during preparation. The mean numbers of infected customers estimated for 21 scenarios were compared to the estimate for a baseline scenario representing current practices. Results show that prevention strategies examined could not prevent norovirus transmission to food when a symptomatic employee was present in the food establishment. Compliance with exclusion from work of symptomatic food employees is thus critical, with an estimated range of 75–226% of the baseline mean for full to no compliance, respectively. Results also suggest that efficient handwashing, handwashing frequency associated with gloving compliance, and elimination of contact between hands, faucets, and door handles in restrooms reduced the mean number of infected customers to 58%, 62%, and 75% of the baseline, respectively. This study provides quantitative data to evaluate the relative efficacy of policy and practices at retail to reduce norovirus illnesses and provides new insights into the interactions and interplay of prevention strategies and compliance in reducing transmission of foodborne norovirus.

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**KEY WORDS:** Discrete event model; microbial risk assessment; norovirus; retail food establishment

## 1. INTRODUCTION

Noroviruses are often spread through person-to-person contact; however, foodborne transmission can cause widespread exposures and presents important prevention opportunities.<sup>(1)</sup> Norovirus is the leading

cause of foodborne illness globally and within the United States.<sup>(2–4)</sup> Restaurants are the most common setting (64%) of food preparation reported in outbreaks in the United States.<sup>(1)</sup> Most foodborne norovirus outbreaks linked to food establishments are traced to contamination of food that is not cooked or otherwise treated before consumption (“ready-to-eat” [RTE] food).<sup>(4–7)</sup>

The disease is characterized by a sudden onset of vomiting, diarrhea, and abdominal cramps, with a duration of one to three days before reaching a full resolution of symptoms.<sup>(8)</sup> Large numbers of virus are

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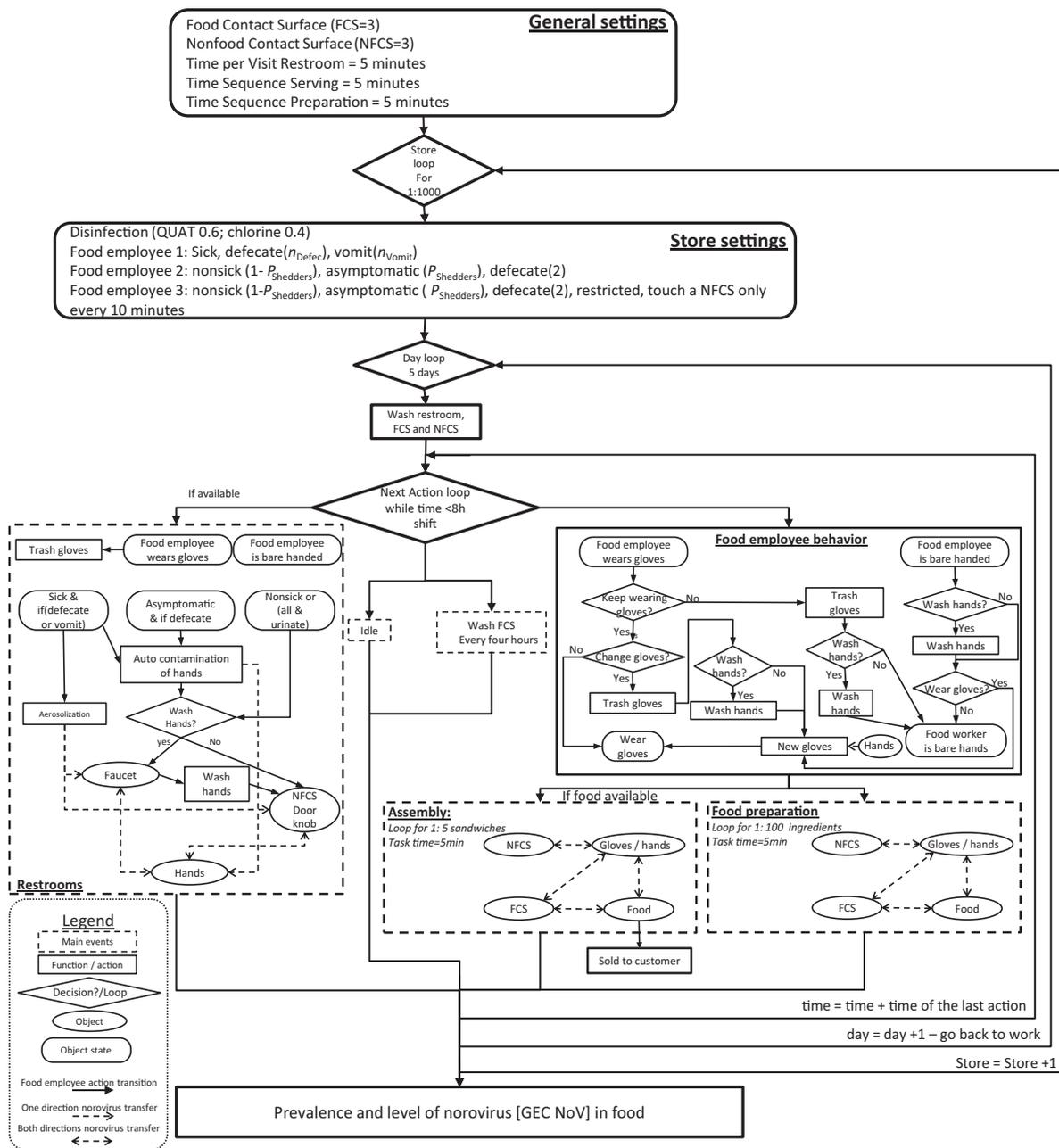


Fig. 1. General algorithm of the model for the transmission of norovirus in food establishment.

shed in the vomit and stools of infected individuals, primarily during the period of active symptoms, with as much as  $10^{12}$  genome equivalent copies of norovirus (GEC NoV) per gram of feces in symptomatic individuals with diarrhea,<sup>(9)</sup> and  $8 \times 10^5$  GEC NoV per milliliter in vomit.<sup>(10)</sup> Duration of viral shedding in adults lasts 20–30 days,<sup>(11)</sup> with a gradual decline in the amount shed during asymptomatic period.<sup>(12)</sup>

The lack of availability of a single effective prevention strategy for controlling norovirus has led to the adoption of a combination of prevention strategies used by many jurisdictions.<sup>(7,13,14)</sup> The U.S. Food and Drug Administration (FDA) has included a combination of prevention strategies focused on reducing viral contamination of food and surfaces from infected food employees in the FDA Food Code<sup>(14)</sup> and the FDA Employee Health and Personal

Hygiene Handbook.<sup>(15)</sup> Current prevention strategies involve the restriction or exclusion of infectious food employees from work, proper hand hygiene, food contact surface (FCS) sanitation, and eliminating barehand contact with RTE food.<sup>(14)</sup>

While individual prevention strategies have been studied, the relative impact of each of these strategies, their level of compliance, and the interplay of combinations of these strategies on norovirus transmission in food establishments have not been well studied. This study was conducted specifically to evaluate these impacts on the mean number of contaminated food servings and infected customers. Additional prevention strategies such as increasing the current efficacy of handwashing or preventing hand contact with faucets and doors in the restrooms were also tested to identify effective ways to reduce the risk associated with norovirus in a food establishment.

## 2. BACKGROUND AND METHODS

### 2.1. Food Establishment Setting

The model was developed to study the spread of norovirus in a food establishment. A discrete event model was selected as the most suitable model framework to describe the series of consecutive tasks undertaken by food employees. A main advantage of the discrete event model framework is its flexibility, which allows for the inclusion of additional events or the modification of event sequences. This flexibility facilitates comparison of different situations or scenarios such as the impact of new regulations or a change in level of compliance in the quantitative risk assessment.<sup>(16)</sup>

The conceptual model developed is presented in Fig. 1. The shift (work period) of a food employee was represented as a chronological sequence of events occurring at discrete instants in time. The main tasks (events) of the food employees are: (i) prepare food (sequence of five minutes), (ii) assemble food (sequence of five minutes), (iii) wash and sanitize FCS, (iv) use the restrooms, or (v) do nothing (idle). At any time ( $t$ ), food employees executed one of the five different main events (tasks—dashed rectangle), each task including sequences of actions (e.g., wash hands, change gloves, touch an FCS, etc.) described with function/action, decision/loop, objects, and object states. Solid and dashed arrows represent

action transition and norovirus transfer between the objects, respectively.

Three employees, referred as FE-1, FE-2, and FE-3, working together during one eight-hour shift per day for five consecutive days, were considered. FE-1 and FE-2 prepared food and touched FCS and nonfood contact surfaces (NFCS), while FE-3 did not prepare food but sporadically touched NFCS. One type of food, consisting of a three-item sandwich (e.g., bacon, lettuce, and tomato sandwich), was served to the customers. The two employees FE-1 and FE-2 both prepare a total of 200 sandwiches per shift. It is assumed that the food ingredients are initially free of norovirus. The food establishment included two different areas: a food preparation and sandwich assembly area and the restrooms. The food preparation and assembly area included three generic FCS (e.g., knife, cutting board, stainless work surface, etc.) and three generic NFCS (e.g., refrigerator door handle, microwave handle, etc.) (Fig. 1). The restrooms, the FCS, and NFCS were washed and sanitized before the beginning of each shift. The FCS were additionally washed and sanitized every four hours, as recommended by the Food Code.<sup>(14)</sup>

#### 2.1.1. Restrooms

The restrooms included three potentially contaminated objects: the door handle, the faucet, and the air environment. The number of visits in the restroom for each employee was related to their health status (symptomatic or not) (Table I) and will be further discussed (Section 2.2). The visits to the restrooms were randomly distributed within the shift. The level of compliance with required handwashing after using the restroom was assumed to be 100% after emesis and 65% and 90% after urination and defecation, respectively.<sup>(17)</sup> Table I describes other parameters regarding the norovirus concentration in feces and vomit, as extracted from the literature.

#### 2.1.2. Food Preparation/Sandwich Assemblage

Food preparation and sandwich assemblage sequences were adapted from Mokhtari *et al.*<sup>(18)</sup> and Stals *et al.*<sup>(19)</sup> The food preparation and sandwich assemblage were considered to be two distinct events. We assumed that the food ingredients (e.g., lettuce, tomato, and bacon) were first prepared (e.g., sliced) by batch, and later assembled to make sandwiches. The objects and actions initiated during the

Table 1. Model Parameter Distributions and Sources

Input	Definition [Unit]	Distribution	Mean [0.025; 0.5; 0.975 Quantiles]	Reference
<b>Inputs Associated with Food Employees in the Restrooms</b>				
$V_{Rest}$	Volume of the restrooms [m <sup>3</sup> ]	<i>cste</i> (12.1)	-	27
$n_D$	Number of defecations per shift on day 0 of sickness, divided by 2 each day while sick	<i>Poisson</i> (4.5)	4.5 [1; 4; 9]	24
$P_{vomit}$	Probability that the sick food employee vomits	<i>cste</i> (0.72)	-	10
$n_V$	Number of vomit events per shift minus 1 each day while sick	<i>cste</i> (3)	-	57
$n_U$	Number of restroom visits to urinate per shift	<i>cste</i> (2)	-	Assumed
$m_H$	Mass of feces on hands after defecation [log <sub>10</sub> g]	<i>BetaPert</i> (min=-8; mode=-3; max=-1)	-3.5 [-6.17; -3.38; -1.44]	58,59
$S_H$	Hand surface [m <sup>2</sup> ]	<i>cste</i> (0.01)	-	19
$V_H$	Volume of vomit on hands after vomiting events [mL]	<i>cste</i> (10)	-	Assuming 1 mm of vomit on all hand surface $S_H$
$NoV_v$	Norovirus concentration in vomit [log <sub>10</sub> GEC NoV/mL]	<i>BetaPert</i> (3; 4.5; 7)	4.67 [3.37; 4.62; 6.16]	43
$NoV_{sh}$	Shedding level of food employee [log <sub>10</sub> GEC NoV/g]	<i>BetaPert</i> (4; 8; 10)	7.67 [5.40; 7.74; 9.52]	9,60,61
$D_{sh}$	Time to 1 log <sub>10</sub> reduction of NoVs in shedding food employees [minutes] (eq. one log <sub>10</sub> decrease per week)	<i>cste</i> (10,080)	-	9,60,61
$T_{Env, d}$	Aerosol contamination during diarrhea events [NoV/m <sup>3</sup> ]	<i>lognormal</i> (7.6820; 0.468)	2,420 [867; 2,168; 5,425]	27
$T_{Env, V}$	Aerosol contamination during vomit events [GEC Nov/m <sup>3</sup> ]	<i>lognormal</i> (7.6820; 0.468)+1,100	3,520 [1,967; 3,268; 6,525]	27,28
$d_s$	Symptom duration [minutes]	<i>gamma</i> (scale=1.508; rate=0.000513)	2,940 [218; 2,321; 9,140] (eq. 49 [4, 39, 152] hours)	24
$P_{Wash,H;Rest}$	Probability of washing hands in the restrooms (vomit, defecate, urinate)	<i>cste</i> (1; 0.9; 0.65)	-	17
<b>Inputs Associated with Food Employees Characteristics and Behavior</b>				
$n_{Hwash;NFH}$	Number of handwashings per shift for nonfood handling employees	<i>cste</i> (4)	-	Assumed
$P_{Shedders}$	Probability of asymptomatic shedders	<i>cste</i> (0.15)	-	23
$P_{wear_gloves}$	Probability of wearing gloves during food preparation (0; .5; .9; 1 of the time)	(0.336; 0.14; 0.12; 0.40)	-	20
$P_{change_gloves}$	Probability of changing gloves when engaging in food preparation	<i>cste</i> (0.37)	-	22
$P_{wash_H}$	Probability of washing hands when engaging in food preparation	<i>cste</i> (0.41)	-	22
$P_{wash_H}$	Probability of washing hands while changing gloves	<i>cste</i> (0.30)	-	22

(Continued)

Table I (Continued)

Input	Definition [Unit]	Distribution	Mean [0.025; 0.5; 0.975 Quantiles]	Reference
<b>Inputs Associated with Transfer of Norovirus from Surface 1 to Surface 2 (Tr<sub>1,2</sub>)</b>				
<i>Tr<sub>H,S</sub></i>	Norovirus transferred from hand to surface	inv.logit(normal(-3.82, ResTrans))	0.02 [4.61 × 10 <sup>-4</sup> ; 0.02; 0.51]	Meta-analysis: 51,52,62-69
<i>Tr<sub>S,H</sub></i>	Norovirus transferred from surface to hand	inv.logit(normal(0.11, ResTrans))	0.53 [2.30 × 10 <sup>-2</sup> ; 0.53; 0.98]	
<i>Tr<sub>G,S</sub></i>	Norovirus transferred from glove to surface	inv.logit(normal(-2.14, ResTrans))	0.11 [2.47 × 10 <sup>-3</sup> ; 0.11; 0.85]	
<i>Tr<sub>S,G</sub></i>	Norovirus transferred from surface to glove	inv.logit(normal(-1.34, ResTrans))	0.21 [5.48 × 10 <sup>-3</sup> ; 0.21; 0.93]	
<i>Tr<sub>F,H</sub></i>	Norovirus transferred from food (nonmeat) to hand	inv.logit(normal(-3.86, ResTrans))	0.02 [4.43 × 10 <sup>-4</sup> ; 0.02; 0.50]	
<i>Tr<sub>H,F</sub></i>	Norovirus transferred from hand to food (nonmeat)	inv.logit(normal(-2.95, ResTrans))	0.05 [1.10 × 10 <sup>-3</sup> ; 0.05; 0.71]	
<i>Tr<sub>Fm,H</sub></i>	Norovirus transferred from food (meat) to hand	inv.logit(normal(-2.62, ResTrans))	0.07 [1.53 × 10 <sup>-3</sup> ; 0.07; 0.78]	
<i>Tr<sub>H,Fm</sub></i>	Norovirus transferred from hand to food (meat)	inv.logit(normal(-0.034, ResTrans))	0.49 [0.02; 0.49; 0.98]	
<i>Tr<sub>F,G</sub></i>	Norovirus transferred from food (nonmeat) to glove	inv.logit(normal(0.90, ResTrans))	0.71 [0.05; 0.71; 0.99]	
<i>Tr<sub>G,F</sub></i>	Norovirus transferred from glove to food (nonmeat)	inv.logit(normal(-0.82, ResTrans))	0.31 [0.01; 0.31; 0.95]	
<i>Tr<sub>Fm,G</sub></i>	Norovirus transferred from food (meat) to glove	inv.logit(normal(-0.13, ResTrans))	0.47 [0.02; 0.47; 0.98]	
<i>Tr<sub>G,Fm</sub></i>	Norovirus transferred from glove to food (meat)	inv.logit(normal(-0.29, ResTrans))	0.43 [0.02; 0.43; 0.97]	
<i>Tr<sub>F,S</sub></i>	Norovirus transferred from food (nonmeat) to surface	inv.logit(normal(-2.82, ResTrans))	0.06 [1.25 × 10 <sup>-3</sup> ; 0.06; 0.74]	
<i>Tr<sub>S,F</sub></i>	Norovirus transferred from surface to food (nonmeat)	inv.logit(normal(0.87, ResTrans))	0.70 [0.05; 0.70; 0.99]	
<i>Tr<sub>Fm,S</sub></i>	Norovirus transferred from food (meat) to surface	inv.logit(normal(-0.94, ResTrans))	0.28 [0.01; 0.28; 0.95]	
<i>Tr<sub>S,Fm</sub></i>	Norovirus transferred from surface to food (meat)	inv.logit(normal(4.45, ResTrans))	0.99 [0.64; 0.99; 1.00]	
<i>Tr<sub>H,G</sub></i>	Norovirus transferred from hand to glove	inv.logit(normal(-2.78, ResTrans))	0.06 [1.30 × 10 <sup>-3</sup> ; 0.06; 0.75]	
ResTrans	Residuals of the meta-analysis for transfer	cste(1.97)	-	
<i>D<sub>WH</sub></i>	Handwashing efficiency [log <sub>10</sub> NoV]	<i>BetaPert</i> (0.17; 0.45; 6; shape=4)	1.33 [0.23; 1.13; 3.47]	Meta-analysis: 55,56,58,62,70-81
<b>Inputs Associated with Survival of Norovirus on Surfaces</b>				
<i>D<sub>H</sub></i>	Time to 1 log reduction of GEC NoV on hands [minutes]	<i>lognormal</i> (6.50; ResSurv)	1,154 [85; 665; 5,208] (eq.: 19 [1, 11, 87] hours)	Meta-analysis: 63,64,82-95
<i>D<sub>S</sub></i>	Time to 1 log reduction of GEC NoV on hard surface [minutes]	<i>lognormal</i> (10.17; ResSurv)	45,309 [3,334; 26,108; 204,426] (eq.: 755 [56, 435,3407] hours)	

(Continued)

Table I (Continued)

Input	Definition [Unit]	Distribution	Mean [0.025; 0.5; 0.975 Quantiles]	Reference
$D_G$	Time to 1 log reduction of GEC NoV on gloves [minutes]	$lognormal(11.02; ResSurv)$	106,006 [7,801; 61,083; 478,285] (eq.: 1,766 [130, 1,018, 7,971] hours)	
$D_F$	Time to 1 log reduction of GEC NoV on food [minutes]	$lognormal(9.57; ResSurv)$	24,866 [1,829; 14,328; 112,191] (eq.: 414 [30, 238, 1,870] hours)	
ResSurv	Residuals of the meta-analysis for survival	$cste(1.05)$	–	
<b>Inputs Associated with Disinfection</b>				
$P_{dis}$	Probability of using a type of disinfectant in store (quaternary ammonium; chlorine)	$(0.6; 0.4)$	–	
$Dis_{QUAT}$	GEC NoV reduction due to disinfection of hard surfaces with quaternary ammonium	$log_{10}(inv.logit(norm(-3.44, ResDis)))$	-1.51 [-4.55; -1.51; -0.01]	Meta-analysis: 75–79, 85, 93, 94, 96–105
$Dis_{QUAT}$	GEC NoV reduction due to disinfection of hard surfaces with chlorine	$log_{10}(inv.logit(norm(-6.02, ResDis)))$	-2.61 [-5.67; -2.61; -0.13]	
$Dis_{QUAT}$	GEC NoV reduction due to disinfection of hands with quaternary ammonium	$log_{10}(inv.logit(norm(-6.16, ResDis)))$	-2.67 [-5.73; -2.67; -0.15]	
$Dis_{QUAT}$	GEC NoV reduction due to disinfection of hands with chlorine	$log_{10}(inv.logit(norm(-8.74, ResDis)))$	-3.80 [-6.85; -3.80; -0.81]	
ResDis	Residuals of the meta-analysis for disinfection	$cste(3.59)$		

Cste: constant; BetaPert: betapert distribution with shape parameter  $4^{(30)}$ ,  $X \sim lognormal(a, b)$  if  $\ln(X) \sim normal(mean=a, SD=b)$ ;  $inv.logit(x) = \exp(x)/(1+\exp(x))$ .

assemblage and preparation events were similar (Fig. 1). First, an FCS for food preparation/assembly was randomly assigned to the employee. Then for each ingredient, contacts between FCS, gloves/hands, or food occurred twice in a random sequence. Contact with NFCS occurred once during each random sequence. Food employees prepared 20 pieces of one ingredient per minute (e.g., sliced 20 tomato slices). An additional cooking step was included for one of the ingredients (e.g., bacon), eliminating any norovirus present on this ingredient at the time. A pace of one sandwich assembled per minute was considered. If at least one type of food ingredient was not available, a sandwich could not be assembled; the food employee would instead prepare this type of ingredient and then return to sandwich preparation.

### 2.1.3. Food Employee Practices

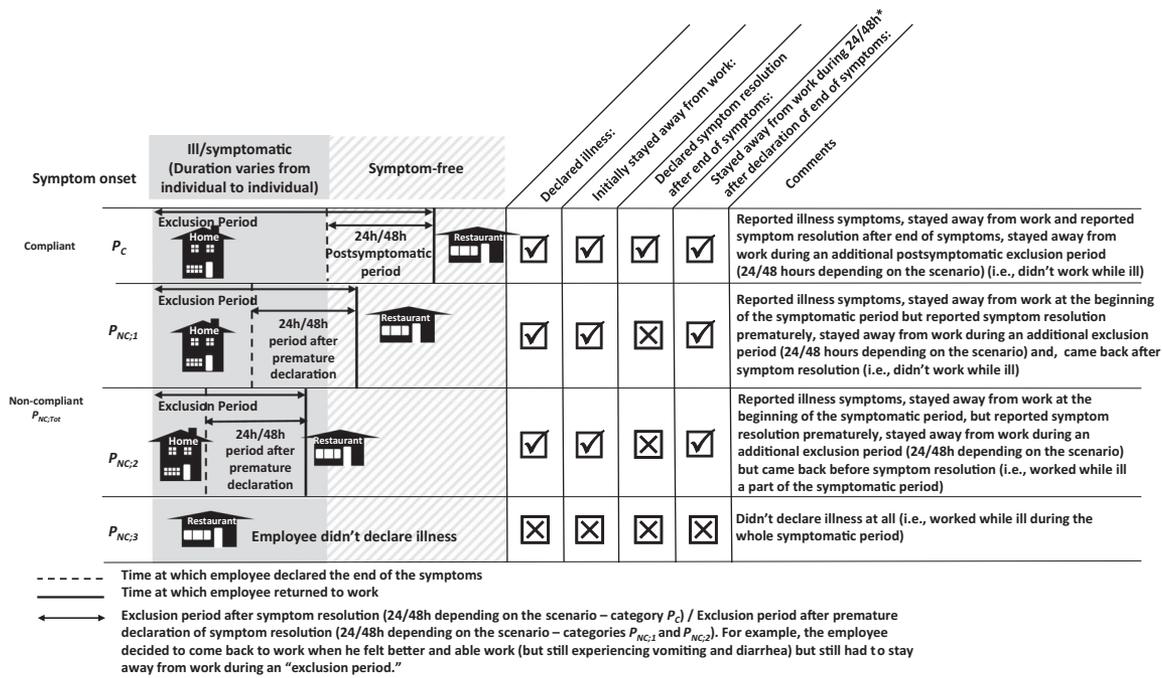
The behavior of food employees was included in the model using data from surveys.<sup>(17,20–22)</sup> Frequency of handwashing when engaging in food preparation was based on data from CDC,<sup>(22)</sup> which reported that food employees washed their hands in 27% of activities in which they should have. Regarding glove-use frequency when touching RTE food (Table I), food employees reported that they never (33%), sometimes (6%), almost always (14%), or always (40%) wore gloves. Food employees changed gloves 37% of the time when engaging in food preparation, based on a CDC report.<sup>(21)</sup> We note that use of food contact utensils such as spatulas or tongs instead of gloves were not modeled because of limitations in data on the frequency of use and efficiency of transfer to and from these objects.

Some individuals infected with norovirus will develop asymptomatic infection, while others will develop symptoms of vomiting and diarrhea. In the model, two food employees (FE-2 and FE-3) were not sick but had an independent probability to be asymptomatic shedders of 15%.<sup>(23)</sup> Only one employee (FE-1) was assumed to be symptomatic. The duration of the symptoms was modeled using a gamma distribution so that the mean duration was 49 hours with a standard deviation of 40 hours.<sup>(24)</sup> We assumed that a symptomatic food employee (FE-1) always experienced diarrhea. The number of defecations per day was assumed to be 4.5 on average per shift at the onset of the symptoms,<sup>(24)</sup> and this average was reduced by two each day until the end of the symptomatic illness. Seventy-two percent of symp-

tomatic cases experienced vomiting,<sup>(10)</sup> with three vomiting events on the first day, two vomiting events on the second day, and one vomiting event on the third day, if still sick. Other parameters regarding the concentration of norovirus in feces and vomit are described in Table I.

In order to protect consumers from symptomatic food employees that may have an undiagnosed norovirus infection (which represent the majority of norovirus cases since most will not be specifically diagnosed), the FDA Food Code recommends an exclusion period of food employees from work when they are experiencing vomiting and/or diarrhea symptoms and for at least 24 hours after the symptoms resolve in the absence of confirmation of the norovirus infection.<sup>(14)</sup> However, food employees do not always comply with this exclusion period. Surveys have shown that, for various reasons, some food employees have worked while ill.<sup>(25)</sup> A survey by Sumner *et al.*<sup>(26)</sup> reported that 20% of food employees declared having experienced vomiting or diarrhea while working during the year preceding the interview. We included a rate of compliance  $P_c$  in the model to account for ill employees (FE-1) who reported illness and complied with the exclusion period and food employees who did not report or did not comply with the exclusion period and may have worked while ill. We considered that FE-1 was ill and could belong to four categories (“compliant,” “non-compliant 1,” “noncompliant 2,” and “noncompliant 3”) to accurately represent compliance with the exclusion guidance, as presented in Fig. 2:

- Compliant ill food employee: Reported illness symptoms, stayed away from work and reported symptom resolution after end of symptoms, stayed away from work during an additional postsymptomatic exclusion period (24/48 hours depending on the scenario) (i.e., did not work while ill).
- Noncompliant ill food employee; type 1 (“non-compliant 1”): Reported illness symptoms, stayed away from work at the beginning of the symptomatic period but reported symptom resolution prematurely, stayed away from work during an additional exclusion period (24/48 hours depending on the scenario) and came back after symptom resolution (i.e., did not work while ill).
- Noncompliant ill food employee; type 2 (“non-compliant 2”): Reported illness symptoms, stayed away from work at the beginning of



**Fig. 2.** Graphical illustration of food employee behavior regarding declaration of illness/symptom resolution and compliance with the exclusion period. Note that the duration of the sickness (from symptom onset to symptom resolution) varies from one simulation to the other in the model.

the symptomatic period, but reported symptom resolution prematurely, stayed away from work during an additional exclusion period (24/48 hours depending on the scenario) but came back before symptom resolution (i.e., worked while ill a part of the symptomatic period).

- Noncompliant ill food employee; type 3 (“non-compliant 3”): Did not declare illness at all (i.e., worked while ill during the whole symptomatic period).

Each category is represented by a proportion with:

$$P_{NC} = 1 - P_C = P_{NC,1} + P_{NC,2} + P_{NC,3}, \quad (1)$$

where  $P_{NC}$  is the proportion of noncompliant food employees,  $P_C$  is the proportion of compliant food employees, and  $P_{NC,i}$  is the proportion of noncompliant food employees of type  $i$ . We assumed that the category “noncompliant 3” represented 50% of the proportion of total noncompliant:

$$P_{NC,3} = 0.5 \times P_{NC} = P_{NC,1} + P_{NC,2}. \quad (2)$$

Food employees of categories “noncompliant 1” and “noncompliant 2” declared premature symptom resolution within 24 hours after symptom

onset, according to a uniform distribution  $Uniform(0;24)$ (hours), with an average of 12 hours. The values of  $P_{NC,2}$  and  $P_{NC,3}$  are determined from the exclusion period time and the cumulative function of the gamma distribution of symptom duration. For an exclusion period of 24 hours, food employees will come back to work at time  $12 + 24 = 36$  hours on average. According to the gamma distribution used to model the duration of symptoms, the symptoms are resolved for 46% of food employees at 36 hours. Then:

$$P_{NC,1} = p_{asympt;36h} \times 0.5 \times P_{NC}, \quad (3)$$

where  $p_{asympt;36h} = 0.46$  is the proportion of asymptomatic food employees at  $t \geq 36$  hours according to the considered gamma distribution and

$$P_{NC,2} = (1 - p_{asympt;36h}) \times 0.5 \times P_{NC}. \quad (4)$$

This dynamic of symptomatic illness leads to a reduction of symptoms (diarrhea, vomiting) with time, and thus as a function of the exclusion period. As an example, for an extended exclusion period of 48 hours, food employees will come back to work at time  $12 + 48 = 60$  hours on average and  $p_{asympt;60h} = 70\%$ .

## 2.2. Norovirus Transfer in the Retail Environment

### 2.2.1. Sources of Contamination

Initial transfer of norovirus from infected food employees to the retail environment takes place in the restrooms via defecation (symptomatic and asymptomatic food employees) and vomiting events (symptomatic food employees). Hand contamination during defecation was considered for symptomatic and asymptomatic food employees. The level of norovirus on hands  $NoV_H$  after defecation and vomit were calculated using:

$$NoV_H = NoV_{Sh} \times m_H \quad [\text{GECNoV}], \quad (5)$$

$$NoV_H = NoV_V \times V_H \quad [\text{GECNoV}], \quad (6)$$

where  $NoV_{Sh}$  is the level of norovirus shed by the food employee at that time,  $m_H$  is the mass of feces on hands,  $NoV_V$  is the level of norovirus in vomit, and  $V_H$  the volume of vomit on hands after vomit.

In addition, for symptomatic employees, norovirus aerosolization within restrooms, and subsequent contamination of the environment ( $NoV_{Env,t=0}$ ) within the restrooms, was considered for toilet flushing of diarrheal events and during vomiting, using data extracted from Barker *et al.*<sup>(27)</sup> and Tung-Tompson *et al.*,<sup>(28)</sup> respectively.

$$NoV_{Env,t=0} = V_R \times Tr_{Env,d} \quad [\text{GECNoV}], \quad (7)$$

$$NoV_{Env,t=0} = V_R \times Tr_{Env,V} \quad [\text{GECNoV}], \quad (8)$$

where  $V_R$  is the restroom volume and  $Tr_{Env;d}$  and  $Tr_{Env;V}$  are the transfer rate of norovirus to the restroom environment during diarrheal and vomiting events, respectively. The aerosol contaminated the door handle and the faucet handle through sedimentation of suspended norovirus on those surfaces. A sedimentation rate of  $1 \log_{10}$  of norovirus per  $D_{sed} = 30$  minutes is used in the model.<sup>(27)</sup> The total amount of norovirus during a sedimentation time  $\Delta t$  (minutes) was simulated with:

$$NoV_{sed} \sim \text{binomial} \left( NoV_{Env,t=0}, 1 - 10^{-\frac{\Delta t}{D_{sed}}} \right) \quad [\text{GECNoV}]. \quad (9)$$

The amount of norovirus on the faucet handle  $NoV_f$  was calculated using a binomial distribution:

$$NoV_f \sim \text{binomial} \left( NoV_{sed}, \frac{S_f}{S_R} \right) \quad [\text{GECNoV}], \quad (10)$$

where  $S_f$  is the surface of the faucet handle (assumed equal to the hand surface  $S_H$ ) and  $S_R$  is the surface of the restrooms. The same methodology was used for the contamination of the door handle. Self-contamination of hands and transfer between hands, faucet, and door handle were also considered (Table I).

### 2.2.2. Norovirus Transfer and Survival

For each physical contact between two objects/surfaces, the quantities of norovirus transferred from surface S1 to surface S2,  $NoV_{S1;S2}$ , and from surface S2 to surface S1,  $NoV_{S2;S1}$ , were calculated using a binomial distribution:

$$NoV_{S1;S2} \sim \text{binomial} (NoV_{S1;t}, Tr_{S1;S2}) \quad [\text{GECNoV}], \quad (11)$$

$$NoV_{S2;S1} \sim \text{binomial} (NoV_{S2;t}, Tr_{S2;S1}) \quad [\text{GECNoV}], \quad (12)$$

where  $NoV_{S1;t}$  and  $NoV_{S2;t}$  are the respective levels of norovirus on surface S1 and S2 at the time  $t$  of the contact and  $Tr_{S1;S2}$  is the transfer probability of norovirus. The levels of norovirus  $NoV_{S1;t+1}$  and  $NoV_{S2;t+1}$  on surfaces S1 and S2 after the contact were calculated with:

$$NoV_{S1;t+1} = NoV_{S1;t} - NoV_{S1;S2} + NoV_{S2;S1} \quad [\text{GECNoV}], \quad (13)$$

$$NoV_{S2;t+1} = NoV_{S2;t} - NoV_{S2;S1} + NoV_{S1;S2} \quad [\text{GECNoV}]. \quad (14)$$

The survival on surfaces during a time step was calculated using a log linear reduction model:

$$NoV_{S1;t+1} \sim NoV_{S1;t} - \text{binomial} \left( NoV_{S1;t}, 1 - 10^{-\frac{\Delta t}{D_{S1}}} \right) \quad [\text{GECNoV}], \quad (15)$$

where  $\Delta t$  (minutes) is the time step and  $D_{S1}$  is the time (minutes) for a  $1 \log_{10}$  reduction of norovirus on the surface S1.

The level of norovirus  $NoV_{S1;t+1}$  after disinfection of the surface S1 was calculated with:

$$NoV_{S1;t+1} \sim NoV_{S1;t} - \text{binomial} (NoV_{S1;t}, 1 - 10^{-Dis}) \quad [\text{GECNoV}], \quad (16)$$

where  $Dis$  is the norovirus reduction due to disinfection. Removal of norovirus from hands by handwashing is defined similarly with:

$$NoV_{S1;t+1} \sim NoV_{S1;t} - binomial(NoV_{S1;t}, 1 - 10^{-D_{WH}}) [GECNoV]. \quad (17)$$

### 2.3. Data Sources

A meta-analysis was conducted to collect data from peer-reviewed articles for survival, transfer, handwashing, and disinfection through the online libraries PubMed and Web of Science in field tags “titles and abstracts” and using the Boolean logic {(norovirus OR norovirus surrogates) AND (inactivation OR persistence OR survival OR disinfection OR transfer OR wash)}. A total of 846 abstracts were studied, and 330 articles were screened according to the relevance of the abstract. Articles were selected for transfer from surface to surface (10 articles), persistence on surfaces (16 articles), handwashing (16 articles), and disinfection (18 articles) based on the quality of the data, the validity of the surrogates, and the methodology.

The inclusion criteria included a variety of surrogate viruses. These surrogates have been extensively described in the literature as having similar properties with norovirus as far as some of their morphological, cultural, genetic, and structural characteristics. In addition to norovirus genogroup I (GI) and genogroup II (GII), the surrogates used were the feline calicivirus (FCV F9 or KS20), murine norovirus (MNV-1 or MNV99), and the most recently discovered Tulane virus (TV). Additionally, nontraditional surrogates outside the calicivirus family, such as rotavirus, poliovirus, hepatitis A virus, or even nonanimal viruses like F-specific RNA coliphage MS2, were also included for certain studies. Particularly, the transfer and handwashing analysis data were supplemented with those from other viruses as these events are mainly physical and assumed independent of the physiology of each particular virus.

Detection through reverse transcriptase-polymerase chain reaction (RT-PCR) is currently the only method to quantify norovirus titer, which is expressed in terms of genomic copies, or genome equivalents (RNA copies or transcripts if they were generated by real-time system or just RT-PCR amplifiable units for conventional platforms). Data for both norovirus genogroups GI and GII were extracted, where available, but not reported separately.

For all the surrogate viruses, as they are all culturable, data generated by both RT-PCR detection and infectivity assays (plaque assay and TCID50) were extracted. All data were expressed as genomic copy equivalents of norovirus (GCE NoV) as, currently, there are no infectivity data available for norovirus. Publications that did not adequately describe methodologies and did not include controls to justify any heterogeneity among the test viruses were excluded. Regarding disinfection, only disinfectants typically used in food service (i.e., quaternary ammonium and sodium hypochlorite) were included.

Additional information on the data collected for the meta-analysis and fitted models is presented in Table II. Models were fitted using fixed and mixed effects linear models. The specific study from which a set of data was collected was used as a random effect in mixed models. Models were compared using the  $F$ -test (95% confidence interval) or likelihood ratio test when nested. When two models were not nested, the Akaike information criterion (AIC)<sup>(29)</sup> was used to select the preferred one. Besides handwashing, for which a *BetaPert* distribution<sup>(30)</sup> was fitted, mixed effect models were preferred to fixed effect models because of the nonnegligible impact of the study effect (results not shown). Moreover, mixed effect models allow generalizing the results to a population of studies that were not included in the analysis.<sup>(31)</sup> The factors resulting from the meta-analysis and used in the model to predict transfer, disinfection, handwashing, and survival of norovirus are shown in Table I.

### 2.4. Customer Probability of Infection

A dose–response model was used to evaluate the number of infected customers and the number of illnesses resulting from the consumption of prepared sandwiches in the population. Teunis *et al.*<sup>(32)</sup> developed a dose–response model for norovirus from experimental infection data. For a discrete number of norovirus, as considered in the model, this dose–response model can be written:<sup>(33)</sup>

$$\text{Prob}\{\text{infection}|NoV_i, \alpha, \beta\} = 1 - \frac{\Gamma(\alpha + \beta) \Gamma(\beta + NoV_i)}{\Gamma(NoV_i) \Gamma(\alpha + \beta + NoV_i)},$$

where  $\Gamma(x)$  is the gamma function,  $NoV_i$  is the number of ingested norovirus,  $\alpha = 0.040$ , and  $\beta = 0.055$ . These parameters were estimated for a susceptible (positive secretor,  $Se^+$ ) population. The probability of illness given infection for an  $Se^+$  individual at random ingesting  $NoV_i$  norovirus is:

$$\text{Prob}\{\text{illness}|infection, NoV_i, \eta, r\} = 1 - (1 + \eta NoV_i)^{-r},$$

**Table II.** Details of the Meta-Analyses

Meta-Analysis (Number of Selected Articles/ Observations)	Dependent Variable <sup>a</sup>	Considered Independent Variables								Model	Model Normalization
		Virus and Surrogates	Method	Type of Surface	Surface Characteristic	Temperature	Disinfectant	Model			
Transfer (10/420 data points)	<i>Trst:sz</i>	Norovirus(GI, GII), FCV, MNV1, MS2, Tulane, HAV	Plaque assay Real-time RT-PCR	Hard surface, hand, glove, nonmeat food, meat	Wet, dry	NA	NA	Mixed effect	for GECNoV at: Wet, real-time RT-PCR, NoV		
Persistence (16/138 curves)	<i>Ds</i>	Norovirus (GI, GII), FCV, MNV1, MS2, Tulane, MS2	Plaque assay Real-time RT-PCR	Hard surface, hand, gloves, nonmeat food, meat	NA	Refrigerated, room	NA	Mixed effect	for GECNoV at: Room temperature and real-time RT-PCR		
Disinfection (18/249 data points)	<i>Dis</i>	Norovirus (GI, GII), FCV, MNV1, MNV99, MS2, Tulane	Plaque assay Real-time RT-PCR TCID50	Hard surface food, meat	Wet, dry	NA	Quaternary ammo- nium, chlorine	Mixed effect	for GECNoV at: Wet, real-time RT-PCR, NoV		
Handwashing (16/50 data points)	<i>Dwh</i>	Norovirus (GI, GII), FCV, MNV1, MNV99, MS2, Tulane, HAV, Rotavirus, Poliovirus	Plaque assay Real-time RT-PCR TCID50	Hand	NA	NA	NA	<i>BetaPerr</i> (0.17;0.45;6; shape=4)	NA		

<sup>a</sup>See Table I. FCV: Feline calicivirus, MNV: murine norovirus, MS2: F-specific RNA coliphage MS2, Tulane: Tulane virus, HAV: hepatitis A virus, NA: nonavailable.

where  $r = 2.55 \times 10^{-3}$  and  $\eta = 0.086$  from Teunis *et al.*<sup>(32)</sup> We considered that 80% of the population was Se<sup>+</sup> and that the remaining population was fully resistant to the infection.<sup>(34)</sup>

As an alternative to the estimate of number of infected and sick customers, we provide the proportion of servings including more than 0, 100, and 1,000 GEC NoV as an indicator of the potential of norovirus infection from consumption of sandwiches by a susceptible population prepared in the setting.

## 2.5. Baseline and Scenarios

A total of 22 scenarios describing specific prevention strategies (Table III) and presented in Table IV were compared to evaluate the impact of model parameters on the risk of illness associated with norovirus contamination of foods served in this setting.

Scenario 1 is the baseline of this study in the sense that it represents existing knowledge of current practices and food employee behavior in food establishments. FE-1 was ill and belonged to categories “compliant,” “noncompliant 1,” “noncompliant 2,” and “noncompliant 3” in 74%, 6.0%, 7.0%, and 13% of simulated stores, respectively. FE-2 and FE-3 were asymptomatic shedders in 15% of the stores. Restrooms, NFCS, and FCS were washed every morning before the beginning of the shift. FCS were washed every four hours. Current practices based on existing knowledge were used to describe the frequency of handwashing in restrooms, and the frequency of handwashing, wearing, and changing of gloves when engaging in food preparation (Table I).

A scenario in which FE-1 was not ill (but could be asymptomatic shedder as FE-2 and FE-3; scenario 2—lower baseline) and a scenario in which FE-1 systematically worked while ill during the whole symptomatic period (scenario 3—upper baseline) were included.

The 19 other scenarios were variations around the baseline to test the impact of different parameters of the model corresponding to specific prevention strategies and their compliance to reduce norovirus transmission (Tables III and IV). The impacts of extending the exclusion period after symptom resolution from 24 to 48 hours and associated compliance with this exclusion period was studied in scenarios 4–9. The impacts of the frequency of handwashing in restrooms (scenario 10), no barehand contact (scenario 11), compliance with handwashing and glove use when engaging in food preparation according to

the Food Code recommendation (scenario 18), and handwashing efficacy were also studied (scenarios 18 and 19). The impact of food employee restriction was also evaluated (scenarios 14–17).

## 2.6. Implementation of the Model

This model was written in the open-source language R version 3.2.4 (R Core Team).<sup>(35)</sup> In view of the numerous scenarios and the discrete event framework of the model, the code was written to be launched on parallelized processors using high-performance computing tools (Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA, Silver Spring, MD, USA). Nonetheless, the code can be run on a desktop. For each tested scenario, 1,000 stores in which the actions of the employees are different were simulated. The model was vectorized to simulate 1,000 independent teams of three food employees for each of the 1,000 stores, each team doing the same events at the same time, but, for example, with different transfer coefficients or handwashing efficacy, for each of the 1,000 stores, resulting in a total of 1,000,000 simulated stores. Variability in (asymptomatic) infection of FE-2 and FE-3, in different transfer coefficients sampled at each contact, as well as the probability to wear gloves and wash hands was considered for each food establishment team. A thousand stores serving 400 sandwiches per day during five days were studied. The total number of servings for each of the 22 scenarios is  $2 \times 10^9$ . The convergence of all output was checked graphically.

The code is available on request to the corresponding author.

## 3. RESULTS

The proportion of contaminated servings (prevalence), the proportion of highly contaminated servings (>100 and >1,000 GEC NoV), and the mean number of infected and ill customers (according to the Teunis *et al.*<sup>(32)</sup> dose response model) for each of the 22 scenarios are presented in Table V. The estimated mean number of infected customers and the proportion of highly contaminated servings (>1,000 GEC NoV) for each scenario were normalized to the scenario 1 (baseline of this study), to provide a relative measure. In addition to the mean, the 90% variability interval, i.e., the 5th and 95th percentiles of the distribution of the number of infected and sick customers over 1,000,000 stores, is presented in

**Table III.** Overview of the Prevention Strategies and Factors Studied

Preventive Strategy	Factors	Scenarios <sup>a</sup>
Exclusion period from work (time to stay away from work while symptomatic and after declaration of symptom resolution)	Duration (symptomatic period + 24 hours after symptom resolution, symptomatic period + 48 hours after symptom resolution) and compliance	1, 3, 4, 5, 6, 7, 8, 9, 15, 17
Restroom cleaning	Frequency	10
No hand contact with faucet and door in restrooms	–	13
Restriction from food preparation area, no contact with food	Duration (24 hours, 48 hours)	14, 15, 16, 17
No barehand contact with food (using gloves in food preparation area)	Frequency (wear and change, compliance according to Food Code when engaging in food preparation)	11, 18
Handwashing	Frequency (compliance in restrooms and before engaging in food preparation and while changing gloves) and efficacy	12, 18, 19, 20

<sup>a</sup>All details of scenarios are described in Table III. All scenarios are to be compared with scenario 1 (baseline) representing existing knowledge of current practices and food employee behavior in retail food establishment.

Table V. Fig. 3 illustrates model results on the relative amount of norovirus transmitted via each pathway in the model for three representative scenarios.

In the baseline scenario, including an exclusion period of 24 hours after symptom resolution and a compliance rate  $P_C$  of 74%, the expected proportion of contaminated servings ( $>0$  GEC NoV) is 9.7% and the proportion of highly contaminated servings ( $> 1,000$  GEC NoV) is 0.5%, leading to an expected number of infected and sick customers of 74 and 1.7, respectively, over a total number of 2,000 servings. In this scenario, as is true for all scenarios, a high variability in the number of contaminated servings and in the number of resulting infections and illnesses is observed from store to store, as a function of the specific set of parameters characterizing this store. As an example, the 5th, the median, and the 95th percentiles of the numbers of infected customers estimated from the 1,000,000 simulated stores are 2.1, 48, and 233.7, respectively, in the baseline. This variability reflects notably the variability in the characteristics of the sick food employee (illness duration, shedding level, compliance with exclusion period).

In the lower baseline (scenario 2), in which no food employee is sick but 15% are asymptomatic shedders, the proportion of contaminated servings was evaluated at 1.3%, the proportion of highly contaminated servings at 0.04%, and the mean number of infections and illness at 9.6 and 0.1, respectively. In the upper baseline (scenario 3), where all ill FE-1 did not declare illness and worked while ill (“*noncompli-*

*ant 3*”), the mean number of infected customers increased by 226% compared to the baseline scenario.

The three prevention strategies leading to the smallest numbers of infected customers included either full compliance with handwashing and glove use and no barehand contact (scenario 18, estimated as 58% of infected customers relative to the baseline) or increased handwashing efficiency (additional 1 or 2  $\log_{10}$  reduction during handwashing, scenarios 19 (62%) and 20 (53%), respectively).

Fig. 3 illustrates the norovirus transmission in the retail environment over five shifts for scenario 1 (baseline), scenario 13 (no contact between hands, faucet, and door in restrooms), and scenario 18 (full compliance with handwashing in restrooms, full compliance with handwashing, and wearing and changing gloves when engaging in food preparation), when FE-1 is sick and from category “*non compliant 2*,” with FE-2 and FE-3 nonill and nonshedders. The main route of contamination is the direct contact with hands in the restrooms (during defecation and vomiting) of the ill food employee (FE-1), with high levels of norovirus removed during handwashing ( $>6 \log_{10}$  over five shifts) in the three scenarios. Fig. 3(a) shows a high level of norovirus transmission to FE-2 hands ( $>5 \log_{10}$  over five shifts) and to FE-3 hands ( $>4 \log_{10}$  over five shifts), while this food employee is not in contact with FCS and foods. Figs. 3(b) and 3(c) show that the level of transmission to food servings and nonill employees is reduced with prevention strategies.

Table IV. Scenarios

#	Descriptions of the Scenario	Compliance with Exclusion Time $P_e/P_{NC,1}/P_{NC,2}/P_{NC,3}$ (%)	Exclusion Period after Symptom Resolution	Compliance with Exclusion	Compliance with Handwashing in Restrooms	Compliance with Handwashing When Engaging in Food Preparation	Compliance with Wear Gloves When Engaging in Food Preparation	Compliance with Change Gloves When Engaging in Food Preparation
1	<b>Baseline Scenario:</b> FE-1 is ill, FE-2 and FE-3 are asymptomatic shedders in 15% of the stores. Restrooms and NFCs are washed before shift each day. FCSs are washed every four hours. Current practices regarding level of compliance with exclusion from work of 24 hours after symptom resolution + current practice with regard to level of compliance with handwashing in restrooms, handwashing when engaging in food preparation, and glove use when engaging food preparation. <sup>a</sup>	74 / 6.0 / 7.0 / 13	24 hours	Current <sup>a</sup>	Current	Current	Current	Current
2	Baseline + no ill food employees, FE-1, FE-2, and FE-3, are asymptomatic shedders in 15% of the stores.	-	-	-	Current	Current	Current	Current
3	Baseline + no compliance with exclusion from work (all sick employees work while ill, $P_{NC,3} = 100\%$ ).	0 / 0 / 0 / 100	-	None	Current	Current	Current	Current
4	Baseline + full compliance with exclusion from work while symptomatic and for 24 hours after symptom resolution.	100 / 0 / 0 / 0	24 hours	Full	Current	Current	Current	Current
5	Baseline + full compliance with exclusion from work while symptomatic and for 48 hours after symptom resolution.	100 / 0 / 0 / 0	48 hours	Full	Current	Current	Current	Current
6	Baseline + exclusion from work of 48 hours after symptom resolution.	74 / 9.1 / 3.9 / 13	48 hours	Current	Current	Current	Current	Current
7	Baseline + slight decreased compliance with exclusion from work while symptomatic and for 48 hours after symptom resolution.	64 / 12.6 / 5.4 / 18	48 hours	Decreased	Current	Current	Current	Current

(Continued)

Table IV (Continued)

#	Descriptions of the Scenario	Compliance with Exclusion Time $P_c/P_{NC:1}/P_{NC:2}/P_{NC:3}$ (%)	Exclusion Period after Symptom Resolution	Compliance with Exclusion	Compliance with Handwashing in Restrooms	Compliance with Handwashing When Engaging in Food Preparation	Compliance with Wear Gloves When Engaging in Food Preparation	Compliance with Change Gloves When Engaging in Food Preparation
8	Baseline + significant decreased compliance with exclusion from work while symptomatic and for 48 hours after symptom resolution.	54 / 16.1 / 6.9 / 23	48 hours	Decreased	Current	Current	Current	Current
9	Baseline + increased compliance with exclusion from work while symptomatic and for 24 hours after symptom resolution.	84 / 3.7 / 4.3 / 8	24 hours	Increased	Current	Current	Current	Current
10	Baseline + restrooms washed every four hours.	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current
11	Baseline + employees always wearing gloves without necessarily changing gloves.	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Full	Current
12	Baseline + employees always wash their hands in the restrooms.	74 / 6.0 / 7.0 / 13	24 hours	Current	Full	Current	Current	Current
13	Baseline + touchless faucet and door handles in restrooms.	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current
14	Baseline + FE-3 replacing FE-1, FE-1 is excluded from the food preparation area (no contact with food and FCS, contact with NFCS every 10 minutes) during 24 hours, FE-1 is not replaced when he does not declare illness at all (category noncompliant 3).	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current
15	Baseline + 48-hour exclusion after symptom resolution + FE-3 replacing FE-1, FE-1 is excluded from the food preparation area (no contact with food and FCS, contact with NFCS every 10 minutes) during 24 hours, FE-1 is not replaced when he does not declare illness at all (category noncompliant 3).	74 / 6.0 / 7.0 / 13	48 hours	Current	Current	Current	Current	Current
16	Baseline + FE-3 replacing FE-1, FE-1 is excluded from the food preparation area (no contact with food and FCS, contact with NFCS every 10 minutes) during 48 hours, FE-1 is not replaced when he does not declare illness at all (category noncompliant 3).	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current

(Continued)

Table IV (Continued)

#	Descriptions of the Scenario	Compliance with Exclusion Time $P_e/P_{NC,1}/P_{NC,2}/P_{NC,3}$ (%)	Exclusion Period after Symptom Resolution	Compliance with Exclusion	Compliance with Handwashing in Restrooms	Compliance with Handwashing When Engaging in Food Preparation	Compliance with Wear Gloves When Engaging in Food Preparation	Compliance with Change with Gloves When Engaging in Food Preparation
17	Baseline + full compliance with exclusion from work + FE-3 replacing FE-1, FE-1 is excluded from the food preparation area (no contact with food and FCS, contact with NFCS every 10 minutes) during 24 hours, FE-1 is not replaced when he does not declare illness at all (category noncompliant 3).	100 / 0 / 0 / 0	24 hours	Current	Current	Current	Current	Current
18	Baseline + full compliance of handwashing in restrooms + full compliance with handwashing in food preparation area, wearing and changing gloves when engaging in food preparation according to the FDA Food Code.	74 / 6.0 / 7.0 / 13	24 hours	Current	Full	Full	Full	Full
19	Baseline + improved handwashing efficacy (+1 log <sub>10</sub> ).	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current
20	Baseline + improved handwashing efficacy (+2 log <sub>10</sub> ).	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current
21	Baseline + considering all food employees who worked while symptomatic are noncompliant type 3 (i.e., all come to work during the whole symptomatic period).	80 / 0 / 0 / 20	24 hours	Equivalent <sup>b</sup>	Current	Current	Current	Current
22	Baseline + considering all food employees who worked while symptomatic are noncompliant type 3 (i.e., come to work during the whole symptomatic period) + exclusion from work of 48 hours after symptom resolution.	80 / 0 / 0 / 20	48 hours	Equivalent <sup>b</sup>	Current	Current	Current	Current

<sup>a</sup>Current: Based on observational surveys; see Table I for the value of parameters; -; not used.

<sup>b</sup>In the baseline and in scenarios 21 and 22, 20% of food employees came to work while symptomatic and 80% came to work after symptom resolution. In the baseline, categories  $P_{NC,2}$  (7%) and  $P_{NC,3}$  (13%) came to work while symptomatic (7+13=20%), and categories  $P_c$  (74%) and  $P_{NC,i}$  (6%) came back to work after symptom resolution (74 + 6 =80%).

**Table V.** Simplified Description and Results of the Scenarios (Scenario 1 Is Considered as the Baseline)

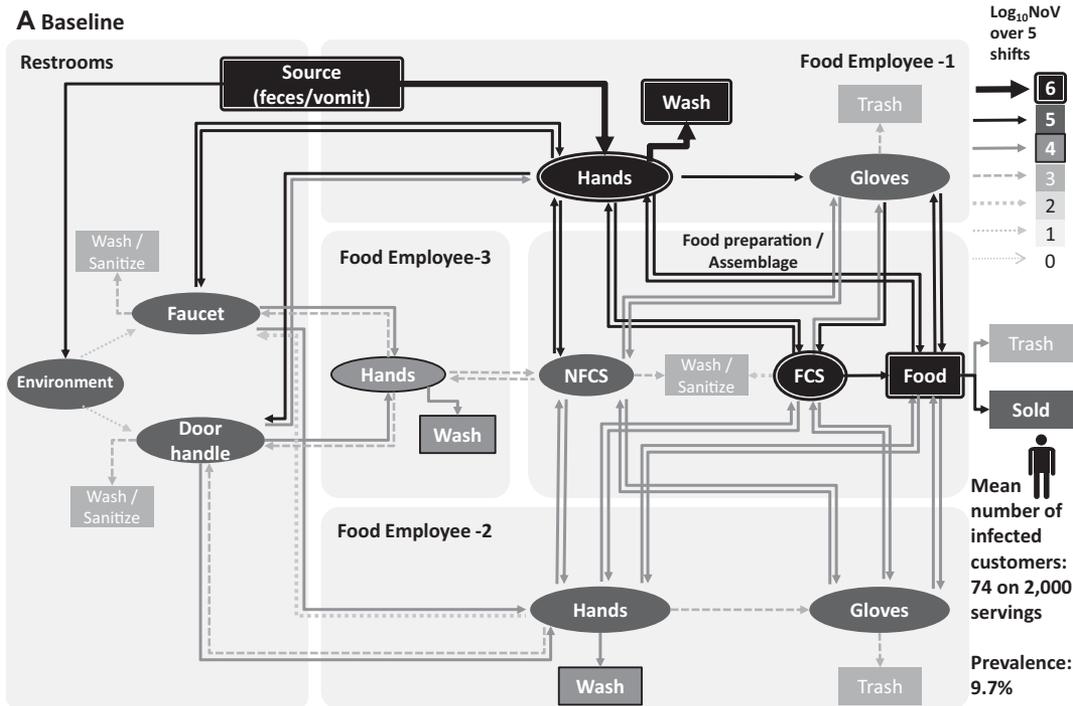
#	Compliance with Exclusion Period $P_c/P_{NC1}/P_{NC2}/P_{NC3}$ (%)	Exclusion Period after Symptom Resolution	Simplified Description of the Scenario	Proportion of Servings (%) with			Number of (on 2,000 Servings)			% Baseline Number of Servings > 1,000
				> 0 NoV	> 100 NoV	> 1,000 NoV	Infected Customers, Mean [90% Variability Interval]	Sick Customers, Mean [90% Variability Interval]	% Baseline Number of Infected Customers	
1	74 / 6.0 / 7.0 / 13	24 hours	<b>Baseline</b>	9.7	1.7	0.54	74.0 [2.1, 233.7]	1.7 [0.0, 7.9]	100	100
2	-	-	FE-1 not sick, 15% asymptomatic shedder (lower baseline)	1.3	0.1	0.04	9.6 [0.0, 61.0]	0.1 [0.0, 0.4]	13	7
3	0 / 0 / 0 / 100	-	FE-1 always work while ill (upper baseline)	21.5	4.9	1.76	167.4 [29.0, 357.7]	5.2 [0.1, 17.2]	226	324
4	100 / 0 / 0 / 0	24 hours	Full exclusion compliance, 24 hours	7.4	1.0	0.31	55.8 [1.4, 176.4]	1.0 [0.0, 4.8]	75	58
5	100 / 0 / 0 / 0	48 hours	Full exclusion compliance, 48 hours	6.8	0.9	0.26	51.2 [1.1, 165.5]	0.8 [0.0, 4.1]	69	48
6	74 / 9.1 / 3.9 / 13	48 hours	Exclusion extension	8.9	1.5	0.47	67.9 [1.7, 222.8]	1.5 [0.0, 7.1]	92	87
7	64 / 12.6 / 5.4 / 18	48 hours	Exclusion extension, slight decrease in compliance	9.7	1.7	0.55	74.2 [1.8, 240.3]	1.7 [0.0, 8.1]	100	101
8	54 / 16.1 / 6.9 / 23	48 hours	Exclusion extension, significant decrease in compliance	10.5	1.9	0.63	80.5 [2.1, 255.1]	1.9 [0.0, 9.1]	109	116
9	84 / 3.7 / 4.3 / 8	24 hours	Improved compliance	8.7	1.4	0.45	66.3 [1.8, 211.6]	1.4 [0.0, 6.6]	90	82
10	74 / 6.0 / 7.0 / 13	24 hours	Wash restrooms every four hours	9.4	1.6	0.53	71.7 [2.1, 225.4]	1.6 [0.0, 7.7]	97	98
11	74 / 6.0 / 7.0 / 13	24 hours	No barehand contact, 100% wear gloves, current compliance with changing gloves	11.1	1.7	0.49	84.1 [1.4, 266.9]	1.6 [0.0, 7.8]	114	91
12	74 / 6.0 / 7.0 / 13	24 hours	Full handwashing compliance in restrooms, 100% wash hands in restrooms	9.2	1.5	0.48	69.9 [1.7, 223.7]	1.5 [0.0, 7.2]	94	89
13	74 / 6.0 / 7.0 / 13	24 hours	Touchless faucet and door in restroom	7.3	1.3	0.46	55.8 [0.7, 191.3]	1.4 [0.0, 6.8]	75	85
14	74 / 6.0 / 7.0 / 13	24 hours	Food handling restriction, FE-3 replaces FE-1 during 24 hours	10.1	1.7	0.56	77.0 [2.1, 237.3]	1.7 [0.0, 8.2]	104	103

(Continued)

Table V (Continued)

#	Compliance with Exclusion Period $P_c/P_{NC1}/P_{NC2}/P_{NC3}$ (%)	Exclusion Period after Symptom Resolution	Simplified Description of the Scenario	Proportion of Servings (%) with			Number of (on 2,000 Servings)		%Baseline Number of Infected Customers	%Baseline Number of Servings > 1,000
				> 0 NoV	> 100 NoV	> 1,000 NoV	Infected Customers, Mean [90% Variability Interval]	Sick Customers, Mean [90% Variability Interval]		
15	74 / 6.0 / 7.0 / 13	48 hours	Food handling restriction, FE-3 replaces FE-1 during 24 hours	9.3	1.5	0.48	70.5 [1.7, 225.8]	1.5 [0.0, 7.3]	95	89
16	74 / 6.0 / 7.0 / 13	24 hours	Food handling restriction, FE-3 replaces FE-1 during 48 hours	10.4	1.8	0.57	79.3 [2.1, 241.3]	1.8 [0.0, 8.5]	107	105
17	100 / 0 / 0 / 0	24 hours	Full exclusion compliance + food handling restriction, FE-3 replaces FE-1 during 24 hours	7.7	1.1	0.33	58.5 [1.5, 181.9]	1.0 [0.0, 5.0]	79	60
18	74 / 6.0 / 7.0 / 13	24 hours	100% wear gloves, 100% change gloves, 100% wash hands while changing gloves and in restrooms	5.7	0.7	0.17	42.6 [0.0, 160.0]	0.6 [0.0, 3.1]	58	31
19	74 / 6.0 / 7.0 / 13	24 hours	Handwashing efficacy (additional 1log <sub>10</sub> reduction)	6.1	0.8	0.25	45.9 [0.7, 152.0]	0.8 [0.0, 3.9]	62	46
20	74 / 6.0 / 7.0 / 13	24 hours	Handwashing efficacy (additional 2log <sub>10</sub> reduction)	5.2	0.7	0.20	38.9 [0.3, 133.3]	0.7 [0.0, 3.3]	53	37
21	80 / 0 / 0 / 20	24 hours	Baseline + considering only compliant and noncompliant type 3 (did not declare illness and worked while symptomatic)	10.1	1.8	0.6	77.3 [2.1, 246.9]	1.8 [0.0, 8.7]	104	111
22	80 / 0 / 0 / 20	48 hours	Baseline + considering only compliant and noncompliant type 3 (did not declare illness and worked while symptomatic) + 48 hours	9.7	1.7	0.56	73.9 [1.7, 243.4]	1.7 [0.0, 8.3]	100	100

$P_c$ : Proportion of compliant food employees regarding the Food Code exclusion recommendation;  $P_{NC1}$ : proportion of noncompliant food employee type 1,  $P_{NC2}$ : proportion of noncompliant food employee type 1,  $P_{NC3}$ : proportion of noncompliant food employee type 1 (see text and Fig. 2 for further details). FE-1: food employee 1 (see text and Fig. 2 for further details). The 90% variability interval represents the 5th and the 95th percentiles of the distribution of the number of infected and sick customers over 1,000,000 stores.



**Fig. 3.** Transmission of norovirus in the retail environment for three scenarios: (A) baseline, (B) scenario 13: no contact with the faucet and the door handle in the restrooms, and (C) scenario 18: no barehand contact, 100% compliance with changing gloves and handwashing while changing gloves according to the FDA Food Code. Food employee 1 is sick and considered *noncompliant 2* regarding exclusion period, food employee 2 and food employee 3 are nonshedders. Thickness and gray level of arrows and objects represent the mean value of 1,000 iterations of norovirus transmitted over five shifts.

## 4. DISCUSSION

### 4.1. Limitations of the Model/Data

Federal agencies have recommended a number of prevention strategies for mitigating the risk of foodborne illness from norovirus in the retail setting. Even though these prevention strategies are each science based,<sup>(14)</sup> it is difficult not only to measure their relative and combined impacts, but also the relative impact of their level of compliance on public health. Large-scale experiments would be the gold standard to obtain a better understanding of these impacts, but issues linked to ethics, feasibility, and costs limit the possibility of obtaining data through such experiments. Risk assessment models are a useful alternative in these situations and can inform risk managers on which prevention strategies can best reduce the considered risk of foodborne illness.<sup>(36)</sup>

Building a model for all these settings was out of the scope of this article. The situation modeled here is typical of what can be observed and, even though the absolute estimate of the risk may vary

in different settings, the relative impact of various preventions and the conclusions of this study are expected to be generalizable. Presymptomatic shedding of the food employees,<sup>(37)</sup> transmission of norovirus between food employees, presence of infected and/or ill customers contaminating the environment, emesis in the kitchen or in the dining room, and presence of contaminated incoming products<sup>(38-40)</sup> were not included in this study. These features could certainly be included in this discrete event framework.

In risk assessment models, limitations rely on included data and assumptions. The main assumptions of the model are presented in Table VI in three categories: assumptions related to employee practices/behavior and retail setting; assumptions related to illness and norovirus; and assumptions related to data and statistical analysis. It is important to ensure that model results are driven by robust literature data. Our model is based on an extensive literature review and meta-analyses regarding the survival, disinfection, and transfer of norovirus, hand hygiene, and food employee behavioral practices, including compliance with prevention strategies such

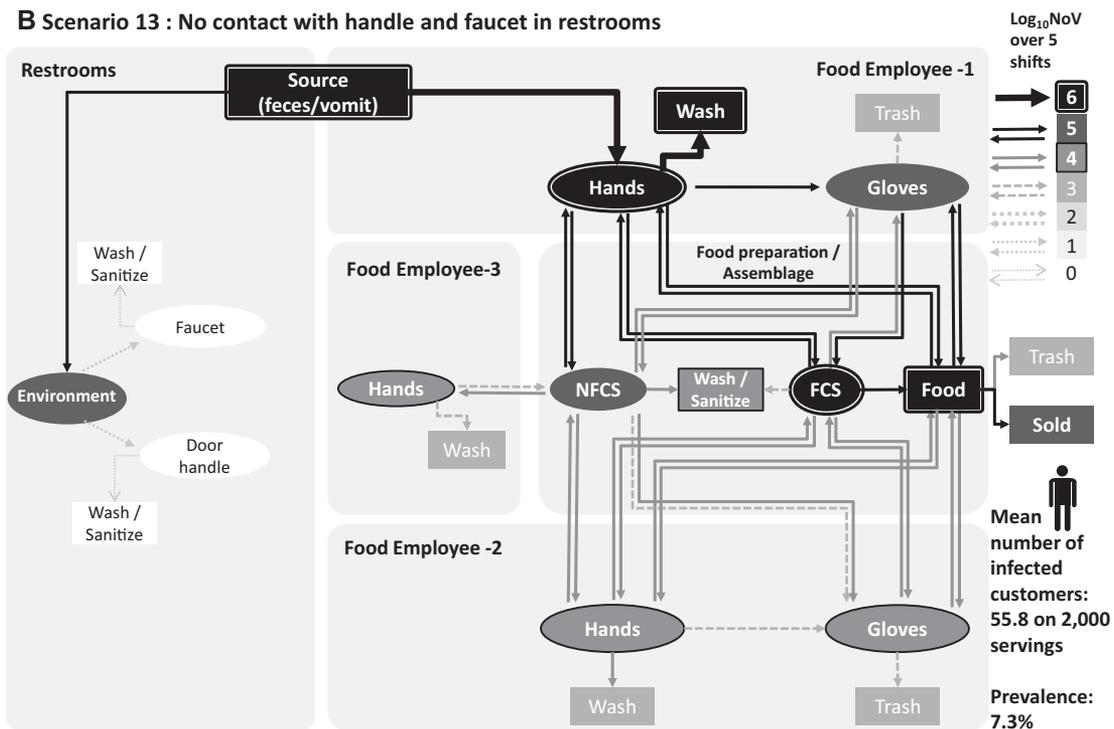


Fig. 3. Continued.

as no barehand contact with RTE food. Although many efforts were made during the last decade to conduct observational studies of food employee behavior,<sup>(20,25,26,41)</sup> some practices are not always observable and were assumed in this model such as the number of contacts between food, hands, FCS, and NFCs during food preparation.

The number of infected consumers was used as the major output of our risk assessment model. Teunis *et al.*'s<sup>(32)</sup> dose-response model leads to a high probability of infection for a low dose that plateaus when a high dose of norovirus is ingested. Indeed, according to this model, the probability of being infected following the ingestion of exactly one norovirus is 0.42; it is 0.67 following the ingestion of 10<sup>6</sup> norovirus for an Se+ individual, for a 50% human infectious dose (HID<sub>50</sub>) of 18 norovirus. This dose-response relationship leads to almost direct proportionality between the estimated number of infected individuals and the prevalence of contaminated products (>0 GEC NoV). In contrast, according to these authors, the probability of illness once infected is low if infected with a low dose, and increases with the ingested dose. The probability of symptomatic illness once infected following the ingestion of one norovirus is 9.2 × 10<sup>-5</sup>; it is 0.33

following the ingestion of 10<sup>6</sup> norovirus. We took into account preexisting immunity of negative secretors (nonsusceptible population due to a lack of soluble blood group antigens that are believed to interact with the virus)<sup>(34)</sup> but did not include immunity associated with prior episodes of norovirus infection or the fact that genetic susceptibility factors of different norovirus strains may differ from what has already been described for the prototype virus.<sup>(32,42)</sup> Actually, the accuracy and applicability of this dose-response model is still debated.<sup>(42-45)</sup> Atmar *et al.*<sup>(43)</sup> suggested that the 50% human infectious dose for norovirus could be higher, i.e., 2,800 GEC NoV for Se+ individuals. We propose the prevalence of servings with more than 100 and more than 1,000 GEC NoV as an alternative output to the number of infected or sick consumers.

## 4.2. Discussion of the Results

### 4.2.1. Routes of Contamination

The contamination of hands in the restrooms, directly from the source or from objects, is the major route of norovirus transmission to the retail environment (Fig. 3). Removing hand contact in the

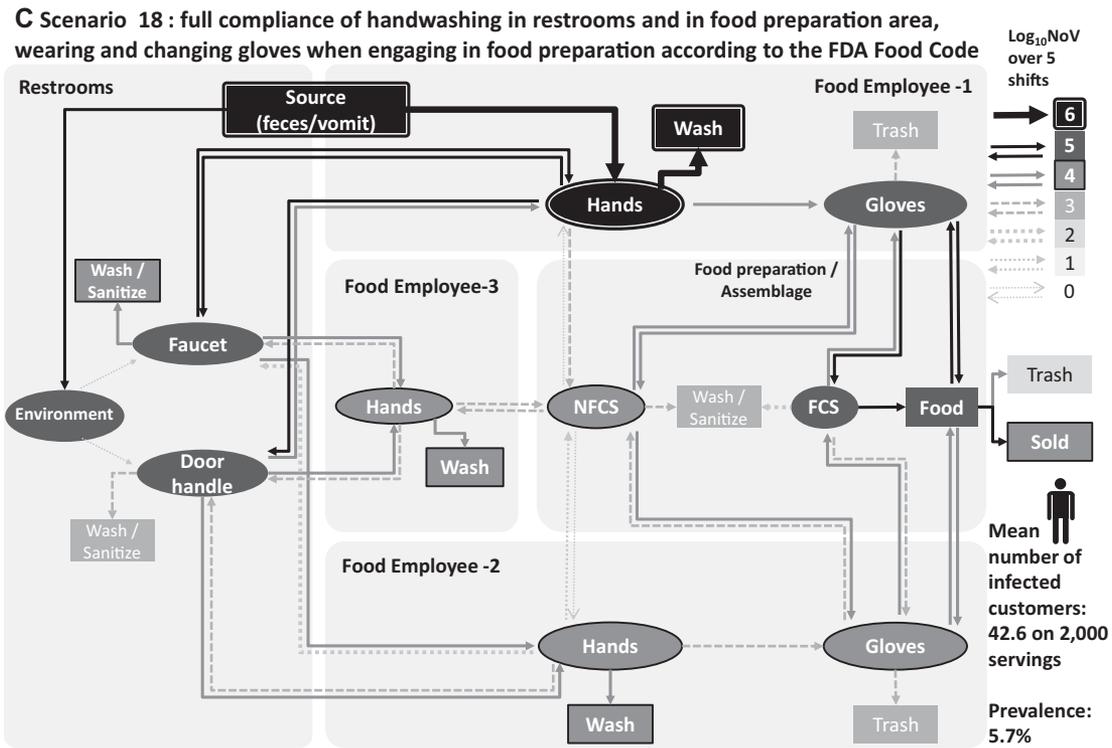


Fig. 3. Continued.

restrooms through the installation of touchless faucets and doors (scenario 13) is much more efficient in reducing the mean number of infected customers (75% compared to the baseline) than increasing the frequency of cleaning restrooms (scenario 10, 97% compared to the baseline).

In contrast to earlier studies,<sup>(18,19)</sup> emesis in the restroom in addition to diarrhea was incorporated in our model. Vomiting has been recognized to contribute significantly to norovirus transmission, especially in confined environments such as food establishment settings.<sup>(46,47)</sup> Our analysis found that norovirus particle transfer to objects through aerosolization is much less important than direct hand contact (Fig. 3). This is because a very small number of norovirus particles are transferred through the aerosol to surfaces that the food employees touch.

4.2.2. Impact of Exclusion

Our results confirm the importance of removing symptomatic employees from food establishments as recommended by Hall *et al.*<sup>(48)</sup> For example, the model estimates a 226% increase in the number of

infected customers when ill food employees are not excluded (scenario 3) and a decrease to 75% compared to the baseline with full compliance with the exclusion period (scenario 4).

The importance of removing ill food employees from work can be further illustrated by the mean number of infected customers according to the category of ill food employee present in the store. In fact, if an ill employee was compliant with the exclusion period, or “noncompliant 1,” and hence did not work while ill (as explained in Fig. 2), the mean number of infected customers was estimated to 56 or 60 in the baseline scenario, respectively. However, for the categories “noncompliant 2” and “noncompliant 3,” who worked while ill, the mean number of infected customers was estimated to 109 and 164, respectively. The high levels of infected customers when food employees worked while ill are explained by the high level of norovirus introduced in the retail environment by the ill food employee (FE-1) due to frequent visits to the restrooms to vomit or defecate. Those visits to the restrooms lead to hand contamination of the ill employee (FE-1) who then directly contaminate their gloves, the FCS, the NFCS, and the food, or indirectly contaminate the hands of the other food

Table VI. Major Assumptions of the Model

**Assumptions Related to Employee Practices/Behavior and Retail Setting**

The food establishment includes one food preparation area and one restroom  
 Three workers are present in the food establishment, and two of these workers are food workers  
 Five shifts of eight hours were simulated, with 200 servings per food worker and per shift (total of 2,000 servings)  
 The food serving includes three ingredients, one of the ingredients is cooked  
 Food preparation and assembly tasks take place in five-minute sequences  
 Contact between food, hands/gloves, and FCS occurs twice for each ingredient during food preparation and assembly  
 Contact between hands/gloves and NFCS occurs once for each ingredient during food preparation and assembly  
 The pace of sandwich assembly is 1 per minute  
 The pace of ingredient preparation is 20 pieces per minute  
 Restroom had two hand-touch points: the hand sink faucet handle and the restroom door handle.  
 Settings studied in the literature used for the meta-analyses are representative or comparable to this setting  
 Category “noncompliant 3” represents 50% of the proportion of total noncompliant

**Assumptions Related to Illness and Norovirus**

Ingredients are initially free of norovirus  
 Restroom, food facility, and food contact equipment are initially free of norovirus  
 Transmission of norovirus to customer only occurs through food  
 Only one employee (FE-1) is symptomatic  
 Symptomatic employees always experience diarrhea  
 All assumptions from Teunis *et al.*<sup>(32)</sup> dose–response models (infection and illness)

**Assumptions Related to Data and Statistical Analysis**

RT-PCR data represent the number of norovirus particles in the dose–response model  
 All actions on norovirus particles (transfer, survival, washing, and disinfection) are applied independently on each particle  
 Norovirus surrogates have similar properties (up to a scaling factor) as norovirus (survival, transfer, handwashing, and disinfection)  
 Norovirus genogroup GI and GII have similar properties and infection probability

employees, as shown in Fig. 3(a). The impact of a symptomatic food employee in contaminating RTE food items is so strong that other prevention strategies cannot prevent the norovirus contamination of RTE food if a symptomatic food employee is in the food establishment (Figs. 3(b) and 3(c)).

An increase of the exclusion period from 24 to 48 hours after symptom resolution leads to a relatively small decrease in estimated numbers of infected customers when compared with other prevention strategies explored in this risk assessment. This is true whether food employees are fully compliant with the exclusion requirement (8% reduction, scenarios 4 and 5) or not (8% reduction, baseline and scenario 6, or 4% reduction, scenarios 21 and 22). The small decrease in estimated numbers of infected customers when extending the exclusion period to 48 hours primarily arises via the decrease in the level of norovirus in feces during these additional 24 hours away from work, and results from recent human volunteer challenge studies suggest that this decrease is slow.<sup>(9)</sup> Moreover, norovirus shedding continues long after symptoms have resolved.<sup>(11)</sup> The larger impact of the exclusion period extension predicted for the 24 hours (baseline)/48 hours (scenario 6) pair compared with that for the 24 hours (scenario 21)/

48 hours (scenario 22) pair arises from preventing some food employees who would have had active symptoms (returned to work too soon before symptom resolution) in the food establishment from working while ill (shift of food employees from NC-2 to NC-1 category). In other words, requiring food employees to stay away from work an extra 24 hours could reduce the impact of food employees prematurely declaring the end of symptoms and this is reflected in the overall 8% reduction predicted for scenario 6 as compared with the baseline. The impact of extending the exclusion period depends on the distribution of food employees working while ill among categories NC-2 and NC-3.

If implementation of an extended exclusion period to 48 hours after symptom resolution leads to a reduction in compliance with the exclusion, the reduction of norovirus transmission associated with the extended exclusion period shown in scenario 6 could be completely eliminated (scenario 7) or could even lead to an increase in infections and illnesses (scenario 8), depending on the magnitude of the reduction in compliance and the distribution of food employees working while ill among categories NC-2 and NC-3. More data are needed to quantify the impact of an extended exclusion period on food employee

compliance. Previous studies suggested that as many as 60% of food employees have worked while ill and 20% while experiencing diarrhea or vomiting.<sup>(25,26)</sup> Many of the influential factors cited by food employees leading to working while ill, such as loss of pay,<sup>(49)</sup> (lack) of severity of illness, and not wanting to leave co-workers short staffed,<sup>(25,50)</sup> may become even more important when the period of exclusion is extended.

The model results indicate that a decrease in infected customers comparable to that achieved by extending the exclusion period from 24 to 48 hours could be achieved if compliance with the current 24-hour exclusion period is increased (compare scenario 6 and 9).

#### 4.2.3. *Impact of Restriction*

Restricting food employees from preparing food after being ill seems to be counterproductive (scenarios 14 and 16) in our setting. Norovirus transfers from the restricted food employee FE-1 to hands and gloves of the other food employees FE-2 and FE-3 via contamination of the restroom environment and via contact with NFCS (compare scenarios 1 and 14). This result is highly sensitive to the level of interaction between the restricted food employee and the food preparation environment (our results, not shown). We modeled one contact between the hand of the restricted food employee and one NFCS every 10 minutes on average in our model. The increased risk of transmission from a restricted employee was observed because those restricted employees do not wear gloves and wash their hands much less frequently than if they were engaged in food preparation, thereby transferring more norovirus in the setting than they would while preparing food.

#### 4.2.4. *Impact of Handwashing, Glove Use, and No Barehand Contact*

Our results suggest that handwashing and sanitation (scenarios 19 and 20), no barehand contact with RTE food via glove use in addition to handwashing (scenario 18), and no contact in the restrooms between faucet, door handle, and hands (scenario 13) are highly effective in reducing the transmission of norovirus compared to the baseline. However, glove wearing alone (scenario 11) with current compliance with changing gloves and handwashing when engaging in food preparation does not have a clear impact on decreasing the risk of norovirus transmission.

Interestingly, our results suggest that this scenario would increase to 114% the mean number of infected customers, while reducing to 91% compared to the baseline the number of heavily contaminated products (>1,000 GEC NoV). Note that, in our model, we consider norovirus transfer from hands to gloves while the food employee is putting on gloves, as observed in Casanova *et al.*<sup>(51)</sup> and Ronnqvist *et al.*<sup>(52)</sup> This unexpected outcome may be explained by the higher norovirus transfer coefficients from gloves to surface and food items than from barehands (see meta-analysis results in Table I), as shown previously for bacteria.<sup>(53)</sup> This supports that wearing gloves without compliance with handwashing and changing gloves when engaging in food preparation is not enough to reduce the transmission of norovirus in retail settings and highlights the necessity to change gloves and wash hands as recommended in the FDA Food Code. Indeed, scenario 18 shows that it is highly efficient if the food employees regularly change their gloves and wash their hands when they engage in preparation and, importantly, wash their hands in the restrooms.

Interestingly, an increase in the efficiency of handwashing appears to be very successful in reducing the risk linked to norovirus transmission in the retail food service setting (scenarios 19 and 20). A typical handwashing procedure usually removes 1–2 logs of norovirus from the hands.<sup>(54–56)</sup> Improving this efficiency, through better training, improved handwashing efficacy (such as through the use of soap that increases the level of friction on the hands, without damaging the skin), or other means would reduce the risk of norovirus transmission and foodborne illness in food establishments.

## 5. CONCLUSIONS

This risk assessment provides a better understanding of the norovirus transmission pathway from infected food employees to RTE food in food establishments and supports the importance of removing symptomatic food employees to prevent norovirus foodborne illnesses. Infected food employees who return to work too soon before full symptom resolution may continue to spread the virus and contaminate food. The effectiveness of exclusion as a preventive control depends on the level of compliance, which, in turn, depends on the reasons and motivations of why food employees may work while ill. This study evaluated the impact of extending the exclusion period after symptom resolution from 24 to 48 hours

and found that (1) reduction in mean numbers of infected customers is relatively small when compared with the other prevention strategies; (2) a comparable reduction could be achieved by increasing compliance with the 24-hour exclusion period; and (3) if compliance with the exclusion requirement is reduced as a consequence of the extension of the postsymptomatic exclusion period, the public health benefit could be reduced, eliminated, or lead to an increase in the mean number of infected customers. Whether or not a public health benefit results from the extension of the postsymptomatic exclusion period and the magnitude of that benefit/harm depend on food employee behavior and more specifically on the level of compliance with the exclusion provision and, among those not complying, the extent to which the change results in these food employees being excluded longer from the food establishment.

This risk assessment identified major areas of improvement to prevent norovirus transmission in these settings, including (1) avoiding the presence of any symptomatic food employees; (2) avoiding the transfer of norovirus from feces or vomit to the hands of food employees by using touchless faucets and eliminating hand contact with the door in restrooms; and (3) avoiding the transfer of norovirus from the hands of food employees to food through proper hand hygiene and the prevention of barehand contact with RTE food. Results of the impact of all preventive strategies on controlling norovirus foodborne illness are largely in line with what was expected in these settings such as the large impact of compliance with exclusion from work while ill, handwashing, or glove use when engaging in food preparation. This research has demonstrated that when evaluating the impact of preventive controls, level of compliance with each preventive strategy should be evaluated separately. More research is needed to identify factors influencing compliance with existing prevention strategies.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-020**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Sanitation Controls at Community Kitchens (AKA: Shared-Kitchens, Incubators)

**Issue you would like the Conference to consider:**

Lack of awareness, ownership & accountability for sanitary standards is a common theme observed during audits we've conducted in community kitchen settings. This includes the upkeep of the facilities (floors, walls, ceilings, related structures & welfare facilities) as well the sanitation of shared food processing equipment (FCS & NFCS) prior and in between uses. This is routinely demonstrated by:

1. The staff that is assigned to these tasks often do not have formal sanitation training and do not demonstrate proficiency in cleaning and sanitizing objectives and inspection standards.
2. Ownership does not have formal Sanitation SOP procedures in place (no pre or operation sanitation inspections/checklists)
3. Tenants of the shared spaces often report that maintenance work order related requests are typically met with slow response time and ineffective corrective actions.
4. Audits that we have conducted reveal that obvious deficiencies are either not being seen or not being attended to (we often point out deficiencies in very basic, fundamental requirements - broken or empty soap dispensers, broken dishwashing machines, leaks, etc.)
5. Confusion as to who is responsible for verifying the sanitation of common areas and shared equipment is a common theme amongst both ownerships and operators.

**Public Health Significance:**

Since a wide variety of foods are being prepared in these facilities, including many RTE food products, the lack of effective sanitation programs poses risk for *Listeria* & other pathogenic contamination as well allergen cross-contact/cross-contamination.

**Recommended Solution: The Conference recommends...:**

a committee be created to identify concerns with shared kitchens. The committee charges are....

1. *clearly identify roles and responsibilities amongst and between parties (tenant and facility management/ownership),*
2. *Identify job-specific training to reduce gaps in the prevention of food safety hazards (i.e. - facility porters commonly assigned to sanitation tasks do not have formal training on basic sanitary standards),*
3. *Recommend preventive controls based on the risks commonly associated with the diverse operations conducted within (examples. - Pre-operational and operation self-monitoring inspections are not commonly practiced (SSOPs), effective allergen cross-contact prevention procedures are not in place for shared equipment exposed to multiple allergen-bearing ingredients, facilities are commonly ill-equipped for the rapid and continuous cooling of TCS foods)*
4. *Recommend active managerial controls from an overall facility food safety oversight perspective (As just one of many examples - in a scenario where multiple foodservice operations are working in a common/shared production area and an unforeseen hazard was suddenly introduced [someone left the back door open allowing a swarm of flies to enter], who would take action to identify and eliminate this potential public health hazard?) It's highly unlikely that an independent operator would lead that charge, but without a qualified and dedicated individual on the facility management team who is charged with that level of oversight and control, it is highly likely that scenarios like this one would go without proper corrective actions or preventive measures.*
5. *Report back to the 2022 biennial meeting of the Conference for Food Protection*

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**Supporting Attachments:**

- "AFDO Guidelines for Incubator Kitchens (abbreviated copy)"
- "DC Shared Kitchen Audit"
- "LA Shared Kitchen Visit"
- "LA Shared Kitchen Visit (2)"

- "DC Shared Kitchen Audit (2)"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*



Description (Above): Food service operations in a shared kitchen.

## 4. Definitions

The following definitions shall apply for the purposes of these guidelines.

4.1 **“Incubator Kitchen, or Commercial/Shared Kitchen”** a fully equipped commercial food processing facility designed to allow multiple entrepreneurs or food processing operators to grow their businesses by providing a kitchen space with food and packaging equipment. For example, some new entrepreneurs might not be able to afford to build or buy their own kitchens, so they rent or reserve a shared kitchen on an hourly basis. This allows them to complete small-scale food processing in a shared kitchen used by multiple operators. They may be commercial kitchens, food hubs, or kitchens permitted by a regulatory agency, social club, church, firehouse, or other.

4.2 **“Incubator Kitchen Owner”** the owner of the commercial kitchen location to be rented.

- 4.3 **“Incubator Kitchen Operator”** a licensed person or company that rents space at the commercial kitchen location.
- 4.4 **“TCS Foods”** foods that require time and temperature control for safety and must be kept out of the Danger Zone (41-135\* F) to limit pathogenic growth of microorganisms and the production of toxins. TCS foods include milk, eggs, fish, meats, untreated garlic and oil mixtures, raw seed sprouts, cut melons, cut leafy greens, and cut tomatoes.
- 4.5 **“Food Safety Operations”** the procedures and practices needed to comply with food safety regulatory requirements, including those pertaining to employee hygiene and practices, handwashing, use of gloves, safe food sources, safe food temperatures, cross contamination, and equipment cleaning and sanitizing.
- 4.6 **“Food Safety Standard Operating Procedures (SOPs)”** written practices and procedures that are critical to producing safe food. It is essential to have SOPs in place and to train employees and operators to use them.
- 4.7 **“Process Review”** a process whereby the manufactured product and written process is reviewed by a process authority, and food classification (such as low-acid, formulated-acid, high-acid, shelf stable, etc.) is determined.
- 4.8 **“Scheduled Process”** a process developed by a process authority and selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a product that will not permit the growth of microorganisms having public health significance.

## 5. Owner Responsibilities

- 5.1 Complying with all applicable state and local codes and ordinances. They should collaborate with regulatory agencies to ensure the

kitchen and all operators are properly licensed and/or permitted with the appropriate agency.

- 5.2 Maintaining the building and property in an acceptable sanitary manner, including pest control measures and sufficient garbage disposal.
- 5.3 Providing sufficient handwashing facilities, equipment washing and sanitizing facilities, and restroom facilities.
- 5.4 Maintaining an incubator kitchen operator schedule/calendar, including the date and time of processing. The calendar should be shared with the appropriate food safety regulatory jurisdiction when requested.
- 5.5 Limiting operations to only those for which the kitchen has the appropriate equipment, space, and facilities for production.
- 5.6 Maintaining a file for each kitchen operator, including but not limited to the business contract, business certificate, license, inspection results, and scheduled processes.
- 5.7 Identifying their rental capacity to regulatory representatives and not rent beyond the identified capacity. Incubator owners may not overbook, or schedule rentals in a manner such that the needed capacity exceeds the identified capacity and causes operators to process with insufficient production space.
- 5.8 Having a method for dealing with storage for clients' raw ingredients and finished product. This can be accomplished in various ways:
  - 5.8.1 Best practice indicates that individual operators' storage spaces should be separated in locked cages, if possible. All ingredients and finished products should identify the operator with designated storage spaces, labels, and tags, etc.
  - 5.8.2 Operators can rent their own off-site storage, which should also be licensed and inspected. If the operator does not need

storage, all ingredients must be purchased on the way to the kitchen and used during the rental period. Remaining ingredients must be discarded or used for personal consumption at home.

5.8.3 Finished products must be delivered to accounts directly after they are manufactured. They must not be stored. The kitchen manager is responsible for ensuring that all ingredients used are commercially sealed.

## 5.9 Providing guidance to incubator kitchen operators regarding:

5.9.1 Contract Agreements – The incubator kitchen owner/manager should discuss the particular contractual agreement between the incubator kitchen and incubator kitchen operator. The contract agreements may include, but not be limited to, rent, liability insurance, times of operations, list of foods to be produced in the kitchen, food safety SOPs, cleaning and sanitizing, regulatory agency inspection, and licenses and permits, etc.

5.9.2 Jurisdiction – Various food safety regulatory jurisdictions throughout the United States will be responsible for regulating incubator kitchens. The local health departments will have jurisdiction in other cases, while the state health or agriculture departments will have jurisdiction in others. Some states operate under a Memorandum of Understanding (MOU) which will determine the appropriate jurisdiction.

5.9.2.1 Once the appropriate jurisdiction has been determined, the applicant for an incubator kitchen license will undergo a consultation with a representative from the appropriate regulatory agency. An on-site inspection must be performed by the regulatory agency prior to issuance of the license. The consultation should include a review of proposed business practices, the type of equipment to be used within the facility, food safety operations, and proposed menus, to include a list of all food items that

the user intends to prepare, store, taste test, develop, package, or otherwise handle or use for food-related purposes.

5.9.3 As part of this consultation, the individual or entity should be required to provide a Food Safety Manager Certificate or equivalent in the licensee's name or in the name of an employee of the licensee, if the licensee intends to prepare, taste, handle, package, prepare for storage, serve, or otherwise use food, the name and address of the shared kitchen(s) the user intends to lease space from, the license number of the shared kitchen(s) the user intends to lease space from, and a signed statement of intent, or lease, from the owner or operator of each licensed shared kitchen that the applicant intends to lease space from, including the start date and end date (if applicable) for the agreement.

5.9.4 Based on the information provided, the regulatory agency will assess and assign a risk level to the shared kitchen user. That risk level will be based on criteria provided in these guidelines. Additionally, the regulatory agency will review its records on the licensed incubator kitchen to confirm it is properly licensed and capable of supporting the proposed practices. The menu or product list will be reviewed and approved.

## 6. Operator Responsibilities

6.1 Obtaining the appropriate regulatory agency license/permit.

6.2 Not commencing food processing prior to being inspected and/or prior to the submission of the appropriate license application.

6.3 Ensuring that all equipment is properly cleaned and sanitized prior to and subsequent to processing.

6.4 Addressing cross-contamination concerns for allergens and bacterial contamination, prior to and subsequent to processing.

6.5 Proper temperature controls of ingredients and finished product, including transportation.

6.6 Ensuring that all processing occurs at the incubator kitchen facility from start to finish. Product may not be moved to an unlicensed or uninspected facility for further processing. Products manufactured in unlicensed/unapproved facilities are subject to seizure and destruction. All ingredients must be from a known, approved source.

6.7 Verifying that all finished products and stored ingredients are appropriately packaged and labeled.

6.8 Ensuring that specialized processing operations, such as vacuum packaging, are not conducted if required approvals or documentation is not on file with the appropriate regulatory agency.

6.9 Evidence of Licensure – If an incubator kitchen operator has one or more employees, such employee(s) may work at the kitchen without the licensed user on the premises if all of the following requirements are met.

6.9.1 At least one employee possesses a Food Safety Handler Certificate or equivalent and is present when TCS foods are being prepared, tasted, handled, packaged, prepared for storage, served, or otherwise used, and

6.9.2 The incubator kitchen licensee keeps a copy of the following in the shared kitchen user's file:

6.9.2.1 A copy of the incubator kitchen user's employee Food Safety Handler Certificate,

6.9.2.2 The name and contact information (including home address and telephone number) of all employees (paid or unpaid), along with the date and times that all employees worked, and,

6.9.2.3 Records for a period of at least 60 days after the date of entry.

## 7. Regulatory Inspector Responsibilities

- 7.1 Scheduling the initial consultation and/or initial inspection.
- 7.2 The inspector should review with the incubator kitchen owner/incubator kitchen operator that food processing licenses and permits are location-specific and that all production, packaging, labeling, and storage should take place at the incubator kitchen. If applicable, the inspector should inspect off-site storage locations.
- 7.3 Confirm the operator's business information.
- 7.4 Confirm the operator's list of food to be processed at the incubator kitchen.
- 7.5 Conduct Risk Assessment: Determine if the product is shelf-stable, acidified, water-activity-controlled, vacuum packaged, etc.
- 7.6 Review and confirm if the operator requires a Process Review/Schedule Process for the intended food process. Verify the processes were prepared by an approved processing authority to assure the safety and integrity of the process and finished product. Regulator should obtain copies of the Process Authority letter and/or scheduled process.
- 7.7 Determine the applicable regulation under which the food produced will be regulated. Applicable regulations include:
  - 7.7.1 Local and state food safety regulations.
  - 7.7.2 FDA Food Code.
  - 7.7.3 GMP Regulations 21 CFR pt. 110 (old) cGMP Subpart B 117 (new).
- 7.8 Determine the applicable process-specific regulations, which include:

- 7.8.1 Fish and Fishery Products 21 CFR pt. 123.
- 7.8.2 Juice Products 21 CFR pt. 120.
- 7.8.3 Acidified foods 21 CFR Part 114.
- 7.8.4 Low-Acid Canned Foods 21 CFR pt. 113 LACF.
- 7.8.5 Alcoholic Beverages, including farm breweries, farm wineries, farm distilleries and farm cideries - applicable liquor authority license and GMP Regulations 21 CFR pt. 110 (old) cGMP Sub part B 117 (new).
- 7.8.6 USDA 9 CFR - USDA (United States Department of Agriculture), under the right conditions, would inspect a commercial kitchen if separation between official and unofficial establishments can be maintained.
- 7.9 Inspect the ingredients, food processing, food equipment, food assembly, and sanitary conditions of the premises.
- 7.10 Review production records, including cooking temperature records, pH records, thermometer calibration records, pH meter calibration records, product coding, and others.
- 7.11 Review recall traceability method.
- 7.12 Inspect packaging and labeling. The inspector should review all labeling requirements.
  - 7.12.1 The common and/or usual name of the product.
  - 7.12.2 The business name, business phone number, and business website (if any), of the shared kitchen user, along with the city, state, and zip code of the shared kitchen where the product was prepared or packaged.
  - 7.12.3 The net weight of the package.

7.12.4 A list of ingredients in the order of their predominance by weight with ingredients shown by their common or usual name, including all allergens.

7.12.5 A list of any artificial color, artificial flavor or preservative used.

## 8. Food Safety Controls for Consideration

8.1 Kitchen required to be licensed (nonfood processing), accountability.

8.2 Kitchen Owner – maintain operator schedule – maintain operator production records.

8.3 Kitchen required to provide storage (ingredients, finished product, packaging).

8.4 Regulatory agency / incubator kitchen owner should maintain open dialogue (new, inactive or OOB operators).

8.5 Food Safety Training requirement.

8.6 Compliance letters – inspection required.

8.7 License renewal – current inspection required.

8.8 Jurisdictions should maintain relationship and opened dialogue with each other.

8.9 Cross-contamination risk (multiple products).

8.10 Operating times (after normal working hours) – inspector scheduling.

8.11 Inspect during processing operations.

- 8.12 Obtain food processing license and do not return – manufacture at an unknown location.
- 8.13 Alter food processing (add high-risk processing and food items).
- 8.14 Process deviations and documented corrective actions.
- 8.15 Scheduled inspections.
- 8.16 Confirmed ingredient and finished product storage.
- 8.17 Tamper-proof ingredient storage (multiple users / competitors).
- 8.18 Issue incubator-kitchen-specific labels to assure food production at an approved source.

## 9. Evolution of a Shared Kitchen



Description (Above): Workers convene in a shared kitchen in the early 1900's.



Description (Above): Shared kitchen in the 2000's. Stainless steel, futuristic equipment.



Description (Above): Shared kitchen in the 2000's. Stainless steel, futuristic equipment.

## 10. Acknowledgments

Angela Montalbano, New York State Department of Agriculture and Markets

Joseph Corby, Association of Food and Drug Officials (AFDO)

John Luker, New York State Department of Agriculture and Markets

Erin Sawyer, New York State Department of Agriculture and Markets

AFDO Retail Food Committee

## DC Shared Kitchen Visit - 25 July, 2019

The following is a summary of the observations of Chef X production within XXX Kitchen, in D.C. This is meant to serve as a training document with all observations being called out solely for the purpose of awareness and continual improvement:

### ➤ Temperature Logs Incomplete

- **Observation:** No readily available to up-to-date production logs for the preparation of Cooked Carrots and Red Sauce. It was explained by the operators that they take photos on their phones (more on this further down) during production and fill out the log later in the day. At the time of the observation, the Carrots were in the middle of cooling, without a recorded starting cooking temperature -- The cook had failed to take the photo before taking a break.
  - **Recommendation:** Provided the team the Standard Territory Foods cooling log, informed the team on how to utilize it, and was informed that it would immediately be utilized and uploaded to GoCanvas, per the expectation -- *This was observed occurring during the visit.*



### ➤ Team Member Beverages/Medical Devices

- **Observation:** Observed two team member screw-cap bottles on the in-use production table, and one open soda can underneath the table, stored next to cooking equipment. Additionally observed a Blood Pressure Cuff stored on the in-use production table. These are potential contamination risks to food. This was explained to all staff on-site.
  - **Recommendation:** Provide staff with a labeled pan “*Employee Beverages,*” and train them to only store within this pan **at all times**. Failure to abide by this creates potential risks to food, and should not be allowed. Additionally recommend utilizing a cup with a lid/straw. Screw cap bottles, and soda cans both pose a contamination risk to team members handling the bottles if residual saliva runs down the side of the bottle/can. Straws eliminate this risk. Medical

devices/medication/personal items should all be kept in a location away from food production. Union Kitchen provides lockers for this purpose.

### ➤ Staff Habits/Phone Handling

- **Observation:** To eliminate the necessity of filling out the temperature log as needed, staff are taking photos of thermometers in product for reference and recording them on the temperature log at a later time. Observed a team member pull out their personal phone while preparing food, and place it back in their pocket without washing their hands between this action and preparing food.
  - **Recommendation:** All personal items/device use should be minimized to prevent the risk of potential cross-contamination while preparing/handling food items and equipment, as these can harbor a large quantity of bacteria. Team members observed handling their phones should be instructed to perform a proper handwas before returning to work. Further recommend limiting the use of phones to breaks to maximize efficiency of the team.



### ➤ Hierarchy of Food in the Walk-In Cooler

- **Observation:** Observed a case of raw chicken setting atop a box of bagged peas in the WIC on a pallet of product. This is an immediate risk, and a poor storage practice which was relayed for immediate correction. Improper storage promotes the potential for cross-contamination of harmful pathogens that may not always be properly destroyed when following proper cooking procedures.
  - **Recommendation:** Please ensure all foods are stored in accordance to the required [Hierarchy](#); to mitigate the risk of cross-contamination.



➤ **Protection from Contamination - Cooling Racks in the Walk-In Cooler**

- **Observation:** Observed a speed rack of carrots on sheet trays cooling in the WIC stored directly under an AC Unit fan with a caked on dust on the fan-guards.
  - **Recommendation:** Inform Union Kitchen of the condition of these fan guards -- They should be providing you with a safe environment to cook and store food. However; it is your job to ensure the safety of your food, therefore you need to ensure the speed rack of cooling products are adequately covered (loosely when cooling) to mitigate this risk.

## Facility Concerns

The following is a list of items observed in the Union Kitchen facility that are potential vectors for cross-contamination within the operation. These are facility concerns are not directly associated with your production, but should be brought to light to ensure you all are preparing food in a safe facility that is working to maintain safe and sanitary working conditions. **If you need assistance addressing this with the facility, let us know:**



### ➤ Food Contact Surfaces, Unclean - Ice Machine

- **Observation:** Observed a large accumulation of organic growth and biofilm formation within the ice-chute of the communal ice machine that is used during production. This organic accumulation can harbor potentially harmful bacteria that can make individuals very sick.
  - **Recommendation:** This piece of equipment should be visually inspected daily prior to use to ensure there is no organic accumulation or particles that can pose a contamination risk to food (ice is a food.) It should be cleaned by the facility on a frequency adequate enough to prevent this accumulation (typically bi-weekly.)



➤ **Handsink Misuse**

- **Observation:** Observed the runoff line of the water filtration system near the dish room hand sink routed directly into the hand sink basin with an accumulation of pink organic growth in the tube. This is a potential cross-contamination risk.
  - **Recommendation:** All hand sinks should be used solely for the purpose of handwashing -- Any misuse creates an opportunity for harmful pathogens to transfer to the hands of workers and contaminate food. This drain line should be replaced and directed elsewhere (not a hand sink.)



➤ **Improper Storage, Risk for Contamination**

- **Observation:** Observed clean pots and pans stored right-side up at the communal storage shelf. This promotes the potential for dust/debris to fall into the item prior to use, and permit residual water to stay in the item and potentially promote the growth of potentially harmful bacteria.
  - **Recommendation:** When cleaned, these should be properly inverted to prevent this risk, and allow the pans to properly dry out.



➤ **Toxic Substance - DDVP (Dichlorvos) Pest Strips in the Food Service Operation**

- **Observation:** Observed a DDVP pest strip stuck in the drain of the ice machine. These items are [potentially harmful](#) and are clearly labeled to not place them in “Food service operations, or areas where food is prepared and served.” They pose a potential health risk to all individuals exposed to them for >4 hours.
  - **Recommendation:** The facility should remove this item, and focus on cleaning more. DDVP strips are short-term, *lazy* ways to address a problem (typically fruit flies.)

Date	11/4/19	Facility	Marbled L.A.	Purpose of Visit	Preliminary Visit	Grade	
<b>FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS</b>							
Circle designated compliance status (IN, OUT, N/O, N/A) for each numbered item Mark "X" inappropriate box for COS and/or R IN=in compliance OUT=not in compliance N/O=not observed N/A=not applicable COS=corrected on-site during inspection R=repeat violation							
	<b>Status</b>				<b>COS</b>	<b>Repeat</b>	
<b>Demonstration of Knowledge</b>							<b>0</b>
1			Certification By Accredited program, compliance with Code, or correct responses				
<b>Employee Health</b>							<b>0</b>
2			Management Awareness; policy present				
3			Proper Use Of reporting, restriction exclusion				
<b>Good Hygienic Practices</b>							<b>0</b>
4			Proper Eating, tasting, drinking, or tobacco use				
5			No Discharge From Eyes, nose, and mouth				
<b>Preventing Contamination by Hands</b>							<b>0</b>
6			Hands Clean properly washed				
7			No Bare hand contact with RTE foods or approved alternate method properly followed				
8			Adequate Handwashing Facilities supplied accessible				
<b>Approved Source</b>							<b>0</b>
9			Food Obtained From Approved Source				
10			Food received at proper temperature				
11			Food In good condition, safe, unadulterated				
12			Required Records Available:shellstock tags, parasite destruction				
<b>Protection from Contamination</b>							<b>10</b>
13			Food separated & protected				
14	Out	Pf	Food-contact surfaces: cleaned & sanitized				5
15	Out	Pf	Proper Disposition Of returned, previously served, reconditioned, unsafe food				5
<b>Potentially Hazardous Food Time/Temperature</b>							<b>5</b>
16			Proper cooking time & temperatures				
17			Proper reheating procedures for hot holding				
18			Proper cooling time & temperatures				
19			Proper Hot holding temperatures				
20			Proper cold holding temperatures				
21	Out	Pf	Proper Date Marking disposition				5
22			Time as Public health control: procedures record				
<b>Consumer Advisory</b>							<b>0</b>
23			Consumer advisory provided for raw or undercooked foods				
<b>Highly Susceptible Populations</b>							<b>0</b>
24			Pasteurized foods used; prohibited foods not offered				
<b>Chemical</b>							<b>5</b>
25			Food Additives: approved properly used				
26	Out	Pf	Toxic Substances Properly identified, stored, & used				5
<b>Conformance with Approved Procedures</b>							<b>0</b>
27			Compliance with variance, specialized process, & HACCP plan				
Risk Factors Are improper practices or procedures identified as the most prevalent contributing factors of foodborne illness or injury.Public Health Interventions control measures to prevent foodborne illness or injury.							
<b>GOOD RETAIL PRACTICES</b>							
GoodRetailPracticesare preventative measures to control the addition of pathogens, chemicals, and physical objects into foods. Mark "X" in box if numbered item is not in compliance Mark "X" inappropriate box for COS and/or R COS=corrected on-site during inspection R=repeat violation							
	<b>Status</b>				<b>COS</b>	<b>Repeat</b>	
<b>Safe Food and Water</b>							<b>0</b>
28			Pasteurized Eggs used where required				



			<b>Recommendation</b>	Please ensure team members are diligent in their cleaning of their workstations and equipment. Recommend requiring visual inspection of workstations before workers are cut.
15	6-404.11	Pf	<b>Dented Cans</b>	
			<b>Observation</b>	Observed a collection of dented cans stored with the wholesome cans in the dry goods storage rack. Per Food Code: "Products that are held by the PERMIT HOLDER for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES."
			<b>Recommendation</b>	Please ensure your receiving staff are diligent in observing potentially compromised goods and isolating them in a clearly labeled storage area to prevent accidental use.
21	3-501.17	Pf	<b>Date-Marking, Expired Product</b>	
			<b>Observation</b>	Observed a container of hard boiled eggs and overnight oats in the Walk-In Cooler with an expiration date of 10/24 and 10/21 respectively. (A) Except when PACKAGING FOOD using a REDUCED OXYGEN PACKAGING method as specified under § 3-502.12, and except as specified in ¶¶ (E) and (F) of this section, refrigerated, READY-TO-EAT, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD prepared and held in a FOOD ESTABLISHMENT for more than 24 hours shall be clearly marked to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded when held at a temperature of 5°C (41°F) or less for a maximum of 7 days. The day of preparation shall be counted as Day 1.
			<b>Recommendation</b>	Please ensure team members are periodically inspecting the date marks of products within the facility and discarding product as needed. Also ensure team members are properly trained to follow FIFO and place things in specific locations in the Walk-In to avoid missing product that can be used.
26	7-202.12	Pf	<b>Pesticides Stored in Facility</b>	
			<b>Observation</b>	Observed a large collection of pesticides stored on the kitchen's chemical storage shelf; these are stored here from the building's owner. Per the Food Code: "POISONOUS OR TOXIC MATERIALS shall be: (A) Used according to: (1) LAW and this Code, (2) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a FOOD ESTABLISHMENT, P (3) The conditions of certification, if certification is required, for use of the pest control materials, P and (4) Additional conditions that may be established by the REGULATORY AUTHORITY;
			<b>Recommendation</b>	Inform the building owner that these chemicals are not permitted in the kitchen and ask to have them removed. Also ensure the building owner is paying for professional pest treatments; if they are treating for pests themselves, they are in violation.
45	4-202.16	C	<b>Sink Disrepair</b>	
			<b>Observation</b>	Observed the three compartment sink of the facility with a blocked leg, being propped up on wood. Additionally observed the basin of the left sink splitting and separating from the frame, forming a gap that is collecting bio-film and debris. Per the Food Code: "NonFOOD-CONTACT SURFACES shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.
			<b>Recommendation</b>	Request the building owner service the sink, sealing up this gap and providing a proper leg replacement that isn't using a wooden block to support the weight of the sink.
47	1-601.11	Pf	<b>Non-Food Contact Surface Cleanliness</b>	
			<b>Observation</b>	Observed a large accumulation of organic matter dripping down the front of the three-compartment sink. This accumulation is a harborage site for potentially harmful bacteria and also serves as a pest attractant. Per the Food Code: "(C) NonFOOD-CONTACT SURFACES of EQUIPMENT shall be kept free of an accumulation of dust, dirt, FOOD residue, and other debris.."
			<b>Recommendation</b>	Please ensure team members are diligent about cleaning all food/nonfood contact surfaces throughout their daily duties to prevent the accumulation of this buildup.
53	5-501.113	C	<b>Storing Maintenance Tools</b>	
			<b>Observation</b>	Observed a collection of brooms/dustpans stored by a slop sink in a disorganized manner that helps to form a potential harborage site for small pests. The recommendation from the Food Code states: "Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be: (A) Stored so they do not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES; and (B) Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools
			<b>Recommendation</b>	Recommend providing broom hangers to elevate these tools off of the floor in an organized manner to mitigate this risk.
53	6-202.15	C	<b>Outer Openings Protected</b>	

			<b>Observation</b>	<p>Observed the two doors leading to the exterior of the building with large gaps in them leading to the outside. The Food Code states: "(A) Except as specified in ¶¶ (B), (C), and (E) and under ¶ (D) of this section, outer openings of a FOOD ESTABLISHMENT shall be protected against the entry of insects and rodents by:</p> <p>(1) Filling or closing holes and other gaps along floors, walls, and ceilings;</p> <p>(2) Closed, tight-fitting windows; and</p> <p>(3) Solid, self-closing, tight-fitting doors.</p> <p>(B) Paragraph (A) of this section does not apply if a FOOD ESTABLISHMENT opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.</p> <p>(C) Exterior doors used as exits need not be self-closing if they are:</p> <p>(1) Solid and tight-fitting;</p> <p>(2) Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the FOOD ESTABLISHMENT; and</p> <p>(3) Limited-use so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.</p> <p>(D) Except as specified in ¶¶ (B) and (E) of this section, if the windows or doors of a FOOD ESTABLISHMENT, or of a larger structure within which a FOOD ESTABLISHMENT is located, are kept open for ventilation or other purposes or a TEMPORARY FOOD ESTABLISHMENT is not provided with windows and doors as specified under ¶ (A) of this section, the openings shall be protected against the entry of insects and rodents by:</p> <p>(1) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen</p> <p>(2) Properly designed and installed air curtains to control flying insects; or</p> <p>(3) Other effective means.</p> <p>(E) Paragraph (D) of this section does not apply if flying insects and other pests are absent due to the location of the ESTABLISHMENT, the weather, or other limiting condition.</p>
			<b>Recommendation</b>	Please ensure these doors are properly sealed with door sweeps and weatherstripping as necessary.
53	6-501.112	C	<b>Exterior Premises Cleanliness</b>	
			<b>Observation</b>	Observed an old Fly Trap affixed to the office adjacent to the kitchen entrance full of old decaying flies. These old traps only serve to attract further pests and should be discarded. Per the Food Code: "Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the PREMISES at a frequency that prevents their accumulation, decomposition, or the attraction of pests."
			<b>Recommendation</b>	Ensure the exterior of the facility is given as much attention as the interior when cleaning, as exterior attractants will serve to bring pests into the interior of the facility.
53	6-201.11	C	<b>Floor Cleanability</b>	
			<b>Observation</b>	Observed the interior floor of the kitchen to be unfinished concrete, which collects food debris and has a sheen of oil on it. "Per the Food Code: "Except as specified under § 6-201.14 and except for antislip floor coverings or applications that may be used for safety reasons, floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are SMOOTH and EASILY CLEANABLE."
			<b>Recommendation</b>	In lieu of applying a smooth coating of a floor sealer; this floor should be appropriately scrubbed as necessary to maintain it clean.
53	6-501.12	C	<b>Ceiling Cleanliness</b>	
			<b>Observation</b>	Observed portions of the ceiling above the food storage/preparation areas with an accumulation of dust and oil buildup. This serves as a potential attractant for pests and contamination for food. Per the Food Code: "(A) PHYSICAL FACILITIES shall be cleaned as often as necessary to keep them clean. (B) Except for cleaning that is necessary due to a spill or other accident, cleaning shall be done during periods when the least amount of FOOD is exposed such as after closing."
			<b>Recommendation</b>	Perform routine cleaning of the ceiling as necessary to maintain the surface clean.
54	6-303.11	C	<b>Lighting</b>	
			<b>Observation</b>	<p>Observed one of the light ballasts in front of the walk-in cooler burned out; creating an area of poor illumination. These areas are potential harborage sites for pests. Food Code requirements for illumination state: "Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up. Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.</p> <p>(C) At least 540 lux (50 foot candles) at a surface where a FOOD EMPLOYEE is working with FOOD or working with UTENSILS or EQUIPMENT such as knives, slicers, grinders, or saws where EMPLOYEE safety is a factor.</p>
			<b>Recommendation</b>	Ensure the facility owner is diligent about replacing burned out bulbs as necessary.
54	6-202.11	C	<b>Light Bulbs, Protective Shielding</b>	

			<p><b>Observation</b></p> <p>Observed the bulbs through out the facility sporadically shielded. Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter-resistant are necessary to protect exposed food, clean equipment, utensils and linens, and unwrapped single-service and single-use articles from glass fragments should the bulb break. The Food Code states: "(A) Except as specified in ¶ (B) of this section, light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; or unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES."</p>
			<p><b>Recommendation</b></p> <p>Ensure the facility owner is properly shielding the lights installed within the facility.</p>

Date	11/5/19	Facility	Spotted Hen	Purpose of Visit	Preliminary
<b>FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS</b>					
Circle designated compliance status (IN, OUT, N/O, N/A) for each numbered item Mark "X" in appropriate box for COS and/or R IN=in compliance OUT=not in compliance N/O=not observed N/A=not applicable COS=corrected on-site during inspection R=repeat violation					
	<b>Status</b>				<b>COS</b>
<b>Demonstration of Knowledge</b>					
1			Certification By Accredited program, compliance with Code, or correct responses		
<b>Employee Health</b>					
2			Management Awareness; policy present		
3			Proper Use Of reporting, restriction exclusion		
<b>Good Hygienic Practices</b>					
4	Out	C	Proper Eating, tasting, drinking, or tobacco use		
5			No Discharge From Eyes, nose, and mouth		
<b>Preventing Contamination by Hands</b>					
6	Out	P	Hands Clean properly washed		
7			No Bare hand contact with RTE foods or approved alternate method properly followed		
8			Adequate Handwashing Facilities supplied accessible		
<b>Approved Source</b>					
9			Food Obtained From Approved Source		
10			Food received at proper temperature		
11			Food In good condition, safe, unadulterated		
12			Required Records Available: shellstock tags, parasite destruction		
<b>Protection from Contamination</b>					
13			Food separated & protected		
14	Out	Pf	Food-contact surfaces: cleaned & sanitized		
15			Proper Disposition Of returned, previously served, reconditioned, unsafe food		
<b>Potentially Hazardous Food Time/Temperature</b>					
16			Proper cooking time & temperatures		
17			Proper reheating procedures for hot holding		
18	Out	P	Proper cooling time & temperatures		
19			Proper Hot holding temperatures		
20			Proper cold holding temperatures		
21			Proper Date Marking disposition		
22			Time as Public health control: procedures record		
<b>Consumer Advisory</b>					
23			Consumer advisory provided for raw or undercooked foods		
<b>Highly Susceptible Populations</b>					
24			Pasteurized foods used; prohibited foods not offered		
<b>Chemical</b>					
25			Food Additives: approved properly used		
26			Toxic Substances Properly identified, stored, & used		
<b>Conformance with Approved Procedures</b>					
27			Compliance with variance, specialized process, & HACCP plan		

Risk Factors Are improper practices or procedures identified as the most prevalent contributing factors of foodborne illness or injury. Public Health Intervention:

Inspection	Grade
<b>Repeat</b>	
	0
	0
	3
	3
	11
	11
	0
	5
	5
	11
	11
	0
	0
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	0

s control measures to prevent

foodborne illness or injury.

**GOOD RETAIL PRACTICES**

GoodRetailPracticesare preventative measures to control the addition of pathogens, chemicals, and physical objects into foods.  
 Mark "X" in box if numbered item is not in compliance Mark "X" in appropriate box for COS and/or RCOS=corrected on-site during inspection R=repeat violation

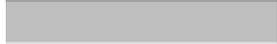
Status							COS
<b>Safe Food and Water</b>							
28				Pasteurized Eggs used where required			
29				Water & ice from approved source			
30				Variance Obtained For specialized processing methods			
<b>Food Temperature Control</b>							
31				Proper cooling methods used; adequate equipment for temperature control			
32				Plant food properly cooked for hot holding			
33				Approved thawing methods used			
34				Thermometers Provided Accurate			
<b>Food Identification</b>							
35				Food Properly labeled; original container			
<b>Prevention of Food Contamination</b>							
36	X	C		Insects, rodents, animals not present;no unauthorized persons			
37	X	C		Contamination prevented during food preparation, storage display			
38				Personal Cleanliness			
39	X	C		Wiping cloths:properly used stored			
40	X	C		Washing fruits & vegetables			
<b>Proper Use of Utensils</b>							
41				In-use utensils: properly stored			
42	X	C		Utensils, equipment linens: properly stored, dried, handled			
43				Single-use single-service articles: properly stored used			
44				Gloves Used properly			
<b>Utensils, Equipment and Vending</b>							
45				Food & non-food contact surfaces cleanable, properly designed, constructed, & used			
46				Warewashing Facilities: installed, maintained, & used; teststrips			
47				Non-food contact surfaces clean			
<b>Physical Facilities</b>							
48				Hot & cold water available; adequate pressure			
49	X	Pf		Plumbing Installed; proper backflow devices			
50				Sewage & waste water properly disposed			
51				Toilet facilities:properly constructed, supplied, & cleaned			
52				Garbage & refuse properly disposed;facilities maintained			
53				Physical facilities installed, maintained, & clean			
54	X	C		Adequate ventilation & lighting; designated areas used			
<b>TEMPERATURE OBSERVATIONS</b>							
Item	Location		Temp	Item	Loca		
Chicken Gumbo	Plating Assembly Line		67 °F				
Cauliflower Rice	Plating Assembly Line		54 °F				
Chicken Gumbo	Walk-in Cooler		66 °F				

n	
<b>Repeat</b>	
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<b>tion</b>	<b>Temp</b>

Cauliflower Rice	Walk-in Cooler	50 °F		

**OBSERVATIONS AND CORRECTIVE ACTIONS**

Item #	Code #	Severity	Violations cited in this report must be corrected within the timeframe below, or as stated in sections	
4	2-401.11	C	<b>Storage of Employee Food</b>	
			<b>Observation</b>	<p>Observed team members preparing meals while drinking out of open top conta prep surfaces. These improper storage areas and methods promote potential r. Per the Food Code: "(A) Except as specified in ¶ (B) of this section, an EMPLC eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES; or other items needing protection can not result.</p> <p>(B) A FOOD EMPLOYEE may drink from a closed BEVERAGE container if the container is handled to prevent contamination of:</p> <p>(1) The EMPLOYEE'S hands;</p> <p>(2) The container; and</p> <p>(3) Exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.</p>
			<b>Recommendation</b>	<p>Ensure team members are utilizing approved beverage containers, and storing Creating a designated area in the facility with a hotel pan labled "Employee Be mitigate them being placed in random places in the facility.</p>
6	2-301.14	P	<b>Improper Handwashing</b>	
			<b>Observation</b>	<p>Observed a team member actively plating meals with gloved hands take a sip 1 before attempting to continue plating. When questioned as to what to do when the team member discarded his gloves, and donned a new pair. No handwash Food Code: "FOOD EMPLOYEEES shall clean their hands and exposed portion their arms as specified under § 2-301.12 immediately before engaging in FOOD preparation including working with exposed FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLESP and:</p> <p>(A) After touching bare human body parts other than clean hands and clean, exposed portions of arms; P</p> <p>(B) After using the toilet room; P</p> <p>(C) After caring for or handling SERVICE ANIMALS or aquatic animals as specified in ¶ 2-403.11(B); P</p> <p>(D) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking; P</p> <p>(E) After handling soiled EQUIPMENT or UTENSILS; P</p> <p>(F) During FOOD preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks; P</p> <p>(G) When switching between working with raw FOOD and working with READY-TO-EAT FOOD; P</p> <p>(H) Before donning gloves to initiate a task that involves working with FOOD; P and</p> <p>(I) After engaging in other activities that contaminate the hands.P"</p>
			<b>Recommendation</b>	<p>Ensure team members are properly trained on what behaviors and processes t ensure the manager on duty is actively monitoring staff for compliance. Failure method of contamination of food.</p>
14	4-303.11	C	<b>Sanitizer Availability</b>	
			<b>Observation</b>	<p>Observed no readily available sanitizer in the facility, or designated sanitizer bu the Manager on Duty said that they were out, but more would be arriving the fo sanitize work surfaces is a serious means of transmitting potentially harmful pa never occur -- Always keep Sanitizer on hand. Per the Food Code: "(A) Cleanii clean EQUIPMENT and UTENSILS as specified under Part 4-6, shall be provic during all hours of operation.</p> <p>(B) Except for those that are generated on-site at the time of use, chemical SANITIZERS that are used to sanitize EQUIPMENT and UTENSILS as specified under Part 4-7, shall be provided and available for use during all hours of operation.</p>

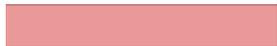



8-405.11 of the food code.



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ng agents that are used to  
ted and available for use*

			<b>Recommendation</b>	<i>The Manager on Duty should ensure all team members are appropriately setting properly concentrated sanitizer and changing it as recommended per the manu</i>
14	4-601.11	Pf	<b>Food Contact Surface Cleanliness</b>	
			<b>Observation</b>	<i>Observed the interior of the ice machine supplying Food-Grade ice in poor con discoloration and pink organic accumulation. Per the Food Code: "(A) EQUIPM SURFACES and UTENSILS shall be clean to sight and touch."</i>
			<b>Recommendation</b>	<i>Please ensure the ice machine is routinely inspected and cleaned on a schedu cleanliness. Falure to do so creattes opportunities for the growth of potentially l</i>
18	3-501.14	P	<b>Improper Cooling</b>	
			<b>Observation</b>	<i>Observed team members playing Chicken Gumbo and Cauliflower Rice at 67° food was prepared at 2100 the night prior, and plating was observed at 0430 in Code: "(A) Cooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD sh cooled: (1) Within 2 hours from 57°C (135°F) to 21°C (70°F); P and (2) Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less. P (B) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled within 4 hours to 5oC (41oF) or less if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna. P (C) Except as specified under ¶ (D) of this section, a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD received in compliance with LAWS allowing a temperature above 5oC (41oF) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5oC (41oF) or less. P"</i>
			<b>Recommendation</b>	<i>Please ensure team members are properly trained on correct cooling techniqu is actively participating in the process by vaillidating the work done by the team. required thresholds must include corrective actions to show safe handling of th</i>
36	6-501.112	C	<b>Pest Activity</b>	
			<b>Observation</b>	<i>Observed a German Cockroach carcass stuck to the wall of the dry storage are Food Code: "Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the PREMISES at a frequency that prevents decomposition, or the attraction of pests."</i>
			<b>Recommendation</b>	<i>Ensure the PCO servicing the facility is diligent in changing their traps; addition are throughly sweeping these areas to remove any old/dessicated carcasses.</i>
37	3-305.11	C	<b>Food Stored on Floor</b>	
			<b>Observation</b>	<i>Observed a cambro container of raw red potatoes, uncovered, stored on the flc be protected from contamination by storing the FOOD: (1) In a clean, dry location; (2) Where it is not exposed to splash, dust, or other contamination; and (3) At least 15 cm (6 inches) above the floor. (B) FOOD in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot handling EQUIPMENT as specified under § 4-204.122."</i>
			<b>Recommendation</b>	<i>Ensure team members are storing food in designated safe areas, this should b Duty.</i>
39	4-802.11	C	<b>Wet Wiping Cloth Storage</b>	

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manufacturer's specification.

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harmful bacteria.

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e verified by the Manager on

			<b>Observation</b>	<p>Observed team members carrying around several visibly soiled rags, using the oven mitts, and wiping tables. These count as a wet-wiping cloth and should be the Food Code: "(A) Cloths in-use for wiping FOOD spills from TABLEWARE as occur as FOOD is being served shall be:</p> <p>(1) Maintained dry; and  (2) Used for no other purpose.</p> <p>(B) Cloths in-use for wiping counters and other EQUIPMENT surfaces shall be:</p> <p>(1) Held between uses in a chemical sanitizer solution at a concentration specified under § 4-501.114; and  (2) Laundered daily as specified under ¶ 4-802.11(D).</p> <p>(C) Cloths in-use for wiping surfaces in contact with raw animal FOODS shall be kept separate from cloths used for other purposes.  (D) Dry wiping cloths and the chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be free of FOOD debris and visible soil.  (E) Containers of chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, SINGLE-SERVICE, or SINGLE-USE ARTICLES.</p>
			<b>Recommendation</b>	Ensure team members are away of the requirements for wet-wiping cloth storage provided buckets of sanitizer to store them in.
40	3-302.15	C	<b>Produce Washing</b>	
			<b>Observation</b>	<p>Observed team members take pineapples directly from a produce box, and begin slicing them into pieces, no attempt to wash the produce was made. This is a risk as pathogens on the exterior of the produce can be introduced into the food. The Food Code states: "Except as specified in ¶ (B) of this section and except for whole, raw fruits and vegetables for washing by the CONSUMER before consumption, raw fruits and vegetables shall be washed in water to remove soil and other contaminants before being cut, combined with other ingredients, or served, or offered for human consumption in READY-TO-EAT form."</p>
			<b>Recommendation</b>	Ensure all produce being brought into the facility is appropriately rinsed in a clean sink prior to preparation. This can be done prior to production to ensure all received produce is safe for use.
42	3-304.12	C	<b>Improper Storage of Utensils</b>	
			<b>Observation</b>	<p>Observed a knife steel stored on the power line feeding the power outlet over the counter. This is a risk as this surface is not clean and may contaminate the tool. Per the Food Code in FOOD preparation or dispensing, FOOD preparation and dispensing UTENSILS shall be stored:</p> <p>(A) Except as specified under ¶ (B) of this section, in the FOOD preparation area with their handles above the top of the FOOD and the container;  (B) In FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD with their handles above the top of the FOOD within containers or EQUIPMENT that can be closed, such as bins of sugar, flour, or cinnamon;  (C) On a clean portion of the FOOD preparation table or cooking EQUIPMENT only if the in-use UTENSIL and the FOOD-CONTACT SURFACE of the FOOD preparation table or cooking EQUIPMENT are cleaned and SANITIZED at a frequency specified under §§ 4-602.11 and 4-702.11;  (D) In running water of sufficient velocity to flush particulates to the drain, if used with moist FOOD such as ice cream or mashed potatoes;  (E) In a clean, protected location if the UTENSILS, such as ice scoops, are used only with a FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD; or</p>
			<b>Recommendation</b>	Ensure tools and utensils not currently in use are stored away clean and sanitized to prevent contamination.
49	5-205.11	Pf	<b>Handsink Disrepair</b>	
			<b>Observation</b>	Observed the handsink by the prep station taped-off due to it not working. Per the Food Code: "HANDWASHING SINK shall be maintained so that it is accessible at all times for use."
			<b>Recommendation</b>	If ever a handsink is broken, it should be reported to the Manager on Duty for immediate repair. To promote proper handwashing is a significant risk to food safety as pathogens can be transferred to hands.
54	6-303.11	C	<b>Lighting</b>	

m for wiping their hands,  
e stored in accordance with  
nd carryout containers that

ge and ensure they are

gin processing them by  
isk to food as harmful  
Food Code states: "(A)  
vegetables that are intended  
s shall be thoroughly washed  
h other ingredients, cooked,

an and sanitized prep sink  
! goods are clean prior to

op of the production area.  
Food Code: "During pauses  
ILS shall be stored:

ed in a designated area to

the Food Code: "(A) A  
or EMPLOYEE use."

mmediate correction; failure  
s can be present on unclean

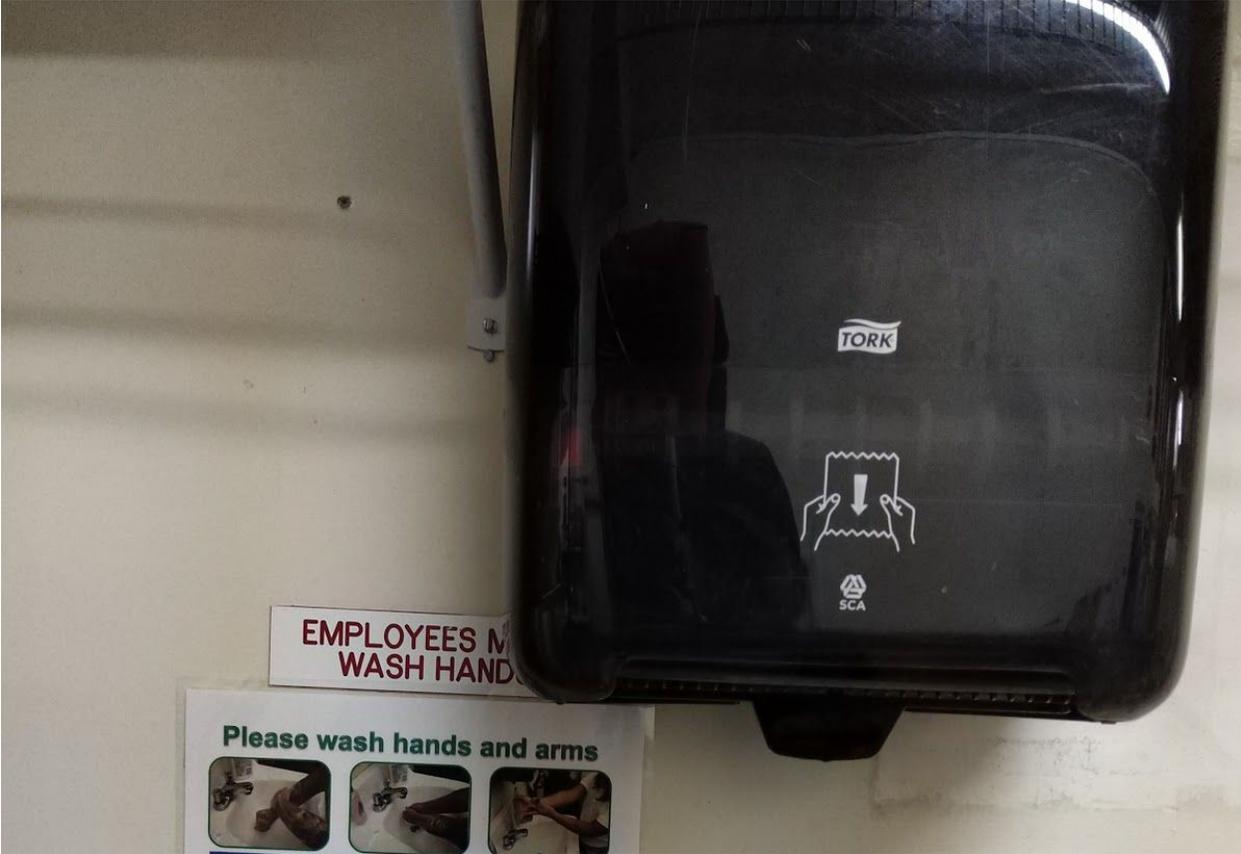
			<p>Observation</p> <p>Observed one of the light ballasts in front of the walk-in cooler burned out; creating inadequate illumination. These areas are potential harborage sites for pests. Food Code requires adequate lighting levels. Food Code states: "Lighting levels are specified so that sufficient light is available to enable certain functions such as reading labels; discerning the color of substances; identifying the condition of food, utensils, and supplies; and safely conducting operations and clean-up. Properly distributed light makes the need for cleaning and sanitizing accumulations of soil conspicuous.</p> <p>(C) At least 540 lux (50 foot candles) at a surface where a FOOD EMPLOYEE is working with FOOD or working with UTENSILS or EQUIPMENT such as knives, slicers, grinders, or saws where EMPLOYEE safety is a factor.</p>
			<p>Recommendation</p> <p>Ensure the facility owner is diligent about replacing burned out bulbs as necessary.</p>

*ting an area of poor  
requirements for illumination  
employees to perform  
identifying toxic materials;  
general food establishment  
apparent by making*

*sary.*

**Shared Kitchen Visit - 30 August, 2019**

The following is a summary of the observations of XXXX production within their facility. This is meant to serve as a training document with all observations being called out solely for the purpose of awareness and continual improvement:





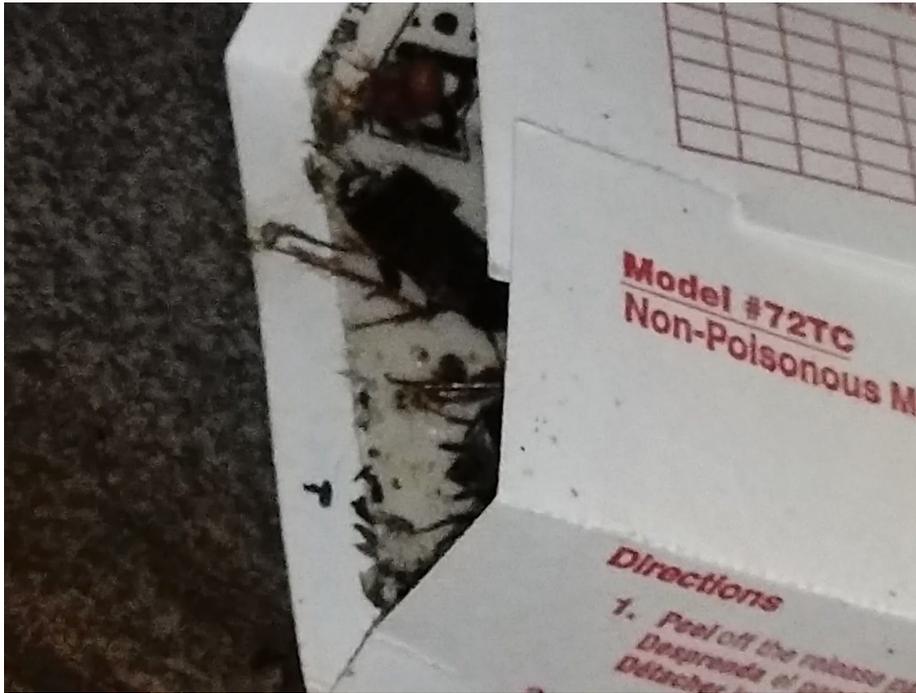
➤ **Handwashing Sinks Not Stocked**

- **Observation:** Observed the hand sink paper towel dispensers in the vicinity of the production space empty. The closest paper towel dispenser that was stocked was across the kitchen, in a back production room. Failure to provide adequate hand drying provisions will cause staff members to wash their hands less, promoting the potential for cross-contamination or unsafe food handling practices.
  - **Recommendation:** Discuss with the plan to keep the paper towels stocked with the site operator and ensure these are filled as needed to promote proper handwashing.



➤ **Non-Food Contact Surfaces/Floors & Walls**

- **Observation:** Observed the floor and walls behind the production room oven/smoker coated in a thick layer of visible dust and food debris. These unclean areas are potential harborage and attractant sites for small pests and should be kept clean to mitigate this.
  - **Recommendation:** Review the cleaning schedule with the team/facility and ensure adequate attention is given to the space to promote proper cleaning.



➤ **Pest Activity**

- **Observation:** Observed a glue board trap stored underneath castoff equipment in the dish room with an accumulation of caught American Cockroach carcasses. This castoff equipment and dim lighting (two of the ballasts are burned out,) promotes harborage sites for small pests.
  - **Recommendation:** Work with the facility to ensure their minimizing the amount of unused equipment just sitting around in the facility. Additionally ensure the Pest Control Operator aware of the activity and is coming frequently enough to mitigate the presence.



➤ **Food Contact Surfaces / Can Openers**

- **Observation:** Observed the industrial can opener in-use by the facility in poor condition, with accumulated food debris caught on the blade that could harbor potential pathogens and contaminate food when used.

- **Recommendation:** Replace the can openers as condition warrants, and train team members on the proper cleaning procedures to ensure this level of buildup and disrepair does not form on the equipment.



➤ **Chemical Labeling / Identification**

- **Observation:** Observed two sanitizer spray bottles in the dish room, one was labeled “Sanitizer,” the other was unlabeled but filled with a overly-strong concentration of Steramine. Additionally observed no sanitizer buckets setup for team members in the kitchen preparing food. Improperly mixed sanitizer poses a contamination risk to food as too-little makes for improper cleaning, and too-much is unsafe as it sits on the surface it was applied to.
  - **Recommendation:** Ensure team members are able to properly setup their stations and mix the sanitizer solutions. Team members should always ensure as apart of their initial setup to make and test sanitizer buckets for appropriate concentration before production starts. All chemical spray bottles should be properly labeled and only ever filled with what went into that bottle *first* to prevent the potential for mixing chemicals or misuse.



➤ **Deterioration**

- **Observation:** Observed two parts of the wall in the kitchen that have either been water-damaged or damaged. These areas create attractants and harborage sites for small pests and should be addressed to mitigate these risks.
  - **Recommendation:** Please discuss with the facility management a solution to have these areas fixed. Failure to do so puts the production area at an increased risk for pest activity.

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-021**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Use of Personal Containers for non-TCS Bulk Foods

**Issue you would like the Conference to consider:**

Allow the use of personal containers to fill non-TCS bulk foods.

**Public Health Significance:**

In our current environment, recycling is becoming more popular and the reduction of waste is on the rise. Because the use of bulk foods in grocery store settings are also on the rise, the reduction of plastic waste is important. Most environmentally conscience individuals now shop with reusable bags and would like the option to do the same when buying non-TCS bulk foods.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

That a letter be sent to the FDA requesting that Section 3-304.17 of the most current edition of the Food Code be amended as follows:

(F) Consumer-owned containers may be filled with non-TCS bulk foods.

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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-022**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code to Harmonize the Definition Reusable Container

**Issue you would like the Conference to consider:**

The language in Food Code 2017 does not provide adequate guidance on allowed practices surrounding several emerging reuse scenarios in food retail. These include but are not limited to the use of customer owned containers in restaurants, markets, temporary food facilities and closed loop schemes.

Of specific concern is the interchangeable use of undefined terms: returnable, reusable, and take-home- in reference to refillable containers in section 3-304.17. The opacity of these terms obscures the intended scope of regulated scenarios.

**Public Health Significance:**

As the "conscious consumption" movement grows, consumers increasingly demand sustainable ways to process, store, and procure food. Food handling regulations must accommodate these new ways to reduce waste and excess packaging. Reducing uncertainty in the language of the regulation encourages food handling practices that are both safe and sensitive to these emerging values and preferences.

What's more, updates to the Food Code will have strong downstream benefits for state and regional regulatory agencies who rely on federal synthesis of pertinent issues in the retail and food service landscape. Significant time and resources can be saved by agencies and industry alike with the adoption of guidance that is clear and uniformly enforceable. Consensus on comprehensive reusable standards by the Conference is critical for progress, and with a four year interval between Food Code updates, the time to address these scenarios is now.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting that the most current edition of the Food Code be amended to update the title of section 3-304.17 from "Refilling Returnables" to "Filling

Reusable Containers" and further include a definition of a "Reusable Container" in section 1-2 Definitions.

New language should be based on the following, proposed definition:

Reusable Container means 1) a vessel under the ownership or care of the CONSUMER, which is intended for filling with FOOD or BEVERAGE at the FOOD ESTABLISHMENT. 2) is designed and constructed for reuse in accordance with the requirements specified under Parts 4-1 and 4-2.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-023**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code to Address New Reusable Scenarios in Food Retail

**Issue you would like the Conference to consider:**

The language in Food Code 2017 does not provide adequate guidance on allowed practices surrounding several emerging reuse scenarios in food retail. These include but are not limited to the use of customer-owned containers in restaurants, markets, temporary food facilities and closed loop schemes.

The mixed terms used in the current Code, specifically section 3-304.17, are undefined and therefore the scenarios intended for regulation are ambiguous. This ambiguity, in conjunction with an exception as opposed to rule-based orientation makes for guidance that resists complete understanding by either agency or industry audiences.

**Public Health Significance:**

As the "conscious consumption" movement grows, consumers increasingly demand sustainable ways to process, store, and procure food. Food handling regulations must accommodate these new ways to reduce waste and excess packaging. Reducing uncertainty in the language of the regulation encourages food handling practices that are both safe and sensitive to these emerging values.

What's more, updates to the Food Code will have strong downstream benefits for state and regional regulatory agencies who rely on federal synthesis of pertinent issues in the retail and food service landscape. Significant time and resources can be saved by agencies and industry alike with the adoption of guidance that is clear and uniformly enforceable. Consensus on comprehensive reusable standards by the Conference is critical for progress, and with a four year interval between Food Code updates, the time to address these scenarios is now.

**Recommended Solution: The Conference recommends...:**

that section 3-304.17 proactively address a wider range of scenarios by clarifying safety standards surrounding the use of reusable containers, including but not limited to:

1. Replacement of conflicting or ambiguous terms: Taking inspiration from recent CA legislation (see "Assembly Bill No 619 in Supporting Attachments), define reusable containers as those either provided by or returned to the food facility.
2. Better identify the scenarios being regulated: Stipulate that for ready-to-consume TCS foods, reusable containers must be designed and constructed for reuse per Section 3-304.17(B)(1) of the Code. Remove the arbitrary distinction between food and beverage handling scenarios, with the exception of water vending.

The Conference further recommends a letter be sent to the FDA requesting that the most current edition of the Food Code be amended to replace section 3-304.17 with new language below. Explanatory notes are found in the attached content document entitled "Refilling Reusables Language".

### 3-304.17 Refilling Returnables Refilling Reusable Containers

~~(A) Except as specified in ¶¶ (B)–(E) 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.~~

(A) A reusable container is designed and constructed for reuse in accordance with the requirements specified under Part 4-1 and 4-2.

~~(B) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with FOOD if the FOOD container is:~~

(B) Only reusable containers returned to a food establishment may be refilled with ready-to-eat or TCS foods either by a food employee or the consumer, except as specified in ¶¶ (1)-(2) of this section.

~~(1) Designed and constructed for reuse and in accordance with the requirements specified under Part 4-1 and 4-2;~~

(1) A consumer-owned container not specifically designed for reuse may be refilled by the same consumer with a non-TCS food or beverage in a contamination-free transfer process.

~~(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;~~

(2) Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.

~~(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 of this Code;~~

~~(b) Sanitized as specified under Part 4-7 of this Code; P and~~

~~(c) Visually inspected by a FOOD EMPLOYEE to verify that the container, as returned, meets the requirements specified under Part 4-1 and 4-2. P~~

~~(C) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT 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 if the BEVERAGE system includes a contamination-free transfer process as specified under §§ 4-204.13(A), (B), and (D) that cannot be bypassed by the container owner.~~

(C) Establishment-owned, managed, or provided reusable containers returned to a food establishment for refilling with food shall be cleaned as specified under Part 4-6 and sanitized as specified under Part 4-7 of this Code prior to refilling.

~~(D) Consumer-owned, personal take-out BEVERAGE containers, such as thermally-insulated bottles, nonspill 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).~~

(D) Reusable containers returned to a food establishment for refilling by a food employee or the consumer must be refilled in a contamination-free transfer process such that:

(1) Any consumer-owned container is isolated from food-serving surfaces or such surfaces are sanitized by an employee after each filling.

(2) The food establishment shall prepare, maintain and adhere to written procedures to prevent cross-contamination which additionally address waste water disposal. The food establishment shall make the written procedures available to the enforcement agency upon request.

~~(E) CONSUMER-owned containers that are not FOOD-specific may be filled at a water-VENDING MACHINE or system.~~

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### **Content Documents:**

- "Refilling Reusables Language"
- "Refilling Reusables Proposed Requirements"

**Supporting Attachments:**

- "Assembly Bill No. 619"

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### 3-304.17 Refilling Reusable Containers

(A) A reusable container is designed and constructed for reuse in accordance with the requirements specified under Part 4-1 and 4-2.

Define acceptable reusable container under scope of the code.

(B) Only reusable containers returned to a food establishment may be refilled with ready-to-eat or TCS foods either by a food employee or the consumer, except as specified in ¶¶ (1)-(2) of this section.

(1) A consumer-owned container not specifically designed for reuse may be refilled by the same consumer with a non-TCS food or beverage in a contamination-free transfer process.

This allows items like shelled nuts, bread, or produce to be placed in a cloth bag or similar by the consumer. These items are considered ready-to-eat foods, but should not be subjected to container restrictions or mandatory sanitization per consumer.

(2) Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.

As in the 2017 code, water vending is accepted from additional restrictions. The equivalent clause is simply moved for readability.

(C) Establishment-owned, managed, or provided reusable containers returned to a food establishment for refilling with food shall be cleaned as specified under Part 4-6 and sanitized as specified under Part 4-7 of this Code prior to refilling.

Encompasses clear guidance for emerging scenarios such as rented vessels or closed loop schemes in a variety of settings (i.e. dine-in, take-out, or temporary food facilities).

(D) Reusable containers returned to a food establishment for refilling by a food employee or the consumer must be refilled in a contamination-free transfer process such that:

(1) Any consumer-owned container is isolated from food-serving surfaces or such surfaces are sanitized by an employee after each filling.

(2) The food establishment shall prepare, maintain and adhere to written procedures to prevent cross-contamination which additionally address waste water disposal. The food establishment shall make the written procedures available to the enforcement agency upon request.

Consistent with California Assembly Bill No. 619. See supporting documents.

Filling Reusable Containers : Proposed Regulatory Requirements by Scenario

	Food establishment-owned reusable container	Consumer-owned reusable container	Consumer-owned container
Refilled by Food Employee	Must be cleaned as specified under Part 4-6 and sanitized as specified under Part 4-7 of this Code prior to refilling. Refilling must be a contamination-free process.	Any consumer-owned container is isolated from food-serving surfaces or such surfaces are sanitized by an employee after each filling. Refilling must be a contamination-free process.	Prohibited
Refilled by Consumer	Must be cleaned as specified under Part 4-6 and sanitized as specified under Part 4-7 of this Code prior to refilling. Refilling must be a contamination-free process.	Any consumer-owned container is isolated from food-serving surfaces or such surfaces are sanitized by an employee after each filling. Refilling must be a contamination-free process.	May be refilled by the same consumer only with non-TCS food or beverages. Any consumer-owned container is isolated from food-serving surfaces or such surfaces are sanitized by an employee after each filling. Refilling must be a contamination-free process.
<b>All cases:</b>	The food establishment shall prepare, maintain and adhere to written procedures to prevent cross-contamination which additionally address waste water disposal. The food establishment shall make the written procedures available to the enforcement agency upon request.		

## **Assembly Bill No. 619**

### **CHAPTER 93**

An act to amend Sections 114121 and 114353 of the Health and Safety Code, relating to retail food facilities.

[Approved by Governor July 12, 2019. Filed with Secretary of State July 12, 2019.]

#### LEGISLATIVE COUNSEL'S DIGEST

AB 619, Chiu. Retail food: reusable containers: multiuse utensils.

Existing law, the California Retail Food Code, provides for the regulation of health and sanitation standards for retail food facilities, as defined, by the State Department of Public Health. Under existing law, local health agencies are primarily responsible for enforcing the California Retail Food Code, and a person who violates any provision of the code is guilty of a misdemeanor, except as otherwise provided.

Existing law requires returned empty containers intended for refilling with food or beverage to be cleaned and refilled in an approved facility, except that consumer-owned containers may be refilled and returned to the same consumer if the container is refilled by an employee of the food facility or the owner of the container and the dispensing system includes a contamination-free transfer process.

This bill would instead provide that clean consumer-owned containers provided or returned to the food facility for filling may be filled by either the employee or the owner of the container, and would require the food facility to isolate the consumer-owned containers from the serving surface or sanitize the serving surface after each filling. The bill would require the consumer-owned containers to be designed and constructed for reuse, as specified. The bill would require the food facility to prepare, maintain, and adhere to written procedures to prevent cross-contamination, and to make the written procedures available to the enforcement agency.

Existing law defines a temporary food facility, for purposes of the California Retail Food Code, as a food facility approved by the enforcement officer that operates at a fixed location for the duration of an approved community event or at a swap meet and only as a part of the community event or swap meet. Under existing law, a temporary food facility is required to provide single-use articles for use by the consumer.

This bill would authorize a local enforcement agency to allow a temporary food facility to use multiuse utensils that are cleaned, rinsed, and sanitized at either the temporary food facility or an approved food facility.

Because any violation of these provisions would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

*The people of the State of California do enact as follows:*

SECTION 1. Section 114121 of the Health and Safety Code is amended to read:

114121. (a) Except as specified in subdivisions (b), (c), and (d), returned empty containers intended for filling with food or beverage shall be cleaned and filled in an approved facility.

(b) (1) Clean consumer-owned containers provided or returned to the food facility for filling may be filled and returned to the same consumer if the container is filled by either an employee of the food facility or the owner of the container. For the purposes of this section, a consumer-owned container shall be designed and constructed for reuse in accordance with Section 3-304.17(B)(1) of the 2017 Food Code published by the federal Food and Drug Administration.

(2) The food facility shall either isolate the consumer-owned containers from the serving surface or sanitize the serving surface after each filling.

(c) The food facility shall prepare, maintain, and adhere to written procedures to prevent cross-contamination, as described in Section 113986, and the written procedures shall address waste water disposal. The food facility shall make the written procedures available to the enforcement agency upon request or at the time of an inspection.

(d) Consumer-owned containers that are not food specific may be filled at a water vending machine or system.

(e) The food facility shall ensure compliance with the handwashing requirements specified in Article 4 (commencing with Section 113952) of Chapter 3.

SEC. 2. Section 114353 of the Health and Safety Code is amended to read:

114353. (a) Except as provided in subdivision (b), a temporary food facility shall provide only single-use articles for use by the consumer.

(b) Based on local environmental conditions, location, and similar factors, including the type and number of utensils, as defined in Section 113934, the volume and storage of potable water for warewashing, as defined in Section 113940, and waste water capacity, the local enforcement agency may allow a temporary food facility to use multiuse utensils that are cleaned, rinsed, and sanitized pursuant to Chapter 5 (commencing with Section 114095), as applicable, at either the temporary food facility or an approved food facility.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that

may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-024**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Creation of a Committee - Address Reusable Scenarios in Food Retail

**Issue you would like the Conference to consider:**

The language in Food Code 2017 does not provide adequate guidance on allowed practices surrounding several emerging reuse scenarios in food retail. These include but are not limited to the use of consumer-owned containers in restaurants, markets, temporary food facilities and closed loop schemes.

The current code is exception instead of rule-based on this matter, to the extent that the guidance is nearly unreadable. Moreover, the current code does not universally differentiate between consumer-owned and food establishment-owned containers. This leaves significant room for interpretation, with the undesirable consequences of varied enforcement and stakeholder uncertainty.

**Public Health Significance:**

As the "conscious consumption" movement grows, consumers increasingly demand sustainable ways to process, store, and procure food. Food handling regulations must accommodate these new ways to reduce waste and excess packaging. Reducing uncertainty in the language of the regulation encourages food handling practices that are both safe and sensitive to these emerging values and preferences.

What's more, updates to the Food Code will have strong downstream benefits for state and regional regulatory agencies who rely on federal synthesis of pertinent issues in the retail and food service landscape. Significant time and resources can be saved by agencies and industry alike with the adoption of guidance that is clear and uniformly enforceable. Consensus on comprehensive reusable standards by the Conference is critical for progress, and with a four year interval between Food Code updates, the time to address these scenarios is now.

**Recommended Solution: The Conference recommends...:**

That a committee be created to address the safe use of reusable containers in restaurants, markets, temporary food facilities and vending. This includes a review of the Food Code, specifically section 3-304.17,

Scenarios for Committee consideration:

- The use of consumer-owned containers for the sale of bulk dry goods, baked goods, and other food categories
- The filling of customer-owned containers for restaurant takeaway (dining & to-go)
- The appropriate handling of Time/Temperature Control for Safety Foods when sold in reusable containers

The Committee charges are:

1. Clarify the scenarios within the scope of regulation.
2. Develop a comprehensive policy proposal for reusables.
3. Draft recommended guidance around those scenarios.
4. Report back to the 2022 Biennial Meeting the committee findings and recommendations.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-025**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code– Update definitions in relation to food for animals

**Issue you would like the Conference to consider:**

In an effort to prevent and reduce human foodborne illness as a result of food for animals, modifying definitions to be able to achieve this should be considered. Modify the definition of "food" to align more with the Federal definition of food to include food for animals should be considered. Modify the definition of "food establishment" to ensure this change should only be effective at existing establishments, therefore exclude establishments that exclusively prepare, sell, or hold food for animals. Modify the definition of "ready-to-eat food" to account for uncooked or partially cooked food for animals such as but not limited to raw pet food or dried pet treats.

Note: Utilizing the term "food for animals" instead of "animal food" to reduce confusion with the "animal foods" definition in the 2017 Food Code.

**Public Health Significance:**

Problem that needs to be addressed:

Human foodborne illness can be caused by food for animals. Several outbreaks with whole genome sequencing traceback have revealed food for animals as the source for human illness. A recent national human foodborne illness outbreak affecting 34 states with over 154 reported cases and 25 hospitalizations was traced back to pig ear pet treats. Twenty-seven cases were children younger than 5 years old. Examples of nationwide human foodborne illness contributed to contaminated pet food has been associated with both raw and dry pet food products. It is possible food for animals could have been a source for even more outbreaks in the past. Foodborne illness surveys used in epidemiological investigations typically have not addressed exposure to food for animals; therefore, an association may have been missed during previous investigations.

Additionally, food for animals is currently not regulated to prevent human foodborne illness at all levels throughout its entire supply chain. Consistent and collaborative regulation of food for animals may mitigate the associated risks. The same pathogens causing

foodborne illness in humans are present in pet foods. Although the same safety measures apply, they are often overlooked when the products are intended for animals. Often consumers are handling animal pet foods in their own kitchens and simultaneously preparing human foods. Pet owners regularly handle their pet's foods and treats, and thereby unknowingly, or possibly unconsciously, expose themselves to potential foodborne pathogens.

Recalls of pet food for animals have been issued as a precaution as the products contain pathogen strains harmful to both humans and animals. While helpful, precautionary recalls are a reactive response to a problem where preventative measures exist. A unified, one health approach to prevention is necessary.

#### Cause of the problem:

The extent of the human-companion animal bond is undeniable and ever-growing. Humans are now viewing their pets as a member of their family. By default, humans have significantly more exposure to their pets' food. Food for animals can be found in thousands of establishments of varying types such as grocery stores, farmer's markets, and home improvement stores across the country. An explosion of new varieties of food for animals such as refrigerated and frozen pet food, are increasing in popularity and availability. Most animal food regulatory programs do not have the capacity to verify safety measures at even a fraction of these establishments nor do most have the training or tools required for time/temperature control for safety food for animals. A significant misperception may exist among consumers and regulators alike dismissing human foodborne illness caused by contaminated food for animals or how these two outwardly different worlds connect.

#### Why the status quo is not addressing the problem:

As stated above, the exponential expansion of the pet food market into traditional human food establishments has exceeded the resources of animal food regulatory programs. The regulatory focus has generally been at the manufacturing level. This has left less resources for the retail sector. Most animal food regulators are untrained in the requirements for time/temperature control for safety food for animals associated with refrigerated and frozen pet foods. Often they do not have the equipment, such as thermometers, to properly regulate risk factors associated. Science tells us proper cold holding and freezing significantly limits the exponential growth of bacteria. Also, proper handling and storage reduces risk of cross-contamination. Some jurisdictions may have instituted authorities to enforce these prevention measures such as New York State Department of Agriculture and Markets where they recently seized almost 100 pounds of refrigerated raw meat dog food packages for temperature abuse in a chain supermarket or Seattle-King County Public Health that created a Zoonotic Disease Prevention Regulation implementing safety measures in pet food retail businesses. However, these authorities are rare and inconsistent across the country.

The Food Safety Modernization Act (FSMA) was enacted into law in 2011 with the main purpose to prevent adulteration. Most animal food regulatory agencies adopt FSMA regulations and/or AAFCO (Association of American Feed Control Officials) Model Bill and Regulations. Within these laws and regulations, there are very little safety measures existing for the retail sector since neither properly address known retail prevention measures. Furthermore, the Food Code does not address food for animals, even though the federal definition of "food" includes food for other animals since the definition's

inception in 1906 with the Pure Food and Drug Act and food for animals is offered at Food Code establishments.

Another goal of FSMA is to build and maintain an integrated food safety system with mutual reliance, essentially viewing public health through a one-health approach which recognizes that all components are interconnected. In the past, there has been limited collaboration between human food regulators and animal food regulators, resulting in silos and lack of awareness of how each type of food is regulated. Utilizing diverse expertise on both ends of the food spectrum, a unified approach to addressing food for animals in commerce could be enhanced to a level of prevention, mutual reliance, and in integrated food safety system; thus advancing the desired outcomes of FSMA.

Recommended policy solution:

In an effort to reduce or prevent human foodborne illnesses caused by food for animals, amendment of relevant definitions in the Food Code is recommended. To enact these updates a letter should be sent to FDA requesting the amendment of relevant definitions in the Food Code.

Potential consequences with recommendation:

Human food regulatory agencies will have to determine if their laws grant them authority to utilize the federal definition of food (Federal Food, Drug & Cosmetic Act, §321(f)) or if they have an equivalent definition. This would allow these agencies the proper authority if they were to adopt the new Food Code that contained the proposed changes. Otherwise, they would need to modify their law's definition.

Human food regulators will likely only have an additional aisle to inspect when in the human food establishments; those that store food for animals. The proposed changes will only be applied to human food regulator's existing inventory. Grocery stores, being the most likely example, are already accustomed to this type of regulation; however, the product companies may not be as familiar with retail regulation. Outreach and inclusion of the animal food industry is needed. To ensure equivalent and consistent regulation on the retail level, language updates will be proposed to AAFCO Model Bills and Regulations Committee for retail animal food establishments.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to FDA requesting §1-201.10(B) of the most recent edition of the Food Code be amended as follows (new language underlined, deleted language strikeout):

"Food" means a raw, cooked, or processed edible substance, ice, BEVERAGE, or ingredient used or intended for use or for sale in whole or in part for human or other animal consumption, or chewing gum.

Food Establishment.

(1) "Food establishment" means an operation that:

(a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides FOOD for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; ~~or~~ FOOD bank; or stores FOOD for animal consumption; and

(b) relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(2) "Food establishment" includes:

(a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the REGULATORY AUTHORITY; and

(b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.

(3) "Food establishment" does not include:

(a) An establishment that offers only prePACKAGED FOODS that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOODS;

(b) A produce stand that only offers whole, uncut fresh fruits and vegetables;

(c) A FOOD PROCESSING PLANT; including those that are located on the PREMISES of a FOOD ESTABLISHMENT

(d) A kitchen in a private home if only FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY;

(e) An area where FOOD that is prepared as specified in Subparagraph (3)(d) of this definition is sold or offered for human consumption;

(f) A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; ~~or~~

(g) A private home that receives catered or home-delivered FOOD; ~~or~~

(h) An establishment that offers FOOD for animal consumption or serves animals as their main function, such as pet food retail business, a feed store, or a groomer.

(2) "Ready-to-eat food" includes:

(a) Raw animal FOOD that is cooked as specified under § 3-401.11 or 3-401.12, ~~or~~ frozen as specified under § 3-402.11, or uncooked or partially cooked if for animal consumption;

(b) Raw fruits and vegetables that are washed as specified under § 3-302.15;

(c) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;

(d) All TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked to the temperature and time required for the specific FOOD under Subpart 3-401 and cooled as specified under § 3-501.14 or uncooked or partially cooked if for animal consumption;

(e) Plant FOOD for which further washing, cooking, or other processing is not required for FOOD safety, and from which rinds, peels, husks, or shells, if naturally present are removed;

(f) Substances derived from plants such as spices, seasonings, and sugar;

(g) A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for FOOD safety;

(h) The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured MEAT and POULTRY products, such as prosciutto ham, country cured ham, and Parma ham; and dried MEAT and POULTRY products, such as jerky or beef sticks; and

(i) FOODS manufactured as specified in 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

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**Supporting Attachments:**

- "Supporting Attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Supporting Attachments:** (documents submitted to provide background information to Council)

- IFPTI Fellowship Research Paper- “Refrigerated and Frozen Pet Food: Estimating Risk Factors and Analyzing Regulatory Authority”: <https://ifpti.org/fellowship-program/published-works/refrigerated-and-frozen-pet-food-estimating-risk-factors-and-analyzing-regulatory-authority/>
- The definition of “food” in the §321(f) of the Food, Drug, & Cosmetic Act: <https://uscode.house.gov/view.xhtml?path=/prelim@title21/chapter9&edition=prelim>
- The definition of “food” in the §6 of Pure Food & Drug Act of 1906: [https://en.wikisource.org/wiki/Pure\\_Food\\_and\\_Drug\\_Act\\_of\\_1906](https://en.wikisource.org/wiki/Pure_Food_and_Drug_Act_of_1906)
- <https://www.cdc.gov/> to view current and previous human foodborne illness outbreaks that have identified food for animals as a source.
  - 2019- multi-drug resistant *Salmonella* in pig ear pet treats: <https://www.cdc.gov/salmonella/pet-treats-07-19/index.html>
  - 2018- multi-drug resistant *Salmonella* in raw chicken products (including raw pet food): <https://www.cdc.gov/salmonella/infantis-10-18/index.html>
  - 2018- multi-drug resistant *Salmonella* in raw turkey products (including raw pet food): <https://www.cdc.gov/salmonella/reading-07-18/index.html>
  - 2012- *Salmonella* Infantis in dry dog food: <https://www.cdc.gov/salmonella/dog-food-05-12/index.html>
  - 2007- *Salmonella* Schwarzengrund in dry pet food: <https://www.cdc.gov/salmonella/2007/pet-food-9-4-2007.html>
  - 2005- Human Salmonellosis Associated with Animal-Derived Pet Treats, United States and Canada: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5525a3.htm>; <https://promedmail.org/promed-post/?id=2208026>
- <https://www.fda.gov/animal-veterinary/news-events/outbreaks-and-advisories> to view current and previous outbreaks and advisories from food for animals
  - 2007-2015 Jerky pet treat investigation: <https://www.fda.gov/animal-veterinary/news-events/fda-investigates-animal-illnesses-linked-jerky-pet-treats>
- <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts> to view recalls of food for animals contaminated with pathogens that can cause human foodborne illness.
- FDA- “Get the Facts! Raw Pet Food Diets can be Dangerous to You and Your Pet”: <https://www.fda.gov/animal-veterinary/animal-health-literacy/get-facts-raw-pet-food-diets-can-be-dangerous-you-and-your-pet>
- CDC- “Pet Food Safety”: <https://www.cdc.gov/healthypets/publications/pet-food-safety.html>
- Title 8 King County Board of Health Zoonotic Disease Prevention Regulations, §8.03.290 to 8.03.310 (2010). <https://www.kingcounty.gov/depts/health/communicable-diseases/zoonotic/facts-resources/~media/depts/health/board-of-health/documents/code/BOH-Code-Title-8.ashx>
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- Review of the Impact of Imported Contaminated Food and Feed Ingredients and of Recent Food Safety Emergencies on Food Safety and Animal Health Systems Special Hearing, 110<sup>th</sup> Cong. 1-23 (2007). <https://www.govinfo.gov/content/pkg/CHRG-110hrg41165/html/CHRG-110hrg41165.htm>
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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-026**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code – Preventing Contamination By (and To) Consumers

**Issue you would like the Conference to consider:**

In an effort to prevent and reduce human foodborne illness as a result of food for animals, modifying a section in the Food Code to be able to achieve this should be considered. Modifying the "Preventing Contamination by Consumers" section to include language to prevent direct access to exposed uncooked or partially cooked food for animals such as pig ears or other similar pet treats. This measure would help encourage the practice of reducing barehand contact with these products as well as limiting access by preschool age children with the storage height restrictions.

Note: Utilizing the term "food for animals" instead of "animal food" to reduce confusion with the "animal foods" definition in the 2017 Food Code.

**Public Health Significance:**

Problem that needs to be addressed:

Human foodborne illness can be caused by food for animals. Several outbreaks with whole genome sequencing traceback have revealed food for animals as the source for human illness. A recent national human foodborne illness outbreak affecting 34 states with over 154 reported cases and 25 hospitalizations was traced back to pig ear pet treats. Twenty-seven cases were children younger than 5 years old. Examples of nationwide human foodborne illness contributed to contaminated pet food has been associated with both raw and dry pet food products. It is possible food for animals could have been a source for even more outbreaks in the past. Foodborne illness surveys used in epidemiological investigations typically have not addressed exposure to food for animals; therefore, an association may have been missed during previous investigations.

Additionally, food for animals is currently not regulated to prevent human foodborne illness at all levels throughout its entire supply chain. Consistent and collaborative regulation of food for animals may mitigate the associated risks. The same pathogens causing foodborne illness in humans are present in pet foods. Although the same safety measures

apply, they are often overlooked when the products are intended for animals. Often consumers are handling animal pet foods in their own kitchens and simultaneously preparing human foods. Pet owners regularly handle their pet's foods and treats, and thereby unknowingly, or possibly unconsciously, expose themselves to potential foodborne pathogens.

Recalls of pet food for animals have been issued as a precaution as the products contain pathogen strains harmful to both humans and animals. While helpful, precautionary recalls are a reactive response to a problem where preventative measures exist. A unified, one health approach to prevention is necessary.

#### Cause of the problem:

The extent of the human-companion animal bond is undeniable and ever-growing. Humans are now viewing their pets as a member of their family. By default, humans have significantly more exposure to their pets' food. Food for animals can be found in thousands of establishments of varying types such as grocery stores, farmer's markets, and home improvement stores across the country. An explosion of new varieties of food for animals such as refrigerated and frozen pet food, are increasing in popularity and availability. Most animal food regulatory programs do not have the capacity to verify safety measures at even a fraction of these establishments nor do most have the training or tools required for time/temperature control for safety food for animals. A significant misperception may exist among consumers and regulators alike dismissing human foodborne illness caused by contaminated food for animals or how these two outwardly different worlds connect.

#### Why the status quo is not addressing the problem:

As stated above, the exponential expansion of the pet food market into traditional human food establishments has exceeded the resources of animal food regulatory programs. The regulatory focus has generally been at the manufacturing level. This has left less resources for the retail sector. Most animal food regulators are untrained in the requirements for time/temperature control for safety food for animals associated with refrigerated and frozen pet foods. Often they do not have the equipment, such as thermometers, to properly regulate risk factors associated. Science tells us proper cold holding and freezing significantly limits the exponential growth of bacteria. Also, proper handling and storage reduces risk of cross-contamination. Some jurisdictions may have instituted authorities to enforce these prevention measures such as New York State Department of Agriculture and Markets where they recently seized almost 100 pounds of refrigerated raw meat dog food packages for temperature abuse in a chain supermarket or Seattle-King County Public Health that created a Zoonotic Disease Prevention Regulation implementing safety measures in pet food retail businesses. However, these authorities are rare and inconsistent across the country.

The Food Safety Modernization Act (FSMA) was enacted into law in 2011 with the main purpose to prevent adulteration. Most animal food regulatory agencies adopt FSMA regulations and/or AAFCO (Association of American Feed Control Officials) Model Bill and Regulations. Within these laws and regulations, there are very little safety measures existing for the retail sector since neither properly address known retail prevention measures. Furthermore, the Food Code does not address food for animals, even though the federal definition of "food" includes food for other animals since the definition's

inception in 1906 with the Pure Food and Drug Act and food for animals is offered at Food Code establishments.

Another goal of FSMA is to build and maintain an integrated food safety system with mutual reliance, essentially viewing public health through a one-health approach which recognizes that all components are interconnected. In the past, there has been limited collaboration between human food regulators and animal food regulators, resulting in silos and lack of awareness of how each type of food is regulated. Utilizing diverse expertise on both ends of the food spectrum, a unified approach to addressing food for animals in commerce could be enhanced to a level of prevention, mutual reliance, and in integrated food safety system; thus advancing the desired outcomes of FSMA.

Recommended policy solution:

In an effort to reduce or prevent human foodborne illnesses caused by food for animals, amendment of relevant sections in the Food Code is recommended. To enact these updates a letter should be sent to FDA requesting the amendment of relevant sections in the Food Code.

Potential consequences with recommendation:

Human food regulatory agencies will have to determine if their laws grant them authority to utilize the federal definition of food (Federal Food, Drug & Cosmetic Act, §321(f)) or if they have an equivalent definition. This would allow these agencies the proper authority if they were to adopt the new Food Code that contained the proposed changes. Otherwise, they would need to modify their law's definition.

Human food regulators will likely only have an additional aisle to inspect when in the human food establishments; those that store food for animals. The proposed changes will only be applied to human food regulator's existing inventory. Grocery stores, being the most likely example, are already accustomed to this type of regulation; however, the product companies may not be as familiar with retail regulation. Outreach and inclusion of the animal food industry is needed. To ensure equivalent and consistent regulation on the retail level, language updates will be proposed to AAFCO Model Bills and Regulations Committee for retail animal food establishments.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to FDA requesting §3-306.13 of the most recent edition of the Food Code be amended as follows: (new language underlined, deleted language strikeout)

Preventing Contamination by or to Consumers

3-306.13 Consumer Self-Service Operations.

(A) Raw, unPACKAGED animal FOOD, such as beef, lamb, pork, POULTRY, and FISH may not be offered for CONSUMER self-service. <sup>P</sup>

*This paragraph does not apply to:*

(1) *CONSUMER self-service of READY-TO-EAT FOODS at buffets or salad bars that serve FOODS such as sushi or raw shellfish;*

(2) *Ready-to-cook individual portions for immediate cooking and consumption on the PREMISES such as CONSUMER-cooked MEATS or CONSUMER-selected ingredients for Mongolian barbecue; or*

(3) *Raw, frozen, shell-on shrimp, or lobster; or*

(4) *Uncooked or partially cooked FOOD for animal consumption such as but not limited to dried pet treats.*

(B) CONSUMER self-service operations for READY-TO-EAT FOODS shall be provided with suitable UTENSILS or effective dispensing methods that protect the FOOD from contamination. <sup>Pf</sup>

(C) CONSUMER self-service operations such as buffets and salad bars shall be monitored by FOOD EMPLOYEES trained in safe operating procedures. <sup>Pf</sup>

(D) Containers for display and service of READY-TO-EAT FOODS, unPACKAGED, bulk FOOD for CONSUMER self-service must have a CONSUMER access point no less than 30 inches above floor level.

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**Supporting Attachments:**

- "Supporting Attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Supporting Attachments:** (documents submitted to provide background information to Council)

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- The definition of “food” in the §321(f) of the Food, Drug, & Cosmetic Act: <https://uscode.house.gov/view.xhtml?path=/prelim@title21/chapter9&edition=prelim>
- The definition of “food” in the §6 of Pure Food & Drug Act of 1906: [https://en.wikisource.org/wiki/Pure\\_Food\\_and\\_Drug\\_Act\\_of\\_1906](https://en.wikisource.org/wiki/Pure_Food_and_Drug_Act_of_1906)
- <https://www.cdc.gov/> to view current and previous human foodborne illness outbreaks that have identified food for animals as a source.
  - 2019- multi-drug resistant *Salmonella* in pig ear pet treats: <https://www.cdc.gov/salmonella/pet-treats-07-19/index.html>
  - 2018- multi-drug resistant *Salmonella* in raw chicken products (including raw pet food): <https://www.cdc.gov/salmonella/infantis-10-18/index.html>
  - 2018- multi-drug resistant *Salmonella* in raw turkey products (including raw pet food): <https://www.cdc.gov/salmonella/reading-07-18/index.html>
  - 2012- *Salmonella* Infantis in dry dog food: <https://www.cdc.gov/salmonella/dog-food-05-12/index.html>
  - 2007- *Salmonella* Schwarzengrund in dry pet food: <https://www.cdc.gov/salmonella/2007/pet-food-9-4-2007.html>
  - 2005- Human Salmonellosis Associated with Animal-Derived Pet Treats, United States and Canada: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5525a3.htm>; <https://promedmail.org/promed-post/?id=2208026>
- <https://www.fda.gov/animal-veterinary/news-events/outbreaks-and-advisories> to view current and previous outbreaks and advisories from food for animals
  - 2007-2015 Jerky pet treat investigation: <https://www.fda.gov/animal-veterinary/news-events/fda-investigates-animal-illnesses-linked-jerky-pet-treats>
- <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts> to view recalls of food for animals contaminated with pathogens that can cause human foodborne illness.
- FDA- “Get the Facts! Raw Pet Food Diets can be Dangerous to You and Your Pet”: <https://www.fda.gov/animal-veterinary/animal-health-literacy/get-facts-raw-pet-food-diets-can-be-dangerous-you-and-your-pet>
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- Title 8 King County Board of Health Zoonotic Disease Prevention Regulations, §8.03.290 to 8.03.310 (2010). <https://www.kingcounty.gov/depts/health/communicable-diseases/zoonotic/facts-resources/~media/depts/health/board-of-health/documents/code/BOH-Code-Title-8.ashx>
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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-027**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Creation of Committee- Review of Food Code in relation to food for animals

**Issue you would like the Conference to consider:**

Since human foodborne illness as a result of food for animals continues to occur, a creation of a committee should be considered. This committee would examine if adding food for animals to the Food Code with language to help ensure proper storage and handling at the establishments the Food Code regulates is a viable solution to help prevent or reduce such illnesses. Additionally, this committee would review current research, the Preface, Annexes, and/or the need for guidance documents.

Endorsed by Ernest Julian, current AFDO President

Note: Utilizing the term "food for animals" instead of "animal food" to reduce confusion with the "animal foods" definition in the 2017 Food Code.

**Public Health Significance:**

Problem that needs to be addressed:

Human foodborne illness can be caused by food for animals. Several outbreaks with whole genome sequencing traceback have revealed food for animals as the source for human illness. A recent national human foodborne illness outbreak affecting 34 states with over 154 reported cases and 25 hospitalizations was traced back to pig ear pet treats. Twenty-seven cases were children younger than 5 years old. Examples of nationwide human foodborne illness contributed to contaminated pet food has been associated with both raw and dry pet food products. It is possible food for animals could have been a source for even more outbreaks in the past. Foodborne illness surveys used in epidemiological investigations typically have not addressed exposure to food for animals; therefore, an association may have been missed during previous investigations.

Additionally, food for animals is currently not regulated to prevent human foodborne illness at all levels throughout its entire supply chain. Consistent and collaborative regulation of food for animals may mitigate the associated risks. The same pathogens causing

foodborne illness in humans are present in pet foods. Although the same safety measures apply, they are often overlooked when the products are intended for animals. Often consumers are handling animal pet foods in their own kitchens and simultaneously preparing human foods. Pet owners regularly handle their pet's foods and treats, and thereby unknowingly, or possibly unconsciously, expose themselves to potential foodborne pathogens.

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#### Cause of the problem:

The extent of the human-companion animal bond is undeniable and ever-growing. Humans are now viewing their pets as a member of their family. By default, humans have significantly more exposure to their pets' food. Food for animals can be found in thousands of establishments of varying types such as grocery stores, farmer's markets, and home improvement stores across the country. An explosion of new varieties of food for animals such as refrigerated and frozen pet food, are increasing in popularity and availability. Most animal food regulatory programs do not have the capacity to verify safety measures at even a fraction of these establishments nor do most have the training or tools required for time/temperature control for safety food for animals. A significant misperception may exist among consumers and regulators alike dismissing human foodborne illness caused by contaminated food for animals or how these two outwardly different worlds connect.

#### Why the status quo is not addressing the problem:

As stated above, the exponential expansion of the pet food market into traditional human food establishments has exceeded the resources of animal food regulatory programs. The regulatory focus has generally been at the manufacturing level. This has left less resources for the retail sector. Most animal food regulators are untrained in the requirements for time/temperature control for safety food for animals associated with refrigerated and frozen pet foods. Often they do not have the equipment, such as thermometers, to properly regulate risk factors associated. Science tells us proper cold holding and freezing significantly limits the exponential growth of bacteria. Also, proper handling and storage reduces risk of cross-contamination. Some jurisdictions may have instituted authorities to enforce these prevention measures such as New York State Department of Agriculture and Markets where they recently seized almost 100 pounds of refrigerated raw meat dog food packages for temperature abuse in a chain supermarket or Seattle-King County Public Health that created a Zoonotic Disease Prevention Regulation implementing safety measures in pet food retail businesses. However, these authorities are rare and inconsistent across the country.

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Recommended policy solution:

In an effort to reduce or prevent human foodborne illnesses caused by food for animals, a creation of a diverse committee to review the Food Code and potential language updates, provide resolutions, and report back to the 2022 CFP Biennial Meeting is recommended. This committee would review the Food Code to reflect safety measures at the retail level for food for animals, specifically at human food establishments to help reduce or prevent human foodborne illness. Potential language updates have been provided as a starting point for this committee.

Potential consequences with recommendation:

Human food regulatory agencies will have to determine if their laws grant them authority to utilize the federal definition of food (Federal Food, Drug & Cosmetic Act, §321(f)) or if they have an equivalent definition. This would allow these agencies the proper authority if they were to adopt the new Food Code that contained the proposed changes. Otherwise, they would need to modify their law's definition.

Human food regulators will likely only have an additional aisle to inspect when in the human food establishments; those that store food for animals. The proposed changes will only be applied to human food regulator's existing inventory. Grocery stores, being the most likely example, are already accustomed to this type of regulation; however, the product companies may not be as familiar with retail regulation. Outreach and inclusion of the animal food industry is needed. To ensure equivalent and consistent regulation on the retail level, language updates will be proposed to AAFCO Model Bills and Regulations Committee for retail animal food establishments.

**Recommended Solution: The Conference recommends...:**

that a committee with all stakeholders be formed with the following charges:

1. Gather and review relevant research on human foodborne illnesses as a result food for animals;
2. Review the need for or the proposed language updates in the Food Code, Annex, or Preface as necessary, provide resolutions;
3. Review the need for relevant guidance documents or other consumer/industry materials; and
4. Report back with findings and recommendations to the 2022 Conference Biennial Meeting.

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**Supporting Attachments:**

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  - 2005- Human Salmonellosis Associated with Animal-Derived Pet Treats, United States and Canada: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5525a3.htm>; <https://promedmail.org/promed-post/?id=2208026>
- <https://www.fda.gov/animal-veterinary/news-events/outbreaks-and-advisories> to view current and previous outbreaks and advisories from food for animals
  - 2007-2015 Jerky pet treat investigation: <https://www.fda.gov/animal-veterinary/news-events/fda-investigates-animal-illnesses-linked-jerky-pet-treats>
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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-028**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code – Permit Pet Dogs in Outdoor Dining Areas

**Issue you would like the Conference to consider:**

Within the past 13 years, 19 states and the District of Columbia have adopted policies through various mechanisms to allow pet dogs in outdoor dining areas, a map of which is included as a supporting attachment titled "States Allowing Pet Dogs in Outdoor Dining Areas." However, significant confusion remains for food establishment owners as to whether they are permitted to allow pet dogs in their jurisdiction, and if they are, what additional procedures are necessary to ensure food safety is not compromised. Amending Section 6-501.115 of the Food Code to allow pet dogs in outdoor dining areas would provide clear guidance to states and municipalities that such activity would not compromise public health, provided the safeguards included in this proposal are followed.

**Public Health Significance:**

As pet ownership rises in the United States, an increasing number of people are looking to incorporate their pets into more aspects of their daily lives, including bringing them to retail and dining establishments. With this increasing demand, more and more restaurants are adopting pet-friendly policies that allow pet dogs in their outdoor dining areas.

The movement to allow pet dogs in outdoor dining areas began in the mid- to late-2000s when four states passed legislation giving municipalities discretion to permit pet dogs in outdoor dining areas, provided they follow certain regulatory requirements: Florida, Illinois, Minnesota, and Tennessee. In 2011, Maryland and New Mexico went a step further and enacted laws allowing restaurants to permit the practice under certain circumstances. However, there was still limited research as to the public safety effects and risks of allowing pet dogs in outdoor dining facilities.

In 2012, Food Standards Australia New Zealand (FSANZ), the government agency responsible for developing food standards for Australia and New Zealand, proposed amending its Food Standards Code to allow pet dogs in outdoor dining areas of food establishments. As part of its deliberation, FSANZ conducted a risk assessment to

determine the food safety implications arising from the proposal. A copy of the risk assessment is included as a supporting attachment, titled "FSANZ Risk Assessment - Companion Dogs in Outdoor Dining Areas." The agency determined that the risk to humans is "very low to negligible" and approved the proposal for the following reasons:

- Dogs would not be ordinarily allowed into food preparation areas, making the risk of direct contact with food negligible;
- Indirect foodborne transmission of diseases through an intermediary, such as rodent, insects, or food establishment personnel, is highly unlikely. This relies on the occurrence of two events: (1) a successful transmission from pet dog to intermediary, and (2) successful transmission from intermediary to customer. The probability of either event was determined to be low;
- Potential direct or indirect contamination of food from pet dogs can be managed through compliance with general food safety and hygiene standards; and
- Studies indicated that contact between people and dogs that are not their own is limited, minimizing the potential for contact and, consequently, transmission of diseases from dogs to humans.

Since then, more states have enacted policies that would allow pet dogs in outdoor dining areas, e.g.:

- In 2014, California passed legislation allowing the practice under certain circumstances, citing the FSANZ risk assessment in the bill analysis.
- New York passed legislation similar to the California bill in 2015.
- In November 2019, due to increasing pressure from restaurant owners and local officials, Mississippi State Department of Health announced a policy change, whereby restaurants may apply for a variance to the state's Food Code to create dog-friendly outdoor dining spaces.

As a result of these different approaches, there is a hodgepodge of states and municipalities that allow pet dogs in outdoor dining areas, each with their own set of food safety standards for restaurants to follow. This has led to confusion on the part of restaurant owners and customers as to whether food establishments are allowed to have dog-friendly outdoor dining areas and, if so, what sanitary requirements they are required to follow.

This submission would neutralize this problem by giving food establishments the flexibility to allow pet dogs in outdoor dining areas and establish strong regulatory requirements restaurants to ensure food safety. Many retailers have outdoor seating areas, and this proposal is in line with their business practices and customer needs. One national set of standards for businesses brings clarity to businesses and customers and embraces the growing trend of people incorporating their pets into everyday activities, without compromising public safety.

#### **Recommended Solution: The Conference recommends...:**

A letter be sent to the FDA requesting that Section 6-501.115 of the most current edition of the Food Code be amended as follows (new language is underlined; existing language to be deleted is in strikethrough format):

## 6-501.115 Prohibiting Animals.

A. Except as specified in ¶¶ (B) and (C) of this section, live animals may not be allowed on the premises of a food establishment.

B. Live animals may be allowed in the following situations if the contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles can not result:

1) Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;

2) Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;

3) In areas that are not used for food preparation and that are usually open for customers, such as dining and sales areas, service animals that are controlled by the disabled employee or person, if a health or safety hazard will not result from the presence or activities of the service animal;

4) Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, or residential care facilities at times other than during meals if:

a. Effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas,

b. Condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present, and

c. Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; ~~and~~

5) In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly confined, such as in a variety store that sells pets or a tourist park that displays animals; and

6) Pet dogs under the control of a person in an outdoor dining area, or a designated portion of it, if:

a. The owner of the food establishment elects to allow pet dogs.

b. The pet dog is on a leash or confined to a pet carrier.

c. A separate outdoor entrance is present where pet dogs enter without going through the food establishment.

d. Signs are conspicuously posted indicating that pet dogs are allowed in the outdoor dining area.

e. Pet dogs are not allowed on chairs, benches, seats, or other fixtures.

f. The outdoor dining area is not used for food or drink preparation or the storage of utensils.

g. Food and water provided to dogs shall only be in single-use disposable containers.

h. Food establishment employees are prohibited from having direct contact with dogs while on duty. Any employee who does have such direct contact shall wash their hands thoroughly.

i. The outdoor dining area is maintained clean, and surfaces that have been contaminated with dog excrement or other body fluids shall be cleaned and sanitized.

j. A covered refuse container shall be located in the outdoor dining area and shall be used exclusively to store all pet waste generated.

k. The food establishment owner ensures compliance with local ordinances related to sidewalks, public nuisance, and sanitation, and

l. The food establishment owner shall request that a pet dog owner remove from the establishment any dog that menaces, threatens or bites any person or other dog. The food establishment owner shall not serve a dog owner who refuses to comply with a request to remove such a dog.

C. Live or dead fish bait may be stored if contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles can not result.

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**Supporting Attachments:**

- "Pet Dogs In Outdoor Dining Areas - Current State Policies"
- "FSANZ Companion Dogs in Outdoor Dining Areas Risk Assessment"
- "Letter of Support - Mayor of St. Petersburg, FL"
- "Letter of Support - Mississippi State Department of Health"

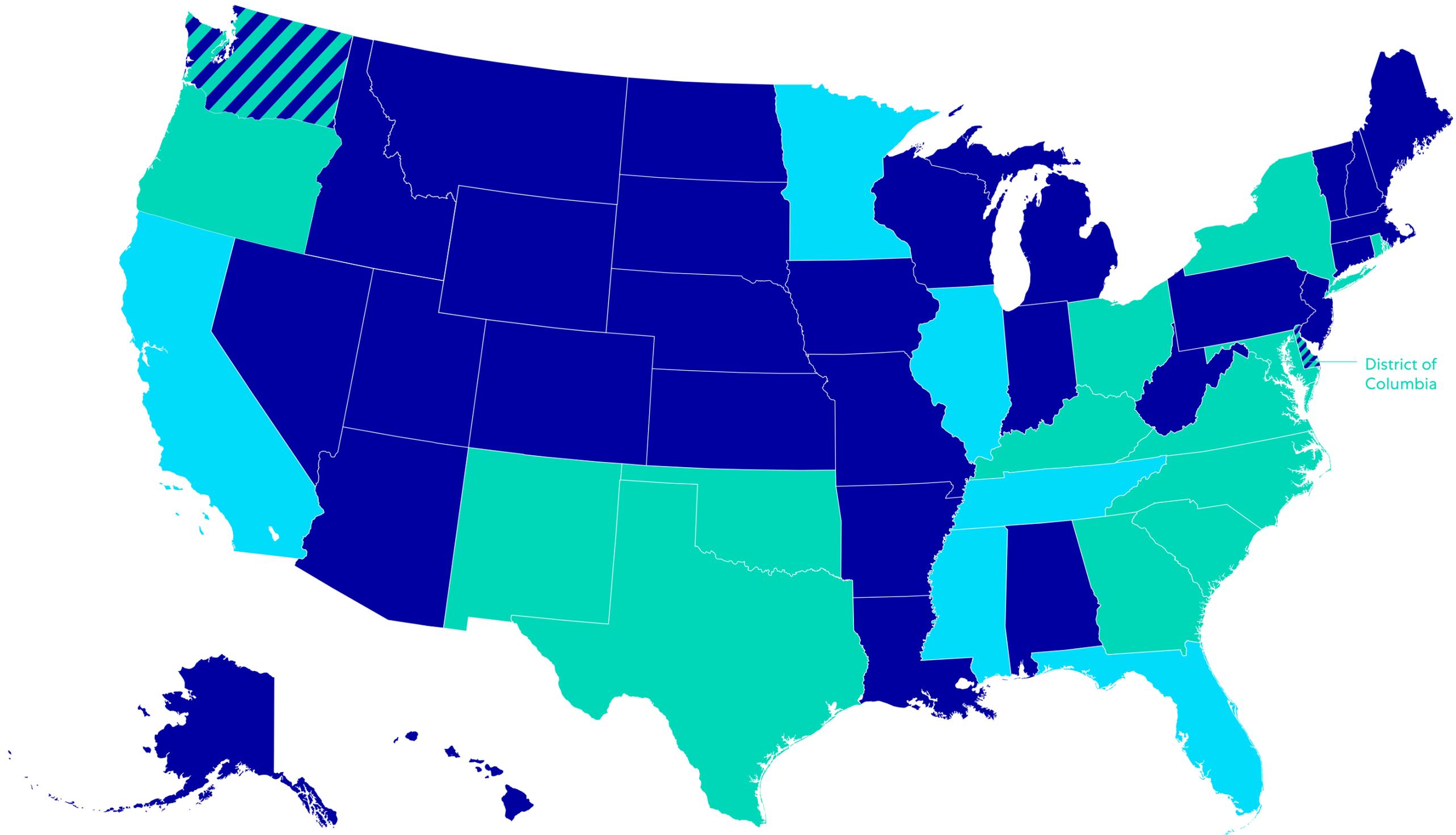
*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

# Pet Dogs in Outdoor Dining Areas

## Current state policies

December 2019

-  Pets allowed in outdoor dining areas (14)
-  Pets NOT allowed in outdoor dining areas (29)
-  Local municipalities decide if pets are allowed in outdoor dining areas (6)
-  Rulemaking underway to allow pets in outdoor dining areas (2)



## Supporting document 1

### Risk assessment – Proposal P1018

### Companion Dogs in Outdoor Dining Areas

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#### Background

Clause 24 of Standard 3.2.2 of *Australia New Zealand Food Standards Code* (the Code), shown in the box below, specifies food safety requirements in relation to the control and management of live animals and pests in areas in which food is handled<sup>1</sup>. It is the food business's responsibility to manage live animals and pests in the food preparation and service area to ensure food and drink handled in the premises are safe for consumers. This includes not permitting live animals in areas in which food is handled.

#### 24. Animals and pests

- (1) A food business must –
- (a) subject to paragraph (b), not permit live animals in areas in which food is handled, other than seafood or other fish or shellfish;
  - (b) permit an assistance animal only in dining and drinking areas and other areas used by customers;
  - (c) take all practicable measures to prevent pests entering the food premises; and
  - (d) take all practicable measures to eradicate and prevent the harbourage of pests on the food premises and those parts of vehicles that are used to transport food.

(2) In subclause (1), 'assistance animal' means an animal referred to in section 9 of the *Disability Discrimination Act 1992* of the Commonwealth.

#### Editorial note:

Section 9 of the *Disability Discrimination Act 1992* refers to a guide dog, a dog trained to assist a person in activities where hearing is required and any other animal trained to assist a person to alleviate the effect of a disability.

Different approaches have been taken to manage the implementation of the presence of companion dogs in outdoor dining areas which form part of the food business premises. The presence of companion dogs in the outdoor dining areas of the premises operated by a food business, in addition to guide dogs, is permitted in New South Wales, South Australia, and Victoria, subject to the permission of the food businesses operating the outdoor dining areas. In Western Australia, local government authorities will actively enforced the compliance by a food business with the above standard only when there is evidence of a present risk of unsafe or unsuitable food being sold by a particular food business.

This risk assessment is prepared to describe food safety implications arising from the presence of companion dogs in outdoor dining areas attached to a food business.

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<sup>1</sup> In Standard 1.1.1 of the Code, **handling** of food includes the making, manufacturing, producing, collecting, extracting, processing, storing, transporting, delivering, preparing, treating, preserving, packing, cooking, thawing, serving or displaying of food. Clause 24 of Standard 3.2.2 therefore prohibits pet animals from being present in outdoor dining areas where food for sale is being served to customers. This prohibition does not apply if the food consumed has already been purchased.

## Scope of the assessment

The following risk assessment presents an outline of the common zoonotic pathogens<sup>2</sup> potentially associated with companion dogs in Australia; their common modes of transmission; the likelihood that these pathogens are transmitted to humans through a foodborne route; and the food safety risk posed to consumers in outdoor dining areas if companion dogs were permitted to be present.

## Human pathogens potentially carried by companion dogs and routes of transmission

### 1. Pathogens carried by dogs

Zoonotic pathogens potentially carried by dogs include bacteria, fungi, parasites, protozoa and viruses. Pathogens shown to be transmittable to humans from domestic dogs in Australia are summarised in Table 1.

**Table 1: Zoonotic pathogens potentially carried by dogs**

Pathogens	Microbiological and epidemiological characteristics	Comments and likely mode of transmission
<b>Bacteria</b>		
<i>Campylobacter</i> spp.	<i>Campylobacter</i> species are commonly found in the intestines of food animals, birds, dogs and cats.	Known to be foodborne; young animals are more likely to excrete the pathogen.
Shiga toxin-producing <i>Escherichia coli</i> (STEC)	STEC bacteria have been isolated from animals such as cattle, pigs, sheep, dogs, cats, horses, and birds including seagulls and geese.	Known to be foodborne; children and immune-compromised individuals are at higher risk of STEC caused illnesses.
<i>Leptospira interrogans</i>	<i>Leptospira</i> species, notably <i>L. interrogans</i> are pathogenic, causing leptospirosis in humans and animals.	Leptospirosis is a rare disease of dogs in Australia; can be foodborne but mostly an occupational disease associated with cattle or through exposure to contaminated (by animal urine) waterways.
<i>Salmonella</i> spp.	<i>Salmonella</i> spp. are found in a wide range of animals including ruminants, poultry and dogs, and in various environmental sources, such as water, soil and animal faeces.	Known to be foodborne; children and immune-compromised individuals are at higher risk of <i>salmonella</i> cause illnesses.
<i>Yersinia enterocolitica</i> and <i>Y. pseudotuberculosis</i>	<i>Y. enterocolitica</i> and <i>Y. pseudotuberculosis</i> infects humans and a wide range of animals including dogs. <i>Y. enterocolitica</i> is usually transmitted to humans through ingestion of insufficiently cooked pork or contaminated water.	Known to be foodborne; transmission to humans is achieved through ingestion of contaminated food.
<b>Protozoa</b>		
<i>Cryptosporidium</i> spp.	Humans and animals such as horses, pigs, sheep, goats, cattle, dogs and cats can be infected by <i>Cryptosporidium</i> spp.	Can be foodborne but person to person transmission is more common; children and immune-compromised individuals are at higher risk of disease.
<i>Giardia</i> spp.	<i>Giardia</i> spp. can infect humans and many animals. <i>Giardia</i> is transmitted from host to host by ingesting cysts through contaminated feed or water.	Can be foodborne but person to person and contact with waterways are more common forms of transmission.
<b>Parasites</b>		
<i>Dipylidium</i> (dog tapeworm)	<i>Dipylidium</i> and <i>Echinococcus</i> are tapeworms of cats and dogs. People become infected	Hydatids are rare in domestic dogs in Australia and infection of dogs requires

<sup>2</sup> Zoonotic pathogens refer to pathogens that can be transmitted (sometimes via a vector) to humans through non-human animals, both domestic and wild.

<i>Echinococcus</i> (hydatids)	when they accidentally swallow tapeworm (Dipylidium) larvae excreted by flea or eggs in ( <i>Echinochoccus</i> ) infected faeces. Infection with <i>Echinococcus</i> results in hydatid disease.	an intermediate (sheep) host. Not known to be foodborne.
<i>Ancylostoma caninum</i> (dog hookworm)	<i>Ancylostoma caninum</i> is a parasite nematode. It lives in the small intestine of its host, such as dogs. <i>A. caninum</i> can infect humans.	Not known to be foodborne; contact with environment and skin penetration is the most common form of transmission to humans.
<i>Toxocara canis</i> (dog roundworm)	Adult worms of the <i>Toxocara canis</i> live in the small intestine of dogs and puppies. Almost all puppies are infected at or soon after birth. <i>Toxocara</i> eggs can survive for years in the environment, and humans typically ingest the eggs via oral contact with contaminated hands.	Not known to be foodborne; direct contact with animals is the most common form of transmission to humans.

Although uncommon, companion dogs fed with raw meat can also be infected by *Bacillus anthracis*, *Clostridium botulinum*, *C. perfringens*, *Listeria monocytogenes*, *Mycobacterium bovis*, *M. tuberculosis*, and *Yersinia enterocolitica* (Lejeune and Hancock 2001).

While it is out of the scope of this assessment, it is also relevant to note that dog bites can transmit multiple microorganisms. Some of them are pathogenic to humans, most commonly *Pasteurella* species. Infections acquired through dog bites are the most common form of disease transmitted to humans from dogs.

Symptoms of human diseases caused by pathogens listed in Table 2 are described in Appendix 1.

## **2. Prevalence of pathogens in dogs**

Although there are published data indicating the prevalence of zoonotic pathogens in dogs, most of the data relate to investigations after dogs have been exposed to zoonotic pathogens through raw food diets. The following data demonstrates the variability in positive stool samples detected for several common pathogenic agents in dogs:

- pathogenic *Campylobacter* spp. in dogs has been reported to be in the range of 2.4% to 47% (Lenz et al. 2009, McKill et al. 2009, Workman et al. 2005);
- STEC O157 has been reported at 3% prevalence (Hancock et al. 1998); and
- pathogenic *Salmonella* spp. has been reported in the range of 14% to 44% (Joffe and Schlesinger 2002; Finley et al. 2007; Lenz et al. 2009).

In general only a small number of samples were collected in the above studies. This would also contribute to the variability in the observed prevalence. Despite this, and the different methodologies used, it is apparent that dogs may at times harbour and excrete pathogens of public health concern to a varying extent.

## **3. Routes of transmission of zoonotic pathogens from dogs to humans**

The pathogens listed in Table 2 can be transmitted to humans through one or more of the following routes:

- consumption of food and/or water contaminated by faeces of infected dogs
- direct contact with parts of the infected companion dog that may have been contaminated with faeces of infected dogs, such as the skin, fur, or mouth
- an intermediate vector, for example ticks or fleas carried by dogs (Stehr-Green and Schantz 1987).

Situations where human illness has been caused by consumption of food contaminated by pathogens originating from an infected dog are most likely rare and no reports have been identified in a literature scan. Therefore the studies described below focus on illness caused by direct contact with pathogens carried by dogs and provide a basis for identifying the pathogens which theoretically are transmissible via a foodborne route.

The most common route of transmission of zoonotic pathogens from dogs to humans is through direct contact with faecally contaminated material. Dogs, particularly puppies, are more likely to carry and therefore readily excrete pathogens. They present a significant risk of transmitting zoonotic pathogens to young children who come into contact with them in a family environment (Salfield and Pugh 1987; Hald and Madsen 1997). Transmission of STEC O157 to young children from infected dogs through direct contact has been demonstrated (Trevena et al. 1996).

Published Australian data demonstrating an epidemiological link between human illness and contact with pet animals are scarce. In a case-control study of risk factors associated with *Campylobacter* infection in Australia, Stafford et al. (2008) reported that contact with domestic dogs aged less than 6 months was an independent risk factor for acquiring campylobacteriosis. The study however, did not reveal any association that dogs were a significant risk factor for acquiring campylobacteriosis through foodborne exposure.

One Australian publication reported an investigation of 27 human cases of *Cryptosporidium* infection that occurred in association with an animal nursery at an agricultural show. Although several species of animals were present including dogs, puppies, calves, chickens, goats, pet rats, rabbits, sheep, and some native animals, the investigation (Ashbolt et al. 2003) concluded that *Cryptosporidium* was most likely acquired through human contact with infected faeces present in hay used by ruminants. An Australian PhD study<sup>3</sup> that examined gastrointestinal parasites in dogs and cats in Australia concluded that *Cryptosporidium* arising from companion animals is of limited significance in terms of transmitting disease to healthy people.

Parasites such as hookworm, roundworm and tapeworm in dogs are commonly under control in Australia as a result of preventative worming programs for domestic dogs and present a low risk to consumers if the health of companion dogs is appropriately maintained. Again direct transmission through close contact with dogs, particularly in children, is the most common route of transmission for these agents.

Human leptospirosis caused by *Leptospira interrogans* is commonly associated with outdoor water activities where transmission is a result of exposure to contaminated water, most often through rodents. Published data of Australia's National Notifiable Disease Surveillance System indicate that approximately 100 to 150 cases of human leptospirosis are reported each year in Australia. Human leptospirosis in Australia is largely occupational and associated with those working in the intensive animal farming sector and livestock industries. Eating contaminated food or drinking contaminated water however can be responsible occasionally for the transmission of *Leptospira interrogans* to humans according to a factsheet on leptospirosis prepared by the NSW Department of Health (NSW Health, 2007). However, clinical leptospirosis in dogs is rare in Australia (Biosecurity Australia, 2000).

The available literature indicates that *Campylobacter* spp., STEC and pathogenic *Salmonella* spp. are the most likely pathogenic organisms that could be transmitted, via food, to humans from infected dogs. This could potentially arise through consumption of food contaminated

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<sup>3</sup> <http://researchrepository.murdoch.edu.au/703/1/01Front.pdf>

with dog faecal material or through food handlers who have been in contact with faeces of infected dogs.

#### **4. Factors influencing shedding of pathogenic microorganisms in dogs**

Faecal shedding of zoonotic pathogens in dogs is influenced by a range of factors. It is known that inclusion of ingredients such as raw pork, chicken and eggs in the diet of dogs can increase the faecal shedding of pathogens such as *Campylobacter* spp., STEC and *Salmonella* spp. Intake of raw meat has been assumed to be the main vehicle through which dogs acquire these pathogens (Fox 1998; Green 1998; Lenz et al. 2009).

Shedding of zoonotic pathogens such as STEC and *Salmonella* by animals is frequently higher in summer and autumn (NASPHV, 2007). During this period, outdoor dining activities are more common and therefore higher exposure to people from potential pathogens may occur.

#### **5. Studies on interactions between humans and dogs**

The nature and extent of interaction between humans and their companion dogs has been examined in some communities in the United Kingdom with a view to assessing the risk of disease transmission from pets (Westgarth et al. 2007 and 2008). In general, the greatest and most intimate contact (e.g. playing, cuddling, feeding, allowing pets to lick the owner and sleeping in close proximity) was seen between the owner and his or her dog, suggesting that the highest risk of zoonotic disease transmission would occur in the home and with family members. When dogs were outside the home, there was minimal contact (mainly patting) with other people and this mainly occurred when walking the dog. Other dog-owners tended to have most of this contact as opposed to people that did not own dogs (Westgarth et al. 2007).

Heller et al. (2011) also studied the interactions between humans and companion dogs in a Scottish community to explore the differences between dog-owners and non-dog-owners with respect to hygiene and knowledge of zoonotic disease. This study confirmed that closer contact occurred between dog-owners and their own dogs compared with dogs of other owners. However, it also showed that dog owners were no more likely to have intimate interactions (play, cuddle, feed treats) with non-owned dogs compared to those not owning a dog. The study implied that the potential routes for pathogen transmission from non-owned dogs are similar and minimal for both dog owners and non-dog-owning humans. This was in contrast to the comparatively greater number of routes and risk factors that are likely to be present between dog-owners and their own dogs.

#### **6. Potential modes of transmission of pathogens from companion dogs to food**

Food served in outdoor dining settings may potentially be contaminated with zoonotic pathogens carried by companion dogs via the following routes (Figure 1).

Food hygiene and safety regulations in most jurisdictions include basic measures to restrict the movement of companion dogs in outdoor dining areas such that food prepared and/or served by food businesses would not come into direct contact with companion dogs or dog faeces. It is therefore considered that transmission of pathogens by companion dogs in outdoor dining areas to consumers through the direct contact scenario in Figure 1 is unlikely.

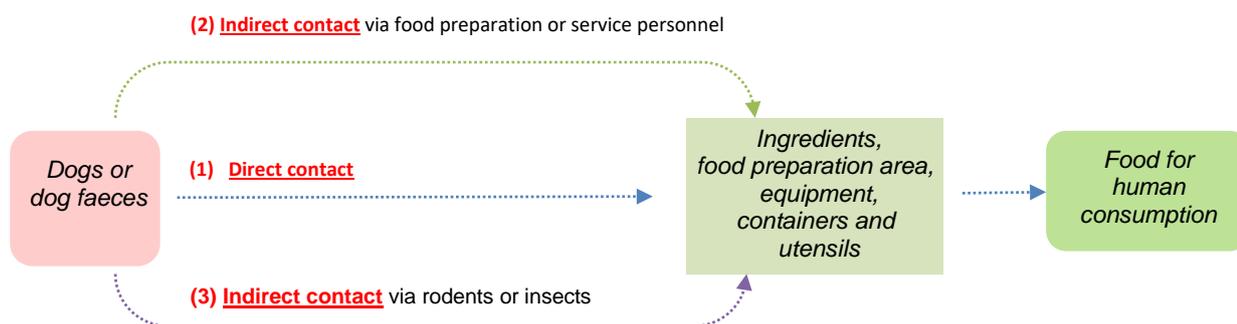


Figure 1: Mode of transmission of pathogens from infected dogs to food

A second possibility by which food could become contaminated with infectious faecal material of companion dogs is through the restaurant staff that prepares and/or serves food (scenario 2 shown in Figure 1). This route involves personnel handling or touching an infectious companion dog and then handling food or food preparation equipment or utensils without washing hands thoroughly. Therefore, in these circumstances food contamination would be due to unhygienic practices of food preparation or service personnel and not due to direct contact of dogs with food preparation areas. Clause 13 of Standard 3.2.2 requires a food handler not handle food or surfaces likely to come into contact with food in a way that is likely to compromise the safety and suitability of food. Clause 15 of Standard 3.2.2 requires a food handler must wash his or her hands whenever his or her hands are likely to be a source of contamination of food. Provided that the food preparation and service personnel and the food businesses comply with these requirements, transmission of pathogens from companion dogs through food via scenario 2 above is also unlikely.

A third route of food contamination could arise through rodents or insects acting as carriers of human pathogens (scenario 3 in Figure 1). However, the likelihood of this occurring is again dependent on the general hygiene, as well as pest management control measures, maintained by the food business. A food business is required to ensure its premises are kept clean (clause 19 of Standard 3.2.2 of the Code), to take all practicable measures to prevent pests entering the food premises, and to eradicate and prevent the harbourage of pests on the food premise (clause 24 of Standard 3.2.2 of the Code). Provided that food businesses comply with these requirements, transmission of pathogens to food via indirect contact with rodents or insects is also unlikely.

## 7. Assistance animals

Clause 24 of Standard 3.2.2 of the Code permits assistance animals to be present in dining, drinking or other areas of food establishments used by customers. This is to ensure compliance with the Commonwealth *Disability Discrimination Act (1992)*. Although assistance animals, such as guide dogs, present the same potential to carry zoonotic pathogens, these animals are generally thoroughly trained to follow a set of standard behaviour in public areas. Companion dogs which are not trained to this level of standard behaviour may present a slightly higher risk of transmitting zoonotic diseases to consumers through food if they were allowed in alfresco dining areas.

## Conclusion

The potential risk of foodborne transmission of zoonotic agents from companion dogs in outdoor dining settings to humans is considered to be very low to negligible. This is supported by the following factors:

- The likelihood of direct contact of food or food preparation areas with infected companion dogs or dog faeces is negligible as dogs would not ordinarily be allowed into food preparation areas.
- Acquiring diseases through indirect foodborne transmission routes requires the involvement of an intermediate vector. As illustrated in Figure 1, such vectors may include food preparation personnel, food service personnel or rodents/insects. A successful foodborne disease transmission through an intermediate vector is dependent on (1) a successful transmission of pathogens carried by companion dogs to an intermediate vector, and (2) a successful transmission of such pathogens to humans through food contaminated by the intermediate vector. Therefore the likelihood of acquiring diseases carried by companion dogs in outdoor dining areas involving an intermediate vector is predicted to be very low, because the probability of the occurrence of one event that is dependent on the occurrence of two consecutive events<sup>4</sup> is very low when the probabilities of the occurrence of the two consecutive events are themselves both low.
- Potential contamination of food directly from companion dogs, or indirectly through contaminated intermediate vectors, in outdoor dining settings is managed through compliance with general food safety standards and food safety management or control programs for restaurant food hygiene.
- Studies on human-dog interactions indicate that, in general, contact between people and dogs that are not their own pet/s is limited. This minimises the potential for contact and consequently the transmission of pathogens from dogs in outdoor dining settings to humans.

Zoonotic pathogens originating from companion dogs present in outdoor dining areas represent a theoretical foodborne disease risk to consumers dining in these settings in Australia. This risk may be slightly higher for young children and immune-compromised individuals. However, the overall level of food safety risk arising from the presence of companion dogs in such settings is expected to be very low to negligible. Adherence to good hygienic practices in food preparation and service, maintenance of cleanliness, and proper pest control by food businesses should contribute to the minimisation of any potential risk of foodborne transmission of pathogens potentially carried by companion dogs in outdoor dining areas.

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<sup>4</sup> The probability of the occurrence of one event ( $P_A$  for the probability of occurrence of event A) that is dependent on the occurrence of two consecutive events (event B and C) is the product of the probabilities of occurrence of the two consecutive events ( $P_B$  for the probability of occurrence of event B and  $P_C$  for the probability of occurrence of event C), i.e.  $P_A = P_B \times P_C$ .

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## APPENDIX 1: Symptoms of human diseases caused by zoonotic pathogens potentially carried by dogs<sup>5</sup>

Pathogen	Symptoms of human infection
<b>Bacteria</b>	
<i>Campylobacter</i> spp.	Both <i>Campylobacter jejuni</i> and <i>C. coli</i> cause diarrhoea, fever, abdominal pain, nausea, and headache and muscle pain in humans. Most symptoms caused by <i>Campylobacter</i> are self-limiting. <i>Campylobacter</i> are responsible for the highest number of gastroenteritis cases in humans in Australia. <i>Campylobacter</i> transmission to humans occurs primarily through food consumption, for example, consumption of unpasteurised milk, non-chlorinated water and undercooked poultry meat.
Shiga toxin-producing <i>Escherichia coli</i> (STEC)	Human illness caused by STEC is characterised by severe abdominal pain and diarrhoea, initially watery but becoming grossly bloody. Occasionally vomiting occurs. Fever is either low-grade or absent. The illness is usually self-limiting and lasts for an average of 8 days. More severe disease may be seen in children and immune-compromised persons, including haemolytic uraemic syndrome in children. STEC have been identified as the cause of some of the major foodborne outbreaks in Australia and overseas.
<i>Leptospira interrogans</i>	Various serovars of <i>L. interrogans</i> can cause leptospirosis in humans. Leptospirosis is most common in the tropics, and has recently been recognized as a re-emerging infectious disease among animals and humans. Leptospirosis begins with fever, chills, muscle aches, intense headache, and vomiting, followed by meningitis, liver damage and renal failure if not treated. The symptoms in humans appear after a 4–14 day incubation period.
<i>Salmonella</i> spp.	<i>Salmonella</i> infection causes acute enteritis and individuals can display nausea, vomiting, abdominal cramps, diarrhoea, fever, and headache. Infected individuals may develop arthritic symptoms 3-4 weeks after onset of acute symptoms. The onset time is 6-48 hours after infection. <i>Salmonella</i> spp. is a major cause of foodborne illnesses in Australia.
<i>Yersinia enterocolitica</i> and <i>Y. pseudotuberculosis</i>	Yersiniosis mainly occurs in these children younger than 5 years old and is frequently characterized as gastroenteritis, with diarrhoea and/or vomiting accompanied by fever and abdominal pain. A small proportion of children (less than 10%) produce bloody stools. <i>Yersinia</i> infections mimic appendicitis and mesenteric lymphadenitis, but the bacteria may also cause infection in other sites, such as wounds, joints, and the urinary tract. The illness might last from a few days to 3 weeks.
<b>Protozoa</b>	
<i>Cryptosporidium</i> spp.	The pathogen causes cryptosporidiosis in humans. Infected individuals may show symptoms 2 to 10 days after infection of watery diarrhoea, stomach cramps, dehydration, nausea, vomiting, and fever and weight loss. The symptoms usually last about 1 to 2 weeks, and may progress in cycles.
<i>Giardia</i> spp.	The pathogen causes giardiasis in humans. Infected individuals may show symptoms, mainly diarrhoea, 1 to 2 weeks after infection. Other symptoms include flatulence, greasy stools and stomach cramps and nausea. The symptoms usually last 2 to 6 weeks but can be persistent.
<b>Parasites</b>	
<i>Dipylidium</i> (dog tapeworm)  <i>Echinococcus</i> (dog tapeworm)	Human infection caused by <i>Dipylidium</i> (dog tapeworm) or <i>Echinococcus</i> (dog tapeworm) has not been shown to be foodborne. Dipylidiosis in humans is often asymptomatic but can result in anal itching and abdominal pain. In humans, <i>Echinococcus</i> infection may result in tissue cysts that can persist and grow for years. They are regularly found in the liver and are asymptomatic until their growing size produces symptoms or are accidentally discovered. Disruption of the cysts (spontaneous or iatrogenic) can be life threatening due to anaphylactic shock.
<i>Ancylostoma caninum</i> (dog hookworm)	Larvae of <i>A. caninum</i> typically enter a human host by skin penetration, although infection by oral ingestion is possible. These larvae probably remain dormant in skeletal muscles and create no symptoms. In some individuals, larvae may reach the gut and mature into adult worms. Adult worms secrete various potential allergens into the intestinal mucosa. Some patients have been reported to have increasingly severe recurrent abdominal pain, which may be analogous to a response to repeated insect stings.
<i>Toxocara canis</i> (dog roundworm)	Most infections mild and self-limiting. A proportion may result in larvae migrating to the eyes causing ocular larva migrans, which occurs most commonly in children 6-14 years old. In children younger than 5 years, roundworm larvae tend to migrate to the organs such as the lungs and liver.

<sup>5</sup> Information in the table was collected from various food safety risk assessments prepared by FSANZ and supplemented with data sourced from the website of U.S. Food and Drug Administration.



OFFICE OF THE MAYOR

CITY OF ST. PETERSBURG

RICK KRISEMAN, MAYOR

December 20, 2019

Conference for Food Protection  
2020 Biennial Meeting  
30 Elliott Court  
Martinsville, IN 46151-1331

**RE: Amend Food Code – Permit Pet Dogs in Outdoor Dining Areas**

To Whom It May Concern:

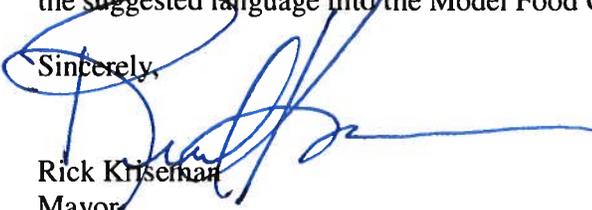
I write on behalf of the City of St. Petersburg, Florida to provide my strong support for the 2020 Issue Submission titled Amend Food Code – Permit Pet Dogs in Outdoor Dining Areas.

St Petersburg is committed to the highest standards in food safety to protect a consumer's health and well-being. We also recognize that pets are increasingly becoming an integral part of the family – in fact, more than 84 million American families have a pet. Restaurants that allow pet dogs into outdoor dining areas provide greater opportunities for people to bond with their pets and interact with other pet owners, which creates stronger communities and drives economic benefits for businesses. It is our opinion that if rigorous food safety requirements are incorporated in the Model Food Code, allowing pet dogs in a restaurant's outdoor dining area would pose little to no public health risks. A growing number of states across the country have come to this conclusion as well and have begun enacting policies that allow pet dogs to accompany their owners into outdoor dining areas.

Eighteen states and the District of Columbia have already enacted policies to allow pet dogs in outdoor dining areas – including California, Florida, Ohio, Mississippi, Tennessee, and Texas. However, each state has implemented different regulatory schemes, including differing signage and sanitation requirements. These differences have caused confusion for both customers and businesses. The proposed language would eliminate confusion by creating one national set of standards for businesses that wish to allow pet dogs in outdoor dining areas, while establishing strong regulatory requirements to ensure public safety.

The City of St. Petersburg urges the Conference for Food Protection to accept this Issue and incorporate the suggested language into the Model Food Code.

Sincerely,



Rick Kriseman  
Mayor  
City of St. Petersburg



MISSISSIPPI STATE DEPARTMENT OF HEALTH

December 31, 2019

Conference for Food Protection  
2020 Biennial Meeting  
30 Elliott Court  
Martinsville, IN 46151-1331

**RE: Amend Food Code – Permit Pet Dogs in Outdoor Dining Areas**

To Whom It May Concern:

I write on behalf of the Mississippi State Department of Health (MSDH) to provide our strong support for the standardized language for the Model Food Code outlined in the 2020 Issue Submission titled: Amend Food Code – Permit Pet Dogs in Outdoor Dining Areas.

MSDH is committed to the highest standards in food safety to protect a consumer's health and well-being. Until recently, MSDH enforced the existing prohibition on pet dogs in any dining area of a food establishment in the Model Food Code. In July 2019, unaware of the prohibition, the *Mississippi Clarion Ledger* published a list of restaurants that allow dogs in outdoor dining areas. MSDH responded to the article with a reminder that the Mississippi Food Code did not allow pets in outdoor dining areas, and that any restaurant allowing the same was in violation of the state Food Code. That response was published by the *Mississippi Clarion Ledger* and engendered a public outcry from residents and restaurants alike, who had not been aware of the prohibition, and were confused as to why a practice they were already doing successfully was, in fact, illegal. After considering public sentiment, and keeping food safety concerns paramount, MSDH ultimately decided to adopt a new policy. As of November 2019, restaurants in Mississippi can now apply for a variance from MSDH to allow pet dogs in outdoor dining areas.

Eighteen additional states and the District of Columbia have already enacted similar policies to allow pet dogs in outdoor dining areas. However, each state has implemented different regulatory schemes, including differing signage and sanitation requirements. These differences have caused confusion for both customers and businesses. The proposed language would eliminate confusion by creating one national set of standards for businesses that wish to allow pet dogs in outdoor dining areas, while establishing strong regulatory requirements to ensure public safety.

MSDH urges the Conference for Food Protection to accept this Issue and incorporate the standardized language into the Model Food Code.

Sincerely,

A handwritten signature in blue ink that reads "Thomas Dobbs".

Thomas Dobbs, MD, MPH  
State Health Officer

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-029**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Prohibiting Animals to Allow for Dogs in Outside Areas of Premises

**Issue you would like the Conference to consider:**

The premises of a food establishment includes outdoor seating areas such as patios, picnic tables and decks as the Food Code definition states.

"Premises" means:

- (1) The PHYSICAL FACILITY, its contents, and the contiguous land or property under the control of the PERMIT HOLDER; or
- (2) The PHYSICAL FACILITY, its contents, and the land or property not described in Subparagraph (1) of this definition if its facilities and contents are under the control of the PERMIT HOLDER and may impact FOOD ESTABLISHMENT personnel, facilities, or operations, and a FOOD ESTABLISHMENT is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

Section 6-501.115 does not address dogs in these outer areas. We are requesting that if a facility has adequate standard operating procedures, dogs could be allowed on the premises.

**Public Health Significance:**

Dogs are more prevalent and it has become customary for people to enjoy meals with their dogs. Dogs on patios and outdoor seating areas are noted throughout the country from Florida to Colorado. Jurisdictions are either turning a blind eye to dogs in these areas or they are issuing variances to allow them. In Wisconsin, we have issued almost 50 variances to allow dogs in outdoor seating areas with very specific requirements spelled out in the variance approval. Language includes:

- This variance applies to the exterior areas of outdoor dining of a restaurant only. Dogs are not allowed in the interior portions of the restaurant.
- A separate entrance is present where pets do not enter through the food establishment to reach the outdoor dining area.

- The facility shall provide signage alerting customers that dogs are allowed in outdoor seating areas. Signage provided and is deemed adequate.
- No food preparation shall be allowed at the outdoor dining area, including the dispensing/mixing of drinks and ice.
- Customer multi-use or reusable utensils such as plates, silverware, glasses and bowls shall not be stored, displayed or pre-set at the outdoor dining area.
- Food from the restaurant shall not be served to pets on the exterior portions of the outdoor dining areas of a restaurant. However, food provided by the dog owner for consumption by the dog on the premise of the restaurant shall be provided in single-use disposable containers and/or water provided by the restaurant shall be provided in single-use disposable containers.
- Employees shall be prohibited from having direct contact with pets while on duty.
- Pets shall not be allowed on chairs, seats, benches, and tables.
- The exterior areas of outdoor dining areas of a restaurant shall be maintained clean at all times
- In cases where excrement or other bodily fluids (urine, saliva, and vomit) are deposited, an employee shall immediately clean and sanitize the affected areas.
- The outdoor dining area shall not be fully enclosed (a fully enclosed dining area shall be considered to be part of the interior area of the facility).

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

That a letter be sent to the FDA requesting that Section 6-501.115 of the most current edition of the Food Code be amended as follows:

6-501.115 (B)

(6) Only dogs be allowed in outdoor areas of the premises if a food establishment has written procedures and prior approval from the REGULATORY AUTHORITY.

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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-030**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2016 I-046; new or additional information has been included or attached and the recommended solution has been revised.

**Title:**

Removing the Reference to Restricted Use Pesticides in 7-202.12(B)(2)

**Issue you would like the Conference to consider:**

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) governs the classifications of pesticides as general use or restricted use, called Restricted Use Pesticides (RUP).

7-202.12(B)(2) of the latest edition of the Food Code provides basic requirements to prevent contamination from Toxic or Poisonous Materials, which include pesticides, used in food establishments. However, the requirements in subparagraph (B)(2) are limited to Restricted Use Pesticides (RUPs).

Almost no pesticides being used in food establishments are RUPs.

For example, searching the Wisconsin Department of Agriculture, Trade and Consumer Protection pesticide registration site shows that there are no RUPs registered for use in "Restaurants," "Restaurants (residual Crack And Crevice Treatment)," "Restaurants (indoor Edible)," or "Drive in Restaurants (residual Crack And Crevice Treatment)," "Food Serving Areas", "Food Markets", and "Packaged Food (storage Areas)."

Although pesticides labeled for use in food establishments will have use directions that require taking precautions to prevent contamination of food or food contact surfaces, having the requirements in the Food Code directly eliminates the need to document the label use directions in instances where the precautions are not taken.

**Public Health Significance:**

Limiting the applicability of the listed precautions to Restricted Use Pesticides (RUPs) makes it more difficult to enforce those necessary precautions for all other pesticides, which constitute virtually the entirety of pesticides used in Food Establishments.

**Recommended Solution: The Conference recommends...:**

The Conference recommends that a letter be sent to FDA recommending that Section 7-202.12 of the Food Code be amended as follows:

7-202.12 Conditions of Use.

POISONOUS OR TOXIC MATERIALS shall be:

(A) Used according to:

(1) LAW and this Code,

(2) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a FOOD ESTABLISHMENT, <sup>P</sup>

(3) The conditions of certification, if certification is required, for use of the pest control materials, <sup>P</sup> and

(4) Additional conditions that may be established by the REGULATORY AUTHORITY; and

(B) Applied so that:

(1) A HAZARD to EMPLOYEES or other PERSONS is not constituted, <sup>P</sup> and

(2) Contamination including toxic residues due to drip, drain, fog, splash or spray on FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES is prevented, and for a ~~RESTRICTED-USE PESTICIDE~~, pesticide this is achieved by: <sup>P</sup>

(a) Removing the items, <sup>P</sup>

(b) Covering the items with impermeable covers, <sup>P</sup> or

(c) Taking other appropriate preventive actions, <sup>P</sup> and

(d) Cleaning and SANITIZING EQUIPMENT and UTENSILS after the application. <sup>P</sup>

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**Supporting Attachments:**

- "RUP Search Results"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*



### Search by Multiple Criteria

#### Search by Multiple Criteria

Enter/select a Site(Crop):  [\(open search-window for sites/crops\)](#) and

Enter/select a Pest:  [\(open search-window for pests\)](#) and

Enter/select Ingredient:  [\(open search-window for AI's\)](#) and

Select Pesticide Type:  and

Select Formulation:  and

Restricted Use (RUP) Only ?

(you may leave any of the above options blank to leave them out of the search)  
(if no results are found, use the 'select' functions to make sure that pest, site and AI are spelled accurately)

Product Name	EPA Reg. No.	Registration Status	Expiration Date
<a href="#">"Bug-X" 100 2.5 Permethrin Concentrate / Repellent</a>	1021-1758-11741	Full/Active	12/31/2019
<a href="#">10 Seconds Shoe Disinfectant &amp; Deodorizer</a>	44446-67-75242	Full/Active	12/31/2019
<a href="#">102 DIS Disinfectant Spray</a>	706-69-527	Full/Active	12/31/2019
<a href="#">128 E-Fecticide</a>	6836-365-5449	Full/Active	12/31/2019
<a href="#">14-0-0 Green Pro .2 Imidacloprid Professional Fertilizer</a>	53883-362-45065	Full/Active	12/31/2019
<a href="#">2,4-D Amine 4</a>	83520-13	Full/Active	12/31/2019
<a href="#">22 Express</a>	1022-596-71581	Full/Active	12/31/2019
<a href="#">90 Years of HTH Perfect Pools Blue Sparkle Skimmer Tabs</a>	1258-1371	Full/Active	12/31/2019
<a href="#">Absorbine Ultra Shield Flea &amp; Tick Collar</a>	1543-3	Discontinued	12/31/2019
<a href="#">Absorbine Ultra Shield Green Gel Natural Fly Repellent</a>	1543-25B	Discontinued	12/31/2019
<a href="#">Absorbine UltraShield Green Natural Fly Repellent for use on all Dogs</a>	1543-25B	Discontinued	12/31/2019
<a href="#">Absorbine UltraShield Green Wool Pouf Flea &amp; Tick Bath Pouf</a>	1543-25B	Discontinued	12/31/2019
<a href="#">Accel Concentrate</a>	74559-4	Full/Active	12/31/2019



### Search by Multiple Criteria

#### Search by Multiple Criteria

Enter/select a Site(Crop):  [\(open search-window for sites/crops\)](#) and

Enter/select a Pest:  [\(open search-window for pests\)](#) and

Enter/select Ingredient:  [\(open search-window for AI's\)](#) and

Select Pesticide Type:  and

Select Formulation:  and

Restricted Use (RUP) Only ?

(you may leave any of the above options blank to leave them out of the search)  
(if no results are found, use the 'select' functions to make sure that pest, site and AI are spelled accurately)

Product Name	EPA Reg. No.	Registration Status	Expiration Date
No records returned.			

Database Last Updated: 12/22/2019

Search By: [Company Name](#) [Company ID](#) [Product Name](#) [Product EPA ID](#) [Active Ingredient](#) [Pest](#) [Site](#) [Formulation](#) [Pest-Days](#) [RUP](#) [Multiple Criteria](#)



### Search by Multiple Criteria

#### Search by Multiple Criteria

Enter/select a Site(Crop):  [\(open search-window for sites/crops\)](#) and  
 Enter/select a Pest:  [\(open search-window for pests\)](#) and  
 Enter/select Ingredient:  [\(open search-window for AI's\)](#) and  
 Select Pesticide Type:  and  
 Select Formulation:  and

#### Restricted Use (RUP) Only ?

(you may leave any of the above options blank to leave them out of the search)  
 (if no results are found, use the 'select' functions to make sure that pest, site and AI are spelled accurately)

Product Name	EPA Reg. No.	Registration Status	Expiration Date
<a href="#">102 DIS Disinfectant Spray</a>	706-69-527	Full/Active	12/31/2019
<a href="#">105 Task Foaming Disinfectant Cleaner</a>	706-65-527	Full/Active	12/31/2019
<a href="#">22 Multi-Quat Sanitizer</a>	1677-198	Full/Active	12/31/2019
<a href="#">256 Century Q</a>	47371-129-5449	Full/Active	12/31/2019
<a href="#">3M Neutral Quat Disinfectant Cleaner Concentrate</a>	47371-129-10350	Full/Active	12/31/2019
<a href="#">3M Sanitizer Concentrate</a>	47371-147-10350	Full/Active	12/31/2019
<a href="#">4 Quat Sanitizer</a>	10324-81-82882	Full/Active	12/31/2019
<a href="#">4-Quat Sanitizer</a>	10324-81-43497	Full/Active	12/31/2019
<a href="#">64 Millennium Q</a>	1839-95-5449	Full/Active	12/31/2019
<a href="#">7 Select Bleach Regular Concentrate</a>	70271-24-92371	Full/Active	12/31/2019
<a href="#">ABC Extra Wipes</a>	6836-313-86339	Full/Active	12/31/2019
<a href="#">Ace 64 Neutral Disinfectant and Detergent</a>	10324-154-12120	Discontinued	12/31/2019
<a href="#">Acid Sanitizer FP</a>	10324-67-5741	Full/Active	12/31/2019
<a href="#">Acid-Free Neutral Disinfectant Washroom Cleaner</a>	1839-169-70627	Full/Active	12/31/2019
<a href="#">Acidquat 4</a>	10324-67-82882	Full/Active	12/31/2019
<a href="#">Acidquat Multi-Purpose Sanitizer</a>	10324-67-527	Full/Active	12/31/2019



### Search by Multiple Criteria

#### Search by Multiple Criteria

Enter/select a Site(Crop):  [\(open search-window for sites/crops\)](#) and  
 Enter/select a Pest:  [\(open search-window for pests\)](#) and  
 Enter/select Ingredient:  [\(open search-window for AI's\)](#) and  
 Select Pesticide Type:  and  
 Select Formulation:  and

#### Restricted Use (RUP) Only ?

(you may leave any of the above options blank to leave them out of the search)  
 (if no results are found, use the 'select' functions to make sure that pest, site and AI are spelled accurately)

Product Name	EPA Reg. No.	Registration Status	Expiration Date
No records returned.			

Database Last Updated: 12/22/2019

Search By: [Company Name](#) [Company ID](#) [Product Name](#) [Product EPA ID](#) [Active Ingredient](#) [Pest](#) [Site](#) [Formulation](#) [Pest-Code](#) [RUP](#) [Multiple Criteria](#)

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-031**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Person in Charge 2-103.11

**Issue you would like the Conference to consider:**

Last CFP (2018), the Conference voted to change the violation designation of 3-501.13 from Core to Priority Foundation. FDA has agreed with the designation. Thawing is another piece of the risk based inspection that should be controlled under Active Managerial Control.

**Public Health Significance:**

Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved. An important duty of the Person in Charge is to identify and ensure that any required temperatures are achieved or maintained when foods are cooked, cooled or held in a food establishment.

**Recommended Solution: The Conference recommends...:**

send a letter to FDA requesting the addition of language under 2-103.11 Person In Charge of the most current edition of the Food Code to include:

"(Q) EMPLOYEES are properly maintaining the temperatures of TIME/TEMPERATURE CONTROL FOR SAFETY FOODS during thawing through daily oversight of the EMPLOYEES' routine monitoring of FOOD temperatures; Pf

**Submitter Information:**

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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-032**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018-I-011; the recommended solution has been revised.

**Title:**

Whole Muscle Intact Beef Labeling

**Issue you would like the Conference to consider:**

The Food Code language with regard to Whole Muscle Intact labeling requirement be removed and language within the Food Code align with the Food Safety and Inspection (FSIS) labeling requirements of mechanically tenderized beef products.

On May 18, 2015, Food Safety and Inspection Services (FSIS) published a final rule to establish labeling requirements for raw or partially cooked mechanically tenderized beef products (Descriptive Designation of Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Product (80 FR 28153)). The rule amends the regulations by adding 9 CFR 317.2(e)(3).

The new labeling requirements provide household consumers, official establishments, restaurants, and retail stores the information they need to distinguish a cut of beef that is an intact, non-tenderized product, from a non-intact, mechanically tenderized product.

With this requirement, those cuts of beef that are not manipulated can be considered as WHOLE MUSCLE, INTACT BEEF if they are not labeled with the requirement as set forth by FSIS.

Field inspections of retail food establishments have shown that facilities are in compliance with the FSIS requirement and are meeting the labeling requirements of mechanically tenderized beef steak products.

**Public Health Significance:**

The requirement that steaks, to meet the lower cooking requirements of a surface temperature of 145 F with no consumer advisory, be labeled as WHOLE MUSCLE, INTACT BEEF no longer applies. As long as beef steak packaging does not have the required labeling, they can be considered WHOLE MUSCLE, INTACT BEEF.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends...*

That a letter be sent to the FDA requesting language with regard to Whole Muscle Intact labeling requirement be removed and language within the Food Code align with the Food Safety and Inspection (FSIS) labeling requirements of mechanically tenderized beef products.

**Submitter Information 1:**

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**Submitter Information 2:**

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Address: 2811 Agriculture DrivePO Box 8911  
City/State/Zip: Madison, WI 53708-8911  
Telephone: 414-369-9047  
E-mail: Katie.Matulis@Wisconsin.gov

**Supporting Attachments:**

- "FSIS Notice 33-17"
- "Steak labeling"

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UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
WASHINGTON, DC

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# FSIS NOTICE

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33-17

6/7/17

## VERIFYING LABELING OF DESCRIPTIVE DESIGNATION FOR NEEDLE- OR BLADE-TENDERIZED RAW BEEF PRODUCTS AS REQUIRED BY 9 CFR 317.2(e)(3)

### I. PURPOSE

This notice provides instructions for Office of Investigation, Enforcement and Audit (OIEA) Compliance and Investigations Division (CID) Investigators to verify whether retail stores are meeting labeling requirements for raw or partially cooked needle or blade tenderized beef as specified in [9 CFR 317.2\(e\)\(3\)](#), as instructed in [FSIS Directive 8010.1](#), *Methodology for Conducting In-Commerce Surveillance Activities*, Section IV.

### II. BACKGROUND

A. On May 18, 2015, FSIS published a final rule to establish labeling requirements for raw or partially cooked mechanically tenderized beef products ([Descriptive Designation of Needle- or Blade-Tenderized \(Mechanically Tenderized\) Beef Product \(80 FR 28153\)](#)). The rule amends the regulations by adding [9 CFR 317.2\(e\)\(3\)](#).

B. The new labeling requirements provide household consumers, official establishments, restaurants, and retail stores the information they need to distinguish a cut of beef that is an intact, non-tenderized product, from a non-intact, mechanically tenderized product.

### III. REQUIREMENTS OF THE FINAL RULE

A. Under [9 CFR 317.2\(e\)\(3\)](#) the product name for a mechanically tenderized beef product must contain a descriptive designation:

1. "Mechanically Tenderized" or, if needle tenderized the product can be described as "Needle Tenderized," or if blade tenderized, the product can be described as "Blade Tenderized."
2. The product name and the descriptive designation must be printed in a single easy-to-read type style and color and must appear on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than one-third (1/3) the size of the largest letter, and with no intervening text between the identity of the meat and the descriptive designation. The descriptive designation may be above, below, or next to the product name without intervening text or graphic on the principal display panel.

**NOTE:** See Attachment for label examples.

B. The labels of raw or partially cooked needle- or blade-tenderized raw beef products destined for household consumers, hotels, restaurants, or similar institutions must also bear validated cooking instructions. Validated cooking instructions must include, at a minimum:

1. The cooking method (e.g. grill or bake);

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**DISTRIBUTION:** Electronic

**NOTICE EXPIRES:** 6/1/18

**OPI:** OPPD

2. That these products need to be cooked to a specified minimum internal temperature;
3. Whether these products need to be held for a specified time at that temperature or higher before consumption to ensure that potential pathogens are destroyed throughout the product; and
4. A statement that the internal temperature should be measured by a thermometer.

**NOTE:** The validated cooking instructions may appear anywhere on the label. An example of an instruction that contains these minimum elements is "Grill until product reaches 145°F, as measured by a food thermometer, and hold the product at or above that temperature for 3 minutes."

C. Beef products that are not subject to the requirements of the final rule include:

1. Non-intact beef products that are clearly non-intact (e.g. ground beef patties, hamburger patties, or beef patties).
2. Beef products that are tenderized by other than needle and blade, such as pounding or cubing, which visibly changes the appearance of the product (e.g. cubed beef steak).
3. Any beef product that has been fully cooked.
4. Raw or partially cooked products labeled as "Corned Beef" that have been mechanically tenderized (including through injection of a solution).
5. Raw mechanically tenderized beef products that are less than 1/8" thick, such as, beef bacon or carne asada, or raw mechanically tenderized beef products that are diced, such as stew meat.

#### **IV. APPLICABILITY AT RETAIL STORES**

When retail stores produce and package or repackage raw or partially cooked needle- or blade-tenderized raw beef products, the retail label must comply with [9 CFR 317.2\(e\)\(3\)](#) with the exception of products wrapped in butcher paper or placed in a carry-out container at a retail store upon a consumer's request.

#### **V. OIEA COMPLIANCE INVESTIGATOR (CI) RESPONSIBILITIES IN A RETAIL STORE THAT PRODUCES AND PACKAGES OR REPACKAGES MECHANICALLY TENDERIZED RAW BEEF**

A. If a retail store packages or repackages raw or partially cooked needle- or blade-tenderized raw beef product that was produced at an official establishment, the CI is to verify that the descriptive designation and validated cooking instructions from the incoming product label appear on the retail label and comply with [9 CFR 317.2\(e\)\(3\)](#).

B. If a retail store produces and packages raw or partially cooked needle- or blade-tenderized, the CI is to verify that the retail store is complying with the requirements in [9 CFR 317.2\(e\)\(3\)](#), including verification that the retail store has the appropriate supporting documentation to validate the cooking instructions provided on the label. NOTE: If the CI has questions regarding the adequacy of the support, they are to seek guidance from their immediate supervisor or submit a question via [askFSIS](#).

C. CIs are to be aware that retail stores may wish to include additional information within the validated cooking instructions that will make the labels more useful to consumers; however, FSIS does not require additional information on the product labels. For example, retail stores may wish to include the temperature setting of the cooking device, time to complete cooking, whether the product needs to be flipped during cooking, the amount of time to cook on each side exposed to the heat source, recommendations to thaw the product, if applicable, or recommendations to measure the temperature in thickest part of the product, etc.

D. When a CI observes labeling that does not meet the requirements in [9 CFR 317.2\(e\)\(3\)](#), he or she is to document the violation in accordance with [FSIS Directive 8010.4](#), *Report of Investigation*, recommending issuance of a Notice of Warning.

## VI. QUESTIONS

Refer questions regarding this notice to the Labeling and Program Delivery Staff through [askFSIS](#). When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Notice 33-17**  
Question Field: Enter your question with as much detail as possible.  
Product Field: Select **Labeling** from the drop-down menu.  
Category Field: Select **Labeling Regulations, Policies and Claims** from the drop-down menu.  
Policy Arena: Select Domestic (U.S.) Only from the drop-down menu.

When all fields are complete, press Continue and at the next screen press Finish Submitting Question.

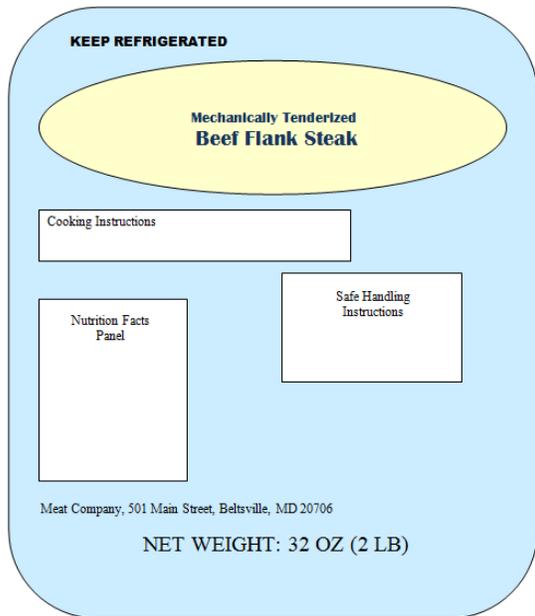
**NOTE:** Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



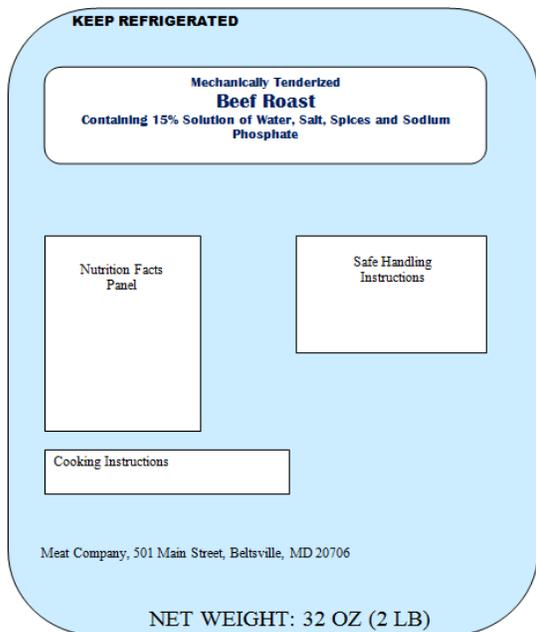
Assistant Administrator  
Office of Policy and Program Development

**EXAMPLES OF LABELS ON BEEF PRODUCTS PRODUCED AND PACKAGED OR RE-PACKAGED AT A RETAIL STORE**

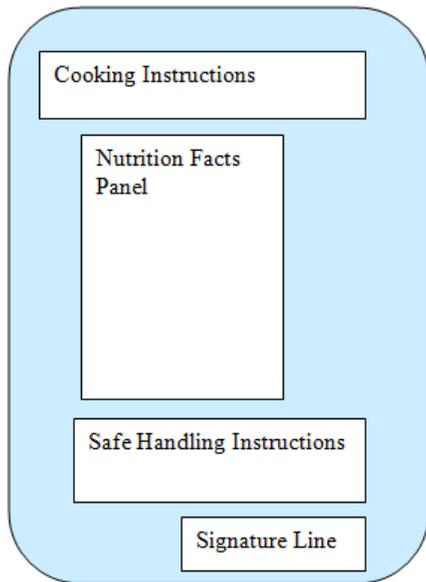
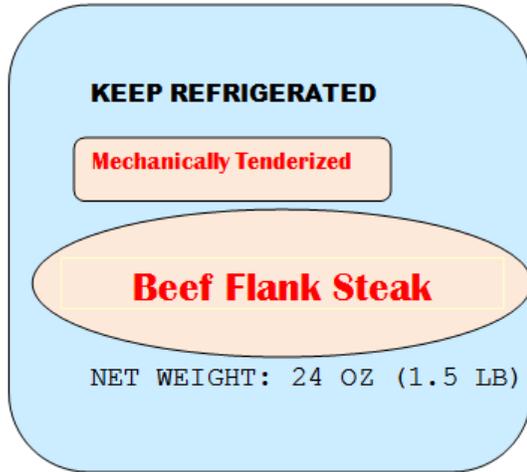
1. A mechanically tenderized flank steak label with all required information:



2. A mechanically tenderized beef roast with added solution label with all required information:



3. The principal display panel and information panel for a mechanically tenderized flank steak:



7  
**5418**

**USDA SELECT CENTER CUT B**  
**TOP SIRLOIN BUTT STEAK**

MECHANICALLY TENDERIZED

UP TO 12% OF A SEASONING SOLUTION OF WATER, RICE STARCH AND

PROZEN

**NET WT. 30.00 LB**

COOKED TO 145°F. REHEATED BY A FOOD THERMOMETER, AND SERVED WITHIN 30 MINUTES

**5033 V**

**USDA SELECT BEEF LOIN  
T - BONE STEAKS**

**MECHANICALLY TENDERIZED**

AINS UP TO 18% OF A SOLUTION OF WATER, SEASONING (SALT, HYDROLYZED SOY PROTEIN, DEXTROSE  
A POWDER, GARLIC POWDER, SPICES, ASCORBIC ACID, SPICE EXTRACTIVES), SODIUM PHOSPHATES, IS  
PRODUCT, FLAVOR (WATER, BEEF STOCK, SALT, HYDROLYZED CORN PROTEIN, DISODIUM INOSINATE AN  
ANYLATE, THIAMINE HYDROCHLORIDE), MODIFIED FOOD STARCH.  
CONTAINS: SOY

**KEEP FROZEN NET WT. 29.25 LBS**

AND HOLD TIME

GRILL UNTIL PRODUCT REACHES 145°F. AS MEASURED BY A FOOD THERMOMETER, AND HOLD THE  
PRODUCT AT OR ABOVE THAT TEMPERATURE FOR 3 MINUTES.

28.96

IS  
CT  
BEF

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-033**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Designated Areas to Include Vaping

**Issue you would like the Conference to consider:**

6-403.11 (A) only addresses designated areas for employees to eat, drink and use tobacco. It does not address vaping under the requirement for designated areas.

**Public Health Significance:**

Vaping is becoming increasingly popular and is the act of inhaling and exhaling the aerosol, often referred to as vapor, which is produced by an e-cigarette or similar device. The term is used because e-cigarettes do not produce tobacco smoke, but rather an aerosol, often mistaken for water vapor, that actually consists of fine particles. Not all vaping includes tobacco and therefore it has been difficult to enforce separate and designated areas.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

That a letter be sent to the FDA requesting that Section 6-403.11 (A) of the most current edition of the Food Code be amended as follows:

(A) Areas designated for EMPLOYEES to eat, drink, and use tobacco or vape shall be located so that FOOD, EQUIPMENT, LINENS, and SINGLESERVICE and SINGLE-USE ARTICLES are protected from contamination.

**Submitter Information 1:**

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-034**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Eating, Drinking, or Using Tobacco to Include Vaping

**Issue you would like the Conference to consider:**

2-401.11 Eating, Drinking or Using Tobacco does not include vaping. We would like vaping to be included in the current version of the FDA Food Code.

**Public Health Significance:**

Vaping is becoming increasingly popular and is the act of inhaling and exhaling the aerosol, often referred to as vapor, which is produced by an e-cigarette or similar device. The term is used because e-cigarettes do not produce tobacco smoke, but rather an aerosol, often mistaken for water vapor, that actually consists of fine particles. Not all vaping includes tobacco and therefore it has been difficult to enforce separation.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

That a letter be sent to the FDA requesting that Section 2-401.11 (A) of the most current edition of the Food Code be amended as follows:

(A) Except as specified in ¶ (B) of this section, an EMPLOYEE shall eat, drink, vape or use any form of tobacco only in designated areas where the contamination of exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES; or other items needing protection can not result.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 I-035**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

When to Wash to Include Vaping

**Issue you would like the Conference to consider:**

Vaping is on the rise and it should be reflected in the Food Code as an incident that would require employee handwashing. The current code does not include vaping in 2-304.14 (D). (D) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking; <sup>P</sup>

**Public Health Significance:**

Vaping is the act of inhaling and exhaling the aerosol, often referred to as vapor, which is produced by an e-cigarette or similar device. The term is used because e-cigarettes do not produce tobacco smoke, but rather an aerosol, often mistaken for water vapor, that actually consists of fine particles. Contamination of hands can occur through the act of vaping as it can when smoking.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends...*

That a letter be sent to the FDA requesting that Section 2-304.14 (D) of the most current edition of the Food Code be amended as follows:

(D) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, vaping, or drinking; <sup>P</sup>

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-001**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

FPMCC Final Report - Food Protection Manager Certification Committee

**Issue you would like the Conference to consider:**

Acknowledging the Food Protection Manager Certification Committee (FPMCC) final report with attachments and extending thanks to the Committee members for their work.

**Public Health Significance:**

The credentialing process for *Certified Food Protection Managers* assists in the protection and promotion of food safety by carefully determining the competencies necessary to prevent foodborne illness, unbiased education and training for acquisition of competencies necessary to maintain food safety, and fair assessment practices to ensure that individuals have achieved mastery of these competencies.

**Recommended Solution: The Conference recommends...:**

The Conference recommends acknowledgement of the 2018 - 2020 Food Protection Manager Certification Committee (FPMCC) Final Report and thanking the committee members for their work.

The Conference further recommends the continuation of the following charge (from Issue #: 2018 II-009) assigned to the Food Protection Manager Certification Committee (FPMCC), a standing committee, for the 2020-2022 biennium:

*To carry out charges assigned via the Conference Issue process and from the Conference Executive Board relating to food protection manager certification and to adopt sound, uniform accreditation standards and procedures that are accepted by the Conference while ensuring that the conference Standards for Accreditation for Food Protection Manager Certification programs and the accreditation process are administered in a fair and responsible manner.*

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**Submitter Information 2:**

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City/State/Zip: San Antonio, TX 78218  
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E-mail: wood.sharon@heb.com

**Content Documents:**

- "Attachment I\_FPMCC Final Report"
- "Attachment II\_FPMCC Final Roster Nov2019"
- "Attachment III\_CFP FPMCC Standards Version 1.9.2020"
- "Attachment IV\_FPMCC Bylaws 2019"

**Supporting Attachments:**

- "2018-09-18 FPMCC Conference Call minutes"
- "2018 Fall Meeting San Diego minutes"
- "2019 Spring Meeting Austin minutes"
- "FPMCC 2019 Fall Meeting Pittsburgh minutes"
- "FPMCC CFP Communication Outreach PowerPoint 10.24.19"
- "Revised FAQ for CFP Website 10.24.19"

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## Conference for Food Protection – Committee FINAL Report

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

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**COMMITTEE NAME:** *Food Protection Manager Certification Committee (FPMCC)*

**DATE OF FINAL REPORT:** 10.31.19

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

**REPORT SUBMITTED BY:** Sean Dunleavy, Chair and Sharon Wood, Vice Chair

### COMMITTEE CHARGE(S):

The FPMCC exists to carry out charges assigned via the Conference Issue process and from the Conference Executive Board relating to food protection manager certification. The objective of this standing committee is to adopt sound, uniform accreditation standards and procedures that are accepted by the Conference while ensuring that the conference Standards for Accreditation for Food Protection Manager Certification programs and the accreditation process are administered in a fair and responsible manner.

### COMMITTEE WORK PLAN AND TIMELINE:

The standing charge for this committee is stated above and work on this charge began with a conference call in September 2018. This initial call in September was used to welcome committee members and align on committee activities and outputs.

### COMMITTEE ACTIVITIES:

- |                       |                                      |
|-----------------------|--------------------------------------|
| 1. September 18, 2018 | Conference Call                      |
| October 23-24, 2018   | Face to Face meeting – San Diego, CA |
| March 26, 2019        | Conference Call                      |
| April 11 – 12, 2019   | Face to Face meeting – Austin, TX    |
| September 9, 2019     | Conference Call                      |
| October 15 – 16       | Face to Face meeting – Pittsburg, PA |

2. **Overview of committee activities:** While there were no new charges for the FPMCC, the standing charges were completed as follows:

- The Standards Workgroup of the FPMCC completed their work under the leadership of Kate Piche. The Workgroup did this through email assignments, meeting twice in person during the FPMCC face to face meetings and holding one web conference on July 31, 2019. The Standards for Accreditation of Food Protection Manager Certification Programs was reviewed, edited and discussed. Among the recommended changes will be changing the title word “Standards” to read “Standard”. If approved, this will have affects on other CFP references made to this document. (See Issue 1: Attachment III\_CFP Food Protection Manager Certification Standards version 1.9.2020)
- The Bylaws Workgroup of the FPMCC completed their work under the leadership of Jeff Hawley. The Workgroup had calls on 3/19, 4/3, 5/22 and 6/13. Additionally, they met in person on 4/11 during our FPMCC meeting. Most of the work was done by email correspondence. New language was added in Article VI, Sections 2 and 5. This Workgroup was also assigned the task of reviewing and making recommendations to the Board regarding the contract between CFP and ANSI. This work was completed, reviewed with the Committee and presented to the Board at the Fall Board meeting for actions and next steps. (See Issue 1: Attachment IV\_Revised FPMCC Bylaws 2019)
- The Communications Workgroup of the FPMCC was led by Tara Paster Cammarata. The focus of this Workgroup was to continue to build upon the informational PowerPoint deck that was approved last biennium to be posted on the CFP website. Four teams were formed as follows:

**Team 1:** - Define and create illustrations for Certificate vs. Certification and Food Employee vs. Person-in-Charge

**Team 2:** - FAQ review and update – (See below for Board Request)

**Team 3:** - Information Sharing PowerPoint – (See below for Board Request)

**Team 4:** - Information Outreach Plan: Abstract Submission – (See below for Board Request) – A CFP member survey was created and approved by the FPMCC for submission to the Board. The request is that this survey be distributed by Board leadership prior to the 2020 Biennial Meeting and data be collected to assist in better understanding educational outreach preferences of members. The FPMCC has a psychometrician on the committee that has offered to collect and analyze the data and report back to the Board as appropriate.

## Conference for Food Protection – Committee FINAL Report

The survey is the first step prior to developing the Information Outreach Plan and this will be completed in the next biennium. The Information Outreach Plan will include various elements such as social media, links, blog, other organizations (interaction to leverage distribution channels).

A call with the Board leadership on recommended next steps will determine follow up actions. (See Issue 1: Attachment V\_FPMCC Communication Outreach PowerPoint 10.24.19)

- The Logistics Workgroup of the FPMCC was lead by Geoff Luebkekmann. The Workgroup conducted approximately 24 vendor calls during this biennium to plan and execute FPMCC meetings on 10-23-2018 (San Diego), 04-11-2019 (Austin), and 10-15-2019 (Pittsburgh). Additionally, Logistics produced meeting minutes for each of these meetings as well as conference call meetings conducted on 09-18-2018 and 09-09-2019. Lastly, on 10-15-2019 Logistics surveyed the FPMCC members present for the FPMCC 2019 Fall Meeting (Pittsburgh) to obtain feedback on FPMCC meeting planning, communication, and execution.

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

See above

### 4. **Charges INCOMPLETE and to be continued to next biennium:**

Not Applicable

## 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.**
- 1. To repost the Educational PowerPoint on the CFP website with newly added notes in the notes section of slides.
- 2. To review the revised FAQ document which was edited and updated and if approved, post on the CFP website.
- 3. Review a proposed CFP member survey and if approved, distribute prior to the upcoming 2020 Biennial meeting.

## LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

### 1. Issue #1: Report – Food Protection Manager Certification Committee

List of content documents submitted with this Issue:

- (1) Committee Final Report (see attached PDF)
- (2) Committee Member Roster (see attached PDF)
- (3) CFP FPMCC Standards Version 1.9.2020 (see attached PDF)
- (4) FPMCC Bylaws 2019 (see attached PDF)

### 2. List of supporting attachments: No supporting attachments submitted

- 2018 Fall Conference Call Minutes
- 2018 Fall Meeting Minutes – San Diego
- 2019 Spring Meeting Minutes - Austin
- 2019 Fall Meeting Minutes – Pittsburgh
- FPMCC CFP Communication Outreach PowerPoint 10.24.19
- Revised FAQ for CFP Website 10.24.19

### 3. Committee Issue #2:

FPMCC Standards for Accreditation of Food Protection Manager Certification

### 4. Committee Issue #3

FPMCC - Bylaw Revisions

**Committee Name: FOOD PROTECTION MANAGER CERTIFICATION revised 09-23-2019**

Last Name	First Name	Position	Vote / Non-vote	Constituency	Employer	City	State	Telephone	Email
Dunleavy	Sean	Chair	Non-Voting	State Regulator	Michigan Department of Agriculture and Rural Development	Lansing	MI	517-243-8895	dunleavys@michigan.gov
Wood	Sharon	Vice Chair	Voting	Retail Food Industry	H-E-B	San Antonio	TX	210-938-6511	wood.sharon@heb.com
Algeo	Susan	Member	Voting	Food Industry Support	Savvy Food Safety, Inc.	MD	MD	855-644-3787	susan@savvyfs.com
Anderson	Tom	Member	Voting	CERT ORG - 360 new	360 Training	Austin	TX	512-212-7343	tom.anderson@360training.com
Borwegen	Dawn	Member	Voting	State Regulator	Wyoming Department of Agriculture	Dubois	WY	307-455-3144	dawn.borwegen@wyo.gov
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Dela Cruz	Hector	Member	Voting	Local Regulator	Los Angeles County Environmental Health	Panorama City	CA	818-672-2230	hsdelacruz@gmail.com
Derr	Samuel	Member	Voting	TRAINING (he incorrectly listed Academia)	Elite Food Safety Training	Naperville	IL	630-776-3430	sderr@elitefoodsafety.com
Guzzle	Patrick	Member	Voting	AT LARGE	Consultant / Training		ID	208-371-0485	plguzzle@gmail.com
Halbrook	Courtney	Member	Voting	Food Service Industry	Topgolf	Dallas	TX	704-236-0890	courtney.halbrook@topgolf.com
Hawley	Jeff	Member	Voting	Retail Food Industry	Harris Teeter	Matthews	NC	704-844-3098	jhawley@harristeeter.com
Hussein	Sima	Member	Voting	Food Industry Support - INDEPENDENT	Ecolab	Greensboro	NC	336-931-2625	sima.hussein@ecolab.com
Kender	Linda	Member	Voting	ACADEMIA	Johnson & Wales University, CCA	Providence	RI	401-598-1278	lkender@jwu.edu
Kramer	Gina	Member	Voting	Food Industry Support - AT LARGE	Savour Food Safety International, Inc.	Worthington	OH	614-507-5105	gina@savourfoodsafety.com

Luebkekmann	Geoffrey	Member	Voting	Food Service Industry	Florida Restaurant & Lodging Association	Tallahassee	FL	850-224-2250	gluebkekmann@frla.org
Corchado	Liz	Member	Voting	Food Industry Support - CERT ORG	National Registry of Food Safety Professionals	Orlando	FL	407-352-3830 ext. 48126	lcorchado@nrfsp.com
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Paster	Tara	Member	Voting	Food Industry Support - TRAINING	Paster Training, Inc.	Gilbertsville	PA	610-970-1776	tara.paster@pastertraining.com
Piche	Kate	Member	Voting	Food Industry Support - CERT ORG	National Restaurant Association / ServSafe	Chicago	IL	312-261-5348	kpiche@restaurant.org
Quam	Susan	Member	Voting	Food Industry Support - AT LARGE	Wisconsin Restaurant Assoc.	Madison	WI	608-270-9950	squam@wirerestaurant.org
Roughan	George	Member	Voting	Food Industry Support - TRAINING	TAP Series	Westlake Village	CA	818-889-8799 x 101	gr@tapseries.com
Smith	Melissa	New proposed Member post sign up via Dave		Food Industry Support At Large	eFoodHandlers	Portland	OR	503-729-5667	melissa.smith@efoodhandlers.com
Smith	Terri	Member	Voting	Retail Food Industry	Publix Supermarkets	Lakeland	FL	813-404-6111	terri.smith2@publix.com
Straughn	Ki	Member	Voting	Local Regulator - AT LARGE	Public Health Seattle & King County	Bellevue	WA	206-263-8088	kstraughn@kingcounty.gov
Tyjewski	Susan	Member	Voting	Food Service Industry - FOODSERVICE	CKE Restaurants Holdings, Inc.	Rancho Cucamonga	CA	714-254-4552	styjewski@ckr.com
Beckham	Renee	Member	Voting	Local Regulator	Houston Health Department	Houston	TX	832-393-5133	Renee.beckham@houstontx.gov
Brown	Lydia	Member	Voting	State Regulator - AT LARGE	RIDOH Center for Food Protection	Providence	RI	401-222-7723	lydia.brown@health.ri.gov
Hilton	DeBrena	Member	Voting	Local Regulator - AT LARGE	Tulsa Health Department	Tulsa	OK	918-595-4302	dhilton@tulsa-health.org
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Conley	Mark	Member	Voting	Food Industry Support	National Restaurant Association	Chicago	IL	312-676-7106	mconley@restaurant.org
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# Conference for Food Protection

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## Standards for Accreditation of Food Protection Manager Certification Programs

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### Preamble

The Conference for Food Protection, hereinafter referred to as the CFP, is an independent voluntary organization that has identified the essential components of a nationally recognized Food Protection Manager *Certification* Program and established a mechanism to determine if *certification organizations* meet ~~these~~ this Standards. The CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs ~~are~~ is intended for all *legal entities* that provide *certification* for this profession. The Standards ~~have~~ has been developed after years of CFP's research into, and discussion about, Food Protection Manager *Certification* Programs.

All *certification organizations* attesting to the *competency* of Food Protection Managers, including *regulatory authorities* that administer and/or deliver *certification* programs, have a responsibility to the individuals desiring *certification*, to the employers of those individuals, and to the public. *Certification organizations* have as a primary purpose the evaluation of those individuals who wish to secure or maintain Food Protection Manager *Certification* in accordance with the criteria and Standards established through the CFP. *Certification organizations* issue *certificates* to individuals who meet the required level of *competency*.

The professionals involved in the credentialing process for *Certified Food Protection Managers* shall recognize that the justification for regulating entrance to the occupation of *Certified Food Protection Manager* is to:

- protect and promote food safety for the welfare of the public;
- ensure that the responsibility and liability for overseeing the protection of safety and welfare of the public lies with those governmental jurisdictions at the Federal, state and local levels having the power to set forth laws regulating entrance to and performance in this occupation;
- ensure that the rights of the public at large and of those members of the public who wish to enter this occupation shall be balanced in terms of fairness and due process in the form of a credentialing process for admitting qualified persons to perform in that occupation; and
- ensure that the *validity* of the credentialing process for *Certified Food Protection Manager* is dependent on unbiased application of all aspects of that process, requiring careful determination of the competencies necessary to prevent foodborne illness,

unbiased education and training for acquisition of those competencies, and fair assessment practices to ensure that individuals have achieved mastery of the competencies.

Therefore, professionals involved in the credentialing process for *Certified Food Protection Manager* accept responsibilities based on these considerations.

The CFP Standards ~~are~~ is based on nationally recognized principles used by a variety of organizations providing *certification* programs for diverse professions and occupations. *Accreditation*, through the process recognized by CFP, indicates that the *certification organization* has been evaluated by a third-party *accrediting organization* and found to meet or exceed all of the CFP's established Standards.

To earn *accreditation*, the *certification organization* shall meet the following CFP Standards and provide evidence of compliance through the documentation requested in the application. In addition, the *certification organization* shall agree to abide by *certification* policies and procedures, which are specified by the CFP Food Protection Manager *Certification* Committee, hereinafter referred to as the FPMC Committee, approved by the CFP, and implemented by the *accrediting organization*.

The *accrediting organization* shall verify and monitor continuing compliance with the CFP Standards through the entire *accreditation* period. The CFP FPMC Committee will work directly with the *accreditation organization* to enhance and maintain *certification* policies and procedures that meet the specific needs of Food Protection Managers while ensuring a valid, reliable and *legally defensible* evaluation of *certification* programs.

The American National Standards Institute (ANSI) was selected as the *accrediting organization* for the CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs and assumed its duties in January 2003. The CFP FPMC Committee continues to work within the Conference structure to monitor the criteria and selection process for the organization serving as the accrediting body for Food Protection Manager *Certification* Programs.

The CFP strongly encourages regulatory authorities and other entities evaluating credentials for Food Protection Managers to recognize and endorse these Standards and the *accreditation* process. The CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs provides the framework for universal acceptance of individuals who have obtained their credentials from an *accredited certification program*. In the U.S Food and Drug Administration's Food Code, hereinafter referred to as the

FDA Food Code, Section 2-102.20 recognizes Food Protection Manager *certificates* issued by an *accredited certification program* as one means of meeting the FDA Food Code's "Demonstration of Knowledge" requirement in Section 2-102.1: and as satisfying the requirement of section 2-102.12 for the Person in Charge to be a certified food protection manager.

Please note that words that appear in italics are defined terms.

## Modifications and Improvements

The FPMC Committee followed the Conference directive to use the 1996 conference working document, Standards for Training, Testing and *Certification* of Food Protection Managers, in the development of accreditation standards. Extensive revision of this document was presented to CFP's 2012 Biennial Meeting of the Conferences for Food Protection under the title, Standards for *Accreditation* of Food Protection Manager *Certification* Programs.

The charge to the FPMC Committee from the 2010 Biennial Meeting of the Conference for Food Protection resulted in revisions to the Standards to enhance the integrity of the entire examination process, which included identification and analysis of root causes of security violations and implementation of solutions.

The revision and reformatting of the document were made after a comprehensive FPMC Committee review of each section. This revision of the Standards for *Accreditation* of Food Protection Manager *Certification* Programs:

1. adds and improves definitions that are more precise and more consistent with terminology and definitions used in the *psychometric* community and by *accreditation* organizations;
2. reorganizes Standards to eliminate duplication and align with purpose;
3. modifies or creates Standards to better address professional credibility and training of *test administrators/proctors*; handling of examination packages; shipping irregularities; location (site) irregularities; and breach of the *certification organization's test administrators/proctor's* protocols and requirements;
4. uses "*test administrator/proctor*" in the Standards to indicate duties for both "*test administrator*" and "*proctor*;" and
5. adds a standard for management systems.

## **Annexes**

[Annex A is the result of the deliberation and recommendations from the FPMCC from the 2016 Biennial Meeting of the Conference for Food Protection, and represents the process and requirements for CFP to recognize a certification body that is accredited by ANSI under the ISO/IEC 17024 STANDARD.](#)

~~The annex located at the back of the document~~ [Annex B](#) is **NOT not** part of the Standards, but provides information to guide those responsible for implementing or reviewing Food Protection Manager *Certification* Programs. ~~The~~ [This](#) annex provides guidelines for specific responsibilities that affect the effective implementation of the Conference Standards for *Accreditation* of Food Protection Manager *Certification* Programs.

[Annex B](#) ~~A~~ provides guidance to regulatory authorities that incorporate Food Protection Manager *Certification* as part of their requirements to obtain or retain a permit to operate. The CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs is designed to be a set of voluntary unifying national standards providing a mechanism for the universal acceptance of food protection managers who obtain their *certificates* from an *accredited certification program*.

Over the past twenty-five years, many regulatory authorities have developed their own Food Protection Manager *Certification* Programs. This has resulted in a variety of ~~S~~standards for *certification* programs. The CFP ~~national~~ Standards for universal acceptance of *Certified Food Protection Managers* provide regulatory authorities reliable and *legally defensible* criteria for evaluating *certification* programs. In addition, they eliminate duplication of testing and additional cost for the industry.

*Regulatory authorities* that may not be in a position to eliminate their existing programs are encouraged to recognize food protection managers certified in accordance with ~~these~~ this Standards as fulfilling their program requirements. Annex A ~~B~~ provides additional guidance, developed through the CFP, for the implementation of these regulatory *certification* programs.

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## SECTION 1.0 - DEFINITIONS

### 1.0 Definitions.

- 1.1 **Accreditation** means that an *accrediting organization* has reviewed a Food Protection Manager *Certification* Program and has verified that it meets Standards set by the CFP as set forth in this document. ~~(a review of a certification organization by an independent organization using specific criteria, to verify compliance with the Food Protection Management Certification Program Standards).~~
- 1.2 **Accrediting organization** means an independent organization that determines whether a Food Protection Manager *Certification* Program meets the Standards set by the CFP.
- 1.3 **Accredited certification program** means a Food Protection Manager *Certification* Program that has been evaluated and listed by an *accrediting organization* as being in conformity with ~~accepted by the CFP and has met~~ the CFP Standards for such programs as set forth in this document. This does not refer to training functions or educational programs.
- A. ~~refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, continued proficiency, discipline, and grievance procedures; and examination development and administration.~~
- B. ~~does not refer to training functions or educational programs.~~
- 1.4 **Algorithm** means a set of procedures or rules pertaining to the selection of questions on an examination.
- 1.5 **Certificate** means documentation issued by a *certification organization*, verifying that an individual has complied with the requirements of an *accredited certification program*.
- 1.6 **Certification** means the process wherein a *certificate* is issued.
- 1.7 **Certification organization** means an organization that provides a *certification* program and issues the *certificate*.
- 1.8 **Certified Food Protection Manager** means a person who has successfully passed an accredited ~~food safety certification examination-accredited under these Standards,~~ demonstrating that he/she has the *knowledge, skills and abilities (KSA's)* required to protect the public from foodborne illness.

- 1.9 Competency** means a defined combination of *knowledge, skills and abilities (KSA's)* required in the satisfactory performance of a job.
- 1.10 Competency examination** means an instrument that assesses whether an individual has attained at least a the minimum level of *competency* ~~that has been determined to be~~ necessary to perform effectively and safely in a particular occupation or job. ~~It shall be based on a thorough analysis of requirements for safe and effective performance.~~
- 1.11 Computer-adaptive testing (CAT)** means a method of *computer-based testing* that uses *algorithms* ~~based on the statistics of the examination questions~~ to select items at various difficulty levels to determine the an examinee's proficiency ~~by selecting items at various difficulty levels.~~
- 1.12 Computer-based testing (CBT)** means an examination administered on a computer.
- 1.13 Continued proficiency** means a *certification organization's* process or program designed to assess continued *competence* and/or enhance the *competencies* of *Certified Food Protection Managers*.
- 1.14 Demographic data, in this context,** means the ~~statistical data of a population, especially the data concerning age, gender, ethnic distribution, geographic distribution, education,~~ credentials, stakeholder representation, and other relevant ~~or other information that will describe the characteristics of the referenced group.~~
- ~~**1.15 Educator**, in this instance, means a teacher in a secondary or post-secondary program leading to a degree or *certificate* in a course of study that includes *competencies* in prevention of foodborne illness.~~
- 1.15 1.16 Entry level performance** means carrying out job duties and tasks effectively at a level that does not pose a threat to public safety but not necessarily beyond that level. ~~It requires safe performance of tasks expected of a worker who has had at least the minimal training (either in a formal school or on the job setting), but not long experience.~~
- 1.16 1.17 Equivalency** (in "equivalent examinations") means that ~~there is specific *psychometric statistical* evidence~~ demonstrates that the passing scores of various forms of an examination, assessing the same content, ~~cover the same content and their respective passing scores represent the same degree of~~ examinee competence.
- 1.17 1.18 Examination Aadaptation** means a process by which an examination is transformed from a source language and/or culture into a target language and/or culture.
- 1.18 1.19 Examination Bblueprint** means the plan that specifies how many questions from every job/task analysis content area must be included on each test form.
- 1.19 1.20 Examination Ddevelopers** means the individuals involved in the process of creating the Food Safety *Certification Examination*.

- 1.20** ~~1.21 Examination forms~~ means equivalent, alternate, and differing sets of items, compiled according to the same examination blueprint and examination questions (with at least 25% alternate questions) to assess the same *competencies*, conforming to the same *examination specifications*.
- 1.21** ~~1.22 Examination Materials~~ means all paper (ex. Examination booklet) or electronic versions and/or forms of the *food safety certification examination* and associated examination documents: materials necessary for creating, disseminating, retrieving, administering, and grading examination items and forms.
- 1.22** ~~1.23 Examination specifications~~ means the description of the specific content areas of an examination, stipulating the number or proportion of *items* for each area of measured competency, the total number of scored and unscored items, the amount of time allotted to complete the exam, and requirements for receiving a passing score, and the level of complexity of those *items*. The specifications are based on the *job analysis* and its verification.
- 1.23** ~~1.24 Examination version~~ means an examination in which the exact set of *items* in an *examination form* is presented in another order, language, manner, or medium.
- 1.24** ~~1.25 Examinee~~ means a person who takes an examination.
- 1.25** ~~1.26 Exposure Plan~~ means the policies and procedures in place to ensure that examination *items* and forms are not made available to such a degree that their discrimination value is diminished are not exposed to *examinees* or other people that may result in an examination *item* being memorized and/or shared.
- 1.26** ~~1.27 Food establishment~~ A. Food establishment means an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption as defined in the FDA Food Code 2017.
- ~~1) such as a restaurant, satellite or catered feeding location, catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people, market, vending location, conveyance used to transport people, institution, or food bank; and~~
  - ~~2) that relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.~~
- B. including:
- ~~1) an element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority; and~~
  - ~~2) an operation that is conducted in a mobile, stationary, temporary or permanent facility or location; where consumption is on or off the premises; and regardless of whether there is a charge for the food not including: an establishment that offers only prepackaged foods that are not potentially hazardous; a produce stand that only offers whole, uncut fresh fruits and vegetables;~~

- ~~3) a food processing plant; kitchen in a private home if only food that is not potentially hazardous is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by law and if the consumer is informed by a clearly visible placard at sales or service locations where the food is prepared in a kitchen that is not subject to regulation and inspection by the *regulatory authority*;~~
- ~~4) an area where food that is prepared as specified in Subparagraph (C) of this definition is sold or offered for human consumption;~~
- ~~5) a kitchen in a private home, such as a small family day care provider; or a bed and breakfast operation that prepares and offers food to guests if the home is occupied, the number of available guest bedrooms does not exceed six, breakfast is the only meal offered, the number of guests served does not exceed eighteen, and the consumer is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration areas where the food is prepared in a kitchen that is not regulated and inspected by the *regulatory authority*; or a private home that receives catered or home-delivered food.~~

- 1.27** ~~1.28~~ **Food safety certification examination** means an examination in food safety approved in accordance with the provisions of this program.
- 1.28** ~~1.29~~ **Instructor** means an individual who teaches a course that includes *competencies* in prevention of foodborne illness. May also be called “educator” or “trainer.”
- 1.29** ~~1.30~~ **Item** means an examination question.
- 1.30** ~~1.31~~ **Item bank** means all of the *items* that have been developed for the several forms of an examination. It includes all of the *items* available to create *examination forms*.
- 1.31** ~~1.32~~ **Item sequence** means the presentation order of examination *items* in an examination.
- 1.32** ~~1.33~~ **Job Task Analysis** means the description of functions or tasks required for an individual to perform to entry-level standards in a specific job or occupation, including information about the attributes required for that performance. It defines the performance dimension of a job and includes *knowledge, skills and abilities (KSA's)* necessary to carry out the tasks.
- A. **Tasks** are the individual functions, whether mental or physical, necessary to carry out an aspect of a specific job.
- B. **Knowledge, skills, and abilities (KSAs)** include the information and other attributes that the worker shall possess in order to perform effectively and safely. They include information and understanding as well as learned behaviors and natural attributes.
- 1.33** ~~1.34~~ **Legal entity** means an organization structured in a manner that allows it to function legally and be recognized as a responsible party within the legal system.

- 1.34** ~~1.35~~ **Legally defensible** means the ability to withstand a legal challenge to the appropriateness of the examination for the purpose for which it is used. ~~The challenge may be made by actual or potential examinees or on behalf of the public. Examinees' challenges may pertain to perceived bias of the examination or inappropriately chosen content. Challenges on behalf of the public may claim that the examination does not provide adequate measures of an examinee's knowledge, skills and abilities (KSA's) required to protect the consumer from foodborne illness.~~
- 1.35** ~~1.36~~ **Linear Examination Form** means a fixed examination form, in any delivery format, where the form does not change or adapt based on the examinee's responses.
- 1.36** ~~1.37~~ **Overexposure** means ~~the relative frequency in which an examination item is presented across test forms to the extent that it may undermine the integrity of the examinations.~~ refers to an item that has been selected or viewed to such a degree that its discrimination value is diminished.
- 1.37** ~~1.38~~ **Potential examinee** means a person capable of taking an examination. **Exam Candidate** means an individual who may be reasonably expected to take a food safety certification examination.
- 1.38** ~~1.39~~ **Proctor** means a person under the supervision of a *test administrator*, who assists by assuring that all aspects of an examination administration are being carried out with precision, with full attention to security and to the fair treatment of *examinees*. ~~Proctors have the responsibility and shall have the ability to observe examinee behaviors, accurately distribute and collect examination materials, and assist the test administrator as assigned. They shall have training or documented successful experience in monitoring procedures and shall affirm in writing an agreement to maintain examination security and to ensure that they have no conflict of interest. There must be at least one proctor for every 35 examinees. The proctor can also be a test administrator.~~
- 1.39** ~~1.40~~ **Psychometric** means scientific measurement or quantification of human qualities, traits, or behaviors.
- 1.40** ~~1.41~~ **Psychometrician** means a professional with specific education and training in development and analysis of examinations and other assessment techniques and in statistical methods. Psychometricians measure the validity, reliability, and fairness of an examination and are an integral part in the process of creating valid and reliable tests.
- 1.41** ~~1.42~~ **Regulatory authority** means a government agency that has been duly formed under the laws of that jurisdiction to administer and enforce the law.
- 1.42** ~~1.43~~ **Reliability** means the degree of consistency with which an examination measures the attributes, characteristics or behaviors that it was designed to measure.
- 1.43** ~~1.44~~ **Retail food industry** means those sectors of commerce that operate *food establishments*.

**1.44** ~~1.45~~ **Test administrator** means the individual at the test site who has the ultimate responsibility for conducting a *food safety certification examination*. The *test administrator* can also be a *proctor*.

~~1.46~~ ~~**Test encryption and decoding**~~ means the security aspects of a computer examination to prevent the examination from being read by unauthorized persons if downloaded or otherwise accessed without authorization. Encryption refers to how a computer examination is coded. Decoding refers to how the computer examination is translated back from the code.

~~1.47~~ ~~**Trainer**~~, in this instance, means a professional with appropriate expertise who conducts a course in food safety for *potential examinees* for *certification* as Food Protection Managers.

**1.45** ~~1.48~~ **Validity** means the extent to which an examination score or other type of assessment measures the ~~attributes~~ competencies that it was designed to measure. In this instance, does the examination produce scores that can help determine if *examinees* are competent to protect the public from foodborne illness in a *food establishment*?

## SECTION 2.0 – PURPOSE OF CERTIFICATION ORGANIZATIONS

- 2.0** Purpose of *Certification Organizations*.
- 2.1** The *certification organization* shall have as a purpose the evaluation of those individuals who wish to secure or maintain Food Protection Manager *Certification* in accordance with the criteria and Standards established through the CFP, and the issuance of *certificates* to individuals who meet the required level of *competency*.
- 2.2** A *certification organization* responsible for attesting to the *competency* of Food Protection Managers has a responsibility to the individuals desiring *certification*, to the employers of those individuals, and to the public.
- 2.3** A *certification organization* for Food Protection Manager *Certification* Programs shall not be the *accrediting organization* nor shall the *certification organization* have any conflict of interest with said *accrediting organization*.

## SECTION 3.0 – STRUCTURE AND RESOURCES OF CERTIFICATION ORGANIZATIONS

- 3.0 Structure and Resources of *Certification Organizations*.
- 3.1 **Structure of *certification organizations*.** The *certification organization* shall be incorporated as a *legal entity* (applies to the parent organization if the *certification organization* is a subsidiary of another organization).
- 3.2 A *certification organization* shall conform to all CFP Standards for *accreditation* and demonstrate that the relationship between the *certification organization* and any related association, organization or agency ensures the independence of the *certification* program and its related functions.
- 3.3 If a *certification organization* provides both education and *certification*, the *certification organization* shall at a minimum, demonstrate that the education part of the organization has no undue influence the certification process. Additionally, the Certification Organization shall demonstrate that the certification process is not financially dependent on the associated education part of the organization. ~~administratively and financially separate any education and certification functions that are specific to Food Protection Manager Certification to ensure that the certification program is not compromised. This may be satisfied if the governing structure documents to the accrediting organization the distinct separation of the two functions, confirming that no undue influence is exercised over either the education or the certification process by virtue of the structure within the association, organization, agency or another entity.~~
- 3.4 **Resources of *Certification Organizations*.** A *certification organization* shall conform to all CFP Standards for *accreditation* and demonstrate
- A. the availability of financial resources to effectively and thoroughly conduct regular and ongoing *certification* program activities.
  - B. that ~~staff possesses the knowledge and skills necessary to conduct the certification program or has available and makes use of non-staff consultants and professionals to sufficiently supplement staff knowledge and skills.~~ its employees and any contracted professionals possess the skills and knowledge necessary to conduct the certification program activities.
  - C. that the roles and responsibilities of certification personnel are adequately defined.

## SECTION 4.0 – FOOD SAFETY CERTIFICATION EXAMINATION DEVELOPMENT

### 4.0 *Food Safety Certification Examination Development.*

4.1 *Food safety certification examinations administered by accredited certification organizations shall comply fully with all criteria set by the CFP and shall meet explicit and implicit Standards to protect the public from foodborne illness. The accredited certification organization shall provide a food safety certification examination that:*

- A. conforms to all CFP Standards for *Accreditation of Food Protection Manager Certification Programs*;
- B. has been developed from secure *item bank* that is of adequate the size and composition to assemble and support a valid, legally defensible examination and

For paper- or computer-based *linear examination forms*, the number of active items in any given content domain must be a minimum of three (3) times the number of items specified in the *examination blueprint*. For computer adaptive examination programs (*Computer Adaptive Testing*), the number of active items for each content domain must be a minimum of six (6) times the number of items specified in the *examination blueprint*.

Type of Form Assembly	Scaling Factor of Bank vs. Blueprint
<i>Linear Examination Forms</i> (paper or computer-based)	Minimum of 3 times the number listed in the blueprint
<i>Computer Adaptive Testing</i>	Minimum of 6 times the number listed in the blueprint

- C. *Certification organizations* must have a policy that supports the monitoring and controlling of item exposure rates, use of an appropriate and defensible number of concurrent, equivalent *linear examination forms* (for print-based or computer-based), or an item bank of sufficient size and composition to support and deliver *computer adaptive testing*.

4.2 The certification organization shall apply acceptable psychometric standards to:

- a. examination development, maintenance, and delivery;
- b. certification decisions;
- c. *examination materials* and data storage;
- d. reporting;
- e. resolution of complaints and appeals;
- f. impartiality; and
- g. examination security.

The certification organization is responsible for defending its policies, procedures, processes, and decisions to the accrediting organization.

4.3 The *certification organization* shall provide complete information about the *food safety certification examination*, including information related to procedures and personnel involved in all aspects of the examination development and analysis. Actual or potential conflicts of interest that might influence judgment or performance of *Examination Developers* shall be disclosed. The information required for *accreditation* will include but is not necessarily limited to:

- A complete description of the scope and usage of the examination;
- B. *job task analysis task list*, with *knowledge, skills, and abilities (KSAs)*;
- C. *examination specifications*;
- D. evidence that the number of active items in the *item bank* is (1) aligned with the weight specified in the *examination blueprint*, (2) appropriate for the format of the examination, with special consideration for *computer-adaptive testing*, and (3) meets the requirements of the item exposure plan;
- E. statistical performance of each *item* in the bank;
- F. number of *examination forms* and evidence of their *equivalence* to each other;
- G. description of method used to set passing score;
- H. copies of all logs, diaries, and personnel lists and descriptions kept as required in the development process;
- I. appropriate summary statistics for each *examination form*, regardless of assembly or delivery method; and
- J. names, credentials, and *demographic* information for all persons involved in the *job task analysis*, *item* writing and review, and setting the passing score.

4.4 **Job Task Analysis.** ~~The content validity of a A food safety certification examination shall be based on a psychometrically valid job task analysis. The job task analysis shall be developed by qualified individuals, including retail food industry and public health stakeholders and subject matter experts. developed by psychometricians and a demographically and technically representative group of individuals with significant experience in food safety. The representative group shall include but not necessarily be limited to persons with experience in the various commercial aspects of the retail food industry, persons with local, state or national regulatory experience in retail food safety, and persons with knowledge of the microbiology and epidemiology of foodborne illness, and shall be sufficiently diverse as to avoid cultural bias and ensure fairness in content according to all Federal requirements.~~

4.5 The *job task analysis* shall provide a complete description of the *knowledge, skills, and abilities (KSAs)* required to function competently in the occupation of *Certified Food Protection Manager*, with emphasis on those tasks most directly related to the *Certified Food Protection Manager's* role in the prevention of foodborne illness and controlling foodborne pathogens.

4.6 ~~Detailed food safety certification examination specifications shall be derived from a valid study of the job analysis tasks and their accompanying knowledge, skills, and abilities (KSAs) and shall be appropriate to all aspects of the retail food industry. The job analysis shall include consideration of scientific data concerning factors contributing to foodborne~~

~~illness and its epidemiology. The examination specifications, consisting of percentage weights or number of items devoted to each content area, shall be available to examinees and to the public. The examination blueprint shall be derived from a valid study of the job task analysis. Examination specifications deriving from the exam blueprint shall be publicly available.~~

- 4.7 The credential awarded upon passing a food safety certification examination is designed to be recognized nationwide and throughout the retail food industry. As such, the certification organization shall regularly evaluate practices in the retail food industry to ensure the job task analysis on which its examination is based remains appropriate and relevant. ~~certification organization is required to systematically evaluate practices in the retail food industry to ensure that the job analysis on which an examination is based remains appropriate for the development of food safety certification examinations on which the universal credential is awarded. The maximum length of use for any job *task analysis* is five years from the date of validation.~~
- 4.8 **Psychometric Standards.** *Food safety certification examination* development, including setting the passing score, shall be based on the most recent edition of Standards for Educational and Psychological Testing, developed jointly by the American Psychological Association, American Educational Research Association and National Council for Measurement in Education, and on all appropriate Federal requirements (for example, Americans with Disabilities Act). *Food safety certification examinations* shall be revised as needed to ~~be in compliance~~ **comply** with changes in the Standards for Educational and Psychological Testing or in any of the Federal requirements.
- 4.9 The *food safety certification examination* development procedures shall ensure that the *competencies* assessed in the *accredited certification program* are those required for *competent entry level performance* in the role of *Certified Food Protection Manager*, as defined by law and industry standards, and that they focus on factors related to the prevention of foodborne illness in the *retail food industry*.
- 4.10 ~~The *food safety certification examination* shall be based on psychometrically valid procedures to ensure the relative equivalence of scores from various *examination forms*. The certification organization shall ensure relative equivalence and reliability across its various examination forms and administration methodologies (e.g., paper-pencil, CBT). The ~~certification organization~~ provide evidence of such equivalence as public information.~~
- 4.11 The *food safety certification examination* shall be developed to be **as** free from bias **as possible**. Certification organizations shall provide evidence that all examinations are evaluated for sensitivity and appropriateness with respect to a diverse population of examinees. Characteristics such as gender, ethnicity, race, socioeconomic status, age, or anything unrelated to the ability to apply the required competencies will not be allowed to influence *examinee* performance or scores.
- ~~4.12 When the *food safety certification examination* is administered in a medium other than the common pencil and paper format, evidence shall be provided to ensure that all *competencies* are assessed in a reliable manner and that the *validity* of the examination is preserved.~~

Evidence of comparability with other *examination forms* shall be provided.

**4.12** ~~4.13~~ When any *food safety certification examination* (~~forms, items, banks, etc.~~) is translated or adapted into another language, the *certification organization* shall demonstrate comparability between the source examination and the translated or adapted examination (~~example: forward/backward translation or review by bilingual SME~~). The *certification organization* is responsible for defending its translation/*adaptation* processes to the accrediting organization. To avoid potential problems in translation of industry-specific terminology, the *certification organization* shall work in consultation with a food safety subject matter expert (SME) who is fluent in both the original language and the target language and who does not pose a conflict of interest or examination security risk.

**4.13** ~~4.14~~ *Examination Developers* shall maintain a log and diary of the procedures and a list of the qualifications, identities, and *demographic data* of the persons who participated in *item* development, examination development, translations, setting the passing score, and the statistical analyses of the examination *items* and of the full examination. Those materials shall be provided to the *accrediting organization* on demand.

~~All examinations shall be delivered and administered in a format that ensures the security of the examination (i.e. in a secured environment with a *test administrator/proctor*). Un-proctored examinations are not acceptable regardless of the mode of administration.~~

**4.14** ~~4.15~~ **Examination Development Security.** The certification organization will demonstrate that procedures are developed and implemented to ensure that individual items, item banks, food safety certification examinations presented in all media (~~printed, taped and computerized~~), test answer sheets and examinee scores are and remain secure. ~~Demonstration shall include an overall examination security plan that covers each step in the examination development, culminating in the production of the examination~~ The certification organization is required to demonstrate how its examination security plan covers each step in the examination development, administration, scoring, and maintenance.

All examinations shall be delivered and administered in a format that ensures the security of the examination (i.e. in a secured environment with a *test administrator/proctor*). Un- proctored examinations are not acceptable regardless of the mode of administration.

**4.15** ~~4.16~~ **Periodic Review.** At least ~~semi~~annually, each *certification organization* shall report to the accrediting organization, providing a review of its *food safety certification examination(s)*. The report will include at minimum the following summary information for all examinations (for each examination used) administered during the preceding ~~six~~12 months, as well as other information that may be reasonably requested by the *accrediting organization*.

- A. number of *food safety certification examinations* administered;
- B. mean, corresponding standard deviation, and range of candidate scores;
- C. A measure of form-level reliability;
- D. A measure of decision consistency;
- E. Passing rates (both number and percentage of examinees that passed the examination in the given ~~6~~12-month period); and
- F. Summary statistics for all items used during the preceding 12-month period, which

may be presented using classical test theory, item response theory, or similar models. Item statistics, including but not limited to a summary of item difficulty, discrimination, and exposure for all items presented during the reporting period.

- G. For the purposes of clarity and identifying data trends, annual summary information may need to be presented in concise reports, such as semi-annual or quarterly, to the accrediting organization.

**4.16 4.17 Requirements for Examination Standardization.** *Certification organizations* shall specify conditions and procedures for administering all *food safety certification examinations* in a standard manner ~~to ensure that all examinees are provided with the opportunity to perform according to their level of ability and to ensure comparability of scores. Examination booklets shall be of high quality printing to ensure ease of reading~~ to provide examinees with a fair and equitable opportunity to demonstrate competency.

## SECTION 5 – FOOD SAFETY CERTIFICATION EXAMINATION ADMINISTRATION

**5.0** *Food Safety Certification Examination Administration.* All sections of these Standards apply to *Computer Based Testing (CBT)* Administration except Section 5.1.

**5.1** *Security for Examination Materials.*

A. Policies and procedures shall be developed and documented by the *certification organization* to ensure the security of *examination materials*. At a minimum, security provisions shall address:

- 1) The type of test materials (i.e. electronic or paper);
- 2) The locations of the test materials (i.e. transportation, electronic delivery, disposal, storage, examination center (when applicable));
- 3) The steps in the examination process (e.g. development, administration, results reporting);
- 4) The threats arising from repeated use of examination materials

B. Packaging by *certification organization*.

- 1) Each individual examination booklet shall be securely sealed before packing.
- 2) Secure tamper-resistant shipping material, such as Tyvek envelopes or similar materials that are designed to reveal any tampering or violation of the package's security, is required for all shipment of materials in all phases.
- 3) Packaging must include a packing list that contains:
  - a. *examination form* language(s) or version(s) enclosed; and
  - b. quantity of examinations enclosed.

C. Shipping to the *test administrator/proctor* from the *certification organization*.

- 1) Shipping shall be done by certifiable, traceable means, with tracking numbers so that the location can be determined at any given time.
- 2) A signature is required upon delivery.
- 3) Only an individual authorized by the *test administrator/proctor* may sign for the package.

D. Storage by *test administrator/proctor*.

The package(s) of examination booklets shall be secured at all times immediately upon delivery. Under no circumstances may examination booklets, *examinee* used answer sheets, or other examination materials be kept where other employees or the public has access.

E. Shipping to the *certification organization* from the *test administrator/proctor*

- 1) After examination administration, examination booklets and answer sheets shall remain in secure storage until returned to *certification organization*.
- 2) The following shall be in tamper-resistant shipping material:

- a. all used and unused examination booklets for each examination administration;
  - b. *examinees'* used answer sheets; and
  - c. all required *certification organization* forms.
- 3) Shipping shall be done within two business days following the examination date by certifiable, traceable means, with tracking numbers so that the location can be determined at any given time.
- F. Handling unused examination booklets that have been held for up to ninety days. The *test administrator/proctor* will:
- 1) ensure that all examination booklets are accounted for;
  - 2) package examination booklets securely as described above; and
  - 3) ship to the certification organization securely packaged and according to these *Standards* and the *Certification Organization's* instructions.

## 5.2 Test Site Requirements.

Sites chosen for administering *food safety certification examinations* shall conform to all legal requirements for safety, health, and accessibility for all ~~qualified~~ *examinees*.

- A. Additionally, the accommodations, lighting, space, comfort, and workspace for taking the examination shall reasonably allow *examinees* to perform at their highest level of ability.
- B. Requirements at each test site include, but are not limited to:
- 1) ~~accessibility~~ reasonable accommodation requests, in accordance with the requirements of the Americans with Disabilities Act, shall be ~~reasonably available fulfilled~~ for all ~~qualified~~ *examinees*, whether the examination administration occurs at the main examination location site, or at an alternative examination location site that meets the same location requirements as the main examination location site;
  - 2) conformity to all fire safety and occupancy requirements of the jurisdiction in which they are located;
  - 3) sufficient spacing between each *examinee* in the area in which the actual examination is conducted, or other appropriate and effective methods, to preclude any *examinee* from viewing another *examinee's* examination;
  - 4) acoustics allowing each *examinee* to hear instructions clearly, using an electronic audio system if necessary;
  - 5) lighting at each *examinee's* workspace adequate for reading;
  - 6) ventilation and temperature appropriate for generally recognized health and comfort of *examinees*;
  - 7) use of private room(s) where only examination personnel and *examinees* are allowed access during the examination administration; and
  - 8) no further admittance into the test site once examination administration has begun.

### 5.3 Test Site Language Translation.

A *certification organization* shall have a published, written policy regarding test site language translation of *food safety certification examinations*. If a *certification organization* allows test site language translation of a *food safety certification examination* when an *examination version* is not available in the *examinees'* requested language, the *certification organization* shall have a published, formal application process available to all *potential examinees*. Procedures shall include but not be limited to:

- A. An application process for *potential examinees* that includes an evaluation and documentation component to determine the eligibility of the *potential examinee* for test site language translation,
- B. An application process for translators that includes clear and precise qualifications that shall include but not be limited to the following:
  - 1) being fluent in both languages;
  - 2) have a recognized skill in language translation;
  - 3) trained in the principles of objective examination administration;
  - 4) have no personal relationship with the *examinee* (may not be another *examinee*, may not be a relative or friend of the *examinee* and may not be a co-worker, employer, or an employee of the *examinee*);
  - 5) ~~not being a Certified Food Protection Manager~~ nor having any vested interest in Food Protection Manager *certification* or conflict of interest;
  - 6) provide references or other proof attesting to the translator's competencies and professional acumen; and
  - 7) agree in writing to maintain the security of the examination.
- C. A proctored environment where the translator and *examinee* are not a distraction to other *examinees*, and
- D. A proctored environment where the translator is not active as the *test administrator/proctor*.

### 5.4 Scoring.

- A. Only the *certification organization* may score the examination by methods approved by the *accrediting organization*. No official scoring is to be done at the test site.
- B. *Food safety certification examination* scores will not be released as being official until verified and approved by the *certification organization*.
- C. *Examinee* scores will be confidential, available only to the *examinee*, the Certification Organization, the Accrediting Organization, and to persons or organizations approved in writing by the *examinee*.
- D. Score reports will be available to *examinees* in a time frame specified in the application, which will not exceed fifteen business days following the administration of the *food safety certification examination*. If there is a delay due to problems in

verification or authentication of scores, *examinees and the test administrator/proctor* will be so informed and an approximate date for release of the scores will be announced. ~~The certification organization will have ongoing communication with examinees and with the test administrator/proctor until the scores are verified and released.~~

**5.5 Test Administrator/Proctor(s) Role.** *Test administrators/proctors* shall have successfully completed the *certification organization's* specific training in examination administration and security procedures. They shall provide written assurance of maintaining confidentiality of examination contents, of adhering to the *certification organization's* standards and ethics of secure examination administration, and of agreeing to abide by the *certification organization's* policies, procedures, and rules.

**5.6 Test Administrator/Proctor Roles and Requirements.** To serve as a *test administrator/proctor* for an accredited *certification organization* the qualified individual shall complete the *certification organization's*:

A. signed Application;

B. non-Disclosure Agreement (NDA);

C. training program for *test administrators/proctors*; and

D. conflict of Interest Disclosure Agreement (can be a part of the NDA).

**5.7 Test Administrator/Proctor Renewal.** *Test administrators/proctors* shall renew the training program for *test administrators/proctors* and Non-Disclosure Agreement with the *certification organization* a minimum of every three (3) years.

**5.8 Instructor/~~Educator/Trainer~~ as Test Administrator/Proctor.**

When a person acts as an *instructor/~~educator/trainer~~* and a *test administrator/proctor*, that person relinquishes the role of *instructor/~~educator/trainer~~* when acting in the role of *test administrator/proctor*.

**5.9 Test Administrator/Proctor Responsibilities.**

*Test Administrators/proctors* shall utilize documented procedures provided by the certification body to ensure a consistent examination administration. These include, but are not limited to:

A. Schedule examinations. *Food safety certification examinations* shall be scheduled far enough in advance to allow for timely shipment of supplies or pre-registration for computer-based examinations.

B. The *certification organization's* criteria for conditions for administering examinations shall be followed. Conditions can include, but are not limited to: lighting, temperature, separation of candidates, noise, candidate verification and

safety, *test administrator/proctor* conduct and *examination materials* security throughout examination process, etc.

- C. Report possible security breaches and examination administration irregularities in compliance with the *certification organization's* policies.

**5.10** The number of approved *proctors* assigned to a *test administrator* shall be sufficient to allow each *examinee* to be observed and supervised to ensure conformance to security requirements. The *certification organization* shall develop and justify to the *accrediting organization*, through documented policies, the ratio of test administrator/proctor to examinees.

**5.11 Examination Security.**

A. All aspects of *food safety certification examination* administration are to be conducted in a manner that maximizes the security of the examinations, in keeping with the public protection mandate of the CFP. This shall be accomplished in a manner that ensures fairness to all *examinees*.

B. All *examinees* shall begin taking the examination at the same time. No *examinee* shall be admitted into the test site once examination administration has begun.

C. Where reasonable accommodations shall be is provided made for otherwise qualified *examinees* under provisions of the Americans with Disabilities Act, care shall be taken to ensure that security of the examination is maintained. Individuals assisting in providing accommodation (Assistants) shall disclose in writing any actual or potential conflict of interest prior to assisting in any exam administration. The certification organization shall address any identified conflicts of interest and maintain a signed nondisclosure agreement with Assistants. ~~Arrangements shall be such that the food safety certification examination contents are not revealed to any test administration personnel with any conflict of interest. A written affirmation to that effect and a written nondisclosure statement from the individual who was chosen to assist the otherwise qualified examinee shall be provided to the certification organization.~~

**5.12** The *certification organization* shall provide procedures to be followed in any instance where the security of a *food safety certification examination* is, or is suspected to be, breached.

A. Included shall be, at a minimum, specific procedures for handling and for reporting to the *certification organization*, any suspected or alleged:

- 1) cheating incidents;
- 2) lost or stolen examination materials;
- 3) intentional or unintentional divulging of examination *items* by *examinees* or examination administration personnel; or
- 4) any other incidents perceived to have damaged the security of the examination or any of its individual *items*.

B. Corrective actions to guard against future security breaches shall be established and

implemented.

- C. Documentation of corrective actions and their effectiveness shall be made available to the *accrediting organization*.

**5.13 Item and Examination Exposure.**

The *certification organization* shall have an *exposure plan* that:

- A. controls for *item* and examination exposure;
- B. accounts for the number of times an *examination item*, *examination form*, and *examination version* is administered;
- C. ensures that no *examination form* is retained by any *examination administration* personnel for more than ninety days;
- D. at all times accounts for all copies of all used and unused examination booklets; and
- E. systematically and actively demonstrates that every used answer sheet, examination booklet, and any other examination materials and answer keys are accounted for to prevent, reduce, or eliminate examination exposure.

**5.14 Certification Organization's Responsibility to Test Administrators/Proctors.**

- A. The *certification organizations* shall specify the responsibilities of *test administrator/proctor*, set minimum criteria for approval of *test administrators/proctors*, and provide a training program to enable *potential examinees* to meet the approval criteria. Responsibilities, duties, qualifications and training of *test administrators/proctors* shall be directed toward assuring standardized, secure examination administration and fair and equitable treatment of *examinees*.
- B. The *certification organization* shall define and provide descriptions for the roles of *test administrators/proctors*, ~~and certification organization personnel~~ clearly indicating the responsibilities for these roles. The *certification organization* shall demonstrate how it ensures ~~that all certification personnel, as well as test administrators/proctors;~~ understand and practice the procedures identified for their roles.
- C. *Test administrator/proctor* training programs shall include:
  - 1) specific learning objectives for all ~~of the~~ activities of *test administrator/proctor*; and
  - 2) an assessment component that shall be passed before an ~~examinee~~ applicant for *test administrator/proctor* will be approved.

**5.15 Certification Organization Test Administrator/Proctor Agreements.** The *certification organization* shall enter into a formal agreement with the *test administrator/proctor*. The formal agreement shall at a minimum address:

- A. provisions that relate to code of conduct;

- B. conflicts of interest; and
- C. consequences for breach of the agreement.

**5.16** The *certification organization* shall assess and monitor the performance of *test administrators/proctors* in accordance with all documented procedures and agreements.

**5.17** The *certification organization* is not permitted to hire, contract with, or use the services of any person or organization that claims directly or indirectly to guarantee passing any certification examination. ~~Instructors/educators/trainers~~ making such a claim, whether as an independently or as an employee of another organization making the claim, are not eligible to serve as *test administrators/proctors* for any *certification organization*.

~~In order to retain the integrity of the certification process, 5.17 is intended to provide Certification Organizations a method of evaluating individuals' and/or organizations' claims to guarantee passing any certification examination if they are performing the role of instructor/educator/trainer and proctor/administrator. This area of the Standard does not apply to training organizations and their employees not contracted to a Certification Organization.~~

**5.18** Policies and procedures for taking corrective action(s) when any *test administrator* or *proctor* fails to meet job responsibilities shall be implemented and documented. *Test administrators/proctors* that have been dismissed by the *certification organization* for infraction of policies or rules, incompetence, ethical breaches, or compromise of examination security will be reported to the *accrediting organization*.

**5.19 Examination Administration Manual.**

The *certification organization* shall provide each *test administrator/proctor* with a manual detailing the requirements for all aspects of the *food safety certification examination* administration process. The Examination Administration Manual shall include a standardized script for the paper examination *test administrator/proctor* to read to *examinees* before the examination commences. For computer—based tests (CBT), standardized instructions shall be available for *examinees* to read.

**5.20 Examination Scripts.** Separate scripts/instructions may be created for different delivery channels or *certification organizations*. *Certification organizations* may customize elements of the scripts to fit their particular processes, but each script shall contain the following:

- A. Introduction to the Examination Process
  - 1) composition of the examination (number of questions, multiple choice, etc.);
  - 2) time available to complete the examination;
  - 3) role of the *test administrator/proctor*;
  - 4) process for restroom breaks; and
  - 5) process for responding to *examinee* comments and questions.

B. Copyright and Legal Responsibilities

- 1) description of what constitutes cheating on the examination;
- 2) penalties for cheating; and
- 3) penalties for copyright violations.

C. Examination Process

- 1) maintaining test site security;
- 2) description of examination components unique to the *certification organization* (examination booklet, answer sheet completion, computer process in testing centers, etc.);
- 3) instructions for proper completion of personal information on answer sheets/online registration and examination booklets;
- 4) instructions on properly recording answers on answer sheets or online; and
- 5) instructions on post-examination administration process.

## SECTION 6.0 – COMPUTER-BASED TESTING (CBT)

- 6.0 Computer-Based Test Development and Administration** All sections of these Standards apply to *Computer Based Testing* (CBT) Administration except Section 5.1.
- 6.1 Computer-Based Test Development.** *Examination specifications* for *computer-based testing* shall describe the method for development, including the *algorithms* used for test *item* selection, the *item* response theory model employed (if any), and examination *equivalency* issues.
- 6.2** *Items* shall be evaluated for suitability for computer delivery, be reviewed in the delivery medium, and be reviewed in the presentation delivery medium. Assumptions shall not be made that *items* written for delivery via a paper/pencil medium are suitable for computer delivery nor should it be assumed that computer test *items* are suitable for paper/pencil delivery.
- 6.3** When *examination forms* are computer-generated, whether in *Computer-Adaptive Testing* (CAT) or in a simple linear *algorithm*, the *algorithm* for *item* selection and the number of *items* in the *item bank* from which the examination is generated shall ensure that the *items* are protected from *overexposure*. *Item* usage statistics shall be provided for all available *items* in the pool.
- 6.4 Computer-Based Testing Administration.** Where examination environments differ (for example, touch screen versus mouse) evidence shall be provided to demonstrate equivalence of the *examinees'* scores.
- 6.5** Tutorials and/or practice tests shall be created to provide the *examinees* adequate opportunity to demonstrate familiarity and comfort with the computer test environment.
- 6.6** If the time available for computer delivery of an examination is limited, comparability of scoring outcomes with non-timed delivery of the exam shall be demonstrated. Data shall be gathered and continually analyzed to determine if scoring methods are comparable.
- 6.7** Evidence of security in the *computer-based testing* environment shall be provided. Factors affecting test security include, but are not limited to, *examinee* workspace, access to personal materials, level of *examinee* monitoring, and *test encryption and decoding*.
- 6.8** Documentation of precautions to protect *examination forms* and the *item bank* from unauthorized access shall be provided.
- 6.9** Policies and procedures regarding the recording and retention of the *item sequence* and *item* responses for each *examinee* shall be developed and followed. Computer examinations using a unique sequence of *items* for each *examinee* shall record the information necessary to recreate the sequence of *items* and *examinee* responses on the computer examination.

- 6.10** Systems and procedures shall be in place to address technical or operational problems in examination administration. For example, the examination delivery system shall have the capability to recover *examinee* data at the appropriate point in the testing session prior to test disruption. Policies regarding recovery for emergency situations (such as retesting) shall be developed.
- 6.11** **Due Process.** *Examinees* shall be provided with any information relevant to *computer-based testing* that may affect their performance or score. Examples of such information might include but not be limited to: time available to respond to *items*; ability to change responses; and instructions relating to specific types of *items*.

## SECTION 7.0 – CERTIFICATION ORGANIZATION RESPONSIBILITIES TO POTENTIAL EXAMINEES, EXAMINEES AND THE PUBLIC

### 7.0 A certification organization's Responsibilities to Examinees and the Public.

#### 7.1 Responsibilities to Potential Examinees and/or Examinees for Certification. A certification organization shall develop and implement policies, which address the following:

- A. an overview to exam candidates of the process ~~to potential examinees and examinees~~ to by which one obtains certification;
- B. a notice to ~~potential examinees and examinees~~ exam candidates of non-discrimination.
- C. protocols for the periodic review of examination policies and procedures to ensure fairness;
- D. procedures for uniformly and prompt reporting of *food safety certification examination* results to *examinees*;
- E. procedures for providing *examinees* failing the *food safety certification examination* with information on general areas of deficiency;
- F. protocols that assure the confidentiality of each *examinee's food safety certification examination* results; and
- G. appeals procedures for ~~potential examinees and examinees~~ exam candidates questioning eligibility or regarding any part of the *accredited certification program*.

#### 7.2 Qualifications for Initial Certification. To become a *Certified Food Protection Manager* an individual shall pass a *food safety certification examination* from an *accredited certification program* recognized by the CFP. The *certificate* shall be valid for no more than five years.

#### 7.3 Individual Certification Certificates:

- A. Each *certification organization* will maintain a secure system with appropriate backup or redundancy to ~~provide verification of current~~ verify validity of individual *certification certificates*.
- B. *Certificates* shall include, at a minimum:
  - 1) issue date/date examination was taken;
  - 2) length of time of *certification* validity;
  - 3) name and *certification* mark of *certification organization*;
  - 4) ANSI accrediting organization ~~accreditation~~ mark;
  - 5) name of certified individual;
  - 6) unique *certificate* number;

- 7) name of *certification*;
  - 8) contact information for the *certification organization*; and
  - 9) examination form identifier
- C. Replacement or duplicate *certificates* issued through an *accredited certification organization* shall carry the same issue date, or date of examination, as the original *certificate*, and will be documented by the *certification organization*.
- 7.4 Discipline of Certificate Holders and Examinees.** A *certification organization* shall have formal *certification* policies and operating procedures including the sanction or revocation of the *certificate*. These procedures shall incorporate due process.
- 7.5 Continued Proficiency.** An *accredited certification program* shall include a process or program for assessing continued competence that includes an examination component at an interval of no more than five years. The outcome of the process or program shall demonstrate that the person has maintained the minimum competencies as determined by the ~~current Job Task Analysis~~.
- 7.6 Responsibilities to the Public and to Employers of Certified Personnel.** A *certification organization* shall maintain a registry of individuals certified. Any title, ~~or credential, or certificate~~ awarded by the *certification organization* shall ~~appropriately reflect the Food Protection Manager's daily food safety responsibilities and shall not be confusing to employers, consumers, related professions, and/or other interested parties.~~ be relevant to the retail food industry and role of Food Protection Manager and not designed to mislead or intentionally confuse examinees and other stakeholders.
- 7.7** Each ~~accredited certification program~~ *certification organization* shall have a published protocol ~~procedure~~ for systematically investigating problems presented by users of the Program, including specific concerns about examination *items*, administration procedures, treatment of *examinees and potential examinees*, or other matters involving potential legal defensibility of the examination or program. The protocol will include a published time frame for reporting findings to the User addressing complaints and appeals. Such procedures shall include a stated timeframe for response from the certification organization.
- 7.8 Misrepresentation.** Only Food Protection Manager ~~Certification Programs~~ *certification organizations* that conform to all requirements of the Standard ~~of Standards for Accreditation of Food Protection Manager Certification Programs~~ and are accredited by the agent selected by the CFP as the *accrediting organization* for such programs are allowed to refer to themselves as being *accredited*. Those programs may not make any other reference to the CFP in their publications or promotional materials in any medium.

## SECTION 8.0 – CERTIFICATION ORGANIZATION RESPONSIBILITIES TO THE ACCREDITING ORGANIZATION

### 8.0 *Certification Organization Responsibilities to the Accrediting Organization.*

8.1 **Application for Accreditation.** *A certification organization seeking accreditation for development and/or administration of a certification program shall provide at least the following information, as well as other information that might be requested by the accrediting organization:*

- A. the name and complete ownership structure of the *legal entity*.
- B. the address, telephone/fax number(s) and other contact information of the *certification organization's* headquarters.
- C. the name, position, address and telephone/fax/e-mail information of the contact person for projects related to the CFP Standards for Accreditation of Food Protection Manager Certification Programs.
- D. such fiscal information as may be needed to establish evidence of ability to carry out obligations under these Standards.

8.2 **Summary Information.** *A certification organization shall:*

- A. provide evidence that the mechanism used to evaluate individual competence is objective, fair, and based on the knowledge and skills needed to function as a *Certified Food Protection Manager*;
- B. provide evidence that the evaluation mechanism is based on standards which establish *reliability* and *validity* for each form of the *food safety certification examination*;
- C. provide evidence that the pass/fail levels are established in a manner that is generally accepted in the *psychometric* community as being fair and reasonable;
- D. have a formal policy of periodic review of evaluation mechanisms and shall provide evidence that the policy is implemented to ensure relevance of the mechanism to knowledge and skills needed by a *Certified Food Protection Manager*;
- E. provide evidence that appropriate measures are taken to protect the security of all *food safety certification examinations*;
- F. publish a comprehensive summary or outline of the information, knowledge, or functions covered by the *food safety certification examination*;

- G. make available general descriptive materials on the procedures used in examination construction and validation and the procedures of administration and reporting of results; and
- H. compile at least ~~semi~~-annually a summary of *certification* activities, including number of *examinees*, number tested, number passing, number failing, and number certified.

**8.3 Responsibilities to the Accrediting Organization.** The *certification organization* shall:

- A. make available upon request to the *accrediting organization* copies of all publications related to the *certification* program,
- B. ~~advise~~ notify the *accrediting organization* of any proposed changes in structure or activities of the *certification organization*,
- C. advise the *accrediting organization* of substantive change in *food safety certification examination* administration,
- D. advise the *accrediting organization* of any major changes in testing techniques or in the scope or objectives of the *food safety certification examination*,
- E. annually complete and submit to the *accrediting organization* information requested on the current status of the Food Protection Manager *Certification* Program and the *certification organization*,
- F. submit to the *accrediting organization* the report requirements information specified for the Food Protection Manager *Certification* Program, and
- G. be re-accredited by the *accrediting organization* at least every five years.

## SECTION 9.0 – MANAGEMENT SYSTEMS

### 9.0 Management Systems.

9.1. Each *certification organization* shall have a formal management system in place to facilitate continuous quality improvement and produce preventive and corrective actions. The management system shall contain the following three components.

A. Document control to include:

- 1) lists of all documents pertaining to the *certification organization*;
- 2) dates for documents approved for implementation by the *certification organization*;
- 3) the person(s) within the *certification organization* responsible for the documents; and
- 4) listing of individuals who have access to the documents.

B. Internal audits to include:

- 1) identification of critical activities;
- 2) data collection process and evaluation schedule;
- 3) audit methodology and evaluation process;
- 4) the person(s) authorized to perform audits; and
- 5) report audit findings and identify corrective action required.

C. A Management Review that includes:

- 1) a documented annual review of internal audit results;
- 2) a management group that conducts the review;
- 3) a review of the audit results to determine corrective actions needed;
- 4) a review of the audit results to determine preventive actions needed; and
- 5) the effectiveness of corrective and preventive actions taken.

## **ANNEX A**

# **Conference for Food Protection**

## **Conference for Food Protection Requirements for Certification Organizations to Provide Food Protection Manager Certifications using the ISO/IEC 17024 Personnel Certification Standard**

### **Preamble/History**

The Conference for Food Protection (“CFP”), is an independent voluntary organization that promotes food safety and consumer protection and includes in its responsibilities the establishment and maintenance of the *Standards for Accreditation of Food Protection Manager Certification Programs* (“CFP STANDARD”).

Starting in 2012 CFP began consideration of the *ISO/IEC 17024, Conformity assessment—General requirements for bodies operating certification of persons* (“ISO 17024 STANDARD”) as an alternative accreditation standard for certification bodies accredited or seeking accreditation under the existing CFP food Protection manager standards.

As an outcome of the 2016 Biennial Meeting of the Conference for Food Protection, the following charge was given to the Food Protection Manager Certification Committee (“FPMCC”):

Determining the process and requirements for potential acceptance of the International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) 17024 2012 for food protection manager certification as an additional option to and without impact on the existing CFP Standards for Accreditation of Food Protection Manger Certification Programs, with the input of standards development expertise from American National Standards Institute (ANSI).

This document is the result of the deliberation and recommendations from the FPMCC and represents the process and requirements for CFP to recognize a certification body that is accredited by ANSI under the ISO-17024 STANDARD.

The requirements described in this document shall be applied in conjunction with the ISO/IEC 17024 standard (International Organization for Standardization/ International Electrotechnical Commission). All clauses of ISO/IEC 17024 standard continue to apply. This document provides supporting criteria to that standard for certification bodies that want to be recognized by the CFP.

### **SECTION 1.0 – CONFERENCE FOR FOOD PROTECTION ACCEPTANCE OF ISO/IEC 17024 ACCREDITED PROGRAMS**

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. A) ISO/IEC 17024 Standard, B) FDA Food Code.

- A1.0** Conference for Food Protection acceptance of *ISO/IEC 17024* accredited Food Protection Manager Certification programs.
- A1.1** Wherein, the Conference for Food Protection (“CFP”) maintains the *Standards for Accreditation of Food Protection Manager Certification Programs* (“CFP ~~Standard~~TANDARD”);
- A1.2** And, the CFP recognizes *ISO/IEC 17024, Conformity assessment – General requirements for bodies operating certification of persons* (“ISO/IEC 17024 ~~Standard~~TANDARD”) as an alternative personnel certification standard to the CFP Standard;
- A1.3** And, that the recognition of ISO/IEC 17024 Standard does not impact the CFP Standard;
- A1.4** And, that the CFP recognizes that certification organizations accredited under either the CFP Standard or ISO/IEC 17024 Standard may offer Food Protection Manager Certifications;
- A1.5** So long as organizations seeking accreditation to provide Food Protection Manager Certifications using the ISO/IEC 17024 Standard abide by the requirements listed herein.

## SECTION 2.0 – DEFINITIONS

- A2.0** Definitions
- A2.1** For definitions please refer to *FDA Food Code, section 1-201.10*.

## SECTION 3.0 – SCHEME

- A3.0** Scheme
- A3.1 Purpose.** The Purpose of the ISO 17024 Standard, as it relates to the CFP Food Protection Manager Certification is to ensure that:
  - “...the competencies assessed in the accredited certification program are those required for competent entry level performance in the role of Certified Food Protection Manager, as defined by (United States) law and industry standards, and that they focus on factors related to the prevention of foodborne illness in the retail food industry,” (CFP Standard Section 4.10).
- A3.2** A food protection manager as addressed in *FDA Food Code, section 2-102.12* and *FDA Food Code, section 2-102.20*.
- A3.3** A Certified Food Protection Manager may work in a “food establishment” as defined in *FDA Food Code, section 1-201.10*.
- A3.4 Scope.** The Food Protection Manager Certification is based on the *FDA Food Code*. Certification organizations must update their programs to the latest *FDA Food Code* version within five (5) years of its release.
- A3.5 Geographic Limitations.**
  - A.** The scope of this personnel certification is based on the United States FDA Food Code; therefore it is inherently for individuals working in the United States or those who utilize its FDA Food Code;
  - B.** So long as an applicant outside of the United States is certified through an accredited program adhering to the requirements set forth in this document, the CFP recognizes that certification as a Food Protection Manager Certification.
- A3.6 Job Task Analysis.** Certification organizations must complete a job task analysis using the requirements defined in CFP Standard, section 4.4-4.76.

## SECTION 4.0 – PRE-REQUISITES

- A4.0** Pre-requisites
- A4.1** There are no training or other pre-requisites for Food Protection Manager Certification candidates.

## SECTION 5.0 – TRANSLATOR/TRANSLATION REQUIREMENTS

**A5.0** Translator/Translation Requirements

**A5.1 Application Process.** In the event a personnel certificate candidate requires an onsite translator, the application process for translators must include clear and precise qualifications for those translators.

**A5.2 Test Site Language Translation.** Certification organizations must follow the requirements set forth in CFP STANDARD, section 5.3.

## SECTION 6.0 – REPRESENTATION

**A6.0** Representation

**A6.1 Certificates.** All certificates delivered upon the successful passing of a certification exam accredited under the ISO 17024 Standard must include the Conference for Food Protection logo and the ANSI accreditation mark.

## SECTION 7.0 – DOCUMENT REFERENCES

**A7.0** The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

~~7.1~~ **A. FDA Food Code.** ~~The FDA Food Code 2013.~~

~~7.2~~ **B. CFP Standard.**

~~————~~ **C. ISO 17024.**

## ANNEX AB

### Guidelines for Regulatory Authorities Implementing Food Protection Manager Certification Programs

**AB1.** Each permitted *food establishment* should have a minimum of one designated *Certified Food Protection Manager* who is accountable for food safety.

Documentation of *certification* of *Certified Food Protection Manager(s)* should be maintained at each *food establishment* and shall be made available for inspection by the *regulatory authority* at all times.

**AB2.** A *Certified Food Protection Manager* is responsible for:

- 1) identifying hazards in the day-to-day operation of a *food establishment*;
- 2) developing or implementing specific policies, procedures or standards aimed at preventing foodborne illness;
- 3) coordinating training, supervising or directing food preparation activities and taking corrective action as needed to protect the health of the consumer; and
- 4) conducting in-house self-inspection of daily operations on a periodic basis to see that policies and procedures concerning food safety are being followed.

**AB3. Qualifications for Certification.** To become a *Certified Food Protection Manager*, an individual shall pass a *food safety certification examination* from an accredited *certification organization* recognized by the CFP. The CFP recognizes the importance and need for the provision of food safety training for all food employees and managers. The CFP recommends the content of food protection manager training be consistent with paragraph 2-102.11 (C) of the most recent FDA Food Code. The CFP promotes the information contained in the FDA Food Code as well as content outlines based on job tasks analyses, provided on the CFP website, which may be of value in developing or evaluating training.

**AB4.** Regulatory authorities should work with the *certification organization* on a mutually agreeable format, medium and time frame for the submission of score reports pertaining to the administration of *food safety certification examinations*.

# Food Protection Manager Certification Committee Bylaws

## Preamble

The Food Protection Manager Certification Committee, hereinafter referred to as the Committee, of the Conference for Food Protection, hereinafter referred to as the Conference, exists to carry out charges assigned via the Conference Issue process and from the Conference Executive Board, hereinafter referred to as the Board, relating to food protection manager certification and operates within the objectives stated in the Constitution and Bylaws of the Conference.

### **Article I. Name.**

The Name of the Committee is Food Protection Manager Certification Committee.

### **Article II. Objectives.**

- Section 1. Systematically identify and address issues concerning Food Protection Manager Certification Programs.
- Section 2. Adopt sound, uniform accreditation standards and procedures that are accepted by the Conference.
- Section 3. Promote uniformity among all jurisdictions that subscribe to the principles of the Conference by obtaining their recognition and adoption of the Conference Standards for Accreditation of Food Protection Manager Certification Programs.
- Section 4. Promote strategies to enhance equivalence among food protection manager certificates issued by certifying organizations.
- Section 5. Establish and refine policies and standards to which certifying organizations shall conform.

### **Article III. Organization and Operation.**

- Section 1. The Committee is a standing committee within the Conference.
- Section 2. The Committee shall consider all Issues charged to the Committee and shall work to develop consensus. The Board may submit charges to the Committee at any time. The Committee is to deliberate the charges expeditiously, or within the time frame determined by the Board or the Committee Chair.
- Section 3. The Committee shall use the protocol established in these Bylaws to address its charges.

Section 4. All Committee recommendations shall be submitted as Issues to the Conference for deliberation. The Committee shall follow the protocol for Issue submission as established by the Conference.

Section 5. All Issues, intellectual properties, and/or inventions created by the Committee and approved by the Assembly of Delegates become the property of the Conference.

#### **Article IV. Quorum**

A quorum to conduct Committee meetings and conference calls shall be the presence or participation of one more than half of the filled Committee positions. A Committee quorum shall be considered a sufficient number for voting on issues under deliberation. The decisions resulting from a quorum vote shall be deemed representative of the Committee.

#### **Article V. Composition of Organizational Components and Eligibility Requirements for Serving in Official Capacities.**

Section 1. The Committee shall be chaired by a Chair and Vice-Chair. Prior to each biennial Conference meeting, the incoming Chair and Vice-Chair shall be selected by the outgoing committee. The Chair, Vice-Chair and committee members shall be approved by the Board.

The Chair and Vice-Chair shall not be selected from the same constituency affiliation.

Section 2. The Committee Chair and Vice-Chair shall serve until the conclusion of the next biennial Conference meeting.

Section 3. The Committee Chair and Vice-Chair may serve consecutive terms with approval of the Board.

#### **Article VI. Committee Structure and Representation.**

Section 1. To be eligible to serve on the Committee as a voting member or non-voting alternate, individuals must commit in writing to active participation and be approved by the Conference Chair and the Board.

Section 2. The Committee Chair and Vice-Chair will select committee members and alternates from the list of volunteers from the most recent biennial meeting or recruit volunteers as appropriate to balance the committee as delineated in these Bylaws. In the event of a Committee vacancy with no designated alternate in that constituency, the Chair will first recruit from the remaining list of volunteers provided during the initial Committee selection process.

Section 3. The composition of voting members of the Committee is a balanced representation of industry, regulatory, academia, certification organizations, training providers, and consumers. The Committee membership representation shall consist of a maximum of thirty (30) full votes from the following constituencies:

Subsection 1. Nine (9) representatives from regulatory agencies with food safety responsibilities:

- a. Two (2) from State regulatory agencies;
- b. Two (2) from local regulatory agencies;
- c. Two (2) from federal government agencies; and
- d. Three (3) “At Large” appointments;

Subsection 2. Nine (9) industry representatives:

- a. Three (3) from the foodservice (restaurant) industry;
- b. Three (3) from the retail food store industry; and
- c. Three (3) “At Large” appointments. (\*At large selections may include professional or trade organizations that directly represent the restaurant, retail food, institutional foodservice, and food vending segments of the industry, and whose mission incorporates a public health protection component.)

Subsection 3. Five (5) total votes for certification organizations that are accredited by the Conference’s accreditation process. Although there is no limit to the number of accredited certification organizations, this constituency shall have a maximum of five (5) votes.

Subsection 4. Three (3) Food Protection Manager training providers;

Subsection 5. Two (2) representatives from academia; and

Subsection 6. Two (2) consumer/independent representatives/public members.

Section 4. Committee members will serve a two (2) year term, concurrent with the cycle of the biennial Conference meeting. Committee members are eligible to serve for consecutive terms contingent upon an assessment by the Committee Chair and Vice-Chair to ensure a balance between members who have previously served on the Committee and new members.

- Section 5. Up to two (2) non-voting alternates will be included on the Committee roster each for industry, regulatory, academia, training providers, and consumers to best represent the category of each constituency. Each certification organization participating on the Committee may designate one (1) alternate from their own organization. In the event a Committee member resigns or is no longer able to serve the remainder of their term, the Chair shall select an alternate from the affected constituency to fill the open seat.
- Section 6. The incoming Chair of the Committee shall make every effort to retain at least 50% of the Committee membership for a continuing term. This retention is recommended due to the complexity of issues, the need to retain continuity of Committee functions, and the short time frame between biennial Conference meetings.
- Section 7. In the event a Committee member changes constituency during their term, the Chair may consider them for any open seat on the Committee which needs representation from their constituency or consider any open alternate position. If the Chair determines that there are no appropriate openings available, the Committee member will be asked to resign from the committee.

## **Article VII. Committee Organization, Operation, and Meetings**

- Section 1. The Committee shall receive its direction from the Board. The Board shall assign the Committee its charges as approved during the biennial Conference meeting. The Board may assign additional charges to the Committee to ensure that the Conference Standards for Accreditation of Food Protection Manager Certification Programs and accreditation process are administered in a fair and responsible manner.
- Section 2. The Committee shall meet in-person at least annually and at the biennial Conference meeting. All Committee meetings are open to anyone to attend. In addition to meetings, the Committee shall schedule conference calls, as deemed appropriate, for addressing issues under deliberation. In the event that sensitive, financial or proprietary information is under consideration by the Committee, the Chair shall have the option to conduct an executive session until the confidential portion of the proceedings has been concluded.
- Section 3. In addition to the charges received from the Board, Committee members may submit Issues and alternative recommendations to the Committee for discussion. Issues and recommendations introduced by Committee members shall be submitted using the Conference format.
- Section 4. Presentations for in-person Committee meetings shall be submitted to the Committee Chair and Vice-Chair for review at least 2-weeks prior to meeting dates.

## Section 5. Voting.

Subsection 1. A consensus building decision process will be used. When Committee members are asked to vote, each member will be able to express one of three positions.

- A thumb up indicates agreement with the issue on the floor
- A thumb sideways means the position on the floor is not the member's optimal solution, but they can accept the position
- A thumb down indicates that a member does not agree with the issue on the floor and would like an alternative recommendation considered.

The Committee Chair shall provide an opportunity for the dissenting member(s) to express the alternative position(s). After discussion of these alternative positions, the Chair will call for a final vote from the Committee.

Subsection 2. Except for certification organizations, all voting Committee members and alternates designated for that meeting shall have one (1) vote.

Subsection 3. All certification organizations accredited by the Conference's accreditation process participating on the Committee shall not to exceed a total of five (5) votes.

- If more than five (5) certification organizations volunteer to participate on the Committee, the five (5) votes allocated to certification organizations shall be fractionalized (evenly divided).
- The voting fraction shall be determined when the final committee membership is approved by the Board and shall remain in effect until the next biennial Conference meeting.
- Each certification organization shall be allowed no more than one (1) vote or one (1) voting fraction at any meeting.

Subsection 4. The Vice-Chair may voice positions on issues and may vote on all matters before the Committee.

Subsection 5. The Chair is a non-voting member of the Committee; however, in the event of a tie, the Chair may vote as the tie-breaker.

Section 6. Committee funding. The Board may allocate funds to the Committee for its charges. These funds may be used to contract the services of outside experts to assist the Committee, attend meetings with potential accreditation entities, and other miscellaneous expenses that the Committee must incur, e.g., use of meeting rooms. Funding shall not be allocated to cover an individual Committee member's

travel or per diem expenses to attend meetings. Committee funding may be used only as directed by the Board.

### **Article VIII. Duties of the Committee Chair**

Section 1. The Chair and Vice Chair, with the approval of the Board shall select Committee members in accordance with these Bylaws.

Section 2. The Chair, with concurrence of two-thirds (2/3) of the voting members of the Committee may appoint non-voting Ex-Officio consultants and advisors to the Committee in accordance with these Bylaws.

Section 3. The Chair shall preside at all meetings of the Committee, except as provided in these Bylaws.

Section 4. The Chair shall coordinate the arrangement of meetings and conference calls and ensure that meeting dates and locations are posted in advance on the Conference web site.

Section 5. The Chair shall be responsible for distributing to Committee members and other meeting participants an agenda for the meeting or conference call. This agenda may be distributed by email, fax, mail, or other suitable means.

Section 6. The Chair may assign a Committee member, using a rotation basis or other appropriate means among all Committee members, to take minutes during designated meetings and conference calls.

Section 7. The Chair shall be responsible for distributing minutes of all Committee meetings or conference calls in a timely manner, usually within three weeks of the event.

Section 8. The Chair may designate ad hoc workgroups to conduct research, study proposals, and develop procedures or recommendations related to complex issues and/or charges to address the charges of the Board and complete the duties of the Committee.

### **Article IX. Duties of the Committee Vice-Chair**

Section 1. In the event the Chair is unable to perform the duties of the Chair, the Vice-Chair shall act as Chair.

Section 2. When acting as Chair, the Vice-Chair shall perform all the necessary duties for the Committee as outlined in these Bylaws.

Section 3. The Vice-Chair shall perform all duties assigned by the Chair.

### **Article X. Duties of Committee Members/Alternates**

- Section 1. Committee members shall have the responsibility to notify the Committee Chair of their inability to attend a meeting or participate on a conference call at least fifteen (15) days prior to the scheduled meeting or conference call. For any committee member that is unable to attend a scheduled meeting or conference call, an alternate will be assigned. Selection of the designated alternate will be agreed upon by the Committee Chair and the absent member and chosen to best represent the constituency of the absent member. This designated alternate may vote on issues before the committee only during the specified meeting or conference call.
- Section 2. Committee members and alternates shall have the responsibility to review for comment standards, reports, recommendations, issues or other Committee documents distributed within the time frames designated by the Committee.
- Section 3. Committee members and alternates shall have the responsibility to complete work assignments within time frames designated by the Committee.
- Section 4. Committee members and alternates shall have the responsibility to notify the Committee Chair or the Chair's designee of their inability to complete a work assignment.
- Section 5. Committee members that do not participate for three (3) consecutive meetings and/or conference calls shall have their continued participation as Committee member assessed by the Committee Chair and evaluated by the Committee. The Committee member may be subject to being removed from their membership position. Removal of a Committee member for failure to perform duties as specified in these Bylaws, shall require the concurrence of two-thirds (2/3) of the voting members of the Committee.

#### **Article XI. Committee Advisors, Subject Matter Experts, Paid Consultants and Conference Appointments**

- Section 1. Federal participants (FDA/USDA/CDC) may appoint an advisor and an alternate to serve as non-voting ex-officio members of the Committee. The alternate may act in the advisor's place if the advisor is unable to attend.
- Section 2. The Conference Chair, at the request of the Committee Chair, with approval of the Executive Board, may appoint a psychometrician advisor to serve as a non-voting ex officio member of the Committee.
- Section 3. The Chair and Vice-Chair may invite, with approval from the Committee, subject matter experts, external to the Committee, to participate in meetings and conference calls, or to work with an ad hoc workgroup, if it is determined that such individuals would provide additional information, insight, clarification,

guidance or other assistance to the Committee, for a specified purpose. These subject matter experts will be non-voting guests in meetings and conference calls.

Section 4. The Committee may contract the services of a paid consultant for issues beyond the scope of the Committee's expertise, if deemed necessary or if charged by the Board. Contractual obligations for paid consultant services shall have the concurrence of two-thirds (2/3) of the voting members of the Committee and be approved by the Board.

Section 5. Conference appointments to the ANSI-CFP Accreditation Committee (ACAC) shall serve as non-voting ex-officio members of the Committee.

## **Article XII. Workgroups**

Section 1. Workgroups shall report to the Committee Chair and Vice-Chair as determined by the Committee Chair.

Section 2. Each workgroup shall select a group leader who is responsible to report group activities to the Committee Chair and Vice-Chair.

Section 3. Workgroups shall provide written reports and recommendations to the full Committee for deliberation.

## **Article XIII. Committee Reports**

Section 1. The Committee Chair shall be responsible for preparing written or oral reports to the Board detailing the activities and expenditures of the Committee. Written reports of the Committee's activities shall be submitted as required by the Conference procedures.

Section 2. The Committee Chair shall coordinate the development of a final report of the Committee activities to Council II with recommended actions. The final report shall be done as part of an Issue submission and shall comply with all Conference procedures.

Section 3. The Committee Chair, Vice-Chair, or designee as specified in writing to the Council II Chair, shall be in attendance when Council II meets during the Conference meeting to present and discuss the Committee's report and any Issues submitted by the Committee.

## **Article XIV. Amendments**

The Food Protection Manager Certification Committee Bylaws may be altered, amended, or repealed by two-thirds (2/3) vote of the Committee and final concurrence from the Board, and then submitted as an Issue during the next biennial meeting.

**Food Protection Manager Certification Committee (FPMCC)**  
**Organizational Conference Call Meeting**  
**September 18, 2018**  
Dial 669-900-6833 / meeting ID 210 249 8057

**MINUTES OF THE MEETING**

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**CONFERENCE CALL AGENDA**

I. Roll Call

Vice Chair Sharon Wood called the meeting to order at 1:05 PM EST, roll was called and a quorum established. Vice Chair Wood referenced the anti-trust policy, and reminded the FPMCC members of the gravity of this issue. Members may access the statement in its entirety on the CFP website at [CFP antitrust policy](#).

II. Introduction of Chair and Vice Chair

Chair Sean Dunleavy and Vice Chair Sharon Wood welcomed returning and new members and introduced themselves.

III. Review of Standing Charges for Food Protection Manager Certification Committee – Chair Dunleavy

Chair Dunleavy reviewed the FPMCC charges for the 2018-20 biennium and advised no additional charges have been assigned by the CFP Executive Board. A priority for this cycle will be consideration and development of a “normative document” and its utility.

Member George Roughan advised he may not make the Fall meeting and may ask Ryan McMillion to present an agenda item. The Committee was invited to add agenda items for the Fall Meeting; none were offered.

Vice Chair Wood presented an overview of the methodology and focus for the Committee’s work this cycle and advised the CFP Executive Board has requested the FPMCC consider a more formal process in how it interfaces and works together with ANSI.

Cynthia Woodley advised ANSI Vijay Krishna may be unavailable for the Fall meeting and indicated an alternate may need to be designated; Vice Chair Wood offered to follow up on that.

IV. Review of proposed Agenda for Upcoming Face to Face meeting in San Diego – Vice Chair Wood

Vice Chair Wood presented expectations for committee activity this cycle, including an overview of the topics to be discussed such as orientation, past activity, consideration of focus and accomplishments for this biennium, the potential for some self-appointed goals, and the committee workgroup process.

Chair Dunleavy added work on the normative document would be a priority for the committee this biennium.

Cynthia Woodley requested that the ANSI re-accreditation application process be discussed.

A member asked that training and “remote location” CFPM delivery be discussed.

Vice Chair Wood advised that academic constituents are needed for the FPMCC and requested input.

V. Meeting in San Diego details

Geoff Luebkekmann requested that anyone planning to attend the Fall Meeting and not staying at the HQ hotel advise him by email ([gluebkekmann@firla.org](mailto:gluebkekmann@firla.org)) for planning purposes.

VI. Adjourn

Chair Dunleavy adjourned the meeting at 1:30 PM EST.



**TUESDAY 10/23/2018**

<b>Attendance – Voting Members Present, Present by Phone (P), or Absent</b>					
1	Dunleavy, <i>Chair</i>	11	Derr	21	Paster
2	Wood, <i>Vice Chair</i>	12	Guzzle	22	Piche
3	Algeo	13	Halbrook	23	Quam
4	Borwegen	14	Hawley	24	Roughan
5	Brown	15	Hilton	25	Smith, C
6	Chapman	16	Hussein (P)	26	Smith, T
7	Corchado	17	Kender	27	Straughn
8	Daniel	18	Kramer	28	Tyjewski
9	Davis	19	Luebkemann	29	Vacant - Academia
10	Dela Cruz	20	McMillion	30	Vacant - Academia

<b>Attendance – Alternates, Consultants, Others Interested Present or Present by Phone (P)</b>
<b>Alternates present, not activated</b> Mark Conley (National Restaurant Association), Michael Baker (National Registry of Food Safety Professionals), Emilee Follett (P) (StateFoodSafety) Harry Klein (Prometric), Renee Beckham (Regulatory – Local)
<b>Consultants present</b> Beth Wittry (CDC), Laurie Williams (FDA), Julie Albrecht (ACAC), Katie Calder (ANSI, alt for Vijay Krishna)
<b>Other Interested Parties present</b> Larry Lynch (National Registry), Thomas Larson (StateFoodSafety)

## **FOOD PROTECTION MANAGER CERTIFICATION COMMITTEE (FPMCC) MEETING AGENDA**

1. Welcome & Introductions
2. CFP Anti-trust Statement, housekeeping
3. Orientation & Standards Workshop
4. Committee Administration
  - a. Standing committee, reports to Executive Board
  - b. Purpose of Committee
  - c. Constituencies
    - Academia
    - Certification Providers
    - Consumer/Independent
    - Industry (Food Service, Retail)
    - Regulatory (Local, State, Federal)
    - Training Providers
  - d. Voting, non-voting, alternates
  - e. Advisors/consultants (ACAC, ANSI, FDA/USDA, Psychometrician) (non-voting)
  - f. Meeting procedures
  - g. Voting procedures
5. Review of Committee Bylaws
6. Review of FPMC Standards
7. Charges from CFP
8. ANSI-ACAC Report
9. Workgroup formation and tasking
10. Next “live” meeting - Spring 2019 (April, TBD)

**1. Welcome & Introductions, roll call, housekeeping**

Chair Sean Dunleavy convened the meeting at 8:30 AM, members were welcomed and introduced themselves. Roll was called, a quorum of 20/30 voting members established, and 29 people total were in attendance.

**2. CFP Anti-trust statement** was read by Chair Dunleavy.

**3. Minutes of Sept. 18, 2018 conference call** were approved as corrected.

**MOTION**

**Paster** moved, **Dela Cruz** seconded that:

The minutes of Sept 18, 2018 be approved with one typo corrected. Motion passed unanimously.

**4. FPMCC Orientation & Standards Workshop**

Patrick Guzzle presented CFP orientation and an overview of the FPMCC and its work.

**5. FPMCC Committee Administration, Committee Bylaws review, and 2018-20 Charge**

Vice Chair Sharon Wood reviewed the 2018-20 FPMCC charge; forecast the work of the current biennium, reviewed the FPMCC member composition and described the various stakeholder constituencies; the FPMCC Bylaws; and conveyed the expectation that members embrace the responsibility and obligation to engage and participate in the work of this FPMCC.

**2018-20 FPMCC Charge**

The Food Protection Manager Certification Committee 2018-20 is charged:

To carry out charges assigned via the Conference Issue process and from the Conference Executive Board relating to food protection manager certification and to adopt sound, uniform accreditation standards and procedures that are accepted by the Conference while ensuring that the Conference Standards for Accreditation for Food Protection Manager Certification programs and the accreditation process are administered in a fair and responsible manner.

**6. Food Protection Manager Certification Standards review**

Vice Chair Sharon Wood reviewed the history and importance of the FPMC Standards, their purpose and importance, and the work FPMCC workgroups produced in support of these during the 2016-18 cycle, including the study of ISO Standard 17024 for harmonization with existing FPMC Standards.

2016-18 Workgroup Chair Bryan Chapman reviewed the concept of a “normative document” that was developed last biennium.

2016-18 Communications Workgroup Chair Tara Paster described the communications workgroup activity, and thanked Co-Chair Ryan McMillion for his efforts, and Cynthia Woodley for her edits.

2016-18 Standards Workgroup Chair Kate Piche presented a review of the FPMC Standards and previous Committee work related thereto.

**7. American National Standards Institute (ANSI) and ANSI-CFP Certification Accrediting Committee (ACAC) reports**

Katie Calder, ANSI representative (alternate for Vijay Krishna) is ANSI Senior Director of Accreditation Services and reported: her role and responsibilities with ANSI; that as ANSI celebrates its 100<sup>th</sup> anniversary in 2018 it is undergoing a “digital evolution;” that ANSI is the official US member body to the International Standards Organization (ISO), holds several permanent roles with ISO, and works extensively with federal agency members; ANSI’s role in accreditations and conformity assessment and the diversity of these undertakings; the differentiation between “certificate” and “certification” and self- second- and third-party demonstrations of standards conformance; revisions to the ANSI ISO 17011 accreditation process; the ANSI certifying body accreditation application process; ACAC roles, members, and the contract between CFP and ANSI; that the FPMC Standards pre-date the existence of ISO 17024 and ANSI involvement in food safety; and ANSI 2019 initiatives.

## 8. Workgroup Formation and Tasking

Workgroup Chairs and participants from the 2016-18 biennium recapped their activities and framed the work for the current biennium. These Workgroups were formed and action items assigned:

### Standards Workgroup – Kate Piche, Chair

Members: Emily Follett, Susan Algeo, Liz Corchado-Torres, Hector Dela Cruz, Michael Baker, Sue Tyjewski, Beth Wittry

- 1) Review ANSI's application for accreditation for alignment with the FPMC Standards.
- 2) Review the "Normative Document" relative to FPMC Standards, ANSI application for accreditation, and alignment with any FPMC Standards revisions.

### Bylaws Workgroup – Jeff Hawley, Chair

Members: Liz Corchado-Torres, Patrick Guzzle, Susan Quam, Hector Dela Cruz, DeBrena Hilton, Dawn Borwegen, Justin Daniel, Courtney Halbrook, Susan Algeo, Sharon Wood, K. Calder/V.Krishna, Sima Hussein

- 1) Review the current CFP-ANSI contract and:
  - a) consider whether it meets CFP needs, addresses rules of engagement for the parties, and establishes service expectations, and produce related recommendations for improvement.
  - b) consider adding a clause that establishes coordination and alignment of ANSI accreditation application updates and the FPMC Standards.
  - c) ensure current version of the FPMC Bylaws are posted on FPMCC web page.

### Communications Workgroup – Tara Paster, Chair

Members: Terri Smith, Shana Davis, Laurie Williams, Bryan Chapman, Renee Beckham, Harry Klein, Gina Kramer, Mark Conley, Ryan McMillion, Patrick Guzzle

- 1) Develop communication that clearly differentiates "food handler certificate" and "food protection manager certification," support correct characterization of these in regulators' information, and:
  - a) create clarity in the differentiation of "ANSI accredited certification bodies" and "training providers," recommend methods to communicate that.
  - b) create clarity in the differentiation of "food manager certification" and "food handler training," and recommend methods to communicate same.
- 2) Review and update the "Regulatory Outreach" powerpoint presentation, and
  - a) complete the speaker's notes for each slide, create user instructions.
- 3) Develop a communication marketing/outreach plan that includes
  - a) a social media strategy.
  - b) methods to best engage and educate regulatory and industry stakeholders on the CFP; the FPMCC; the differentiation among training, certificate and certification activity.
  - c) leveraging meetings of FDA Regionals, NACCHO, NEHA, AFDO and similar conferences; direct outreach to industry, health departments, and professional stakeholder groups.
  - d) a promotion and distribution plan for the "Regulatory Outreach" powerpoint presentation.
- 4) Review and revise FPMCC web page FAQs (circa 2005) for relevance and accuracy.

### Logistics Workgroup – Geoff Luebke, Courtney Halbrook, Co-Chairs

- 1) Plan and support meetings for remainder of the 2018-20 biennium.

### FPMCC - all

- 1) Provide feedback to the CFP Executive Board on its position statement re: ServSafe and National Registry as separate entities, for the sole purpose of judging the statement to be clear or unclear, without debate or discussion on the merits of the statement, and without revision thereto.

## 9. Next "live" meeting - Spring 2019

Tentatively scheduled April 11-12, 2019, at a location to be determined.

### MOTION

**Chapman** moved, and **Corchado** seconded that:

The FPMCC adjourn, and the Workgroups meet during the remainder of the Fall Meeting time.

Motion passed unanimously.



**THURSDAY 04/11/2019**

<b>Attendance – Voting Members Present, Present by Phone (P), or Absent</b>					
1	Dunleavy, Chair	11	Dela Cruz	21	McMillion
2	Wood, Vice	12	Derr	22	Paster
3	Algee	13	Guzzle	23	Piche
4	Anderson	14	Halbrook	24	Quam
5	Borwegen	15	Hawley	25	Roughan
6	Brown	16	Hilton	26	Smith, T
7	Chapman	17	Hussein	27	Straughn
8	Corchado	18	Kender	28	Tyjewski
9	Daniel	19	Kramer	29	Vacant - Academic
10	Davis	20	Luebkemann	30	Vacant - Academic

<b>ATTENDANCE – ALTERNATES, CONSULTANTS, OTHER INTERESTED PARTIES</b>
<p><b>Alternates present and activated</b>            Michael Baker (for Corchado); Renee Beckham (for Straughn); Emilee Follett (for Chapman); Harry Klein (for McMillion); Bridget Sweet (for Vacant – Academic)</p>
<p><b>Alternates present, not activated</b>            Mark Conley; Jason Fine; Melissa Smith;</p>
<p><b>Consultants present</b>            Vijay Krishna (04/11 only); Laurie Williams; Cynthia Woodley</p>
<p><b>Other Interested Parties present</b>            Tom Larsen (State Food Safety)</p>

**I. Welcome and opening**

Meeting called to order 8:30 AM; intros, roll call, anti-trust, sponsor thank-yous, quorum established. – Sharon.

Sponsor recognition:

1. Susan Quam     Wisconsin Restaurant Association
2. Kate Piche     National Restaurant Association
3. Larry Lynch     National Registry of Food Safety Professionals
4. Ryan McMillion Prometric
5. Tom Anderson 360 Training
6. Emilee Follett State Food Safety
7. The Florida Restaurant and Lodging Association

## II. Review and Approval of Fall 2018 FPMCC meeting minutes

### MOTION

Hawley moved, Dela Cruz seconded that:

The minutes of Sept 18, 2018 be approved with one typo corrected. Motion passed unanimously.

### III. Executive Board meeting updates – Sharon Wood reported for David Lawrence:

Next Executive Board meeting is Aug 13, 14 at Diversey headquarters; the 2022 Biennial Meeting location is Houston, TX; Vicki Everly was announced as the new CFP Executive Assistant, succeeding Aggie Hale. Nomenclature for CFP is under study and consideration being given to “Congress for Food Protection.” Wood presented the FPMCC interim report to the Executive Board. New media (apps, social, etc) are under review for use by CFP to help promote the mission and general understanding of CFP activity.

### IV. ANSI Updates – Vijay Krishna

Krishna reported on history and evolution of ANSI: over the last 100 years, over 200 professional societies have participated in developing ANSI standards in their respective industries; ANSI is the U.S. representative to ISO, which has over 120 member countries and covers over 30,000 standards.

Krishna further reported on ANSI’s relationship with CFP: the CFP develops the FPMC standards, and ANSI audits and affirms conformity with the letter and intent of those standards; provides annual training to approximately 350 assessors across all content areas; in 2019 FPMC audits will be made against the 2018 revision of the associated standards, in addition to ISO 17024 plus the associated normative documents (the application for audit is under development); some FPMC providers will be dually audited and accredited. The history of harmonization and application of both FPMCC Standards and ISO 17024 was explained, along with the benefit of unifying assessment / reducing duplication in compliance auditing.

On May 29-30, 2019, ANSI will host an open workshop for understanding CFP FPMC accreditation at its Washington, DC, offices. The target audience is currently accredited organizations, those contemplating accreditation, and the various members of that organization that participate in the accreditation process.

Piche noted new items in the application appear to have been added and asked for explanation on the inclusion and benefit of those; Krishna responded that the 2018 Standards change invited an opportunity to revise the application and assure the appropriate evidence is being collected; in summary the changes were due to both the Standards change and the opportunity for ANSI to continually improve the process; development of the normative documents questions for the application are anticipated to follow.

Wood recognized Jeff Hawley, who explained the CFP process for benefit of newer members.

**ACAC updates** – no ACAC information was presented.

### V. Workgroup Break-out time

Overviews – Wood called on each workgroup chair for a brief overview of their purpose and work for benefit of newer committee participants, then the workgroups convened.

### VI. Workgroup reports, work product review, deadlines

#### A. Standards – Piche

Piche reported three task areas were assigned to the workgroup:

1 - “guidance document” discussion revealed it would have no requirement for conformity, and consensus was that the accrediting org is the appropriate entity to formulate any guidance and the ANSI CFP Workshop will fill some of that need.

2 - ISO 17024 “normative document” – the workgroup recommended that this be added as a stand-alone Appendix B to the Standards

3 – Look at the Standards as relates to “remote proctoring;” provide recommendations related thereto to the FPMCC.

## MOTION

**Piche** moved, **Dela Cruz** seconded that:

The ISO 17024 normative document be added to the FPMC Standards as a new Appendix A and be required for compliance with the FPMC Standards, and the current Appendix A be relabeled Appendix B. Motion passed with unanimous consent.

- The workgroup reviewed the ANSI application for accreditation, based on the 2018 changes to the Standards and ANSI continual improvement opportunities: some semantic changes to application questions were developed with consensus support; the matter of application questions regarding “alternate non-traditional proctoring” was discussed and Krishna offered characteristics on how this would be acceptably deployed and recommends not creating specific additions to the Standards for this type of proctoring; Anderson suggested there is a need to assess whether the current Standards are sufficient to address alternate, non-traditional proctoring; Woodley suggested consideration of reference adoption of standards currently under development by NCTA-NTPA regarding non-traditional proctoring; discussion ensued regarding a number of questions – derived directly from the Standards – that bear opportunity for improved clarity and potential for improvement; the workgroup will follow those opportunities and continue developing recommendations to the Committee.

### B. Communications – Paster

The workgroup was tasked with developing communication tools and content for public dissemination to foster understanding among the regulatory and industry communities of the work and mission of the CFP, and formed 4 teams:

1) Food Handler vs. Food Manager – a document was developed to describe and clarify these two roles and their differences; the Committee reviewed the content and developed consensus on the final version.

2) FAQs document – last updated in 2005, the team focused on making these brief and less technical; the Committee reviewed the content and developed consensus on the final version.

3) User guide document for the “FPMCC explainer powerpoint” – after deliberation and feedback, the team decided to eliminate this document and incorporate the relevant content directly into the previously developed “FPMCC explainer powerpoint.”

4) Information Outreach Plan – need to catalog organizations, events, conferences, and meetings where the target audience that would benefit from these communications tools gather; this plan will incorporate social, links, blogs, and the direct communication channels of relevant organizations; need to develop communication tools for the target audiences.

Wood recessed the Committee at 4:30 PM to allow additional workgroup time.

Attendance – Voting Members Present, Present by Phone (P), or Absent					
1	Dunleavy, Chair	11	Dela Cruz	21	McMillion
2	Wood, Vice	12	Derr	22	Paster
3	Algee	13	Guzzle	23	Piche
4	Anderson	14	Halbrook	24	Quam
5	Borwegen	15	Hawley	25	Roughan
6	Brown	16	Hilton	26	Smith, T
7	Chapman	17	Hussein	27	Straughn
8	Corchado	18	Kender	28	Tyjewski
9	Daniel	19	Kramer	29	Vacant - Academic
10	Davis	20	Luebkemann	30	Vacant - Academic

ATTENDANCE – ALTERNATES, CONSULTANTS, OTHER INTERESTED PARTIES
<p><b>Alternates present and activated</b>                      Michael Baker (for Corchado); Renee Beckham (for Straughn); Emilee Follett (for Chapman); Harry Klein (for McMillion); Bridget Sweet (for Vacant – Academic)</p>
<p><b>Alternates present, not activated</b>                      Mark Conley; Jason Fine; Melissa Smith;</p>
<p><b>Consultants present</b>                      Laurie Williams; Cynthia Woodley</p>
<p><b>Other Interested Parties present</b>                      Tom Larsen (State Food Safety)</p>

Wood reconvened the Committee at 830 AM; attendance taken; a quorum established.

C. Bylaws – Hawley

Hawley explained the Committee composition, the role of alternates and the importance of their attendance to remain informed and ready to serve as needed.

Hawley explained two proposed Bylaw revisions, to Sections 2 and 5, both of which codify and clarify current operating practice.

The recommended revisions proposed:

Article VI, Section 2 - (underlined section is new text)

The Committee Chair and Vice-Chair will select committee members and alternates from the list of volunteers from the most recent biennial meeting [...]

Article VI, Section 5 - (underlined section is new text)

In the event a Committee member resigns or is no longer able to serve the remainder of their term the Chair shall select an alternate from the affected constituency to fill the open seat.

## MOTION

**Hawley** moved, **Sweet** seconded that:

The FPMCC Bylaws be revised as follows in underlined text:

Article VI, Section 2 - (underlined section is new text)

The Committee Chair and Vice-Chair will select committee members and alternates from the list of volunteers from the most recent biennial meeting [...]

Article VI, Section 5 - (underlined section is new text)

In the event a Committee member resigns or is no longer able to serve the remainder of their term the Chair shall select an alternate from the affected constituency to fill the open seat.

Motion passed with unanimous consent.

Hawley then explained the current Bylaws certification organization fractionalized voting formula, and recommended this be revised. Discussion ensued regarding capping the certification organization members at the current 5, and if additional providers become accredited, then the 5 voting attendees be selected for each meeting.

Anderson suggested that the certification organization voting members could be capped at a percentage of the voting memberships, and / or establish term limits for the certification organization voting members. He further suggested the constituency vote weighting be capped. Additional discussion ensued.

## MOTION

**Hawley** moved, **Hilton** seconded that:

the Bylaw Workgroup be authorized to develop language to cap voting certification organization members at 9. Motion passed, with one sideways (Roughan) based on the importance that certification organizations not be limited in their voice.

Discussion ensued regarding meeting attendance, regulator commitment and challenges to attendance, use of technology to facilitate meetings and help for travel-challenged regulators, obstacles for regulators to access technology (i.e., federal prohibitions on certain web applications). More discussion will be raised at future meetings.

Hawley advised the Executive Board requested the FPMCC review the ANSI contract, executed in 2002, for recommendations. Among the topics to review: deliverables and reporting expectations (currently scant); expiration date; performance review function (none currently exists); ANSI attendance at FPMCC meetings (none currently exists); provision for an alternate to the primary ANSI attendee (none currently exists); any other expectations to consider.

Discussion took place and a number of recommendations were generated for reporting to the CFP Executive Board.

Hawley then raised the matter of nominating a successor to ACAC representative Joyce Jensen, whose term expires in 2020, and encouraged the Committee to immediately begin considering candidates due to the difficulties presented by experience requirements and avoiding conflicts of interests. It was suggested that nominee qualifications be communicated to the FPMCC members for dissemination and recruiting purposes.

Hawley then covered items in the CFP Master Calendar:

- June 5, 2019 Council application deadline
- Nov. 1, 2019 FPMCC Final report deadline; Committee Issues submission deadline

- Dec. 31, 2019 Issue submission deadline

D. Logistics – Luebkekmann

- Logistics was asked to save Oct. 15 & 16, 2019, for the FPMCC Fall meeting
- Discussion ensued regarding meeting logistics, i.e., is F&B important, whether the current schedule pattern (Tuesday all day, Wednesday half day) meets the FPMCC needs.
- the members expressed desire to allocate workgroup break out time during meetings
- volunteers were sought to complete a meeting logistics survey: Daniel, Hilton, Beckham, Anderson, Smith M, Wood, Roughan, Woodley, Paster, Williams, Dawn, Gina, Hawley

**VII. Committee Housekeeping**

These items were covered in other sections of the agenda.

Wood adjourned the meeting at 10:25 AM, encouraging the workgroups to use that time as needed.

DRAFT

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**Food Protection Manager Certification Committee (FPMCC)**  
**Austin, TX | April 11- 12, 2019**  
**Accepted by the Committee April 11, 2019**

**Thursday 8:30 a.m. Meeting Call to Order**

- I. Welcome and opening procedures
  - A. Chair welcome and comments
  - B. Committee member and guest introductions
  - C. Reading of the CFP Anti-trust Statement
  - D. Attendance, quorum, and alternate activations
  - E. Review of Bylaws requirements for membership and voting alternates – Sharon Wood
- II. Review and approval of FPMCC Fall 2018 Meeting minutes – Geoff Luebkemann
- III. Board Meeting Update – Notes from David Lawrence
- IV. ANSI, ACAC Updates – Vijay Krishna
- V. Workgroup Breakout Sessions – 2 hours
- VI. Workgroup reports, work product review, deadlines
  - A. Standards
  - B. Communications

**Friday 8:30 Meeting Call to Order**

- Continue Workgroup reports, work product review, deadlines
- C. Bylaws
  - D. Logistics
- VII. Committee housekeeping
- A. Member roster review, vacancies, contact info verification
  - B. CFP 2020 Biennial Meeting Reports and Deadlines
  - C. Fall 2019 meeting dates

Adjournment



**TUESDAY 10/15/2019**

<b>Attendance – Voting Members Present or Absent</b>					
1	Dunleavy, Chair	11	Dela Cruz	21	McMillion
2	Wood, Vice	12	Derr	22	Paster
3	Algeo	13	Guzzle	23	Piche
4	Anderson	14	Halbrook	24	Quam
5	Berwegen	15	Hawley	25	Roughan
6	Brown	16	Hilton	26	Smith, T
7	Chapman	17	Hussein	27	Straughn
8	Corchado	18	Kender	28	Tyjewski
9	Daniel	19	Kramer	29	Vacant - Academia
10	Davis	20	Luebkemann	30	Vacant - Academia

<b>ATTENDANCE – ALTERNATES, CONSULTANTS, OTHER INTERESTED PARTIES</b>
<b>Alternates present and activated</b> Renee Beckham (for Hilton)
<b>Alternates present, not activated</b> Michael Baker, Mark Conley, Jason Fine, Samantha Montalbano
<b>Consultants present</b> Vijay Krishna (04/11 only), Laurie Williams; Beth Wittry, Cynthia Woodley
<b>Other Interested Parties present</b> None.

**I. Welcome and opening procedures**

Meeting called to order at 8:30 AM by Chair Sean Dunleavy and Vice Chair Sharon Wood. Member introductions were made, roll called, and the CFP anti-trust statement was read and explained. A quorum of 15 voting members of 28 filled seats was established.

Meeting Sponsors recognized for their generous support:

1. Wisconsin Restaurant Association, Susan Quam
2. National Restaurant Association, Kate Piche
3. National Registry of Food Safety Professionals, Larry Lynch
4. Prometric, Ryan McMillion
5. 360 Training, Tom Anderson
6. State Food Safety, Bryan Chapman
7. The Florida Restaurant and Lodging Association

## II. Review and Approval of Spring 2019 FPMCC meeting minutes

### MOTION

**HAWLEY** moved, **PASTER CAMMARATA** seconded that:  
The minutes of the Spring 2018 minutes be approved. Motion passed unanimously.

## III. Executive Board updates – Chair Sean Dunleavy

Hawley was recognized and reported he presented suggested revisions to the ANSI contract to the Executive Board. These will be available in the Executive Board minutes, which will be posted to the CFP website soon. The CFP Biennial Meeting begins March 30, 2020 in Denver, and the FPMCC will meet onsite at that time for its last meeting of the cycle.

It was also reported that the FPMCC must nominate to the Executive Board an ACAC representative to succeed Joyce Jensen, as well as leaders for FPMCC 2020-22.

Wood asked the FPMCC members to consider persons for Chair and Vice Chairs for the 2020-22 biennium. Dunleavy declined to be considered, and Wood stated she would accept consideration.

## IV. ANSI, ACAC Updates

### ANSI – Krishna

Krishna provided an overview of ANSI, including its activities in approving standards as American National Standard (ANS) and explained ANSI's role as the U.S. member body to the International Organization for Standardization (ISO). Krishna explained how ANSI was created, and that it performs work typically undertaken by government bodies outside the US. ANSI maintains over 10,000 US standards and works with over 30,000 international standards.

Krishna updated the committee about ANSI National Accreditation Board (ANAB), a wholly owned subsidiary of ANSI. All accreditation services previously offered by ANSI including the CFP program are now offered through ANAB. WorkCred is an ANSI affiliate whose mission is to strengthen workforce by improving the credentialing system. Additional information about ANAB and WorkCred are available at [www.anab.org](http://www.anab.org) and [www.workcred.org](http://www.workcred.org) respectively.

Krishna provided details about the publication of the application for meeting CFP Normative Requirements for certification bodies applying under ISO/IEC 17024 and CFP-PR-817: ANSI-CFP accreditation under the ISO 17024 pathway. This document is available on the ANSI website at <https://www.ansi.org/Accreditation/credentialing/personnel-certification/food-protection-manager/DocumentDetail?DRId=20927>.

Lastly, ANSI offered a workshop on the CFP 2018 standard in Washington, D.C. on May 29-30, 2019. Approximately 15 participants attended the workshop

### ACAC – no ACAC representative present

Jeff Hawley reported that Sheri Morris, PA Dept. of Agriculture, is willing to serve as ACAC representative, which will be further discussed later in the meeting.

## V. Workgroup Break-out time

Wood tasked the workgroups to break out and finalize work products.

## VI. ACAC Representative for FPMCC 2020-22 – Hawley

[covered earlier and later]

## VII. Workgroup reports, work product review, deadlines

A. Standards – Piche

Piche thanked the members for their extensive participation and input and presented the workgroup's proposed revisions. The FPMCC reviewed each, provided comment and discussion, and expressed consensus support for the revisions as submitted. Upon final approval of the revised Standard content, the entire document will be reviewed for proper formatting.

**MOTION**

**CORCHADO** moved, **QUAM** seconded that:

The Standard workgroup revisions be accepted as presented. Motion passed unanimously.

B. Bylaws - Hawley

Jeff Hawley reviewed the FPMCC Bylaw revisions previously approved by the FPMCC at the 2019 Spring Meeting Austin. No additional revisions were proposed by the FPMCC. Additional Bylaw revisions could be necessitated by any associated, subsequent changes to the CFP-ANSI contract.

Hawley additionally reported on proposed revisions to the CFP-ANSI contract - which has been in effect without revision since May 15, 2002 - undertaken by request of the Executive Board. Hawley was asked to lead that review, and presented at the August 2019 CFP Executive Board meeting. The revisions were developed in consultation with ANSI representative Katie Calder, and accepted by the Executive Board with minor edits. The Executive Board will next seek outside legal review of the proposed revised contract for sufficiency and efficacy.

In the revised contract, the term "ANSI" is replaced by "ANSI National Accreditation Board (ANAB)", a wholly owned subsidiary of ANSI.

C. Communications – Tara Paster Cammarata

Paster Cammarata provided an overview of four elements to the workgroup's Outreach Plan:

- 1) CFP FAQs and an integrated Food Handler - Food Manager Comparison Chart
- 2) CFP Communication Outreach PowerPoint 2019
- 3) Workgroup sub-team content areas
- 4) Targeting elements of the Outreach Plan:
  - a) organizations to contact
  - b) specific communication channels to deploy
  - c) need for a CFP statement of authority to replicate and disseminate the outreach material
  - d) a survey tool to shape the tactical aspects of the Outreach Plan

The documents were reviewed at length, in depth, and finalized with comments and edits from the FPMCC. Some recommended revisions may require CFP Executive Board approval which Sharon Wood will pursue.

**MOTION**

**LUEBKEMANN** moved, **ROUGHAN** seconded that:

The documents and elements of the Outreach Plan prepared by the Communications Workgroup and finalized by consensus of the FPMCC, be transmitted to the Executive Board for approval and execution. Motion passed unanimously.

D. Logistics

The Logistics Workgroup planned and executed the Fall Meeting Pittsburgh, and circulated a survey to FPMCC members to further refine and improve meetings. Results will be compiled and reported to the FPMCC.

Vice Chair Wood recessed the meeting at 4:30 PM, to reconvene October 15, 2019 at 8:30 AM.

<b>Attendance – Voting Members Present or Absent</b>					
1	Dunleavy, Chair	11	Dela Cruz	21	McMillion
2	Wood, Vice Chair	12	Derr	22	Paster
3	Algee	13	Guzzle	23	Piche
4	Anderson	14	Halbrook	24	Quam
5	Berwegen	15	Hawley	25	Roughan
6	Brown	16	Hilton	26	Smith, T
7	Chapman	17	Hussein	27	Straughn
8	Corchado	18	Kender	28	Tyjewski
9	Daniel	19	Kramer	29	Vacant - Academia
10	Davis	20	Luebkemann	30	Vacant - Academia

<b>ATTENDANCE – ALTERNATES, CONSULTANTS, OTHER INTERESTED PARTIES</b>
<b>Alternates present and activated</b> Renee Beckham (for Hilton)
<b>Alternates present, not activated</b> Michael Baker, Mark Conley
<b>Consultants present</b> Laurie Williams
<b>Other Interested Parties present</b>

Vice Chair Wood reconvened the FPMCC at 8:35 AM. Roll was called and a quorum of 15 voting members of 28 filled seats established.

**Communications – Tara Paster Cammarata**

Wood recognized Tara Paster Cammarata to continue workshoping the Communication Workgroup Outreach Plan. The FPMCC reviewed and provided comments on a survey document that Paster Cammarata produced overnight, to be used to gauge CFP members’ communication preferences. The FPMCC provided comments and suggestions, and the survey document was accepted by consensus as edited. Paster Cammarata will circulate the final product.

**ACAC representative**

Wood returned the FPMCC to discussion of ACAC representation, and directed the members attention to the resume of Sheri Morris, PA Dept. of Agriculture. Jeff Hawley explained Morris’ background and qualifications and advised she expressed willingness to serve.

<b>MOTION</b>
<b>HAWLEY</b> moved, <b>PASTER CAMMARATA</b> seconded that: Sheri Morris be nominated to the Executive Board for approval as ACAC representative. Motion passed with unanimous consent.

Discussion then moved to selecting FPMCC leaders for the 2020-22 biennium. Nominations were made from the floor that Sharon Wood be selected Chair, and Susan Quam Vice Chair. In Chair Dunleavy’s absence, Wood passed the gavel to past Chair Jeff Hawley and the candidates left the room. No additional nominations were advanced, and discussion closed.

## **MOTION**

**HAWLEY** moved, **HALBROOK** seconded that:

Sharon Wood be nominated to the Executive Board for FPMCC 2020-22 Chair and Susan Quam for FPMCC 2020-22 Vice Chair. Motion passed unanimously.

The candidates returned to the room and were congratulated on their nominations.

### **VIII. Committee Housekeeping and Final Comments**

Wood recognized Hawley to review deadlines and dates for reports and issues submission leading into the 2020 Biennial Meeting, which are posted on the CFP website (browse foodprotect.org, click conference administration, click calendar). Vice Chair Wood is authorized to prepare the necessary FPMCC documents and reports for submission, and will circulate them to the FPMCC members for informational purposes.

A final meeting of this FPMCC is scheduled 5-6 PM Sunday, March 29, 2020 in conjunction with the CFP Biennial Meeting in Denver.

The FPMCC members then discussed ideal length and format for the FPMCC meetings, with consensus that these could be shorter, could use distance meeting technology, should be driven by the FPMCC workload and charges, and determined by the Chair and Vice Chair as needs dictate.

Tom Anderson of 360Training, an accredited certification body, stated his organization had employees conduct more than twenty "audits" using prohibited practices to test CFPM exam security.

Discussion ensued regarding the general state of exam security and related technology, with consensus emerging that this be considered in the next biennium.

The meeting was adjourned at 10:00 AM.

**Food Protection Manager Certification Committee Fall Meeting**  
**October 15–16, 2019 | Sheraton Pittsburgh Station Square**  
**Pittsburg, PA**  
rev. 2019-09-09

**October 15, 2019**

8:30 a.m. Meeting Call to Order - Sharon Wood, Vice Chair

- I. Welcome and opening procedures
  - o Chair welcome and comments
  - o Committee member and guest introductions
  - o Reading of the CFP Anti-trust Statement
  - o Attendance, quorum, and alternate activations
  - o Review of Bylaws requirements for membership and voting alternates
- II. Review and approval of FPMCC Fall 2018 Meeting minutes – Geoff Luebkekmann
- III. Board Meeting Update – Sean Dunleavy
- IV. ANSI, ACAC Updates – Vijay Krishna
- V. ACAC Representative for FPMCC 2020 - 2022
- VI. Workgroup Breakout Sessions – 1 hour
- VII. Begin Workgroup reports, work product review, deadlines
  - A. Standards
  - B. Bylaws
  - C. Communications
  - D. Logistics

**October 16, 2019**

8:30 Meeting Call to Order

- Continue Workgroup reports, work product review, deadlines
  - o Standards
  - o Bylaws
  - o Communications
  - o Logistics
- VIII. Committee housekeeping
  - o Member roster review, vacancies, contact info verification
  - o CFP 2020 Biennial Meeting Reports and Deadlines
- Adjourn

# ANSI-CFP Accredited Food Protection Manager Certification Programs

## Education Outreach

Benefits of the ANSI-CFP Accredited Certification Programs



# ANSI-CFP Accredited Food Protection Manager Certification Programs

## Education Outreach

**Disclaimer:** The purpose and intent of this presentation is to educate regulatory, industry, academia, and consumer constituents. The Conference for Food Protection (CFP) and the American National Standards Institute (ANSI) does not assume any responsibility for the organizations, companies, and government agencies in this presentation. This is strictly a method of educational outreach to increase the understanding of all constituents as it relates to the Conference for Food Protection.

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# Agenda

**Welcome and thank you for your commitment to the global food supply!**

- Section 1:** Conference for Food Protection (CFP), American National Standards Institute (ANSI), and ANSI-CFP Accredited Food Protection Manager Certification Exam Providers
- Section 2:** Legally defensible, Certification vs. Certificate, and Test Development Principles
- Section 3:** FDA, 2013 FDA Food Code, and FDA Risk Factor Study
- Section 4:** Benefits, Security Solutions, and Call To Action
- Section 5:** Resources, Conclusion, and Invitation



# Section 1:

## CFP, ANSI, and ANSI-CFP Accredited Food Protection Manager Certification Programs



# What is CFP?

- The Conference for Food Protection (CFP) <http://www.foodprotect.org/> is an organization that brings together representatives from the food industry, government, academia, and consumer organizations to identify and address emerging problems of food safety and to formulate recommendations.
- The CFP has been actively working to standardize Food Protection Manager Certification across the United States and Maintains the Standards for Accreditation of Food Protection Manager Certification Programs
- The CFP meets biennially to collaboratively discuss the issues submitted to it.



# What is ANSI?

- As the voice of the U.S. standards and conformity assessment system, the American National Standards Institute (ANSI) <https://www.ansi.org/> empowers its members and constituents to strengthen the U.S. marketplace position in the global economy while helping to assure the safety and health of consumers and the protection of the environment.
- ANSI maintains a conformity assessment division that conducts conformity assessment (accreditation) activities.
- ANSI is the body selected to conduct accreditation activities on behalf of CFP.



# Did you know there are currently five ANSI-CFP Accredited Certification Programs?

- 360training.com <https://www.360training.com/>
- National Registry of Food Safety Professionals <http://www.nrfsp.com/>
- Prometric <https://www.prometric.com/>
- ServSafe <https://www.servsafe.com/>
- State Food Safety <https://www.statefoodsafety.com/>



# Competency and Competency Examination

- **Competency** means a defined combination of *knowledge, skills and abilities* (KSAs) required in the satisfactory performance of a job.
- **Competency examination** means an instrument that assesses whether an individual has attained at least a minimum level of *competency* that has been determined to be necessary to perform effectively and safely in a particular occupation or job. It shall be based on a thorough analysis of requirements for safe and effective performance.<sup>1</sup>



## Section 2:

Legally Defensible

Certification vs. Certificate

CFP Standards for Exam Development



# Legally Defensible

It is important that certification programs adopted for use by regulatory bodies be *legally defensible*.

**Legally defensible** means the ability to withstand a legal challenge to the appropriateness of the examination for the purpose for which it is used.

Accreditation by a third party such as ANSI adds to the legal defensibility of the certification programs by ensuring the certification programs adhere to best practice standards such as the CFP Standards for Accreditation of Food Protection Manager Certification Programs.



# Certification vs. Certificate

- There is a difference between Certification Programs and Certificate Programs.
- The CFP Standards for Accreditation of Food Protection Manager Certification Program is designed to be a set of voluntary unifying national standards providing a mechanism for the universal acceptance of food protection managers *certification* programs.
- The CFP national Standards for universal acceptance of *Certified Food Protection Managers* provide *regulatory authorities reliable* and *legally defensible criteria* for ANSI-CFP Accredited Certification Programs.



# Certification vs. Certificate

Certification Programs	Certificate Programs
<p>Credential awarded to candidates based on a third-party assessment of competence by a credentialing body.</p>	<p>Credential awarded to candidates based on successful completion of a training or educational program. It may include an assessment of learning.</p>
<p>The content of certification is based on a job or practice analysis that identifies the tasks and associated knowledge, skills and attributes (KSAs) required for competent performance</p>	<p>The content of a certificate program is based on the required learning objectives for the course curriculum.</p>
<p>Certification is time limited and must be regularly renewed as the candidate demonstrates continued competence</p>	<p>Certificates from certificate programs generally do not have to be renewed.</p>



# Certification vs. Certificate

Certification Programs	Certificate Programs
Certificate is “owned” by the Certification Body and may be taken away from the certified person.	Certificates from certificate programs are owned by the graduate and are not taken away even if the person eventually forgets what he or she has learned.
Accreditation involves looking at how the scheme was developed and how competence is assured (i.e. how the assessment and examinations are developed).	Accreditation involves looking at how the curriculum is developed, delivered and evaluated and how learning is developed.

The Food Protection Manager Certification Programs are designed to be Certification Programs and not Certificate Programs. Seat time and completion of educational or training do not meet the definition of certification programs.



# The *CFP Standards for Accreditation of Food Protection Manager Certification Programs* require accredited food manager programs to meet best practice standards

Best practice standards apply to:

- Examination development
- Examination administration
- Security of confidential information



# Examination Development

CFP Standards associated with examination development include:

- A *Job-Task Analysis (JTA)* that identifies the tasks that a Food Protection Manager would be responsible for doing and the knowledge, skills and attributes (KSAs) that are associated with those tasks. (Clause 4.4)
- Involvement of a representative sample of subject matter experts in the development of the JTA. (Clause 4.4)
- *Examination Specifications* that include a percentage or number of items for each content area. (Clause 4.6)



# Examination Development

CFP Standards associated with examination development include:

- Requirements associated with *how the test items are written, reviewed and evaluated*. The certification body must use a fair, valid, reliable and legally defensible method for the development and maintenance of examinations. (Section 4.0)
- Requirements associated with the *qualifications of the experts* who write, review and evaluate test items. The certification body must maintain records on the qualifications of the Subject Matter Experts (SMEs) who participate in the development of the program. (Clause 4.7)
- Translation of examinations. *Equivalency* of translated examinations must be demonstrated. (Clause 4.14)



# Examination Administration

CFP Standards associated with examination administration include:

- Test site requirements including requirements associated with the *physical location*. (Clause 5.2)
- Scoring considerations that include *how, when and where examinations will be scored*. (Clause 5.4)
- Test Administrator/Proctor requirements including information pertaining to their qualifications, training, roles and responsibilities and the *test administrator/proctor to candidate ratio*. (Clauses 5.5, 5.6, 5.7, 5.8 and 5.9)



# Security of Confidential Information

Standards requirements associated with security of confidential information include:

- Examination booklet security (Clause 5.1)
- Examination security (Clause 5.11)



# Section 3:

U.S. Food & Drug Administration (FDA)



2013 Food Code  
Risk Factor Study



# FDA Risk Factor Study and how it relates to the ANSI Accredited Food Protection Manager Certification Exam

- “The FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurants, and Retail Food Store Facility Types (1998-2008) presents the results of the examination of data from three collections over the ten-year period. The analysis focuses on the **detection of trends** over the study timeframe to determine what progress has been made toward the goal of reducing the occurrence of foodborne illness risk factors at retail.”



# FDA Risk Factor Study and how it relates to the ANSI Accredited Food Protection Manager Certification Exam

- “A study was needed to determine the **effectiveness of the nation’s retail food protection system** and to establish performance measures.”
- “FDA will also continue to **promote adequate training and certification of facility personnel**, including a deliberate move towards increased use of certified food protection managers as common practice.”



# Why should Regulators require FPM Certifications?

- FDA encourages food regulatory authorities and others evaluating credentials for food protection managers to recognize the ANSI-CFP Food Protection Manager Certification Accreditation Program.
- The ANSI-CFP Accreditation Program provides a means for universal acceptance of certified individuals who successfully demonstrate knowledge of food safety.
- ANSI-CFP Accreditation provides officials assurance that food safety certification is based on valid, reliable, and legally defensible criteria.
- In addition, universal acceptance eliminates the inconvenience and unnecessary expense of repeating training and testing when managers work across jurisdictional boundaries.”



# FDA 2-102.12 Certified Food Protection Manager

- (A) The PERSON IN CHARGE shall be a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM.
- (B) *This section does not apply to certain types of FOOD ESTABLISHMENTS deemed by the REGULATORY AUTHORITY to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and extent of FOOD preparation.*



# FDA Definition: Person in Charge (PIC)

“Person in charge” means the individual present at a FOOD ESTABLISHMENT who is responsible for the operation at the time of inspection.”



# FDA 2-102.20 Food Protection Manager Certification

- (A) A PERSON IN CHARGE who demonstrates knowledge by being a FOOD protection manager that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of FOOD Protection Manager Certification Programs is deemed to comply with §2-102.11(B).
- (B) A FOOD ESTABLISHMENT that has an EMPLOYEE that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of FOOD Protection Manager Certification Programs is deemed to comply with §2-102.12.



# Section 4:

Benefits

Security Solutions

Call To Action



# Benefits

- The ANSI-CFP Accreditation Program to the CFP Standards provides regulatory authorities with a valid, reliable, and legally defensible method for evaluating Food Protection Manager Certification Programs.
- A fair, valid, reliable, legally defensible, credible and objectively evaluated Food Protection Manager Certification Program is important to ensure food safety and ultimately for consumer protection.
- Regulatory authority universal acceptance of Certified Food Protection Managers in accordance with the CFP Standards for Accreditation benefits all stakeholders.



# What are the benefits to Regulatory Jurisdictions?

Regulatory Jurisdictions benefits include:

- savings on human and financial resources required to evaluate and administer Food Protection Manager Certification Programs;
- limits of legal liability resulting from a lack of the required expertise on staff to develop, administer or evaluate Food Protection Manager Certification Programs (such as the lack of an individual with expertise in the psychometric development of written examinations);
- assurance by a third-party accreditor (ANSI) that all accredited certification programs meet the CFP Standards; and
- opportunities for regulatory agencies to devote their limited resources to their retail food protection program rather than the credentialing of Food Protection Managers.



# What are the benefits to Industry?

Industry benefits include:

- increased reciprocal acceptance of certification across jurisdictional lines;
- increased value of the Food Protection Manager Certification;
- third party quality assurance conducted on the certification programs that are offered;
- a consistent meaning for certification within the profession; and
- enhanced confidence that the certification process is fair, valid, reliable, and legally defensible.



# Security Solutions

- The charge to the Food Protection Manager Certification (FPMC) Committee is to maintain the Standards to enhance the **integrity** of the entire examination process, which includes identification and analysis of **root causes of security violations** and implementation of **solutions**.



# Security Solutions in the Standard

- All examinations shall be delivered and administered in a format that ensures the **security of the examination** (i.e. in a secured environment with a *test administrator/proctor*).
- **Unproctored** examinations are **not** acceptable regardless of the mode of administration.



# Security Solutions Call To Action – We need You!

[If you see something, say something!](#)

Please notify the appropriate ANSI Accredited Food Protection Manager Certification Exam Provider:

- 360training.com <https://www.360training.com/>
- National Registry of Food Safety Professionals <http://www.nrfsp.com/>
- Prometric <https://www.prometric.com/>
- ServSafe <https://www.servsafe.com/>
- State Food Safety <https://www.statefoodsafety.com/>



# Section 5:

## Conclusion Invitation



# Conclusion

- Currently, there are **five choices** for Food Manager Certification in the industry.
  - **Regulators:** ANSI has accredited five Food Protection Manger Certification Programs!
  - **Industry:** You have options! Choose the specific certification that meets or exceeds your business needs but always follow your regulatory requirements!
- **Bottom line:** Regardless of the provider, the examination, or the delivery method, the outcome will be the **same!**



# Invitation – ALL are welcome!

Join us at the next Biennial Meeting!

**Make A Difference! Get Involved Today!** [www.foodprotect.org](http://www.foodprotect.org)

Identify and address emerging food safety issues and make recommendations!



**Conference for Food Protection**  
**Standards for Accreditation of Food Protection Manager Certification Programs**  
**Frequently Asked Questions**

Updated 10.24.2019

**Q1. What is the Conference for Food Protection (CFP)?**

**A1.** CFP is an independent, national, and voluntary nonprofit organization with a purpose that includes identifying food safety problems, adopting fair and workable procedures to address those problems, maintaining a working relationship among government, industry, academia, professional and consumer groups, and promoting uniformity of regulation in food protection. In order to support those goals, CFP encourages active participation by representatives of diverse stakeholder groups and seeks to produce high quality standards by consensus.

**Q2. Why did the Conference for Food Protection develop the Standards for Accreditation of Food Protection Manager Certification Programs (Standard)?**

**A2.** The Standard for Food Protection Managers was developed to assist regulatory authorities in identifying organizations who have valid, reliable and legally defensible certification programs. The Standard was developed to assess the competence of certification organizations to administer certification exams based on industry defined competence requirements. This assessment of the competence of certification organizations is conducted by a third-party accreditation body American National Standards Institute (ANSI) National Accreditation Board.

**Q3. How did CFP develop the Standard?**

**A3.** The Standard was developed by the CFP Food Protection Manager Certification Committee through a consensus-based process and approved by CFP. The CFP Food Protection Manager Certification Committee includes representatives of food industry stakeholders including Federal, State, and local regulatory agencies, academia, foodservice and retail food store industries, trade associations, operators, consumer groups, certifying organizations, and test providers. The Committee's approach provides for balanced decisions arrived by collaboration and consensus.

**Q4. How can I obtain a copy of the CFP Standard?**

**A4.** The Standard may be obtained from the CFP website [www.foodprotect.org](http://www.foodprotect.org).

**Q5. What is a Certified Food Protection Manager?**

**A5.** A Certified Food Protection Manager is an individual who has demonstrated by means of passing a food protection manager certification examination from an accredited certifying organization that he/she has the knowledge, skills and abilities required to protect the public from foodborne illness. The duties of a Certified Food Protection Manager could include but are not limited to:

- identifying hazards in the day-to-day operation of a food establishment that provides food for human consumption;
- developing and implementing specific policies, procedures or standards aimed at preventing foodborne illness;
- coordinating training, supervising food preparation activities, and taking corrective action as needed to protect the health of the consumer; and
- completing in-house self-inspections of daily operations on a periodic basis to see that policies and procedures concerning food safety are being followed.

**Q6. What is the difference between Certified Food Protection Manager and Food Handler?**

**A6.** The differences between a Certificate Food Protection Manager and Food Handler are illustrated in the table below:

	<b>Certified Food Protection Manager</b>	<b>Food Handler</b>
<b>Role</b>	Someone who is responsible for a food establishment operations and/or processes, has direct authority over food employees at the time of an inspection, and has been certified by an ANSI-accredited certification.	Someone who handles unpackaged food, food equipment or utensils or food contact surfaces but does not manage/supervise employees, processes, or operations.
<b>Title</b>	May be called Food Safety Manager, Food Service Manager, Food Manager or equivalent. The regulatory term is Person-In-Charge (PIC).	May be called Food Employee, Food Worker, or equivalent.
<b>Responsibilities</b>	Responsible for following Food Code requirements which include: <ul style="list-style-type: none"> <li>• Overseeing operation and Food Employees</li> <li>• Reporting certain illnesses to the local regulatory authority and restricts/excludes Food Employees as required</li> <li>• Ensuring that Food Employees are trained in food safety standards and practices and that those standards and practices are followed</li> <li>• Answering food safety questions during regulatory authority inspections</li> </ul>	Responsible for following Food Code requirements which include: <ul style="list-style-type: none"> <li>• Reporting to PIC</li> <li>• Reporting symptoms and illnesses to the PIC, and comply with restriction/exclusion as required</li> <li>• Maintaining cleanliness and personal hygiene</li> <li>• Following food preparation standards and practices set in place by PIC</li> </ul>
<b>ANSI-Accredited Programs</b>	<a href="#"><u>ANSI-CFP Accredited Food Protection Manager Programs</u></a>	<a href="#"><u>ANSI Accredited Food Handler Programs</u></a>

**Q7. What is the difference between a certificate program and certification?**

**A7.** There are significant differences between a “certificate program” and “certification”.

A certificate program is a non-degree-granting education or training program consisting of:

(1) a learning event or series of events designed to educate or train individuals to achieve specified learning outcomes within a defined scope, and

(2) a system designed to ensure individuals receive a certificate only after verification of successful completion of a program.

On the other hand, certification is a time-limited, revocable, renewable credential awarded by an independent, third-party certification organization.

The differences between a Certificate Program and Certification are illustrated in the table below:

<b>Certificate Program</b>	<b>Certification</b>
The certificate is awarded by an education or training organization	The certificate is awarded by an independent, third party certification organization
The assessment is knowledge based and intended to measure learning objectives and outcomes	The assessment measures competencies (knowledge, skills and abilities) related to a specific job in an occupation or profession
The individual owns the certificate. It may not be revoked	Certification organization owns certificate and can revoke it

**Q8. What is accreditation?**

**A8.** Accreditation is third party verification by an independent organization (such as ANSI National Accreditation Board) confirming a certification organization’s competence to carry out a certification program according to a standard (in this case the CFP Standard).

**Q9. Who accredits Food Protection Manager Certification organizations according to the Standard developed by CFP?**

**A9.** ANSI National Accreditation Board is under agreement with CFP to accredit certification organizations administering Food Protection Manager Certification programs. The final decision to accredit is determined by the ANSI-CFP Accreditation Committee (ACAC). CFP has two representatives on ACAC.

**Q10. Who is eligible to enter the ANSI-CFP accreditation process?**

**A10.** All Food Protection Manager Certification organizations will be eligible to apply for the accreditation if they meet ANSI National Accreditation Board's eligibility requirements.

Interested organizations can contact ANSI National Accreditation Board at [www.ansi.org](http://www.ansi.org) for more information.

**Q11. How does a certification organization achieve ANSI-CFP accreditation?**

**A11.** The certification organization must provide documented evidence through the ANSI-CFP accreditation process that it meets the CFP Standard. ANSI National Accreditation Board will review the evidence provided and evaluate the entire certification program, using specific criteria to verify compliance with the CFP Standard.

**Q12. What Food Protection Manager Certification Organizations are currently accredited?**

**A12.** ANSI National Accreditation Board maintains a current listing of accredited Food Protection Manager Certification Organizations on their website [www.ansi.org](http://www.ansi.org).

**Q13. Why should a regulatory agency adopt the CFP Standard and recognize the ANSI National Accreditation Board accreditation process?**

**A13.** Beginning with the 2009 FDA Food Code, the FDA has recommended that states adopt the Food Protection Manager Certification as one way to demonstrate knowledge. In many states, persons-in-charge (PIC) are required to obtain a Food Protection Manager Certification.

Adopting this requirement provides regulatory agencies with a valid, reliable, and legally defensible mechanism to ensure that PICs who have passed a Food Protection Manager Certification exam have the knowledge, skills, and abilities required to protect the public from foodborne illness.

**Q14. What confidence can regulatory agencies have in the Food Protection Manager Certification?**

**A14.** The ANSI-CFP accreditation process includes a third-party assessment from qualified professionals at ANSI National Accreditation Board who measure and monitor each certification organization to ensure conformity with the CFP Standard. Therefore, regulatory agencies can confidently assume that any Food Protection Manager Certificate issued by an accredited Certification Organization has been issued according to the CFP Standard.

**Q15. Is one Food Protection Manager Certification exam better than another?**

**A15.** Passing an exam from **any** certification organization accredited to the CFP Standard by ANSI National Accreditation Board will satisfy the requirement for certification. While the examinations may be different (different number of questions, different passing score, etc.) being certified by any of the accredited certification organizations implies that the certified person has met the requirements for competence.

**Q16. Do all Food Protection Manager certificates satisfy the requirement for certification?**

**A16.** Certificates satisfy the requirement for certification only if they have been awarded by a certification organization that has been accredited to the CFP Standard by ANSI National Accreditation Board. Certificates that satisfy the requirement will bear the ANSI-CFP accreditation mark:



**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-002**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

FPMCC Standards for Accreditation of Food Protection Manager Certification

**Issue you would like the Conference to consider:**

Approval of revisions to the Standards for Accreditation of Food Protection Manager Certification Programs.

**Public Health Significance:**

The credentialing process for *Certified Food Protection Managers* assists in the protection and promotion of food safety by carefully determining the competencies necessary to prevent foodborne illness, unbiased education and training for acquisition of competencies necessary to maintain food safety, and fair assessment practices to ensure that individuals have achieved mastery of these competencies.

**Recommended Solution: The Conference recommends...:**

The Conference recommends:

1. approval of the revised Standards for Accreditation of Food Protection Manager Certification Programs (attached to Issue titled: FPMCC Final Report - Food Protection Manager Certification Committee; attachment title: Attachment III\_CFP Food Protection Manager Certification Standards Version 1.9.2020.);
2. authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
3. that the revised Standards be posted on the CFP website in PDF format.

**Submitter Information 1:**

Name: Sean Dunleavy  
Organization: FPMCC

Address: 525 West Allegan  
City/State/Zip: Lansing, MI 48933  
Telephone: 517-243-8895  
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**Submitter Information 2:**

Name: Sharon Wood  
Organization: FPMCC  
Address: 5105 Rittiman Road  
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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-003**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

FPMCC - Bylaw Revisions

**Issue you would like the Conference to consider:**

Approval of the revisions to the Food Protection Manager Certification Committee Bylaws.

1. All revisions are contained within the revised document: "Revised FPMCC Bylaws 2019". Strike-through font indicates content being removed and underline indicates content added.

**Public Health Significance:**

The credentialing process for *Certified Food Protection Managers* assists in the protection and promotion of food safety by carefully determining the competencies necessary to prevent food-borne illness, unbiased education and training for acquisition of competencies necessary to maintain food safety, and fair assessment practices to ensure that individuals have achieved mastery of these competencies. The Bylaws which govern the Food Protection Manager Certification Committee ensure a standardized approach to management of this credential.

**Recommended Solution: The Conference recommends...:**

The Conference recommends:

1. approval of the revised Food Protection Manager Certification Committee Bylaws (attached to Issue titled: FPMCC Final Report; attachment title: Attachment IV\_ FPMCC Bylaws 2019);
2. authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
3. that the revised Bylaws be posted on the CFP website in PDF format.

**Submitter Information 1:**

Name: Sean Dunleavy  
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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-004**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Limit CPFM accredited exam certificate validity to four years

**Issue you would like the Conference to consider:**

Accredited exams for the Certified Food Protection Manager (CPFM) expire at five years from issue. This has been the case since before the Conference began meeting. The FDA Retail Food Code is published every four years. Reducing the valid period for the exam certificate will better synchronize the knowledge the Person In Charge must demonstrate to regulators with the knowledge demonstrated at the time of testing for the exam. A significant number of people could skip an entire Food Code update without being tested on it.

**Public Health Significance:**

The impact to the industry will include

1. CPFMs with more current and accurate information who will be able to make good decisions about food safety practices.
2. In a span of twenty years in the industry a CPFM who keeps their certification current will take only one additional exam, so cost is minimal.
3. Many large corporations and franchisees require their managers to recertify every three years, so no impact on them.

The impact to the regulatory agencies will be interacting with more knowledgeable Persons in Charge who better understand current food safety strategies.

**Recommended Solution: The Conference recommends...:**

that accredited testing organizations validate their Certified Food Protection Manager examination certificates for a time period not to exceed four years from date of issuance, aligning knowledge demonstration by examination with the routine four year update and publication of the FDA Retail Food Code.

**Submitter Information:**

Name: Lars Johnson  
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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name  
or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-005**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018 II-24; new or additional information has been included or attached.

**Title:**

Report-Constitution ByLaws and Procedures Committee (CBPC)

**Issue you would like the Conference to consider:**

At the 2018 Biennial Meeting the CBPC was charged with:

1. Review the Conference for Food Protection governing documents (Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Manual, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Issues 2012-II-001, 2012-II-004, 2014-II-018 and 2016-II-026)
2. Review membership and constituency at-large members on all committees and offer recommendations on how to address the quantity and functionality of committees
3. Report back to the Executive Board; and submit recommendations as Issues at the 2020 Biennial Meeting

**Public Health Significance:**

The Constitution, Bylaws and Procedure Committee shall submit recommendations to improve the Conference administrative functions through proposals to amend the Constitution and Bylaws.

The CFP Constitution is our foundational document; and therefore needs to be unassailable.

**Recommended Solution: The Conference recommends...:**

Acknowledgement of the 2018-2020 Constitution Bylaws and Procedures Committee Final Report and thanking the committee members for their hard work.

**Submitter Information 1:**

Name: Davene Sarrocco-Smith  
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Address: 5966 Heisley Road  
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Telephone: 440-350-2543  
E-mail: dsarrocco\_smith@lcghd.org

**Submitter Information 2:**

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E-mail: squam@wirerestaurant.org

**Content Documents:**

- "Committee Final Report"
- "Committee Member Roster"
- "CBPC At-Large Constituency options"
- "Categorization of CFP Documents"
- "Draft Revised CFP Constitution and Bylaws"
- "Draft Final MOU between CFP and NACCHO"

**Supporting Attachments:**

- "Meeting Minutes"
- "Attendance at conference calls"

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## Conference for Food Protection – Committee FINAL Report

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

*With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.*

**COMMITTEE NAME: Constitution ByLaws and Procedures Committee**

**DATE OF FINAL REPORT: November 1, 2019**

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

**REPORT SUBMITTED BY: Davene Sarrocco-Smith, Chair**

### COMMITTEE CHARGE(S):

#### **Issue #2018 II-024**

1. Review the Conference for Food Protection governing documents (Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Manual, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Issues 2012-II-001, 2012-II-004, 2014-II-018 and 2016-II-026)
2. Review membership and constituency at-large members on all committees and offer recommendations on how to address the quantity and functionality of committees.
3. Report back to the Executive Board; and submit recommendations as Issues at the 2020 Biennial Meeting.

### Executive Board Charges

1. Work with the Strategic Planning Committee to discuss the impact of changing the name of our organization from "Conference for Food Protection" to "Congress for Food Protection".
2. Work with Issue Committee Chairs regarding framework of Issue management process, specifically what is taking place from Issues being made public until the Biennium.
3. Add "App Liaison" position to the CFP Procedures document.
4. Define "student" for registration purposes, self-reporting and what happens if they get a job during the cycle? Do they have to pay again or registration fee or just let the student registration fee carry over until the next cycle?
5. Chair to review the Issue management process with the Issue Committee Chairs to determine if the CFP governing documents have language preventing Issue submitters from contacting Council members in advance of the Biennial Meeting.
6. A general point of clarification was raised asking if committee and council chairs, and vice- or co-chairs, are to be included on a roster, and if their voting status is to be indicated or counted towards constituency balance.
7. CB&P Committee to categorize the CFP documents included on the list in the CB&P Committee report dated 03/01/2019 and use the category titles of "governing," "administrative," and "instructional."
8. Chair to work independently with Issue Committee Chairs regarding Issue integrity.
9. CB&P Committee to bring to the Board meeting in August 2019 a single revised Constitution and Bylaws document, using underline and strikeover for any changes, so the Board can extract those items they feel need to be submitted as separate Issues.
10. Review the CFP MOU with NACCHO.
11. Define roles of Co-Chair and Vice Chair in the CFP Biennial Meeting/Conference Procedures document

### COMMITTEE WORK PLAN AND TIMELINE:

1. Fourth Wednesday of every month conference calls took place. As of the February 27, 2019, conference call frequency had been increased to the 2<sup>nd</sup> and 4<sup>th</sup> Wednesday of every month with the primary goal of continuing review and editing the Constitution and By Laws
2. Sub-committees were formed fall 2018: At-Large Constituency; Strategic Planning; Constitution review.
3. Sub-committees were formed spring 2019 and worked independently: Student Registration; Formatting; Grammar review, and MOU review.
4. Council Chair to work independently with Issue Committee Chairs regarding Issue integrity, spring 2019.

### COMMITTEE ACTIVITIES:

1. Full committee conference calls took place; 9/26/18, 10/24/18, 12/12/18, 1/23/19, 2/13/19, 2/27/19. 3/27/19, 4/10/19, 5/8/19, 5/22/19, 6/12/19, 6/26/19, 7/10/19, 10/9/19, 10/30/19.
2. Subcommittees were formed
  - a. At-Large constituency subcommittee
    - i. Brought drafts to full committee for discussion. Full committee reviewed and agreed on Committee At-Large document Jan. 23, 2019.
  - b. Strategic Plan
    - i. Worked with SPC and brought document for full committee review and agreement on Oct. 24, 2018, with an additional week for comments before SPC chairs were given last feedback on October 31, 2018.
  - c. Constitution Review
    - i. Continual review and editing of the 2018 Constitution and By Laws took place.

- d. Formatting for the Constitution
  - i. Current Constitution has inconsistent formatting throughout the document. Subcommittee provided this format: *Article/Section/Subsection/a)1. to be used throughout the document. The full committee voted and this format was agreed upon.*
  - ii. The reformatting of the Constitution will wait until after the Fall 2019 Executive Board meeting. Committee agreed.
- e. Grammar review of the Constitution
  - i. Discussion regarding review for the edited version of the Constitution took place. Subcommittee thought it best to wait until after the Fall 2019 Executive Board meeting. At that time grammar corrections to the Constitution will be made. Full committee agreed.
- f. Student Registration subcommittee
  - i. Objective was to develop a procedure for what CFP should do when “students” gain employment during the 2-year, already paid, membership. (See Content document)
    - (1) Recommendation to not require additional monies but may require update to member constituency group to reflect area of gainful employment.
    - (2) Recommendation that the Board should establish a set fee reduction for students to easily guide fees for future biennial conferences and publish fees in all Conference materials that reference fees.
  - ii. The draft was brought to the full committee for discussion. Full committee reviewed and agreed on document..
- g. *MOU subcommittee reviewed the MOU between NACCHO & CFP*
  - i. Verbage changes in sections III B, III C were recommended for clarification and section III D added a relevant example.
  - ii. No conflicts were found within the Constitution and the MOU with CFP & NACCHO.
  - iii. The full committee voted and the additions to the MOU were agreed upon.
- 3. Review the Conference for Food Protection governing documents (Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Manual, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Issues 2012-II-001, 2012-II-004, 2014-II-018 and 2016-II-026)
  - i. In order to create a merge of existing documents, the documents being merged need to be harmonious with each other. Due to discord within the same documents as well as discord between documents, the rational approach was to have a solid foundational document. The CFP’s foundational document is our Constitution. Once the Constitution is a solid foundational document, steps can be taken to make the rest of the CFP documents harmonious with the Constitution and each other.
- 4. Chair corresponded with Issue Committee Chairs regarding Issue integrity
  - a. Communications between Constitution, Bylaws, and Procedures Chair and Issue Co-chairs were held in March, 2019 to discuss Issue Submission Procedures. It was decided the best course of action was to add to the Council Member Position Description under Responsibilities and Duties “COMMIT ONESELF TO ISSUE INTEGRITY AND ETHICAL CONDUCT”. This gives the ability for Council Chairs and Council members to approach items of concern with Issues and have been submitted but not yet discussed at council to handle situations that might arise with integrity and ethics.
- 5. A general point of clarification was raised asking if committee and council chairs, and vice- or co-chairs, are to be included on a roster, and if their voting status is to be indicated or counted towards constituency balance. *Council Chair completed*
  - a. Council Committee Chairs and all Council committee members are to be on a roster approved by the Executive Board. CFP Biennial Meeting/Conference Procedures 2018 document VIII A. 1. This is also in the Constitution with existing conflicting language.
    - i. Article XIV Section 13, subsection 1 of the 2018 CFP Constitution state that the Committee Chair and Vice Chair each have a vote.
    - ii. Council Chairs or Council Vice Chairs are not on a Council Committee roster.
    - iii. Standing Committees shall be made to provide a balance in representation like all Conference committees.(Constitution Article XIV Section 1 and CFP Biennial Meeting/Procedures document VIII C 1)
    - iv. There is nothing in the Constitution regarding Standing Committee membership. The Procedures document lumps all Committees together with no notation of size or who votes.

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

- a. Worked with the Strategic Planning Committee to discuss the impact of changing the name of our organization from “Conference for Food Protection” to “Congress for Food Protection”.
- b. Addressed At Large constituency and provided board with several options. (See Content Document)
- c. Worked with Issue Committee Chairs regarding framework of Issue management process, specifically what is taking place from Issues being made public until the Biennium.
- c. Added “App Liaison” position to the CFP Procedures document Section V, C. passed by Executive Board 1/28/19.
- d. Defined “student” for registration purposes, self-reporting and what happens if they get a job during the cycle? Do they have to pay again for registration fee or just let the student registration fee carry over until the next cycle? (See Content Document) Executive Board approved Fall 2019. All changes are administrative.
- e. Chair reviewed Issue management process with the Issue Committee Chairs to determine if the CFP governing documents have language

## Conference for Food Protection – Committee FINAL Report

preventing Issue submitters from contacting Council members in advance of the Biennial Meeting (Issue integrity). No written language exists.

- f. Chair reviewed governing documents for point of clarification if committee and council chairs, and vice- or co-chairs, are to be included on a roster, and if their voting status is to be indicated or counted towards constituency balance.
  - (1) Recommendation
    - Council Committee Chairs and all Council committee members are to be on a roster approved by the Executive Board. CFP Biennial Meeting/Conference Procedures 2018 document VIII A. 1. This is also in the Constitution with existing conflicting language. Addressed in new draft Constitution.
    - Article XIV Section 13, subsection 1 of the 2018 CFP Constitution state that the Committee Chair and Vice Chair each have a vote.
    - Council Chairs or Council Vice Chairs are not on a Council Committee roster.
- g. CB&P Committee to categorize the CFP documents included on the list in the CB&P Committee report dated 03/01/2019 and use the category titles of “governing,” “administrative,” and “instructional.” Executive Board passed 11/1/19 (see Content document)
- h. Chair to work independently with Issue Committee Chairs regarding Issue integrity.
  - (1) Recommendation
    - Add to the Council Member Position Description under Responsibilities and Duties “COMMIT ONESELF TO ISSUE INTEGRITY AND ETHICAL CONDUCT”. This gives the ability for Council Chairs and Council members to approach items of concern with Issues that have been submitted but not yet discussed at council to handle situations that might arise with integrity and ethics. Approved at Fall 2019 Executive Board meeting.
- i. CB&P Committee to bring to the Board meeting in August 2019 a single revised Constitution and Bylaws document, using underline and strikeover for any changes, so the Board can extract those items they feel need to be submitted as separate Issues. (see Content document)
- j. Reviewed the CFP MOU with NACCHO and had grammatical changes the Executive Board accepted Fall 2019 Board meeting. (see Content document)
- k. Issue 2018 II-024 the Conference for Food Protection governing documents (Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Manual, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Issues 2012-II-001, 2012-II-004, 2014-II-018 and 2016-II-026)
  - (1) In order to create a merge of existing documents, the documents being merged need to be harmonious with each other. Due to discord within the same documents as well as discord between documents, the rational approach was to have a solid foundational document. The CFP's foundational document is our Constitution. Once the Constitution is a solid foundational document, steps can be taken to make the rest of the existing CFP documents harmonious with the Constitution and each other.

### 2. Charges **INCOMPLETE and to be continued to next biennium:**

- a. Define roles of Co-Chair and Vice Chair in the CFP Biennial Meeting/Conference Procedures document

### COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

- 1. Committee is requesting the Board to have verbiage added to the Biennial Meeting/Conference Procedures document. The verbiage could be added under VII B9; or it can be a stand alone item; or under VIII A. 1 (a).
    - The proposal: After the Assembly approves Constitutional changes, those changes be automatically sent to the Constitution and ByLaws Committee . The CB & P will review the Constitution and ByLaws and Biennial Meeting/Conference Procedures document and update all sections that would apply to the changes the Assembly of Delegates approved.
- Reasoning: to attempt to keep the two governing documents updated and consistent.

### LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

- 1. **CBPC Issue #1: Report – Constitution ByLaws & Procedures**
  - a. **List of content documents submitted with this issue:**
    - (1) *Committee Final Report*
    - (2) *Committee Member Roster*
    - (3) *CB & P At-Large Committee Membership Options*
    - (4) *Categorization of CFP documents*
    - (5) *Draft revised CFP Constitution and ByLaws*
    - (6) *Draft Memorandum Of Understanding between CFP & NACCHO*
  - b. **List of supporting attachments**
    - (1) Conference call meeting minutes
    - (2) Attendance at conference calls

2. *CBPC Issue #2: Draft Revised Constitution and ByLaws*
3. *CBPC Issue #3: At Large constituency*
4. *CBPC Issue #4: Draft Memorandum Of Understanding between CFP and NACCHO*

2012-2014 Issues Committee Roster

Committee Name Constitution, Bylaws and Procedures								
Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Barney	Rick	voting	Retail Food	Southeastern Grocers	Jacksonville	FL		<a href="mailto:rickbarney@segrocers.com">rickbarney@segrocers.com</a>
Gifford	Dave	voting	State Regulator	Washington State Dept of Health		WA	360-236-3074	<a href="mailto:dave.gifford@doh.wa.gov">dave.gifford@doh.wa.gov</a>
Gilliam	Scott	voting	Retail Food	Meijer	Grandville	MI	616-249-6034	<a href="mailto:scott.gilliam@meijer.com">scott.gilliam@meijer.com</a>
Hollingsworth	Jill	voting	Industry Support	Chemstar	Lithia Springs	GA	843-341-6640	<a href="mailto:jillh@chemstarcorp.com">jillh@chemstarcorp.com</a>
Horn	Jason	voting	Food Service	In-N-Out Burger		CA	626-813-5326	<a href="mailto:jhorn@innout.com">jhorn@innout.com</a>
Lindholm	Jeffrey	voting	Industry Support	iCertainty	Chevy Chase	MD	443-452-1950	<a href="mailto:jeff.lindholm@icertainty.com">jeff.lindholm@icertainty.com</a>
Mandernach	Steve	voting	Industry Support	AFDO	York	PA	717-757-2888	<a href="mailto:smandernach@afdo.org">smandernach@afdo.org</a>
Quam	Susan	voting	Industry Support	Wisconsin Rest. Assoc.	Madison	WI	608-270-9950	<a href="mailto:squam@wirerestaurant.org">squam@wirerestaurant.org</a>
Reich	Allen	voting	Academia	Northern Arizona University	Flagstaff	AZ	928-853-6340	<a href="mailto:allen.reich@nau.edu">allen.reich@nau.edu</a>
Sanchez	Angela	voting	Food Service	CKE Restaurant Holdings	Rancho Cucamonga	CA	714-254-4556	<a href="mailto:asanchez@ckr.com">asanchez@ckr.com</a>
Sarrocchio-Smith	Davene	Chair	Local Regulatory	Lake County General Health District	Mentor	OH	440-350-2543	<a href="mailto:dsarrocchio_smith@lcghd.org">dsarrocchio_smith@lcghd.org</a>
Lewis	Glenda	consultant	FDA				240-402-1382	<a href="mailto:Glenda.Lewis@fda.hhs.gov">Glenda.Lewis@fda.hhs.gov</a>
Liggans	Girvin	alternate consultant	FDA				240-402-382	<a href="mailto:Girvin.Liggans@fda.hhs.gov">Girvin.Liggans@fda.hhs.gov</a>
Barlow	Kristina	consultant	USDA FSIS					<a href="mailto:Kristina.Barlow@fsis.usda.gov">Kristina.Barlow@fsis.usda.gov</a>

**At Large Constituency Options**  
**ORGANIZATIONAL OPTIONS FOR COMMITTEES**

**I. “Balanced Representation” –**

**A. Composition –**

- 1) **Model A (smaller) – 17** member committee with **15** voting members.
    - 1 Committee Chair (from any sector) selected by the Conference Chair and approved by the Executive Board;
    - 6 Regulatory members (one from each CFP region);
    - 6 industry members (selected by the industry caucus);
    - 1 consumer group member;
    - 1 academic member;
    - 1 FDA advisor; and
    - 1 USDA advisor].
      - a) The advisory roles would not be voting members of the committee.
  
  - 2) **Model B (larger) – 29** member committee with **27** voting members.
    - 1 Committee Chair (from any sector) selected by the Conference Chair and approved by the Executive Board;
    - 12 Regulatory members (two from each CFP region);
    - 12 industry members (selected by the industry caucus);
    - 1 consumer group member;
    - 1 academic member;
    - 1 FDA advisor; and
    - 1 USDA advisor.
      - a) The advisory roles would not be voting members of the committee.
- 
- 3) **Model C (smaller) – 16** member committee with **13** voting members
  - 1 Committee Chair (from any sector) selected by the Conference Chair and approved by the Executive Board. The Chair would NOT hold a vote on the committee.
  - 6 Regulatory members (one from each CFP region);
  - 6 industry members (selected by the industry caucus);
  - 1 consumer group member;
  - 1 academic member;
  - 1 FDA advisor; and
  - 2 USDA advisors.
    - a) The advisory roles would not be voting members of the committee.
- 
- 4) **Model D (larger) -28** member committee with **25** voting members.
  - 1 Committee Chair (from any sector) selected by the Conference Chair and approved by the Executive Board. The Chair would NOT hold a vote on the committee

**12** Regulatory members (two from each CFP region);  
**12** industry members (selected by the industry caucus);  
**1** consumer group member;  
**1** academic member;  
**1** FDA advisor; and  
**1** USDA advisor.

a) The advisory roles would not be voting members of the committee.

**B. Composition Details –**

- 1) The regulatory members would be selected by each CFP region.
- 2) The industry members would be selected by the private sector caucus.
- 3) The consumer member nomination would be recruited by the committee chair and approved by the committee membership.
- 4) The academic member nomination would be recruited by the committee chair and approved by the committee membership.
- 5) The FDA advisor (non-voting) and USDA advisor (non-voting) would be selected by their respective agencies. It was noted that advising agencies may not have staffing for all committees so advisory roles could be offered, but not mandatory, to agencies.
- 6) The advisors would not have voting privileges, but the other **15** or **27** members would have voting privileges.

**C. Format –**

- 1) This model would use two equally balanced (in number) groups. Each of the **15** or **27** members would represent the voice of their region/group and be responsible for representing that voice during committee activities.

**D. Pros:**

- 1) This model (can) makes committees smaller and easier to manage so things can move quicker and more issues can be worked (not as easily as the “Regional” model, but easier than the “Organizational” model).
- 2) The chair has an easier role under this type of model (not as easy as the “Regional” model, but easier than the “Organizational” model).

**E. Cons:**

- 1) This type of model puts more of the burden on the representative as opposed to the individual voice (not as much as with the “Regional” model, but more so than the “Organizational” model).
- 2) Anyone who has desired input would have to contact their representative and provide their input.

- 3) Opens the discussion to criticism if individuals don't feel they have had their voice heard or feel they didn't have the ability to provide input (not as much as with the "Regional" model, but more so than the "Organizational" model).
- 4) Representatives would be responsible for any necessary discussions leading up to the committee meetings in order to provide accurate representation (not as much as with the "Regional" model, but more so than the "Organizational" model).
- 5) Difficulty ensuring the representatives are accurately conveying the voices of whom they represent (not as much as with the "Regional" model, but more so than the "Organizational" model).

**F. Discussion Points:**

- 1) This model creates mid-sized committees and is somewhere in the middle between the "Regional" and "Organizational" models.
- 2) The Conference Chair would select a committee chair with approval from the BOD.
- 3) In order to maintain an odd number of members to avoid tie votes a committee chair in addition to the other members would be selected from any sector by the Conference Chair.
- 4) The committee chair would have the option to recognize others not on the committee for further clarification or explanation of input on issues.
- 5) This would apply to the eleven standing committees, but not necessarily to the ad-hoc committees.
- 6) This model does provide a relatively balanced vote within the committee considering the number from each sector represented.
- 7) Important for members of CFP to reach out to their representatives to provide input and opinions. It is then incumbent upon the representatives to relay that information to the committee. The identity of the representatives would be published on the CFP website to allow ease of identification and access to all CFP members.
- 8) Non-committee members may listen in on calls and meetings but would not have a voice during the calls or meetings unless called upon by the Chair.

**II. "Organizational Representation"**

**A. Composition – Unlimited** (at the discretion of the committee chair);

- 1 FDA advisor; and
- 1 USDA advisor.

**B. Composition Details:**

- 1) Allows for the committee to be as large as the chair would like.
- 2) Comprised of as many members from any sector as granted by the committee chair.
- 3) The FDA advisor (non-voting) and USDA advisor (non-voting) would be selected by their respective agencies. It was noted that advising agencies

may not have staffing for all committees so advisory roles could be offered, but not mandatory, to agencies.

- 4) The advisors would not have voting privileges, but the other members would have voting privileges (one per organizational membership).

**C. Format –**

- 1) Each organizational membership gets one vote (even if multiple members from a single organization are on the committee) and represents their own voice.

**D. Pros:**

- 1) Each member is solely responsible for representing their own voice.
- 2) Anyone (voting members, non-voting members, and non-members) can participate in meetings and speak.
- 3) Voting limited to those on the membership roster only.
- 4) Each organization that is member of the committee (on the roster) has one vote only.

**E. Cons:**

- 1) This model makes committees larger and more difficult to manage.
- 2) Potential for dialogue to extend beyond necessity.
- 3) Need an experienced and/or strong chair with good time management skills.
- 4) Committee output can be swayed by singular interests.
- 5) Requires member organizations to be grouped together to distribute if balanced voting is used.
- 6) Roster maintenance is necessary to ensure regular participation.
- 7) A balanced voting system/formula is usually also necessary.

**F. Discussion Points:**

- 1) The Conference Chair would select a committee chair with approval from the BOD.
- 2) The chair would likely need officers to assist with the oversight and maintenance of this type of committee (if large).
- 3) This would apply to the eleven standing committees, but not necessarily to the ad-hoc committees.
- 4) Committee sizes would be different from one committee to another.
- 5) Important for members of CFP to reach out to their representatives to provide input and opinions. It is then incumbent upon the representatives to relay that information to the committee. The identity of the representatives would be published on the CFP website to allow ease of identification and access to all CFP members.
- 6) Non-committee members may listen in on calls and meetings but would not have a voice during the calls or meetings unless called upon by the Chair.

**III. “Regional Representation”**

**A. Composition –**

- 11** member committee with **9** voting members
- 6** Regulatory members (one from each CFP region);
- 3** industry members (selected by the industry caucus);

- 1 FDA advisor; and
- 1 USDA advisor.

**B. Composition Details:**

- 1) The regulatory members would be selected by each CFP region.
- 2) The industry members would be selected by the private sector caucus.
- 3) The FDA advisor (non-voting) and USDA advisor (non-voting) would be selected by their respective agencies. It was noted that advising agencies may not have staffing for all committees so advisory roles could be offered, but not mandatory, to agencies.
- 4) The advisors would not have voting privileges, but the other 9 members would have voting privileges.

**C. Format –**

- 1) Each of the 9 voting positions would represent the voice of their region/group and be responsible for presenting that voice during committee activities.

**D. Pros:**

- 1) This model makes committees small and easier to manage so things can
- 2) : move quicker and more issues can be worked.
- 3) The chair has an easier role under this type of model.

**E. Cons:**

- 1) This type of model puts more of the burden on the representative rather than the individual voice.
- 2) Anyone who has desired input would have to contact their representative and provide their input.
- 3) Opens the discussion to criticism if individuals don't feel they have had their voice heard or feel they didn't have the ability to provide input.
- 4) Other meetings may be needed to acquire input prior to the committee meeting.
- 5) Representatives would be responsible for any necessary discussions leading up to the committee meetings in order to provide accurate representation.
- 6) Difficulty ensuring the representatives are accurately conveying the voices of whom they represent.

**F. Discussion Points:**

- 1) The Conference Chair would select a committee chair with approval from the BOD.
- 2) The committee chair would have the option to recognize others not on the committee for further clarification or explanation of input on issues.
- 3) This would apply to the eleven standing committees, but not necessarily to the ad-hoc committees.
- 4) Important for members of CFP to reach out to their representatives to provide input and opinions. It is then incumbent upon the representatives to relay that information to the committee. The identity of the representatives would be published on the CFP website to allow ease of identification and access to all CFP members.

- 5) Non-committee members may listen in on calls and meetings but would not have a voice during the calls or meetings unless called upon by the Chair.

	administrative"; "governing"; "instructional
<b>Constitution &amp; Bylaws</b>	governing
<b>Biennial Meeting/Conference Procedures</b>	governing
<b>Position Descriptions</b>	
<b>EXECUTIVE Administration Positions</b>	
Board Member	governing
Director	governing
Executive Treasurer	governing
Executive Assistant	governing
<b>LEADERSHIP Positions</b>	
Conference Chair	governing
Conference Vice Chair	governing
Immediate Past Chair	governing
<b>COUNCIL Positions</b>	
Council Chair	governing
Vice Chair	governing
Council Member	governing
Council Scribe	governing
Council Runner	governing
Parliamentarian	governing
App Liaison	governing
<b>STANDING Committee Positions</b>	
Audit Committee Chair	governing
Constitution & Bylaws Committee Chair	governing
Finance Committee Committee Chair	governing
Food Protection Manager Certification Commit	governing
Issue Committee Committee Chair	governing
Nominating Committee Chair	governing
Program Committee Chair	governing
Program Standards Committee Chair	governing
Publications Committee Chair	governing
Resolutions Committee Chair	governing
Strategic Planning Committee Chair	governing
<b>Committee Chair Handbook</b>	governing
<b>Policies</b>	
Antitrust Policy	governing
Archiving CFP Documents	governing
Audit Policy	governing
Commercialism & Comity Policy	governing
Crumbine Award Policy	governing
Late Issue Submission Policy	governing
Open Meeting Policy	governing
Record Retention Policy	governing

Travel Subsidy Policy	governing
Conference Spokesperson Policy	governing
Invoice Approval Policy	governing
Privacy Policy	governing

**Helpful Templates**

CATEGORIZATION OF ALL CFP DOCUMENTS

Committee Periodic Report Instructions	instructional
Committee Periodic Report Template	administrative
Committee Final Report Instructions	instructional
Committee Final Report Template	administrative
Conference Call Documentation Form Template	administrative
Council Chair Periodic Summary Report Instructions	instructional
Council Chair Periodic Summary Report	administrative
Council Chair Final Summary Report Instructions	instructional
Council Chair Final Summary Report	administrative

**Terms and Conditions of Issue Acceptance**

Issue Pre-submission Form	administrative
Late Issue submission policy	governing
Issue Preparation & Review-Process & Checklist	instructional

**Membership Form/Application**

administrative

**Update Contact Information Form**

administrative

**Sponsorship Application Form**

administrative

**Sustaining Supporter Application**

administrative

Constitution and Bylaws 2018 July	administrative"; "governing"; "instructional
Biennial Meeting / Conference Procedures 2019	governing
Biennial Meeting Information Manual Not posted Removed from website in 2018 pending revision	instructional
<b>Polices</b>	instructional
Antitrust Policy 2001 August	governing
Archiving CFP Documents 2014 April	governing
Audit Policy 2006 August	governing
Commercialism and Comity Policy 2017 August	governing
Crumbine Award Policy 1997 March	governing
Late Issue Submission Policy 2013 August	governing
Open Meeting Policy 2000 August	governing
Record Retention Policy 2006 August	governing
Travel Subsidy Policy 2018 April	governing
Conference Spokesperson Policy 2014 May	governing
Invoice Approval Policy 2017 August	governing
<b>Position Descriptions (PDs)</b>	
<i>Leadership Positions</i>	
Conference Chair 2018 August	instructional
Conference Vice Chair 2018 August	instructional
Immediate Past Chair PD not available	instructional
<i>Executive Administration Positions</i>	
Executive Board Member 2018 August	instructional
Executive Director 2019 April	instructional
Executive Treasurer 2016 February	instructional
Executive Assistant 2018 August	instructional
<i>Council Positions</i>	
Council Chair 2017 August	instructional
Council Vice Chair 2017 August	instructional
Council Member 2019 April	instructional
Council Scribe 2017 August	instructional
Council Runner 2017 August	instructional
Parliamentarian 2017 August	instructional
Council App Liaison 2019 April	instructional
<i>Committee Positions</i>	
Council Committee Chair / Vice Chair 2017 August	instructional
Committee Member 2005 August	instructional
<i>Standing Committee Positions</i>	
Audit Committee Chair 2005 August	instructional
Constitution & Bylaws Committee Chair 2014 August	instructional
Finance Committee Chair 2016 August	instructional
Food Protection Manager Certification Committee Chair 2015 October	instructional
Issue Chair 2017 August	instructional
Nominating Committee Chair Not dated	instructional
Program Chair 2005 August	instructional
Program Standards Committee Chair 2015 April	instructional
Publications Committee Chair PD not available	instructional
Resolutions Committee Chair 2005 August	instructional
Strategic Planning Committee Chair 2015 November	instructional
<b>COUNCIL and COMMITTEE REPORT TEMPLATES Document Date Target Review Cycle Assigned Reviewer Status</b>	
<i>Committees</i>	
Committee Final Report Instructions Not dated	administrative
Committee Final Report Template Not dated	administrative
Committee Periodic Report Instructions 2016 April	administrative
Committee Periodic Report Template 2016 April	administrative
Committee Roster and Instruction Form Template 2018 September Note: instructions do not match template	administrative
CFP Committee Conference Call Documentation Form Template 2018 April	administrative
CFP Council Committee Chair Handbook 2019 April	instructional
<i>Councils</i>	
Council Chair Periodic Summary Report Instructions 2014 May	administrative
Council Chair Periodic Summary Report 2014 May	administrative
Council Chair Final Summary Report Instructions	administrative
Council Chair Final Summary Report Instruction (form) 2018 March	administrative
<b>FORMS Document Date Target Review Cycle Assigned Reviewer Status</b>	
Membership Application 01/30/2019	administrative
Sponsorship Applications – Sustaining and Event Pending Documents currently in the development stage	administrative
Sustaining Supporter Application Not dated Revised January 2019 to update EA contact info	administrative
<b>CFP PRESENTATIONS (organizational) – PowerPoint Document Date Target Review Cycle Assigned Reviewer Status</b>	
CFP Orientation PowerPoint Not dated Location: "about the conference," "current organization"	instructional
Committee Formation PowerPoint 2014 Location: "conference administration," "standing committees"	instructional
New Board Member Orientation PowerPoint Not posted Most recent version from 2014	instructional
CFP Biennial Meeting Council Orientation PowerPoint Not posted Most recent version from 2018	instructional

# CONFERENCE FOR FOOD PROTECTION



## CONSTITUTION AND BYLAWS ~~2018~~ 2020

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~~July 18, 2018~~

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# *Conference for Food Protection Constitution and ByLaws*

*As revised ~~July 18, 2018~~ April 2020*

## **Preface**

The following comments serve as a historical preface to the Constitution and Bylaws for the Conference for Food Protection.

The Conference for Food Protection dates back to the 1971 Conference on Food Protection held in Denver, Colorado. It was sponsored jointly by the Food and Drug Administration (FDA) and the American Public Health Association (APHA). The purpose of the Conference was to provide an inter-professional dialogue on the microbiological aspects of food safety for individuals representing industry, Government, and consumers.

The Second National Conference for Food Protection was held in Washington, D.C. in 1984. The 1984 Conference expanded its scope to cover toxicological as well as microbiological concerns. The purpose of the 1984 Conference was:

“To share perspectives on the toxicological and microbiological aspects of food safety problems in the United States; to identify the needs, direction and opportunities of food production, processing, handling and regulation through the year 1990; and to establish an organization for the continuing study of food safety problems and for promotion of the recommendations of the Conference.”

The 1984 Conference was organized into seven committees: Toxicology; Microbiology; Good Manufacturing and Quality Control; Standards and Regulations; Education and Training; New Foods Processing and Packaging; and Conference Program Committees, with selected individuals also serving as resource persons who prepared “white papers” on various issues that were to be discussed at the Conference. In addition to the Federal, state, and local health officials who had been invited to the 1971 Conference, the 1984 Conference included industry, academic and consumer representatives. The 1984 Conference adopted a recommendation that a continuing Conference organization be established, and that a constitution and bylaws be developed based upon a draft presented at the Conference. It was agreed that the objectives of the Conference would be:

- To identify emerging problems of food safety;
- To address the problems of food safety on a regular basis;
- To formulate recommendations for the solution of the identified problems;
- To follow up on the recommendations of the Conference so that they will be incorporated into public policy and in industry practice;
- To evaluate the effectiveness of the Conference recommendations; and
- To establish a working liaison with professional and trade associations, academic institutions, and Government agencies concerned with food safety.

Following the 1984 Conference, the Constitution and Bylaws were finalized, and the Conference was incorporated in 1985. The National Sanitation Foundation (NSF) agreed to support the Conference financially, and a Conference Executive Director was hired.

The 1986 Conference for Food Protection was held in Ann Arbor, Michigan. The 1986 Conference was again organized into seven committees representing the major science and technical aspects of food protection. A 25-member Executive Committee selected the topics to be discussed and requested “white papers” from technical experts. In addition to the committees, five Councils were formed representing the interests of the participants at the Conference.

Although the purposes of these Conferences were well established and accepted, the organization and procedures of the Conference were long debated. In the early meetings of the Steering Committee preparing for the 1984 Conference, the idea of emulating the National Conference on Interstate Milk Shipments (NCIMS) was introduced. ~~Individuals working during this Conference to write a new constitution began introducing NCIMS-type structure into the Conference organization.~~ During this Conference, individuals working on a new constitution began introducing NCIMS-type structure into the Conference organization. ~~This was the first step leading to the current Constitution and ByLaws.~~ This effort was the first step leading to the current Constitution and Bylaws.

The second step was action taken at the 1984 Conference to reaffirm the intent to model the Conference after the NCIMS. The following is quoted from the Proceedings of the 1984 Conference:

“An Organizational Model: from the beginning it was the intention of the organizers of the Second National Conference that it should include an effort 'to establish an organization for the continuing study of food safety problems and for the promotion of the recommendations of the Conference'. What the organizers had in mind in making that a goal of the Conference was to establish, in the area of food safety, something akin to the Interstate Milk Shipments Conference and the more recent Interstate Shellfish Sanitation Conference, so that a national dialogue on food safety might continue on a regular, periodic basis.” (Page 369)

“A National Conference for Food Protection should be established as an ongoing Conference and be structured similarly to the National Conference on Interstate Milk Shipments. One of the Conference's primary purposes should be to promote the formulation and use of uniform model laws and regulations among all government agencies to assure uniform interpretations and implementation and to eliminate duplication of services. Its membership should consist of federal, state and local food regulatory officials, academia and representatives from industry. It should be governed by an Executive Board with representatives from federal, state and local agencies and industry.” (Recommendation No. 10, Standards and Regulations Committee -- approved by the Conference, page 266).

The draft Constitution and Bylaws adopted by the 1984 Conference were, according to its authors, not meant to be a fully workable source for forming and operating the Conference model after the NCIMS. It was intended as an interim document that would be upgraded to provide a more authoritative foundation for Conference actions.

The final step in the decision to upgrade the Conference organization was taken at the 1986 Conference. The Program Committee reported that:

"It was the unanimous view of the committee that the Conference should operate as an action organization, existing not merely to identify problems and formulate recommendations, but to resolve issues through the implementation of recommendations, much as the Weights and Measures Conference and the Interstate

Milk Shippers do. Specific recommendations in this regard will be presented prior to the next Conference." (Page 410, Proceedings)

To accomplish this, the 1986 Conference agreed:

- To develop a state regulatory ratification mechanism whereby each of the 50 states will have one vote; and
- To create a Constitution and Bylaws Committee to review the entire Constitution and Bylaws and to formulate recommendations for the Executive Committee to consider.

The Constitution and Bylaws Committee approached the review process with three principal needs in mind. First, the Constitution needed to allow for the continuing study of food safety problems, but with a more limited focus. To achieve this, the following changes were made:

1. The objective of the Conference placed greater emphasis on food safety at the point of ultimate sale to consumers through food services, retail food stores, and food vending, and continued to identify and address problems in production, processing, packaging, distribution, sale, and service of food;
2. The seven committees were condensed into three councils to provide a balance between discussing the science and technology of food safety issues and developing various certification guidelines, procedures, and models. However, as in the other two Conference examples, separate committees in each discipline area could still function to deliberate and review issues.

The second principle that guided the review process was the need for the Conference to be more successful in promoting food safety, mutual respect, and uniformity. This was accomplished through the following changes:

1. The final actions taken by the Conference regarding such items as food safety controls, certification procedures, and Memoranda of Understanding, were to be adopted by the regulatory delegates of the Conference with the advice of industry and other non-regulatory members;
2. The Constitution created a Council on Laws and Regulations; a Council on Administration, Certification, and Education; and a Council on Science and Technology. These Councils provided vehicles by which the Conference could deliberate on all food safety issues and promote more uniform and effective food safety controls.

The final guiding principle was the need to ensure that the Conference would provide a national and, to the extent possible, international dialogue on food safety on a regular, periodic basis, and that this dialogue would be among representatives of regulatory, industry, and other non-regulatory organizations. To accomplish this, the Constitution and Bylaws provided for the following:

1. The name of the Conference remained unchanged consistent with the recommendation made by the 1986 Program Committee. In order to increase international information exchange, the Pan American Health Organization (PAHO) and the World Health Organization (WHO) were added. The Food and Agricultural Organization (FAO) was already a member of the Conference;
2. The role that industry plays in the Conference is substantial. Industry is fully represented on all councils, committees, and the Executive Board. Industry

representatives alternate as Chair and Vice Chair on all councils. Industry representatives are elected through industry caucuses. Industry's concerns and advice are fully considered since problems submitted to the Conference are assigned to one of the councils. Regulatory delegates vote on each council's recommended actions;

3. The Science and Technology Council provided a forum for discussion by all concerned parties of the scientific and technological aspects and principles underlying the problems faced by Government and industry in their mutual goal of trying to provide safe foods for consumers and could include formation of individual committees for each scientific discipline.

The Constitution and Bylaws attempt to intertwine these guiding principles so that in pursuing one, each would be pursued. This interdependence is critically important if the Conference recommendations are going to command the respect of the food regulators and the food industry that would be called upon to implement the recommendations. As was stated by Mr. Archie Holliday in his comments on the 1988 proposed Constitution and Bylaws:

“The most important need for an organization of this kind is to have its recommendations respected by the community called upon to implement them. Without the results of our deliberations commanding the highest respect attainable, getting together to identify and study food safety problems will be of little or no value to enough people to support a viable organization. The strength of the organization structure now being proposed by your Constitution and Bylaws Committee is that it provides the means to balance the interests of regulatory and industry people while providing an open forum for the consideration of ideas from any source. At the same time, matters that are supported by the voting delegates will have endured such a process as to command the utmost of respect.”

The Constitution and Bylaws are one step in an evolving process to develop a viable permanent Conference. ~~The next was also discussed~~ As also stated by Mr. Archie Holliday in his comments on the Constitution:

“One should be careful not to conclude that a food service oriented structure would prohibit the free and open study of the wider range of food safety problems. When the values of NCIMS and ISSC organizational structures are discussed, we often fail to acknowledge the importance of procedures to successful operation of these bodies. Well defined, established procedures will be essential to the effectiveness of the Conference operating under our proposal. Procedures should remain as a separate entity from the Constitution and Bylaws. When the new Constitution and Bylaws are adopted, the Executive Board should immediately begin the process of establishing procedures to be approved by the Conference. It is in this process that attention can be given to how broad the scope of the Conference should be. The adoption and revision of Conference procedures should receive the same careful consideration as the adoption of Conference recommendations.”

The Constitution and Bylaws Committee and the Executive Board believed that the Constitution and Bylaws proposed and accepted at the 1988 Conference provided a workable and proven approach that should be followed to develop an effective voice for present and future issues of food safety.

## ***Preamble***

The Conference for Food Protection, hereinafter referred to as the Conference or CFP, is incorporated as a non-profit organization under the laws of the State of Virginia to carry out the objective stated in the Constitution and Bylaws of the Conference.

## ***Constitution and Bylaws***

### **Article I      Objective**

**Section 1.**      The objective of the Conference shall be to promote food safety and consumer protection by:

- Subsection 1.*** Identifying and addressing problems in the production, processing, packaging, distribution, sale, and service of foods;
- Subsection 2.*** Focusing on and facilitating the food protection programs governing the food service, retail food store, and food vending segments of the food industry;
- Subsection 3.*** Adopting sound, uniform procedures which will be accepted by food regulatory agencies and industry;
- Subsection 4.*** Promoting mutual respect and trust by establishing a working liaison among Governmental agencies, industry, academic institutions, professional associations, and consumer groups concerned with food safety;
- Subsection 5.*** Promoting uniformity among states, territories, and ~~the~~ District of Columbia. Territories include American Samoa, Guam, Northern Mariana Islands, Puerto Rico, The Trust Territory and the U.S. Virgin Islands.
- Subsection 6.*** Utilizing as the primary channels for dissemination of information: The United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) in matters under their purview, such as food production, meat and poultry processing, and consumer information; and The United States Department of Health and Human Services, Public Health Service, Food and Drug Administration (HHS/PHS/FDA) in matters under their purview, such as food processing and assistance to other food regulatory agencies based on the model FDA Food Codes and related documents.

### **Article II      Organization and Operation**

**Section 1.**      The Conference shall be directed by the delegates of the states, territories, and District of Columbia, who join together with representatives of regulatory, industry, ~~academic institutions~~ academia, professional associations, and consumer groups to achieve the objective of the Conference.

The Conference shall include an Assembly of State Delegates (hereinafter referred to as the Assembly), an Executive Board (hereinafter referred to as the Board), Officers, an Executive Director (hereinafter referred to as the Director), Executive Assistant, Executive Treasurer, Councils, Council Committees, Standing Committees (~~see Article XIII~~ Article XV Section 2), and any member of the Conference as described in Article III, Sections 1 and 2.

**Section 2.** The Conference shall meet at least biennially during even-numbered years with additional meetings as the need arises as determined by the Board.

**Section 3.** ~~Conference identifies food safety issues by receiving Issues submitted by interested persons. The Conference addresses Issues by assigning them to appropriate Councils or Committees for consideration. Council membership is balanced between government and industry interests. Aspects of Issues may also be assigned to Committees for study, procedure development or for other reasons. All committees that are assigned to a Council shall submit a report to the Council Chair and Conference at least ninety (90) days preceding the CFP Biennial Meeting. Councils then make recommendations to the Assembly, which is composed of delegates designated by the States, each territory and the District of Columbia. The Assembly considers and votes to approve or reject Council recommendations. CFP Biennial Meeting participation is open to all interested individuals who choose to become members and attend. Individuals may serve as appointed or elected members on the Board, Councils, and Committees; or as a participating registered member.~~

~~The Conference shall consider issues related to food safety that are submitted on approved forms and within specified time frames. Any interested person may submit an Issue for consideration. At least one hundred and fifty (150) days preceding the CFP Biennial Meeting, the Executive Director shall notify Conference members of the Conference of the time and place of the CFP Biennial Meeting. Each notice shall include information for submitting Issues, and a statement that all Issues, shall be submitted to the Conference at least ninety (90) days preceding the CFP Biennial Meeting. Issues are to be assigned to appropriate Councils by the Issue Committee. At least forty (40) days preceding the CFP Biennial Meeting, the Executive Director shall make available to members of the Conference copies of the final committee reports and Issues, including Constitution changes that have been received and assigned for CFP Biennial Meeting deliberation.~~

~~The Board may submit special Issues to the Councils at the beginning of the CFP Biennial Meeting as necessary. Councils are to deliberate their Issues and report their recommendations on each to the Assembly. The Assembly considers and votes on recommendations it receives from the Councils.~~

**Section 4.** Interested persons may submit Issues pertaining to food safety to the Conference. Issues may also be created as outcome of Standing, Council and Adhoc Committees. All Issues shall be submitted to the Conference at least ninety (90) days preceding the CFP Biennial Meeting. (Late-breaking food safety Issues must

follow the current version of the “CFP Biennial Meeting/Conference Procedures” document.) Issues are reviewed and assigned to appropriate Councils by the Issue Committee. At least forty (40) days preceding the CFP Biennial Meeting, the Director shall make the Issues available to members of the Conference. After deliberation, each Council will make recommendations on assigned Issues to the Assembly, which is composed of delegates designated by the states, each territory, and District of Columbia. The Assembly considers and votes to approve or reject Council recommendations.

**Subsection 1.** Committees assigned to the Board and to Councils will submit periodic reports including a final report no later than ninety days (90) prior to the Biennial Meeting.

**Subsection 2.** A CFP Issue is a topic submitted for consideration to the Conference by any interested party addressing an identified concern related to retail food safety and offering a recommended solution to that concern.

a. An Issue proposal includes the official Issue Submission Form and all supporting documentation.

### **Article III Registration and Membership**

**Section 1.** ~~Any persons interested in promoting the objective in Article I may attend the CFP Biennial Meetings by registering their name, address, and the business they represent with the Executive Treasurer using forms provided and paying the registration fee established by the Board under Article V, Section 10 and 12.~~ Persons who are interested in promoting the objective in Article I may become members of the Conference by applying to the Executive Treasurer, using forms provided, and paying the membership fee established by the Board under Article VI, Section 12.

**Section 2.** ~~Persons who are interested in promoting the objective in Article I but who cannot attend the CFP Biennial Meeting may become members of the Conference by applying to the Executive Treasurer using forms provided and paying the membership fee established by the Board under Article V, Section 12.~~ Any members interested in promoting the objective in Article I may attend the CFP Biennial Meetings by registering their name, address, and the constituency they represent with the Executive Treasurer, using forms provided, and paying the registration fee established by the Board under Article VI, Section 12. Persons may apply for membership and registration at the same time.

**Section 3.** Persons paying the Conference membership fee through the Executive Treasurer’s office, or by paid registration at the CFP Biennial Meetings, are members of the Conference and are entitled to be on an official list to receive copies of the CFP Biennial Meeting proceedings and other Conference matters determined by the Board to be of interest to all members of the Conference.

**Section 4.** Conference membership begins at the time of payment of the membership fee. Membership paid as part of the CFP Biennial Meeting registration begins on

the first day of one CFP Biennial Meeting and ends the day prior to the next CFP Biennial Meeting.

**Section 5.** Membership in the Conference is classified into constituencies that are representative of the key stakeholder groups which support the objectives of Article I and facilitate the requirements of Article IV. The Conference constituencies are defined as follows:

**Subsection 1.** The Regulatory constituency is comprised of those officers, agents, or authorized representatives having authority over the regulation of food establishments, production, processing, vending, or distribution, or ~~has~~ have oversight for prevention of foodborne illness in accordance with rules and/or laws in their respective Governmental jurisdiction. Sub-categories of this constituency include:

- a. Local Regulator: Government employee or agent representing a territorial division of local government with responsibility for regulation of food establishments, production, processing, vending, or distribution, or has oversight for prevention of foodborne illness.
- b. State Regulator: Government employee or agent representing a territorial division of state government with responsibility for regulation of food establishments, production, processing, vending, or distribution, or has oversight for prevention of foodborne illness.
- c. Federal Regulator: Government employee or agent representing a program or agency of the Federal Government with responsibility for regulation of food establishments, production, processing, vending, or distribution, or has oversight for prevention of foodborne illness.
- d. District/Territory Regulator: Government employee or agent representing the U.S. District of Columbia or one of the six U.S. territories with responsibility for regulation of food establishments, production, processing, vending, or distribution, or has oversight for prevention of foodborne illness.

**Subsection 2.** The Industry constituency is comprised of those employees, agents, or executives representing business entities that operate food establishment(s), production, processing, vending, or distribution, or providers of an industry related service to such food operations, or representatives of a professional organization or trade association that promotes, supports, and/or markets to/for the food industry or its related services. Sub-categories of this constituency include:

- a. Food Service Industry: Employees, agents, or executives representing business entities that operate food service establishments. Examples include, but are not limited to, restaurants of all sizes/types/styles of service, caterers, military food service, institutional and other health care food service, schools and university food service, common

carrier food service (planes, trains, etc.), corporate food service operations, and Government food service.

- b. Retail Food Industry: Employees, agents, or executives representing business entities that operate retail food establishments. Examples include, but are not limited to, grocery stores, supermarkets, convenience stores, retail pharmacies, produce markets, roadside stands, department stores, warehouse sales clubs, seafood markets, retail bakeries, military base PX/groceries, liquor stores, and retail food associations.
- c. Processing Food Industry: Employees, agents, or executives representing business entities that manufacture, process, package, or label food items for wholesale sale. Examples include, but are not limited to, commercial food manufacturing, canning, packaging, commercial bakeries, commercial meat slaughter and processing, packing houses and distribution centers, farming and agricultural processing and packing operations, ice processing, packing plants, and food processing trade associations.
- d. Vending and Distribution Food Industry: Employees, agents, or executives representing business entities that own and/or operate food companies that vend or distribute food either wholesale or retail. Examples include, but are not limited to, coffee and food vending service companies, service companies, commissaries, food supply chain operators, wholesale ~~distributor~~ distributors, shipping lines, brokers, equipment manufacturers, and suppliers of products and services to operating service companies, and food vending and distribution trade associations.
- e. Food Industry Support: Employees, agents, or executives representing business entities that provide direct or support services to food service establishments, retail food establishments, processing food operations, vending and distribution food operations, or regulatory agencies. Examples include, but are not limited to, professional organizations, food protection support trade associations, pest control companies, auditing firms, standards associations, consultants, cleaning and sanitation management operations, training and/or testing companies or services, equipment and supply operations, software and technology, dieticians or dietary managers, and media and legal representatives.

***Subsection 3.*** The Academia constituency is comprised of Academic professionals employed by a college or university involved in education or research involving food sciences, food operations, or food safety. Examples include, but are not limited to, professors, adjunct instructors, researchers, teaching assistants, and extension agents.

***Subsection 4.*** The Consumer constituency is comprised of employees, agents, or executives representing consumer advocacy

organizations supporting food safety, food wholesomeness, allergen awareness, food policy matters, and food standards and guidelines.

**Subsection 5.** The Emeritus constituency is comprised of persons retired or honorably discharged from full-time work and no longer receiving compensation for work related to the Conference's mission. This constituency is designed for those professionals who, prior to retirement, were members of any Conference stakeholder group in good standing of the Conference for Food Protection for at least three biennial cycles (6 years). Previous membership does not have to be in contiguous biennial cycles. An Emeritus member may participate as an attendee/observer in all usual Conference functions such as attending the Biennial Meeting, including workshops, Council deliberations, Assembly of Delegates, and social functions. Emeritus members may serve as a member of a Council Committee, as a Council Committee Chair, and participate and vote in constituency caucus meetings. The ~~Executive Board~~ may elect to assign an Emeritus member to participate in other Conference related activities.

**Subsection 6.** The Student constituency is comprised of any student enrolled in a two-year, four-year, or graduate program in a college or university involving food sciences, food operations, or food safety. A student member may participate as an attendee/observer in all usual Conference functions such as attending the Biennial Meeting, including workshops, Council deliberations, Assembly of Delegates, and social functions. Student members may serve as a member of a Council Committee. The ~~Executive Board~~ may elect to assign a student member to participate in other Conference related activities.

**Article IV**    **Composition of Organizational Components and Eligibility Requirements for Service in Official Capacities**

**Section 1.**    The Assembly shall consist of persons attending the Conference meeting and qualified as voting delegates under Article XVII, ~~Section 5.3 and 4.~~

**Section 2.**    To be eligible to serve on the Board, Councils, Committees, or as Issue Chair or Program Chair; individuals must be members of the Conference and must be in attendance at the CFP Biennial Meeting at which they are appointed or elected, or shall have attended the CFP Biennial Meeting immediately preceding the one at which they are appointed or elected. ~~This requirement in respect to Councils and Committees may be waived by consent of the Board.~~

**Section 3.**    Board Membership

**Subsection 1.** The Board shall be composed of twenty-three (23) voting members as follows:

- a. Six (6) members from state food regulatory agencies (one from each CFP region);

- b. Six (6) members from local food regulatory agencies (one from each CFP region);
- c. Three (3) members from federal agencies (~~one (1) from FDA, one (1) from USDA, and one (1) from CDC~~) (one each from FDA, USDA, and CDC);
- d. Six (6) members from the food industry with at least one (1) each representing food processing, food service, retail food stores, and ~~food~~ vending and distribution;
- e. One (1) member from an academic institution; and
- f. One (1) member representing consumers.

**Subsection 2.** Regulatory agency, industry, academic institution, and consumer Board members shall be elected by a caucus of registrants in each respective group. State and local regulatory Board members shall be elected in regional caucuses of regulatory registrants. Federal Regulatory Board members shall be appointed by the head of their agency.

**Subsection 3.** Such elected Board members shall serve through three (3) general CFP Biennial Meetings of the Conference. Elected Board members may succeed themselves unless reelection would extend the total of consecutive service to more than twelve (12) years. The terms of elected Board members shall be staggered so that one-third (1/3) of the members are elected at each CFP Biennial Meeting.

**Subsection 4.** The Board shall have non-voting Ex-Officio members as follows:

- a. The Immediate Past Chair of the Board;
- b. The Chair and Vice Chair of each Council;
- c. The Conference Program Chair;
- d. Representatives from regulatory agencies regulating retail food operations in other countries of the world, such as Canada, Mexico, etc.;
- e. The ~~Executive~~ Director, Executive Treasurer, Executive Assistant;
- f. The Conference Issue Chair, and
- g. The Conference Constitution and Bylaws/Procedures Chair.

**Section 4.** The Board shall elect a Board Chair and Board Vice Chair, who will also serve as the Conference Chair and Conference Vice Chair, from its membership after caucus elections are held during each biennial meeting of the Conference, and

they may retain their positions at the pleasure of the Board as long as they are officially members of the Board. ~~The Board Chair and Vice Chair shall be the Chair and Vice Chair of Conference meetings.~~ The Board shall retain the services of a qualified person to act as an ~~Executive~~ Director, Executive Treasurer, and Executive Assistant. The Executive Treasurer shall be bonded. The compensation of the ~~Executive~~ Director, Executive Treasurer, and Executive Assistant shall be set by the Board.

**Section 5.** The Immediate Past Board Chair ~~of the Board~~ shall continue to serve on the Board until replaced by the next retiring Conference Chair. If the Immediate Past Board Chair ~~of the Board~~ is unable for any reason to continue to serve on the Board, the position shall remain vacant until filled by the next retiring Conference Chair. Immediate Past Board Chairs shall serve on the Board as non-voting members unless re-elected to the Board in a capacity other than as Immediate Past Chair.

#### **Article V** ***Duties of the Assembly and the Board***

**Section 1.** The Assembly, with recommendation from a Council or the Board, shall accept or reject all recommendations including those pertaining to the Constitution and Bylaws, ~~any Conference procedures,~~ all Memoranda of Understanding or other formal agreements, and other necessary actions including resolutions. ~~; and establish Conference policies and positions on all subjects related to the objective of the Conference except as delegated (by the Assembly) to the Board. If a recommendation is approved, it shall be referred to the Board for appropriate disposition. If a "No Action" recommendation is rejected, the Issue will be referred to the Board for its consideration.~~

**Subsection 1.** If a recommendation is "ACCEPTED", it shall be referred to the Board for appropriate disposition.

**Subsection 2.** If an extracted Issue has a recommendation of "No Action", it is rejected, and the Issue will be referred to the Board for its consideration.

#### **Article VI** ***Duties of the Executive Board***

**Section 21.** The Board shall manage the affairs of the Conference, adhere to the CFP Constitution and By Laws, and abide by the current CFP Biennial Meeting/Conference Procedures document.

**Section 32.** The Board may establish operational policies and procedures, with the ~~concurrence~~ approval of two-thirds (2/3) of the voting Board members, that detail management functions and oversight of the Conference organization. Such operational policies and procedures may include, but are not limited to, budget, finances, expenditures, and coordination and implementation of biennial meeting obligations and operations.

- Section 43.** The Board shall meet at least twice a year ~~prior to each the CFP Biennial Meeting and after the meeting closes.~~ The Board Chair shall call special meetings of the Board at any time at the request of two-thirds (2/3) of its voting members. In addition, the Board Chair is empowered to call special meetings of the Board at any time, as the need arises, with the ~~concurrence-~~approval of two-thirds (2/3) of the voting Board members.
- Section 54.** The Board may, at the discretion of the Board Chair, ~~utilize~~ use a mail service, electronic mail, or fax ~~ballots to establish~~ to provide ballots to establish a position, action, or to confirm telephone conference call votes. Only an authorized ballot approved by the Board shall be used. Once such a position or action has been taken, the Board shall notify all Conference members.
- Section 65.** The Board shall direct the Conference Chair, ~~Executive~~ Director, and Program Chair in the preparation of the programs for each meeting of the Conference.
- Section 76.** The Board shall set the time and place of the meetings of the Conference.
- Section 87.** If elected voting members of the Board are unable to participate in a Board meeting, they may not send a substitute, but may forward by mail, email, or FAX, information for consideration by attending members of the Board. Voting and ex- officio members may participate through a telephone conference call.
- Section 98** Voting Board members who fail to attend two (2) consecutive Board meetings, and who fail to show cause why they were absent, may have their positions declared vacant by the Board Chair.
- Section 109.** If a vacancy occurs for any reason in Board membership between biennial meetings, the Board Chair, with ~~concurrence-~~approval of the Board, may fill the vacancy with a person representing the same discipline as the person being replaced until the next biennial meeting, at which time the vacancy shall be filled by a qualified person who is properly elected.
- Section 110.** The Board shall direct the Executive Treasurer to collect registration and membership fees as necessary to defray the costs of the operation of the Conference. The Board shall cause an annual audit to be made of the Executive Treasurer's financial reports.
- Section 1211.** The Board shall authorize the form used to tally votes in meetings of the Board and Assembly.
- Section 1312.** The Board shall establish the registration and membership fees ~~identified in~~ Article III.
- Section 1413.** ~~The Board shall approve an annual budget for the fiscal year established by the Board.~~ The Board shall approve a biennial budget prepared and presented by the Executive Treasurer.

**Section 1514.** ~~The Board shall appoint Committees as necessary to accomplish the Conference objective. The Board shall appoint Adhoc Committees as necessary to accomplish the Conference objective.~~

**Section 1615.** The Board shall approve the membership of each Standing Committee.

**Article VI-VII Duties of the Conference Chair**

**Section 1.** The Conference Chair shall preside at all meetings of the Assembly and Board, except as provided in Article ~~VII~~, VIII Section 1.

**Section 2.** The Conference Chair shall assist the ~~Executive~~ Director in arranging CFP Biennial Meetings.

**Section 3.** The Conference Chair, with the approval of the Board, shall appoint Council Chairs and Vice Chairs.

**Section 4.** ~~The Chair shall appoint Council consultants required in Article X Regulatory consultants, as required in Article XIII, will be selected for appointment by their respective agencies and presented to the Conference Chair for acceptance to Councils.~~

**Section 5.** The Conference Chair shall appoint Chairs of the ~~Conference~~ Standing Committees established in Article XV Section 2, with the exception of the Nominating Committee.

**Section 6.** The Conference Chair, with the approval of the Board, shall appoint qualified persons to Councils and Committees as provided in the Constitution and Bylaws.

**Section 7.** The Conference Chair shall appoint a Local Arrangements Committee to assist in planning the physical facilities for the next CFP Biennial Meeting.

**Section 8.** The Conference Chair shall appoint a parliamentarian to advise on matters of parliamentary procedures at Board and Assembly meetings.

**Section 9.** The Conference Chair, with Board approval, may retain ~~clerical~~ administrative assistance for the Conference.

**Section 10.** Between Conference meetings, the Conference Chair shall require from each Council Chair a report at least twice a year regarding the status of implementation of each approved recommendation originating in the respective Council. ~~and~~ †This information shall be provided to the Conference participants.

**Section 11.** The Conference Chair shall perform all other responsibilities and duties as detailed in the Conference Chair position description.

**Article VII-VIII Duties of the Conference Vice Chair**

- Section 1.** In the event the Conference Chair is unable to perform the duties of the Chair, the Conference Vice Chair shall act as Chair.
- Section 2.** When acting as Conference Chair, the Vice Chair shall perform all the necessary duties for the Conference as outlined in Article ~~VI~~VII.
- Section 3.** The Conference Vice Chair shall perform all other responsibilities and duties as detailed in the Conference Vice Chair Position Description.

**Article VIII-IX Duties of the Executive Director**

- Section 1.** The ~~Executive~~ Director shall ensure that the minutes of each meeting of the Assembly and the Board are recorded and transcribed.
- Section 2.** The ~~Executive~~ Director shall tally and record all voting of the Assembly on a form authorized by the Board.
- Section 3.** The ~~Executive~~ Director shall notify all members of the time and place of the next CFP Biennial Meeting, and of Issues that are to be deliberated.
- Section 4.** The ~~Executive~~ Director shall accomplish the duties outlined in Article VI, Section ~~4, 5, and~~ Article ~~XVII, XIX,~~ Section 1, Subsections 2, 3, 4, and Sections ~~4, 5 and~~ 6.
- Section 5.** The ~~Executive~~ Director shall maintain an up-to-date list of the qualified delegates designated as required by Article ~~XIV, XVII~~ Sections 2, 3, and 4.
- Section 6.** The ~~Executive~~ Director shall retain, subject to Board's approval, a qualified person to serve as Executive Assistant, and shall direct and oversee duties assigned to the Executive Assistant.
- Section 7.** The ~~Executive~~ Director shall perform all other responsibilities and duties as detailed in the ~~Executive~~ Director position description.

**Article IXX Duties of the Executive Treasurer**

- Section 1.** The Executive Treasurer shall collect registration and membership fees and shall pay bills as directed by the Board. The Executive Treasurer shall obtain a receipt for all disbursements and shall make all such receipts a part of Board records.
- Section 2.** The Executive Treasurer shall prepare a proposed ~~annual~~ biennial budget for presentation to the Board.
- Section 3.** The Executive Treasurer shall prepare all budget and financial reports.

**Section 4.** The Executive Treasurer shall perform all other responsibilities and duties as detailed in the Executive Treasurer position description.

**Article X-XI Duties of the Executive Assistant**

**Section 1.** The Executive Assistant manages the information on the CFP website, with the assistance of the ~~Executive~~ Director and a professional webmaster, and publishes the CFP newsletter.

**Section 2.** The Executive Assistant maintains the CFP membership database, creates reports and rosters, and develops mailing lists.

**Section 3.** The Executive Assistant assists the ~~Executive~~ Director with development of a ~~Standard Operating Procedures Manual to include~~ position descriptions, Board policies, and scripts for presentations, and is responsible for their maintenance.

**Section 4.** The Executive Assistant records, transcribes, and distributes Board meeting minutes.

**Section 5.** The Executive Assistant assists the ~~Executive~~ Director with the Delegate process to include outreach and rosters.

**Section 6.** The Executive Assistant assists the ~~Executive~~ Director with the preparation of the biennial meeting program, provides onsite assistance to the Director at the biennial meeting, and compiles biennial meeting proceedings with the assistance of the ~~Executive~~ Director.

**Section 7.** The Executive Assistant shall perform all other responsibilities and duties as detailed in the Executive Assistant position description.

**Article XI-XII Councils**

**Section 1.** There shall exist three (3) Councils in the Conference to provide for continuity of action in carrying out the objective of the Conference. The Councils shall be known as:

Council I: Laws and Regulations;

Council II: Administration, Education, and Certification;

Council III: Science and Technology.

~~*Subsection 1.* The Councils shall be known as Council I, Council II and Council III.~~

**Section 2.** Each Council shall have a Chair, Vice Chair, and twenty (20) other members to be appointed by the Conference Chair with the approval of the Board. ~~Except as specified in Article X, Section 3, Subsection 3, t~~The term for a Council member shall begin at appointment and expires upon adjournment of that the fall Board meeting following the CFP Biennial Meeting. If a Council member cannot attend a CFP Biennial Meeting, the member's term expires, and the

Conference Chair may appoint a member who can attend the Council meeting during the CFP Biennial Meeting.

**Subsection 1.** Of the twenty-two (22) members of Councils I and II, nine (9) members plus one Council Chair or Vice Chair shall be selected from regulatory agencies, one (1) shall be from a national, state, or local consumer organization, one (1) shall be from academia, and nine (9) members plus one Council Chair or Vice Chair from industry.

**Subsection 2.** Eight (8) of the food regulatory agency representatives on Councils I and II shall be equally apportioned among state and local agencies and two (2) members ~~shall~~ can be from the territories, District of Columbia, or Federal jurisdictions that regulate commercial or institutional operations. If two (2) members cannot be obtained from the territories, District of Columbia, or Federal food inspection programs, these positions may be filled from state or local food regulatory agencies. The ten (10) industry representatives shall be apportioned so at least one (1) member represents food processing, two (2) members represent food service, two (2) members represent retail food ~~stores~~, and one (1) member represents food vending and distribution.

**Subsection 3.** Of the twenty-two (22) members of Council III, at least five (5) shall be from state and local regulatory agencies, at least five (5) from industry, up to ten (10) at-large, plus a Council Chair and Vice Chair. The industry representatives shall include at least one (1) each from food processing, food service, retail food ~~stores~~ and food vending and distribution. At-large members may include members representing Federal agencies, academia, and other stakeholder groups.

**Subsection 4.** If sufficient designated members are not available at a CFP Biennial Meeting to complete a Council's membership, the Conference Chair may appoint other members to the Council so long as the balance between regulatory and industry is maintained as specified.

**Section 3.** The Council Chair and Vice Chair shall select twenty (20) Council members from persons holding membership in the Conference, and offer their names for Conference Chair appointment and Board confirmation.

**Subsection 1.** The Council Chair shall, after appointment, serve through one (1) CFP Biennial Meeting. The Council Vice Chair shall, after appointment, serve through two (2) consecutive CFP Biennial Meetings, one (1) as Vice Chair and the second as Chair.

**Subsection 2.** On Councils I and II, when the Council Chair represents a food regulatory agency, the Vice Chair shall be an industry representative. If the Council Chair represents industry, the Vice Chair shall be a food regulatory agency representative. The Chair and Vice Chair from Council III shall be from one of the following disciplines: Regulatory, Industry, or Academia, and at no time shall both the Chair and Vice Chair represent the same ~~group~~ constituency.

**Subsection 3.** The term for the Council Chair and Vice Chair shall begin at the conclusion of the scheduled CFP Biennial Meeting and expire upon adjournment of the following last through the fall Board meeting following the next biennial CFP Biennial Meeting. At the end of the outgoing Council Chair's term, the Vice Chair shall assume the position of Council Chair, and a new Vice Chair shall be appointed as set forth in Subsection 2 of this Section.

**Section 4.** Each member of the Council, other than the Vice Chair, shall have one vote. The Council Chair shall only vote to break a tie. The Council Vice Chair shall only vote when acting as Chair.

**Article XII XIII Council Consultants**

**Section 1.** The following agencies and international organizations may each provide a non-voting consultant for each of the Councils:

- Centers for Disease Control and Prevention (CDC);
- U. S. Environmental Protection Agency (EPA);
- U. S. Food and Drug Administration (FDA);
- U. S. Department of Agriculture (USDA);
- Food and Agriculture Organization (FAO);
- Pan American Health Organization (PAHO);
- World Health Organization (WHO);
- The Dominion of Canada; and
- Others as deemed appropriate by the Board.

**Article XIII XIV Duties and Responsibilities of Councils**

**Section 1.** Councils shall deliberate on all assigned Issues. Council Chairs shall report the recommendations of their Councils to the Assembly under Article XIX.  
(See also current CFP Biennial Meeting/Conference Procedures document.)

**Subsection 1.** Recommendations are:

- a. "Accept as Submitted"
- b. "Accept as Amended"
- c. "No Action"

**Subsection 2.** When a Council recommends "No Action" on an assigned Issue, the Council shall specify/identify the reason why "No Action" was taken and it shall be recorded by the Scribe and confirmed by the Council Chair.

**Section 12.** Council I: Council on Laws and Regulations

~~**Subsection 1.** Issues submitted to the Conference dealing with laws, regulations and model codes governing the safety of food shall be assigned to Council I by the Conference Issue Committee.~~

**Section 23.** Council II: Council on Administration, Education, and Certification

~~**Subsection 1.** Issues submitted to the Conference dealing with matters relating to the Constitution and Bylaws, Conference procedures, memoranda of understanding, program evaluation, education, training and certification and the like shall be assigned to Council II by the Conference Issue Committee.~~

**Section 34.** Council III: Council on Science and Technology

~~**Subsection 1** Issues submitted to the Conference dealing with science and technology shall be assigned to Council III by the Conference Issue Committee.~~

~~**Section 4.** Councils shall deliberate on all assigned Issues. Council Chairs shall report the recommendations of their Councils to the Assembly.~~

~~**Section 5.** When a Council recommends "No Action" on an assigned Issue, the Council Chair shall record the reason why "No Action" was recommended~~

**Section 65.** Duties of the Councils between CFP Biennial Meetings

~~**Subsection 1.** Following the CFP Biennial Meeting, the Conference Chair shall contact the Council Chairs to review the recommendations approved by the Assembly, of State Delegates and to plan for the implementation of approved recommendations originating in their respective Councils.~~

~~**Subsection 2.** During the period between biennial meetings, The Council Chairs shall monitor, encourage, and proactively support the progress of implementation of approved recommendations originating in their respective Councils.~~

~~**Subsection 3.** Council Chairs shall prepare a written report on the status of implementation of approved recommendations originating in their respective Councils or on the activities of committees assigned to their Council. These reports shall be submitted to the Conference Chair thirty (30) days prior to each Board meeting, or more frequently at the request of the Conference Chair.~~

~~**Subsection 4.** The new Council Chairs shall submit for Board approval the names of Council Committee Chairs and membership of all committees assigned to their Council to the Conference Chair for approval by no later than the by fall Board meeting following the CFP Biennial Meeting.~~

#### **Article XIV-XV Committees**

~~**Section 1.** All appointments to Conference Committees shall be made to provide a balance in representation of the stakeholders in the particular matter under consideration.~~

~~**Subsection 1.** The incoming Council Chairs appoint the Chairs of each Committee formed within their Council with the concurrence of the Conference Chair. The Conference Chair will confirm the appointment of the Committee Chair and then notify the person of their appointment. Once confirmed, the Committee Chair will select the remaining members of the Committee and submit them to the Conference Chair for final Board approval.~~

~~**Subsection 2.** Federal participants (FDA/USDA/CDC) may appoint a member and an alternate for each Committee. The member participates in discussion but does not vote. The alternate may act in the member's place if the member is unable to attend.~~

**Section 1.** CFP members in good standing may express interest to serve on a committee by forwarding their name to the Executive Assistant following the CFP Biennial Meeting. This list will be used in creation of committee rosters. All appointments to Committees shall be made to provide a balance in representation of the stake holders in the particular matter under consideration.

**Subsection 1.** The incoming Council Chairs will select Council Committee Chairs for each committee formed within their Council, and present those names to the Conference Chair for acceptance. The Conference Chair will notify the persons of their appointment. Once confirmed, the Council Chairs and Council Committee Chairs will select the remaining members of the Council Committees. The Council Chairs will submit full committee rosters to the Conference Chair for final Board approval.

**Subsection 2.** Federal participants (FDA, USDA, CDC) may appoint a consultant and an alternate for each committee. The consultant participates in committee discussions but does not vote. An alternate may act in the appointed consultant's place if the consultant is unable to attend. Consultants may or may not be CFP members to serve on a committee, but shall be members to attend Biennial meetings. Only one Federal participant who is a non-CFP member per Council Committee is permitted.

**Subsection 3.** Committees may vote to invite a non-member to present pertinent information related to the committee's charges. Non-members will not have a vote, nor will they participate in debate or discussion.

**Section 2.** The following standing committees shall be established:

~~**Subsection 1.** Audit Committee;~~

~~**Subsection 2.** Constitution and Bylaws/Procedures Committee;~~

~~**Subsection 3.** Finance Committee;~~

~~**Subsection 4.** Issue Committee;~~

~~**Subsection 5.** Food Protection Manager Certification Committee;~~

~~**Subsection 6.** Nominating Committee;~~

~~**Subsection 7.** Program Committee;~~

~~**Subsection 8.** Program Standards Committee;~~

~~**Subsection 9.** Publications Committee;~~

~~**Subsection 10.** Resolutions Committee; and~~

~~**Subsection 11.** Strategic Planning Committee.~~

- Issue Committee
- Program Committee
- Constitution and Bylaws/Procedures Committee
- Resolutions Committee
- Audit Committee
- Food Protection Manager Certification Committee (FPMCC)
- Program Standards Committee
- Finance Committee
- Nominating Committee
- Strategic Planning Committee (SPC)
- Publications Committee

**Section 3.** Other committees may be established by the Board as necessary to accomplish the Conference objectives. ~~Such committees may be for the purpose of focusing Conference resources around specific scientific disciplines, for studying multi-faceted issues, for developing new procedures or for other purposes.~~

*Subsection 1.* Local Arrangements Committee shall be established for each CFP Biennial Meeting.

**Section 4.** A Standing Committee may establish its own bylaws ~~establishing~~ and operational procedures that may include, but are not limited to, objectives, organization and operation, duties, and responsibilities. Bylaws of a committee must be approved by the Board.

**Section 5.** No later than the ~~Fall~~ Board meeting following the CFP Biennial Meeting, the Standing Committee Chairs shall submit the names of their members to the Board for approval.

**Article XV-XVI      Duties and Responsibilities of Committees**

**Section 1.** The Issue Committee shall review all Issues submitted at least ninety (90) days before the CFP Biennial Meeting. ~~The Issue Committee~~ This Committee shall assign ~~for Council deliberation~~ those Issues that have met the ~~Issue~~ acceptance criteria specified in the ~~Conference Procedures Manual~~ current CFP Biennial Meeting/Conference Procedures document. Issue assignments shall be made in accordance with Article XII, ~~Section 1, Subsection 1; Section 2, Subsection 1; and Section 3, Subsection 1.~~ XIV Sections 2-4.

**Section 2.** The Program Committee shall be responsible for the educational workshop, and the reports and updates session at the biennial meeting.

**Section 3.** The Constitution and Bylaws/Procedures Committee shall submit recommendations to improve Conference administrative functions through proposals to amend the Constitution and Bylaws. The Committee shall review proposed memorandums of understanding and ensure consistency among governing documents such as ~~the memorandum of understanding, Conference~~

~~Procedures manual the Constitution and ByLaws, the CFP Biennial Meeting/Procedures document, the Constitution and Bylaws, and other working governing documents.~~ The C ommittee shall report all recommendations to the Board prior to Council II deliberation, and shall follow the direction of the Board.

**Section 4.** The Resolutions Committee shall report to the Board. Except for “thank you” resolutions, the Resolutions Committee shall prepare all ~~necessary~~ resolutions for Board approval.

**Section 5.** The Audit Committee shall report to the Board, and shall audit the Conference’s financial records annually. ~~In addition, Additionally, a certified public accountant shall conduct an audit of the Conference’s financial records at least every 4 years. Except when a certified public accountant conducts an audit of the Conference’s financial records, the Audit Committee shall audit the Conference’s financial records annually.~~

**Section 6.** The Food Protection Manager Certification Committee shall report to the Board, ~~The Food Protection Manager Certification Committee~~ and shall work with the accreditation organization for food protection manager certification programs in order to:

*Subsection 1.* Establish and refine policies and standards to which certifiers must conform in order for them to be accredited;

*Subsection 2.* Provide Conference input ~~into the development of~~ on accreditation standards for certifying organizations specific to food protection manager certification programs;

*Subsection 3.* Develop strategies for enhancing equivalence among food protection manager certificates issued by certifiers; and

*Subsection 4.* Promote universal acceptance of certificates issued by accredited certifiers.

**Section 7.** The Program Standards Committee shall report to the Board ~~The Program Standards Committee~~ and shall provide ongoing input to the FDA on issues that arise with the Voluntary National Retail Food Regulatory Program Standards.

*Subsection 1.* The Committee shall serve the Conference by indirectly assisting Voluntary National Retail Food Regulatory Program Standards enrollees in achieving ~~making~~ progress towards meeting the Standards.

**Section 8.** The Finance Committee shall report to the ~~Executive Board~~ and ~~The Finance Committee~~ shall provide financial oversight for the Conference. ~~Duties of the Finance Committee shall include budgting and finanacial planning, financial reporting, and the creation and monitoring of internal controls and accountability policies~~ The Finance Committee will ~~include between~~ consist of 5 to 7

members from the Executive Board, ~~The Finance Committee membership~~ and should be reflective of the Conference membership. Members will serve a term of at least two (2) years.

**Subsection 1.** The Finance Committee responsibilities include:

- a. Budgeting and Financial Planning
  - i. Develop ~~an annual~~ a biennial operating budget with staff.
  - ii. Approve the budget within the Finance Committee.
  - iii. Monitor adherence to the budget.
  - iv. Set long-range financial goals along with funding strategies to achieve them.
  - v. Develop multi-year operating budgets that integrate strategic plan objectives and initiatives.
  - vi. Present all financial goals and proposals to the ~~CFP's Executive Board~~ for approval.
- b. Reporting
  - i. Develop useful and readable report formats with staff.
  - ii. Work with staff to develop a list of desired reports noting the level of detail, frequency, deadlines, and recipients of these reports.
  - iii. Work with staff to understand the implications of the reports.
  - iv. Present the financial reports to the full Board.
- c. Internal Controls and Accountability Policies
  - i. Create, approve, and update (as necessary) policies that help ensure the assets of the Conference are protected.
  - ii. Ensure policies and procedures for financial transactions are documented in a manual, and that the manual is reviewed annually and updated as necessary.
  - iii. Ensure approved financial policies and procedures are being followed.

**Section 9.** The Nominating Committee shall report to the ~~Executive Board~~. The ~~Nominating Committee~~ shall provide to the Board a list of viable candidates for Conference Chair and ~~Vice Conference~~ Vice Chair prior to each Biennial Meeting.

**Section 10.** ~~The Strategic Planning Committee (SPC) shall report to the Executive Board. The Strategic Planning Committee shall provide an active leadership role in THIS developing both long term and short term goals that will enhance and sustain the relevance and viability of the Conference for Food Protection. To accomplish these goals the SPC will include such activities as:~~

~~**Subsection 1.** Anticipate changing business and regulatory environment;~~

~~**Subsection 2.** Assess membership satisfaction of the CFP and its processes;~~

~~**Subsection 3.** Identify changing expectations of CFP members;~~

~~**Subsection 4.** Explore ways to build membership;~~

~~**Subsection 5.** Assist in efforts to communicate more effectively with membership;~~

~~**Subsection 6.** Expand outreach to collaborate and partner with organizations of similar public safety goals.~~

~~**Subsection 7.** Search for viable funding sources to ensure long term financial sustainability.~~

**Section 10.** The Strategic Planning Committee (SPC) shall report to the Board, and shall advise the Board on the current and future direction for CFP. This Committee shall make recommendations to keep the CFP relevant and increase the viability and growth of the organization. The SPC will actively engage CFP Committees and the Board by:

**Subsection 1.** Positioning CFP to respond to changes in the business and regulatory environment by staying abreast of changing needs to keep CFP a viable and relevant organization.

**Subsection 2.** Assessing member satisfaction, exploring ways to increase membership, improving communication with members, and responding to membership's changing expectations of CFP, its programs, services, and the Biennial meeting.

**Subsection 3.** Finding ways for CFP to collaborate/partner with organizations that hold similar values and interests in retail food safety.

**Subsection 4.** Sustaining the financial stability of CFP by seeking new, increased, or alternative sources of funding.

**Section 11.** The Publications Committee shall report to the Executive Board ~~and The Publications Committee shall~~ make recommendations to the Board to establish, maintain, and improve Conference publications regarding Conference endorsement, copyright, scientific and regulatory accuracy, and external publication approval. The Committee shall report all publication recommendations to the Board for approval prior to internal publication and revisions or external publication.

**Section 12.** All Committees, including Standing Committees, shall submit their reports for the Board meetings ~~in a timely prescribed manner as specified under Article II, Section 3~~ as follows:

**Subsection 1.** Committees assigned to a Council shall submit their report to their respective Councils ~~Chairs~~; and

**Subsection 2.** Standing Committees shall submit their report to the Conference Chair and ~~Executive Director~~.

**Section 13.** Council Committee Size and Constituency: Committee membership discussion is limited to Council Committees only. ~~Membership on Standing Committees or Executive Board Adhoc Committees is defined by the CFP Executive Board.~~

**Subsection 1.** Committee size.

Voting membership for Council Committees should be comprised of at least eleven (11) voting members, with a maximum of no more than twenty-three (23) voting members.

- a. Minimum size: Voting membership for a minimum size Council committee is the Chair, Vice Chair, one (1) representative from state regulatory, one (1) representative from local regulatory, two (2) representatives from industry, one (1) from an academic institution, one (1) consumer representative, and three elective (3) representatives who ~~which~~ may be selected from any Conference constituency with an emphasis on expertise specific to the Committee's charge(s).
- b. Maximum size: Voting membership for a maximum size Council committee is the Chair, Vice Chair, four (4) representatives from state regulatory, four (4) representatives from local regulatory, eight (8) representatives from industry, one (1) from an academic institution, one (1) consumer representative, and three elective (3) representatives who ~~that~~ may be selected from any Conference constituency with an emphasis on expertise specific to the Committee's charge(s).
- c. Any committee comprised of membership numbers between the minimum and maximum shall make every reasonable effort to maintain constituency balances.

**Subsection 2.** The Chair and Vice Chair of a Council Committee may be selected from any of the Conference constituencies as approved by the ~~Council Chair and the Executive Board~~, Conference Chair, provided each is from a different constituency. If a Council Committee Chair does not receive sufficient volunteers in the appropriate constituencies, they shall confer with the Council Chair to seek volunteers from the Conference membership, making every reasonable effort to maintain constituency balances. The Council Committee Chair, in consultation ~~conference~~ with the Council Chair ~~and/or Executive Board~~, shall have the flexibility to fill vacancies in the voting membership with unbalanced constituency representation if deemed necessary to reach a minimum of eleven (11) voting ~~committee~~ members. All proposed Council Committee members must be approved by the ~~Executive Board~~. ~~in accordance with Article XIII, Section 6, Subsection 4 of the Constitution and Bylaws.~~

**Subsection 3.** A maximum of twenty-three (23) voting members are permitted on a Council Committee. All volunteers not selected for a voting position shall be offered an "at-large" non-voting position on the Council Committee. There is no limit to the number of at-large non-voting members that may participate. At-large members will be included and ~~allowed to~~ participate in all Council Committee functions, including but not limited to; meetings, conference calls, emails, deliberations,

research, and activities. At-large members ~~but~~ will not have an individual vote on Council Committee actions. All voting members and at-large non-voting members shall be identified as such on the Council Committee roster along with their respective constituency.

***Subsection 4.*** In the event a Council Committee voting member departs, ~~such~~ ~~Committee~~ during a biennial cycle, an at-large member of the same constituency as the departing member shall be selected by the Council Committee Chair to fill the vacancy, subject to approval by the Council Chair and ~~Executive Board. in accordance with Article XIII, Section 6, Subsection 4 of the Constitution and Bylaws.~~ If a Council Committee voting member changes constituency during a biennial cycle, and there is no vacancy in that member's new constituency, the member will need to transition from service as a voting member ~~on that Committee and may continue to serve as~~ to an at-large non- voting member for the remainder of the biennial cycle. This transition will occur upon notification to the Council Committee Chair.

***Subsection 5.*** ~~A Council Committee Chair who~~ The Chair of a council ~~committee that~~ continues over more than one biennial cycle shall assess the immediate previous Council Committee membership to ensure at least 50% of the ongoing Committee's voting membership are new members that did not serve as voting members on the immediate previous Committee. This ~~provision~~ will ensure that an increased number of at-large members or others have an opportunity to participate as ~~a voting members over time when there are a large number of volunteers.~~

### ***Article XVI-XVII Duties of States, Territories and District of Columbia***

***Section 1.*** The states, territories, and ~~the~~ District of Columbia shall be responsible for ~~designating and~~ keeping the Executive Director informed of the name(s) and address(es) of the person(s) designated to represent them in the Assembly.

***Section 2.*** The food regulatory agency or agencies in each state, territory and District of Columbia participating in the CFP Biennial Meeting will receive from the Director at least one hundred and fifty (150) days prior to the CFP Biennial, a notice of the forthcoming meeting. Each notice shall include a current copy of Article II, Section 3 and Article XVIII and XIX of the current version of the Constitution and Bylaws.

***Section 3.*** Each Agency shall report to the Director the following information, using approved forms:

***Subsection 1.*** The agency's authority and responsibility over the regulation of food establishments, production, processing, vending, or distribution, or the oversight for prevention of foodborne illness;

***Subsection 2.*** The name of the delegate and the alternate, if any; and

**Subsection 3.** Designation of the vote to which that person is entitled, whether one (1) vote or a fraction of one (1) vote.

**Section 4.** In the event that more than one (1) delegate is designated and the sum of the votes designated for the delegates is greater than one (1), the Director shall reject, void, and return the reports to the agencies for correction. Such revision shall be submitted to the Director at least forty-five (45) days before the CFP Biennial Meeting.

**Article XVII-XVIII Rules of the CFP Biennial Meeting**

**Section 1.** The current version of the “CFP Biennial Meeting/Conference Procedures” document contains the rules of the Biennial meeting.

**Section 12.** CFP Biennial meeting participation is open to all interested individuals who choose to become members and attend. Individuals may serve as appointed or elected members on the Board, Councils, and committees, or as a participating registered member.

**Section 23.** CFP Biennial Meetings shall be of at least two (2) days duration, except this requirement may be waived for special meetings called by the Board.

**Section 34.** Except for additional meetings as provided for in Article II, Section 2, the Conference will meet each even-numbered year.

**Section 45.** Robert’s Rules of Order shall prevail unless specified rules are established.

**Section 56.** FDA, CDC, and USDA reports shall be presented.

**Article XVIII-XIX Rules of the Assembly**

**Section 1.** Meetings of the Assembly shall be conducted as follows:

**Subsection 1.** Call to order by the Conference Chair;

**Subsection 2.** Roll call by the Director of states, territories, and District of Columbia, and the announcement of the names of the delegates who will vote for each in the Assembly;

**Subsection 3.** The Director calls for a vote to approve ~~Approval~~ of the minutes of the previous meeting;

**Subsection 4.** Reports from the ~~of the~~ Executive Director and Executive Treasurer;

**Subsection 5.** Council Chair reports, resolutions, and other new business;

**Subsection 6.** Assembly voting (see the current CFP Biennial Meeting/Conference Procedures document);

**Subsection 7.** Authorization that may be required by the Assembly for the Board to conclude and implement any necessary recommendations prior to the next CFP Biennial Meeting; and

**Subsection 8.** Adjournment.

**Section 2.** ~~Each state shall be entitled to one (1) full vote and each territory and the District of Columbia shall be entitled to one half (1/2) vote in the Assembly. When a state has more than one (1) state food regulatory agency enforcing food laws and regulations for food processing, food service, retail food stores and food vending, the vote may be divided into appropriate fractions. State agencies within each state must agree among themselves regarding apportioning the one vote. Only a registrant at the CFP Biennial Meeting who is the designated representative of a state, territory, or District of Columbia can be a delegate in the Assembly.~~

**Section 3.** ~~Only a registrant at the CFP Biennial Meeting who is a representative of a state, territory or District of Columbia food regulatory agency responsible for the enforcement of food laws and regulations for food processing, food service, retail food stores or food vending is entitled to be a delegate in the Assembly. When any state is represented by more than one food regulatory agency, the vote may be cast together as one vote or separately as a fraction of a vote. Representatives of states with more than one regulatory agency delegate certified in compliance with the provisions of Section 4 of this Section may, during any meeting of the Assembly, reassign their voting privilege to another duly certified delegate from their state by giving written notice of such action to the Conference Chair. When a state is represented by only one agency, the state's delegate may cast a full vote for that state in the Assembly.~~

**Section 3.** Each state shall be entitled to one (1) full vote, and each territory and District of Columbia shall be entitled to one-half (1/2) vote in the Assembly

**Section 4.** ~~At least one hundred and fifty (150) days prior to a CFP Biennial Meeting the Executive Director shall send to the food regulatory agency or agencies in each state, territory and District of Columbia participating in the CFP Biennial Meeting a notice of the forthcoming meeting. Each notice shall include a current copy of Article II, Section 3 and Article XVII XVIII, Sections 2 through 6 and 9 of the Constitution and Bylaws.~~

**Section 4.** When any state is represented by more than one food regulatory agency, the vote may be divided into appropriate fractions or may be cast together as one vote. Representatives of states with more than one regulatory agency delegate, in compliance with Section 2 of this Article, can reassign their voting privilege to another duly certified delegate from their state by giving written notice of such action to the Conference Chair.

**Section 5.** ~~Each Agency shall report to the Executive Director on approved forms the following:~~

**Subsection 1.** ~~The agency's officially designated regulatory responsibility regarding food processing, food service, retail food stores and food vending~~

**Subsection 2.** ~~The name of the delegate and the alternate, if any; and~~

~~**Subsection 3.** Designation of the vote to which that person is entitled, whether one (1) vote or a fraction of one (1) vote.~~

~~**Section 6.** In the event that more than one (1) delegate is designated and the sum of the votes designated for the delegates is greater than one (1), the Executive Director shall reject, void and return the reports to the agencies for correction. Such revision shall be submitted to the Executive Director at least forty-five (45) days before the CFP Biennial Meeting.~~

**Section 75.** Delegates shall record their names with the Executive Director and shall cast their votes in the Assembly when called by announcing “yes,” “no,” or “abstain” for one (1) vote; or “yes,” “no,” or “abstain” for the appropriate fraction of one (1) vote.

**Section 86.** Voting in the Assembly shall be recorded by the Executive Director as “yes,” “no,” or “abstain,”

**Section 97.** If delegates wish to caucus, they may “pass” when their names are called for the purpose of caucusing, and then shall vote when the second roll is called.

**Section 108.** To adopt in the Assembly:

**Subsection 1.** A quorum must be present. A quorum is defined as the presence of registered voting delegates from at least two-thirds (2/3) of the states with designated official delegates in attendance at the CFP Biennial Meeting. Each territory and District of Columbia shall count as one half (1/2) state in constituting a quorum.

**Subsection 2.** ~~To change a procedure adopted at a previous CFP Biennial Meeting or T~~to make a change in the Constitution and Bylaws requires a two-thirds (2/3) majority vote.

**Subsection 3.** Other actions require a simple majority unless specifically covered by Robert’s Rules of Order.

#### **Article XIX XX Parliamentary Authority**

**Section 1.** The rules of parliamentary procedure comprised in the current edition of Roberts Rules of Order, Newly Revised, shall govern all proceedings of the Conference and the Executive Board, subject to such special rules as have been or may be adopted.

#### **Article XX XXI Dissolution of the Conference**

**Section 1.** Upon the dissolution of the Conference, assets shall be distributed for one or more exempt purposes within the meaning of section 501(c)(3) of the Internal Revenue Code, or tax code, or shall be distributed to the Federal Government, or to a state or local government, for a public purpose. Any such assets not so disposed of shall be disposed of by the Court of Common Pleas of the county in which the principal office of the corporation is then located, exclusively for

such purposes or to such organization or organizations, as said Court shall determine, which are organized and operated exclusively for such purposes.

**Article ~~XXI~~ XXII Amendments to the Constitution and Bylaws**

**Section 1.** The Constitution and Bylaws may be amended at a duly called CFP Biennial Meeting, the delegates having had ~~thirty~~ forty (40) days notice from the ~~Executive~~ Director of such proposal to amend as provided in Article II, Section 3 and Article ~~VIII~~, Section ~~3.XVI~~, Section 3.

**Section 2.** Amendments to the Constitution and Bylaws will become effective at the close of the biennial meeting at which they are adopted.

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*Appendix*

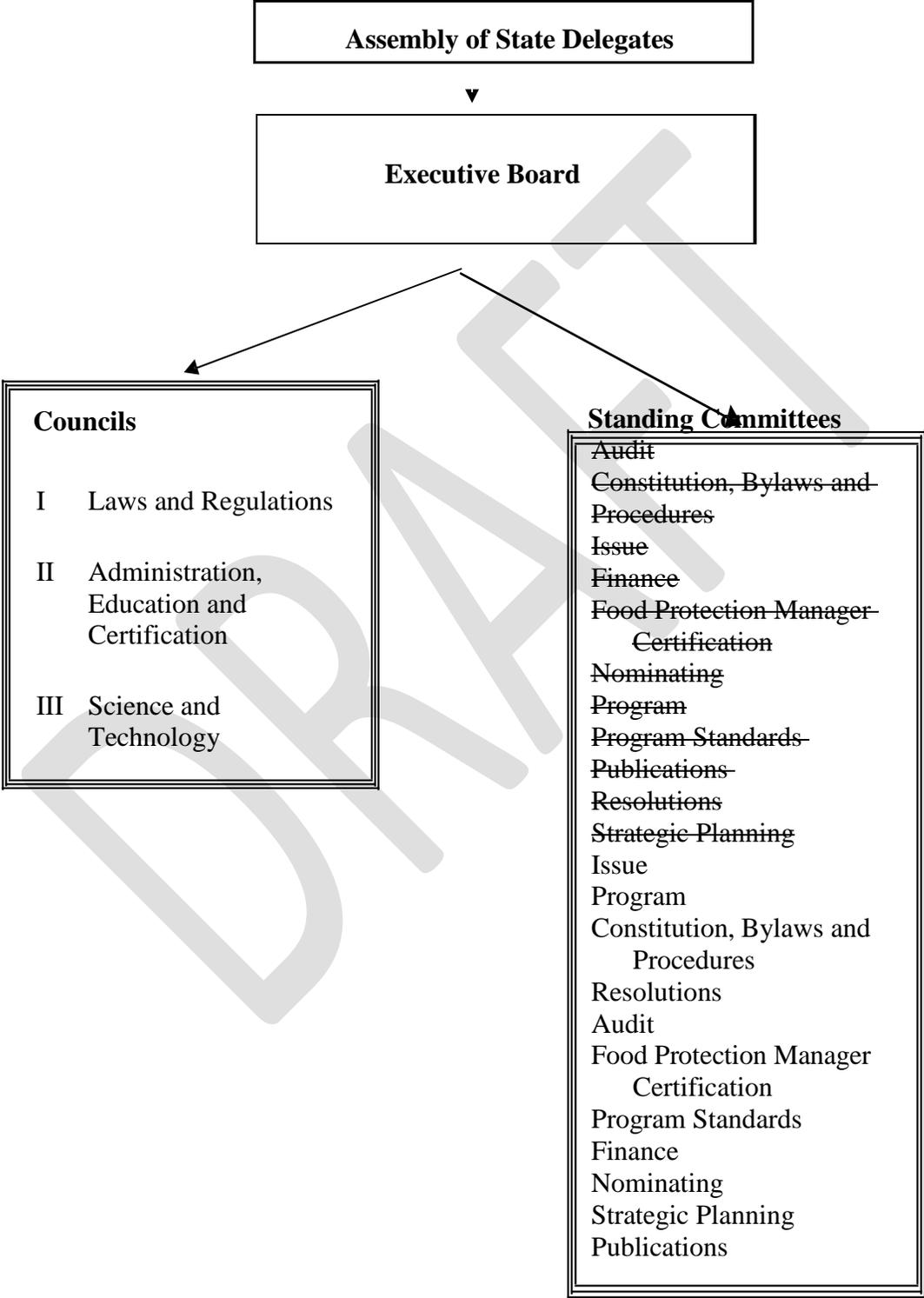
**Map of CFP Regions\***



Non-contiguous states and territories not shown on map  
 \*Used in Allocating Members of Executive Board

Mid-Atlantic	Midwest	Pacific	Southeast	Northeast	Southwest
DE	IL	AK	AL	CT	AR
DC	IN	AS	FL	MA	CO
KY	MI	AZ	GA	ME	IA
MD	MN	CA	LA	NH	KS
OH	ND	CM	MS	NY	MO
NJ	SD	GU	NC	RI	NE
PA	WI	HI	PR	VT	NM
VA		ID	SC		OK
WV		MT	TN		TX
		NV	VI		UT
		OR			WY
		TT			
		WA			

*Conference for Food Protection Organizational Chart*



## *Organizational Structure Composition*

### *Assembly of State Delegates*

- Role:** Approves or rejects all Council recommendations
- Chair and Vice Chair:** Conference Chair and Conference Vice Chair preside at meetings of the Assembly
- Delegates:** Designated by 57 food regulatory agencies representing:  
50 states  
6 territories
- American Samoa
  - Guam
  - Northern Mariana Islands
  - Puerto Rico
  - Trust Territory
  - U.S. Virgin Islands
- 1 District of Columbia
- Voting:** 53 ½ total possible
- Fifty (50) states have 1 vote each. Those states with multiple state regulatory jurisdictions may ~~divide vote equitably~~ cast their vote as one or separating as a fraction of one.
- 6 territories and District of Columbia have ½ votes each

## *Executive Board*

<b>Role:</b>	Manages the affairs of the Conference
<b>Chair and Vice Chair:</b>	<u>Board Chair and Board Vice Chair are also the Conference Chair and Conference Vice Chair</u> Elected from Board Voting Membership
<b>Members:</b>	<b>Twenty-three</b> (23) elected to stagger terms by caucus of registrants in each <del>respective</del> <u>constituency</u> group. Federal members are appointed by agency head.
<b>Voting</b>	6 state regulatory agencies (1 each per CFP Region) 6 local regulatory agencies (1 each per CFP Region) 3 Federal agencies (FDA, USDA, and CDC)) 6 Food Industries 1 Academic Institution 1 Consumer Representative
<b>Non-Voting Ex-Officio</b>	1 Immediate Past <u>Conference</u> Chair 3 Chairs' of each Council 3 Vice Chairs' of each Council 1 Program Chair 1 Issue Chair 1 Constitution and Bylaws/Procedures Chair 1 Program Standards Chair 1 Finance Committee Chair 4 International Representatives (i.e., Canada, Mexico, etc.) 1 Executive Director 1 Executive Treasurer 1 Executive Assistant

## *Councils*

**Role:** Deliberate assigned Issues and develop recommendations for Assembly consideration

**Council Chairs and Vice Chairs:** ~~2 appointed by Conference Chair with approval of~~ Approved by the Board.

For Councils I and II, if the Chair has a regulatory affiliation, the Vice Chair is to be an industry affiliate, and vice versa. The Council Chair affiliation alternates back and forth each term.

Council III Chair and Vice Chair can be from regulatory, industry, and academia. The Council Chair and Vice Chair cannot be from the same constituency.

**Council Members:** 20 selected by Council Chair and Vice Chair for appointment by Conference Chair with approval of the Board

- I. Council on Laws and Regulations
  - Regulatory (including Council Chair or Vice Chair)
    - 4 local
    - 4 states
    - 2 territorial, District of Columbia, or Federal
  - Industry (including Council Chair or Vice Chair)
    - 1 ~~Food~~-Processing
    - 2 Food Service
    - 2 ~~Food Store~~-Retail Food
    - 1 ~~Food~~-Vending and Distribution
    - 4 not specified
  - Consumer and Academia
    - 1 Consumer
    - 1 ~~Academic~~-Academia
- II. Council on Administration, Education, and Certification  
Membership allocated as shown in Council I
- III. Council on Science and Technology
  - 5 Regulatory ~~agencies (min.)~~ selected from state and local
  - 5 Food Industry ~~(min.)~~ with at least 1 each from ~~food~~ processing, food service, retail food, ~~stores~~ and ~~food~~ vending and distribution;
  - 10 At-large ~~including consumer and academia and may include federal and other~~ may include academia, consumer, Federal agencies, and other stakeholders

**Consultants:** 9 possible  
4 Designated Federal agencies

3 Designated international organizations  
additional if necessary, as deemed by the Board.

**Voting:**

Council Chair votes only to break a tie; Council Vice Chair does not vote.

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## *Standing Committees*

### **Appointments**

All appointments to Conference Committees and shall be made to provide a balance in representation of the stakeholders in the particular matter under consideration.

### ***Audit Committee***

**Role:** — Except when a certified public accountant conducts an audit of the Conference's financial records, the Audit Committee audits the Conference's financial records annually. Committee reports to the Board.

**Chair:** — Appointed by Conference

### ***Constitution and Bylaws/Procedures Committee***

**Role:** — Submits recommendations to improve Conference administrative functions through proposals to amend the Constitution and Bylaws. Reviews proposed memoranda of understanding and ensure consistency among the memoranda of understanding, the Conference Procedures manual, the Constitution and Bylaws and other working documents. Reports all recommendations to the Board prior to Council II deliberation and follows the direction of the Board. Committee reports to the Board.

**Chair:** — Appointed by Conference Chair

### ***Issue Committee***

**Role:** — Reviews all Issues submitted to Conference and assigns to Councils for deliberation. Committee reports to the Board.

**Chair:** — Appointed by Conference Chair

### ***Food Protection Manager Certification Committee***

**Role:** — Reports to the Board. Works with the accreditation organization for food protection manager certification programs to:

- a. Establish and refine policies and standards to which certifiers may conform in order for them to be accredited;
- b. Provide Conference input into the development of accreditation standards for certifying organizations specific to food protection manager certification programs;
- c. Develop strategies for enhancing equivalence among food protection manager certificates issued by certifiers; and
- d. Promote universal acceptance of certificates issued by accredited certifiers.

**Chair:** — Appointed by Conference Chair

### ***Nominating Committee***

**Role:** — Selects the nominees for the Conference Chair and Vice Chair.  
— Committee reports to the Board.

**Chair:** — Immediate Past Chair of the Conference

### ***Program Committee***

**Role:** — Assists in planning and arranging of CFP Biennial Meeting.  
— Committee reports to the Board.

~~**Chair:** Appointed by Conference Chair~~

~~***Publications Committee***~~

~~**Role:** To establish, maintain, and improve Conference publications regarding Conference endorsement, copyright, scientific and regulatory accuracy, and external publication approval.~~

~~**Chair:** Appointed by Conference Chair~~

~~***Program Standards Committee***~~

~~**Role:** Provide ongoing input to the FDA on issues that arise with the Voluntary National Retail Food Regulatory Program Standards.~~

~~**Chair:** Appointed by Conference Chair~~

~~***Resolutions Committee***~~

~~**Role:** Except for thank you resolutions, the Resolutions Committee prepares all necessary resolutions for Board approval. Committee reports to the Board.~~

~~**Chair:** Appointed by Conference Chair~~

~~***Strategic Planning Committee***~~

~~**Role:** Provide an active leadership role in developing both long term and short term goals that will enhance and sustain the relevance and viability of the Conference for Food Protection.~~

~~**Chair:** Appointed by Conference Chair~~

~~***Finance Committee***~~

~~**Role:** Provide financial oversight for the Conference including but not limited to budgeting and financial planning, financial reporting, and the creation and monitoring of internal controls and accountability policies.~~

~~**Chair:** Appointed by Conference Chair~~

~~***Other Committees***~~

~~Appointed as needed to carry out Conference objectives.~~

## *Standing Committees*

All Standing Committee Chairs are appointed by the Conference Chair. The Standing Committees shall attempt to provide a balance in representation of the stakeholders in the particular matter under consideration. Standing Committees report to the Board.

### **Standing Committees:**

#### **Issue Committee**

**Role:** Reviews all Issues submitted to Conference and assign them to Councils for deliberation.

#### **Program Committee**

**Role:** Responsible for the Educational Workshop and the Reports and Updates session of the Biennial meeting.

#### **Constitution and Bylaws/Procedures Committee**

**Role:** The Constitution and Bylaws/Procedures Committee shall submit recommendations to improve Conference administrative functions through proposals to amend the Constitution and Bylaws. The Committee shall review proposed memorandums of understanding and ensure consistency among governing documents such as, the Constitution and Bylaws, the CFP Biennial Meeting/Procedures document, and other governing documents. The Committee shall report all recommendations to the Board prior to Council II deliberation, and shall follow the direction of the Board.

#### **Resolutions Committee**

**Role:** Except for thank you resolutions, the Resolutions Committee prepares all necessary resolutions.

#### **Audit Committee**

**Role:** In addition to when a certified public accountant conducts an audit of the Conference's financial records, the Audit Committee audits the Conference's financial records annually.

#### **Food Protection Manager Certification Committee**

**Role:** Works with the accreditation organization for food protection manager certification programs to:

1. Establish and refine policies and standards to which certifiers may conform in order for them to be accredited;
2. Provide recommendations to the Conference on accreditation standards for certifying organizations specific to food protection manager certification programs;
3. Develop strategies for enhancing equivalence among food protection manager certificates issued by certifiers; and
4. Promote universal acceptance of certificates issued by accredited certifiers.

**Program Standards Committee**

**Role:** Provide ongoing input to the FDA on issues that arise with the Voluntary National Retail Food Regulatory Program Standards.

**Finance Committee**

**Role:** Provide financial oversight that includes budgeting, financial planning, reporting, internal controls and accountability policies.

**Nominating Committee**

**Role:** Selects the nominees for the Conference Chair and Vice Chair.

**Strategic Planning Committee**

**Role:** Advise the Board on the current and future direction for CFP. This Committee shall make recommendations to keep the CFP relevant and increase the viability and growth of the organization.

**Publications Committee**

**Role:** To establish, maintain, and improve Conference publications regarding Conference endorsement, copyright, scientific and regulatory accuracy, and external publication approval.

**Other Adhoc Committees**

**Appointed by the Board as needed to carry out Conference objectives.**

## *Timeline for Conference Activities*

This chart outlines the “When, Whom and What” of actions that are to be taken.

Time	1	2 & 3	4	5 & 6	7
Line	0-----0-----	0-----0-----	0-----0-----	-----0-----	-----0-----
Days	-150	-90	-40	During Conference	Afterwards

1.	At least 150 days preceding CFP Biennial Meeting	<del>Executive</del> Director (Article II, Section. 3 <del>and Art. XVII, Sec. 4</del> )	Announces to members the time and place of CFP Biennial Meeting, and provides forms for submitting Issues and proposals
2.	By 90 days preceding CFP Biennial Meeting	Any person (Article. II, Section. 3 4)	May submit Issues on approved forms by this deadline
		<del>Program</del> Issue Committee (Article. II, Section. 34 <del>and Art. XIV, Sec. 1</del> ) <u>Article XVI, Section 1</u> )	Reviews properly submitted Issues and assigns each for Council deliberation
3.	By 90 days preceding CFP Biennial Meeting	All committees (Article II, Section 34, subsection 1)	Shall submit a report to the appropriate Council and Conference
4.	By 40 days preceding CFP Biennial Meeting	<del>Executive</del> Director (Article II, Section 3 4)	Makes available to members committee reports and copies of Issues which have been properly submitted and assigned to Council
5.	During CFP Biennial Meeting	Councils (Article. II, Section 3 4 <del>and Art. XII, Sec. 4</del> ) <u>Article XIV Section 1</u>	Deliberate assigned Issues and develop recommended actions for Assembly consideration
6.	During CFP Biennial Meeting	Assembly (Article V, <del>Sec. 4</del> )	Approves or rejects actions recommended by Councils
7.	Following CFP Biennial Meeting	Board (Article. <del>V</del> VI, Section 1)	Submits approved actions to states and Board for implementation May return rejected actions to originating body explaining basis for rejection or reassignment Distributes Assembly actions to Conference members for implementation

**MEMORANDUM OF UNDERSTANDING**  
**Between The**  
**CONFERENCE FOR FOOD PROTECTION**  
**And The**  
**NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS**

**I. PURPOSE**

The purpose of this Memorandum of Understanding (MOU) is to establish a mutually beneficial relationship between the Conference for Food Protection (CFP) and the National Association of County and City Health Officials (NACCHO). It is to the advantage of CFP and NACCHO to enter into this MOU as a means to enhance dialogue and information sharing related to food safety and defense with an emphasis on local public health support and advocacy.

**II. BACKGROUND**

- A. Article I, Section 1 of the *Constitution and Bylaws* of the CFP state, in part, that the objective of the Conference shall be to promote food safety and consumer protection by:
1. Identifying and addressing problems in the production, processing, packaging, distribution, sale, and service of foods;
  2. Focusing on and facilitating the food protection programs governing the food service, retail food store, and food vending segments of the food industry;
  3. Adopting sound, uniform procedures that will be accepted by state and local food regulatory agencies and industry;
  4. Promoting mutual respect and trust by establishing a working liaison among governmental agencies, industry, academic institutions, professional associations, and consumer groups concerned with food safety; and
  5. Promoting uniformity among states, territories and the District of Columbia. Territories include American Samoa, Guam, Northern Mariana Islands, Puerto Rico, The Trust Territory, and the U.S. Virgin Islands.
- B. The mission of the NACCHO is to improve the health of communities by strengthening and advocating for every local health department in the nation. NACCHO serves 3000 local health departments and is the leader in providing cutting-edge, skill-building, professional resources and programs, seeking health equity, and supporting effective local public health practice and systems. NACCHO promotes food safety and consumer protection by:

1. Supporting and working with local health department to improve food safety and food defense to prevent foodborne illness;
2. Connecting retail food regulatory program practitioners who are experienced in applying the FDA's Voluntary National Retail Food Regulatory Program Standards with those who are newly enrolled and looking for assistance, resources, and recommendations;
3. Advocating for environmental justice with respect to the development, adoption, and enforcement of environmental laws, regulations and policies, including food safety and security;
4. Administering the Samuel J. Crumbine Consumer Protection Award for Excellence in Food Protection at the Local Level. This award is given annually to local environmental health jurisdictions that demonstrate unsurpassed achievement in providing outstanding food protection services to their communities and highlight successful approaches to food safety that can be replicated in other communities;
5. Holding NACCHO's Food Safety Workgroup to advise and guide the improvement of foodborne disease prevention, surveillance, outbreak response, reporting, and control at the local level. The workgroup has provided guidance and feedback on the following:
  - a. Promoting and adopting the Food and Drug Administration's Voluntary National Retail Food Regulatory Program Standards;
  - b. Identifying and sharing model practices related to food safety;
  - c. Promoting and adopting the Council for Foodborne Outbreak and Response (CIFOR) guideline, and associated tools and resources.
  - d. Providing input on and guidance for NACCHO's food safety programs and projects.
  - e. Dissemination of food safety tools, resources, and data to LHDs.
  - f. Developing food safety policies.
  - g. Gaining insight into fostering better partnerships on food safety between local, state, and federal agencies.
6. Convening the NACCHO Foodborne Illness Outbreak Response Community of Practice (CoP) to bring together food safety professionals from across the country to share foodborne illness outbreak response tips and best practices across jurisdictions. Participants include local, state, and federal health staff involved in the investigations of foodborne illness outbreaks. The CoP convenes through regular conference calls and webinars.

### **III. SUBSTANCE OF AGREEMENT**

To enhance dialogue and information sharing related to food safety and defense, the following activities are proposed:

- A. NACCHO leadership and the Executive Board of CFP will engage in an ongoing effort to share information related to food safety and food defense as each organization develops draft position statements, issue papers, resolutions, strategies, reports, and related documents.
- B. Each organization will share with the other any significant dialogue held with federal counterparts (FDA, USDA/FSIS, CDC, etc.) which may result in a final position regarding a national food safety

or food defense issue. Necessarily excluded would be information in confidence obtained through specific federal credentialing.

- C. In order to minimize duplication of effort, each organization, as appropriate and feasible, will work together in a timely manner to solve food safety and food defense related problems that affect the memberships of both organizations.
- D. Information will be shared regarding meeting times and locations, including future meeting dates and sites. CFP shall share with NACCHO important Conference deadlines such as those for committee volunteer application and Issue submission in advance of the biennial meetings.
- E. Both organizations shall include the Presidents and/or Executive Directors in general membership information emails to ensure that each may, in turn, distribute these communications to their respective organizations.
- F. Each organization shall ensure that the organizations are listed on the other's websites as a "food safety partners" link.

**IV: ACCEPTANCE**

This Memorandum of Understanding becomes effective upon signing with the option to renew every other year on even numbered years.

APPROVED AND ACCEPTED FOR THE  
NATIONAL ASSOCIATION OF COUNTY  
AND CITY HEALTH OFFICIALS

APPROVED AND ACCEPTED FOR THE  
CONFERENCE FOR FOOD PROTECTION

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Chief Executive Officer  
National Association of County and City  
Health Officials

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Executive Director  
Conference for Food Protection

Date: \_\_\_\_\_

Date: \_\_\_\_\_

## Meeting minutes from January 23, 2019 Conference Call

Matt, Dave, Scott, Jason, Angela, Susan, Allen, and Davene present on the call

1. Finalized and voted on the “At-Large” constituency choices with the addition of:
  - non-voting Chair Model in the Balanced constituency model
  - in the Composition Details an additional comment in all Three Representations regarding any CFP member can reach out to their constituency member on a committee to give their input.
  - in the Composition Details an additional comment in all Three Representations regarding any CFP member can listen in on any conference call but can not participate in the the conversation.

ACTION ITEM: Matt will update and send to all committee members
2. Regarding the 2016 II-026 Charge: The Committee agreed to clean up the existing documents and not create a new one. Fewer documents that are consistent with each other. Constitution is equivalent to a Law and the Procedures document is equivalent to the Rules for the Law. Discussed needing a system in place so that the governing documents don't get out of sync in the future. Perhaps putting Job Descriptions in the Appendix of the Procedure Manual could be done. Conversation will continue moving forward.
3. Do homework on Constitution. We will be adding a second conference call on February 13<sup>th</sup> at 11:00 EST to work through the Constitution.
4. Student registration is still Tabled for later discussion.

NEXT CONFERENCE CALL WEDNESDAY, FEBRUARY 13<sup>TH</sup> 11:00 a.m. EST

2012-2014 Issues Committee Roster

Committee Name Constitution, Bylaws and Procedures																	
Last Name	First Name	Position (Chair/Member)	9/26/2018	10/24/2018	12/12/2018	1/23/2019	2/13/2019	27-Feb	3/27/2019	4/10/2019	5/8/2019	5/22/2019	6/12/2019	6/26/2019	7/10/2019	10/9/2019	10/30/2019
Barney	Rick	voting	e	P	<u>e</u>	a	P	p	p	p	e	e	p	p	p	e	P
Curran	Matthew	voting	P	P	<u>p</u>	p	P	p	p	p	?	e	e	?	?	removed	
Gifford	Dave	voting				p		p	?	?	P	e	p	e	p	?	?
Gilliam	Scott	voting	P	a	<u>p</u>	p	e	a	e	left early	e	p	p	p	p	?	?
Hollingsworth	Jill	voting	P	a	<u>a</u>	a	P	p	p	p	P	p	p	p	p	p	P
Horn	Jason	voting				p	P	e	e	p	?	?	e	?	e	?	?
Lindholm	Jeffrey	voting	a	P	<u>p</u>		P	e	?	?	?	?	?	?	?	p	?
Mandernach	Steve	voting	P	P	<u>a</u>	a	P	a	?	?	?	?	?	?	?	?	?
Quam	Susan	voting	a	P	<u>p</u>	p	e	p	e	e	P	?	?	?	?	p	e
Reich	Allen	voting	P	P	<u>p</u>	p	a	e	e	p	?	p	p	p	?	p	?
Sanchez	Angela	voting	P	P	<u>p</u>	p	e	p	e	p	on then off	left early	p	left early	p	p	P
Sarrocchio-Smith	Davene	Chair	p	p	<u>p</u>	p	P	p	p	p	p	p	p	p	p	p	P
Lewis	Glenda	consultant	e	a	<u>p</u>	e	P	a	p	p	?	e	e	e	?	e	?
Liggins	Girvin	alternate consultant	e	a	<u>a</u>	e	a	a	e	?	p	e	e	e	?	?	?
Barlow	Kristina	consultant	P	P	<u>p</u>	e	P	p	?	p	p	p	?	p	?	?	P

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-006**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018 II-24; new or additional information has been included or attached.

**Title:**

CBPC 2 - Revised CFP Constitution and ByLaws

**Issue you would like the Conference to consider:**

Acceptance of the Draft of the Revised Conference for Food Protection Constitution and ByLaws 2018

**Public Health Significance:**

2018 II-024 Review the Conference for Food Protection governing documents (Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Manual, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Issues 2012-II-001, 2012-II-004, 2014-II-018 and 2016-II-026)

Current technologies could be investigated to accomplish the same intent.

The existing charge dates back to 2012 and asks for a merger of CFP documents. In order to create a merge of existing documents, the documents being merged need to be harmonious with each other. Due to discord within the same documents as well as discord between documents, the logical approach was to have a solid foundational document. The CFP's foundational document is our Constitution. Once the Constitution is a solid foundational document, steps can be taken to make the rest of the existing CFP documents harmonious with the Constitution and each other.

Continual review of the core governing documents will help prevent contradictory language in the CFP's governing documents.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

1. Acceptance of the Draft of Revised CFP Constitution and ByLaws submitted in Final Report Issue, Content Document #5

2. These governing documents be reviewed on a recurrent basis every biennium, prioritized in this manner

1. Constitution
2. Biennial Meeting/CFP Procedures document
3. Position descriptions
4. Policy documents

unless the Executive Board determines there is a need for a change in priority

**Submitter Information 1:**

Name: Davene Sarrocco-Smith  
Organization: Lake County General Health Department  
Address: 5966 Heisley Road  
City/State/Zip: Mentor, OH 44060  
Telephone: 4403502543  
E-mail: dsarrocco\_smith@lcghd.org

**Submitter Information 2:**

Name: Susan Quam  
Organization: Wisc. Restaurant Association  
Address: 2801 Fish Hatchery Road  
City/State/Zip: Madison, WI 53713  
Telephone: 6082162875  
E-mail: squam@wirerestaurant.org

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-007**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

CBPC #3 - At Large Committee Membership

**Issue you would like the Conference to consider:**

Acceptance of the Draft of the revised version of the Conference for Food Protection Constitution and ByLaws 2018, Article XV Section 13.

**Public Health Significance:**

Issue 2018 II-024 had a charge of: Review membership and constituency at-large members on all committees and offer recommendations on how to address the quantity and functionality of committees and submit recommendations at the 2020 Biennial meeting.

Council Committee size is virtually unlimited due to interest in participation. There have been council committees with as many as 80 members. It is imperative to for committee to complete the assigned charges. When there are unlimited members it becomes very difficult to have all "voices" heard during conference calls, it is very time consuming and impractical to take role, and is not an efficient way to conduct the business of the committee.

Having unduly large committees presents challenges and can impede conducting the business of the Conference of Food Protection.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends...*

Amending the Conference for Food Protection Constitution and ByLaws 2018 as follows:

Article XV Duties of the Committees

Section 13. Council Committee Size and Constituency: Council Committee membership discussion is limited to Council Committees only. Membership on Standing Committees or Executive Board Ad Hoc Committees is defined by the CFP Executive Board.

**Subsection 1.** Committee size.

Voting membership for Council Committees should be comprised of at least eleven (11) voting members with a maximum of ~~no more than~~ twenty-three (23) voting members. Non-voting membership should be comprised of at least six (6) alternates with a maximum of eighteen (18) non-voting alternates.

1. Minimum size: Voting membership for a minimum size committee is the Chair, Vice Chair, o n e ( 1 ) representative from state regulatory, one (1) representative from local regulatory, two (2) representatives from industry, one (1) from an academic institution, one (1) consumer representative, and three elective (3) representatives which may be selected from any Conference constituency with an emphasis on expertise specific to the committee's charge(s).
2. Maximum size: Voting membership for a maximum size committee is the Chair, Vice Chair, four (4) representatives from state regulatory, four (4) representatives from local regulatory, eight (8) representatives from industry, one (1) from an academic institution, one (1) consumer representative, and three elective (3) representatives that may be selected from any Conference constituency with an emphasis on expertise specific to the committee's charge(s).
3. Any committee comprised of membership numbers between the minimum and maximum shall make every reasonable effort to maintain constituency balances.

**Subsection 2. Committee Membership Selection.** The Council Committee Chair and Vice Chair ~~of a Council Committee~~ may be selected from any of the Conference constituencies as approved by the Conference Chair Council Chair and the Executive Board, provided each is from a different constituency. The Council Committee Chair and Vice Chair are responsible for selecting the voting members and alternates from the list of committee volunteers. If a Council Committee Chair does not receive sufficient volunteers in the appropriate constituencies, they shall confer with the Council Chair to seek volunteers from the Conference membership, making every reasonable effort to maintain constituency balance. The Council Committee Chair, in conference with the Council Chair and/or ~~Executive Board~~, shall have the flexibility to fill vacancies in the voting membership with unbalanced constituency representation, if deemed necessary, to reach a minimum of 11 voting committee members. All proposed committee members must be approved by the ~~Executive Board~~ in accordance with Article XIII, Section 6, Subsection 4 of the Constitution and Bylaws. All voting members and alternate non-voting members shall be identified as such on the approved committee roster along with their respective constituency.

**Subsection 3. Alternate member duties.** ~~A maximum of 23 voting members are permitted on a council committee. All volunteers not selected for a voting position shall be offered an "at-large" non-voting position on the committee. There is no limit to the number of at-large non-voting members that may participate. At-large~~ Alternate members will be included and allowed to participate in all committee functions, including but not limited to, meetings, conference calls, emails, deliberations, research and activities, but will not have an individual vote on committee actions. ~~All voting members and at-large non-voting members shall be identified as such on the committee roster along with their respective constituency.~~

**Subsection 4. Committee voting member vacancies.** In the event a Council Committee voting member departs such a committee during a biennial cycle, an ~~at-large~~ alternate member of the same constituency as the departing member shall be selected by the Council Chair to fill the vacancy, ~~subject to approval by the Council-  
Conference Chair and Executive Board in accordance with Article XIII, Section 6,  
Subsection 4 of the Constitution and Bylaws.~~ If a Council Committee voting member changes constituency during a biennial cycle, and there is no vacancy in that member's new constituency, the member will need to transition from service as a voting member on that committee and may continue to serve as an ~~at-large~~ alternate non- voting member for the remainder of the biennial cycle. This transition will occur upon notification to the Council Committee Chair.

**Subsection 5. Committee membership continuity.** ~~The Chair of a council committee~~ A Council Committee Chair that continues over more than one biennial cycle shall assess the immediate previous committee membership to ensure at least 50% of the ongoing committee's voting membership are new members that did not serve as voting members on the immediate previous committee. This will ensure that an increased number of ~~at-large~~ Conference members ~~or others~~ have an opportunity to participate as a voting member over time when there are a large number of volunteers.

**Submitter Information:**

Name: Davene Sarrocco-Smith  
Organization: Lake County General Health District  
Address: 5966 Heisley Rd.  
City/State/Zip: Mentor, OH 44060  
Telephone: 440-350-2543  
E-mail: dsarrocco\_smith@lcghd.org

**Content Documents:**

- "Executive Board's Adhoc Committee for At-Large Committee Membership report"
- "Executive Board's Adhoc Committee for At-Large Committee Membership roster"

**Supporting Attachments:**

- "See CBPC Final Report Issue Content Document #3 – CBPC At-Large Constituenc"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

## Conference for Food Protection – Committee FINAL Report

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

*With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.*

**COMMITTEE NAME:** Ad Hoc Committee Membership Committee

**DATE OF FINAL REPORT:** July 11, 2019

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

**REPORT SUBMITTED BY:** Brenda Bacon, Chair of Ad Hoc Committee Membership Committee

### COMMITTEE CHARGE(S):

1. Review proposals from the CB&P in the “Organizational Options for Committees” attachment to the CB&P Committee periodic status report dated 3/1/2019;
2. Form a single proposal addressing committee constituency size and at-large membership; and
3. Report findings back to the Board at the August 2019 Board meeting.

### COMMITTEE WORK PLAN AND TIMELINE:

1. Conference call(s) by July 9 to determine recommendation to the Executive Board.
2. Submit final report to the Executive Board to deliberate at the August 2019 meeting.

### COMMITTEE ACTIVITIES:

1. Dates of committee conference calls: May 31, 2019 and July 9, 2019.
2. Overview of committee activities.

Dave Gifford, Thomas McMahon, David Lawrence and Brenda Bacon participated on a May 31 conference call. The C&BL committee suggestions in their status report were discussed and it was determined that none of the options were ideal. Discussed replacing the term “at-large” with “alternate”. Discussed the unwieldiness of the very large council committees when there is an abundance of at-large members due to the language in the C & BL requiring all volunteers serve on the committee they signed up for. This Ad Hoc committee determined that a fixed number of alternates would be selected from the committee volunteers. These alternates would be included in all committee activities and could be called upon by Committee Chair and Vice Chair to replace a voting member should they depart the committee voluntarily or from non-participation. This will make it clear to all committee members who are voting and who are alternates (much like Council members during the conference). Other CFP members can listen in on the committee deliberations. The council committee rosters would provide a list of voting members, consultants and alternates. Deliberation included that the primary mechanism for CFP members to get experience to better serve on Council is through committee work. Having the alternates would be easy for committee chairs to select a member to fill a vacancy. Committees should strive for balanced representation.

The conference call on July 9, 2019 finalized discussion of the amount of alternates for committees and to revise language in C&BL Article XV Section 13. Present on this call was Dave Gifford, Amber Daniels, Thomas McMahon, David Lawrence and Brenda Bacon. Ann Johnson provided email comments throughout this process and provided valuable input.

3. Charges COMPLETED and the rationale for each specific recommendation: See 2 above.
4. Charges INCOMPLETE and to be continued to next biennium: N/A

### COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

1. Approve the recommendation provided by the Ad Hoc Committee Membership Committee and assign to C&BL Committee to submit an issue to the 2020 Biennial Meeting of the Conference for Food Protection.

**LISTING OF CFP DOCUMENTS TO BE SUBMITTED BY COMMITTEE:**

1. *Report – Ad Hoc Committee Committee Report*
  - a. List of content documents submitted with this Report:
    - (1) *Committee Member Roster (see attached PDF)*
    - (2) *Article XV Section 13 with strikeouts and additions*
    - (3) *Article XV Section 13 “clean copy”*

2012-2014 Issues Committee Roster

Committee Name: Committee Membership Ad-Hoc Committee								
Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Bacon	Brenda	Chair	Industry	Harris Teeter	Matthews	NC	704-844-4443	bbacon@harristeeter.com
Gifford	Dave	Member	Regulatory	WA State Dept. of Health	Olympia	WA	360-236-3074	<a href="mailto:dave.gifford@doh.wa.gov">dave.gifford@doh.wa.gov</a>
Daniels	Amber	Member	Regulatory	Mecklenburg Co. Health	Charlotte	NC	704-621-2291	<a href="mailto:amber.daniels@meckNC.gov">amber.daniels@meckNC.gov</a>
McMahan	Thomas	Member	Industry	Meijer	Grandville	MI	616-249-6035	<a href="mailto:thomas.mcmahan@meijer.com">thomas.mcmahan@meijer.com</a>
Johnson	Ann	Member	Regulatory	FL Dept of Ag & Consumer Services	Tallahassie	FL	850-728-5894	<a href="mailto:anna.johnson@freshfromflorida.com">anna.johnson@freshfromflorida.com</a>
Lawerence	David	Member	Regulatory	Fairfax Co. Health Dept	Fairfax	VA	703-246-8435	<a href="mailto:david.lawrence@fairfaxcounty.gov">david.lawrence@fairfaxcounty.gov</a>

## Conference for Food Protection – Committee FINAL Report

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

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**COMMITTEE NAME: Constitution ByLaws and Procedures Committee**

**DATE OF FINAL REPORT: November 1, 2019**

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

**REPORT SUBMITTED BY: Davene Sarrocco-Smith, Chair**

### COMMITTEE CHARGE(S):

#### **Issue #2018 II-024**

1. Review the Conference for Food Protection governing documents (Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Manual, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Issues 2012-II-001, 2012-II-004, 2014-II-018 and 2016-II-026)
2. Review membership and constituency at-large members on all committees and offer recommendations on how to address the quantity and functionality of committees.
3. Report back to the Executive Board; and submit recommendations as Issues at the 2020 Biennial Meeting.

### Executive Board Charges

1. Work with the Strategic Planning Committee to discuss the impact of changing the name of our organization from "Conference for Food Protection" to "Congress for Food Protection".
2. Work with Issue Committee Chairs regarding framework of Issue management process, specifically what is taking place from Issues being made public until the Biennium.
3. Add "App Liaison" position to the CFP Procedures document.
4. Define "student" for registration purposes, self-reporting and what happens if they get a job during the cycle? Do they have to pay again or registration fee or just let the student registration fee carry over until the next cycle?
5. Chair to review the Issue management process with the Issue Committee Chairs to determine if the CFP governing documents have language preventing Issue submitters from contacting Council members in advance of the Biennial Meeting.
6. A general point of clarification was raised asking if committee and council chairs, and vice- or co-chairs, are to be included on a roster, and if their voting status is to be indicated or counted towards constituency balance.
7. CB&P Committee to categorize the CFP documents included on the list in the CB&P Committee report dated 03/01/2019 and use the category titles of "governing," "administrative," and "instructional."
8. Chair to work independently with Issue Committee Chairs regarding Issue integrity.
9. CB&P Committee to bring to the Board meeting in August 2019 a single revised Constitution and Bylaws document, using underline and strikeover for any changes, so the Board can extract those items they feel need to be submitted as separate Issues.
10. Review the CFP MOU with NACCHO.
11. Define roles of Co-Chair and Vice Chair in the CFP Biennial Meeting/Conference Procedures document

### COMMITTEE WORK PLAN AND TIMELINE:

1. Fourth Wednesday of every month conference calls took place. As of the February 27, 2019, conference call frequency had been increased to the 2<sup>nd</sup> and 4<sup>th</sup> Wednesday of every month with the primary goal of continuing review and editing the Constitution and By Laws
2. Sub-committees were formed fall 2018: At-Large Constituency; Strategic Planning; Constitution review.
3. Sub-committees were formed spring 2019 and worked independently: Student Registration; Formatting; Grammar review, and MOU review.
4. Council Chair to work independently with Issue Committee Chairs regarding Issue integrity, spring 2019.

### COMMITTEE ACTIVITIES:

1. Full committee conference calls took place; 9/26/18, 10/24/18, 12/12/18, 1/23/19, 2/13/19, 2/27/19. 3/27/19, 4/10/19, 5/8/19, 5/22/19, 6/12/19, 6/26/19, 7/10/19, 10/9/19, 10/30/19.
2. Subcommittees were formed
  - a. At-Large constituency subcommittee
    - i. Brought drafts to full committee for discussion. Full committee reviewed and agreed on Committee At-Large document Jan. 23, 2019.
  - b. Strategic Plan
    - i. Worked with SPC and brought document for full committee review and agreement on Oct. 24, 2018, with an additional week for comments before SPC chairs were given last feedback on October 31, 2018.
  - c. Constitution Review
    - i. Continual review and editing of the 2018 Constitution and By Laws took place.

- d. Formatting for the Constitution
  - i. Current Constitution has inconsistent formatting throughout the document. Subcommittee provided this format:  
*Article/Section/Subsection/a)1. to be used throughout the document. The full committee voted and this format was agreed upon.*
  - ii. The reformatting of the Constitution will wait until after the Fall 2019 Executive Board meeting. Committee agreed.
- e. Grammar review of the Constitution
  - i. Discussion regarding review for the edited version of the Constitution took place. Subcommittee thought it best to wait until after the Fall 2019 Executive Board meeting. At that time grammar corrections to the Constitution will be made. Full committee agreed.
- f. Student Registration subcommittee
  - i. Objective was to develop a procedure for what CFP should do when “students” gain employment during the 2-year, already paid, membership. (See Content document)
    - (1) Recommendation to not require additional monies but may require update to member constituency group to reflect area of gainful employment.
    - (2) Recommendation that the Board should establish a set fee reduction for students to easily guide fees for future biennial conferences and publish fees in all Conference materials that reference fees.
  - ii. The draft was brought to the full committee for discussion. Full committee reviewed and agreed on document.
- g. *MOU subcommittee reviewed the MOU between NACCHO & CFP*
  - i. Verbage changes in sections III B, III C were recommended for clarification and section III D added a relevant example.
  - ii. No conflicts were found within the Constitution and the MOU with CFP & NACCHO.
  - iii. The full committee voted and the additions to the MOU were agreed upon.
- 3. Review the Conference for Food Protection governing documents (Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Manual, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Issues 2012-II-001, 2012-II-004, 2014-II-018 and 2016-II-026)
  - i. In order to create a merge of existing documents, the documents being merged need to be harmonious with each other. Due to discord within the same documents as well as discord between documents, the rational approach was to have a solid foundational document. The CFP's foundational document is our Constitution. Once the Constitution is a solid foundational document, steps can be taken to make the rest of the CFP documents harmonious with the Constitution and each other.
- 4. Chair corresponded with Issue Committee Chairs regarding Issue integrity
  - a. Communications between Constitution, Bylaws, and Procedures Chair and Issue Co-chairs were held in March, 2019 to discuss Issue Submission Procedures. It was decided the best course of action was to add to the Council Member Position Description under Responsibilities and Duties “COMMIT ONESELF TO ISSUE INTEGRITY AND ETHICAL CONDUCT”. This gives the ability for Council Chairs and Council members to approach items of concern with Issues and have been submitted but not yet discussed at council to handle situations that might arise with integrity and ethics.
- 5. A general point of clarification was raised asking if committee and council chairs, and vice- or co-chairs, are to be included on a roster, and if their voting status is to be indicated or counted towards constituency balance. *Council Chair completed*
  - a. Council Committee Chairs and all Council committee members are to be on a roster approved by the Executive Board. CFP Biennial Meeting/Conference Procedures 2018 document VIII A. 1. This is also in the Constitution with existing conflicting language.
    - i. Article XIV Section 13, subsection 1 of the 2018 CFP Constitution state that the Committee Chair and Vice Chair each have a vote.
    - ii. Council Chairs or Council Vice Chairs are not on a Council Committee roster.
    - iii. Standing Committees shall be made to provide a balance in representation like all Conference committees.(Constitution Article XIV Section 1 and CFP Biennial Meeting/Procedures document VIII C 1)
    - iv. There is nothing in the Constitution regarding Standing Committee membership. The Procedures document lumps all Committees together with no notation of size or who votes.

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

- a. Worked with the Strategic Planning Committee to discuss the impact of changing the name of our organization from “Conference for Food Protection” to “Congress for Food Protection”.
- b. Addressed At Large constituency and provided board with several options. (See Content Document)
- c. Worked with Issue Committee Chairs regarding framework of Issue management process, specifically what is taking place from Issues being made public until the Biennium.
- c. Added “App Liaison” position to the CFP Procedures document Section V, C. passed by Executive Board 1/28/19.
- d. Defined “student” for registration purposes, self-reporting and what happens if they get a job during the cycle? Do they have to pay again for registration fee or just let the student registration fee carry over until the next cycle? (See Content Document) Executive Board approved Fall 2019. All changes are administrative.
- e. Chair reviewed Issue management process with the Issue Committee Chairs to determine if the CFP governing documents have language

## Conference for Food Protection – Committee FINAL Report

preventing Issue submitters from contacting Council members in advance of the Biennial Meeting (Issue integrity). No written language exists.

- f. Chair reviewed governing documents for point of clarification if committee and council chairs, and vice- or co-chairs, are to be included on a roster, and if their voting status is to be indicated or counted towards constituency balance.
  - (1) Recommendation
    - Council Committee Chairs and all Council committee members are to be on a roster approved by the Executive Board. CFP Biennial Meeting/Conference Procedures 2018 document VIII A. 1. This is also in the Constitution with existing conflicting language. Addressed in new draft Constitution.
    - Article XIV Section 13, subsection 1 of the 2018 CFP Constitution state that the Committee Chair and Vice Chair each have a vote.
    - Council Chairs or Council Vice Chairs are not on a Council Committee roster.
- g. CB&P Committee to categorize the CFP documents included on the list in the CB&P Committee report dated 03/01/2019 and use the category titles of “governing,” “administrative,” and “instructional.” Executive Board passed 11/1/19 (see Content document)
- h. Chair to work independently with Issue Committee Chairs regarding Issue integrity.
  - (1) Recommendation
    - Add to the Council Member Position Description under Responsibilities and Duties “COMMIT ONESELF TO ISSUE INTEGRITY AND ETHICAL CONDUCT”. This gives the ability for Council Chairs and Council members to approach items of concern with Issues that have been submitted but not yet discussed at council to handle situations that might arise with integrity and ethics. Approved at Fall 2019 Executive Board meeting.
- i. CB&P Committee to bring to the Board meeting in August 2019 a single revised Constitution and Bylaws document, using underline and strikeover for any changes, so the Board can extract those items they feel need to be submitted as separate Issues. (see Content document)
- j. Reviewed the CFP MOU with NACCHO and had grammatical changes the Executive Board accepted Fall 2019 Board meeting. (see Content document)
- k. Issue 2018 II-024 the Conference for Food Protection governing documents (Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Manual, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Issues 2012-II-001, 2012-II-004, 2014-II-018 and 2016-II-026)
  - (1) In order to create a merge of existing documents, the documents being merged need to be harmonious with each other. Due to discord within the same documents as well as discord between documents, the rational approach was to have a solid foundational document. The CFP's foundational document is our Constitution. Once the Constitution is a solid foundational document, steps can be taken to make the rest of the existing CFP documents harmonious with the Constitution and each other.

### 2. Charges **INCOMPLETE and to be continued to next biennium:**

- a. Define roles of Co-Chair and Vice Chair in the CFP Biennial Meeting/Conference Procedures document

### COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

- 1. Committee is requesting the Board to have verbiage added to the Biennial Meeting/Conference Procedures document. The verbiage could be added under VII B9; or it can be a stand alone item; or under VIII A. 1 (a).
    - The proposal: After the Assembly approves Constitutional changes, those changes be automatically sent to the Constitution and ByLaws Committee . The CB & P will review the Constitution and ByLaws and Biennial Meeting/Conference Procedures document and update all sections that would apply to the changes the Assembly of Delegates approved.
- Reasoning: to attempt to keep the two governing documents updated and consistent.

### LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

- 1. **CBPC Issue #1: Report – Constitution ByLaws & Procedures**
  - a. **List of content documents submitted with this issue:**
    - (1) *Committee Final Report*
    - (2) *Committee Member Roster*
    - (3) *CB & P At-Large Committee Membership Options*
    - (4) *Categorization of CFP documents*
    - (5) *Draft revised CFP Constitution and ByLaws*
    - (6) *Draft Memorandum Of Understanding between CFP & NACCHO*
  - b. **List of supporting attachments**
    - (1) Conference call meeting minutes
    - (2) Attendance at conference calls

2. *CBPC Issue #2: Draft Revised Constitution and ByLaws*
3. *CBPC Issue #3: At Large constituency*
4. *CBPC Issue #4: Draft Memorandum Of Understanding between CFP and NACCHO*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-008**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

CBPC 4: Memorandum of Understanding between CFP and NACCHO

**Issue you would like the Conference to consider:**

Acceptance of a Memorandum of Understanding between the Conference for Food Protection and the National Association of County and City Health Officials (NACCHO). A draft final Memorandum of Understanding has been reviewed and approved by NACCHO staff and the CFP Executive Board. The CFP Constitution and Bylaws/Procedures Committee has also determined that the draft final Memorandum of Understanding is not in conflict with other CFP governing documents.

**Public Health Significance:**

The Conference Executive Board wishes to establish a formal working relationship with NACCHO.

**Recommended Solution: The Conference recommends...:**

Adoption of the Memorandum of Understanding with the National Association of County and City Health Officials (NACCHO). *Note: Document is attached to Issue titled Report - CFP Constitution, ByLaws, and Procedures Committee (CBPC), Document #6.*

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-009**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Reestablishment of a Food Defense Committee

**Issue you would like the Conference to consider:**

The Reestablishment of a Food Defense Committee

**Public Health Significance:**

There have been several intentional adulteration events related to food establishments in the United States. Examples include:

- 1984 Rajneeshee attack on 10 salad bars in Oregon (750 ill)
- 2002-2003 Nicotine poisoning of retail meats in Michigan (100 ill)
- 2009 Pesticide poisonings of salsa at a restaurant in Kansas (40 ill)
- 2016 Intentional contamination of RTE food at local grocery stores in Michigan (No ill)
- 2017 Intentional contamination of RTE food at restaurants in South Lake Tahoe in California (4 ill)

Food defense, protecting food from intentional adulteration, is an important concept for the entire farm-to-table system, including food establishments (as defined in Model Food Code). The passage of the Food Safety Modernization Act (FSMA) Intentional Adulteration rule establishes requirements for covered food manufacturing facilities to develop and implement a food defense plan. As food establishment operators and regulators continue to look at risk factor data and supporting a food safety system approach, the need to protect consumers and retailers from potential food adulteration incidents is paramount. Current food defense resources found in the FDA Food Code are not sufficient to meet the needs of food establishments. There are about 3 pages of reference materials in Annex 2, Section 4 (pages 333-336) of the most current published version of the FDA Model Food Code. Many of these references are difficult to find because of broken/outdated links. Additionally, several of the resources are not designed for food establishments.

**Recommended Solution: The Conference recommends...:**

that a Food Defense Committee be reestablished to evaluate ways to improve Food Defense awareness for both operators and regulators in food establishments. Charges for the committee are:

1. Develop a food establishment food defense guide.
2. Develop a food establishment food defense best practices toolkit.
3. Identify current food defense references to be included in Appendix 2, Section 4.
4. Recommend whether an additional knowledge area under 2-102.11(C) relating to Food Defense in food establishments is appropriate.
5. Recommend whether an additional duty of the Person In Charge to take reasonable measures to minimize the risk for intentional adulteration of food is appropriate.
6. Report the committee's findings and recommendations back to the Conference at the 2022 Biennial Meeting.

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**Supporting Attachments:**

- "FMI Food Defense Guide"

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# FOOD DEFENSE

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# GUIDELINE



For inquiries, please contact:

Doug Baker  
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Food Marketing Institute proudly advocates on behalf of the food retail industry, which employs nearly 5 million workers and represents a combined annual sales volume of almost \$800 billion. FMI member companies operate nearly 33,000 retail food stores and 12,000 pharmacies. FMI membership includes the entire spectrum of food retail venues; single owner grocery stores, large multi-store supermarket chains, pharmacies, online and mixed retail stores. Through programs in public affairs, food safety, research, education, health and wellness and industry relations, FMI offers resources and provides valuable benefits to almost 1,000 food retail and wholesale member companies and serves 85 international retail member companies. In addition, FMI has almost 500 associate member companies that provide products and services to the food retail industry. For more information, visit [www.fmi.org](http://www.fmi.org) and for information regarding the FMI Foundation, visit [www.fmifoundation.org](http://www.fmifoundation.org)

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# FOOD PRODUCT TAMPERING AND INTENTIONAL CONTAMINATION GUIDELINES

## Introduction

Food and product contamination are primarily associated with the introduction of a foreign item, bacteria, virus, chemical or any other hazard that may cause injury, illness, or even death when ingested. It can also include the contamination of products that are used on the body, such as lotions and hair sprays, or a component of a product that is not typically ingested but could cause harm, such as the use of lead paint on a toy.

Contamination can occur at any point in the supply chain—from the field or production to the table or household. Contamination can be caused by anyone, including customers, employees, and vendors.

Several different circumstances, mostly related to employee behaviors and preparation practices, can result in unintentional contamination of products. Intentional contamination results from the deliberate and malicious actions taken by an individual or group with the intent of causing harm.

Food defense mitigation strategies are the actions you take to protect food products against intentional contamination. A Food Defense Plan is a tool to help establishments prevent, prepare for, respond to, and recover from intentional food and product tampering and contamination events. A Food Defense Plan provides specific actions to take when tampering or intentional contamination is suspected.

The following information in this document is meant for assisting key personnel to prepare, respond, stabilize, and recover from a tampering or intentional contamination event. Although the goal of these guidelines is to be thorough and detailed, it is meant to serve as a resource and a supplement to the many resources provided by federal government agencies (see References and Resource Section) and partnerships with your local law enforcement agencies. You will most likely want to customize this document to meet the specific needs of your organization, stores and personnel.

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## Prepare

- Assemble a food defense team and assign responsibilities, including identifying a designated person responsible for implementing, managing and updating the Food Defense Plan.
- Conduct Vulnerability Assessment of physical security and operations to assess potential threats and areas vulnerable to attack. Review and verify assessment periodically, at least annually.
- Develop and implement a Food Defense Plan (See [FDA Food Defense Plan Builder](#)) and ensure plan is kept up to date. Plan should include, but should not be limited to, procedures for:
  - Addressing any vulnerabilities identified in the vulnerability assessment.
  - Identifying, responding to, and containing threats and acts of tampering/intentional contamination.
  - Segregating and securing any contaminated or potentially harmful products.
  - Safe handling and disposing of contaminated products and decontamination of the facility.
- Identify contact information for key emergency, law enforcement and public health authorities contact (i.e. police, fire, ems, local hospital, etc.)
- Provide Food Defense Training for all levels of employees (front line associates to leadership).
- Develop internal communication system to inform staff about relevant product and facility protection concerns.
- Develop external communication strategy for communicating with public.
- Purchase products from reputable and trusted suppliers. Suppliers should have a food defense program and should be proactively taking all the necessary steps to monitor and verify the integrity of their products.
- Deliveries should be scheduled and verified against scheduled delivery list.
- Develop procedures for receiving unscheduled deliveries.
- Inspect incoming shipments for signs of damage and tampering. Doors/hatches on delivery vehicles should be locked or sealed and tamper-evident seals should be intact and match information provided on shipping documentation.
- Conduct background checks on all employees, including seasonal, temporary, and contract staff.
- Utilize an identification system to identify employees such as uniforms, name tags or badges with individual control numbers for authorized access to non-public areas of the store.
- Limit access by staff to areas necessary for their job function and only during appropriate hours.
- Limit poisonous and toxic chemicals in the establishment to those that are required for the operation and maintenance of the facility and those that are intended for retail sale.
- Restrict access to areas where poisonous and toxic chemicals (e.g., pesticides, industrial chemicals, cleaning materials, sanitizers, disinfectants, etc.) are stored to only to authorized personnel.

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- Display poisonous and toxic chemicals for retail sale in a location where they can be easily monitored and periodically check these items for signs of tampering.
- Prevent public access to critical areas (e.g., receiving, preparation, storage and dishwashing areas).
- Employees should monitor public areas, customer self-service areas (e.g., salad bars, bulk food bins, etc.) and security of the premises for unusual or suspicious behavior.
- Ensure security measures such as cameras, lighting, alarm systems are working properly.
- Encourage employees to report signs of possible product contamination, unknown or suspicious persons, or any breaks in the food defense system.
- Review, at least annually, the effectiveness of the Food Defense Plan and revise accordingly.

## Respond

- Follow Food Defense response procedures
- Employees should report any signs of possible product contamination, unknown or suspicious persons, or any breaks in the food defense system.
- Notify law enforcement and public health authorities if any suspicious activity is suspected.
- Activate the Crisis Management team immediately.
- If appropriate, appoint a Team Leader to manage the company response and communication with stakeholders.
- Conduct an internal investigation using prescribed procedures in all events.
- Notify manufacturers of the product in all events, and request assistance as needed.
- Identify affected product and follow prescribed procedures to remove, segregate and secure affected product.
- Stop additional distribution to stores of affected product as necessary.

## Stabilize

- Work with regulatory agency to determine if a recall is needed and destroy/return affected product as necessary.
- Audit as necessary, review POS and other data, and follow-up verbally as needed to ensure all affected product has been removed from the shelves/supply chain.
- Communicate with all stakeholders, including customers, when safety has been restored.
- Obtain new source, if necessary, to replenish stock.
- Provide for new product to replace recalled product.

## Recover

- Maintain records related to incident including impacted products.
- Review events and implement corrective actions to prevent future incidents.
- Evaluate incident response and review and revise Vulnerability Assessment and effectiveness of the Food Defense Plan.
- Retrain employees.
- Restore customer confidence in the company and affected food product(s).

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## References and Resources

- **FDA Food Defense and Emergency Response for Retail Food**  
<https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodDefenseEmergencyResponseRetail/default.htm>
- **FDA Food Defense Self-Assessment Tool for Retail Food Stores and Food Service Establishments**  
<https://www.fda.gov/downloads/Food/GuidanceRegulation/ucm125192.pdf>
- **FDA Food Defense Plan Builder** – A user-friendly software program designed to assist owners and operators of food facilities with developing personalized food defense plans for their facilities. <https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm>
- **FDA Food Defense Strategies Database** – A tool designed to assist owners, operators or agents in charge of companies that produce, process, store, package, distribute, and/or transport food with identifying preventive measures to protect the food against intentional adulteration.  
<https://www.accessdata.fda.gov/scripts/fooddefensemmitigationstrategies/>  
**FDA Office of Criminal Investigations (OCI)** -- FDA's criminal law enforcement arm, OCI conducts criminal investigations of illegal activities involving FDA-regulated products.  
<https://www.fda.gov/iceci/criminalinvestigations/default.htm>
- **FSIS Food Defense and Emergency Response Resources -**  
<https://www.fsis.usda.gov/wps/portal/fsis/topics/food-defense-and-emergency-response>
- **Food Protection and Defense Institute (FPDI)** – <https://foodprotection.umn.edu/>
- **FBI Food Defense Awareness and Outreach -** <https://www.fbi.gov/file-repository/commercial-facilities-food-defense.pdf/view>

## Food Defense Training Resources

- **FSPCA Food Defense Awareness for the FDA Intentional Adulteration Rule**  
<https://www.ifsh.iit.edu/fspca/courses/intentional-adulteration>
- **Food Defense 101 – Food Defense Awareness for Front-line Food Industry Workers**  
<https://www.accessdata.fda.gov/scripts/FDTraining/>

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-010**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Local Regulator Voting Representation on the Assembly of State Delegates.

**Issue you would like the Conference to consider:**

Allowing local regulatory voting representation on the Assembly of State Delegates.

**Public Health Significance:**

- Foodborne illness in the United States is a major cause of personal distress, preventable illness and death, and avoidable economic burden;
- Most foodborne illnesses occur in persons who are not part of recognized outbreaks;
- The annual cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical costs are estimated to be \$10 - \$83 billion;
- The Food and Drug Administration (FDA) endeavors to assist approximately 75 state and territorial agencies; however,
- More than 3,000 local departments assume the primary responsibility for preventing foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry.

**Recommended Solution: The Conference recommends...:**

1. An amendment to Articles XVI and XVIII to the Constitution and Bylaws to allow for voting representation from local regulators on the *Assembly of State Delegates*;
2. *An amendment to Articles XVI and XVIII to the Constitution and Bylaws to designate two (2) local regulators from each CFP region be entitled to one (1) vote each in the Assembly;*
3. An amendment to the Constitution and Bylaws to change the name of the *Assembly of State Delegates* to *Assembly of State and Local Delegates*, where required, throughout the document.

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**Supporting Attachments:**

- "NACCHO STATEMENT OF POLICY Food System Safety"
- "NACCHO STATEMENT OF POLICY Foodborne Disease Outbreak Response"

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99-08

## STATEMENT OF POLICY

### Food System Safety

#### Policy

The National Association of County and City Health Officials (NACCHO) supports the development of a science-based and fully funded food safety system. It should ensure local health department participation in all areas of food safety as a means to reduce foodborne illness with particular attention to challenges such as new and re-emerging foodborne pathogens, food safety and security issues associated with climate change retail food safety, cottage food industry, and changing demographics.

#### **Safety in the Food System and the Role of Local Health Departments**

NACCHO supports the following:

- The critical role that local health departments play as the first line of defense in preventing foodborne illness at the local level.
- Local health departments' role in working with retail food establishments at the local level to reduce foodborne illness through education efforts, inspections, licensing, training, and technical assistance.
- Effective interaction among local health departments and their state and federal counterparts to enhance the food safety system.
- Enhanced local health department workforce training to identify risks associated with purveying food to the public through active inspection and education programs.
- Policies that enhance and improve education for consumers, food handlers, retail food establishments, and other sectors of the food industry at the local level to prevent foodborne illness.
- Adoption of the most recent Food and Drug Administration (FDA) Model Food Code to promote best practices for the safety and protection of food served at retail and in food service.
- Adoption and promotion of the use of the FDA Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) as a mechanism for continuous quality improvement for local food regulatory programs.
- Local health department involvement on the Partnership for Food Protection, the Food Safety Modernization Act working groups, Conference for Food Protection, and other relevant federal advisory groups aimed at preventing foodborne disease outbreaks.
- Initiatives to prepare for the food safety and security challenges associated with climate change.
- Paid sick leave to promote health by encouraging sick employees to stay home and limit the spread of foodborne disease (see NACCHO's policy statement 11-07 [Paid Sick Leave](#)).
- Recognition of the local health department role in foodborne illness outbreak response efforts (See NACCHO's policy statement 13-07 [Foodborne Disease Outbreak Response](#)).



- Federal efforts to phase out the non-therapeutic use of critical antimicrobial drugs and growth hormones in food-producing animals (see NACCHO's policy statement 12-09 [Antimicrobials in Animals](#)).
- Local and state health department reporting of data from outbreak investigations to CDC's foodborne illness outbreak surveillance systems (National Outbreak Reporting System (NORS); National Environmental Assessment Reporting System (NEARS))<sup>1,2</sup>

### **Funding Local Health Department Actions to Prevent Foodborne Disease**

In funding for local health department actions to prevent foodborne disease, NACCHO:

- Supports enhanced federal, state, and local funding for local health departments to meet the basic food safety capacity and infrastructure needs for routine public health activities related to food safety education and food retail and manufacturing inspection.
- Urges Congress to appropriate funds to support activities authorized in the Food Safety Modernization Act.
- Supports increased federal and state funding for foodborne-illness research, a student education subsidy, and training for the current and future local public health workforce as effective means to protect people from disease and enhance prevention of foodborne illnesses at the local level and throughout the larger food safety system.
- Supports additional federal, state, and local funding to build and improve communications, coordination, and partnerships throughout the food safety system.
- Supports the practice of fee-for-services to ensure continued local funding for retail food inspections and recognition that the retail food industry supports these activities.
- Endorses the inspector/inspection ratio as described in the Retail Program Standard's Standard 8: Program Support and Resources.

### **Justification**

Foodborne illness in the United States is estimated to cause 48 million cases of illness, over 128,000 hospitalizations, and 3,000 deaths each year.<sup>3</sup> Salmonella alone costs \$365 million annually in direct medical expenses.<sup>4</sup> While everyone is susceptible to foodborne disease, 60 million Americans are especially vulnerable to foodborne illness. These populations include children, pregnant women, people with disabilities, the elderly, and individuals with compromised immune systems.<sup>5</sup> Preventing foodborne illness remains one of public health's greatest challenges.

Protecting food safety in the retail setting is an important component of any food safety system. About a third of all meals are eaten outside of the home, meaning that almost half of all consumer food expenditures go toward food made in the retail setting (restaurants, delis, etc).<sup>6</sup> Furthermore, 53% of known sources of foodborne illness occur from food produced in the retail setting.<sup>7</sup> Critical risk factors such as poor personal hygiene, improper food handling, and contaminated food surfaces and equipment remain a significant problem in the retail setting and affect the safety of food at the local level.<sup>8</sup> It is crucial that local health departments work with local retail food establishments such as schools, restaurants, nursing homes, and grocery stores to reduce the risk of foodborne disease at the local level. According to a 2013 survey of local health departments conducted by NACCHO, 78% of local health departments conduct food service inspection and licensing and 72% of local health departments provide food safety education.<sup>9</sup>

Paid sick leave for food service workers and health department inspection staff could help to limit the spread of foodborne disease in retail food establishments. For example, the CDC found that infected food workers transmitted 70% of foodborne noroviruses.<sup>10</sup> According to the Department of Labor, 75% of hospitality and food service workers do not have paid sick leave.<sup>11</sup> In a survey conducted of food workers, nearly 90% responded that they went to work sick. Of those who went to work sick, 45% said they worked because they could not afford to lose pay.<sup>12</sup>

In order to work effectively with retail food establishments, local health departments need a legal framework that is cognizant of local independence, fully funds the work they do, and enables them to apply “practical, science-based guidance and enforceable provisions for mitigating risk factors known to cause foodborne illness.”<sup>13</sup> The FDA Food Code provides a model that state and local governments can adopt to ensure that their licensing and inspections programs are utilizing the most up-to-date, scientific approaches to guide their food regulatory program requirements. Furthermore, as local health departments strive for excellence within their food regulatory programs, the FDA Program Standards provides a continuous quality improvement mechanism that local health departments can implement. The FDA Retail Program Standards recommend a staffing level of one full-time equivalent (FTE) devoted to food for every 280 – 320 inspections performed. Inspections for purposes of this calculation include routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews and other direct establishment contact time such as on-site training.<sup>14</sup>

Even as local health departments seek to prevent foodborne disease and protect the public from foodborne illness, funding and resource allocation has been declining nationally. In a study conducted in 2012, NACCHO found that nearly 3 out of 10 local health departments experienced a reduction of their environmental health staff. Food safety services were reduced or eliminated by the largest percentage by 12.8% of local health departments.<sup>15</sup> These cuts come despite that many local health departments lack sufficient funding to meet the resource and staffing levels recommended by the FDA Program Standards. Federal funds allocated to local health departments for food safety have been modest. Increased financial support from federal, state, and local governments is necessary to help local health departments continue and further enhance their efforts to prevent foodborne disease outbreaks.

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## **Record of Action**

*Proposed by NACCHO Food Safety Workgroup*

*Approved by NACCHO Board of Directors November 7, 1999*

*Updated March 2008*

*Updated May 2013*

*Updated October 2016*

13-07

## STATEMENT OF POLICY

### Foodborne Disease Outbreak Response

#### Policy

The National Association of County and City Health Officials (NACCHO) supports building local health department foodborne disease surveillance, investigation, and control capacities to promote and improve evidence-based public health practice that reduces foodborne disease.

#### **Foodborne Disease Outbreak Response**

NACCHO supports the following:

- Ongoing interaction and involvement among local health departments and state and federal agencies to respond rapidly and effectively to multi-jurisdictional and multi-state outbreaks and recalls.
- A team approach to foodborne outbreak response that fully engages epidemiology, environmental health, laboratory, public health nursing, agriculture departments and other food regulatory agencies and allows for participation from emergency response and industry, as appropriate.
- Enhanced local health department workforce training around surveillance, investigation, and response activities, including cross-training of staff.
- Policies that enhance federal, state, and local laboratory capacity for testing clinical, food, and environmental specimens to identify and respond quickly to foodborne disease outbreaks.
- Local health department representation on national food safety and response initiatives that enhance or impact the ability of local health departments to conduct food safety response activities, such as the Council to Improve Foodborne Outbreak Response, Conference for Food Protection, and the Partnership for Food Protection.
- Training for public health students to fulfill surge capacity interviewing needs during an outbreak.
- Policies and training that enhance healthcare providers' ability to properly diagnose and report incidents of foodborne disease.
- A coordinated communication response for keeping the public well-informed and the message consistent in the event of a multijurisdictional outbreak.
- Paid sick leave because it promotes health by encouraging sick employees to stay home and limit the spread of foodborne disease (see NACCHO's policy statement 11-07 [Paid Sick Leave](#)).
- Preventive action along the farm-to-fork continuum aimed at improving the safety of the food system (see NACCHO's policy statement 99-08 [Food System Safety](#)).



- Federal efforts to phase out the non-therapeutic use of critical antimicrobial drugs and growth hormones in food-producing animals (see NACCHO's policy statement 12-09 [Antimicrobials in Animals](#)).
- Policies and training that support local and state health department reporting of data from outbreak investigations to CDC's foodborne illness outbreak surveillance systems (National Outbreak Reporting System (NORS); National Environmental Assessment Reporting System (NEARS)).<sup>1,2</sup>

### **Foodborne Disease Response Funding**

In funding for foodborne disease response, NACCHO:

- Supports the development of methods for reimbursement from federal and state governments to local health departments for special requests and assistance during foodborne disease outbreaks and recalls.
- Supports enhanced federal, state, and local funding for local health departments' food safety capacity and infrastructure and for routine public health activities related to foodborne-illness surveillance, investigation, and control.
- Supports additional federal, state, and local funding to build and improve communication, coordination, and partnerships to improve foodborne disease outbreak response (for example federal agencies, state and local health departments, emergency preparedness programs, food industry, consumers, and public health professional organizations).
- Urges Congress to appropriate funds authorized in the Food Safety Modernization Act for activities related to foodborne disease outbreak response.
- Endorses the inspector/inspection ratio as described in the FDA Voluntary National Retail Food Regulatory Program Standards' (Retail Program Standards) Standard 8: Program Support and Resources.

### **Justification**

The extent of the problem is difficult to accurately define because foodborne disease incidence in general is probably under-reported. However, foodborne illness in the United States is estimated to cause 48 million cases of illness, over 128,000 hospitalizations, and 3,000 deaths each year.<sup>3</sup> A specific pathogen cause can be identified in only 20 percent of the [48 million] cases (9.4 million illnesses). In the cases when a pathogen can be identified, over 90 percent of these cases are caused by only 15 pathogens. According to a report from the United States Department of Agriculture/Economic Research Service, foodborne illnesses pose an annual economic burden of over \$15.5 billion.<sup>4</sup> Foodborne illness remains a major threat to public health and local health departments serve as the frontline defense against foodborne disease outbreaks.

Foodborne illnesses are diseases or infections caused by consuming contaminated food or drink. While single cases of foodborne illness are common, the true number of foodborne outbreaks is not known because of underreporting and or misdiagnosis. The proportion of cases of foodborne illness reported to public health authorities can depend on the severity of the case, medical provider and consumer reporting rates to health officials, and surveillance capacity at the state and local levels.<sup>5</sup> Improving consumer education, strengthening reporting requirements, and building local health department capacity to respond to foodborne disease outbreaks will continue to be critical to reducing the impact of foodborne illness.

Each reported case of foodborne illness is identified, investigated, and controlled primarily at the local and state levels. State and local governments investigate the majority of foodborne illnesses and are responsible for sampling food products for contamination during an outbreak investigation.<sup>6</sup> According to the CDC, of the 4,163 foodborne outbreaks in 2010–2014, 120 (or about 3%) were multistate.<sup>7</sup> The first steps taken by local and state health departments are critical to preventing and responding to foodborne illness in the United States. Furthermore, coordinating foodborne surveillance, investigations, and control efforts between the local, state, and federal levels is crucial because a disproportionate amount of outbreak-associated hospitalization and death are attributed to multistate foodborne outbreaks compared with single state outbreaks in the United States. Multistate foodborne outbreaks cause 11% of outbreak – associated illnesses, 34% of hospitalizations, and 56% of deaths.<sup>7</sup>

Paid sick leave for food service workers and health department inspection staff could help limit the spread of foodborne disease in retail food establishments. For example, the CDC found that infected food workers transmitted 70 percent of foodborne noroviruses.<sup>8</sup> According to the Department of Labor, 75 percent of hospitality and food service workers do not have paid sick leave.<sup>9</sup> In a survey conducted of food workers, nearly 90 percent responded that they went to work sick. Of those who went to work sick, 45 percent said they worked because they could not afford to lose the pay.<sup>10</sup>

According to a 2013 survey of local health departments conducted by NACCHO, 78 percent of local health departments conduct environmental health surveillance. Since September 2010, 25 percent of local health departments responded to a major foodborne disease outbreak.<sup>11</sup> Expanding resources at the local level may prevent potential foodborne outbreaks and control the spread of illness. In 2012, seven percent of local health departments reduced or eliminated their food safety programs and their epidemiology and surveillance programs.<sup>12</sup> Federal funds allocated to local health departments for food safety have been modest. Increased financial support is necessary to help local health departments continue to further enhance their surveillance, investigation, and control of foodborne disease outbreaks. In addition, the FDA Retail Program Standards recommend a staffing level of one full-time equivalent devoted to food for every 280 – 320 inspections performed. Inspections for purposes of this calculation include routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews and other direct establishment contact time such as on-site training.<sup>13</sup>

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### **Record of Action**

*Proposed by NACCHO Food Safety Workgroup*

*Adopted by NACCHO Board of Directors May 15, 2013*

*Updated October 2016*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-011**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Allergen Committee (AC) Report

**Issue you would like the Conference to consider:**

Issue 2018 I-015 created the Allergen Committee and charged the committee to:

- Review Issues 2018-I-015, 2018-II-007, 2018-II-008 and their original submitted Recommended Solution, including but not limited to:
  - o Evaluation of major food allergen disclaimers in retail food establishments.
  - o Development of methodology for retail food establishments to notify consumers when menu items contain major food allergens.
  - o Determining if any additional staff training for food allergen awareness is needed.
  - o Identifying any supporting research or evidence that supports recommendations.
- Recommend changes to the Food Code that support retail food establishments in their efforts to protect consumers with major food allergens.
- Report back findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**Public Health Significance:**

Food allergies are a significant and emerging public health concern and impact approximately 15 million Americans, including 5.9 million children under the age of 18. Each year, millions of Americans have allergic reactions to food. Although most food allergies cause relatively mild symptoms some food allergies can cause severe reactions that are life-threatening. There is no cure for food allergies. Strict avoidance of food allergens and early recognition and management of allergic reactions to food are important measures to prevent serious health consequences.

Regulatory requirements for labeling major food allergens on packaged foods are very thorough. However, there is a gap in regulatory requirements for notification of major food allergens in food service establishments. Foods that are available for immediate

consumption and not pre-packaged do not provide the same level of disclosure of packaged foods. Food allergic consumers often ask on site staff to share information about ingredients and allergens. They must rely on questions to staff who may not have an answer; or worse, give inaccurate information. Staff error has yielded catastrophic results, including fatalities. To protect consumers that have food allergies food employees must have knowledge of the major food allergens, symptoms they could cause, and methods to prevent problems with food allergens.

**Recommended Solution: The Conference recommends...:**

*acknowledgement of the 2018 - 2020 Allergen Committee Final Report, thanking the committee members for the completed work, and disbanding the committee because all assigned charges have been completed.*

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**Content Documents:**

- "Allergen Committee Report"
- "Allergen Committee Roster"
- "Food Allergy Notifications: A Guidance for Industry"

**Supporting Attachments:**

- "Allergy Training Courses and Laws"
- "Allergen Committee Survey"
- "Allergen Notification Consumer Survey"
- "Food Industry Survey Results"
- "Restaurant servers risk perceptions and risk communication behaviors"
- "Comparing the eating out experience of consumers seeking to avoid allergies"
- "Consumer preferences for written and oral information about allergies"
- "Food allergy knowledge and attitudes of restaurant managers and staff"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

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

**COMMITTEE NAME: Allergen Committee**

**DATE OF FINAL REPORT: 11/1/2019**

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

**REPORT SUBMITTED BY: Jeff Hawley - Committee Chair, Mike Pascucilla - Committee Vice Chair**

**COMMITTEE CHARGE(S): Issue 2018 I-015**

- Review Issues 2018-I-015, 2018-II-007, 2018-II-008 and their original submitted Recommended Solution, including but not limited to:
  - Evaluation of major food allergen disclaimers in retail food establishments.
  - Development of methodology for retail food establishments to notify consumers when menu items contain major food allergens.
  - Determining if any additional staff training for food allergen awareness is needed.
  - Identifying any supporting research or evidence that supports recommendations.
- Recommend changes to the Food Code that support retail food establishments in their efforts to protect consumers with major food allergens.
- Report back findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**COMMITTEE WORK PLAN AND TIMELINE:**

1. This Committee has been holding regular conference calls, and workgroup calls between Committee calls. All Committee work has been completed.

**COMMITTEE ACTIVITIES:**

1. **Dates of committee meetings or conference calls: 9/28/18, 11/9/18, 11/30/18, 1/25/19, 2/22/19, 3/29/19, 4/26/19, 5/31/19, 6/28/19, 7/19/19, 8/9/19, 8/30/19, 9/13/19.**
2. **Overview of committee activities:**

Two workgroups were formed to address Committee charges. Notification Workgroup addressed allergen notification in food service establishments. Training Workgroup addressed food allergen training in food service establishments. Committee members were asked to volunteer for one of the workgroups. Emilee Follett chaired the Notification Workgroup. Betsy Craig chaired the Training Workgroup.

The first order of business was to identify and review current major food allergen requirements for notification, labeling, disclaimers, and training. After reviewing current regulatory requirements the Committee recognized that rules for labeling major food allergens on packaged foods are very thorough. However, there is a gap in regulatory requirements for notification of major food allergens in food service establishments.

Notification Workgroup researched types of allergen notification that are currently being used domestically and internationally, to try and determine which methods are most effective. The Workgroup developed surveys that were sent to industry members within CFP and consumer groups, including food allergy organizations, to get input on how they prefer to be notified about major food allergens in food products.

Notification Workgroup made 3 recommendations that were approved by the Committee.

- 1) **3-602.11 Food Labels** - Amend part (C) to require posting of notification of major food allergens in bulk food that is available for customer self-service. This is currently not required for bulk foods.
- 2) Add new section to Food Code that requires the permit holder to notify consumers of the presence of major food allergens as ingredients in unpackaged food items using brochures, deli case or menu notifications, label statements, table tents, placards, or other effective written means.
- 3) **3-602.12 Other Forms of Information** - Add new part (C) that requires the permit holder to, upon request, provide consumers with a written list of all major food allergen ingredients in food items.

Additionally, the Workgroup developed a food allergy guidance document for food service establishments. Recommendation is to post this guidance document on the CFP website.

Training Workgroup researched food allergy training requirements by state, and county, and compiled a spreadsheet with this information. A survey was developed and sent to representatives of the food industry (restaurant and retail) to gather information about food allergy training provided by these establishments. Slightly more than half of those who completed the retail industry survey responded that they provide food allergy training, separate from food safety training. The survey was also sent to restaurant and retail members of the Allergen Committee. Results indicated that most establishments provide additional training for allergens. It was expressed that food allergen training courses are more specific to restaurants, so majority of retail respondents rely on in-house developed food allergy training. Consensus by the Workgroup was that additional food allergen training is necessary for food employees, but there should not be additional requirements for food allergen training in the Food Code.

Training Workgroup made 1 recommendation that was approved by the Committee.

1) **2-103.11 Person in Charge** - Amend part (N) to remove food allergy awareness training and add a new section (Q) identifying recommended components that should be included in food allergen training:

- Identification of the major food allergens;
- Food allergen ingredient identities and labeling;
- Knowledge of cross-contact concerning the major food allergens;
- Recognition of symptoms of an allergic reaction;
- How to respond to an allergic reaction.

**Other Activity:** Committee Chair Jeff Hawley was interviewed by Eric Athas, writer with the NY Times, on 1/4/19. Mr. Athas is working on an article about food allergies that will cover people with food allergies, labeling and notification rules, manufacturing, etc, and contacted CFP through Jen Jobrack (FARE). I explained the CFP process and why the Allergen Committee was formed. I explained that current rules cover labeling of packaged foods, but there's very little regulation about major food allergen notification in food service establishments. I also explained that states must adopt the Food Code before it can become regulation. We spoke for about 15-20 minutes and I asked him to call or email me if he had further questions.

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

- a. Charge 1: Review Issues 2018-I-015, 2018-II-007, 2018-II-008 and their original submitted Recommended Solution, including but not limited to:
- Evaluation of major food allergen disclaimers in retail food establishments.
  - Development of methodology for retail food establishments to notify consumers when menu items contain major food allergens.
  - Determining if any additional staff training for food allergen awareness is needed.
  - Identifying any supporting research or evidence that supports recommendations.

After reviewing current major food allergen regulatory requirements the Committee determined that there is a gap in regulations for notification of major food allergens in food service establishments. We were also in consensus that the general statement about food allergy awareness training in 2-103.11(N) is weak, and should include recommendations for content of an allergen training programs. Because of these deficiencies in food allergen notification and training in the Food Code four states (Illinois, Massachusetts, Michigan, Rhode Island), one county (Montgomery County, Maryland), and 1 locality (Edison, NJ) have enacted their own food allergen notification and/or training requirements.

- b. Charge 2: Recommend changes to the Food Code that support retail food establishments in their efforts to protect consumers with major food allergens.

The Committee is making recommendations to address deficiencies in major food allergen regulatory requirements in food service establishments. These recommended changes will provide food allergen regulatory requirements that can be applied consistently in all states, counties and localities.

- c. Charge 3: Report back findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**4. Charges INCOMPLETE and to be continued to next biennium:**

- a. None

**COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:**

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

**LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:**

1. **Report - Allergen Committee:** Acknowledge the 2018-20 Allergen Committee final report; thank the Committee members for their work; and disband the Committee.
  - a. **List of content documents submitted with this Issue:**
    - (a.1) **Committee Report**
    - (a.2) **Committee Member Roster**
    - (a.3) **Food Allergy Notifications: A Guidance for Industry**
  - b. **List of supporting attachments:**  **No supporting attachments submitted**
    - (1) **Allergy Training Courses and Laws**
    - (2) **Allergen Committee Survey**
    - (3) **Allergen Notification Consumer Survey**
    - (4) **Food Industry Survey Results**
  
    - (5) **Restaurant servers' risk perceptions and risk communication-related behaviors when serving customers with food allergies in the US**
    - (6) **Comparing the Eating Out Experiences of Consumers Seeking to Avoid Different Food Allergens**
    - (7) **Consumer Preferences for Written and Oral Information about Allergies When Eating Out**
    - (8) **Food Allergy Knowledge and Attitudes of Restaurant Managers and Staff: An EHS-Net Study**
2. **Amend Food Code for Major Food Allergen Training for Food Employees**
3. **Amend Food Code for Notification of Major Food Allergens in Bulk Foods**
4. **Amend Food Code for Written Notification of Major Food Allergens**
5. **Amend Food Code for Major Food Allergen Notification Upon Request by Consumer**

## Committee Name: Allergen

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Hawley	Jeff	Chair	Retail Food Industry	Harris Teeter	Matthews	NC	704-844-3098	jhawley@harristeeter.com
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Brown	Lydia	Voting member	State Regulator	RIDOH Center for Food Protection	Providence	RI	401-222-7723	lydia.brown@health.ri.gov
Campbell	Archer	Voting member	Local Regulator	Thomas Jefferson Health District	Charlottesville	VA	434-972-6256	elizabetha.campbell@vdh.virginia.gov
Craig	Betsy	Voting member	Food Industry Support	MenuTrinfo	Fort Collins	CO	888-767-6368	betsy@menutrinfo.com
Follett	Emilee	Voting member	Food Industry Support	StateFoodSafety.com	OREM	UT	801-805-4679	efollett@statefoodsafety.com
Greco	Darby	Voting member	State Regulator	NYSDOH	Albany	NY	518-402-7600	darby.greco@health.ny.gov
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Hilton	DeBrena	Voting member	Local Regulator	Tulsa Health Department	Tulsa	OK	918-595-4302	dhilton@tulsa-health.org
Jennings	Allison	Voting member	Retail Food Industry	Amazon	Seattle	WA	206-771-4021	jealliso@amazon.com
Jobrack	Jen	Voting member	Consumer	Food Allergy Pros	Skokie	IL	312-399-4171	jjobrack@gmail.com
Koester	Laura	Voting member	Retail Food Industry	Harmons	Salt Lake City	UT	801-349-0407	lauradykman@harmonsgrocery.com
Long	Teresa	Voting member	Local Regulator	Washoe County Health District	Reno	NV	775-328-2641	tlong@washoecounty.us
Love	Alicia	Voting member	State Regulator	State of Montana	Helena	MT	406-444-5303	alicia.love@mt.gov
McInnes	Carol	Voting member	Local Regulator	Boulder County Public Health	Boulder	CO	303-441-1438	cmcinnnes@bouldercounty.org
Meinhardt	Christina	Voting member	Food Service Industry	Aramark	Philadelphia	PA	215-238-6892	meinhardt-christina@aramark.com
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Sigler	Larry	Voting member	Food Service Industry	Waffle House Inc.	Norcross	GA	770-729-5794	larrysigler@wafflehouse.com
Sweet	Bridget	Voting member	Academia	Johnson & Wales	Providence	RI	774-434-5146	bridget.sweet@jwu.edu

Tew	Dan	Voting member	Food Service Industry	Yum! Brands	Rigby	ID	972-338-8422	daniel.tew@yum.com
Williamson	Kenesha	Voting member	Retail Food Industry	Publix Super Markets Inc	Port Charlotte	FL	404-358-1267	kenesha.williamson@publix.com
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# Food Allergen Notifications: A Guidance for Industry

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## Introduction

### Background

Millions of Americans have food allergies, and the numbers appear to be on the rise<sup>1</sup>. The increasing prevalence of food allergies presents a significant challenge for food establishments who manage allergen control alongside the countless other responsibilities associated with retail food service. During the 2018 biennial meeting of the Conference for Food Protection, an Allergens Committee was created with the charge to “develop methodologies for retail food establishments to notify consumers when menu items contain major food allergens, using research or evidence to support recommendations.” This guidance document was created in response to that charge.

### Purpose

To provide food establishment operators with current industry best practices for notifying consumers of major food allergens present in menu items and food that is unpackaged.

### Scope

This guidance document recommends best practices for informing consumers of major food allergen ingredients in menu items that are unpackaged (i.e., not covered by the Food Allergen Labeling and Consumer Protection Act or other labeling requirements). The recommendations outlined herein are supported by published peer-reviewed research, case studies, and survey results from operators and consumers. This guidance is intended for operators of retail food establishments, as defined in the US Food and Drug Administration (FDA) Food Code. For more detailed information, please refer to the appendix.

### Major Food Allergens

The FDA has identified the following foods that account for 90% or more of the documented food allergies in the United States<sup>2</sup>. Known as “major food allergens,” they are:

1. Milk
2. Egg
3. Soy
4. Wheat
5. Fish
6. Crustacean shellfish
7. Peanuts
8. Tree nuts

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<sup>1</sup> (Stallings & Oria, 2017)

<sup>2</sup> (US Food & Drug Administration, 2017)

## Guidance

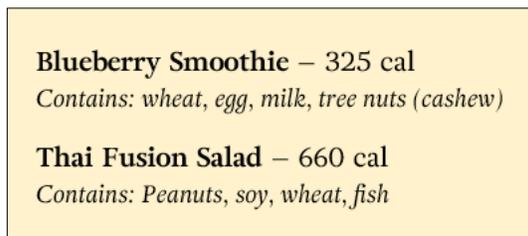
Consumers with food allergies depend on allergen information that is made available on labels and menus (or “notifications”) when making a purchasing decision. In a recent survey of 788 food-allergic consumers and family members, respondents overwhelmingly preferred a **combination of verbal and written allergen notifications** (Appendix B.1). Additionally, they indicated that notifications should be **specific** to menu items and the major food allergens they contain, rather than generic warnings that may apply to the entire menu or food preparation environment. Food allergen notifications should address all ingredients containing major food allergens, including “hidden ingredients,” such as egg washes, sauces, garnishes, etc.

In some cases, a food operation not be able to accommodate an allergen-free order. **Be open and honest** with the consumer about the limitations of the establishment in controlling food allergens.

## Written Notifications

Design menus (including those for online ordering, catering, and take-out) to ensure names and descriptions of food items fully represent the major food allergens they contain. For example:

1. Next to each menu item, include additional text to specify allergens (e.g., *Contains egg, milk*).
2. Use images (or “icons”) of food allergens next to menu items where they are present. Include a key so consumers know what the icons represent<sup>3</sup>. (See Appendix A for icon sets available for commercial use.)
3. Keep a clear and thorough allergen menu available to customers that provides *all* the ingredients for each menu item. This is particularly helpful for customers who are allergic to foods not listed as major food allergens by the FDA.



Example in-menu notification



Example allergen icons

## Verbal Notifications

When allergen information is provided verbally (by servers, managers, etc.), ensure the information is **accurate, verifiable, and consistent**. Food-allergic customers pay close attention to the way food workers respond to their questions and make purchasing decisions based on their perceptions. Food workers who appear uninformed or disinterested can negatively impact a customer’s confidence that their meal will be prepared safely<sup>4</sup>.

<sup>3</sup> (Marra, et al., 2017)

<sup>4</sup> (Begen, et al., 2016)

To provide a safe and enjoyable dining experience, operators are encouraged to implement the following practices:

- Provide a list of menu items and their ingredients for food workers to study so they are well-prepared at the point of sale. Keep the information somewhere it can be easily accessed and used frequently.
- Conduct training for front-of-the-house and back-of-the-house employees on major food allergens and cross-contact prevention. Training is essential to preventing unintended food allergen exposure.
- Appoint at least one team member or manager per shift to respond to customer requests and questions about food allergens. That team member may be a manager or person in charge<sup>5</sup>.

### Additional Notifications

Many food establishments provide information regarding major food allergens in places other than menu (Appendix B.2). These notifications can be very effective when the information provided is specific and assists consumers in making informed decisions.

Depending on the specific food operation, menu, and workflow, an operator may consider using these additional methods for informing consumers about the presence of major food allergens in menu items:

- For operations that emphasize major allergens as key menu items (e.g., bakery or seafood restaurant), add a notification in a highly visible area, such as **on or near the entrance**, informing consumers of the prevalence of that specific allergen.
- When contact with a major food allergen is unavoidable (e.g., french fries prepared in the same fryer as breaded [wheat-containing] items), use **counter cards, table-talkers or signs at the point of sale** to inform consumers.
- **Static clings** on display cases provide major food allergen information in customer view. **Tags or tents** next to food items also work well.

### Conclusion

When food-allergic customers feel confident and well-informed about their food choices, they are more willing to purchase—and they often bring friends and family along! Food operators who employ any combination of practices described in this document are making a business decision that will positively impact public health while simultaneously growing their customer base.

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<sup>5</sup> (Radke, et al., 2016)

# Food Allergen Notifications: A Guidance for Industry

## APPENDIX

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### A) Food Allergens Icons

Recommendations from this guidance include the use of food allergen icons. While there is currently no uniform set of icons to represent the major food allergens identified by the FDA, there are several vector sets available for download online. The following options are available for commercial use.

1. [International Association for Food Protection \(IAFP\) Food Allergen Icons](#)
2. [StateFoodSafety Allergen Icons](#)
3. [Erudus Food Allergy Icons](#)

### B) Allergens Committee Notification Workgroup Surveys

In preparation for the development of this guidance document, the Notification Workgroup of the CFP Allergens Committee conducted two surveys: one to be completed by operators of licensed food establishments (“Industry Survey”) and the second to be completed by food-allergic consumers and their family members and/or caregivers (“Consumer Survey”). These surveys were conducted during April and May 2019 by food operators and consumers in the United States.

#### 1. Consumer Survey

##### Consumer Survey Overview

In May 2019, the Allergens Notification Workgroup created a survey to solicit the opinions of food-allergic consumers and their family members and caregivers. The survey was distributed to CFP members and to email directory recipients of Food Allergy Research and Education (FARE) and Food Allergy and Anaphylaxis Connection Team (FAACT). The survey garnered 788 responses from individuals across 49 US states.

##### Consumer Survey Summary of Responses

- More than 90% of respondents are dealing with food allergies or intolerances.
- The majority of respondents prefer:
  - A combination of written and verbal notifications regarding major food allergens;
  - Menus with major food allergen ingredients listed.
- A significant number of respondents requested cross-contact prevention information to be provided by food establishments claiming to be able to accommodate an allergen-free request.
- There was a consensus among respondents for:
  - Easy-to-recognize major food allergen icons;
  - Major food allergens to be listed directly near menu items rather than in a separate grid of all menu items.

## 2. Industry Survey

### Industry Survey Overview

A survey was sent out to industry regarding allergen notification in order to assess the following: current methods utilized to notify consumers of allergens present in unpackaged food; challenges associated with allergen notification; and to determine if there is a general consensus to provide a standard method for allergen notification across the food service industry.

The survey was distributed to the CFP industry caucus members and Florida Restaurant and Lodging Association members. A total of 72 individuals/organizations responded to the survey. Responses were received from individuals in the grocery and restaurant sectors.

### Industry Survey Summary of Responses

- Of industry respondents, 77% provide written information regarding major food allergens to consumers. This information is provided through a variety of means (menus, pamphlets, table tents, websites, smartphone apps, posters, scale labels, etc.). Many of the respondents use more than one method to provide the information. Of the remaining 23% of the survey respondents, the majority provide verbal information when asked by a customer.
- Of those that provide written information, 13% utilize symbols to identify major food allergens.
- Among respondents, 88% share information verbally when a customer asks about allergens, whereas 12% reported that the server takes a proactive approach and asks the customer if they have a food allergy prior to placing an order.
- In an open-ended survey question, respondents identified several challenges to notifying consumers of major food allergens, including:
  - Employee Training
  - Limited space on labels to provide full details
  - Customer understanding of challenges and requirements
- The majority of the respondents agree that a standard method of allergen notification should be utilized by establishments that serve prepared food that is not pre-packaged.

## C) References

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- Radke, T. J., Brown, L. G., Hoover, E. R., Faw, B. V., Reimann, D., Wong, M. R., . . . Ripley, D. (2016). Food Allergy Knowledge and Attitudes of Restaurant Managers and Staff: An EHS-Net Study. *Journal of Food Protection*, Vol. 29, No. 9, 1588–1598.

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US Food & Drug Administration. (2017, 12 18). *Frequently Asked Questions About Food Allergies*. Retrieved from FDA Web site: <https://www.fda.gov/food/food-allergens/frequently-asked-questions-about-food-allergies>

### Allergy Training Courses and Laws

Data Set	Year	Author Affiliation	Study Population	Report Title	Link	Summary	Conclusions related to training
1	2018	Virginia Polytechnic Institute and State University	Food Service Industry	Food Allergy Awareness Training for the Food Service Industry by Virginia Polytech	<a href="https://vtechworks.lib.vt.edu/bitstream/handle/10919/82732/Stoneman-MALS%20Project%20and%20Report%20Final%20April%204%202018.pdf?sequence=1&amp;isAllowed=y">https://vtechworks.lib.vt.edu/bitstream/handle/10919/82732/Stoneman-MALS%20Project%20and%20Report%20Final%20April%204%202018.pdf?sequence=1&amp;isAllowed=y</a>	This study was conducted in southwest Virginia to determine if an instructor-led food allergy training program specifically designed for foodservice workers could produce an increase in knowledge and potentially change behavior to minimize the risk of food allergy reactions in food service establishments. Virginia Polytech Institute survey on effectiveness of training on knowledge (short term, they recognize the need to go further out) is also interesting, just published last March.	93 people trained: 97% of participants had an increase in knowledge, 98% felt they gained new ideas to implement, and 100% indicated they would recommend this training to others in the industry. Additional studies should assess the long-term effect on knowledge and behavior.
2	2018	Ryerson University	Restaurants and Food Service	A systematic review and meta-regression of the knowledge, practices, and training of restaurant and food service personnel toward food allergies and Celiac disease	<a href="https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0203496">https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0203496</a>	A systematic review to identify and characterize all published research on the prevalence of food allergy and celiac disease knowledge, practices, and training among restaurant and food service personnel. 38 relevant studies were identified with 50% being conducted in the United States. Key knowledge and practice gaps were identified that could be targeted by future training programs. Research gaps were also identified, including a need for more experimental studies to evaluate food allergy and CD training interventions.	Participants generally had a higher knowledge, self-efficacy, and use of practices related to preparing and serving allergen-free meals compared to food allergy emergency response. Participants' reported use of various risk prevention and response practices was generally low. Most participants across studies had not received prior food allergy training (median prevalence of 65% across 12 studies). Key knowledge and practice gaps were identified that could be targeted by future training programs. Research gaps were also identified, including a need for more experimental studies to evaluate food allergy and CD training interventions.

3	2016	CDC	Restaurants	EHS-Net (that's also the CDC) Report	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5321626/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5321626/</a>	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.	Knowledge and attitudes of all groups were higher at restaurants that had a specific person to answer food allergy questions or a plan for answering questions from customers. Food allergy training was not associated with knowledge but was associated with attitude of managers and servers.
	2016	CDC	Restaurants	CDC Report simple conclusions in 2 pages	<a href="https://www.cdc.gov/nceh/ehs/ehsnet/plain_language/food-allergies.pdf">https://www.cdc.gov/nceh/ehs/ehsnet/plain_language/food-allergies.pdf</a>	Simple conclusions from the CDC study produced by the CDC	3 key recommendations: Have a plan, choose a specific person, train staff
	2017	CDC	Restaurants	Restaurant Food Allergy Practices — Six Selected Sites, United States, 2014	<a href="https://www.cdc.gov/mmwr/volumes/66/wr/mm6615a2.htm">https://www.cdc.gov/mmwr/volumes/66/wr/mm6615a2.htm</a>	More of the hard facts from the CDC survey MMWR Report of EHS-Net data presented in 2016 CDC publication below.	278 restaurants at 6 sites: 44% of managers, 41% of food workers, and 33% of servers reported receiving food allergy training.
4	2017	Australian Society of Clinical Immunology and Allergy	Food Service Industry	P53: Addressing food allergy in food service: The National Allergy Strategy Food Service Project	<a href="https://onlinelibrary.wiley.com/doi/full/10.1111/imj.5313578">https://onlinelibrary.wiley.com/doi/full/10.1111/imj.5313578</a>	Project aimed to identify education needs through a Food Service Forum for Food Allergy in Australia and New Zealand.	Forum identified that a standardized, basic level online training course for food service staff should be developed. In addition, consumers should be educated about their responsibility for declaring their food allergy when eating out.
5	2017	University of North Texas	Restaurants	Restaurant servers' risk perceptions and risk communication-related behaviors when serving customers with food allergies in the U.S.	<a href="https://www.sciencedirect.com/science/article/pii/S027843191730275X">https://www.sciencedirect.com/science/article/pii/S027843191730275X</a>	Survey to explore perceived risk and risk communication related behaviors of restaurant servers when serving customers with food allergies in the U.S. 316 participants, split 50/50 between chain operated and independently owned restaurants.	Results indicated that most servers lacked knowledge about food allergies and perceived that initiating communication and preventing allergic reactions were mostly the responsibility of the customer. Respondents who had received training had higher knowledge scores than those who had not. Only 46% of participants had received some type of food allergy training.

6	2016	University of Pennsylvania	Restaurants - Food Allergy Management among restaurant workers in a large U.S. city	Food allergy management among restaurant workers in a large U.S. city	<a href="https://www.sciencedirect.com/science/article/pii/S095671351530298X">https://www.sciencedirect.com/science/article/pii/S095671351530298X</a>	Survey of quick-service Philadelphia restaurants regarding their adherence to 7 best practices to reduce food allergy adverse events.	No restaurant employee used all 7 best practices, few respondents knew how to respond to anaphylaxis, improved training and review of policies is warranted.
7	2016	Iowa State University	University Foodservice	A mixed methods approach to examining food allergy accommodation efforts in colleges and universities	<a href="https://lib.dr.iastate.edu/ashesm_pubs/121/">https://lib.dr.iastate.edu/ashesm_pubs/121/</a>	findings suggest variability in CU foodservice professionals' approaches to accommodations, regardless of policy presence.	
8	2016	Auburn University	Restaurants - Comparison of Food allergy policies and training between Alabama (AL) and National Restaurant Industry	Comparison of Food Allergy Policies and Training between Alabama (AL) and National Restaurant Industry	<a href="https://www.tandfonline.com/doi/abs/10.1080/15428052.2016.1185071?journalCode=wcsc20">https://www.tandfonline.com/doi/abs/10.1080/15428052.2016.1185071?journalCode=wcsc20</a>	Online questionnaires completed by 185 managerial staff (75 AL, 110 US).	Managers viewed employees' lack of commitment and interest as barriers of training provision.
9	2016	Auburn University	Restaurants - Food Allergy knowledge and training among restaurant employees	Food allergy knowledge and training among restaurant employees	<a href="https://www.sciencedirect.com/science/article/pii/S0278431916300627">https://www.sciencedirect.com/science/article/pii/S0278431916300627</a>	Study investigated 229 restaurant employees' food allergy knowledge, prior training, preferred characteristics of future training, and reasons for low interest in training.	Many employees not trained (63%) but expressed interest in training. Participants who had been trained had a higher knowledge score. Preference for self-paced training with real world examples and simple language.

10	2016	University of Bath		Consumer Preferences for Written and Oral Information about Allergens When Eating Out	<a href="https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0156073">https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0156073</a>	Interviews with food allergic/intolerant adults and parents/caregivers of food allergic/intolerant children to identify consumer preferences for written and/or verbal allergen information when eating out or ordering takeout food.	Overwhelmingly, written information was favored in the first instance but credible personal/verbal communication was highly valued and essential to a good eating out experience. When written information is lacking, verbal reliability is more in doubt. Conclusion- Understanding the subtle negotiations and difficulties encountered by FA/FIs when eating out can serve as a guide for legislators and food providers; by encouraging provision of clear written and verbal allergen information, and training of proactive, allergen-aware staff. This, in tandem with legal requirements for allergen information provision, paves the way for FA/FIs to feel more confident in eating out choices; and to experience improved eating out experiences."
11	2015	Auburn University	Restaurants - Food allergy knowledge, attitudes, and preparedness among restaurant managerial staff	Food Allergy Knowledge, Attitudes, and preparedness among restaurant managerial staff	<a href="https://www.tandfonline.com/doi/abs/10.1080/15378020.2015.1093452?journalCode=wfbr20">https://www.tandfonline.com/doi/abs/10.1080/15378020.2015.1093452?journalCode=wfbr20</a>	Survey of 110 restaurant managers to investigate food allergy knowledge, awareness, and preparedness.	69% of managers surveyed have provided employee food allergy training. Identified employee lack of commitment and time constraints as training barriers

11.5	2014	Kansas State University	Child Nutrition professionals	A Focus Group Study of Child Nutrition Professionals' Attitudes about Food Allergies and Current Training Practices	<a href="https://schoolnutrition.org/5--News-and-Publications/4--The-Journal-of-Child-Nutrition-and-Management/Spring-2014/Volume-38,-Issue-1,-Spring-2014---Lee,-Kwon,-Sauer/">https://schoolnutrition.org/5--News-and-Publications/4--The-Journal-of-Child-Nutrition-and-Management/Spring-2014/Volume-38,-Issue-1,-Spring-2014---Lee,-Kwon,-Sauer/</a>	<p>This study conducted focus groups that explored Child Nutrition Professionals' attitudes (in Midwestern States) about food allergies, current practices related to food allergy training, and operational issues related to training in school foodservice operations.</p>	<p>Participants felt that the prevalence and types of food allergies affecting school nutrition programs have increased in recent years. They also felt that communicating with other stakeholders and verifying physicians' recommendations regarding food allergies can be difficult. Participants agreed that training could improve food allergy knowledge and awareness of their employees and improve safety of children with food allergies. However, only a few reported providing specific food allergy training for employees. Cost, scheduling difficulties, and time constraints were identified as barriers to providing food allergy training. Participants preferred having credentialed professionals to conduct employee food allergy training. Support from school administrators and witnessing a food allergic reaction in the cafeteria would trigger a decision to initiate food allergy training.</p>
12	2013	Iowa State University	University Foodservice - Food Allergy Knowledge, attitudes, practices, and training of foodservice workers at a university foodservice operation in the Midwestern United States	Food Allergy Knowledge, attitudes, practices, and training of foodservice workers at a university foodservice operation in the Midwestern United States	<a href="https://www.sciencedirect.com/science/article/pii/S0956713512005816">https://www.sciencedirect.com/science/article/pii/S0956713512005816</a>	<p>193 participants completed a paper-based questionnaire at one large university to assess food allergy knowledge, attitudes, practices, and training among university foodservice employees.</p>	<p>Food allergy training was not provided to 69-79% of respondents but was perceived to be important. Development of training and appropriate policies and procedures is needed. Significant differences between student and non-student employees.</p>

13	2013	University of Houston	Retail Delis - Identifying baseline food safety training practices for retail delis using the Delphi expert consensus method	Identifying baseline food safety training practices for retail delis using the Delphi expert consensus method	<a href="https://www.sciencedirect.com/science/article/pii/S0956713512005671">https://www.sciencedirect.com/science/article/pii/S0956713512005671</a>	3 round Delphi technique used to screen food safety objectives overall. Goal of the study was to identify baseline food safety training objectives that should be included in a new deli employee's food safety training program.	Food allergies were identified as a food safety objective that should be included in deli employee training. None of the current online food safety training materials address deli specific content.
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**Survey Name:** CFP Allergen Committee Survey  
**Response Status:** Partial & Completed  
 Created January 28, 2019  
 10 Responses To Date

1. Does your brand have its own food allergy training class?

3 Yes  
 7 No

2. Does your brand believe you teach enough about food allergies within your food safety program such as a food manager or food handler class?

6 Yes  
 3 No  
 1 N/A

3. Have you used an allergy training class by a 3rd party?

4 Yes  
 6 No

4. If YES than which training class have you used? (Check any/all that apply)

AllerTrain or AllerTrain Lite (MenuTrinfo)	1	25.0%
Allergen or Allergy Awareness (TAP, Always Food Safe or A Plus)	0	0.0%
Basics of Food Allergy Training (Diversys)	0	0.0%
Food Allergen (NRA)	2	50.0%
Food Allergen Training Program (Institute of Food Safety)	0	0.0%
Food Safety Allergen (State Food Safety)	1	25.0%
<b>Total</b>	<b>4</b>	<b>100%</b>

5. Any additional comments about food allergy training classes?

- FARRP, FARE
- I've always wondered why there was a need for a separate allergen training course. Why not update the Manager certification and food handler courses to contain sufficient allergen training rather than create separate courses.
- I strongly believe that while there should be better allergen communication be that labeling or verbal communication at the point of sale I strongly feel the consumer should have the responsibility to educate themselves and make responsible decisions when choosing foods to eat. In other words.. consumer allergen classes as well.
- Our goal is to get every PIC certified.
- We have developed our own Allergen Training Program that focuses heavily on the allergens we have within our operation. The training program is required for all employees.

# CFP Allergen Notification Sub-Committee

Consumer Survey Summary

June 7, 2019

# Agenda

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- Background
- Objective / CFP Allergen Committee Charges
- Executive Summary
- Demographics
- Food Allergens
- Allergen Notification Preference

# Background

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- The Conference for Food Protection (CFP) is a non-profit organization which originated in 1971. It was created to provide a formal process whereby members of industry, regulatory, academia, consumer, and professional organizations are afforded equal input in the development and/or modification of food safety guidance. Such guidance is incorporated into food safety laws and regulations at all levels of government throughout the United States.
- The Allergen Notification Sub-Committee solicited the opinion of consumers in May 2019 in regard to consumer preferences regarding notifications of food allergens in retail food establishments.
- Based on consumer feedback, the responses were reviewed and recommendations will be made during the 2020 biennial CFP meeting.
- Survey results: <https://www.surveymonkey.com/results/SM-2LGT2YK6V/>

# CFP Allergen Committee, 2018-20 Charges

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- Review Issues 2018-I-015, 2018-II-007, 2018-II-008 and their original submitted. Recommended Solution, including but not limited to:
  - Evaluation of major food allergen disclaimers in retail food establishments.
  - Development of methodology for retail food establishments to notify consumers when menu items contain major food allergens.
  - Determining if any additional staff training for food allergen awareness is needed
  - Identifying any supporting research or evidence that supports recommendations.
  
- Recommend changes to the Food Code that support retail food establishments in their efforts to protect consumers with major food allergens.
  
- Report back findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

# Executive Summary

---

➤ 788 respondents (consumers) completed the survey across US 49 states

➤ Over 90% respondents are dealing with food allergies or intolerance

- >90% responded that food allergen menus are very to extremely important to have in retail food establishment for those suffering with food allergies vs >60% for those without allergies
- Similarly, availability of online food allergen menus in food retail establishment are very to extremely important to have for those suffering with food allergies

➤ Type of food allergen notification

- Majority prefer combination of written and verbal food allergen notification
- Majority prefer allergen menu to include ingredients with major allergens listed
- Significant amount of respondents requested cross-contact risk be listed as well (i.e. cooking oil or equipment processing cross contamination risk)
- Consensus is to recommend a set of easy to recognize major food allergen icon to represent the food allergen for consistency
- Consensus is to list allergen information next to menu for easy reference; avoid big or long table to trace the allergen information

# Most Preferred Food Allergen Notification (Example)

---

## Food Item

List ingredients:  
and/or list allergen  
icon:



## Poster

Please inform us if  
anyone in your party  
has **FOOD ALLERGY**  
before ordering

# Food Allergen Notification - Consumer Survey

Friday, June 07, 2019

# 788

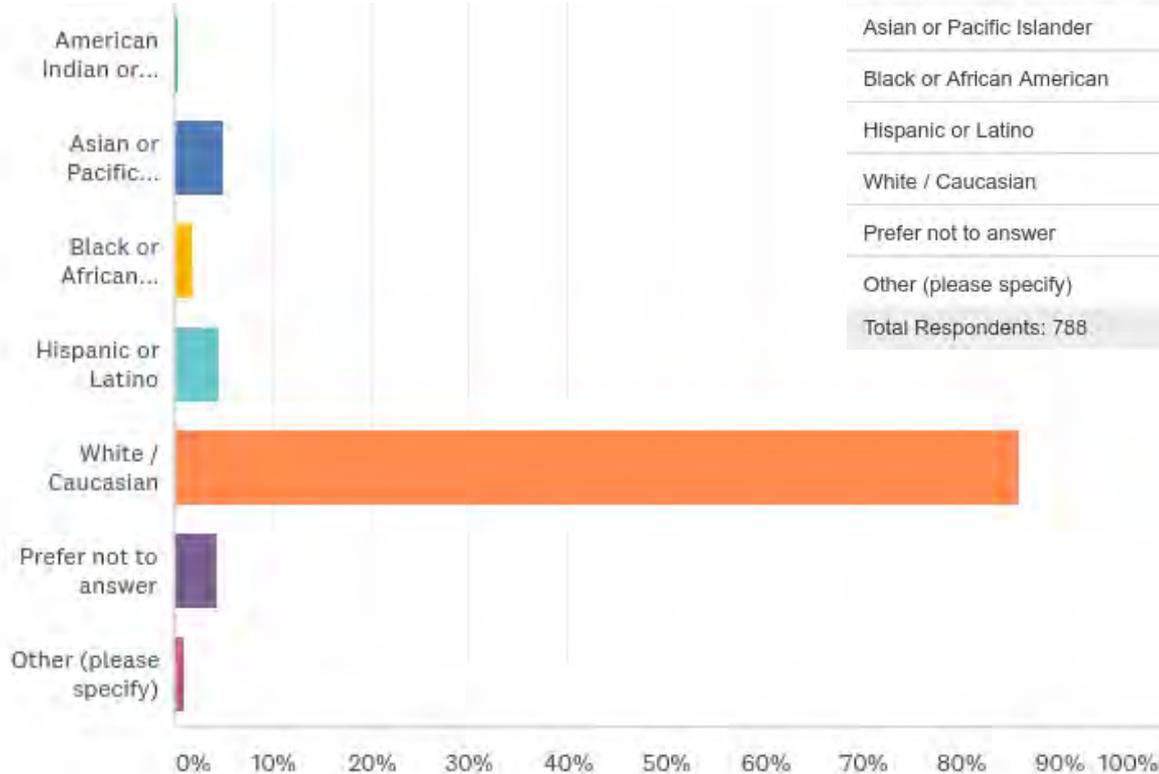
Total Responses

Date Created: Tuesday, April 30, 2019

Complete Responses: 518

# Q1: What is your ethnicity? (Please select all that apply.)

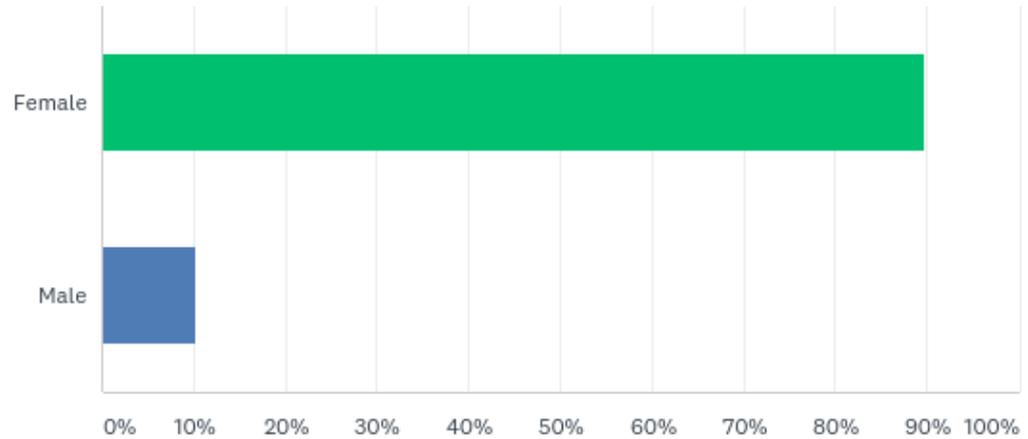
Answered: 788 Skipped: 0



ANSWER CHOICES	RESPONSES	
American Indian or Alaskan Native	0.51%	4
Asian or Pacific Islander	4.95%	39
Black or African American	1.90%	15
Hispanic or Latino	4.57%	36
White / Caucasian	86.04%	678
Prefer not to answer	4.31%	34
Other (please specify)	1.14%	9
Total Respondents: 788		

## Q2: What is your gender?

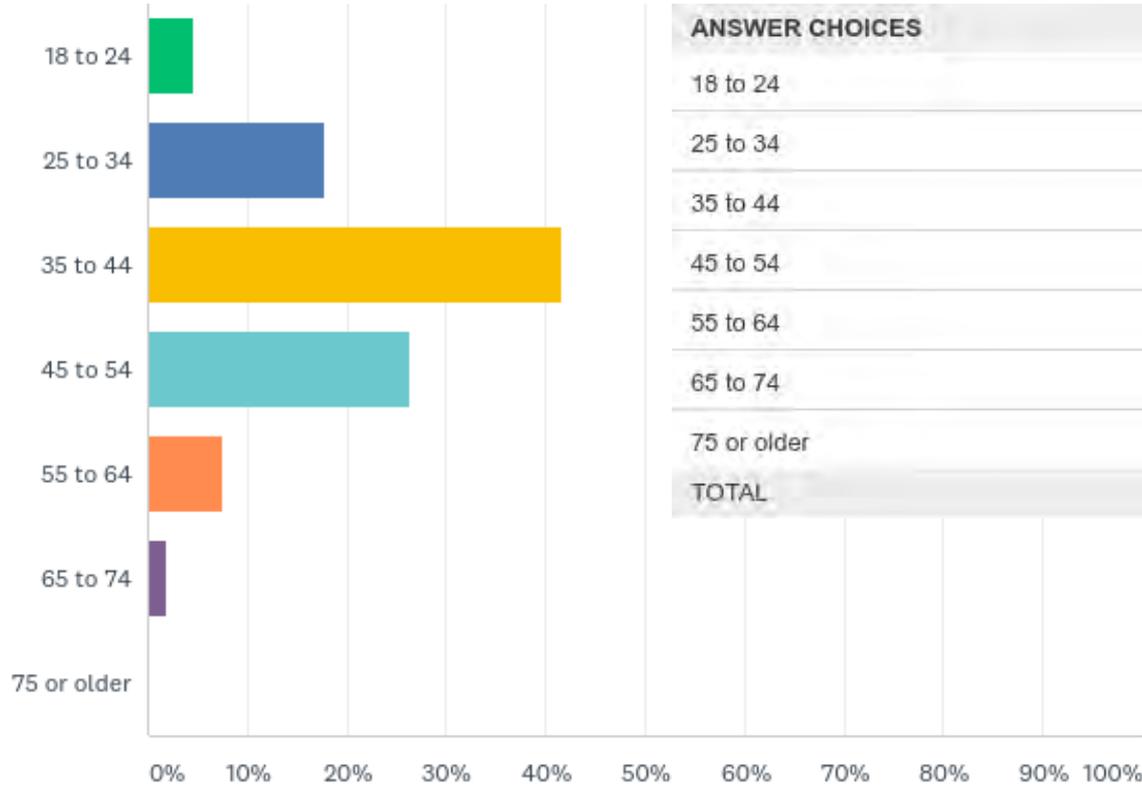
Answered: 779 Skipped: 9



ANSWER CHOICES	RESPONSES	
Female	89.73%	699
Male	10.27%	80
<b>TOTAL</b>		<b>779</b>

### Q3: What is your age?

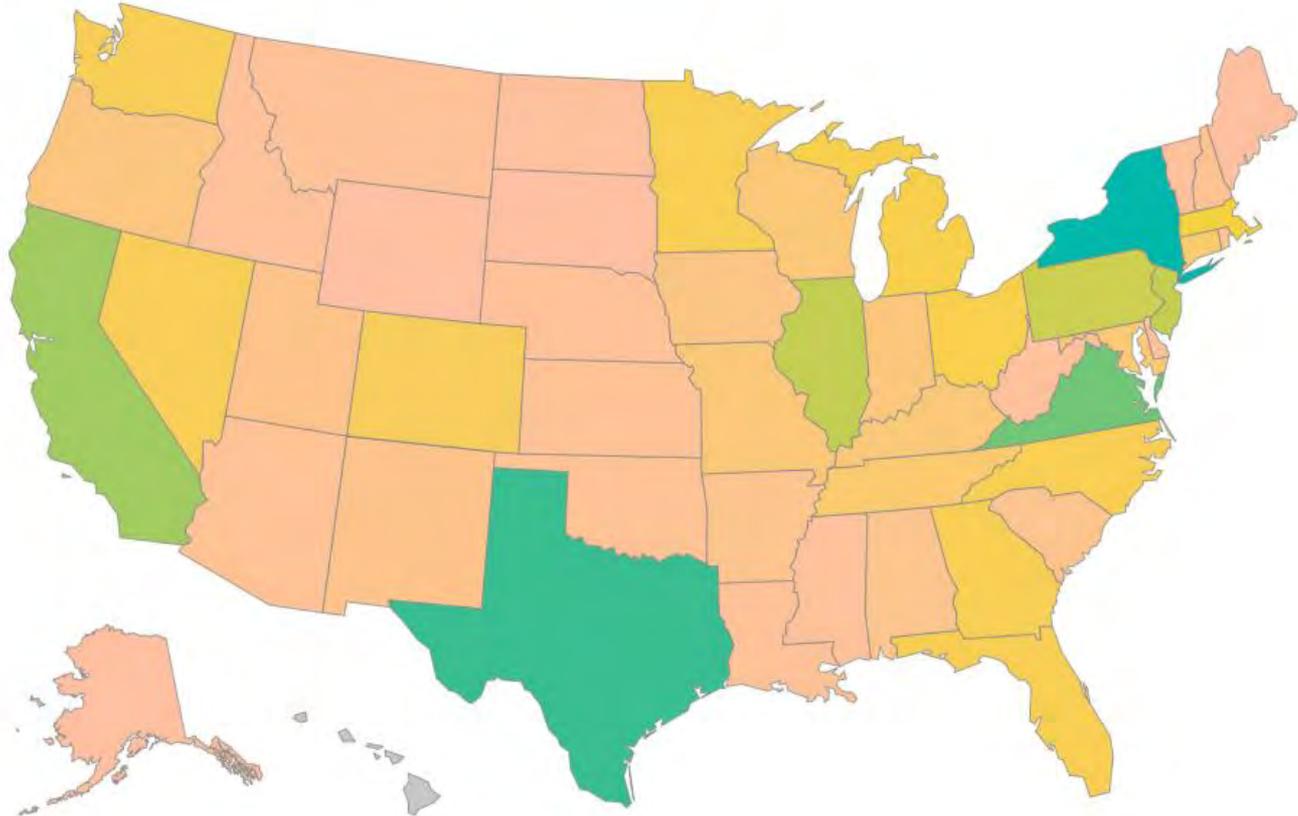
Answered: 786 Skipped: 2



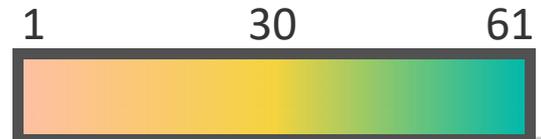
ANSWER CHOICES	RESPONSES	
18 to 24	4.58%	36
25 to 34	17.68%	139
35 to 44	41.73%	328
45 to 54	26.46%	208
55 to 64	7.51%	59
65 to 74	1.78%	14
75 or older	0.25%	2
<b>TOTAL</b>		<b>786</b>

## Q4: What state do you reside in?

Answered: 776 Skipped: 12

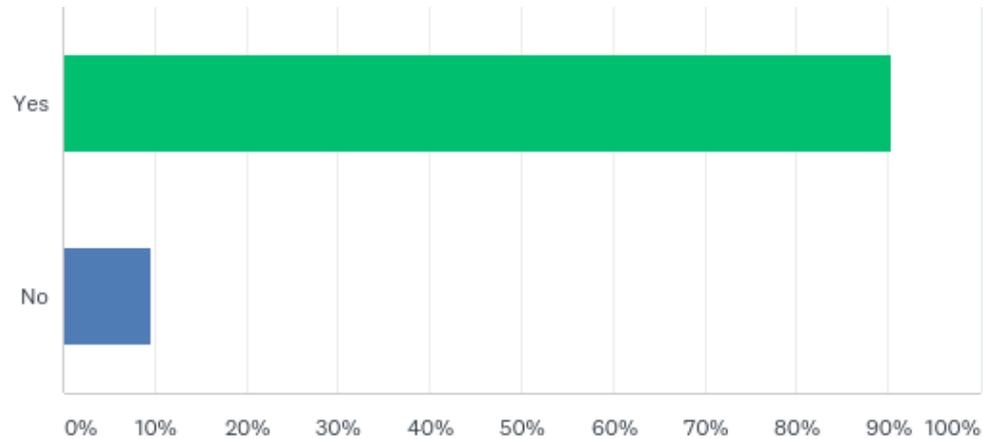


➤ Great participation across 49 states, except from Hawaii



## Q5: Do you or does anyone in your home have food allergies or intolerance?

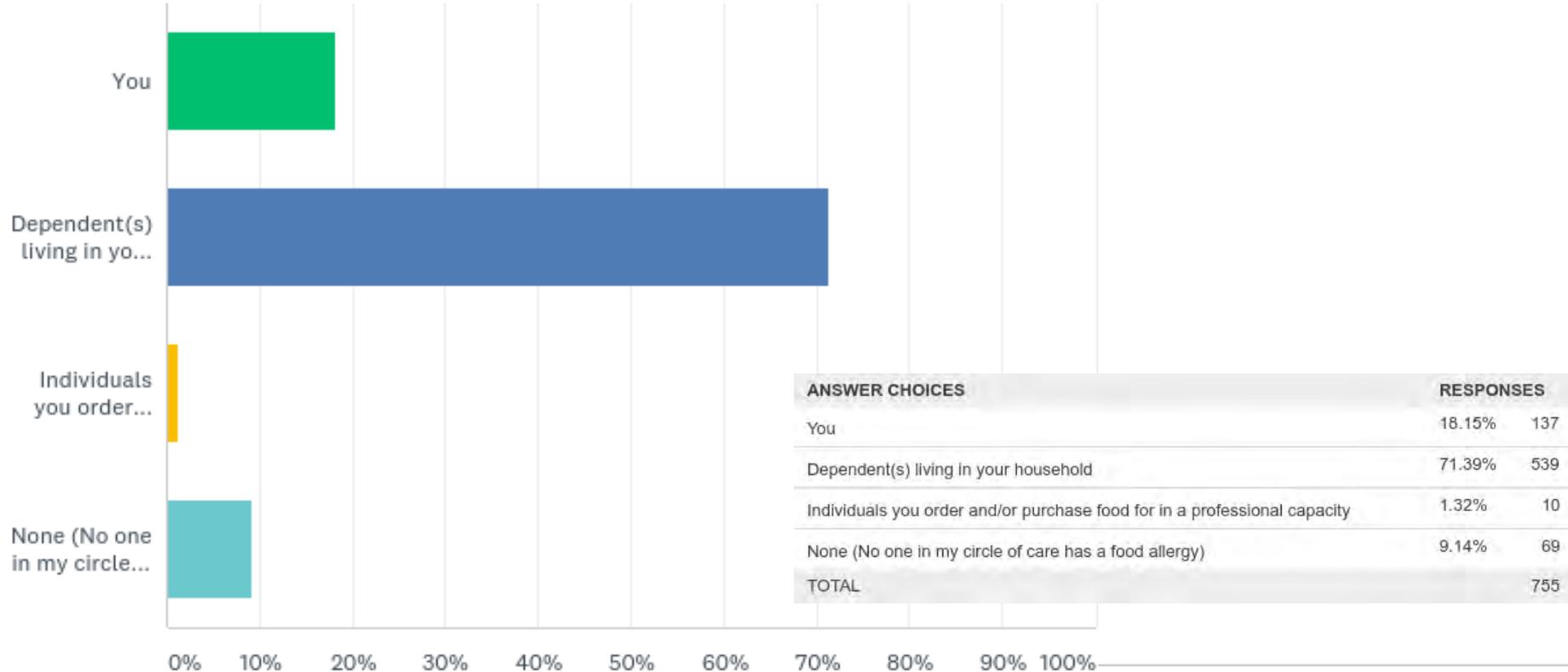
Answered: 786 Skipped: 2



ANSWER CHOICES	RESPONSES	
Yes	90.46%	711
No	9.54%	75
TOTAL		786

## Q6: Who in your home has food allergies/intolerance?

Answered: 755 Skipped: 33

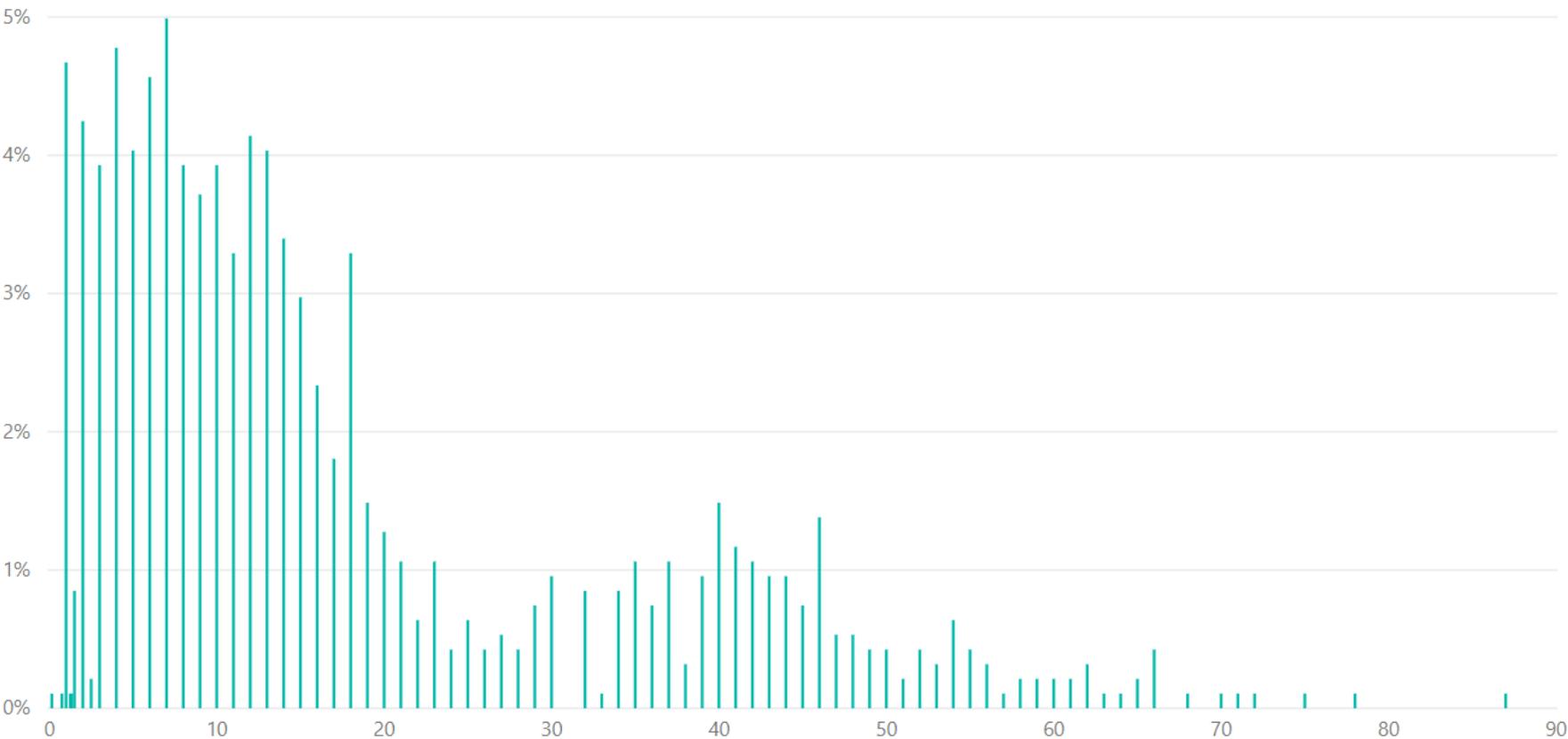


# Ages of those in care with food allergies?

[← Back to report](#)

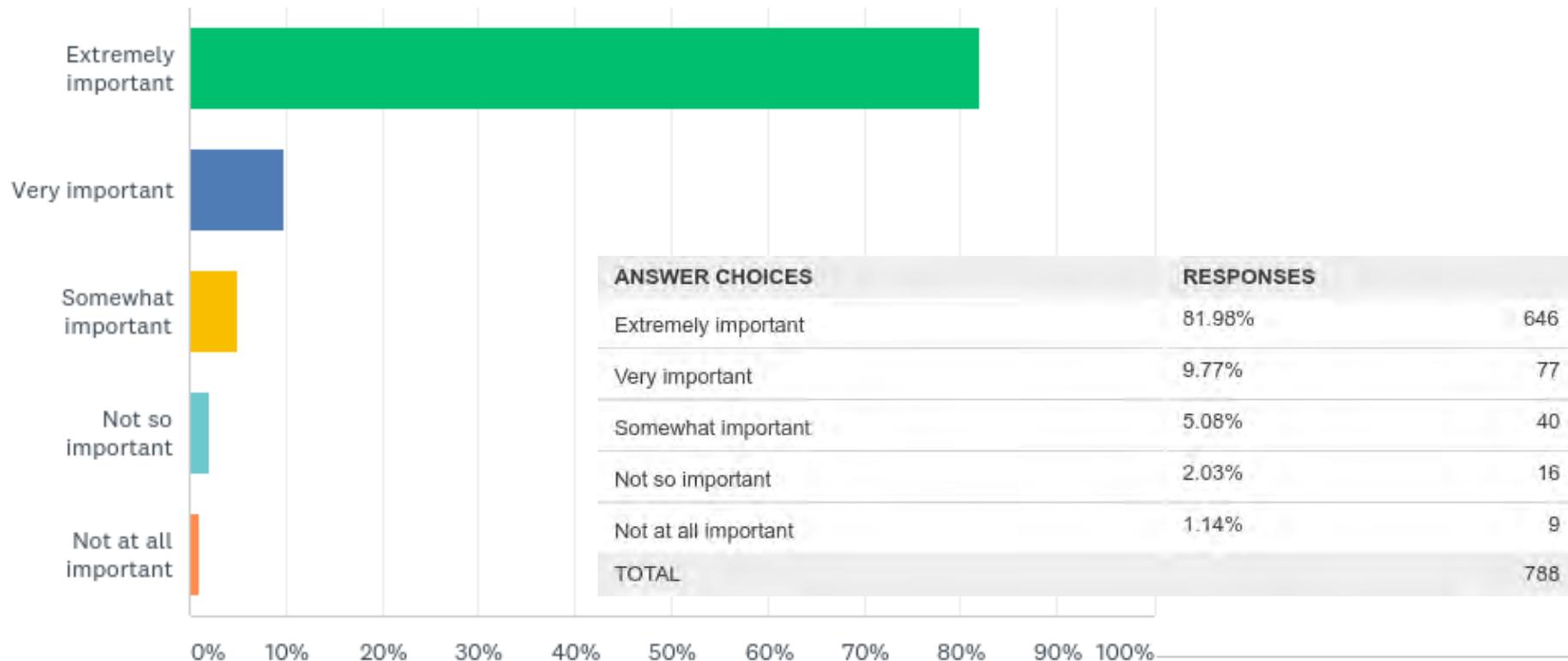
%GT A\_RESPONDENT

BY AGE OF ALLERGIC DEPENDENTS IN CARE



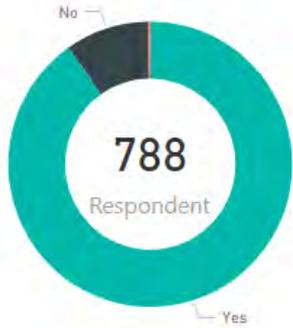
## Q8: How important is having food allergen disclaimers/notifications in retail food establishments to you?

Answered: 788 Skipped: 0

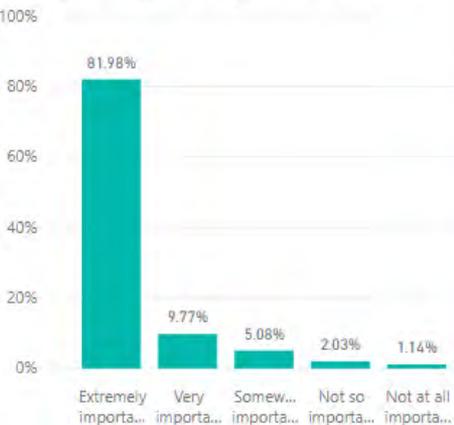


# Q8: How important is having food allergen disclaimers/notifications in retail food establishments to you?

Respondent by Have Food allergies?



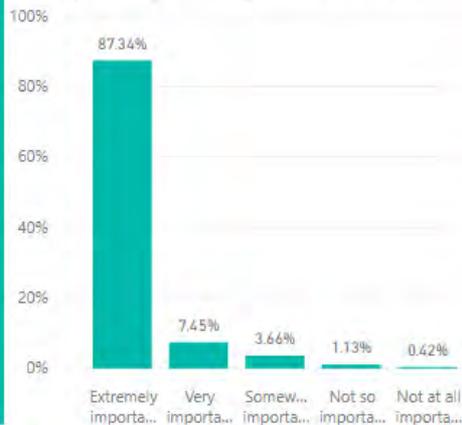
%GT Respondent by Food allergen notifications in RFE?



Respondent by Have Food allergies?



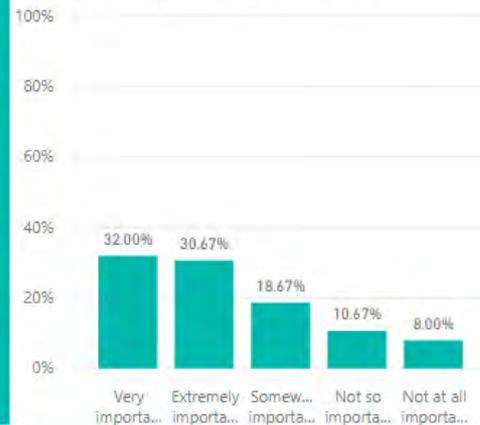
%GT Respondent by Food allergen notifications in RFE?



Respondent by Have Food allergies?



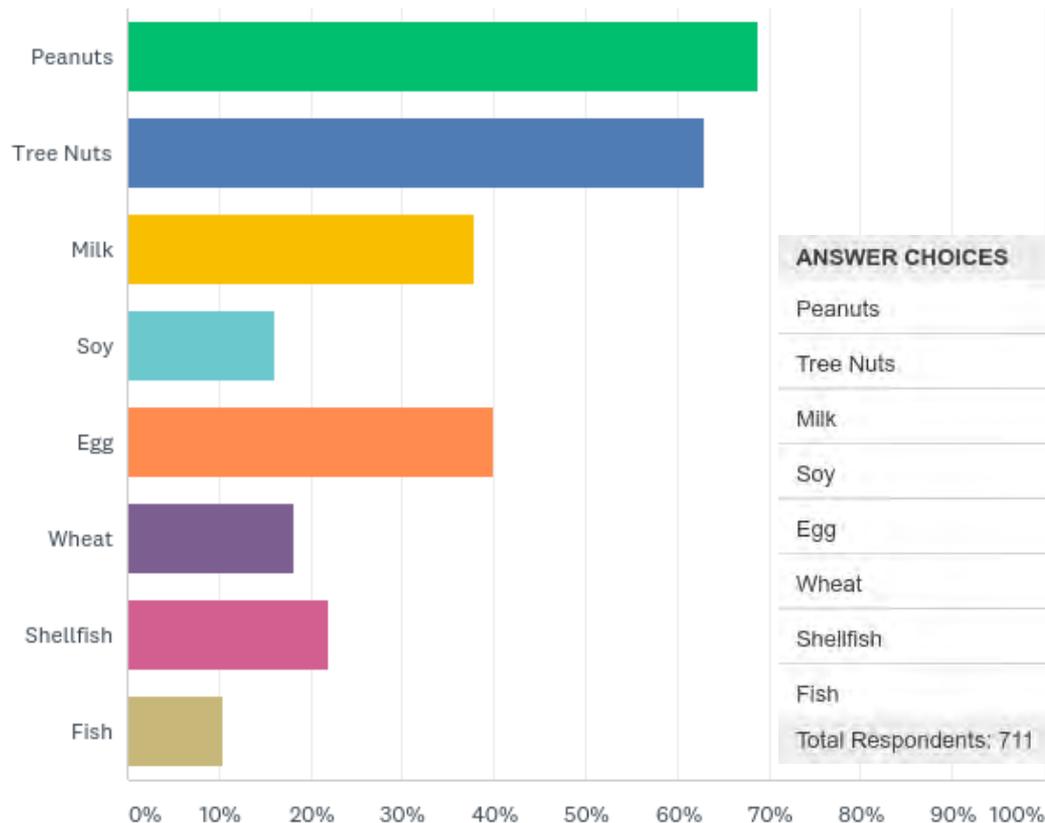
%GT Respondent by Food allergen notifications in RFE?



➤ For those >90% respondent have food allergies; they responded that food allergen notification is very/extremely important; in contrary, those without food allergies, their responses vary greatly

## Q9: Thinking of the food-allergic individuals within your circle of care, select which food allergies they experience:

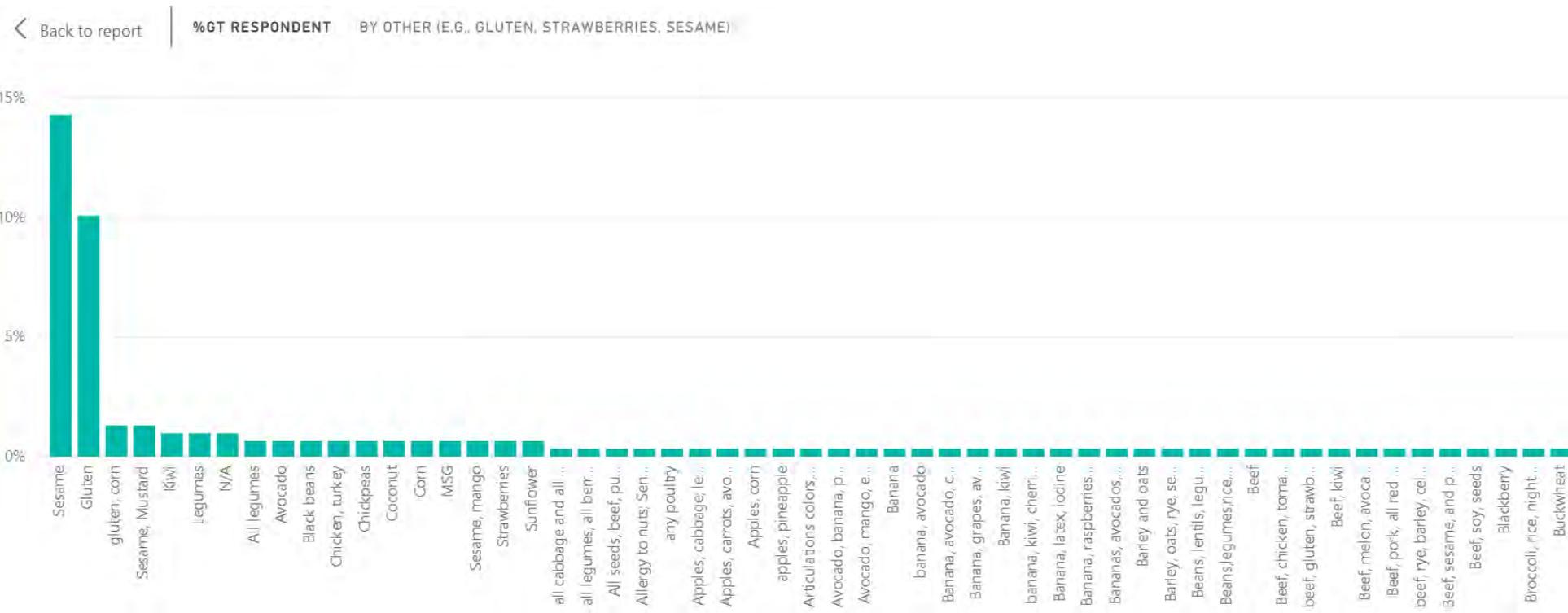
Answered: 711 Skipped: 77



ANSWER CHOICES	RESPONSES	
Peanuts	68.92%	490
Tree Nuts	62.87%	447
Milk	37.83%	269
Soy	16.17%	115
Egg	39.94%	284
Wheat	18.28%	130
Shellfish	21.94%	156
Fish	10.41%	74
Total Respondents: 711		

# Q9: List other food allergies within your circle of care:

Sesame and gluten allergies / intolerance are the leading food allergies outside of the BIG 8 major allergens

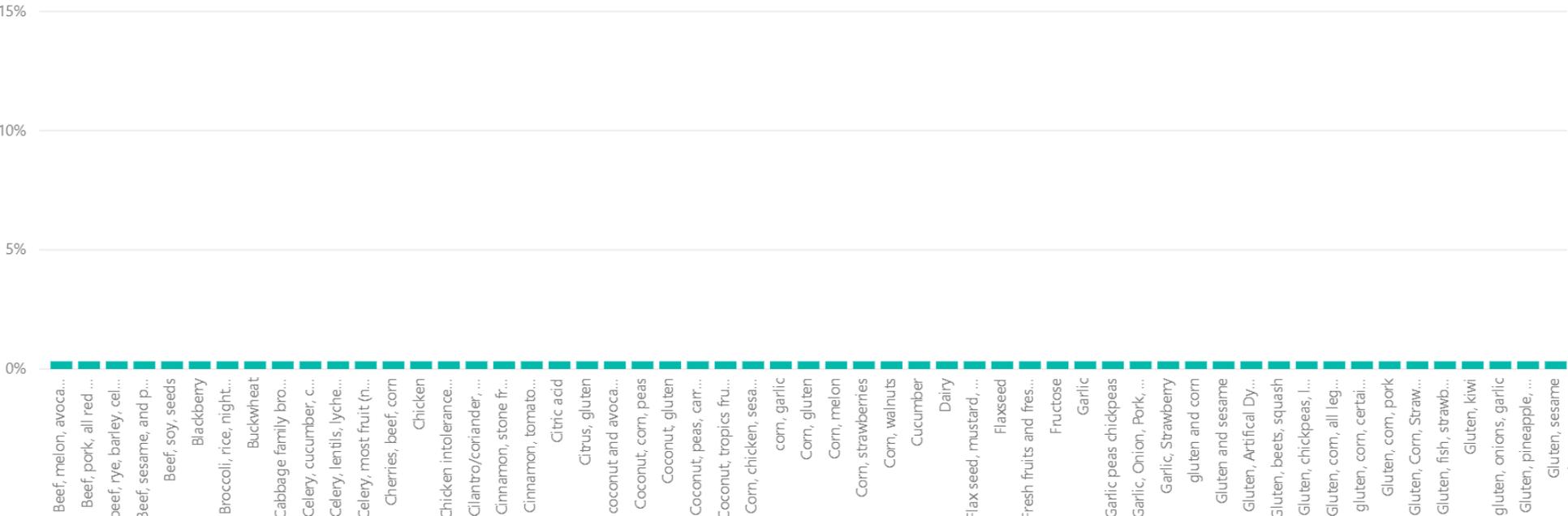


# Q9: List other food allergies within your circle of care:

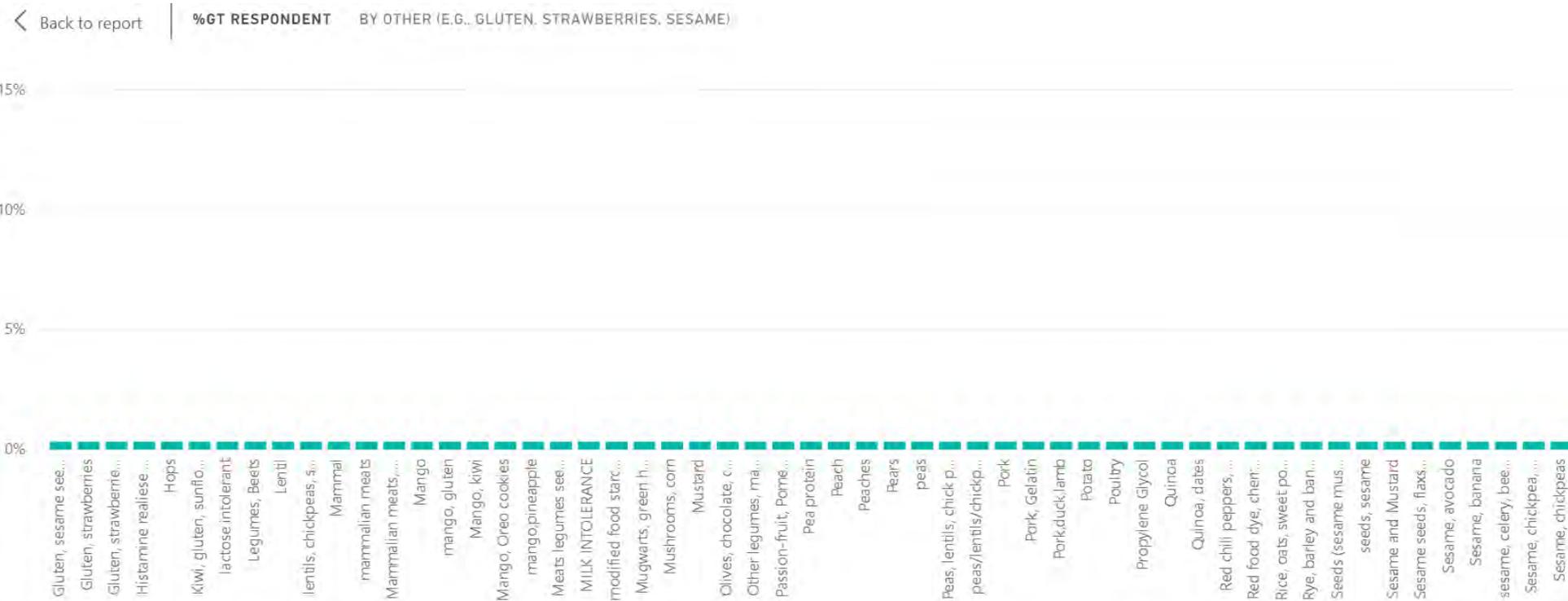
[Back to report](#)

**%GT RESPONDENT**

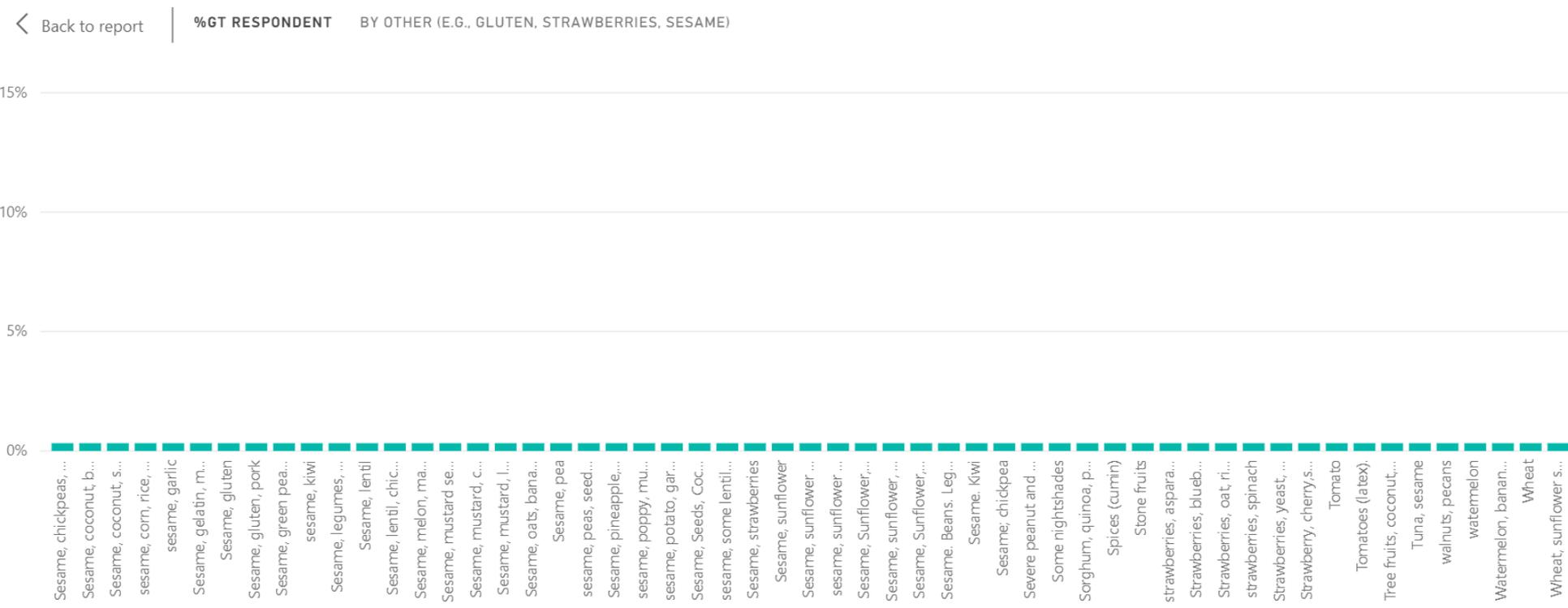
BY OTHER (E.G., GLUTEN, STRAWBERRIES, SESAME)



# Q9: List other food allergies within your circle of care:



# Q9: List other food allergies within your circle of care:



# Q10-Q15: From pictures, please rate effectiveness and ease of use of allergen notification on table menus A, B & C (1=worst, 10 = best)

Answered: 677 Skipped: 111



A



B



C

Menu	Effectiveness	Ease of Use	Comments
A	5.8 ± 2.7	5.3 ± 2.7	Table too busy, hard to understand symbol, need a legend
B	5.0 ± 2.8	5.0 ± 2.8	Like the icon in front/beginning of menu, need a legend
C	6.0 ± 2.4	6.0 ± 2.5	Standardized symbol is a must, easiest to read

# Q16-Q21: From pictures, please rate effectiveness and ease of use of allergen notification on table menus D, E & F (1=worst, 10 = best)

MENU ITEM	MAY CONTAIN ONE OR MORE OF THE FOLLOWING
APPETIZERS	
Chips & Spicy White Queso	Milk, Soybean Oil
Nashville Hot Deviled Eggs	Milk, Soybean Oil, Eggs
O'Charley's Chicken Tender Appetizer, Chipotle	Eggs, Fish, Milk, Peanuts, Shellfish, Soy, Soybean Oil, Tree Nuts, Wheat
O'Charley's Chicken Tenders Appetizer, Buffalo	Eggs, Fish, Milk, Peanuts, Shellfish, Soy, Soybean Oil, Tree Nuts, Wheat
O'Charley's Famous Chicken Tenders Appetizer, Original	Eggs, Fish, Milk, Peanuts, Shellfish, Soy, Soybean Oil, Tree Nuts, Wheat
O'Charley's Famous Chicken Tenders Appetizer, Nashville Hot	Eggs, Fish, Milk, Peanuts, Shellfish, Soy, Soybean Oil, Soy Lecithin, Tree Nuts, Wheat
O'Charley's Fried Green Tomatoes	Soy, Soybean Oil, Wheat
Loaded Potato Skins	Milk, Soy, Soybean Oil
Spinach & Artichoke Dip	Barley, Wheat, Milk, Soybean Oil, Soy Lecithin
Spicy Jack Cheese Wedges	Eggs, Fish, Milk, Peanuts, Shellfish, Soy, Soybean Oil, Tree Nuts, Wheat
Top Shelf Combination Appetizer	Eggs, Fish, Milk, Peanuts, Shellfish, Soy, Soybean Oil, Tree Nuts, Wheat
Crispy Pickle Chips	Eggs, Fish, Soy, Wheat. May also contain Gluten.

## Blueberry Muffin

### Ingredients

Whole grain flour (wheat [gluten]), blueberries, white sugar, egg (egg), butter (milk), milk (milk), baking powder, salt, vanilla extract

## Pistachio Macaron

### Ingredients

Shells: Almond flour (tree nut), pistachio flour (tree nut), powdered sugar, egg whites (egg), cream of tartar, sugar

Filling: Sugar, water, egg yolk (egg), butter (milk), pistachio paste (tree nut)

ALLERGEN CHART	Milk	Egg	Fish	Shellfish	Wheat	Soy	Peanuts	Nuts
ALFREDO SAUCE	•				•	•		
AMERICAN CHEESE	•					•		
ANCHOVIES			•			•		
BACON								
BACON CHEDDAR HOAGIE	•				•	•		
BALSAMIC DRESSING						•		

Menu	Effectiveness	Ease of Use	Comments
D	7.4 ± 2.4	7.3 ± 2.5	Too busy to read; like it clearly stated; don't like "may contain"
E	7.3 ± 2.3	7.3 ± 2.4	Like the dots; hard to scan by column; like the table approach
F	7.0 ± 2.7	6.6 ± 2.8	Easy to read; need to bold out allergen information

# Q22-Q27: From pictures, please rate effectiveness and ease of use of allergen notification on table menus G, H & I (1=worst, 10 = best)

<b>brightside BREAKFASTS</b>	Total calories (cal)	Calories from fat (fat cal)	Total Fat (g)	Saturated Fat (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total carbohydrate (g)	Dietary Fiber (g)	Sugars (g)	Protein (g)	Eggs	Fish	Milk	Peanuts	Shellfish	Soy	Tree Nuts	Wheat	Gluten	
2 Eggs, any style except poached	220	160	18	5	0	475	150	1	0	0	13	•					•				
Egg Whites (4 oz)	120	60	7	1.5	0	0	190	1	0	1	12	•					•				
Low-Cholesterol Egg Substitute (4 oz)	140	80	9	2	0	95	320	1	0	1	13	•					•				

G



**Whataburger®**

**590**   **25**   **29**   **1220**   **62**

Calories   Total Fat (g)   Protein (g)   Sodium (mg)   Carbs (g)

Allergens: Wheat, Soy, Gluten

[SEE MORE](#)

H

Nutrition Facts												Allergens									
MENU ITEMS	Serving Size (oz)	Calories	Calories From Fat (g)	Total Fat (g)	Saturated Fat (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carb (g)	Dietary Fiber (g)	Sugars (g)	Protein (g)	Wheat	Soy	Peanuts	Tree nuts	Fish	Shellfish	Eggs	Milk	
<b>SIDE</b>																					
Chow Mein	9.4 oz	510	180	20	3.5	0	0	860	80	6	9	13	Y	Y							
Chow Fun*	8.5 oz	410	80	9	1	0	0	1110	73	1	6	9	Y	Y							Y
Fried Rice	9.3 oz	520	140	16	3	0	120	850	85	1	3	11	Y	Y						Y	

I

Menu	Effectiveness	Ease of Use	Comments – <b>need cross contamination information</b>
G	6.3 ± 2.3	6.1 ± 2.4	Allergen notification lost with nutritional info
H	6.7 ± 2.7	6.8 ± 2.7	Easy to follow; not enough information
I	6.8 ± 2.3	6.7 ± 2.3	Like the color to differentiate nutrition from allergen , too small

# Q28-Q33: From pictures, please rate effectiveness and ease of use of allergen notification on table menus J, K & L (1=worst, 10 = best)

QUIZNOS Allergen Table		Milk	Eggs	Fish	Shellfish	Tree Nuts	Peanuts	Soybeans	Wheat	Unrefined Oil	Grains	Seeds	Gluten	Sulfites	MSG	HVP	Colorings	Crustaceans	Mollusks
<b>BREAD</b>																			
White									X				X						
Wheat									X				X						

J

Item	Peanut	Tree Nut	Egg	Milk	Wheat	Soy	Fish	Shellfish	Sesame
Crust Options									
Original Hand Tossed Dough					✓				

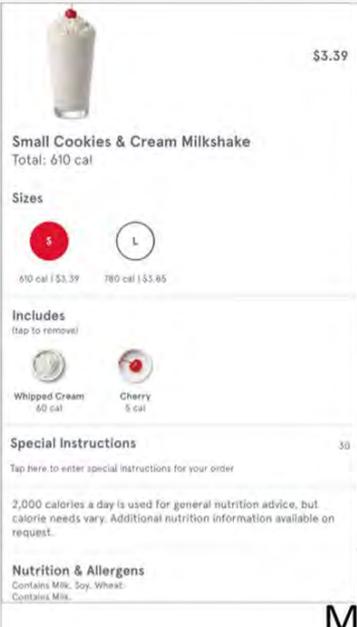
K

Product	Egg	Fish	Milk/ Lactose	Peanuts	Sesame	Shellfish	Soybeans	Tree Nuts	Wheat & Gluten	Sulfites	Nitrites/ Nitrates
✓ Cold Subs (does not include vinegar, oil, mayonnaise, unless otherwise specified)											
✓ #1 BLT											
In a Tub											✓
Wheat or White Roll							✓		✓		✓

L

Menu	Effectiveness	Ease of Use	Comments – <b>would be nice to include actual ingredients</b>
J	7.0 ± 2.2	6.9 ± 2.2	Comprehensive; hard to scan if it's a long list, need sesame info
K	6.5 ± 2.2	6.5 ± 2.2	Need bolder lines; glad it includes sesame
L	6.2 ± 2.3	6.1 ± 2.4	Too many columns to follow; glad it includes nitrites/sulfites

# Q34-Q39: From pictures, please rate effectiveness and ease of use of allergen notification on online menus M, N & O (1=worst, 10 = best)



**Small Cookies & Cream Milkshake**  
Total: 610 cal

Sizes: S (610 cal | \$3.39), L (780 cal | \$3.85)

Includes: Whipped Cream (60 cal), Cherry (5 cal)

**Special Instructions**  
Tap here to enter special instructions for your order

2,000 calories a day is used for general nutrition advice, but calorie needs vary. Additional nutrition information available on request.

**Nutrition & Allergens**  
Contains Milk, Soy, Wheat  
Contains Milk

**Nutrition**

**950** Calories  
**2g** Fiber  
**59g** Protein  
**62g** Fat

**Allergens**

Egg Milk Soy Wheat

**Quarter Pounder™ with Cheese**

**Beef Patty:**  
100% Pure Beef.  
A little salt and pepper is added to season after cooking.

**Quarter Pounder Bun:**  
WHEAT Flour (contains Calcium, Iron, Niacin, Thiamine), Water, Sugar, SESAME seeds, Rapeseed Oil, Salt, Yeast, Emulsifier (Mono- and Diacetyl Tartaric Acid Esters of Mono- and Diglycerides of Fatty Acids), WHEAT Gluten, Preservative (Calcium Propionate), De-activated Yeast, Antioxidant (Ascorbic Acid)

N.B. May contain traces of milk, barley and rye.

**Cheddar Cheese Slice (processed):**  
Vegetarian Cheddar (51%) (MILK), Water, Vegetarian Cheese (9%) (MILK), Whey Powder (MILK), Butter (MILK), Emulsifying Salts (Trisodium Citrate, Citric Acid), MILK Proteins, Natural Cheese Flavouring (MILK), Salt, Colours (Beta Carotene, Paprika Extract), Anti-Caking Agent (Sunflower Lecithin Oil).

**Tomato Ketchup:**  
60% Tomato Puree (equivalent to 184g tomatoes per 100g ketchup), Glucose-Fructose Syrup, Spirit Vinegar, Salt, Spice Extracts.

**Dill Pickle Slices:**  
Gherkins, Water, Spirit Vinegar, Salt, Firming Agent (Calcium Chloride), Natural Flavouring, Preservative (Potassium Sorbate).

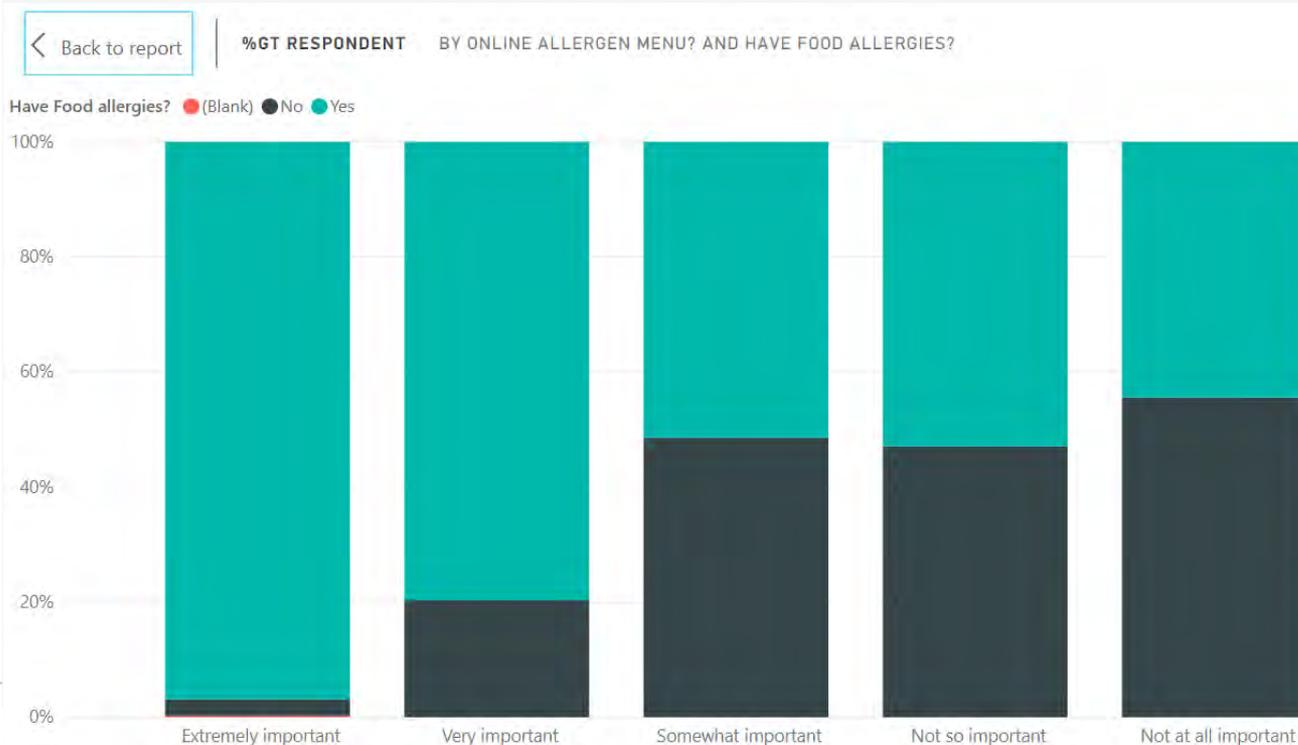
**Onions:**  
100% White Onions.

**Mustard:**  
Water, Spirit Vinegar, MUSTARD Seed (13%), Salt, Spices, Spice Extract.

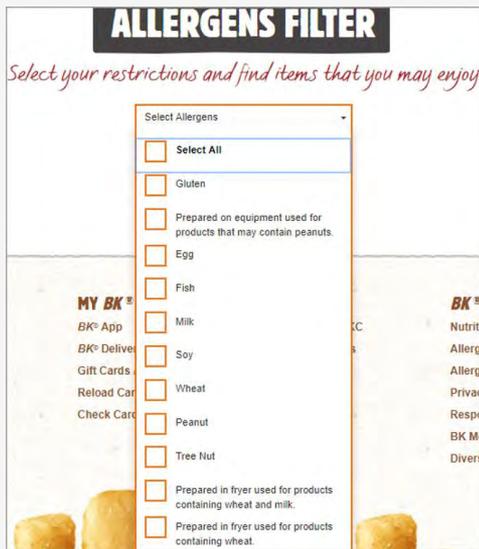
Menu	Effectiveness	Ease of Use	Comments – would be nice to include ingredients
M	5.9 ± 2.4	5.7 ± 2.4	Allergen information is buried, should be listed on top
N	7.5 ± 2.3	7.6 ± 2.3	Easy and simple
O	6.3 ± 3.0	5.6 ± 2.9	Like “may contain” info; too many words to sort through

# Q40: How important is the availability of an online allergen menu to you?

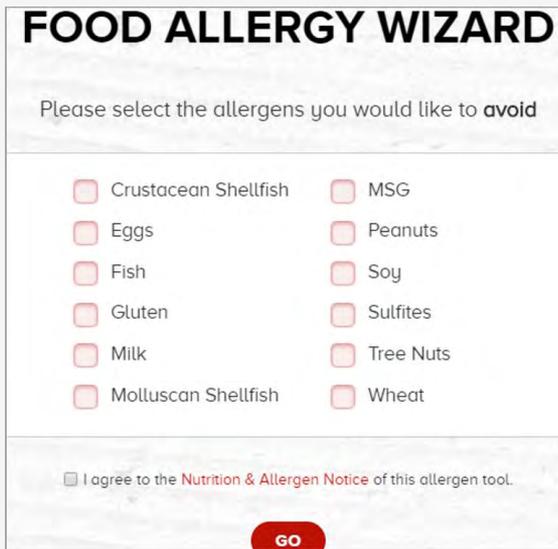
➤ Again, responses vary greatly. Those with food allergies, responded that availability of an online allergen menu is very/extremely important.



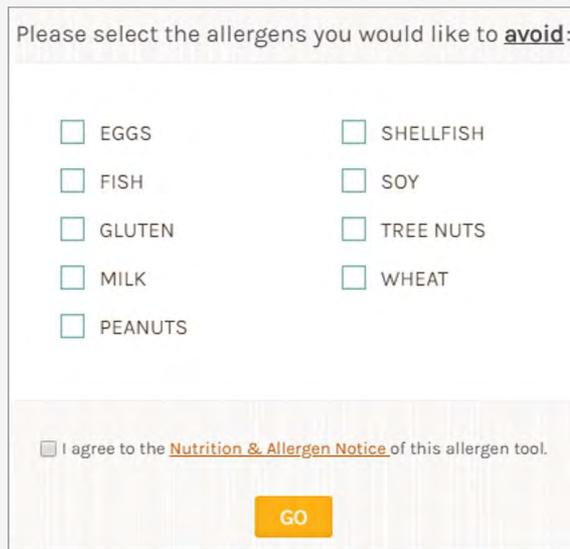
# Q41-Q46: From pictures, please rate effectiveness and ease of use of allergen notification on online menus P, Q & R (1=worst, 10 = best)



P



Q

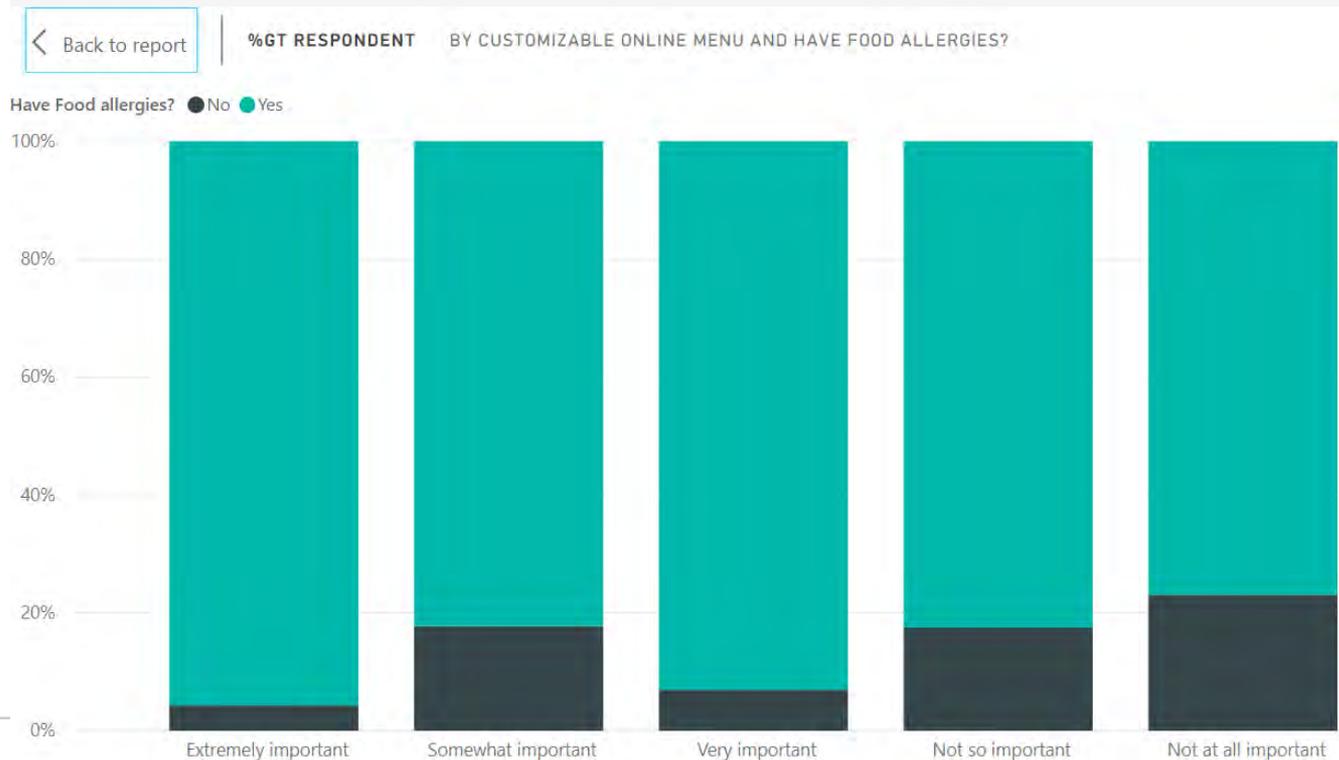


R

Menu	Effectiveness	Ease of Use	Comments – <b>would be nice to include ingredients</b>
P	6.9 ± 2.6	6.8 ± 2.6	Would be nice to include equipment oil and cross-contamination
Q	7.1 ± 2.4	7.2 ± 2.3	Would be nice to include disclaimer; dislike “I agree to...” (risk?)
R	6.9 ± 2.4	7.1 ± 2.3	Prefer ingredient listed for those with allergens outside of big8

## Q47: How important is a customize-able online allergen menu to you?

➤ Again, responses vary greatly. Those with food allergies, responded that availability of a customizable online allergen menu is very/extremely important.



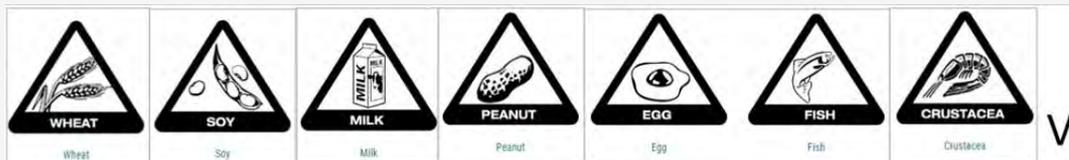
## Q48-Q53: From pictures, please rate effectiveness and ease of use of allergen notification on posters S, T & U (1=worst, 10 = best)

Food Allergies? If you have a food allergy, please speak to the manager, chef or your server. Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of food-borne illness, especially if you have certain medical conditions. S



Menu	Effectiveness	Ease of Use	Comments – <b>would be nice to include ingredients</b>
S	5.7 ± 2.6	5.7 ± 2.6	Nice to have chef included! Worried about relaying correct information
T	<b>7.3 ± 2.4</b>	<b>7.3 ± 2.4</b>	Greatly dependent on staff knowledge and training
U	6.4 ± 2.5	6.4 ± 2.5	Too informal, still greatly dependent on staff knowledge and training

# Q54-Q59: From pictures, please rate effectiveness and ease of use of allergen icons V, W & X (1=worst, 10 = best)



Menu	Effectiveness	Ease of Use	Comments – <b>would be nice to include ingredients</b>
V	6.5 ± 2.5	6.5 ± 2.4	Triangle mimic hazard signage; prefer colors; easy to mix up
W	6.6 ± 2.5	6.6 ± 2.5	Hard to identify food; too many icon
X	<b>7.8 ± 2.0</b>	<b>7.9 ± 2.0</b>	Clear, easy to read; too colorful; make sure words accompany icon

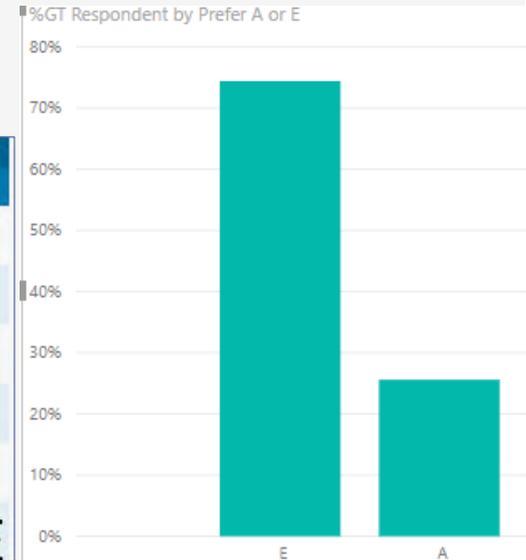
# Q60: Which of the allergen notification menus above do you prefer?

>70% prefer full text as icon was difficult to distinguish unless a legend is provided



ALLERGEN CHART								
	Milk	Egg	Fish	Shellfish	Wheat	Soy	Peanuts	Nuts
ALFREDO SAUCE	•				•	•		
AMERICAN CHEESE	•					•		
ANCHOVIES			•			•		
BACON								
BACON CHEDDAR HO	•				•	•		
BALSAMIC DRESSING						•		

A large letter 'E' is in the bottom right corner.



# Q61: Which of the allergen notification menus above do you prefer?

>60% prefer to include only the major food allergen information be included in notification

ALLERGEN CHART									
	Milk	Egg	Fish	Shellfish	Wheat	Soy	Peanuts	Nuts	
ALFREDO SAUCE	●				●	●			
AMERICAN CHEESE	●					●			

E

MENU ITEMS	Nutrition Facts											Allergens								
	Serving Size (oz)	Calories	Calories From Fat (g)	Total Fat (g)	Saturated Fat (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carb (g)	Dietary Fiber (g)	Sugars (g)	Protein (g)	Wheat	Soy	Peanuts	Tree Nuts	Fish	Shellfish	Eggs	Milk
<b>SIDE</b>																				
Chow Mein	9.4 oz	510	180	20	3.5	0	0	860	80	6	9	13	Y	Y						
Chow Fun*	8.5 oz	410	80	9	1	0	0	1110	73	1	6	9	Y	Y						Y

I

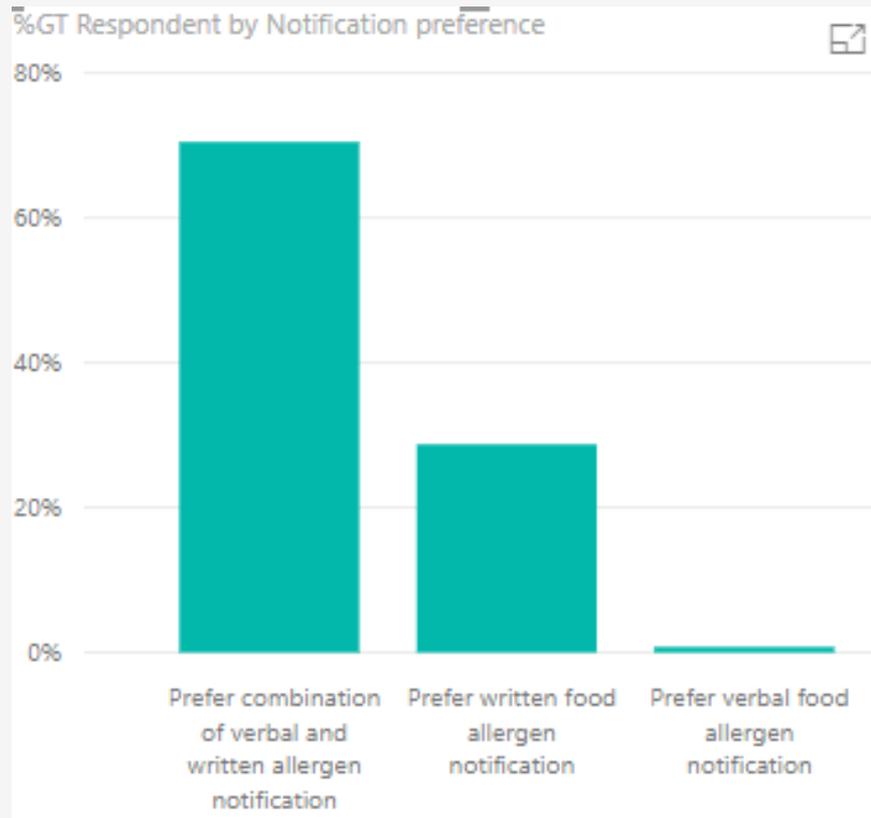
Item	Peanut	Tree Nut	Egg	Milk	Wheat	Soy	Fish	Shellfish	Sesame
<b>Crust Options</b>									
Original Hand Tossed Dough					✓				

K



## Q62: How do you prefer to be notified of food allergens in retail establishments?

- Majority prefer combination of written and verbal notification



# Contributor & Survey Partnership

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## Contributor:

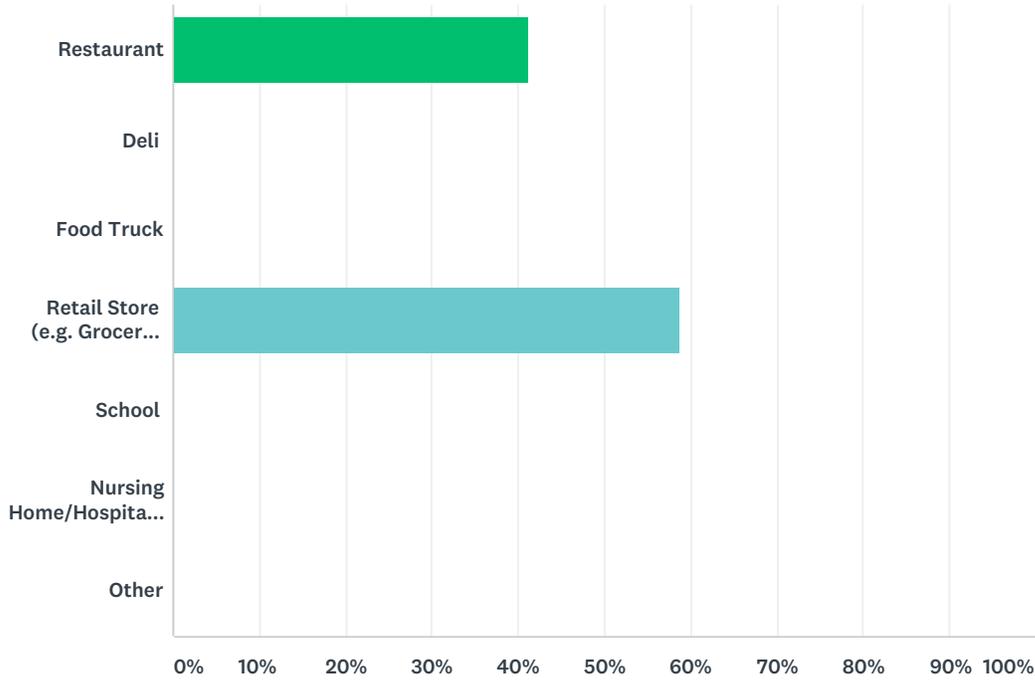
- **Elaine Money**, Principal Regulatory Specialist, Ecolab®
- **Dee Dee Vicino**, Chief Executive Officer, AllerCuisine™
- **Archer Campbell**, Environmental Health Technical Consultant, VA Thomas Jefferson Health District
- **Todd Pelech**, Public Health Sanitarian, Arizona Department of Health Services
- **Crystine Sylvis**, Environmental Health Supervisor, Southern Nevada Health District
- **Emilee Follett**, VP Product Development, StateFood Safety

## In Partnership with and special thanks to:

- **Jon Hoffman**, Associate Director of Advocacy, FARE® (Food Allergy Research & Education)
- **Chef Keith Norman**, Food Safety Manager/Asst Executive Chef, South Point Hotel Casino and Spa

## Q1 What type of food establishment do you represent?

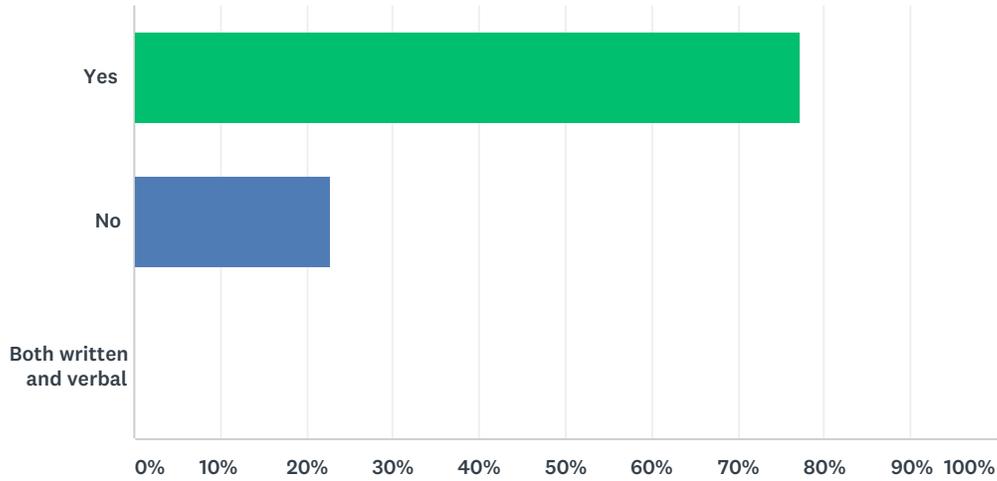
Answered: 51 Skipped: 21



ANSWER CHOICES	RESPONSES	
Restaurant	41.18%	21
Deli	0.00%	0
Food Truck	0.00%	0
Retail Store (e.g. Grocery, Convenience, Deli)	58.82%	30
School	0.00%	0
Nursing Home/Hospital/Assisted Living Facility	0.00%	0
Other	0.00%	0
<b>TOTAL</b>		<b>51</b>

## Q2 Do you provide written information regarding allergens to your customers on things such as a menu/menu board, website, pamphlet, etc.?

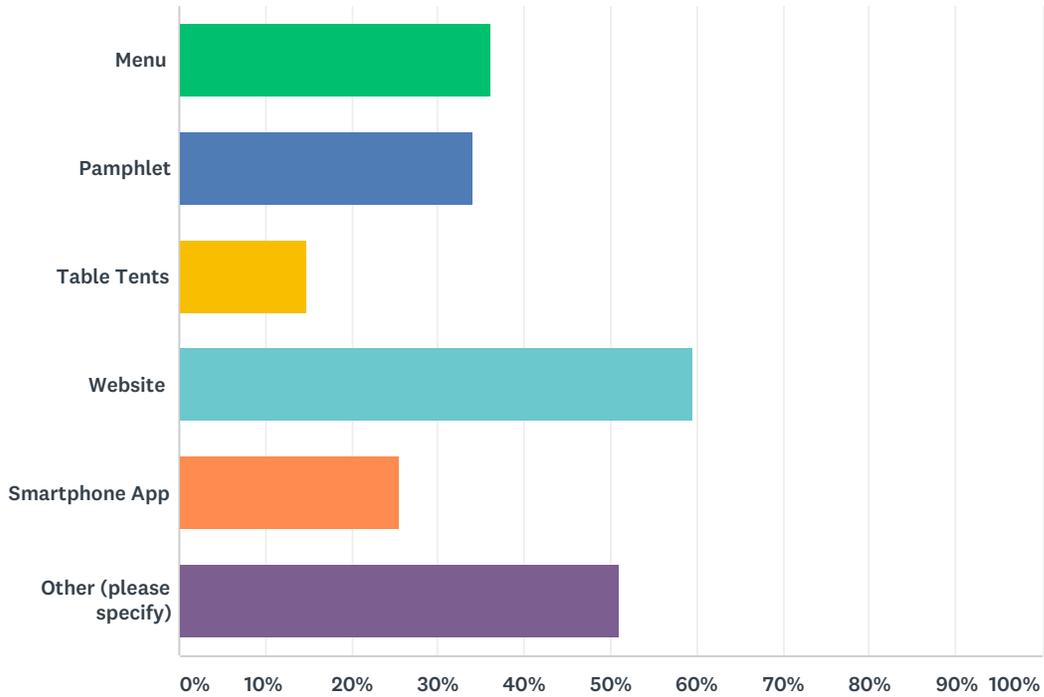
Answered: 66 Skipped: 6



ANSWER CHOICES	RESPONSES	
Yes	77.27%	51
No	22.73%	15
Both written and verbal	0.00%	0
TOTAL		66

### Q3 Where do you use written communication to provide food allergen information to your customers. (List all below)

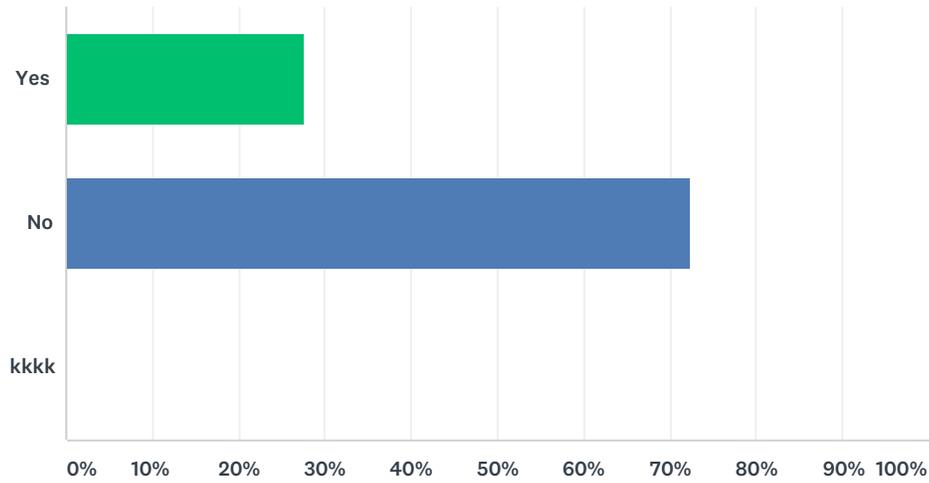
Answered: 47 Skipped: 25



ANSWER CHOICES	RESPONSES	
Menu	36.17%	17
Pamphlet	34.04%	16
Table Tents	14.89%	7
Website	59.57%	28
Smartphone App	25.53%	12
Other (please specify)	51.06%	24
Total Respondents: 47		

### Q4 Do you utilize symbols for the various allergens?

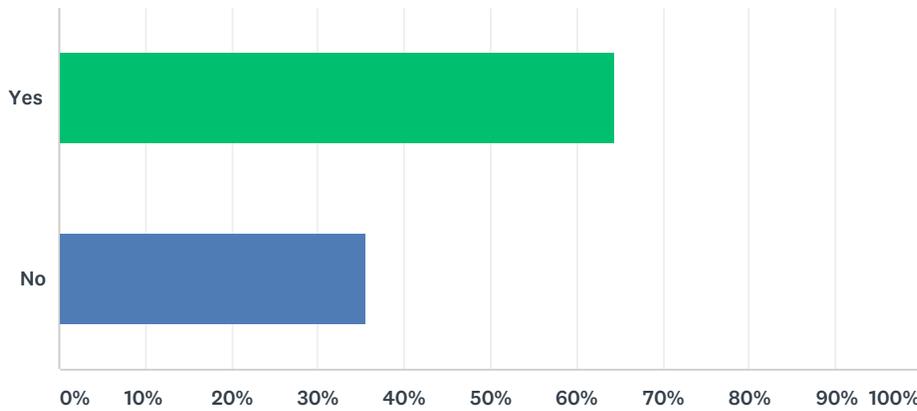
Answered: 47 Skipped: 25



ANSWER CHOICES	RESPONSES	
Yes	27.66%	13
No	72.34%	34
kkkk	0.00%	0
<b>TOTAL</b>		<b>47</b>

### Q5 Do you provide verbal information regarding allergens to your customers?

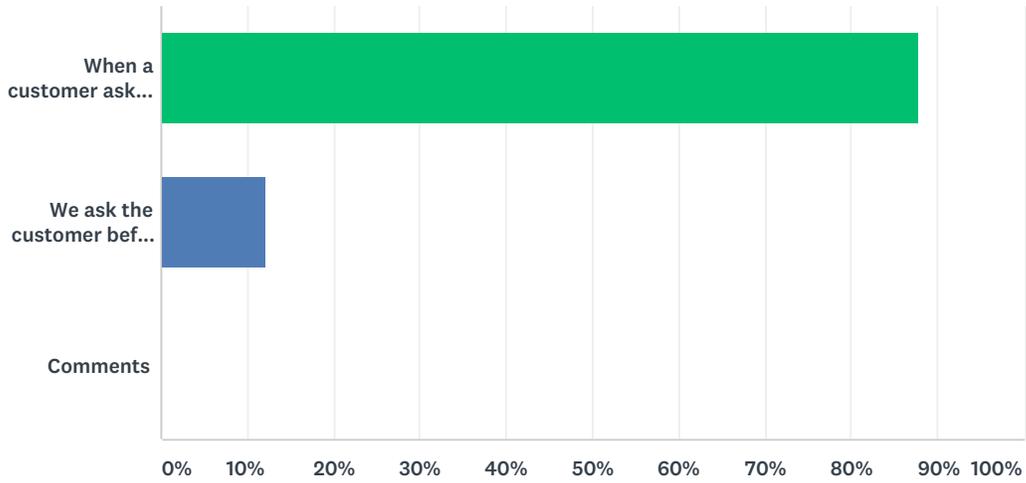
Answered: 59 Skipped: 13



ANSWER CHOICES	RESPONSES	
Yes	64.41%	38
No	35.59%	21
TOTAL		59

## Q6 In which of the following situations do you verbally share food allergen information?

Answered: 33 Skipped: 39



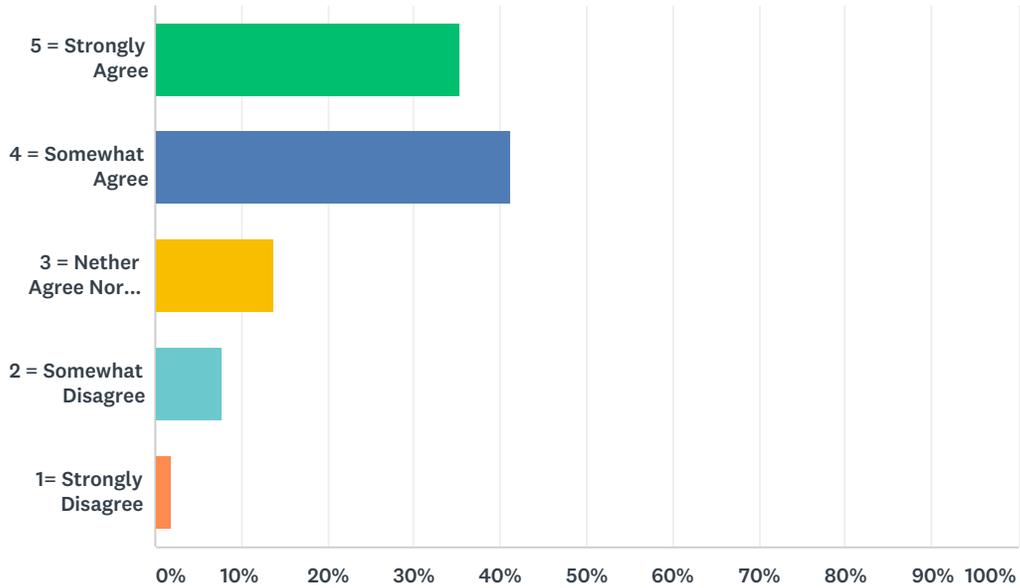
ANSWER CHOICES	RESPONSES	
When a customer asks about allergens	87.88%	29
We ask the customer before they order if they have a food allergy and need more information	12.12%	4
Comments	0.00%	0
<b>TOTAL</b>		<b>33</b>

**Q7 What types of challenges do you encounter with food allergen notification?**

Answered: 47 Skipped: 25

### Q8 How much do you agree or disagree that a standard method for allergen notification should be utilized by establishments that use prepared food (that's not pre-packaged)?

Answered: 51 Skipped: 21



ANSWER CHOICES	RESPONSES	
5 = Strongly Agree	35.29%	18
4 = Somewhat Agree	41.18%	21
3 = Nether Agree Nor Disagree	13.73%	7
2 = Somewhat Disagree	7.84%	4
1= Strongly Disagree	1.96%	1
<b>TOTAL</b>		<b>51</b>

## Q9 Please let us know why you selected your response

Answered: 51 Skipped: 21

# Restaurant servers' risk perceptions and risk communication-related behaviors when serving customers with food allergies in the U.S.

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## article info

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Keywords: Food allergy Restaurant Servers Risk perception Risk communication

## abstract

Communication between and among customers with food allergies and foodservice staff has become a concern in the restaurant industry. The purpose of this research was to explore the perceived risks and risk communication-related behaviors of restaurant servers when serving customers with food allergies in the U.S. An online survey instrument was developed based on interviews with full service restaurant managers, pilot-tested, and distributed through an online survey research firm. The results indicated that most servers lacked knowledge about food allergies and perceived that initiating communication and preventing allergic reactions were mostly the responsibilities of customers with food allergies. Servers' risk reduction and communication behaviors were affected by their perceived severity of food allergy reactions, previous training, sources of media exposure, and the perceived responsibilities of preventing food allergy reactions. Restaurateurs and foodservice educators may use these findings to develop training and strategies for food allergy risk communication in the restaurant industry.

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## 1. Introduction

A food allergy is “an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food” (Boyce et al., 2010, p. S8). Food allergy reactions range from mild to severe and usually appear within the first two hours after the ingestion of allergens (Chafen et al., 2010). Anaphylaxis, one of the most severe food allergy responses, can result in circulatory collapse, coma, and even death (Mandell et al., 2005).

Food allergies are prevalent in the United States (U.S.), affecting about 9 million adults (4% of the U.S. adult population) and 6 million children (8% of the U.S. children ≤18 years) (Branum and Lukacs, 2008; De Blok et al., 2007; Food Allergy Research and Education, 2016). The Centers for Disease Control and Prevention (CDC) estimates an increased number of anaphylaxis caused by food allergies (Centers for Disease Control and Prevention, 2011). Food allergy reactions account for nearly 200,000 emergency room visits, approximately one every three minutes (Clark et al., 2011) and 150–200 deaths each year (Sampson, 2003). Eggs, fish, milk, peanuts, soy, shellfish, tree nuts, and wheat are the “Big 8” food allergens, which have triggered more than 90% of the food allergy

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reactions in the U.S. (Sicherer et al., 2010). For the food manufacturing industry, the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 requires any ingredients or proteins derived from the “Big 8” food allergens to be disclosed on all food labels that are regulated by the U.S. Food and Drug Administration (FDA). However, for the restaurant industry, the Food Code (Food and Drug Administration, 2013) is the only federal level regulation related to the management of food allergies in restaurants. The Food Code states that the person in charge of a foodservice establishment should have knowledge about major food allergens, cross-contacts, and symptoms of food allergy reactions (Food and Drug Administration, 2013). The code also mandates that all establishments “ensure that employees are properly trained in food safety, including food allergy awareness as it relates to their assigned duties” (Food and Drug Administration, 2013, p. 31). These statements in the Food Code, however, lack practical guidelines for operations to follow in order to prevent food allergy reactions. Furthermore, food allergy legislation at the state level is limited only to Massachusetts, Michigan, Rhode Island, and Virginia, where legislation for the management of food allergies in restaurants are established (Food Allergy Research and Education, 2016).

About 33% of all the fatal food allergy reactions (n = 31) that occurred in the U.S. between 2001 and 2006 were triggered by foods prepared away from home (Bock et al., 2001, 2007; Wanich et al., 2008). The existence of hidden allergens and cross-contacts

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from food allergens were the most recognized causes of food allergy reactions in restaurants, followed by miscommunication between and among restaurant staff and customers with food allergies (Furlong et al., 2001; Kwon and Lee, 2012; Leftwich et al., 2011). Communication researchers have found that risk communication plays an important role in controlling and preventing negative consequences (McComas, 2006; Parrott, 2004) such as food allergy reactions in restaurants. Establishing proper communication between and among customers and foodservice employees may be one of the first and most important steps in preventing food allergy reactions in restaurants (Leftwich et al., 2011). Proper communication among stakeholders would initiate increased attention to food preparation and service staff when serving customers with food allergies. Although there are other food allergy-related publications available, no research has been published regarding food allergy risk communication.

Therefore, the purpose of this study was to explore the perceived risks and risk reduction and communication-related behaviors of restaurant service staff when serving customers with food allergies in the U.S. The specific objectives were to examine the perceived risks of restaurant

staff when serving consumers with food allergies, explore factors affecting restaurant service staff's risk reduction and communication-related behaviors, and provide recommendations for the restaurant industry regarding food allergy risk communication strategies and training needs.

## 2. Literature review

### 2.1. Food allergies and the restaurant industry

Considering the fact that the population with food allergies is increasing in the U.S., it is important for restaurant staff to be fully informed about food allergies and ways to prevent allergic reactions (Mandabach et al., 2005). The benefits of accommodating consumers with food allergies include increased sales, customer appreciation, and customer loyalty (Kwon et al., 2013; Tsai, 2013). However, serving consumers with food allergies also poses challenges given the variety of food allergens present at restaurants (Abbot et al., 2007; Ahuja and Sicherer, 2007; Kronenberg, 2012).

Researchers found that restaurant staff lacked knowledge regarding food allergens in the menu, ways to prevent cross-contact, and the severity of food allergy reactions (Abbot et al., 2007). One study from the United Kingdom revealed that about 21% of the peanut-free meals that were prepared right after peanut-containing meals were contaminated with peanut or peanut protein (Leith et al., 2005). Researchers also found that restaurant employees' confidence levels were high even though their knowledge about serving customers with food allergies was not adequate (Ahuja and Sicherer, 2007). Specifically, 70% of the respondents in this study felt that they could guarantee a safe meal, while 35% thought that fryer heat could destroy allergens and 25% thought it was safe to remove allergens from a finished meal (Ahuja and Sicherer, 2007).

Researchers have revealed that most foodservice employees did not receive food allergy training (Ahuja and Sicherer, 2007; Choi and Rajagopal, 2013; Mandabach et al., 2005). If servers lack knowledge and awareness about food allergies, they may not be able to respond to questions and requests from customers with food allergies (Kronenberg, 2012). In addition, servers may incorrectly assume that an item is allergen-free if they are not aware of the hidden ingredients (Mandabach et al., 2005). The high cost of training, high labor turnover rate, time constraints, language barriers, the lack of interest in implementing food allergy training, and the lack of commitment from employees were identified as reasons why such training was not provided to restaurant employees (Abbot et al., 2007; Lee and Xu, 2014; Mandabach et al., 2005).

### 2.2. Dining experiences of customers with food allergies

Strict avoidance of food allergens and early recognition and response to allergic reactions are extremely important for individuals with food allergies to prevent fatal food allergy reactions (Food Allergy Research and Education, 2016; Sicherer and Teuber, 2004). To prevent potential food allergy reactions, customers with food allergies have used various strategies prior to and while dining out (Kwon and Lee, 2012; Kwon et al., 2013). For example, customers chose restaurants with which they were familiar and where they were known by the staff; avoided establishments and cuisines that are considered high-risk such as buffets or ethnic restaurants; and checked online menus, ingredients, and allergen information before dining out (Kwon et al., 2013; Leftwich et al., 2011).

Despite these prevention strategies, customers with food allergies have experienced communication challenges when dining out because some restaurant staff did not seem to have knowledge about food allergies, did not understand special requests, and were not aware of the severity of food allergy reactions (Kwon and Lee, 2012; Kwon et al., 2013). Because many customers with food allergies or parents of children with food allergies have perceived a lack of control in food preparation and service processes, they have felt anxiety or fear when dining in restaurants, especially when going to a restaurant for the first time (Kwon et al. 2013; Leftwich et al., 2011). Such anxiety and fear may also be due to a significant number of customers with food allergies experiencing allergic reactions after eating in restaurants (Bock et al., 2001, 2007; Wanich et al., 2008). In many of these food allergy reaction cases, customers believed that the food they ordered was safe (Sampson et al., 1992) and failed to notify restaurant staff about their food allergies (Mandabach et al., 2005).

Further, even though some restaurant operators or managers provide food allergy training with regard to identifying food allergens and preventing cross-contact, few of them have provided training about the proper communication between the front-of-house and back-of-house employees or between restaurant employees and customers (Lee and Xu, 2014). Considering one of the major causes of food allergy reactions is the lack of proper communication between and among restaurant employees and customers with food allergies (Furlong et al., 2001; Kwon and Lee, 2012; Leftwich et al., 2011), there is a strong need for researchers to address this risk and promote interpersonal communication among restaurant staff and customers.

### 2.3. Food allergy risk perception and risk communication

Risk perception, which refers to an individual's views regarding the risk involved in a particular situation (Schroeder et al., 2007), is a special concern in the food safety context. Food allergies pose one of the food safety risks that has been widely discussed lately throughout food and foodservice industries, as well as related consumer advocacy groups. As for the risk of food allergies in foodservice establishments, scholars contended that zero risk is not realistic or attainable (Kroes et al., 2000; Madsen et al., 2012). Risk perception, as part of the health behavior theories, includes different dimensions or determinants, such as perceived susceptibility and perceived severity (Brewer et al., 2007; Janmimool and Watanabe, 2014). Perceived susceptibility refers to an individual's subjective perception of the risk of contracting a hazard (Janz and Becker, 1984). Perceived severity refers to an individual's feelings regarding the seriousness of contracting a hazard and reflects the extent of the harm a hazard would cause (Brewer et al., 2007; Janz and Becker, 1984). Risk perceptions can also be influenced by different

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RESEARCH ARTICLE

Open Access



# Comparing the eating out experiences of consumers seeking to avoid different food allergens

Julie Barnett<sup>1</sup>, Fiona M. Begen<sup>1\*</sup> , M. Hazel Gowland<sup>2</sup> and Jane S. Lucas<sup>3</sup>

## Abstract

**Background:** Eating outside the home is challenging for consumers with food allergy (FA) and intolerance (FI) and lack of allergen information provision in eating out venues can lead to unnecessary restrictions. Following European legislation (2014) designed to improve allergen information provision, little is known about differences in information provision experienced by consumers seeking to avoid particular allergens, or how this impacts on their eating out experiences. This study compared the information provision that consumers with FA/FI to different allergens experience when eating out.

**Methods:** Using mixed methods, participants were recruited from across the UK and took part in self-report surveys or in-depth interviews. Surveys were completed by 232 participants avoiding either gluten ( $n = 66$ ), nuts (peanuts/tree nuts) ( $n = 94$ ), or milk ( $n = 74$ ), and responses were subject to quantitative analyses. Interviews were carried out with 49 participants avoiding either gluten ( $n = 13$ ), nuts ( $n = 14$ ), milk ( $n = 13$ ) or a combination of these allergens ( $n = 9$ ), and analysed using the framework approach.

**Results:** Although general improvements in information provision following the legislation were reported, variations in provision between allergen groups led participants seeking to avoid milk to conclude that their dietary needs were less well-understood and seen as less important. These perceptions were reflected in a reluctance to involve eating out venue staff in deliberations about the potential for milk-free meal options.

**Conclusions:** The provision of visual indicators of the presence of milk and of staff trained in allergen-awareness would improve the eating out experiences of consumers seeking to avoid milk. Medical professions can play a key role in encouraging these patients to pursue their right to make enquiries about allergens in order to avoid accidental milk ingestion when eating out.

**Keywords:** Food allergy, Food intolerance, Allergen avoidance, Eating out, Information provision, Gluten, Peanuts / tree nuts, Milk

## Background

Allergen avoidance is a key management strategy for food allergic (FA) and food intolerant (FI) individuals, and eating outside the home represents a particular risk of accidental allergen ingestion [1] where the provision of information regarding ingredients and food preparation is inadequate or insufficient [2]. Food allergies are caused by an abnormal immunological response to a food, whereas

food intolerances have a non-immunological basis [3, 4]. As a general rule, allergic reactions occur very rapidly after ingestion and sometimes lead to immediately life threatening symptoms [5], whilst food intolerances have a delayed reaction and extremely rarely have life threatening symptoms although, like FA, they too can result in significant ill health and impaired quality of life [6]. Between 21 and 31% of accidental allergen ingestions occur when eating in restaurants, and 13–23% occur in other eating out settings such as the work-place or school canteens [7]. In cases of children suffering anaphylaxis to a known food allergen, over half of these occurred outside the home [8].

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EU legislation (EU Food Information for Consumer Regulation No. 1169/2011, (EU FIC)) introduced in December 2014 [9], requires food businesses providing and selling non-prepacked foods to provide allergen information relating to the inclusion of any of 14 specified food allergens (peanuts, tree nuts, milk, soya, mustard, lupin, eggs, fish, molluscs, crustaceans, cereals containing gluten, sesame seeds, celery, and sulphur dioxide at levels above 10 mg/kg, or 10 mg/litre) as ingredients in their foods. The legislation thus affects restaurants, takeaway establishments, food stalls, institutions including prisons and nursing homes, as well as workplace and school canteens. Allergen information can be provided in written or verbal form. Where verbal information is provided, written information must also be available to customers within the venue. Thus far however, there has been little consideration of how people's eating out experiences - including the provision of allergen information - varies in relation to different allergens.

Given that adverse reactions can occur in response to any of these allergens, differences in the quality of information provided about them is important. Little work has considered the differential impact of seeking to avoid particular allergens or how experiences of seeking to avoid particular allergens vary. Although adherence to an allergen-free diet has been associated with poorer quality of life, and significant social and behavioural restrictions [10–14], literature tends to generalise across populations avoiding allergens [11, 15] or focus on one specific allergen grouping; most commonly avoidance of peanuts and/or tree nuts [16–18], or gluten in coeliac populations [19, 20]. Where studies have focused on the difficulties encountered by populations seeking to avoid 'staple food' allergens (milk, wheat, eggs) [21–23], no distinction has been made between allergens in order to assess any differences experienced between these groups. Where differences between allergen avoidance groups have been considered in parents of FA children, there was greater psychosocial impact on parents seeking to avoid milk or eggs on behalf of their child than for parents seeking to avoid other food allergens [24, 25].

As yet, the eating out experiences of populations seeking to avoid particular allergens has not been considered. In light of the EU FIC legislation, eating out venues are required to provide information about the content of each of the 14 allergens in their foods, and attention has recently turned to the adequacy of this information provision for each allergen. For example, online resources such as 'Guide to eating out with a food allergy' [26], show how well some eating out venues cater for customers avoiding a particular allergen by reporting the availability of allergen-free meals for each of the 14 allergens.

Evaluating the impact of the EU FIC legislation provided the opportunity to compare the information

provision that customers with FA/FI experience in relation to different allergens when eating out. In order to investigate this, in a mixed methods study we conducted semi-structured interviews and self-report surveys with customers who avoided particular allergens (gluten, nuts: peanuts/tree nuts, or milk) following implementation of the legislation. We assessed differences between these groups based on their satisfaction with allergen information provision, and their preferences for written and verbal forms of information delivery.

## Methods

### Overview

As part of wider programme of longitudinal research into the eating out experiences of adults and parents/carers of children with FA/FI [27] prior to (2014) and following (2016) implementation of EU FIC legislation [28], we recruited participants from across the UK to take part in either (A) In-depth interviews in 2014 and 2016, or (B) Surveys in 2014 and/or 2016. Ethical approval was gained from the institution's departmental ethics committee prior to recruitment (Ref: 14–055/16–146). The current paper reports findings relating to participants who reported avoiding gluten, nuts (peanuts and/or tree nuts) or milk in 2016 interviews or surveys. Interview findings from 2014 are reported elsewhere [2].

### Online survey

#### Recruitment and study population

Survey participants were recruited from across the UK by a professional market research agency: Acumen Fieldwork-Medical (66%) and using the websites and mailing lists of three UK-based charities: Allergy UK (28%), Anaphylaxis Campaign (3%), Coeliac UK (3%). Between November and December 2016, 392 participants completed the survey. Of these, 188 (48%) had been recruited to complete a prior version of the survey in 2014 and returned to complete the 2016 survey, and 204 (52%) were recruited as new participants to complete the 2016 survey. Of the total 2016 survey population, 232 (59%) participants were included in analyses because they avoided either gluten, nuts or milk when eating out.

### Online survey

Participants completed a screening questionnaire to ensure that they met the minimum requirements for inclusion in the study. The inclusion criteria were that participants aged over 18, or their child in the case of parents/caregivers: a) experienced reactions to one or more of the 14 allergens covered by the EU FIC legislation; b) ate out at, or ordered takeaway food from a restaurant, café, coffee shop, fast food outlet, or any other place where they can buy non-prepacked food; c) sought to avoid one or more of the 14 allergens covered by the

EU FIC legislation when eating out or ordering takeaway food; d) experienced one or more symptoms typically associated with IgE-mediated food allergy or non-IgE-mediated reactions (classified as food intolerance in this study). Survey results for participants seeking to avoid nuts (tree nuts and peanuts), gluten or milk are reported. Classification criteria are shown in Table 1.

### Survey content

We designed an online survey relating to attitudes and behaviours when eating out specifically for the study. Survey design was informed by a literature review, discussions with support groups and interviews conducted in 2014, prior to EU FIC legislation [2]. Interviews were coded and analysed using the framework approach. Themes derived from these interviews were used as the basis for survey items, which were worded and sense-checked by the research team before being piloted with a small sample ( $n = 20$ ) of participants. Survey subscales included: 'Reliance on speaking to staff'; 'Satisfaction with written information'; 'Staff as an additional information source'; 'Preference for separate allergen menu'; and two single items-'Menu invites you to ask staff' and 'Sign invites you to ask staff'. All 2014 survey items were retained in the 2016 survey. Full details of subscale items and item reversals are shown in Table 2.

### Procedure

Following provision of informed consent, participants meeting the inclusion criteria were routed to the survey for completion.

### Data analyses

Statistical analyses were carried out using IBM SPSS Statistics (v22). Data was screened to ensure no violation of the assumptions of normality, linearity, and homoscedasticity. The extent of missing data (less than 2%) and non-response patterns were assessed to see if missing items would impact on analyses (Little's MCAR test ( $p > .05$ )). Missing values for items within subscales were imputed using expectation-maximization (EM) [29] and subscale reliabilities were calculated. Differences between

allergen groups (gluten, nuts or milk) were analysed using mixed ANOVAs including 'Adult/Parent', 'food allergy/intolerance' as independent variables (IVs), and the four eating out subscales and two single-item questions as outcome variables. Post hoc analyses was carried out using Bonferroni procedure. A post hoc cut-off of  $p \leq .05$  was used, although post hoc tests approaching significance ( $p = .051 - p = .056$ ) are also reported.

### In-depth interviews

#### Recruitment and population

Full details of 2014 interview recruitment procedure, populations and results are reported elsewhere [2]. Of the 57 participants who completed interviews between June and July 2016, all had been recruited through a professional research agency (as above) and had completed previous interviews in 2014. Of the total interview population in 2016, 49 (86%) participants were included in analyses because they avoided gluten, nuts and/or milk when eating out.

#### Procedure

In-depth semi-structured interviews were carried out in participants' homes following an interview protocol detailing questions and possible prompts (a copy of this interview protocol can be provided on request from the corresponding author). Each interview was audio-recorded with participants' permission. Initial questions related to any changes that had occurred in returning participants' lives; and in relation to their food allergy in particular. The interview then focused on participants' recent eating out experiences and any changes in these, including their encounters with information about food allergens. They were asked for their reflections and evaluations of these changes, and about the impact of the legislation on allergen information provision in relation to their eating out experiences. Interviews lasted between 27 and 76 min.

#### Analyses

Interview recordings were transcribed verbatim and explored in detail using framework analysis [30]. Interviews

**Table 1** Allergy or intolerance classification criteria and allergy severity classification criteria

Classification	Symptoms	Severity
ALLERGY: Symptoms associated with IgE-mediated reactions	'Stinging nettle' rash, urticaria, hives, Itching or swelling of the lips, tongue or mouth, asthma, wheezing, facial swelling (does not experience 'severe' symptoms)	MILD/MODERATE (Does not include 'severe' symptoms)
	Breathing difficulties, anaphylaxis, collapse (May additionally include symptoms associated with non-IgE-mediated reactions)	SEVERE (May additionally include 'mild/moderate' symptoms)
INTOLERANCE: Symptoms associated with non-IgE-mediated reactions	Vomiting, Diarrhoea, Sneezing, Catarrh, Hyperactivity, Tiredness, Stomach cramps, Other digestive problems (e.g. bloating, constipation), Eczema flare, Migraines/headaches, Aching joints/muscles, Behavioural/mood changes (Does not include symptoms associated with IgE-mediated reactions)	

**Table 2** Details of survey subscales

Survey subscale	Survey item <sup>a</sup> (R) = Reverse scored	Response scale	Cronbach's alpha
Reliance on speaking to staff	- I am happy to ask serving staff about allergens in the food they are serving - I ask to speak to the manager if I want more information about allergens in the dishes - I ask to speak to the chef if I want more information about the meal being cooked for me - I don't like asking staff questions about allergens (R) - I feel awkward and embarrassed to ask staff questions about the food they are serving (R)	0 → 6 Never → Always	.685
Satisfaction with written information	- Menu information online (R) - The menu displayed outside the place (R) - The menu displayed at the counter (R) - The menu at the Table (R) - Phone apps (R) - Information folder about ingredients of foods being served (R)	1 → 5 Very satisfied → Very dissatisfied	.827
Staff as an additional information source	- Even if there was information about allergens on the menu I would like to ask a member of staff about the dish (R) - No matter how good the written information is I would prefer to talk to staff (R)	1 → 5 Strongly agree → Strongly disagree	.834
Preference for a separate allergen menu	- I would like to see separate menus for people with particular food intolerance or allergies. (R) - I want to know from the menu how the food is cooked not just what is in it (R) - It is reasonable to expect that there are separate menus to help people avoid particular allergens (R)	1 → 5 Strongly agree → Strongly disagree	.730
Menu invites you to ask staff about allergens	- I like it when it says in the menu that they welcome customers with allergies and intolerances asking about dishes (R)	1 → 5 Strongly agree → Strongly disagree	Single item
Sign invites you to ask staff about allergens	- I like it when there is a sign up that says that they welcome customers with allergies and intolerances asking about dishes (R)	1 → 5 Strongly agree → Strongly disagree	Single item

<sup>a</sup>Survey items were not subject to factor analysis

were coded and analysed using QSR-NVivo (version 10). Identified themes are illustrated in results. In order to maintain anonymity, participant details are indicated in brackets as follows: A/P refers to Adult/Parent; participant number; and reported food allergens. Italicised text within quotes reflects interviewer prompts.

## Results

### Online survey

Characteristics of survey participants are shown in Table 3 (further demographic details are shown in Additional file 1). Of the 392 participants who completed surveys, 232 (59%) avoided one of the target food allergens, either: gluten, nuts or milk. Participants who avoided more than one target food allergen ( $n = 121$ , 31%) and those who avoided an allergen other than gluten, nuts or milk ( $n = 39$ , 10%) were excluded from analyses.

Summarised in Table 4, the survey revealed significant differences in participants' perceptions of information provision depending on whether they wished to avoid gluten, nuts or milk when eating out. Unless otherwise stated, there were no interactions between 'allergen

avoided' and other IVs ('Food allergy/Food intolerance' or 'Adult/Parent') (all  $ps > .05$ ).

### Reliance on speaking to staff

There was a significant main effect of 'allergen' (gluten/nuts/milk) on participants' reliance on speaking to staff ( $p < .05$ ). Participants avoiding nuts reported a greater reliance on speaking to staff than those avoiding gluten ( $p = .019$ ), and those avoiding milk ( $p = .003$ ).

### Satisfaction with written information

There was a significant main effect of 'allergen' (gluten/nuts/milk) on participants' satisfaction with written information ( $p < .05$ ). Post hoc analysis approached significance ( $p = .053$ ) suggesting that those who avoided nuts were more satisfied that written information could aid confident food choices than those avoiding gluten.

### Staff as an additional information source

There was a significant main effect of 'allergen' (gluten/nuts/milk) on participants' preference for staff as an additional information source ( $p < .05$ ). Participants avoiding

**Table 3** Characteristics of survey population based on allergen avoided

Variable	Gluten (n = 66) n (%) or M (SD)	Nuts (n = 94) n (%) or M (SD)	Milk (n = 72) n (%) or M (SD)
Adult	56 (84.8)	40 (42.6)	39 (54.2)
Parent	10 (15.2)	54 (57.4)	33 (45.8)
Gender			
Adult/Parent			
Male	13 (19.7)	12 (12.8)	9 (12.5)
Female	53 (80.3)	81 (86.2)	61 (84.7)
Child <sup>a</sup>			
Male	4 (40.0)	32 (59.3)	19 (57.6)
Female	6 (60.0)	21 (38.9)	14 (42.4)
Age (yrs)			
Adult/Parent	41.2 (11.9)	39.6 (9.7)	37.6 (10.5)
Child	8.5 (3.8)	10.6 (4.2)	5.1 (3.8)
Food allergic	8 (12.1)	86 (91.5)	27 (37.5)
Food intolerant	58 (87.9)	8 (8.5)	45 (62.5)
Diagnosis			
Clinical diagnosis (by GP; Dietician or Allergy specialist at hospital)	47 (71.2)	84 (89.4)	44 (61.1)
Self diagnosis	19 (28.8)	10 (10.6)	28 (38.9)
Severity of reaction (FA only) <sup>b</sup>			
Mild/Moderate	5 (62.5)	28 (32.6)	23 (85.2)
Severe	3 (37.5)	58 (67.4)	4 (14.8)
Time since diagnosis (yrs)			
< 2	12 (18.2)	3 (3.2)	14 (19.2)
2–4	20 (30.3)	23 (24.5)	24 (33.3)
5–9	18 (27.3)	24 (25.5)	22 (30.6)
≥ 10	16 (24.2)	43 (45.7)	11 (15.3)
Treatment			
Avoidance	66 (100)	94 (100)	72 (100)
Antihistamines	4 (6.4)	67 (71.3)	15 (20.8)
Injectable adrenaline	1 (1.5)	66 (70.2)	2 (2.8)
Inhaler	1 (1.5)	33 (35.1)	10 (13.9)
Special diet	32 (48.5)	9 (9.6)	25 (34.7)
Support group membership	27 (40.9)	36 (38.3)	7 (9.7)

<sup>a</sup>Child % calculation based on total parent participants per allergen group

<sup>b</sup>Severity % calculation based on total FA participants per allergen group

Where % total < 100, there are missing values. Where % total > 100, participants could select multiple responses

nuts ( $p = .009$ ) and those avoiding gluten ( $p = .001$ ) both preferred staff as an additional source of information in comparison to those avoiding milk.

#### **Preference for separate allergen menu**

There was a significant main effect of ‘allergen’ (gluten/nuts/milk) on participants’ preference for a separate allergen menu ( $p < .01$ ). Participants avoiding nuts ( $p = .007$ )

and those avoiding gluten ( $p = .001$ ) had greater preference for a separate allergen menu as a potential source of information than those avoiding milk.

#### **Menu invites you to ask staff**

There was a significant main effect of ‘allergen’ (gluten/nuts/milk) on participants’ perceptions of a statement on the menu inviting customers to ask staff about dishes ( $p < .05$ ). Participants avoiding nuts were more positive

**Table 4** Differences in perceptions of information provision for participants avoiding Gluten, Nuts and Milk following legislation<sup>a</sup>

Survey subscale	Gluten	Nuts		Milk		$\eta_p^2$	p
		Mean (SD)	df	F	df		
Reliance on speaking to staff	3.26 (1.25)	3.79 (1.27)	2, 220	3.15 (1.22)	4.20	.037	.016
Satisfaction with written information	3.30 (0.91)	3.59 (0.73)	2, 220	3.41 (0.73)	3.13	.028	.046
Staff as an additional information source	3.48 (1.29)	4.00 (1.02)	2, 220	3.10 (1.23)	4.13	.036	.017
Preference for separate allergen menu	4.11 (0.87)	3.93 (0.97)	2, 219	3.49 (0.99)	5.15	.045	.007
Menu invites you to ask staff about allergens	4.55 (0.79)	4.67 (0.67)	2, 218	4.33 (0.87)	3.53	.031	.031
Sign invites you to ask staff about allergens	4.59 (0.78)	4.60 (0.81)	2, 217	4.29 (0.94)	3.83	.034	.023

<sup>a</sup>Higher mean score indicates greater levels of agreement

about the menu inviting customers to ask about dishes than those avoiding milk ( $p = .016$ ).

#### **Sign invites you to ask staff**

There was a significant main effect of ‘allergen’ (gluten/nuts/milk) on participants’ perceptions of a sign inviting customers to ask staff about dishes ( $p < .05$ ). Post hoc analysis approached significance ( $p = .056$ ) suggesting that those avoiding nuts were more positive about the sign inviting customers to ask about dishes than those avoiding milk.

#### **In-depth interviews**

Characteristics of interview participants are shown in Table 5. Of the 57 participants who completed interviews in 2016, 49 (86%) avoided gluten, nuts and/or milk. Participants who avoided an allergen other than gluten, nuts or milk ( $n = 8$ , 14%) were excluded from analyses.

Following implementation of the legislation, three overall themes were described by participants in relation to their observations and experiences of allergen information provision when eating out. Participant responses focused on management of their FA/FI when eating out and related to: ‘disparities in allergen information provision’, ‘understanding the needs of customers avoiding different allergens’, and ‘customer demand for information about specific allergens’.

#### **Disparities in allergen information provision**

Following implementation EU FIC, the majority of participants had observed general improvements in the provision of allergen information when eating out; though they noted that these improvements were largely focused on the provision of information for customers seeking to avoid nuts or gluten. For many participants, a disparity in allergen-specific information was observed, regardless of the allergen that they themselves sought to avoid (Table 6: quote 1).

For participants seeking to avoid gluten, the separate ‘gluten-free’ menu was seen as a gold standard which was becoming increasingly available. In the absence of this provision, the use of a symbol or letter displayed beside each dish on the main menu served as a simple and

trusted indicator which facilitated food choices (Table 6: quote 2). Similarly, for participants seeking to avoid nuts, the display of a symbol or letter ‘N’ beside menu items had become widespread, and enabled them to make independent food choices without the need to involve staff in their decision-making process. (Table 6: quote 3).

Participants seeking to avoid milk had also observed the improvements in information provision for those avoiding nuts or gluten, but had not seen similar improvements in relation to their own dietary needs. These participants were impressed by the gluten-free provision that was now available, and wished that similar information was available for milk-free diets (Table 6: quote 4). They also noted that diets which might be deemed ‘lifestyle choices’ were also catered for, whilst their need for information about the milk content of foods remained largely neglected and misunderstood (Table 6: quotes 4 & 5); a scenario that they felt could be resolved with little effort on the part of eating out venues (Table 6: quote 6).

#### **Understanding the needs of customers avoiding different allergens**

Many participants seeking to avoid milk felt that their dietary needs were not well understood, and that this in turn might be leading to a lack of appropriate allergen information provision in eating out environments. Participants noted that many eating out staff failed to understand their need for avoidance of milk as a ‘hidden ingredient’ within many dishes. In the absence of tangible written allergen information, participants used subtle social cues to detect misunderstanding on the part of venue staff (Table 7: quote 1), and often interpreted these cues as a more generalised indicator that their needs were underestimated or undervalued (Table 7: quote 2).

For participants seeking to avoid gluten, the issue of gluten as a ‘hidden ingredient’ coupled with indicators of confusion exhibited by venue staff had been experienced in the past, and were now less common in light of increased staff awareness and improved information provision (Table 7: quote 3). These improvements, whilst welcomed, did not guarantee a gluten-free eating out experience however. A minority of participants expressed concern that the

**Table 5** Characteristics of interview population based on allergen avoided

Variable	Gluten (n = 13) n (%) or M (SD)	Nuts (n = 14) n (%) or M (SD)	Milk (n = 13) n (%) or M (SD)	Multiple <sup>a</sup> (n = 9) n (%) or M (SD)
Adult	12 (92.3)	11 (78.6)	8 (61.5)	9 (100)
Parent	1 (7.7)	3 (21.4)	5 (38.5)	0
Gender				
Adult/Parent				
Male	1 (7.7)	5 (34.7)	4 (30.8)	1 (11.1)
Female	12 (92.3)	9 (64.3)	9 (69.2)	8 (88.9)
Child <sup>a</sup>				
Male	0	2 (66.7)	2 (40.0)	0
Female	1 (100)	1 (33.3)	3 (60.0)	0
Age (yrs)				
Adult/Parent	37.5 (18.0)	38.9 (15.2)	43.1 (10.8)	39.78 (13.3)
Child <sup>b</sup> < 10	0	0	1 (20.0)	0
10–14	0	2 (66.7)	0	0
> 14	1 (100)	1 (33.3)	4 (80.0)	0
Food allergic	1 (7.7)	14 (100)	2 (15.4)	5 (55.6)
Food intolerant	12 (92.3)	0	11 (84.6)	4 (44.4)
Diagnosis				
Clinical diagnosis (by GP, Dietician or Allergy specialist at hospital)	10 (76.9)	13 (92.9)	7 (53.8)	3
Self diagnosis	3 (23.1)	1 (7.1)	6 (46.2)	2
Severity of reaction (FA only) <sup>c</sup>				
Mild/Moderate	1 (100)	7 (50.0)	2 (100)	3 (60.0)
Severe	0	7 (50.0)	0	2 (40.0)
Time since diagnosis (yrs)				
< 3	0	1 (7.1)	0	0
3–7	8 (61.5)	3 (21.4)	5 (38.5)	4 (44.4)
≥ 7	5 (38.5)	10 (71.4)	8 (61.5)	1 (11.1)
Treatment				
Avoidance	13 (100)	14 (100)	13 (100)	9 (100)
Antihistamines	2 (15.4)	7 (50.0)	3 (23.1)	3 (33.3)
Injectable adrenaline	1 (7.7)	7 (50.0)	0	1 (11.1)
Inhaler	0	4 (28.6)	0	0
Special diet	8 (61.5)	2 (14.3)	5 (38.5)	1 (11.1)
Support group membership	2 (15.4)	3 (21.4)	0	2 (22.2)

<sup>a</sup>Two or more target allergens avoided- e.g. gluten and milk

<sup>b</sup>Child % calculation based on total parent participants per allergen group

<sup>c</sup>Severity % calculation based on total FA participants per allergen group

Where % total > 100, participants could select multiple responses. Where % total < 100, there are missing values

popularity of gluten-free diets as a 'lifestyle choice' had undermined staff perceptions of the importance of gluten avoidance for those with the medical need to remain gluten-free (Table 7: quote 4). Similarly for those seeking to avoid nuts, whilst improvements in information provision were appreciated, the risk of cross-contamination and potential for staff underestimation of that risk undermined

their confidence in ensuring an nut-free eating out experience (Table 7: quote 5).

#### Customer demand for information about specific allergens

One participant, who worked in an eating out venue, provided insights into the relative frequency of customer

**Table 6** Disparities in the provision of allergen information

1)	'I've definitely seen it [allergen information] a lot more about. It's kinda really visible in a lot of places which is alright... I think it is just a few of them [allergens]... Just nuts and gluten.' (A32, FI: Gluten)
2)	'... they have an entirely separate menu so I feel very comfortable going there... my preference is a separate gluten free menu but I realise it's probably unrealistic to expect everywhere to do that so I guess, if I'm going into a place I know doesn't have a gluten free menu it just makes things 10 times easier if they've got a little symbol... the little symbols and then a key under every dish. Just printed those symbols and then it's done, easy.' (A13, FI: Gluten)
3)	'... going out it normally says on the menu now. It will have a little 'N' next to it or something... <i>Is that a new thing?</i> It's getting better since I last saw you. Most places do it now and they do it for gluten free and things... It will say if it's got nuts in. It makes it easier for them because they're not having to answer your questions all the time. You can read the menu and say "that has got nuts in".' (A58, FA: Peanuts & tree nuts)
4)	'In my experience it's [the legislation] been ineffective for his condition and I have actually been in a restaurant with a friend that was presented with a gluten free menu for breakfast and I was so impressed that they could do that with the gluten free but [it] wasn't available for dairy- and in fact the same restaurant was able to present a different menu for [healthy weight loss] diets which I thought was amazing- that they could go to that effort but yet it wasn't available for something that seems to effect a lot of people.' (P7, FI: Milk)
5)	'... mainly vegetarian and vegan, yep, and gluten free and they were the main ones. <i>But not dairy?</i> Not dairy, nothing. I haven't come across a single place that talks about dairy free. But I think it's because it's not very well understood.' (A51, FI: Milk)
6)	'On the menu where you see the 'V' or the 'G' and all that business, to have a 'D' for dairy so that covers any type of dairy then at least you could say, actually for me, I would rule it all out...' (A44, FI: Milk)

enquiries about the allergens. They noted that such enquiries were infrequent; relating to the gluten and nuts, but not to the milk content of foods (Table 8: quote 1). Participants who sought to avoid milk speculated that their own lack of communication with staff might imply to food businesses that there was little demand for the provision of milk-related allergen information (Table 8: quote 2 & 3). Participants compared the relative impact of their milk-related symptoms with those who experience life-threatening reactions to nuts. Whilst they wished that eating out venues could appreciate the discomfort that they experienced due to accidental allergen consumption (Table 8: quote 4 & 5), they equally tended to underplay such reactions and often failed to inform the eating out venue that a problem had occurred.

## Discussion

Using a mixed methods approach, this study indicates that the eating out experiences of consumers with FA/FI

differ depending on the food allergen that they are seeking to avoid, and that allergen-based inequities in information provision are impacting on some consumers with FA/FI following the introduction of EU FIC legislation in December 2014. Specifically, not only do those avoiding milk have less positive experiences, but in addition they perceive that the provision made for those avoiding other allergens tends to be better. Participants seeking to avoid milk had also observed the improvements in information provision for those avoiding nuts or gluten, but had not seen similar improvements in relation to their own dietary needs. They noted that many staff in eating out venues failed to understand their need for avoidance of milk as a 'hidden ingredient' within many dishes.

In general, survey participants reported being moderately satisfied with the availability and adequacy of allergen information provision when eating out, and interview participants suggested that this provision was an improvement on the allergen information made available prior to EU

**Table 7** Understanding the needs of customers avoiding different allergen

1)	'... there's so many different things it [milk] could be in so that's why I think people who work in restaurants and cafes they just sort of panic and don't fully understand... they just assume dairy for me is cheese or butter or it's got cream on it. Well no, it's not the cream I'm talking about, I'm talking about the content in the scone for example or in the cake.' (A44, FA: Milk)
2)	'I just feel that actually some people don't feel like it's actually worthy of a restaurant going out of your way for it. I still don't feel comfortable, I still don't think [milk allergy/intolerance is] an acceptable thing to legitimately have. <i>You think there's a stigma attached?</i> Yeah, I still think people have.' (A51, FI: Milk)
3)	'When I used to say coeliac or gluten free they would look at you a bit... now I think staff are more totally up on it. So I think in the majority of places they are told about it, I mean obviously there is nut allergies and things, but nut allergy is quite obvious, it's nuts. When you say gluten they think "well" you know "what's that in?"... unless you've come across it, I would have been the same. But I have found it much better.' (A57, FI: Gluten)
4)	'... things have changed and got better yet I've still had reactions- and of course with the growing increase of "fad diets" there is always the risk that you're not taken seriously and you know, yeah great, "gluten free" is getting awareness these days but it's about whether it's the "right type", or whether people just think it's... you have to be taken quite seriously as a coeliac sufferer and I don't think we are anymore. So it's kind of swings and roundabouts.' (A13, FI: Gluten)
5)	'I think what the problem is particularly with the nuts is that there are so many things made without nuts and get cross contaminated, so they tend to see it as not as problematic as someone who is coeliac. I think they look at it as "oh you've got a nut allergy", yes. I think there are places that don't tend to think it's serious.' (P2, FA: Peanuts, Tree nuts)

**Table 8** Customer demand for information about specific allergens

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1)	'... out of interest what are the sort of allergies and intolerances that you hear more of, most of? Gluten, nuts and seafood. Okay right and very often? No, not often at all actually. Like a lot, gluten more than anything... Nuts maybe four or five times in a year, yeah not often at all. I don't know whether it's not that common, or people just don't mention it and seafood maybe once or twice a year to be fair, not often at all.' (A59, FA: Peanuts, Tree nuts)
2)	'... I think there aren't enough people who are lactose intolerant for companies to see it as viable. Or enough people to make a fuss. So I'm part of the problem I think. There aren't enough people making a fuss about it because of people not wanting to make it a big thing so companies don't have to make a big deal about it, but if everyone who had slight lactose intolerance... pushed in restaurants I think there would be a bigger appeal for it. We are part of the problem.' (A51, FI: Milk)
3)	'Well, if everywhere could do soya milk that would be excellent, or start having optional lactose or dairy free cheese as options rather than having to not have anything that's a milk product but I don't know if there's an economic imperative for shops. If there'd be enough customers who would be interested in that, there might be. There might be plenty of people who are just avoiding these things who would buy them if they knew that they could have nachos with lactose free cheddar, then they would but I suppose until they try that they don't know.' (A10, FI: Milk)
4)	'Nut allergies I think prevail a lot. I think they are aware of nut allergies... I don't think they think anything else is... it's a killer, do you know what I mean? But I'm not going to die eating a sandwich, but I can be in pain for hours and it can have a massive effect, because you can't do anything.' (A34, FI: Gluten, Milk)
5)	'... it's not life threatening like if I had nut [allergy] or anything like that. So, I just know that night I'm going to suffer... I think if I was nut intolerant I would be very... but because it's not life threatening I think I tend to put up with it and think "I won't have that again".' (A45, FA: Milk)

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FIC. However, satisfaction levels and perceived improvements in provision differed depending on whether participants sought to avoid gluten, nuts, or milk as ingredients in foods. Amongst survey participants, those seeking to avoid milk were less satisfied with the information provided for their specific dietary needs in comparison to participants avoiding nuts, and to a lesser degree those avoiding gluten. In particular, they were less likely to involve staff in their deliberations about the potential for allergen free meal options- either by asking staff directly about the allergen content of foods or as an additional information resource following inspection of the menu. They were also less likely to take a positive view of written statements inviting customers to 'ask staff'. Although this is in part unsurprising given that research prior to the implementation of EU FIC indicated that consumers with FA/FI were often reluctant to make enquiries of staff [2], crucially, such reluctance was similar across allergen groups at this earlier time-point. Prior to the legislation, there were no differences between gluten, nut or milk avoiding participants in relation to their satisfaction with the information provided for specific dietary needs or their likelihood to involve staff in deliberations about allergen-free meal options [27, 31] (see also Additional file 2). Therefore, findings suggest that these differences have arisen since the legislation.

Under the themes 'disparities in allergen information provision', 'understanding the needs of customers avoiding different allergens', and 'customer demand for information about specific allergens', in-depth interviews provided insights into the potential reasoning behind participant survey responses. Whilst participants seeking to avoid gluten and nuts reported improvements in written allergen information provision when eating out, those seeking to avoid milk observed no such improvements. It is likely that this post-legislative disparity

between groups created feelings of inequity of provision that did not exist prior to the legislation's implementation, thus fragmenting allergen avoiding populations. This is an important consideration for eating out venues given that consumers with FA/FI tend to equate the adequacy of allergen information provision with wider judgements about the venue's 'understanding', 'allergen-awareness' and 'capacity' to accommodate specific dietary needs safely [2]. For participants seeking to avoid milk, an absence of relevant allergen information suggested a lack of understanding on the part of eating out venues and their staff. These participants were less likely to trust staff as an information source, and were potentially less likely to patronise such venues as a result. Furthermore, as noted in previous research consumers with FA/FI attempt to balance their need for allergen avoidance, with their wish to avoid being seen as 'making a fuss' and creating 'misunderstanding' [32, 33]. For those seeking to avoid milk, insufficient allergen information provision suggested that asking staff might indeed lead to misunderstanding and potential social embarrassment. They were less willing to speak to staff about their dietary requirements, and more likely to expose themselves to the risk of accidental allergen consumption as a consequence.

The perceived understanding of the needs of some consumers with FA/FI (nuts and gluten) in comparison to others (milk), led participants seeking to avoid milk to conclude that the implications of their accidental allergen consumption were taken less seriously, and their concerns seen as less legitimate than other allergen-avoiding groups. This distinction has been observed in FA and FI populations, where FI can be viewed as more 'socially problematic' than FA, due to the ambiguity of FI symptoms and diagnosis when compared to FA [34]. Some of

our participants who sought to avoid milk due to lactose intolerance perceived that there was 'stigma' attached to the condition and recognised that their own reticence in speaking to staff due to concerns about being seen as 'making a fuss' might in turn be viewed as a lack of 'demand' for milk allergen information provision on the part of eating out venues.

Equally, it is important for eating out venues to consider the implications of accidental allergen consumption for customers with severe FA to milk. Whilst FA to peanuts/tree nuts is more common, and the potential for anaphylaxis amongst this population more widely understood, cow's milk is the most common cause of anaphylaxis amongst UK children [5] and persistence of milk FA into adulthood is associated with greater risk of severe reactions [35].

### Implications

This study is the first to provide insight into the perceived differences in allergen information provision for particular allergens, and most importantly, the difficulties that consumers with FA/FI report when seeking to avoid milk whilst eating outside the home.

Alongside their legal responsibilities to provide allergen information for consumers as a result of EU FIC, it is important that eating out providers understand that FA/FI customers are sensitive to inequities in allergen information provision and interpret these as a wider indicator of customer care and food safety in venues. Any such inequities are likely to be magnified for FA/FI customers who seek to avoid 'staple foods' (milk, wheat, eggs) which are ubiquitous in the western diet and more difficult to avoid as a result [21–23]. An absence of customer enquiries about particular allergens- in this case milk - should not be interpreted as a lack of demand for information about the allergen, and participants felt that venues can usefully convey their willingness and ability to accommodate these customers using simple, visible visual indicators such as letters/symbols on the menu. Increased staff allergen awareness training [36] and effective communication systems between food preparation and serving areas [2] will help to ensure that FA/FI customers feel more confident and secure in their food choices when eating out; regardless of the allergen that they are seeking to avoid. Normalising the notion that customers are able and entitled to make their allergen requirements known may be particularly helpful. For example, serving staff could take a proactive approach at the table, by enquiring as to whether customers have any specific dietary requirements [2]. They should be particularly aware that those seeking to avoid milk may be less confident in the ability of the venue to provide a meal without the presence of this allergen.

Health professionals (allergists, dieticians, general practitioners), support groups and charities have important contributions to make by educating and encouraging their FA/FI patients- and those avoiding milk in particular - to be confident in requesting and expecting the provision of allergen information when eating out, as they are entitled to do since the introduction of EU FIC. Patients can also be encouraged to use proactive techniques such as informing eating out venues in advance [15] or carrying an allergy/coeliac information card [37] in order to ameliorate their fears of embarrassment in the inherently social setting of the eating out environment.

### Limitations

Participants self-reported their FA/FI status, and a minority were self-diagnosed alongside those who reported receiving a clinical diagnosis. Entry to the study was through the careful application of symptom-based FA/FI criteria although we recognise it is unlikely that classification of patients as FA or FI would accord with a medical diagnosis. However, our approach of making the distinction between populations based on the allergen that they were seeking to avoid rather than between FA and FI renders this limitation as less problematic. Our approach allowed us to highlight the common difficulties experienced by milk avoiding FA/FI participants, and these difficulties were particularly salient given that no allergen-based differences between FA and FI populations were shown in analyses. Furthermore, in the context of eating out, the distinction between FA and FI becomes less relevant because the legal requirement for venues to provide allergen information applies for all customers and is not contingent on their FA/FI status.

We also acknowledge that we took a conservative approach in survey analyses. In order to ensure that responses were attributable to each particular allergen avoided, we only included participants who avoided either gluten or nuts or milk and did not include those who reported avoiding multiple allergens. It is likely that participants who sought to avoid multiple allergens experienced greater difficulties when eating out [11]. Lastly, we recognise that we were unable to include other allergens in our analyses due to insufficient participant numbers. It is possible that populations seeking to avoid different allergens- and in particular those seeking to avoid eggs which are also a 'staple food' [21–23] - would have reported inequities in allergen information provision akin to those reported for milk allergen in this study. Possible limitations to generalisability of the survey results should be borne in mind in the light of these issues.

### Conclusion

A mixed methods approach was valuable in exploring the experiences of those seeking to avoid gluten, milk and

nuts when eating out. Through the application of surveys and interviews, FA/FI participants reported that there were general improvements in allergen information provision in eating out venues following introduction of EU FIC legislation. However, inequities in the provision of allergen information for particular allergens (gluten, nuts, milk) led participants seeking to avoid milk to conclude that their dietary needs were less well-understood and seen as less important. These perceptions were reflected in a reluctance to involve eating out venue staff in deliberations about the potential for allergen free meal options, and limited the food choices of those seeking to avoid milk as a result. The provision of visible visual indicators on menus of the presence of milk and increased allergen-awareness training for staff can play a key role in increasing confidence in the eating out venues and improve the eating out experience of customers seeking to avoid milk. Medical professionals also have a key role to play in educating and encouraging their FA/FI patients to pursue their legal right to make allergen enquiries in order to avoid accidental milk allergen consumption when eating out.

## Additional files

**Additional file 1:** Further demographic and background characteristics of survey participants, Description of data: Further demographic and background characteristics of survey participants. (DOCX 14 kb)

**Additional file 2:** Perceptions of information provision for participants avoiding Gluten ( $n = 149$ ), Nuts ( $n = 272$ ) and Milk ( $n = 77$ ) prior to legislation, Description of data: Perceptions of information provision for participants avoiding Gluten ( $n = 149$ ), Nuts ( $n = 272$ ) and Milk ( $n = 77$ ) prior to legislation. (DOCX 14 kb)

## Abbreviations

FA: Food Allergy; FI: Food Intolerance

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## Availability of data and materials

Interview and survey data on which the conclusions of the manuscript rely are presented in the main paper. Full interview transcripts and survey data are available from the corresponding author on reasonable request.

## Authors' contributions

MHG provided advice as an allergic consumer to the project throughout. JSL provided clinical expertise as an allergist to the project throughout. MHG, JSL contributed to reviewing and commenting on early drafts of the paper. JB, MHG, JSL conceived and designed the project. FMB, JB analysed the data. JB, FMB wrote the paper. All authors read and approved the final manuscript, and agreed to be accountable for all aspects of the work.

## Ethics approval and consent to participate

Ethical approval was gained from the University of Bath, Department of Psychology Ethics Committee (Ethical Approval Ref: 14–055/16–146). All participants were fully briefed about the nature of the study and their rights as participants before providing written informed consent prior to interview.

## Consent for publication

Not applicable.

## Competing interests

JB, FMB, MHG & JSL declare no competing interests.

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RESEARCH ARTICLE

# Consumer Preferences for Written and Oral Information about Allergens When Eating Out

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## Abstract

### Background

Avoiding food allergens when eating outside the home presents particular difficulties for food allergic (FA) and intolerant (FI) consumers and a lack of allergen information in restaurants and takeaways causes unnecessary restrictions. Across Europe, legislation effective from December 2014, aims to improve allergen information by requiring providers of non-prepacked foods to supply information related to allergen content within their foods.

### Methods

Using in-depth interviews with 60 FA/FI adults and 15 parents/carers of FA/FI children, we aimed to identify FA/FI consumers' preferences for written and/or verbal allergen information when eating out or ordering takeaway food.

### Results

A complex and dynamic set of preferences and practices for written and verbal allergen information was identified. Overwhelmingly, written information was favoured in the first instance, but credible personal/verbal communication was highly valued and essential to a good eating out experience. Adequate written information facilitated implicit trust in subsequent verbal information. Where written information was limited, FA/FIs depended on social cues to assess the reliability of verbal information resources, and defaulted to tried and tested allergen avoidance strategies when these were deemed unreliable.

### Conclusion

Understanding the subtle negotiations and difficulties encountered by FA/FIs when eating out can serve as a guide for legislators and food providers; by encouraging provision of clear written and verbal allergen information, and training of proactive, allergen-aware staff. This, in tandem with legal requirements for allergen information provision, paves the way for

consultancy funded by the FSA through subcontract to collect the interview data. The specific roles of this author are articulated in the author contributions section. The research based at University of Southampton was further supported by The Asthma, Allergy and Inflammation Research Charity (AAIR).

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FA/FIs to feel more confident in eating out choices; and to experience improved eating out experiences.

## Introduction

For individuals who experience food allergy (FA) and food intolerance (FI) avoidance of allergens is the key recommended strategy in preventing negative health outcomes. Accidental allergen ingestion is potentially life threatening for many FA individuals [1, 2], and can account for a substantial number of 'healthy' days lost in FA/FI populations [3]. Twenty-one to 31% of such accidental allergen ingestion occurs when eating in restaurants and 13–23% occurs in other eating out environments such as work or school canteens [4]. As a result, eating out presents a particular challenge for FA/FI individuals, and is a broader public health concern for legislators, food providers, and the wider community as a whole.

In order to improve the provision of food allergen information for FA/FI consumers when eating out, Europe wide EU legislation was introduced in December 2014. This requires providers of non-prepacked foods to supply written and verbal information related to the content of one or more of 14 specified food allergens within their foods. Within the UK, the Food Standards Agency (FSA) has provided guidance on how allergen information might be provided [5]. However, the guidance regarding the format for delivery of this information is broad and at the discretion of individual eating out providers. Little is known about the preferences for such information provision from FA/FI populations' perspectives. Understanding these perspectives prior to the legislation's introduction was vital in order to provide legislators and eating out providers with insights into FA/FI's information delivery preferences; thereby informing initial and ongoing implementation of improvements in allergen information provision for the benefit of FA/FI consumers.

We explored the allergen-related information delivery preferences of FA/FI populations when eating out or ordering takeaway foods. Results serve to inform legislators in their future recommendations for allergen information provision, and act as a guide of 'good practice' for food providers who are required to supply food allergen information for FA/FI consumers.

## Background

Within Europe, FA affects up to 5% of adults and 8% of children [6], and the prevalence of FI is thought to be substantially greater [7, 8]. For FAs, accidental consumption of food allergens accounts for 32.2% of anaphylaxis-related hospital admissions [9], and eating outside the home has been implicated in 50% of deaths related to food allergen consumption [10]. Whilst morbidity and mortality rates are generally low, symptom-based figures underestimate the ongoing impact of food allergen avoidance on FA/FI individuals' well-being, and decrements in quality of life have been reported alongside significant restrictions in social and behavioural outcomes for these populations [11–14].

The implications of having to exclude one or more foods from the diet can present wide-ranging and unique challenges for FA and FI populations. FA populations describe the need for constant vigilance, with no guarantee that their efforts will be effective in ensuring successful avoidance of the offending food. This has been termed 'trying to control the uncontrollable' [15](p. 284). Both FA and FI consumers express concerns regarding the risks posed when consuming foods which they have not prepared; and eating out or ordering takeaway food in particular [16–19]. This apprehension may be justified given literature suggesting a mismatch

between restaurant staff's confidence in their knowledge of food allergens, and the knowledge actually exhibited in practice [20] [21].

EU legislation [22] introduced in December 2014 affects restaurants, takeaway shops, food stalls, institutions like prisons and nursing homes as well as workplace and school canteens. The regulations require food providers to supply customers with accurate and accessible information relating to the inclusion of any of the allergens—peanuts, tree nuts, milk, soya, mustard, lupin, eggs, fish, molluscs, crustaceans, cereals containing gluten, sesame seeds, celery, and sulphur dioxide at levels above 10mg/kg, or 10 mg/litre—in their foods. Allergen information can be provided in written or verbal form. Where verbal information is provided, there must also be written information within the venue that customers can be directed to.

Whilst the intention of the legislation is to provide FA/FI populations with clearer information regarding allergenic ingredients, little is known about how consumers prefer allergen information to be delivered when they eat out—through staff or through written sources of information—or what leads to trust or distrust in these sources. Findings from research into the labelling of pre-packed foods suggest that FA customers combine information seeking strategies by using allergen advice boxes in conjunction with ingredients lists and familiarity cues to minimise their risk of accidental allergen consumption [23]. When offered the option of an information resource in addition to packet labelling, FAs favoured a telephone advice line over an information website; perhaps suggesting that verbal information—though not face to face in this instance—has a particular role in generating trust [24]. The relationship between verbal and written information preferences becomes much more significant when eating out and consuming non-prepacked foods. Although in theory FA/FI individuals have the opportunity to discuss their dietary requirements with staff when eating out, communication difficulties are common; leading to social embarrassment, misunderstanding, and misinformation [16, 17]. This can lead FA/FIs to unduly limit their food selections, or to take unnecessary risks when eating out.

We aimed to understand the preferences and trust cues used by FA/FI individuals when eating out in order to inform the provision of allergen information resources and to outline the implications of this for legislators, food providers, and the wider community. Conducted in the 6 months immediately prior to implementation of EU FIC (1169/2011) legislation, our research is the first to assess the allergen information delivery preferences of both FA and FI populations when eating out; and in particular, their preferences for written and verbal information. This research constitutes phase 1 of the project and ongoing follow-up research will assess the impact of ongoing changes in allergen information provision on FA/FI's eating out preferences and behaviours.

## Methods

### Recruitment and population

Ethical approval was gained from the University of Bath, Department of Psychology Ethics Committee prior to participant recruitment (Ethical Approval Ref: 14–055). A specialist market research agency recruited 75 participants to complete in-depth interviews. Of the total population, 60 were adults reporting FA/FI, and 15 were parents/carers of children aged up to 17 years with FA/FI. Within the latter group, although the experience of parents/carers was the primary focus of the interview, their FA/FI children were sometimes present and contributed to it. In order to represent the views of consumers throughout the UK, participants were recruited from England, Wales, Scotland, and Northern Ireland. A breakdown of participant characteristics is shown in [Table 1](#).

**Table 1. Characteristics of the 75 food allergy/intolerance adult participants and children of parent/ carer participants.**

Variable	Allergy n = 39	Intolerance n = 36	Total (%) N = 75
Sex:			
Male	7 (17.9)	9 (25.0)	16 (21.3)
Female	32 (82.1)	27 (75.0)	59 (78.7)
Age:			
<8	2 (5.1)	2 (5.5)	4 (5.3)
8–12	3 (7.7)	0	3 (4.0)
13–17	4 (10.3)	4 (11.1)	8 (10.7)
18–30	9 (23.1)	8 (22.2)	17 (22.7)
31–45	10 (25.6)	8 (22.2)	18 (24.0)
46–60	5 (12.8)	9 (25.0)	14 (18.7)
60+	6 (15.4)	5 (13.9)	11 (14.7)
Region:			
England	15 (38.5)	17 (47.2)	32 (42.7)
N Ireland	4 (10.3)	6 (16.7)	10 (13.3)
Scotland	10 (25.6)	8 (22.2)	18 (24.0)
Wales	10 (25.6)	5 (13.9)	15 (20.0)

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Prior to interview, participants completed a screening questionnaire characterising their or (for parents) their child’s reactions to one or more of the 14 specified allergens. Characteristics were based on nature of reaction, speed of onset, and how FA/FI was diagnosed. This information was used to classify participants as IgE-mediated FA; or non IgE-mediated FA/FI which was either medically or non-medically/self-diagnosed. Thirty-nine participants (52%) were classified as having IgE-mediated FA, and thirty-six (48%) were classified as non IgE-mediated FA/FI. Of the 14 allergens covered by the legislation, FA/FI to peanuts, tree nuts, milk, soya, mustard, lupin, fish, crustaceans, cereals containing gluten, sesame seeds, celery, and/or sulphur dioxide were reported. No participants reported FA/FI to lupin or molluscs.

### Procedure

Following written informed consent, in-depth semi-structured interviews were carried out with participants in their own homes on the basis of an interview protocol detailing questions and possible prompts (a copy of this interview protocol can be provided on request from the corresponding author). Interviews were carried out by RP, JB, or DR, and each interview was audio-recorded with participants’ permission. Initial questions engaged participants with the topic of food and experiences relating to allergy/intolerance diagnoses, adaptation, and day-to-day coping strategies. The interview then focused on participants’ experiences and behaviours when eating out. Participants were encouraged to discuss strategies and environmental/social cues which influenced their decision-making processes; and to consider these preferences in relation to current and future information provision within the new legislation. Interviews lasted between 60–90 minutes.

### Analyses

In order to communicate the diversity of views and perspectives surrounding participants’ eating out experiences, interview recordings were transcribed verbatim and explored in detail using framework analysis [25]. Framework analysis has become popular in social, policy, and

health research because it applies a systematic approach to qualitative analysis which prioritises the transparency of the analytical process; thereby maximising accessibility and strengthening confidence in subsequent results and conclusions [26, 27]. Interviews were coded and analysed using QSR NVivo (version 10). Although participants were classified based on their, or (for parents) their child's, IgE-FA or non IgE-FA/FI status, interviews were analysed across the population as a whole. The analysis was led by FMB and refined and developed in discussion with JB.

Identified themes are illustrated in results. In order to maintain anonymity, participant details are indicated in brackets as follows: A/P refers to Adult/Parent; participant number; country of residence—E = England, S = Scotland, W = Wales and NI = Northern Ireland; and food allergens associated with FA/FI responses. Italicised text reflects interviewer prompts.

## Results

Participants described written food allergen information resources in terms of day to day 'use', the 'adequacy' of the information, and 'preferences' for information provision. Additional theme-based quotes are available in [S1 File](#).

### Use of written information resources

Where possible, participants preferred to rely on written information in preparation for, and during, their eating out experiences. For many, particularly in relation to unfamiliar venues, written information provided the first tangible point of contact on which to base their initial food choices. Preliminary enquiries were made using venue websites to explore food options ([Box 1A](#)); and checking recipes of potential meals on the internet ([Box 1B](#)). Before committing to dine in a venue, participants gathered information about their potential food options by inspecting menus displayed in the restaurant window ([Box 1C](#)). Within the eating out venue itself, participants emphasised the role of the menu in providing detail in relation to ingredients and preparation method ([Box 1D and 1E](#)), and additional sources of written information ([Box 1F](#)).

When written information, on menus in particular, was considered to provide adequate information about ingredients and food preparation, participants reported a sense of autonomy and control when making choices. In part, this normalised the process of their food selections by allowing participants to choose their meals without recourse to additional resources. This in turn gave them greater freedom and a sense of relaxation when eating out.

### Adequacy of written resources

Participants had mixed experiences in relation to the adequacy of written information resources and provided examples of good and poor practice. It was generally perceived that venues which provided more detailed allergen information would be more accommodating and caring towards FA/FI consumers ([Box 2A and 2B](#)). For some participants, the experience of poor written resources was variously a source of frustration, annoyance and anxiety; which potentially reduced their enjoyment in the entire eating out experience and caused them to avoid certain venues or eating out as a whole ([Box 2C and 2D](#)).

### Preferences regarding written information provision

Within the context of the new legislation and more generally, participants had clear, though varied ideas on how best to convey allergen information in a written /visual format. As a basic principle, the overwhelming majority of respondents believed that written information

### Box 1. Use of written information.

#### *Preparation for eating out:*

1. I'll look usually online—I thank God for the internet—at what their menu is. As I said, before we went to (European restaurant), I'd decided. . .I'd looked it up online and looked at their menu and gone, right, and I know I had a penne pasta dish. . .so I knew that one was going to be fine. (A14 G2 S: Milk)
2. If you're going in a few days, you can Google what the recipe is sort of thing, a rough guide, and you think, mm, that's okay, and then you just reiterate when you get there, right, I'm allergic to this. So, you know, it's just basically Googling things. . . (A39 G1 W: Peanuts, tree nuts, celery)
3. We look in the windows and we try and read, they'll put a sample menu or whatever, or outside and you try and read what kind of things are in there and if you can see that there is something that you think would be okay then it's worth a try. (P1 G1 E: Peanuts, tree nuts, milk)

#### *In the venue:*

1. . .I'd look at the menu. . . . I'd sort of look at the list, oh, yeah, I like that one, and then I'd look underneath, which would tell me the ingredients, most times, with most of them, and then I'd order it. (A6 G1 E: Peanuts, tree nuts, cereals containing gluten)
2. . .it's fine because it (the menu) normally gives me, 9 times out of 10, it will tell me what's in the food. So, if I go to a restaurant and there's a fish, it will tell me how. . .it will normally say "Cooked with a white wine sauce" or cooked with whatever. It'll say how it's served. (A23 G2 NI: Milk)
3. Well pizza (chain outlet) . . .have the thing on the menu that says if you want to make sure of anything else in the ingredients, take a picture of this QR code, and if you take a picture of the QR code, it takes you to (chain outlet's) website and you can check yourself. (A33 G1 S: Peanuts, fish)

regarding food allergen content in meals should be readily available. Ideally, information provision requiring minimal effort on the part of the consumer, whilst avoiding the potential risk of reliance on staff as intermediaries in information provision, was desired ([Box 3A](#)). Expectations regarding the levels of complexity and detail for that information differed however. Many advocated the use of abbreviations or symbols ([Box 3B and 3C](#)), or a simple notification inviting further enquiries ([Box 3D](#)); whilst others appreciated more detailed allergen information provided as a section within the menu or as a separate and comprehensive written resource ([Box 3E and 3F](#)).

Although many participants requested a more detailed menu, it was also recognised that the inclusion of such detail might pose practical problems for menu presentation and readability; particularly in the case of comprehensive ingredient lists within main menus. A minority of participants also raised concerns about their own ability to identify and recognise the relevant allergens listed ([Box 3G](#)). Similar reservations in relation to the use of abbreviations/symbols as a more simplified form of allergen warning were also highlighted. Although this was a preferred method of information delivery for many, a small number of respondents raised

## Box 2. Adequacy of written resources.

1. I think it was in (chain restaurant). . .they've just started doing a gluten-free burger. . .with a gluten-free bun, and they even said. . .we try our best to avoid cross-contamination. . . So, when they actually mention that, it's kind of reassuring that, oh, they actually know what they're doing. (A13 G2 W: Cereals containing gluten)
2. . . if it's clearly labelled and I don't have to be the one getting someone to search through a file or go and ask a chef. It makes a massive difference. You just feel comfortable. (A56 G1 E: Egg)
3. Very poor. . .I think they ought to provide more information. It's like they brought out that thing with calories now. They put the calories next to the menu, the meal. It's a good idea but they should do that for allergies as well. A lot of places don't do that. (P12 G2 W: Peanuts, tree nuts, milk)
4. British restaurants and those sorts of things, they just add wheat to absolutely everything, so it's impossible. . . Things like that really aggravate me, and you find, particularly in restaurants, like the list of ingredients, it's just not adequate. (A60 G1 E: Peanuts, tree nuts, cereals containing gluten)

questions relating to the consistent use of symbols across venues and countries, and the potential for confusion and accidental allergen ingestion that might result from the inconsistent application of symbols or abbreviated messages.

## Verbal information resources

As an inherently social experience, participants reported that the seeking of verbal information relating to food allergens within dishes varied based on their familiarity with the eating out venue. In regularly attended venues, where a successful track record of eating out had been established over time, participants valued the feelings of confidence and relaxation which resulted from their previous interactions with helpful and accommodating staff. In unfamiliar venues, where no such prior relationships had been established and written information was judged to be incomplete, participants used a number of cues to assess the reliability of the allergen information provided by staff. Primarily, participants based these assessments on staff knowledge and more subtle perceptions of staff interest, engagement and attitude with regard to their dietary needs. Where staff knowledge ([Box 4A and 4B](#)) and demeanour ([Box 4C and 4D](#)) were deemed to be good, trust and confidence in the safety of their meal was raised. Equally, the opposite was the case when knowledge ([Box 4E and 4F](#)) and demeanour ([Box 4G and 4H](#)) was deemed to be poor.

Participants identified other factors which inspired trust or served as barriers to their perceptions of staff members as reliable information resources. Younger staff members were viewed as inherently less reliable as information resources. This was largely due to an absence of life experience, and the potential for a lack of personal investment in their appointed roles. For some, this perceived lack of reliability did not necessarily lie with young frontline staff per se, but pointed instead to a potential systemic problem relating to eating out establishments as a whole. Better training was thought to hold the key to greater levels of trust and confidence in the information provided by staff.

### Box 3. Preferences for written information.

1. If you're going to be providing information, provide the information—don't make the customer go and ask for it. . . Human beings are human and they make mistakes. . . In a busy restaurant where people are talking to you, you know, you could be given the wrong information actually, so I would like that information provided in written form somehow. . . I wouldn't want to have to ask for it. (A52 G1 S: Tree nuts, cereals containing gluten)
2. . . they've got the "V" and the "N" on the menu, it would need to be a symbol-based thing, I think. . . . Because if you. . . had a particular allergy, you would just be scanning the menu for that particular symbol or letter or whatever it may be. I think that would be far more useful than having the huge long list of every ingredient. (A7 G1 E: Peanut, tree nuts)
3. All it's got to have is a GF next to it and I'm happy. Or even if it says 'not GF'. It would be better. . . I think that would be really, really useful, and if it doesn't do that then I feel like I'm a pain. (P5 G2 E: Cereals containing gluten)
4. . . if they just had a nice wee clear "We supply gluten-free" or "Ask our staff", you know, to provide a list. . . if you do have any form of intolerances, and we can leave any ingredients out or something. (A30 G3 NI: Cereals containing gluten)
5. . . the menu, that "Oh, we've got a gluten-free section," . . . that is something that they can start doing more, because some people may be embarrassed to talk about it and, you know, not. . . ask the question. (A4 G2 E: Cereals containing gluten)
6. . . they have the list on every single item in there—you know, dressings. . . sauces. . . all the allergy ingredients information, is listed on there. So. . . you know what you're getting and you know exactly what's in everything. . . and they update it as well. . . so that's brilliant. (A39 G1 W: Peanuts, tree nuts, celery)
7. I would prefer a simple description, but I have been in restaurants where. . . I'm not too sure what it means. . . They maybe list about six different ingredients and. . . I can recognise so many of them, and some of them, I'm not too sure about. (A20 G1 NI: Peanuts, tree nuts)

Whilst a minority of participants sought verbal information as a safety clarification in addition to written information resources, the majority reported a sense of reluctance and embarrassment when making enquiries of staff. Although asking questions of staff was seen as a necessity by many participants; for others the perceived embarrassment of asking staff for further information led to self-imposed limitations in food selections, or unnecessary risk taking.

## Discussion

Written information of sufficient quality was used as a baseline resource which liberated FA/FIs to make their food selections independently and without recourse to other information seeking strategies. Beyond the written resource itself, FA/FIs inferred a wider message of 'understanding' on the part of venues that provided adequate written allergen information, and were reassured by notices encouraging customers to ask staff about the allergen content of foods. This implied awareness gave FA/FIs permission to ask questions of staff with the

#### Box 4. Staff knowledge and demeanour.

1. The (Asian restaurant), as I said, they done gluten-free. They were able to offer an alternative to soy sauce and everything. So, she was able to say, 'Well, you can't have noodles but you can have rice noodles.' So, she was actually more knowledgeable than me on coeliac, so that was good. (A48 G2 S: Cereals containing gluten)
2. (Sandwich chain) are usually quite good because I . . . went to one a couple of years ago now, and I said, "Oh can I have that, but I'm allergic to cucumbers so you're going to have to completely. . ." you know, and she said, "Well, that's cut in the same machine, so you can't have that." So, they kind of know. . . what's cut what and what's doing what. So, (Sandwich chain) are quite good for knowing what's in the products and stuff. (A39 G1 W: Peanuts, tree nuts, celery)
3. You get some people that are quite perky and cheery and. . . Also, asking specifically as well. . . So, I'd say, like I might accidentally say "No milk" and they'd be like "Do you also not want cheese?" or "No prawns" and they're like, "Are you okay with..?" you know, this other thing. So, you know, you get some people that are quite on the ball in that sense. (A11 G1 S: Milk, Crustaceans)
4. . . if a waiter is really keen on like listening and just writing all the ingredients, just to make sure she speaks or he speaks to the chef. So, yeah, just basically communication and the way they treat those things. (A9 G1 E)
5. The trust is in the staff, to begin with. I mean, they're your first contact, aren't they? If they have knowledge of the food, then I'm quite confident. If they have no knowledge of the food, then I think I'm not coming here again. (A18 G3 E: Milk)
6. Some do say, "What do you mean, dairy, what do you mean?" and I say cream, cheese, milk, anything like that, and. . . what makes me laugh, people think I'm going to be allergic to mayonnaise because it's from the eggs, and. . . I said, "Actually, it's not dairy, even though it's from the hen, it's not dairy, it's not a cow. . ." (A26 G2 E: Milk)
7. There's been times in the past when I know. . . I can read people, and I know that they're thinking "Oh, for God's sake, this is a fad!" sort of thing, you know, and it's not good enough. (A18 G3 E: Milk)
8. I've had them just shrug their shoulders and say "I don't know." "Well, does the chef know?" "I don't think he will," you know, sort of thing. . . and you're thinking, you're joking. . .! (A53 G2 E: Cereals containing gluten)

expectation of an informed response; and without fear of embarrassment. At its best, accurate and trustworthy food allergen information delivered verbally by staff also enhanced FA/FI's eating out experience. Judgements regarding the potential for accidental exposure to food allergens were contingent on subtle social cues suggestive of staff knowledge; and were assessed by FA/FIs accordingly. Where doubts surrounding verbal allergen information occurred, FA/FIs retreated to their default position of reliance on written information resources, and in turn limited the potential variety of venues and food options available to them as a result. However, with adequate written allergen information, and the positive interactions of reliable allergen-aware staff; FA/FIs experienced an increase in trust and loyalty to eating out/takeaway venues concerned.

Fundamental to FA/FI's concerns surrounding allergen information provision when eating out, was the need for constant vigilance to ensure allergen avoidance, balanced against a wish to avoid 'drawing attention' [16]. EU FIC (1169/2011) legislation has the potential to address these issues by making the provision of food allergen information mandatory, thereby validating and normalising food allergies and intolerances. By empowering FA/FIs with the right to ask and expect adequate information provision, it is to be hoped that the latter fear of embarrassment and resultant social isolation will be reduced [14, 17].

Given that strict allergen avoidance is necessary for many FA/FIs [28, 18] and the risk of food allergen exposure when eating out is high [4], our research indicates that FA/FIs clearly have no coherent set of preferences for the delivery of allergen information within an eating out setting. At its best, legislators should aim to cater for this diversity of preferences by recommending a combination of written and face to face allergen information provision to accommodate the varying needs and preferences of FA/FI populations. Food providers can play a crucial role in meeting FA/FI's needs through the provision of clear written allergen information, increased allergen-awareness training for staff, and effective communication mechanisms between food preparation and serving areas. Alongside written information, our results indicate that staff use of simple, proactive face to face strategies to make enquiries and reassure customers, is favoured by FA/FIs. For example, training staff to ask diners about any food sensitivities from the outset, would convey allergen awareness, and would likely diminish much of reticence exhibited by FA/FIs within this study and in wider literature [14, 16].

In recognising the insights gained through the in-depth analysis of FA/FIs information preferences when eating out, we also acknowledge the limitations of the study. Given that we were seeking to understand the perspectives of those with both FA and FI it was necessary to use self-report measures to assess FA/FI status. Although this was done through the careful application of strict symptom-based FA/FI criteria; the assignment of some participants presented a challenge. However accuracy of allocation was less critical within the remit of the current study which sought a broader perspective on FA/FI populations' preferences for written and/or verbal food allergen information when eating out. Due to the qualitative nature of our research we were also unable to account for the impact of demographic factors such as sex, age and region of residence within the UK. These factors may have affected FA/FI's preferences in terms of allergen information provision and willingness to communicate with staff.

## Conclusion

In light of EU legislation requiring that eating out providers supply consumers with information regarding the allergen content of their foods, this study is the first to gain in-depth insights into FA/FI consumers' preferences for the provision of allergen information when eating out or ordering takeaway foods. Findings indicate that FA/FI consumers were often ambivalent or conflicted in their preferences for written and verbal allergen information provision. FA/FIs overwhelmingly favoured tangible, written information in the first instance; and adequate written information often led to an implicit trust in subsequent verbal information. Where written information was limited, FA/FIs depended on social cues to assess the reliability of verbal information resources, and defaulted to tried and tested allergen avoidance strategies when these were deemed unreliable. Understanding the subtle negotiations and difficulties encountered by FA/FIs when eating out can serve as a guide for legislators and food providers; by encouraging the provision of clear written and verbal allergen information, and the training of proactive, allergen aware staff. This, in tandem with legally enforceable requirements for food allergen information provision provided by the EU legislation, paves the way for FA/FIs to feel more confident in their eating out choices; and to experience a safer eating out experience.

## Supporting Information

**S1 File. Additional theme-based quotes from interviews.**  
(DOCX)

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## Author Contributions

Conceived and designed the experiments: JB MHG JSL. Performed the experiments: JB RP DR FMB. Analyzed the data: FMB JB. Wrote the paper: FMB JB. Provided advice as an allergic consumer to the project throughout: MHG. Provided clinical expertise as an allergist to the project throughout: JSL. Contributed to reviewing and commenting on early drafts of the paper: MHG JSL RP DR. Conceived and designed the project: JB MHG JSL. Collected the data: RP JB DR. Analyzed the data: FMB JB. Wrote the paper: FMB JB. Approved the manuscript for submission: FMB JB RP DR MHG JSL. Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: FMB JB RP DR MHG JSL.

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

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### ABSTRACT

Dining outside of the home can be difficult for persons with food allergies who must rely on restaurant staff to properly prepare allergen-free meals. The purpose of this study was to understand and identify factors associated with food allergy knowledge and attitudes among restaurant managers, food workers, and servers. This study was conducted by the Environmental Health Specialists Network (EHS-Net), a collaborative forum of federal, state, and local environmental health specialists working to understand the environmental factors associated with food safety issues. EHS-Net personnel collected data from 278 randomly selected restaurants through interviews with restaurant managers, food workers, and servers. Results indicated that managers, food workers, and servers were generally knowledgeable and had positive attitudes about accommodating customers' food allergies. However, we identified important gaps, such as more than 10% of managers and staff believed that a person with a food allergy can safely consume a small amount of that allergen. Managers and staff also had lower confidence in their restaurant's ability to properly respond to a food allergy emergency. The knowledge and attitudes of all groups were higher at restaurants that had a specific person to answer food allergy questions and requests or a plan for answering questions from food allergic customers. However, food allergy training was not associated with knowledge in any of the groups but was associated with manager and server attitudes. Based on these findings, we encourage restaurants to be proactive by training staff about food allergies and creating plans and procedures to reduce the risk of a customer having a food allergic reaction.

Key words: 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

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the manager and kitchen staff to requests for allergen-free 7310; E-mail: tradke@cdc.gov.

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

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variables were recoded to provide approximately even groups to facilitate interpretation. For example, managers' experience was split into <math>\leq 4</math> 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  $P = 0.10$ ) to further explore the relationship between 20 potential explanatory variables and the outcomes. We chose  $P = 0.10$  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

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  $\frac{1}{4}$  1, disagree  $\frac{1}{4}$  2, unsure  $\frac{1}{4}$  3, agree  $\frac{1}{4}$  4, and strongly agree  $\frac{1}{4}$  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 ( $P < 0.05$ ) 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

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



277)  
 Male 184 66.4 Female 93 33.6 Primary language spoken (N 1/4 277)  
 English 225 81.2 Other 52 18.8 Highest level of education (N 1/4 277)  
 High school diploma or less 108 39.0 Some college or more 169 61.0  
 Experience as a manager in this restaurant (N 1/4 277), 4 yr 144 52.0  
 1/4 yr 133 48.0 Ever been food safety certified (N 1/4 276)  
 Yes 223 80.8 No 53 19.2 Received training on food allergies while working at this restaurant (N 1/4 275) Yes 123 44.7 No 152 55.3

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.

TABLE 1. Continued Parameter n %

customers in the past month (N 1/4 263) 0 73 27.8 1-10 115 43.7 .10 75 28.5 Food worker characteristics<sup>c</sup>  
 Sex (N 1/4 211)  
 Male 142 67.3 Female 69 32.7 Primary language spoken (N 1/4 211)  
 English 164 77.7 Other 47 22.3 Highest level of education (N 1/4 211)  
 High school diploma or less 133 63.0 Some college or more 78 37.0  
 Experience in this restaurant (N 1/4 207) .2 yr 102 49.3  
 1/2 yr 105 50.7 Received training on food allergies while working at this restaurant (N 1/4 209) Yes 86

41.1 No 123 58.9 No. of meals prepared for food allergic customers per month (N 1/4 195) 0 41 21.0 1-10 105 53.9 .10 49 25.1 Server characteristics<sup>d</sup>  
 Sex (N 1/4 155)  
 Male 42 27.1 Female 113 72.9 Primary language spoken (N 1/4 156)  
 English 134 85.9 Other 22 14.1 Highest level of education (N 1/4 156)  
 High school diploma or less 78 50.0 Some college or more 78 50.0  
 Experience in this restaurant (N 1/4 156) .2 yr 74 47.4  
 1/2 yr 82 52.6 Received training on food allergies while working at this restaurant (N 1/4 155) Yes 52 33.5 No 103 66.5  
 No. of meals served to food allergic customers per month (N 1/4 151) 0 19 12.6 1-10 97 64.2 .10 35 23.2

<sup>a</sup> Data were obtained from manager interviews, unless otherwise

noted. <sup>b</sup> Data were obtained from data collector

observations. <sup>c</sup> Data were obtained from food worker

interviews. <sup>d</sup> Data were obtained from server

interviews.

noted. <sup>b</sup> Data were obtained from data collector

observations. <sup>c</sup> Data were obtained from food worker

interviews. <sup>d</sup> Data were obtained from server

interviews.

No. of meals served to food allergic

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 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.

Managers, 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

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  $\bar{x}$  13.7, SD  $s$  2.0,  $n$  277), 12 for food workers (mean  $\bar{x}$  13.0, SD  $s$  2.5,  $n$  211), and 13 for servers (mean  $\bar{x}$  13.5, SD  $s$  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  $\bar{x}$  13.75, SD  $s$  2.01,  $n$  277) had significantly higher knowledge scores than did food workers (mean  $\bar{x}$  12.96, SD  $s$  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

about food allergies. Nearly all servers (98.1%) agreed or strongly

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 14 277) Yes 64 23.1 No 213 76.9 Documentation about

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allergens in the kitchen

area (N 14 278) Yes 101 36.3 No 177 63.7

<sup>a</sup>Data were obtained from manager interviews. <sup>b</sup>Data were obtained from data collector observations.

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.

TABLE 2. Descriptive data on food allergy practices and restaurant environment observations

Parameter n %

Practices

<sup>a</sup>

Restaurant has plan for answering questions

from food allergic customers (N 14 267) Yes 189 70.8 No 78 29.2 Specific person typically on duty to handle

food allergy questions and requests (N 14 276) Yes 147 53.3 No 129 46.7

Observations

<sup>b</sup>

Menu shows anything about allergens (N

14

273) Yes 60 22.0 No 213 78.0 Documentation in the front of the house

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,  $r =$

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$0.04$ ,  $P = 0.653$ ,  $n = 155$ .

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 associ-

TABLE 3. Descriptive data on restaurant manager and staff food allergy knowledge<sup>a</sup>

Question	% n % n %				
	Of the following foods, which do you think are major allergens?				
	Manager (N=277)	Food worker (N=211)	Server (N=156)		
Peanuts (correct)	263 95.0	201 95.3	149 95.5	Tomatoes 53 19.1 47 22.3 37 23.7	
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	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

<sup>a</sup> Responses are shown in the order they were asked. n, the number of managers and workers that affirmatively answered the question.

ated with manager food allergy attitudes (Table 7). Managers in restaurants that served more than 10 meals to  
Mean

food allergic customers in the past month had greater odds difference  
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.

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<sup>a</sup>

Characteristic OR (90% CI) P

Manager scored in top 50%<sup>b</sup>

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%<sup>c</sup>

Restaurant plan for answering questions from food allergic customers

Yes vs no 4.23 (2.20, 8.12) ,0.001 Sex<sup>d</sup>Female vs male 3.63 (1.81, 7.26) 0.002 Experience in this restaurant

12 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%<sup>d</sup>

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

<sup>a</sup> 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). <sup>b</sup>  $\chi^2$  14

17.18, df 14 3,  $P < 0.001$ , N 14 262. <sup>c</sup>  $\chi^2$  14 30.50, df 14 5,  $P < 0.001$ , N 14 192. <sup>d</sup>  $\chi^2$  14 16.97, df 14 4,  $P < 0.002$ , N 14  
149.

95% confidence interval

Knowledge scores<sup>a</sup>

Manager vs food worker 0.785 (0.28, 1.29)<sup>b</sup> Manager vs server 0.292 (À0.26, 0.84) Server vs food worker 0.493 (À0.08, 1.07)  
Attitude scores<sup>c</sup>

Manager vs food worker À0.087 (À0.19, 0.02) Manager vs server À0.157 (À0.27, À0.04)<sup>b</sup> Server vs food worker 0.069 (À0.05,  
0.19)

<sup>a</sup> Fisher's <sup>b</sup>  $P$  one-way ANOVA ( $F_{2,641}$  14 7.45,  $P < 0.001$ ).

0.05. <sup>c</sup> Equal variance not assumed. Welch's one-way ANOVA ( $F_{2,636}$  14  
6.31,  $P < 0.002$ ).

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

A multiple logistic regression analysis identified

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TABLE 6. Descriptive data on restaurant manager and staff food allergy attitudes<sup>a</sup>

Statement	t	
	Manager (N 14 277)	Food worker (N 14 211) Server

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 knowl-

edgeable 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 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

<sup>a</sup> Strongly disagree 1/4 1; disagree 1/4 2; unsure 1/4 3; agree 1/4 4; strongly agree

1/4 5.

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

higher food allergy attitude score than were servers in  
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TABLE 7. Multiple logistic regression analysis of characteristics associated with restaurant managers, food workers, and servers scoring in the top 50% of food allergy attitude scores<sup>a</sup>

Characteristic OR (90% CI) P

Manager scored in top 50%<sup>b</sup>

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%<sup>c</sup>

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%<sup>d</sup>

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

<sup>a</sup> 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).

<sup>b</sup>  $\chi^2 = 52.00$ ,  $df = 7$ ,  $P < 0.001$ ,  $N = 248$ . <sup>c</sup>  $\chi^2 = 27.86$ ,  $df = 4$ ,  $P < 0.001$ ,  $N = 196$ . <sup>d</sup>  $\chi^2 = 24.43$ ,  $df = 4$ ,  $P < 0.001$ ,  $N = 149$ .

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

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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

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

attitudes about accommodating customers with food allergies. We encourage restaurants to develop plans and hire 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

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-012**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

AC #2 - Post Food Allergy Notifications Guidance Document on CFP Website

**Issue you would like the Conference to consider:**

Post the major food allergens notifications guidance document for industry on the CFP website

**Public Health Significance:**

Food allergies are a significant and emerging public health concern and impact approximately 15 million Americans, including 5.9 million children under the age of 18. Each year, millions of Americans have allergic reactions to food. Although most food allergies cause relatively mild symptoms some food allergies can cause severe reactions that are life-threatening. There is no cure for food allergies. Strict avoidance of food allergens and early recognition and management of allergic reactions to food are important measures to prevent serious health consequences.

Regulatory requirements for labeling major food allergens on packaged foods are very thorough. However, there is a gap in regulatory requirements for notification of major food allergens in food service establishments. Foods that are available for immediate consumption and not pre-packaged do not provide the same level of disclosure of packaged foods. Food allergic consumers often ask on site staff to share information about ingredients and allergens. They must rely on questions to staff who may not have an answer; or worse, give inaccurate information. Staff error has yielded catastrophic results, including fatalities. To protect consumers that have food allergies food employees must have knowledge of the major food allergens, symptoms they could cause, and methods to prevent problems with food allergens.

Please refer to Content Document:

Food Allergy Notifications: A Guidance for Industry

**Recommended Solution: The Conference recommends...:**

1. Acceptance of the committee generated guidance document entitled "Food Allergy Notifications: A Guidance for Industry" (attached as content document 3 to Issue titled: Allergen Committee Report); and
2. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
3. Posting the final document on the CFP website in PDF format

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2020 Issue Form**

**Issue: 2020 II-013**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

AC #3 - Amend Food Code for Major Food Allergen Training for Food Employees

**Issue you would like the Conference to consider:**

Amend the Food Code to remove allergy awareness training from Paragraph 2-103.11(N) and add a new Paragraph in Section 2-103.11 with recommended components of food allergy training.

**Public Health Significance:**

Regulatory requirements for labeling major food allergens on packaged foods are very thorough. However, foods that are available for immediate consumption and not pre-packaged do not provide the same level of disclosure of packaged foods. Food allergic consumers often ask on site staff to share information about ingredients and allergens. They must rely on questions to staff who may not have an answer; or worse, give inaccurate information. Staff error has yielded catastrophic results, including fatalities. To protect consumers that have food allergies food employees must have knowledge of the major food allergens, symptoms they could cause, and methods to prevent problems with food allergens.

Even though the Food Code requires that the Person In Charge (PIC) shall ensure that employees are properly trained in food allergy awareness, research and survey results show that food employees are often not adequately trained in food allergy awareness, which puts consumers at risk.

Please refer to Supporting Attachments:

1. Allergy Training Courses and Laws
2. Allergen Committee Survey
5. Restaurant servers' risk perceptions and risk communication-related behaviors when serving customers with food allergies in the US
6. Comparing the Eating Out Experiences of Consumers Seeking to Avoid Different Food Allergens

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

### **Recommended Solution: The Conference recommends...:**

that a letter be sent to FDA requesting that Paragraph 2-103.11(N) of the most recent edition of Food Code be amended as shown below (stricken language with ~~strikeout~~), and a new Paragraph be added to Section 2-103.11, as shown below (new language underlined):

2-103.11 Person in Charge

The PERSON IN CHARGE shall ensure that:

(N) Employees are properly trained in FOOD safety, ~~including FOOD allergy awareness~~, as it relates to their assigned duties;

EMPLOYEES are properly trained in FOOD allergy awareness, as it relates to their assigned duties. This training should include, but is not limited to:

- Identification of the major FOOD allergens;
- FOOD allergen ingredient identities and labeling;
- Knowledge of cross-contact concerning the major FOOD allergens;
- Recognition of symptoms of an allergic reaction;
- How to respond to an allergic reaction.

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2020 Issue Form**

**Issue: 2020 II-014**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

AC#4 Amend Food Code for Notification of Major Food Allergens in Bulk Foods

**Issue you would like the Conference to consider:**

Amend Subparagraph 3-602.11(C)(2) of the Food Code to require notification of MAJOR FOOD ALLERGENS in consumer self-service bulk FOOD.

**Public Health Significance:**

Self-service bulk food items are an increasing source of food products for the American consumer. While these food products are usually purchased by consumers due to their discounted price and convenience, in recent years their popularity has increased due to economic reasons and changing markets of food delivery/consumer consumption trends. Part of the reason American shoppers are so attracted to these items is their belief that bulk-buying not only prevents waste and their role in providing climate change, but can save time and money, providing more value for the dollar<sup>1</sup>.

Regulatory requirements for labeling major food allergens of packaged foods are very thorough. Providing the name of the food source on the label of packaged foods alerts consumers to the presence of a major food allergen, and may prevent an inadvertent exposure. However, these requirements do not include any type of consumer notification of major food allergens in bulk foods that are available for consumer self-dispensing. These consumer self-service bulk foods are typically not monitored by staff of the establishment, so consumers do not have the opportunity to inquire about foods that may contain major food allergen ingredients.

This amendment to the Food Code would provide additional protection to consumers with food allergies who are interested in purchasing bulk foods that are available for consumer self-dispensing.

<sup>1</sup> [https://en.wikipedia.org/wiki/Bulk\\_foods](https://en.wikipedia.org/wiki/Bulk_foods)

**Recommended Solution: The Conference recommends...:**

that a letter be sent to FDA requesting that Subparagraph 3-602.11(C)(2) of the most recent edition of Food Code be amended as shown below (new language underlined):  
3-602.11 Food Labels.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

- (1) The manufacturer's or processor's label that was provided with the FOOD; or
- (2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), (5) and (6) of this section.

The referenced Subparagraph 3-602.11(B)(5) states:

(B) Label information shall include:

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient. Pf

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2020 Issue Form**

**Issue: 2020 II-015**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

AC #5 - Amend Food Code for Written Notification of Major Food Allergens

**Issue you would like the Conference to consider:**

Amend the Food Code to add a new Paragraph to 3-602.12 to require the PERMIT HOLDER to notify CONSUMERS of the presence of MAJOR FOOD ALLERGENS as ingredients in unpackaged FOOD items using brochures, deli case or menu notifications, label statements, table tents, placards, or other effective written means.

**Public Health Significance:**

Each year, millions of Americans have allergic reactions to food. Although most food allergies cause relatively mild symptoms some food allergies can cause severe reactions that are life-threatening. There is no cure for food allergies. Strict avoidance of food allergens and early recognition and management of allergic reactions to food are important measures to prevent serious health consequences.

Food allergies are a significant and emerging public health concern and impact approximately 15 million Americans, including 5.9 million children under the age of 18. That's 1 in 13 children or roughly two in every classroom. Economically, the eight (8) food allergens cost US families 25 billion dollars annually. In addition, tax funded local, state and federal food safety agencies are forced to respond to what can be a preventable food safety/poisoning-type exposure. It also should be noted that a food allergy is an impairment that limits a major life activity and may qualify an individual for protection under the Americans with Disabilities Act of 1990 (ADA) and Section 504 of the Rehabilitation Act of 1973.

The Centers for Disease Control & Prevention reports that the prevalence of food allergies in children increased by 50 percent between 1997 and 2011. Given there is no cure for food allergies, public health prevention measures remain the best method to reduce the number of anaphylactic reactions that result in the following:

- Every three minutes, a food allergy reaction sends someone to the emergency room.<sup>1</sup>

- Each year in the U.S., 200,000 people require emergency medical care for allergic reactions to food.<sup>2</sup>
- Pediatric hospitalizations for food allergies tripled between the late 1990s and the mid - 2000s. Between 2004 and 2006, an average of 9,500 children received in - patient hospital care for food allergies each year.<sup>3</sup>
- About 40 percent of children with food allergies have experienced a severe allergic reaction such as anaphylaxis.?
- Each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food.?

The Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II) (FALCPA) improved food labeling information for the millions of consumers who suffer from food allergies. The Act is especially helpful to children who must learn to recognize the allergens they must avoid.

Furthermore, according to the Food Allergen Labeling and Consumer Protect Act (FALCPA) the eight major allergens must be declared in simple terms either in the ingredient list or via a separate allergen statement. However, FALCPA does not regulate the use of advisory/precautionary labeling (e.g., "may contain," "made in a facility that also processes").?

Consumers with food allergies depend on allergen information that is made available on labels and menus (or "notifications") when making a purchasing decision. In a recent survey of 788 food-allergic consumers and family members, respondents overwhelmingly preferred a combination of verbal and written allergen notifications. Like other developed countries similar to the United States, affording consumers information to make informed decisions provides them the opportunity to prevent unintended food allergen exposures. Given there is no cure, prevention is the best public health food safety control method to prevent unintended illness and death.

#### References:

1. Clark S, Espinola J, Rudders SA, Banerji, A, Camargo CA. Frequency of US emergency department visits for food - related acute allergic reactions. *J Allergy Clin Immunol.* 2011; 127(3):682 - 683.
2. U.S. Department of Education, Office for Civil Rights. Questions and Answers on the ADA Amendments Act of 2008 for Students with Disabilities Attending Public Elementary and Secondary Schools. <https://www2.ed.gov/about/offices/list/ocr/docs/dcl-504faq-201109.html>.
3. Branum A, Lukacs S. Food allergy among U.S. children: Trends in prevalence and hospitalizations. NCHS data brief, no 10. Hyattsville, MD: National Center for Health Statistics. 2008. <https://www.medpagetoday.com/upload/2008/10/23/allergy.pdf>.
4. Gupta RS, Springston MR, Warriar BS, Rajesh K, Pongracic J, Holl JL. The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics* 2011; 128(1):e9 - 17.
5. <https://www.fda.gov/food/food-allergengluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa>

6. *NIAID - Sponsored Expert Panel. Guidelines for the diagnosis and management of food allergy in the United States: Report of the NIAID - sponsored expert panel. J Allergy Clin Immunol. 2010; 126(6):S1 - 58*

Website:

<https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/default.htm>

Please refer to Supporting Attachments:

3. Allergen Notification Consumer Survey
4. Food Industry Survey Results
5. Restaurant servers' risk perceptions and risk communication-related behaviors when serving customers with food allergies in the US
6. Comparing the Eating Out Experiences of Consumers Seeking to Avoid Different Food Allergens
7. Consumer Preferences for Written and Oral Information about Allergies When Eating Out
8. Food Allergy Knowledge and Attitudes of Restaurant Managers and Staff: An EHS-Net Study

**Recommended Solution: The Conference recommends...:**

That a letter be sent to FDA requesting that a new Paragraph be added to Section 3-602.12 of the most recent edition of Food Code as shown below (new language underlined).

3-602.12 Other Forms of Information

The PERMIT HOLDER shall notify CONSUMERS of the presence of MAJOR FOOD ALLERGENS as ingredients in unpackaged FOOD items using brochures, deli case or menu notifications, label statements, table tents, placards, or other effective written means. CONSUMER notifications of MAJOR FOOD ALLERGENS must be specific to FOOD items that contain MAJOR FOOD ALLERGENS and must include either the common name or an easily-understood image of the relevant MAJOR FOOD ALLERGEN.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-016**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

AC#6 Amend Food Code:Major Food Allergen Notification Upon Consumer Request

**Issue you would like the Conference to consider:**

Amend Section 3-602.12 of the Food Code to add a new Paragraph to require the PERMIT HOLDER to, upon request, provide CONSUMERS with a written list of all MAJOR FOOD ALLERGEN ingredients in FOOD items.

**Public Health Significance:**

Each year, millions of Americans have allergic reactions to food. Although most food allergies cause relatively mild symptoms some food allergies can cause severe reactions that are life-threatening. There is no cure for food allergies. Strict avoidance of food allergens and early recognition and management of allergic reactions to food are important measures to prevent serious health consequences.

Food allergies are a significant and emerging public health concern and impact approximately 15 million Americans, including 5.9 million children under the age of 18. That's 1 in 13 children or roughly two in every classroom. Economically, the eight (8) food allergens cost US families 25 billion dollars annually. In addition, tax funded local, state and federal food safety agencies are forced to respond to what can be a preventable food safety/poisoning-type exposure. It also should be noted that a food allergy is an impairment that limits a major life activity and may qualify an individual for protection under the Americans with Disabilities Act of 1990 (ADA) and Section 504 of the Rehabilitation Act of 1973.

The Centers for Disease Control & Prevention reports that the prevalence of food allergies in children increased by 50 percent between 1997 and 2011. Given there is no cure for food allergies, public health prevention measures remain the best method to reduce the number of anaphylactic reactions that result in the following:

- Every three minutes a food allergy reaction sends someone to the emergency room.<sup>1</sup>

- Each year in the U.S., 200,000 people require emergency medical care for allergic reactions to food.<sup>2</sup>
- Pediatric hospitalizations for food allergies tripled between the late 1990s and the mid-2000's. Between 2004 and 2006 an average of 9,500 children received in-patient hospital care for food allergies each year.<sup>3</sup>
- About 40 percent of children with food allergies have experienced a severe allergic reaction such as anaphylaxis.?
- Each year roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food.?

The Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II) (FALCPA) improved food labeling information for the millions of consumers who suffer from food allergies. The Act is especially helpful to children who must learn to recognize the allergens they must avoid.

Furthermore, according to the Food Allergen Labeling and Consumer Protection Act (FALCPA) the eight major allergens must be declared in simple terms either in the ingredient list or via a separate allergen statement. However, FALCPA does not regulate the use of advisory/precautionary labeling (e.g., "may contain," "made in a facility that also processes").?

Consumers with food allergies depend on allergen information that is made available on labels and menus (or "notifications") when making a purchasing decision. In a recent survey of 788 food-allergic consumers and family members, respondents overwhelmingly preferred a combination of verbal and written allergen notifications. Like other developed countries similar to the United States, affording consumers information to make informed decisions provides them the opportunity to prevent unintended food allergen exposures. Given there is no cure, prevention is the best public health food safety control method to prevent unintended illness and death.

References:

1. Clark S, Espinola J, Rudders SA, Banerji, A, Camargo CA. Frequency of US emergency department visits for food - related acute allergic reactions. *J Allergy Clin Immunol.* 2011; 127(3):682 - 683.
2. U.S. Department of Education, Office for Civil Rights. Questions and Answers on the ADA Amendments Act of 2008 for Students with Disabilities Attending Public Elementary and Secondary Schools. <https://www2.ed.gov/about/offices/list/ocr/docs/dcl-504faq-201109.html>.
3. Branum A, Lukacs S. Food allergy among U.S. children: Trends in prevalence and hospitalizations. NCHS data brief, no 10. Hyattsville, MD: National Center for Health Statistics. 2008. <https://www.medpagetoday.com/upload/2008/10/23/allergy.pdf>.
4. Gupta RS, Springston MR, Warrier BS, Rajesh K, Pongracic J, Holl JL. The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics* 2011; 128(1):e9 - 17.
5. <https://www.fda.gov/food/food-allergengluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa>

6. *NIAID - Sponsored Expert Panel. Guidelines for the diagnosis and management of food allergy in the United States: Report of the NIAID - sponsored expert panel. J Allergy Clin Immunol. 2010; 126(6):S1 - 58*

Website:

<https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/default.html>

Please refer to Supporting Attachments:

3. Allergen Notification Consumer Survey

4. Food Industry Survey Results

5. Restaurant servers' risk perceptions and risk communication-related behaviors when serving customers with food allergies in the US

6. Comparing the Eating Out Experiences of Consumers Seeking to Avoid Different Food Allergens

7. Consumer Preferences for Written and Oral Information about Allergies When Eating Out

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

**Recommended Solution: The Conference recommends...:**

that a letter be sent to FDA requesting that a new Paragraph be added to Section 3-602.12 of the most recent edition of Food Code as shown below (new language underlined): ...

3-602.12 Other Forms of Information

Upon request, the PERMIT HOLDER shall provide CONSUMERS with a written list of all MAJOR FOOD ALLERGEN ingredients in FOOD items.

**Submitter Information 1:**

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**Submitter Information 2:**

Name: Mike Pascucilla  
Organization: East Shore District Health Dept  
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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-017**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

PSC Issue #1: Report - 2018-2020 Program Standards Committee

**Issue you would like the Conference to consider:**

The Conference for Food Protection (CFP) Program Standards Committee seeks Council II's acknowledgment of the committee's final report and thank the committee members for their work and dedication during the 2018-2020 biennium.

**Public Health Significance:**

The Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) were developed to serve as a guide for regulatory retail food program managers in the design, management, and execution of a retail food program with the public health outcome of reducing foodborne illness risk factors. The Program Standards Committee is a standing committee reporting to the CFP Executive Board. The Committee provides ongoing input to the FDA on issues that arise with the Retail Program Standards. The Committee serves the Conference by indirectly assisting Retail Program Standards enrollees in making progress towards meeting the Retail Program Standards. The Committee continues to work with the FDA internal Program Standards working group and the FDA Clearinghouse Workgroup to clarify and address questions about the Retail Program Standards.

**Recommended Solution: The Conference recommends...:**

1. Acknowledgment of the 2018-2020 Program Standards Committee Final Report; and
2. Thanking the Committee members for their work and dedication during the 2018-2020 biennium.

The Conference further recommends the Program Standards Committee, a CFP standing committee, be charged with the following during the 2018-2020 biennium:

1. Identify inconsistencies in language between all Standards in the Retail Program Standards;

2. Continue review of initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities; and

3. Maintain the "Crosswalk - Requirements for Foodborne Illness Training Programs" document as a resource for content baseline for foodborne illness training.

**Submitter Information 1:**

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**Submitter Information 2:**

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**Content Documents:**

- "Program Standards Committee Final Report"
- "Program Standards Committee Roster"
- "Program Standards Committee Work Plan"
- "Crosswalk - Requirements for Foodborne Illness Training Programs"
- "Standard 8 - Proposed Model"
- "Draft CFP Training Manual Revision"
- "Draft Attachment A - CFP Training Plan and Log Revision"

**Supporting Attachments:**

- "Program Standards Committee subcommittee #1 final report"
- "Program Standards Committee subcommittee #2 final report"
- "Program Standards Committee subcommittee #3 final report"
- "Program Standards Committee subcommittee #4 final report"
- "Program Standards Committee subcommittee #5 final report"
- "Program Standards Committee Online Supporting Documents"
- "Standard 8 Summary"
- "Standard 8 PowerPoint"
- "Standard 8 Re-Evaluation of Staffing Level Model Pilot Study Report"
- "CFP PSC Subcommittee CWG Questions"
- "CWG Standard 4 Response"
- "Standard 4 - Statistical Methodology"

- "Partial Achievement Survey"
- "Preliminary Plan Review Proposal"
- "PSC Subcommittee #3 Meeting #1 Minutes 12 19 2018"
- "PSC Subcommittee #3 Meeting #2 Minutes 1 09 2019"
- "PSC Subcommittee #3 Meeting #3 Minutes 1 23 2019"
- "PSC Subcommittee #3 Meeting #4 Minutes 2 06 2019"
- "PSC Subcommittee #3 Meeting #5 Minutes 3 13 2019"
- "PSC Subcommittee #3 Meeting #6 Minutes 4 10 2019"
- "PSC Subcommittee #3 Meeting #7 Minutes 5 8 2019"
- "PSC Subcommittee #3 Meeting #8 Minutes 6 12 2019"
- "PSC Subcommittee #3 Meeting #9 Minutes 7 17 2019"
- "PSC Subcommittee #3 Meeting #10 Minutes 8 14 2019"
- "PSC Subcommittee #3 Meeting #11 Minutes 9 11 2019"
- "PSC Subcommittee #3 Meeting #12 Minutes 10 2 2019"
- "PSC Subcommittee #3 Charge 1 Training Evaluation and Cert. Initiatives"
- "PSC Subcommittee #3 Charge 2 Appendix B-1 Reformatted 1st Draft"
- "PSC Subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft"
- "PSC Subcommittee #3 Charge 2 IFPTI Course Review"
- "PSC Subcommittee #3 Charge 3 Quality Elements Cross-referenced"
- "IFSS Curriculum Framework"
- "B2 Allergens IFPTI Course Profile"
- "B17 Laws Regulations IFPTI Course Profile"
- "B23 Public Health Principles IFPTI Course Profile"
- "B25 Sampling IFPTI Course Profile"
- "B26 Sanitation Practices IFPTI Course Profile"
- "B8 Environmental Hazards IFPTI Course Profile"
- "B12 Integrated Food Safety System IFPTI Course Profile"
- "B15 Jurisdiction IFPTI Course Profile"
- "B16 Labeling IFPTI Course Profile"
- "B19 Pest Control IFPTI Course Profile"
- "B20 Plumbing IFPTI Course Profile"
- "B22 Professionalism IFPTI Course Profile"
- "B24 Recalls IFPTI Course Profile"
- "B27 Traceability IFPTI Course Profile"
- "B28 Transportation IFPTI Course Profile"
- "Draft 2017 VNRFRPS Self-Assessment Audit Form"

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

**COMMITTEE NAME: Program Standards Committee (PSC)**

**DATE OF FINAL REPORT: October 31, 2019 Date amended: 12/3/2019**

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

**REPORT SUBMITTED BY: Angie Cyr, Chair; Amanda Douglas, Co-Vice Chair; Andre Pierce, Co-Vice Chair**

**COMMITTEE CHARGE(S):**

**Issue # 2018 II-013 Report - Program Standards Committee (PSC)**

1. Examine whether there is an additional burden placed on enrollees or FDA (in time, money, or added complexity of the Standards) associated with development of a system to ensure that jurisdictions are uniformly recognized for partial achievement of the Standards (charge originally assigned via Issue 2016-II-009);
2. Continue work on a cost/benefit analysis for recognizing partial achievement of the VNRFRPS following clarification from the FDA (as noted above) (charge originally assigned via Issue 2016-II-009);
3. Identify inconsistencies in language between all Standards in the VNRFRPS; and
4. Report back the Committee's findings and recommendations to the 2020 biennial meeting.

**Issue # 2018 II-014 PSC 2 - Improvements to VNRFRPS (Note: These charges were assigned by the Executive Board at their meeting August 21 -22, 2018.)**

1. Work with the FDA to include plan review in the VNRFRPS. The committee recognizes that facility design and construction support behaviors that reduce the occurrence of foodborne illness risk factors.
2. For the Listing of Jurisdictions Enrolled in the VNRFRPS on the FDA's website: Work with the FDA to identify a means to recognize enrolled jurisdictions that are self-reporting partial achievement of a Standard. For example, place an asterisk (\*) by an agency's name under that particular VNRFRPS Standard to denote partial achievement and a footnote that states the reason why the jurisdiction cannot fully meet the Standard.

**Issue # 2018 II-018 PSC 3 - Continue Revision of VNRFRPS Standard 8 Staffing Level Criteria**

1. Continue to collaborate with the FDA internal Program Standards working group on modifying the "Description of Requirements" for "Staffing Level" in Standard 8 of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS);
2. Use the supporting attachments listed in the 2016-2018 Program Standards Committee, Standard 8 Subcommittee report as the foundation to establish a more statistically sound logic model for the FTE (full-time equivalent)/Inspection ratio and provide the new calculation/formula to be used by a VNRFRPS enrollee to assess the Standard 8 "Staffing Level";
3. Propose amendments to Standard 8 of the VNRFRPS and the CFP guidance document titled "Standard 8 Staffing Level Assessment Workbook" and accompanying "Instruction Guide" to incorporate the outcomes of Charges 1 and 2; and
4. Report back committee findings and recommendations to the 2020 Biennial Meeting.

**Issue # 2018 II-019 PSC 7 - Training of Food Safety Regulatory Professionals**

1. Continue review of initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities.
2. Review the results of the PFP TCWG recommendations for the nationally recognized Retail Food Curriculum based on the Retail Food Competency and Curriculum Framework to determine if changes are needed in the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard 2 curriculum; including, but not limited to: a) Identifying any gaps and recommendations for change; and b) Reviewing the time frame for completion of Standard 2, Steps 1 through 4, for new hires or staff newly assigned to regulatory retail food protection programs.
3. Continue to assess if any changes will be needed in VNRFRPS Standard 2 - Trained Regulatory Staff to provide better alignment with Standard 4 of the VNRFRPS.
4. Report back the Committee's findings and recommendations to the 2020 biennial meeting.

**Issue # 2018 II-020 PSC 8 - Approval & Posting of Updated Foodborne Illness Training Crosswalk**

1. Maintaining the "Crosswalk - Requirements for Foodborne Illness Training Programs" document as a resource for content baseline for foodborne illness training;
2. Evaluating the following references for inclusion in the Crosswalk document: a) CDC EHS e-Learning on Environmental Assessment of Foodborne Illness Outbreaks [https://www.cdc.gov/nceh/ehs/elearn/ea\\_fio/](https://www.cdc.gov/nceh/ehs/elearn/ea_fio/) b) FDA Food Related Emergency Exercise Bundle (FREE-B)

- <https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295902.htm>[CA(1] (updated URL: <https://www.fda.gov/food/food-defense-tools-educational-materials/food-related-emergency-exercise-bundle-free-b>) c) IS-305: Environmental Health Training in Emergency Response (EHTER) Awareness Level <https://training.fema.gov/is/> d) NEHA Certified Foodborne Outbreak Investigator Credential (CFOI) <http://neha.org/professional-development/credentials/certified-foodborne-outbreak-investigator-cfoi-credential> e) Integrated Food Safety Center of Excellence (CoE) Webinar Series <https://www.coefoodsafetytools.org/AllCoEProducts.aspx> (updated URL: <https://www.coefoodsafetytools.org>); and
3. Reporting back any findings and recommendations to each biennial meeting of the Conference for Food Protection.

### **Issue # 2018 II-021 Amend VNRFRPS - Standard 4 - Uniform Inspection Program**

#### **...address the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Program Standard No. 4 - Uniform Inspection Program to:**

1. Research a new model, solution and/or recommendation that will allow large and small jurisdictions to have the same statistical compliance requirements;
2. Amend audit requirements to include randomized selection of files to be reviewed; and
3. Report back to the 2020 Biennial meeting of the Conference for Food Protection its findings and recommendations.

#### **COMMITTEE WORK PLAN AND TIMELINE:**

1. See the attached Program Standards Committee Work Plan.
2. All subcommittee work was completed in October, 2019. The PSC final report and issue submittals were drafted and submitted to the Executive Director and Conference Chair for review on October 31, 2019.

#### **COMMITTEE ACTIVITIES:**

##### **1. Dates of committee meetings or conference calls:**

- a. PSC Committee chair and co-vice chairs met via conference call on September 11, 2018 to discuss PSC issues and subcommittee formation.
- b. PSC Committee chair participated in the Clearinghouse Work Group calls on September 25, 2018, February 14, 2019, May 7, 2019 and September 10, 2019.
- c. Full committee meetings were held via conference call or WebEx on October 5, 2018, August 8, 2019 and August 9, 2019.
- d. PSC subcommittee #1 (Issue 2018 II-013 & 2018 II-014) held conference calls on February 19, 2019, March 21, 2019, May 1, 2019, May 30, 2019 and June 27, 2019.
- e. PSC subcommittee #2 (Issue # 2018 II-018) held conference calls on February 19, 2019, March 19, 2019, May 13, 2019, June 18, 2019, October 17, 2019 and October 21, 2019.
- f. PSC subcommittee #3 (Issue # 2018 II-019) held conference calls on December 19, 2018, January 9, 2019, January 23, 2019, February 6, 2019, March 13, 2019, April 10, 2019, May 8, 2019, June 12, 2019, July 17, 2019, August 14, 2019, September 11, 2019 and October 2, 2019. Dates of electronic votes: February 16, 2019 and October 4, 2019.
- g. PSC subcommittee #4 (Issue # 2018 II-020) held a conference call on December 6, 2018. A second call was scheduled for January 23, 2019 but was postponed due to the federal government shutdown. The subcommittee chair reached out to team members individually to discuss progress on their assigned tasks throughout 2019.
- h. PSC subcommittee #5 (Issue #2018 II-021) held conference calls on January 2, 2019, January 30, 2019, February 14, 2019, and February 28, 2019 with biweekly calls scheduled from this date on.

##### **2. Overview of committee activities:**

- a. A full committee meeting was held on October 5, 2018. The CFP Anti-trust statement was read and the CFP Master Calendar and committee charges were discussed. The committee has six issues with charges to be worked on. It was decided that a subcommittee will be formed to work on the charges for each issue.
- b. Amanda Douglas, co-vice chair, Andre Pierce, co-vice chair and Angie Cyr, chair, discussed subcommittee formation further on October 5, 2018. It was decided to combine Issue 2018 II-013 and Issue 2018 II-014 since they are closely related. Five subcommittees were formed to work on the assigned charges.
- c. The PSC chair sent an email on October 8, 2018, requesting that committee member's sign up for the subcommittees that they are interested in. Co-chairs of the subcommittees were also solicited at that time.
- d. The committee chair created teams for each of the subcommittee's within FoodSHIELD on November 6, 2018 and then sent subcommittee rosters to each of the subcommittee co-chairs so they could begin scheduling subcommittee meetings.
- e. Due to the federal government shutdown, the subcommittees had limited dialogue with our FDA partners for part of the biennium. This had an impact on the subcommittee work on the assigned charges.

- f. Subcommittee #1 (Issue # 2018 II-013 & Issue # 2018 II-014) –The PSC co-vice chair, Andre Pierce took the lead on scheduling subcommittee meetings. His work got the subcommittee on track to complete the assigned charges by the deadline. Members of the committee developed a survey related to partial achievement that was sent to VNRFRPS enrolled jurisdictions in North Carolina and Texas. There were 47 respondents- 91% were local jurisdictions. The results showed that most jurisdictions would like some way to track their partial achievement of standards for internal purposes only. Only three of the 47 respondents wanted a public facing website to report. Nearly half (49%) of the respondents had not heard about the tracking spreadsheet. The committee used the data to develop the position that the tracking spreadsheet is a useful tool for internal self-reporting and needs to be marketed, rather than having a public website for reporting. The issue will reflect these discussions and will close this charge. Additionally, the subcommittee discussed the value of plan review to support behaviors that reduce the occurrence of risk factors associated with foodborne illness. The subcommittee developed draft criteria and is recommending that those ideas be explored further in the next biennium with the submittal of *PSC Issue #5 Continuation of Issue 2018 II—014 PSC2 Plan Review Incorporation in the Program Standards*. The subcommittee also discussed potential inconsistencies in the VNRFRPS. No changes were identified at this time.
- g. Subcommittee #2 (Issue # 2018 II-018) - The work of the subcommittee and the subcommittee co-chairs team at Harris County Public Health included surveys of Retail Program Standards enrollees, data compilation, statistical analysis, and providing graphic representations of data and data analysis, as well as conducting a pilot study of the proposed additional method to determine compliance with the staffing levels in Standard 8. Subcommittee documents were posted to the Subcommittee #2 workgroup folder on FoodSHIELD for review during conference calls. The proposed model for Standard 8 staffing level assessment, developed by Mr. Schaffer's team at Harris County Public Health with assistance from this (and the 2016-2018) PSC subcommittee, was presented for subcommittee review. The proposed change provides three options for assessing staffing levels including one which removes the range (280-320 inspections/FTE) and is based on data obtained through surveys conducted by the 2016-18 subcommittee assigned to work on this issue. See the attached *Standard 8 Summary* and *Standard 8 PowerPoint* PDF documents for additional information. FDA continues to express concern that the proposed changes to Standard 8 staffing levels do not adhere to the "Best Practice" approach that the Standards promote and does not present a uniform staffing level standard. The voting members of Subcommittee #2 supported the proposed changes. Mr. Sudler, FDA CFSAN, agreed to contact a FDA statistician and set up a meeting with Mr. Schaffer to further evaluate the most appropriate use of the data (primarily data related to times assigned to inspection categories). However, as of the due date of this report, we have not been notified of a meeting with an FDA statistician. A statistician with Harris County Public Health did review the pilot study methods and data.
- In August 2019, Subcommittee #2 met with the voting members of the PCS to discuss the work that had been completed to date. A key decision made on the call was to pilot the proposed model with a pool of health departments across the nation. In September 2019, Subcommittee #2 conducted a pilot study of a proposed staffing level evaluation model as directed by the PSC. The study consisted of sending a survey to health departments in order to obtain staffing level data and use the proposed model to analyze this data. Harris County Public Health led the study. The subcommittee shared the result of the pilot study with the subcommittee members to get their feedback before drafting an issue requesting modification of the criteria for assessing staffing levels in Standard 8 for consideration by the 2020 CFP. The consensus was to move forward with an issue proposing an additional model for assessing staffing levels in Standard 8. The existing methods in Standard 8 are maintained and may be used to determine compliance with the staffing level rather than using the new proposed model.
- h. Subcommittee #3 (Issue # 2018 II-019) - The conference call on December 19, 2018 was used to review the committee charges, determine the timeline for addressing the charges, and it was decided that FoodSHIELD will be used for document sharing. The conference call on January 9 addressed charge 1, and a list of training, evaluation and/or certification courses available to food safety inspection officers was developed. The conference call on January 23, 2019 addressed charge 3, and the committee started work on a document of the twenty Standard 4 Quality Assurance elements and associated trainings. The conference call on February 6, 2019 provided an overview of the Retail Food Competency and Curriculum Framework from International Food Protection Training Institute (IFPTI) and addressed the time frame for completion of Standard 2, steps 1 through 4. Conference calls March 13, 2019 through July 17, 2019 were to review the IFPTI framework courses. Four teams were assembled with one industry and one regulatory member. Each team was assigned four courses to review (one per month) for its usefulness, whether there is any missing content, and if it should be implemented as "pre" or "post" coursework in the current VNRFRPS Standard 2 curriculum in Appendix B-1. The conference call on August 14, 2019 reviewed the list of charge 1 initiatives for training, certification, and evaluation of food inspection officers, charge 2a, and the recommendations received at that point, i.e. add, replace, or no action and indicating "pre" or "post" coursework. The conference call on September 11, 2019 continued discussion of group recommendations and discussed charge 3. An insufficient number of voting members on the call prohibited voting. On October 2, 2019, the final conference call was held. The group voted on majority of potential issues for charge 2a and charge 3. Voting continued electronically on October 4, 2019. The results of the vote were emailed on October 14 and issue submittal documents compiled.

- i. PSC subcommittee #4 (Issue # 2018 II-020) - The subcommittee had discussions regarding the use of the Crosswalk document for Standard #5. In addition, updating previous resources identified, such as CIFOR, occurred in 2019. EATS 102 was evaluated as a resource. EATS 101 is already a resource, so there was no need to review EATS 101. Subcommittee members continued to identify resources and report at the subcommittee meetings. Emphasis was on industry private sector courses. Four of the eight resources currently identified were reviewed for accuracy in order to maintain the Crosswalk document. Pending resources were reviewed against the Crosswalk document, to verify that the reference citations were still accurate. On February 11, 2019, the PSC committee chair reached out to FDA to request Pathlore access to non-regulatory subcommittee members for purposes of materials review related to the subcommittee charges. The subcommittee chair worked directly with the subcommittee members throughout the biennium as they worked on reviewing their assigned resources. The Crosswalk document was updated with the new resources that were reviewed.
- j. PSC subcommittee #5 (Issue #2018 II-021) - Time has been spent reviewing Standard 4. Subcommittee members reached out to larger jurisdictions who are enrolled in the standards and have indicated that they have met Standard 4. Things explored with these agencies was the burden of conducting the 3 field exercises with applicable file review over the 5 year time period. The agencies that responded were Tri-County Health in Colorado and Florida Dept. of Business and Professional Regulation. The subcommittee reviewed the statistical methodology for Standard 4 and had a discussion with the FDA statistician about the percentage of each quality element in order for compliance to be 75%. The subcommittee also reached out to the original Issue submitter, Veronica Bryant, for further clarification on the Issue that was submitted. The subcommittee reviewed the instructions for auditors and the possibility of random sampling and a randomly selected sample size as opposed to the auditor reviewing all records for each applicable field exercise. Marc Boyer, CFSAN statistician attended the February 14, 2019 meeting and provided Statistical Methodology and Explanation of the Statistical Model for Standard 4. See the attached *Standard 4-Statistical Methodology* document provided by FDA. It was decided at the February 28, 2019 meeting, on advice of Robert Sudler, FDA consultant, to submit the issue via questions to the Clearinghouse Work Group (CWG) and to suspend meetings until the CWG was able to address the questions (see *CFP PSC Subcommittee CWG Questions* attached PDF). The subcommittee submitted the questions to the CWG and provided clarifying information after the May meeting of the CWG. A response was received from the CWG after the September meeting of the CWG. See attached *CWG Standard 4 Response* PDF. With regards to the charge related to the review of files during an audit, this was discussed and interpreted, after extensive review of the standard documentation, that file review is not required by the auditor. The auditor can request a random number of files to review, upon their discretion.
- k. The PSC chair solicited feedback from the committee membership on the formation of a Retail Food Alliance due to a request from the Executive Director. The feedback was provided to the Executive Director on January 25, 2019.
- l. The PSC chair assisted the Executive Director with the development of a Supplemental Funding Proposal that was submitted to AFDO on July 24, 2019. The proposed use of the requested funding, should it be granted, is to hold a 2.5 day meeting in 2020 to focus on sharing information about the VNRFRPS.
- m. A full PSC meeting was held on August 9, 2019 to learn about and provide feedback on the FDA's proposed Flexible Funding Model. Maribeth Niesen, FDA, presented the information to the committee during the meeting.
- n. The PSC chair had a conference call with Robert Sudler, FDA, on August 12, 2019 to discuss the upcoming changes to the VNRFRPS. The majority of the changes were the result of previous CFP issue submittals, along with correcting typographical errors. Further action was not needed by the PSC.
- o. A subcommittee was formed to work on the VNRFRPS special session at the 2020 conference. The workshop will be hands on with stations set up for each of the standards. For each standard, a regulatory agency will showcase something they did related to conformance or continuous improvement with meeting the standard.

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

- a. Issue # 2018 II-013 charge #1 Examine whether there is an additional burden placed on enrollees or FDA (in time, money, or added complexity of the Standards) associated with development of a system to ensure that jurisdictions are uniformly recognized for partial achievement of the Standards (charge originally assigned via Issue 2016-II-009). The subcommittee's survey data indicated that most jurisdictions in the surveyed states wanted internal rather than external recognition. The subcommittee concluded there is an undue burden on volunteer auditors to audit components of a standard as well as for FDA to maintain a public facing website. The subcommittee recommended marketing the Self-Assessment tool (see attached *Draft 2017 VNRFRPS Self-Assessment Audit Form*) for internal self-reporting and will ask FDA to maintain it.
- b. Issue # 2018 II-013 charge #2 Continue work on a cost/benefit analysis for recognizing partial achievement of the VNRFRPS following clarification from the FDA (as noted above) (charge originally assigned via Issue 2016-II-009). The subcommittee's survey data indicated that most jurisdictions in the surveyed states wanted internal rather than external recognition. The Self-Assessment tool is an effective way to track partial achievement and report to internal auditors. Based on this information, a cost-benefit analysis of recognizing partial achievement is no longer necessary.

- c. Issue # 2018 II-013 charge #3 - The subcommittee did not identify any changes for the VNRFRPS.
- d. Issue # 2018 II-013 charge #4 - This report serves as completion of this charge.
- e. Issue # 2018 II-014 charge #2 - Based on the survey that was done, the subcommittee feels that this external recognition is not necessary.
- f. Issue # 2018 II-018 charge #1 - FDA has been consulted and has participated on subcommittee conference calls. See PSC Issue #2 *Recommendation to include a new proposed assessment tool to Standard 8 of VNRFRPS Staffing Level Criteria* which has been submitted to resolve this issue.
- g. Issue # 2018 II-018 charge #2 - Use the supporting attachments listed in the 2016-2018 Program Standards Committee, Standard 8 Subcommittee report as the foundation to establish a more statistically sound logic model for the FTE (full-time equivalent)/Inspection ratio and provide the new calculation/formula to be used by a VNRFRPS enrollee to assess the Standard 8 "Staffing Level". A more statistically sound model for the FTE/inspection ratio has been developed along with a new formula for calculating staffing needs that may be used by enrollees to assess staff level. This model is proposed as an additional method that may be used to determine compliance with the staffing level in Standard 8. The existing methods in Standard 8 are maintained and may be used to determine compliance with the staffing level.
- h. Issue # 2018 II-018 charge #3 - Amendments to Standard 8, the Standard 8 Staffing Level Assessment Workbook and accompanying Instruction Guide have been made and submitted as an Issue.
- i. Issue # 2018 II-018 charge #4 - This report serves as the completion of this charge.
- j. Issue # 2018 II-019 charge #1 - The committee discussed initiatives (existing, new, or under development) involving the training, evaluation and/or certification available to Food Safety Inspection Officers (FSIO) in their respective jurisdictions (see *PSC subcommittee #3 Charge 1 Training Evaluation and Certification Initiatives* attached PDF).
- k. Issue # 2018 II-019 charge #2a - The Committee reviewed 26 Integrated Food Safety System Basic Curriculum courses for Food Protection Professionals provided by the International Food Protection Training Institute (IFPTI) (see attachments *PSC subcommittee #3 Charge 2 IFPTI Course Review and Integrated Food Safety System (IFSS) Food Protection Professionals Curriculum Framework*). Courses B7 Emergency Response and B19 Pest Control were under development and not available for review. After the team's review, the committee discussed the training and voted on whether to (1.) replace existing Standard 2 curriculum in appendix B-1 with the IFPTI course, (2.) add the IFPTI course to existing Standard 2 curriculum in appendix B-1, or (3.) do not include the IFPTI course in existing Standard 2 curriculum in appendix B-1 ("no action"). The committee recommends the following changes to existing Standard 2 (Appendix B-1):
  - i. Reformat Appendix B-1 into a table with training topics in one column and courses which fulfill the curriculum topics in another column. The current formatting implies the course listed is the only course that will fulfill the training requirement. The proposed format better shows that other courses may be used if deemed equivalent by the regulatory jurisdiction. It is anticipated that there may be accessibility issues with ComplianceWire courses in the future and other comparable courses may be needed as substitutions. Attachment *PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1<sup>st</sup> Draft* demonstrates suggested changes to Appendix B-1 using current Standard 2 curriculum; Attachment *PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2<sup>nd</sup> Draft* demonstrates suggested changes to Appendix B-1 with all proposed issues below incorporated.
  - ii. IFPTI Course B2 (CC8029W): Replace FD252, Allergen Management in "post" curriculum. This course is a significant upgrade in course content providing more relevant and up to date information.
  - iii. IFPTI Course B8 Environmental Hazards (CC8024W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new (Food Safety Inspection Officer's) FSIO's baseline knowledge.
  - iv. IFPTI Course B12 Integrated Food Safety System (CC8018W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - v. IFPTI Course B15 Jurisdiction (CC8037W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - vi. IFPTI Course B16 Labeling (CC8038W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.

- vii. IFPTI Course B17 Laws, Regulations, Policies, & Procedures (CC8039W): Replace FDA35, Basic Food Law for State Regulators in “pre” courses. This course is a significant upgrade in course content providing more relevant and up to date information.
  - viii. IFPTI Course B19 Pest Control: Add to “pre” curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO’s baseline knowledge.
  - ix. IFPTI Course B20 Plumbing: Add to “pre” curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO’s baseline knowledge.
  - x. IFPTI Course B22 Professionalism (CC8025W): Add to “pre” curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO’s baseline knowledge.
  - xi. IFPTI Course B23 Public Health Principles (CC8026W): Replace FDA36, “Public Health Principles” in “pre” courses. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO’s baseline knowledge.
  - xii. IFPTI Course B24 Recalls (CC8041W): Add to “post” curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO’s baseline knowledge.
  - xiii. IFPTI Course B25 Sampling (CC8035W): Replace MIC13, Aseptic Sampling, in the pre-requisite curriculum. This course is a significant upgrade in course content providing more relevant and up to date information.
  - xiv. IFPTI Course B26 Sanitation Practices (CC8032W): Replace MIC15, Cleaning & Sanitizing, in “pre” courses. This course is a significant upgrade in course content providing more relevant and up to date information.
  - xv. IFPTI Course B27 Traceability (CC8042W): Add to “post” curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO’s baseline knowledge.
  - xvi. IFPTI Course B28 Transportation (CC8036W): Add to “post” curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO’s baseline knowledge.
- I. Issue # 2018 II-019 charge #2b - The committee reviewed the time frame for completion of Standard 2, Steps 1 through 4, for new hires or staff newly assigned to regulatory retail food protection programs. The committee voted on February 16, 2019 to increase the timeframe from 18 to 24 months to align with Standard 2 of the Manufactured Food Regulatory Program Standards and to provide adequate time for standardization of staff.
- m. Issue # 2018 II-019 charge #3 - The committee reviewed the twenty quality assurance program elements in Standard 4 of the VNRFRPS. It was determined that all but three elements are contained in the CFP Field Training Manual, Training Plan and Log. To better align with training in Standard 2 (see *PSC subcommittee #3 Charge 3 Quality Elements Cross-referenced PDF attached*), the committee recommends adding the following three missing elements to the CFP Field Training Manual, Training Plan and Log:
- i. Standard 4 Performance Element III: “Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met.” Add “Reviewed establishment file for documentation indicating the assigned risk category” to CFP Training Manual Section I Pre-inspection, #2. Reviews establishment file for previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance by the agency. Also add “Verified the establishment is assigned the correct risk category, and when necessary, informs the supervisor when the establishment is not in the proper risk category.” to CFP Training Manual Section II Inspection Observations and Performance, #3 Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.
  - ii. Standard 4 Performance Element IX: “Discuss options for the long-term control of risk factors with establishment managers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction’s policies. Options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans.” Add “Discussed options for the long-term control of risk factors with establishment managers when the same out-of-control risk factor occurs on consecutive inspections (e.g., risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans)” to CFP Training Manual Section II Inspection Observations and Performance, #6 Verifies correction of out of compliance observations identified during previous inspection.
  - iii. Standard 4 Performance Element XVIII: “Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP

Plans.” Add “Documented that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections” to CFP Training Manual Section IV Written Communication, #1 Completes inspection form per jurisdiction’s administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).

- n. Issue # 2018 II-019 charge #4 - This report serves as completion of this charge.
- o. Issue # 2018 II-020 charge #1 - The materials in the current Crosswalk document have been reviewed and the Crosswalk document has been revised. The “Crosswalk - Requirements for Foodborne Illness Training Programs” draft document is attached to this report.
- p. Issue # 2018 II-020 charge #2 - The materials have been reviewed and the Crosswalk document has been revised. The “Crosswalk - Requirements for Foodborne Illness Training Programs” draft document is attached to this report.
- q. Issue # 2018 II-020 charge #3 - This report serves as completion of this charge.
- r. Issue # 2018 II-021 charge #1 - Based on the information provided by the FDA Statistician, small and large jurisdictions already have the same statistical compliance requirements. (See *Standard 4 - Statistical Methodology* attached PDF)
- s. Issue # 2018 II-021 charge #2 - This charge was related to the review of files during an audit. This was discussed and interpreted, after extensive review of the standard documentation, that file review is not required by the auditor. The auditor can request a random number of files to review, upon their discretion.
- t. Issue # 2018 II-021 charge #3 - This report serves as completion of this charge.

**3. Charges *INCOMPLETE* and to be continued to next biennium:**

- a. Issue # 2018 II-013 charge #3 is a standing PSC charge
- b. Issue #2018 II-014 charge #1 - see PSC Issue #5
- c. Issue #2018 II-019 charge #1 is a standing PSC charge
- d. Issue # 2018 II-020 charge #1 is a standing PSC charge

**COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:**

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

**LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:**

**1. PSC Issue #1: Report - 2018-2020 Program Standards Committee**

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

- (a.1) Program Standards Committee Final Report (see attached PDF)
- (a.2) Program Standards Committee Roster (see attached PDF)
- (a.3) Program Standards Committee Work Plan (see attached PDF)
- (a.4) Crosswalk -Requirements for Foodborne Illness Training Programs Based on Standard 5 2019 Final (attached Word document)
- (a.5) Standard 8 - Proposed Model (see attached PDF)
- (a.6) Draft CFP Training Manual Revision
- (a.7) Draft Attachment A - CFP Training Plan and Log Revision (attached Word document)

**b. List of supporting attachments:**

- (b.1) Program Standards Committee subcommittee #1 final report
- (b.2) Program Standards Committee subcommittee #2 final report
- (b.3) Program Standards Committee subcommittee #3 final report
- (b.4) Program Standards Committee subcommittee #4 final report
- (b.5) Program Standards Committee subcommittee #5 final report

- (b.6)** Issue 2018 II-018 (see page 27 <http://www.foodprotect.org/media/biennialmeeting/council-ii-final-issue-recommendations-1.pdf>)
- (b.7)** *2018 Program Standards Committee Final Report*  
[http://www.foodprotect.org/issues/packets/2018Packet/issues/II\\_013.html](http://www.foodprotect.org/issues/packets/2018Packet/issues/II_013.html). See the *Re-evaluation of VNRFRPS Standard 8 Subcommittee Report* and supporting attachments for Standard 8.
- (b.8)** *Standard 8 Summary (see attached PDF)*
- (b.9)** Standard 8 PowerPoint (see attached PDF)
- (b.10)** Voluntary National Retail Food Regulatory Program Standards – Standard 8 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (b.11)** Standard 8 Re-Evaluation of Staffing Level Model Pilot Study Report (see attached PDF)
- (b.12)** CFP PSC Subcommittee CWG Questions (see attached PDF)
- (b.13)** CWG Standard 4 Response (see attached PDF)
- (b.14)** Standard 4 – Statistical Methodology (see attached PDF)
- (b.15)** Partial Achievement Survey (see attached PDF)
- (b.16)** CFP Plan Review Guide (see <http://www.foodprotect.org/media/guide/2016-plan-review-manual.pdf>)
- (b.17)** Preliminary Plan Review Proposal (see attached Word document)
- (b.18)** PSC subcommittee #3 Meeting #1 Minutes 12 19 2018
- (b.19)** PSC subcommittee #3 Meeting #2 Minutes 1 09 2019
- (b.20)** PSC subcommittee #3 Meeting #3 Minutes 1 23 2019
- (b.21)** PSC subcommittee #3 Meeting #4 Minutes 2 06 2019
- (b.22)** PSC subcommittee #3 Meeting #5 Minutes 3 13 2019
- (b.23)** PSC subcommittee #3 Meeting #6 Minutes 4 10 2019
- (b.24)** PSC subcommittee #3 Meeting #7 Minutes 5 8 2019
- (b.25)** PSC subcommittee #3 Meeting #8 Minutes 6 12 2019
- (b.26)** PSC subcommittee #3 Meeting #9 Minutes 7 17 2019
- (b.27)** PSC subcommittee #3 Meeting #10 Minutes 8 14 2019
- (b.28)** PSC subcommittee #3 Meeting #11 Minutes 9 11 2019
- (b.29)** PSC subcommittee #3 Meeting #12 Minutes 10 2 2019
- (b.30)** PSC subcommittee #3 Charge 1 Training Evaluation and Certification Initiatives
- (b.31)** PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1st Draft
- (b.32)** PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft
- (b.33)** PSC subcommittee #3 Charge 2 IFPTI Course Review
- (b.34)** PSC subcommittee #3 Charge 3 Quality Elements Cross-referenced
- (b.35)** Integrated Food Safety System (IFSS) Food Protection Professionals Curriculum Framework
- (b.36)** B2 Allergens IFPTI Course Profile
- (b.37)** B17 Laws Regulations IFPTI Course Profile
- (b.38)** B23 Public Health Principles IFPTI Course Profile
- (b.39)** B25 Sampling IFPTI Course Profile
- (b.40)** B26 Sanitation Practices IFPTI Course Profile
- (b.41)** Standard 2 Appendix B-1 (see <https://www.fda.gov/media/86752/download>)
- (b.42)** B8 Environmental Hazards IFPTI Course Profile
- (b.43)** B12 Integrated Food Safety System IFPTI Course Profile
- (b.44)** B15 Jurisdiction IFPTI Course Profile
- (b.45)** B16 Labeling IFPTI Course Profile
- (b.46)** B19 Pest Control IFPTI Course Profile
- (b.47)** B20 Plumbing IFPTI Course Profile

- (b.48) B22 Professionalism IFPTI Course Profile
- (b.49) B24 Recalls IFPTI Course Profile
- (b.50) B27 Traceability IFPTI Course Profile
- (b.51) B28 Transportation IFPTI Course Profile
- (b.52) VNRFRPS, Standard 2 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (b.53) VNRFRPS, Standard 3 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (b.54) VNRFRPS, Standard 4 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (b.55) CFP Training Manual (see <http://www.foodprotect.org/guides-documents/conference-for-food-protection-cfp-field-training-manual-for-regulatory-retail-food-safety-inspection-officers-5-31-13-cfp-update/>)
- (b.56) Manufactured Food Regulatory Program Standards (see <https://www.fda.gov/MFRPS>)
- (b.57) Draft 2017 VNRFRPS Self-Assessment Audit Form

## 2. **PSC Issue #2 New assessment tool for Standard 8 Staffing Level Criteria**

### a. **List of content documents submitted with this Issue: None**

### b. **List of supporting attachments: No supporting attachments submitted**

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 8 – Proposed Model (see attached PDF)
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #2 final report (attached PDF)
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *2018 Issue* (see page 27 <http://www.foodprotect.org/media/biennialmeeting/council-ii-final-issue-recommendations-1.pdf>)
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *2018 Program Standards Committee Final Report* [http://www.foodprotect.org/issues/packets/2018Packet/issues/II\\_013.html](http://www.foodprotect.org/issues/packets/2018Packet/issues/II_013.html). See the *Re-evaluation of VNRFRPS Standard 8 Subcommittee Report* and supporting attachments for Standard 8.
- (5) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Standard 8 Summary* (see attached PDF)
- (6) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Standard 8 PowerPoint* (see attached PDF)
- (7) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Voluntary National Retail Food Regulatory Program Standards – Standard 8* (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (8) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Standard 8 Re-Evaluation of Staffing Level Model Pilot Study Report* (see attached PDF)

## 3. **PSC Issue #3 Posting updated Crosswalk**

### a. **List of content documents submitted with this Issue: None**

### b. **List of supporting attachments:**

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Crosswalk-Requirements for Foodborne Illness Training Programs Based on Standard 5 2019 Final (attached Word document)
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #4 final report (attached PDF)

## 4. **PSC Issue #4 Maintenance and Posting of the Self-Assessment Tool (SA Tool)**

### a. **List of content documents submitted with this Issue: None**

### b. **List of supporting attachments:**

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #1 final report (see attached PDF)

- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Draft 2017 VNRFRPS Self-Assessment Audit Form* (see attached PDF)

**5. PSC Issue #5 Continuation of Issue 2018 II-014 PSC2**

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

**b. List of supporting attachments:**

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #1 final report (see attached PDF)
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Preliminary Plan Review Proposal (see attached Word document)
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *CFP Plan Review Guide* (see <http://www.foodprotect.org/media/guide/2016-plan-review-manual.pdf>)

**6. PSC Issue #6 Amend Standard 2 Appendix B-1 format**

**a. List of content documents submitted with this Issue: None**

**b. List of supporting attachments:**

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1st Draft
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 2 Appendix B-1 (see <https://www.fda.gov/media/86752/download>)

**7. PSC Issue #7 Amend Std 2 curriculum to replace select courses with updates**

**a. List of content documents submitted with this Issue: None**

**b. List of supporting attachments:**

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B2 Allergens IFPTI Course Profile* (see attached PDF)
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B17 Laws Regulations IFPTI Course Profile* (see attached PDF)
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B23 Public Health Principles IFPTI Course Profile* (see attached PDF)
- (5) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B25 Sampling IFPTI Course Profile* (see attached PDF)
- (6) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B26 Sanitation Practices IFPTI Course Profile* (see attached PDF)

**8. PSC Issue #8 Amend Standard 2 to include additional “pre” and “post” topics**

**a. List of content documents submitted with this Issue: None**

**b. List of supporting attachments:**

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B8 Environmental Hazards IFPTI Course Profile* (see attached PDF)
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B12 Integrated Food Safety System IFPTI Course Profile* (see attached PDF)
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B15 Jurisdiction IFPTI Course Profile* (see attached PDF)
- (5) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B16 Labeling IFPTI Course Profile* (see attached PDF)
- (6) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B19 Pest Control IFPTI Course Profile* (see attached PDF)
- (7) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *B20 Plumbing IFPTI Course Profile* (see attached PDF)

- (8) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *B22 Professionalism IFPTI Course Profile* (see attached PDF)
- (9) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *B24 Recalls IFPTI Course Profile* (see attached PDF)
- (10) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *B27 Traceability IFPTI Course Profile* (see attached PDF)
- (11) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *B28 Transportation IFPTI Course Profile* (see attached PDF)

**9. PSC Issue #9 Amend Std 2 to increase the time for completion of Steps 1-4**

**a. List of content documents submitted with this Issue: None**

**b. List of supporting attachments:**

- (1) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *VNRFRPS, Standard 2* (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (3) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *Manufactured Food Regulatory Program Standards* (see <https://www.fda.gov/MFRPS>)

**10. PSC Issue #10 Amend CFP Training Manual to add Quality Program Elements**

**a. List of content documents submitted with this Issue: None**

**b. List of supporting attachments:**

- (1) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *PSC Subcommittee #3 Charge 3 Quality Elements Cross-referenced* (attached Word document)
- (3) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *Draft Attachment A - CFP Training Plan and Log Revision* (attached Word document)
- (4) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *VNRFRPS, Standard 2* (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (5) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *VNRFRPS, Standard 4* (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (6) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *CFP Training Manual* (see <http://www.foodprotect.org/guides-documents/conference-for-food-protection-cfp-field-training-manual-for-regulatory-retail-food-safety-inspection-officers-5-31-13-cfp-update/>)
- (7) See Issue titled: Report - 2018-2020 Program Standards Committee; Attachment title: *Draft CFP Training Manual Revision*

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# Crosswalk - Requirements for Foodborne Illness Training Programs Based on Standard 5

## Introduction:

The 2014 – 2016 Interdisciplinary Foodborne Illness Training Committee (IFITC) was charged with developing a Crosswalk that would identify areas where training programs could be compared to Standard 5 of the Voluntary National Retail Food Regulatory Program Standards. Using the FSMA 205 C (1) Phases of a Food Incident Response CIFOR/RRT/MFRPS/VNRFPS Crosswalk as a base, the Committee revised the Crosswalk to compare additional training programs that were identified. In addition to the training programs identified in the CIFOR/RRT/MFRPS/VNRFPS Crosswalk, the IFITC also reviewed:

1. National Environmental Health Association (NEHA) course “I-FITT-RR”
2. National Environmental Health Association (NEHA) Epi-Ready – Foodborne Illness Response Strategies, June 2006

The resulting Crosswalk now identified the content of all the training programs and indicated, using a table format, how these compared to Standard 5. This Crosswalk is called Crosswalk – Requirements for Foodborne Illness Training Programs Based on Standard 5.

The Committee also recognized that in the process of determining gaps the Crosswalk could now have an expanded purpose of (1) identifying available resources related to Foodborne Illness Training; (2) setting a content baseline for the development of Foodborne Illness Training Programs; (3) establishing some consistency for training programs as a whole. The Committee considered this a more powerful interpretation of the first Charge and as such did not include any references to best practices.

The Committee also agreed that this document will be useful to regulators, academics and NGO's when new training programs are being considered especially as it would introduce consistency, a much needed component in Foodborne Illness Training Programs.

In 2016-2018, the Program Standards Committee (PSC) was now charged with maintaining the document. The document was updated with current references for the training materials.

In 2018 – 2020, the PSC used this Crosswalk to identify essential education content of foodborne disease outbreak training programs and update the Crosswalk with additional information. Courses added to the document are CDC EHS e-Learning on Environmental Assessment of Foodborne Illness Outbreaks, FDA Food Related Emergency Exercise Bundle (FREE-B0, IS-305: Environmental Health Training in Emergency Response (EHTER) Awareness Level, NEHA Certified Foodborne Outbreak Investigator Credential (CFOI) and Integrated Food Safety Center of Excellence (CoE) Webinar Series.

The resulting Crosswalk now identifies the content of all the training programs as indicated, using a table format, comparing them to Standard 5. In the interest of saving space, identified “Tools” that did not have a correlating “Reference” to the Standard 5 element being evaluated were removed from the Standard 5 element listing.

## Industry Related Sources

The PSC reached out to 50 industry food safety professionals to determine whether or not any companies had developed their own internal training system for investigating foodborne illnesses. We were unable to find any company that have developed their own comprehensive internal training system for investigating foodborne illnesses. There are a variety of documents from public resources, such as from state and federal agencies to teach the basics of investigations. For the most part, the PSC feels that industry needs to be knowledgeable enough to determine if the illness was related to the food that was served or sold and if there was a breakdown in safe food handling practices. Additionally, the industry needs to be as informed as the sanitarians or epidemiologists investigating the outbreak.

### Acronyms Used:

**RRT:** Rapid Response Team

**CIFOR:** Council to Improve Foodborne Outbreak Response

**MFRPS:** Manufactured Food Regulatory Program Standards

**IAFP:** International Association of Food Protection

**NASDA:** National Association of State Departments of Agriculture – Food Emergency Response Plan Template

<https://www.nasda.org/policy/issues/food-safety/emergency-management/food-emergency-response-plans>

**NEHA Epi-Ready:** National Environmental Health Association

**NEHA I-FITT-RR:** Industry-Foodborne Illness Investigation Training and Recall Response

**CDC –** Center for Disease Control

**VNRFRPS:** Voluntary National Retail Food Regulatory Program Standards – Standard 5

**CDC EHS:** Centers for Disease Control Environmental Health Specialist

**NEHA (CFOI):** National Environmental Health Association Certified Foodborne Outbreak Investigator credential \*NOTE: The CFOI procedures relate to policies that are part of the exam for purposes of obtaining the credential. Therefore the applicability of the CFOI to Standard 5 is limited.

**IFSCOE:** Integrated Food Safety Center of Excellence

**CoE:** Center of Excellence

**EATS:** Environmental Assessments Training Series - EATS 102 is a training program designed to reinforce the lessons learned in EATS 101 by providing 4 additional scenarios. The training does reinforce how to perform an environmental investigation and the roles for different team members. It does not necessarily provide written guidelines for a program to incorporate into their procedures.

**EHTER:** Environmental Health Training in Emergency Response \*\*NOTE: EHTER is a face-to-face introductory course designed to provide an overview of potential environmental health topics and guidance that an EH professional may encounter in a disaster situation (primarily focused on natural disasters). It does not address foodborne illness.

STANDARD 5 - Voluntary National Retail Food Regulatory Program Standards	
1. Investigative procedures.	
a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and food- related injury*. The procedures clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.	
Tool	Reference
RRT	II. A. Chapter 1
CIFOR	3.1
MFRPS	5.3
IAFP	Page 3-4
NASDA Version 4.0 August 2011	III, V, VI, VII, IX, X
NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Modules 1, 2, 3, 4,5, 6, 7
NEHA I-FITT-RR	Module 1 Building a Partnership: Who and Why?
NEHA (CFOI)	*Performing Environmental Assessment
IFSCOE	The CoE's are integral to quantitative analysis of foodborne illness investigation. The Crosswalk does more than simply identify the content of the training content but makes it easy to access track and verify through certification.
EATS	Lessons 1-4. All four scenarios provide information on the roles and responsibilities of the investigation team in an outbreak. The material is presented in an e-learning formatted and participants are not provided with written guidelines for further use.
Food Related Emergency Exercise Bundle (FREE)	Information contained in the Resource, Lead planner and Facilitator's guidelines are provided depending on scenario.
b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury* or contamination of food.	
Tool	Reference
RRT	II.B. Chapters 2&3
CIFOR	3.6.2.1
MFRPS	5.3.1.2.6
IAFP	Page3-4
NASDA Version 4.0 August 2011	VI, XIV

NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Module 1
NEHA I-FITT-RR	Module 1 Building a Partnership: Who and Why?
EATS	NEHA, in collaboration with CDC's Environmental Health Services Branch, the National Network of Public Health Institutes (NNPHI), EATS provides training on the role of environmental assessments in the broader context of outbreak investigations and the food safety system.
Food Related Emergency Exercise Bundle (FREE)	Several of the scenarios provide contact lists for appropriate contacts on federal level, websites where key information can be gathered.
c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.	
<b>Tool</b>	<b>Reference</b>
RRT	II.A. Chapter 1
CIFOR	3.1
MFRPS	5.3.1.1
NASDA Version 4.0 August 2011	V, VI, IX, XIII
NEHA I-FITT-RR	Module 1 Building a Partnership: Who and Why? Module 4 Epidemiologic Investigation
IFSCOE	The trainings are subject based.
Food Related Emergency Exercise Bundle (FREE)	The modules would help a jurisdiction to develop the MOU's with the appropriate program/department.
d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury* or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.	
<b>Tool</b>	<b>Reference</b>
RRT	II.E. Chapter 11
CIFOR	4.3.4.9
MFRPS	5.5
IAFP	Page 2,3,4 Example logs: page 139-140
NASDA Version 4.0 August 2011	
NEHA Epi-Ready. Foodborne Illness Response	Module 2

Strategies. Edition 2012	
NEHA I-FITT-RR	Module 2 How Do You Recognize a Foodborne Illness?
IFSCOE	Yes
EHTER	
Food Related Emergency Exercise Bundle (FREE)	Similar logs or databases are used to facilitate discussion throughout several of the scenarios presented.
e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.	
<b>Tool</b>	<b>Reference</b>
RRT	Chapter 9, 10, 11 & 13
CIFOR	Chapter 4, 4.3, Chapter 5
MFRPS	5.5
IAFP	Page 3-11
NASDA Version 4.0 August 2011	VI, IX
NEHA Epi- Ready. Foodborne Illness Response Strategies. Edition 2012	Module 2
NEHA I-FITT-RR	Module 2 How Do You Recognize a Foodborne Illness?
IFSCOE	Yes the methodologies are covered in the COE
Food Related Emergency Exercise Bundle (FREE)	Similar procedures are referenced throughout the scenarios
f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.	
<b>Tool</b>	<b>Reference</b>
RRT	Chapters 9, 10, 11 & 13 (pg.212) Subsection D
CIFOR	Chapter 4,5
MFRPS	5.5
NEHA (CFOI)	Detecting Outbreaks
g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, food-related injury*, or outbreak investigations.	
<b>Tool</b>	<b>Reference</b>
RRT	Chapters 9,10, 11 & 13 (Page 212) Subsection D
CIFOR	Chapter 4, 5
MFRPS	5.5
IAFP	Pages 41-45
NEHA Epi-	Module 3, 5, 8

Ready. Foodborne Illness Response Strategies. Edition 2012	
NEHA I-FITT-RR	Module 3 Environmental Assessment Exercise
CDC Foodborne Illness Outbreak Environmental Assessments	Lesson 4, 5
NEHA (CFOI)	Performing Environmental Assessment
IFSCOE	Step 1: Detect a Possible Outbreak. Step 2: Define and Find Cases Step 3: Generate Hypotheses about Likely Sources Step 4: Test Hypotheses Step 5: Solve Point of Contamination and Source of the Food Step 6: Control an Outbreak Step 7: Decide an Outbreak is Over
EATS	Lessons 1-4 provides guidance on what information to collect during on site evaluations.
Food Related Emergency Exercise Bundle (FREE)	The established procedures are referenced and explained throughout several of the scenarios.
h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.	
<b>Tool</b>	<b>Reference</b>
RRT	Chapter 6, 10
CIFOR	3.1, 3.10, 6.3
MFRPS	5.5
IAFP	Pages 99-103
NASDA Version 4.0 August 2011	V, VI, IX
NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Module 7
Food Related Emergency Exercise Bundle (FREE)	The established procedures are referenced and explained throughout several of the scenarios.
i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.	
<b>Tool</b>	<b>Reference</b>
RRT	Chapter 6, 10
CIFOR	3.1, 3.10, 7.3
MFRPS	5.3.1.2.2

IAFP	Pages 6-7
NASDA Version 4.0 August 2011	IV, V, VI, IX, XII, XV
NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Module 7
CDC Foodborne Illness Outbreak Environmental Assessments	Lesson 7
NEHA (CFOI)	Detecting Outbreaks
IFSCOE	Colorado Integrated Food Safety Center of Excellence (CoE). The CoE's identify and develop model practices in foodborne disease surveillance and outbreak response.
Food Related Emergency Exercise Bundle (FREE)	The established procedures are referenced and explained throughout several of the scenarios.
<b>2. Reporting Procedures</b>	
a. Possible contributing factors to the food-related illness, food-related injury* or intentional food contamination are identified in each on-site investigation report.	
<b>Tool</b>	<b>Reference</b>
RRT	Chapters 9, 10, 11
CIFOR	5.2
MFRPS	5.3
IAFP	Pages 34-41
NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Modules 5, 8
NEHA I-FITT-RR	Module 3 Environmental Assessment Exercise
CDC Foodborne Illness Outbreak Environmental Assessments	Lesson 2
NEHA (CFOI)	Reviewing Investigation Findings
IFSCOE	An example: Evaluation of Nebraska Foodborne Illness and Outbreak Response Using the Council to Improve Foodborne Outbreak and Response (CIFOR) Proposed Performance Measures 01/11/2017
EATS	Lessons 1-4. The training focuses on understanding how the foodborne illness could have occurred and identifying the contributing factors.
Food Related Emergency Exercise Bundle (FREE)	Covered under several modules detailing the foodborne illness investigation.
b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks*	

with CDC.	
<b>Tool</b>	<b>Reference</b>
RRT	Chapters 3, 6, 13
CIFOR	4.2, 4.3, 4.4, 7.5, 9.1
MFRPS	5.5
IAFP	Page 75
NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Module 8
NEHA I-FITT-RR	Module 7 Final Report & Recovery
CDC Foodborne Illness Outbreak Environmental Assessments	Lesson 8
IFSCOE	Yes
EATS	Lessons 1-4. The training includes reporting on findings from the investigation
Food Related Emergency Exercise Bundle (FREE)	Sharing of final reports is outlined within the scenarios
<b>3. Laboratory Support Documentation</b>	
a. The program has a letter of understanding, written procedures, contract or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis, and clinical sample analysis.	
<b>Tool</b>	<b>Reference</b>
CIFOR	4.2, 4.3, 4.4, 9.1,
MFRPS	5.3.3.4
IAFP	
NASDA Version 4.0 August 2011	VI
NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Modules 4 & 5
NEHA I-FITT-RR	Module 5 Collecting Samples and Laboratory Testing
IFSCOE	Yes
Food Related Emergency Exercise Bundle (FREE)	Lab documentation procedures are shared during the scenarios.
b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related	

emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

<b>Tool</b>	<b>Reference</b>
CIFOR	4.2, 4.3, 4.4, 9.1
MFRPS	5.5
NASDA Version 4.0 August 2011	VI
NEHA (CFOI)	Collecting Samples
IFSCOE	Yes
Food Related Emergency Exercise Bundle (FREE)	The scenarios presented in the modules address these issues.

#### 4. Trace-back Procedures

a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

<b>Tool</b>	<b>Reference</b>
RRT	Chapter 9
CIFOR	5.2
MFRPS	5.3.3.3
IAFP	Forms J 1, 2 & 3 (pg. 154-154)
NASDA Version 4.0 August 2011	VI, IX
NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Module 5
NEHA I-FITT-RR	Module 8 Food Recalls
CDC Foodborne Illness Outbreak Environmental Assessments	Lesson 7
NEHA (CFOI)	Conducting Product Tracing
IFSCOE	Yes
Food Related Emergency Exercise Bundle (FREE)	Lab documentation procedures are shared during the scenarios.

#### 5. Recalls

a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.

<b>Tool</b>	<b>Reference</b>
RRT	Chapter 12
CIFOR	5.2.4.1.1
MFRPS	5.3.2.2
NASDA Version 4.0 August 2011	VI, IX
NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Module 5
NEHA I-FITT-RR	Module 8 Food Recalls
Food Related Emergency Exercise Bundle (FREE)	The scenarios presented in the modules address these issues.
b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.	
<b>Tool</b>	<b>Reference</b>
RRT	Chapter 12
CIFOR	5.2
NASDA Version 4.0 August 2011	VI, IX
NEHA I-FITT-RR	Module 8 Food Recalls
Food Related Emergency Exercise Bundle (FREE)	The scenarios presented in the modules address these issues.
c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.	
<b>Tool</b>	<b>Reference</b>
RRT	Chapter 12
CIFOR	5.2
IAFP	
NEHA I-FITT-RR	Module 8 Food Recalls
NEHA (CFOI)	Conducting Product Testing
Food Related Emergency Exercise Bundle (FREE)	The scenarios presented in the modules address these issues.
6. Media Management	
a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.	

<b>Tool</b>	<b>Reference</b>
RRT	Chapters 3 & 6
CIFOR	3.6
MFRPS	5.3.4.2
IAFP	Page 73 and 105
NASDA Version 4.0 August 2011	VI, IX, XI
NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Module 8
NEHA I-FITT-RR	Module 6 Control Measures Module 8 Food Recalls
NEHA (CFOI)	Preparing for Investigation Reviewing Investigation Findings
IFSCOE	Yes
Food Related Emergency Exercise Bundle (FREE)	The scenarios presented in the modules address these issues.
<b>7. Data Review and Analysis</b>	
a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.	
<b>Tool</b>	<b>Reference</b>
RRT	Chapters 13 & 14
CIFOR	4.3, Chapter 8, 5.2.9
IAFP	2 & 3
NASDA Version 4.0 August 2011	XIV
NEHA Epi-Ready. Foodborne Illness Response Strategies. Edition 2012	Module 2
IFSCOE	Yes
Food Related Emergency Exercise Bundle (FREE)	The scenarios presented in the modules address these issues.
b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following: 1) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* in a single establishment; 2) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Disease Outbreaks* in the same establishment type; 3) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* implicating the same food;	

- 4) Foodborne Disease outbreaks\*, Suspect Foodborne Outbreaks\* and Confirmed Foodborne Disease Outbreaks\* associated with similar food preparation processes;
- 5) Number of confirmed foodborne disease outbreaks\*;
- 6) Number of foodborne disease outbreaks\* and suspect foodborne disease outbreaks\*;
- 7) Contributing factors most often identified;
- 8) Number of complaints involving real and alleged threats of intentional food contamination; and
- 9) A number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.

Tool	Reference
RRT	Chapters 13 & 14
CIFOR	4.3, Chapter 8
IFSCOE	Campylobacter Outbreak at a Colorado Correctional Facility A Foodborne Outbreak Investigation Case Study [ Available at the COE in Colorado]

c. In the event that there have been no food-related illness or food-related injury\* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate a response to an actual confirmed foodborne disease outbreak\* and include on-site inspection, sample collection, and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak\* investigations occur.

Tool	Reference
RRT	Chapter 8
IFSCOE	Mock scenarios are part of the investigative process

<b>FTE DATA CALCULATION</b>			
<b>Calculate productive hours per year for an employee doing 100% food inspections</b>			
<b>Information For One Employee</b>	<b>Hours/Year</b>	<b>Hours/Day</b>	<b>Total Hours</b>
<b>Annual FTE Hours Per Year: Industry Standard</b>			2080
Local Holiday Hours Per Year			0
Local Vacation Leave Hours Per Year			0
Local Sick Leave Hours Per Year			0
Local Family-Personal Leave Hours Per Year			0
<b>Productivity Factoring Per Year</b>			
Travel Time For Inspection			2080
Administrative Work (in-office work)			2080
Break time			2080
Others			2080
<b>Personal Development Time Per Year</b>			
Professional Development			2080
Others			2080
<b>Productive Annual FTE Hours Per Year (FTE Conversion Factor)</b>			<b>2080</b>

<b>FOOD SAFETY INSPECTION HOURS PER YEAR</b>			
<b>Position Title</b>	<b>Percent of time spent on food inspections</b>	<b>Number of Employees</b>	<b>Total Hours</b>
			0
			0
			0
			0
			0
			0
<b>Total Food Safety Inspection Hours</b>			<b>0</b>
<b>Total Current FTE</b>			<b>0.00</b>

Actual working days	Actual working weeks
260	52

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**STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION**

	Low Risk Establishments	Frequency of Low Risk Est Inspections Per Year
Routine and Permitting		1.00
Follow Up Inspections/Reinspections		
Foodborne Illness Complaints		
Other		

**Total Number of Required Inspections**

Median Hours Spent Per Inspection	0.75	
Total Inspection Time		

**Total Required FTE**

**Standard 8.1 Staffing Level**

**Sources**

- 2017 Subcommittee # 2 - Survey 1 and 2
- 2019 Pilot Study

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Moderate Risk Establishments	Frequency of Moderate Risk Est Inspections Per Year	High Risk Establishments	Frequency of High Risk Est Inspections Per Year	Total
	2.00		3.00	0
				0
				0
				0
				0
1.25		2.00		0
				0.00
				Standard not met

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## Draft CFP Training Manual Revision

This mock-up includes proposed language in red to be added to the CFP Training Manual, pgs. 7-8, to better align Standard 2 with Standard 4:

### **PERFORMANCE ELEMENTS**

The *CFP Training Plan and Log* contains a total of 23 “performance elements” within the six (6) inspection training areas.

#### I. Pre-Inspection – (2 *Performance Elements*)

- Has the required equipment and forms to conduct the inspection.
- Reviews establishment file for the **current risk category assigned**, previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance.

#### II. Inspection Observations and Performance – (7 *Performance Elements*)

- Provides identification as a regulatory official to the person in charge, confirming agency authority for the inspection, and stating the purpose of the visit.
- Has knowledge of the jurisdiction’s laws, rules, and regulations required for conducting retail food/foodservice inspections.
- Uses a risk-based inspection methodology to assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food **and verify the establishment is assigned the correct risk category.**
- Obtains immediate corrective action for out of compliance employee practices and management procedures essential to the safe storage, preparation and service of food.
- Correctly assesses the compliance status of other regulations (Good Retail Practices) that are included in the jurisdiction’s prevailing statutes, regulations, and/or ordinances.
- Verifies correction of out of compliance observations identified during the previous inspection. **Discusses options for the long-term control of risk factors.**
- Correctly uses inspection equipment during the joint inspection.

#### IV. Written Communication – (3 *Performance Elements*)

- Completes inspection form per the jurisdiction's administrative procedures (e.g., observations, corrective actions, public health reasons, applicable code references, **options for the long-term control of risk factors**, compliance dates).
- Includes with the inspection report any compliance or regulatory documents identified or cross-referenced in written statements (e.g., exhibits, attachments, sample forms, embargo forms, destruction forms, suspension notices).
- Presents the inspection report, and when necessary cross-referenced documents, to the person in charge.

## Draft Attachment A - CFP Training Plan and Log Revision

This mock-up includes proposed language in **red** to be added to Attachment A – CFP Training Plan and Log, to better align Standard 2 with Standard 4:

### I. Pre-Inspection

2. Reviews establishment file for the <b>current risk category assigned</b> , previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer Initials
Reviewed previous inspection report noting documented out of compliance observations and comments.	JFT/OD			
Reviewed establishment file for complaint reports.	JFT/OD			
Reviewed establishment file for documentation indicating a need for a HACCP Plan.	JFT/OD			
Reviewed establishment file for documentation of food production or processes operating under a variance issued by the jurisdiction	JFT/OD			
<b>Reviewed establishment file for documentation indicating the assigned risk category.</b>				

*Addresses Standard 4 - Quality Assurance Program Element III*

### II. Inspection Observations and Performance (continued)

3. Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food and <b>verify the establishment is assigned the correct risk category.</b>	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer Initials
Verified Demonstration of Knowledge of the person in charge.	JFT			
Verified approved food sources (e.g., food from regulated food processing plants; shellfish documentation; game animal processing; parasite destruction for certain species of fish intended for raw consumption; receiving temperatures).	JFT			
Verified food safety practices for preventing cross-contamination of ready-to-eat food.	JFT			
Verified food contact surfaces are clean and sanitized, protected from contamination from soiled cutting boards, utensils, aprons, etc., or raw animal foods	JFT			
Verified the restriction or exclusion of ill employees. Verified no bare hand contact with ready-to-eat foods (or use of a preapproved, alternative procedure)	JFT			
Verified employee handwashing.	JFT			
Verified cold holding temperatures of foods requiring time/temperature control for safety (TCS food), or when necessary, verified that procedures are in place to use time alone to control bacterial growth and toxin production.	JFT			
Verified date marking of ready-to-eat foods TCS food held for more than 24 hours.	JFT			
Verified cooking temperatures to destroy bacteria and parasites.	JFT			
Verified hot holding temperatures of TCS food or when necessary, that procedures were in place to use time alone to prevent the outgrowth of spore-forming bacteria.	JFT			
Verified cooling temperatures of TCS food to prevent the outgrowth of spore-forming or toxin-forming bacteria.	JFT			
Verified reheating temperatures of TCS food for hot holding.	JFT			
Verified the availability of a consumer advisory for foods of animal origin served raw or undercooked.	JFT			
Identified food processes and/or procedures that require a HACCP				

Plan per the jurisdiction's regulations.	JFT			
<u>Verified the establishment is assigned the correct risk category, and when necessary, informs the supervisor when the establishment is not in the proper risk category.</u>	JFT			

*Addresses Standard 4 - Quality Assurance Program Element III*

## II. Inspection Observations and Performance (continued)

6. Verifies correction of out of compliance observations identified during previous inspection. <u>Discusses options for the long-term control of risk factors.</u>	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer Initials
Verified correction of out of compliance observations identified during the previous inspection.	JFT			
<u>Discussed options for the long-term control of risk factors with establishment managers when the same out-of-control risk factor occurs on consecutive inspections (e.g., risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans).</u>				

*Addresses Standard 4 - Quality Assurance Program Element IX*

## IV. Written Communication

1. Completes inspection form per the jurisdiction's administrative procedures (e.g., observations, corrective actions, public health reasons, applicable code references, <u>options for the long-term control of risk factors</u> , compliance dates).	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer Initials
Used correct inspection form.	JFT			
Completed a legible report.	JFT			
Accurately documented observations made during inspection.	JFT			
Completed inspection form in accordance with jurisdiction's administrative procedures.	JFT			
Cited correct code provisions/rules/regulations.	JFT			
Documented immediate corrective action for out-of-compliance foodborne illness contributing factors and Food Code Interventions (listed in Section II, Item 3).	JFT			
Documented time frames for correcting each out of compliance observation.	JFT			
<u>Documented that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections</u>				

*Addresses Standard 4 - Quality Assurance Program Element XVIII*

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COMMITTEE NAME: Program Standards Committee – Subcommittee #1

DATE OF FINAL REPORT: 10/31/2019

COMMITTEE ASSIGNMENT:  Council I     Council II     Council III     Executive Board

REPORT SUBMITTED BY: Andre C. Pierce

COMMITTEE CHARGE(S):

**Issue #2018 II-013**

1. Examine whether there is an additional burden place on enrollees or FDA (in time, money, or added complexity of the Standards) associated with development of a system to ensure that jurisdictions are uniformly recognized for partial achievement of the Standards (charge originally assigned via Issue 2016 II-009)
2. Identify work on a cost/benefit analysis for recognizing partial achievement of the VNRFRPS following clarification from the FDA (charge originally assigned via 2016 II-009)
3. Identify inconsistencies in language between all Standards in the VNRFRPS

**Issue #2018 II-014** – not originally assigned as a charge – Executive Board asked the PSC to continue work with partial recognition (#1) and plan review (#3)

1. 2018 II-014 #1 – Recognize that enrolled agencies, especially local regulator, may not have control over their retail food regulations. Recognize efforts made to achieve this standard when the gap can be documented by the enrollee as part of their Standard 1 self-assessment.
2. 2018 II-014 #3 – Work with PSC to include plan review in the VNRFRPS. The committee recognizes that facility design and construction support behaviors that reduce the occurrence of foodborne illness risk factors.

COMMITTEE WORK PLAN AND TIMELINE:

1. See the Program Standards Committee Work Plan document.
2. All subcommittee work was completed in October, 2019.

COMMITTEE ACTIVITIES:

1. **Dates of committee meetings or conference calls:** 2/19/2019, 3/21/2019, 5/1/2019, 5/30/2019, and 6/27/2019.
2. **Overview of committee activities:** Subcommittee #1 (Issue # 2018 II-013 & Issue # 2018 II-014) –The PSC co-vice chair, Andre Pierce took the lead on scheduling subcommittee meetings. His work got the subcommittee on track to complete the assigned charges by the deadline. Members of the committee developed a survey related to partial achievement that was sent to VNRFRPS enrolled jurisdictions in North Carolina and Texas. There were 47 respondents- 91% were local jurisdictions. The results showed that most jurisdictions would like some way to track their partial achievement of standards for internal purposes only. Only three of the 47 respondents wanted a public facing website to report. Nearly half (49%) of the respondents had not heard about the tracking spreadsheet. The committee used the data to develop the position that the tracking spreadsheet is a useful tool for internal self-reporting and needs to be marketed, rather than having a public website for reporting. The issue will reflect these discussions and will close this charge. Additionally, the subcommittee discussed the value of plan review to support behaviors that reduce the occurrence of risk factors associated with foodborne illness. The subcommittee developed draft criteria and is recommending that those ideas be explored further in the next biennium with the submittal of PSC Issue #5 Continuation of Issue 2018 II—014 PSC2 Plan Review Incorporation in the Program Standards. The subcommittee also discussed potential inconsistencies in the VNRFRPS. No changes were identified at this time.
3. **Charges COMPLETED and the rationale for each specific recommendation:**
  - a. 2018 II-013 #1 – The subcommittee determined through a survey that Jurisdictions need tools to report progress on compliance with the Retail Program Standards to their boards, councils and other policy makers. The self-assessment tool is adequate for presenting data internally. The subcommittee developed an issue asking FDA to maintain and publish the SA Tool
  - b. 2019 II-013 #2 – The subcommittee determine there is minimal burden to maintain and post the SA Tool on the FDA website
  - c. 2018 II-014 #1 - The subcommittee determined through a survey that Jurisdictions need tools to report progress on compliance with the Retail Program Standards to their boards, councils and other policy makers. The self-assessment tool is adequate for presenting data internally. The subcommittee developed an issue asking FDA to maintain and publish the SA Tool
4. **Charges INCOMPLETE and to be continued to next biennium:**
  - a. 2018 II-014 #3 – The subcommittee recommends continuation of Issue 2018 II-014, charge 1, to have the FDA work with the Program Standards Committee (PSC) to incorporate plan review in the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS).

**COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:**

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

**LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:**

**1. PSC Issue #4 Maintenance and Posting of the Self-Assessment Tool (SA Tool)**

**a. List of content documents submitted with this Issue: None**

**b. List of supporting attachments:**

(1) Subcommittee #1 Final Report (see attached PDF)

(2) Draft 2017 VNRFRPS Self-Assessment Audit Form (see attached PDF)

**2. PSC Issue #5 Continuation of Issue 2018 II-014 PSC2**

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

**b. List of supporting attachments:  No supporting attachments submitted**

(1) Subcommittee #1 Final Report (see attached PDF)

(2) Preliminary Plan Review Proposal

(3) CFP Plan Review Guide (see <http://www.foodprotect.org/media/guide/2016-plan-review-manual.pdf>)

## Conference for Food Protection – Committee FINAL Report

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**COMMITTEE NAME:** Program Standards Committee – Subcommittee #2 (Re-evaluation of Standard 8 Staffing Levels)

**DATE OF FINAL REPORT:** October 21, 2019 **Date amended:** 12/3/2019

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

**REPORT SUBMITTED BY:** Michael Schaffer & Peri Pearson, Subcommittee Co-Chairs

**COMMITTEE CHARGE(S):**

**Issue # 2018 II-018**

1. Continue to collaborate with the FDA internal Program Standards working group on modifying the “description of Requirements” for “Staffing Level” in Standard 8 of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS);
2. Use the supporting attachments listed in the 2016-2018 Program Standards Committee, Standard 8 Subcommittee report as the foundation to establish as more statistically sound logic model for the FTE/Inspection ratio and provide the new calculation/formula to be used by a VNRFRPS enrollee to assess the Standard 8 “Staffing Level”;
3. Propose amendments to Standard 8 of the VNRFRPS and the CFP guidance document titled “standard 8 Staffing Level Assessment workbook” and accompanying “Instruction Guide” to incorporate the outcomes of Charges 1 and 2; and
4. Report back committee finding and recommendations to the 2020 Biennial Meeting.

**COMMITTEE WORK PLAN AND TIMELINE:**

The Standard 8 Subcommittee was established by the Program Standards Committee to address the specific charges in Issue #2016 II-020. Michael Schaffer is the submitter of Issue #2016 II-020. The 2018-2020 subcommittee is continuing the work started in 2016. Mr. Schaffer is a local regulator and Ms. Pearson is a State Regulator, other members of this subcommittee include one (1) local regulator, two (2) industry representatives, two (2) FDA consultants, and one (1) CDC consultant. Subcommittee activities have been conducted by conference calls and emails. A great deal of work was accomplished by Mr. Schaffer and his team with Harris County Public Health. Their work included surveys of Retail Program Standards enrollees, data compilation, statistical analysis, and providing graphic representations of data and data analysis, as well as conducting a Pilot Study to the subcommittee. Subcommittee documents were posted to the Subcommittee #2 workgroup folder on FoodSHIELD for review during conference calls.

**COMMITTEE ACTIVITIES:**

**1. Dates of committee meetings or conference calls:**

Subcommittee #2 met eight (6) times by conference call: February 19, 2019; March 19, 2019; May 13, 2019; June 18, 2019; October 17, 2019; and October 21, 2019.

**2. Overview of committee activities:**

The proposed model for Standard 8 staffing level assessment, developed by Mr. Schaffer’s team with assistance from this (and the 2016-2018) PSC subcommittee, was presented for Subcommittee review. The proposed change provides three options for assessing staffing levels including one which removes the range (280-320 inspections/FTE) and is based on data obtained through surveys conducted by the 2016-18 Subcommittee. The presentation and document are available in the Food Shield Subcommittee #2 Folder. FDA continues to express concern that the proposed changes to Standard 8 staffing levels do not adhere to the “Best Practice” approach that the Standards promote and does not present a uniform staffing level standard. The voting members of Subcommittee #2 support the proposed changes. Mr. Sudler, FDA CIFSAN, agreed to contact a FDA statistician and set up a meeting with Mr. Schaffer to further evaluate the most appropriate use of the data (primarily data related to times assigned to inspection categories). However, we have not been notified of a meeting with an FDA statistician to date.

In August 2019, Subcommittee #2 met with the Program Standards Committee to discuss the work that had been completed to date. A key decision made on the call was to pilot the proposed model with a pool of health departments across the nation. In September 2019, Subcommittee #2 conducted a pilot study of a proposed staffing level evaluation model as decided by the Program Standards Committee. The study consisted of sending a survey to health departments in order to obtain staffing level data and use the proposed model to analyze this data. Harris County Public Health led the study. The Subcommittee shared the result of the Pilot Results with the subcommittee members to get their feedback before drafting an issue requesting modification of the criteria for assessing staffing levels in Standard 8 for consideration by the 2020 CFP.

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

- a. Charge 1 has been completed. We have continued to discuss the proposed model with various FDA members. The FDA members agree that the current assessment tool for staffing level was designed on unrealistic logic based on no known data, making the ratio that passes or fails a jurisdiction in the tool inappropriate. However, there is no consensus on if the new proposed model that has been designed with real data and statistical robustness should modify and/or replace the ratio of the current tool. One main concern is that it does not represent “best practice” from their perspective as the proposed model is derived from real world data of what jurisdictions “currently” do and not what they “should” do. To try to alleviate this concern we’ve demonstrated that the methodology creating the proposed model sought to use data focused more heavily from high performing jurisdictions (i.e., ones that met more standards) but statistical testing verified that high performing jurisdictions had no significantly different data than lower performing ones. To keep the effort to make the proposed model something for jurisdictions to strive to meet, we discussed best practices with high performing jurisdictions and used data from our research that sought to capture what jurisdictions should aim for. The FDA members continue to be hesitant if the proposed model should be used to modify and improve the current assessment tool.
- b. Charge 2 has been completed. In order to verify that the proposed model was statistically sound, Subcommittee #2 worked with Dr. Matthew Koslovsky, a Post-Doctoral Research Associate from Rice University focusing in Biostatistics. He reviewed and approved the below methodology used to create the proposed model. This model was created by using data provided by 105 health departments. The logic behind the proposed model requires that food establishments be categorized by risk level (low, moderate, and high). The first step in creating the proposed model was to analyze if the inspection times and frequencies provided by the health departments were significantly related to the number of standards a health department had met. This was important, since the number of standards a health department met was the only information indicating their performance level. If health departments that met more standards had significantly different inspection times and frequencies than those that did not, it would have been better to only use those values. Statistical analysis demonstrated that there was no significant relationship between the number of standards a health department met and their responses related to inspection time and frequency. Due to this, it was considered sufficient to use either the average or median inspection time and frequency values of all respondents. Further statistical analysis confirmed that the average and median inspection frequency and time values were significantly different for each risk category. In other words, inspection time and frequency was lower for low-risk establishments and was higher for high-risk establishments. Lastly, it was decided that the median, not the average, should be used to remove the effects of extreme values. This was important as the median prevents outliers such as jurisdictions that are inspecting establishments fewer times a year than the FDA recommends, or conducting inspections too fast or too slow as deemed reasonable, from influencing the standardized values in the model. The proposed model works by removing the inspection-to-FTE ratio and instead calculates how many FTEs a health department should have. It does this by first using a formula based on standardized inspection times and frequencies based on risk categories to calculate the total inspection hours for each jurisdiction. It automatically divides this total by the FTE productive hours calculated in the current model to obtain the number of FTEs the health department should have. Lastly, it “passes” the health department if the number of FTEs they currently have is greater than or equal to the number of FTEs the jurisdiction should have. If the health department currently has an equal or greater number of FTEs, as calculated by the proposed model, then the health department would be considered sufficiently staffed; consequently, that health department would meet Standard 8. In order to determine if the proposed model would work in a self-audit, we conducted a pilot study from August to September 2019. The details of the pilot can be reviewed in the supporting document “Standard 8 Re-Evaluation of Staffing Level Model Pilot Study Report”.
- c. Charge 3 has been completed. On October 21, 2019, the members of Subcommittee #2 held a vote to determine the proposed amendments to the Standard 8 of the VNRFRPS and the CFP guidance document. The voting members decided to recommend including both the current and proposed amendment tool to assess compliance for Standard 8. The jurisdiction conducting the self-audit will have the option of using either of the assessments tools to determine compliance for staffing level resources.
- d. Charge 4 has been completed. The subcommittee has devised a recommendation to propose an amendment to the Standard 8 “Staffing Level” FTE/Inspection Ratio criteria. The majority of the subcommittee voting members decided to amend Standard 8 to include the proposed model assessment tool as a secondary option to determine compliance. The intent of the recommendation will not be to weaken the Standard but to provide a secondary assessment tool that measures practical performance of the enrollee against the Standard.

4. **Charges INCOMPLETE and to be continued to next biennium:**

- a. None

**COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:**

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

**LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:**

1. PSC Issue #2 New assessment tool for Standard 8 Staffing Level Criteria.

**a. List of content documents submitted with this Issue:** None

**b. List of supporting attachments:**

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 8 – Proposed Model (see attached PDF)
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Program Standards Committee subcommittee #2 final report* (attached Word)
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *2018 Issue* (see page 27 <http://www.foodprotect.org/media/biennialmeeting/council-ii-final-issue-recommendations-1.pdf>)
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *2018 Program Standards Committee Final Report* [http://www.foodprotect.org/issues/packets/2018Packet/issues/II\\_013.html](http://www.foodprotect.org/issues/packets/2018Packet/issues/II_013.html). See the Re-evaluation of VNRFRPS Standard 8 Subcommittee Report and supporting attachments for Standard 8.
- (5) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Standard 8 Summary* (see attached PDF)
- (6) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Standard 8 PowerPoint* (see attached PDF)
- (7) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Voluntary National Retail Food Regulatory Program Standards – Standard 8 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (8) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Standard 8 Re-Evaluation of Staffing Level Model Pilot Study Report* (see attached PDF)

## Conference for Food Protection – Committee Periodic Report

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**Approved 4/20/2016**

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*Committee-submitted documents may impact the image, credibility and integrity of the Conference as an organization. With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.*

**COMMITTEE NAME:** Program Standards (PSC), Subcommittee 3

**DATE OF REPORT:**  Final subcommittee report

**Date submitted:** 10/31/2019

**Date amended (if applicable):** 12/3/2019

**Date accepted by Executive Board:** [Click here to enter a date.](#)

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

**REPORT SUBMITTED BY:** *Christine Sylvis, Co-Chair and Kenesha Williamson, Co-Chair*

**COMMITTEE CHARGE(S):**

**Issue # 2018-II-019**

Collaborate with the FDA Office of Training Education and Development (OTED) and the Partnership for Food Protection Training and Certification Workgroup (PFP TCWG) to:

1. Continue review of all initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities.
2. Review the results of the PFP TCWG recommendations for the nationally recognized Retail Food Curriculum based on the Retail Food Competency and Curriculum Framework to determine if changes are needed in the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard 2 curriculum; including, but not limited to:
  - a. Identifying any gaps and recommendations for change; and
  - b. Reviewing the time frame for completion of Standard 2, Steps 1 through 4, for new hires or staff newly assigned to regulatory retail food protection programs.
3. Continue to assess if any changes will be needed in VNRFRPS Standard 2 Trained Regulatory Staff to provide better alignment with Standard 4 of the VNRFRPS.
4. Report back findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**COMMITTEE WORK PLAN AND TIMELINE:**

An introductory meeting in December 2018 followed by bi-weekly meetings January - February 2019 then monthly meetings through September 2019. Workgroup documents will be shared via FoodSHIELD and attached to calendar invitations. WebEx will be used for presenting workgroup material and reviewing documents, during monthly meetings. The committee's regulatory members will be assigned portions of the national framework courses to evaluate for discussion with the group. Polls will be forwarded via email, as needed, to voting members to finalize recommendations. Periodic reports will be prepared and submitted in February 2019, July 2019, and October 2019, in accordance with the CFP master calendar.

**COMMITTEE ACTIVITIES:**

**1. Overview of committee activities:**

- a. Dates of committee conference calls: December 19, 2018, January 9, 2019, January 23, 2019, February 6, 2019, March 13, 2019, April 10, 2019, May 8, 2019, June 12, 2019, July 17, 2019, August 14, 2019, September 11, 2019, and October 2, 2019. Dates of electronic votes: February 16, 2019 and October 4, 2019.
- b. The conference call on December 19, 2018 was used to review the committee charges, determine the timeline for addressing the charges, and it was decided that FoodSHIELD will be used for document sharing. The conference call on January 9 addressed charge 1, and a list of training, evaluation and/or certification courses available to food safety inspection officers was developed. The conference call on January 23, 2019 addressed charge 3, and the committee started work on a document of the twenty Standard 4 Quality Assurance elements and associated trainings. The conference call on February 6, 2019 provided an overview of the Retail Food Competency and Curriculum Framework from International Food Protection Training Institute (IFPTI) and addressed the time frame for completion of Standard 2, steps 1 through 4. Conference calls March 13, 2019 through July 17, 2019 to review the IFPTI framework courses. Four teams were assembled with one industry and one regulatory member. Each team was assigned four courses to review (one per month) for its usefulness, whether there is any missing content, and if it should be implemented as "pre" or "post" coursework in the current VNRFRPS Standard 2 curriculum in Appendix B-1. The conference call on August 14, 2019 reviewed the list of charge 1 initiatives for training, certification, and evaluation of food inspection officers, charge 2a, and the recommendations received at that point, i.e. add, replace, or no action and indicating "pre" or "post" coursework. The conference call on September 11, 2019 continued discussion of group recommendations and discussed charge 3. Insufficient number of voting members on the call prohibited voting. On October 2, 2019, the final conference call was held. The group voted on majority of potential issues for charge 2a and charge 3. Voting continued electronically on October 4, 2019. The results of the vote were

emailed on October 14.

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

- a. Charge 1: The committee discussed initiatives (existing, new, or under development) involving the training, evaluation and/or certification available to Food Safety Inspection Officers (FSIO) in their respective jurisdictions (see attachment *PSC subcommittee #3 Charge 1 Training Evaluation and Certification Initiatives*).
- b. Charge 2a: The Committee reviewed 26 Integrated Food Safety System Basic Curriculum courses for Food Protection Professionals provided by the International Food Protection Training Institute (IFPTI) (see attachments *PSC subcommittee #3 Charge 2 IFPTI Course Review and Integrated Food Safety System (IFSS) Food Protection Professionals Curriculum Framework*). Courses B7 Emergency Response and B19 Pest Control were under development and not available for review. After the team's review, the committee discussed the training and voted on whether to (1.) replace existing Standard 2 curriculum in appendix B-1 with the IFPTI course, (2.) add the IFPTI course to existing Standard 2 curriculum in appendix B-1, or (3.) do not include the IFPTI course in existing Standard 2 curriculum in appendix B-1 ("no action"). The committee recommends the following changes to existing Standard 2 (Appendix B-1):
  - i. Reformat Appendix B-1 into a table with training topics in one column and courses which fulfill the curriculum topics in another column. The current formatting implies the course listed is the only course that will fulfill the training requirement. The proposed format better shows that other courses may be used if deemed equivalent by the regulatory jurisdiction. It is anticipated that there may be accessibility issues with ComplianceWire courses in the future and other comparable courses may be needed as substitutions. Attachment *PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1<sup>st</sup> Draft* demonstrates suggested changes to Appendix B-1 using current Standard 2 curriculum; Attachment *PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2<sup>nd</sup> Draft* demonstrates suggested changes to Appendix B-1 with all proposed issues below incorporated.
  - ii. IFPTI Course B2 (CC8029W): Replace FD252, Allergen Management in "post" curriculum. This course is a significant upgrade in course content providing more relevant and up to date information.
  - iii. IFPTI Course B8 Environmental Hazards (CC8024W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new (Food Safety Inspection Officer's) FSIO's baseline knowledge.
  - iv. IFPTI Course B12 Integrated Food Safety System (CC8018W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - v. IFPTI Course B15 Jurisdiction (CC8037W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - vi. IFPTI Course B16 Labeling (CC8038W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - vii. IFPTI Course B17 Laws, Regulations, Policies, & Procedures (CC8039W): Replace FDA35, Basic Food Law for State Regulators in "pre" courses. This course is a significant upgrade in course content providing more relevant and up to date information.
  - viii. IFPTI Course B19 Pest Control: Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - ix. IFPTI Course B20 Plumbing: Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - x. IFPTI Course B22 Professionalism (CC8025W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - xi. IFPTI Course B23 Public Health Principles (CC8026W): Replace FDA36, "Public Health Principles" in "pre" courses. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - xii. IFPTI Course B24 Recalls (CC8041W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - xiii. IFPTI Course B25 Sampling (CC8035W): Replace MIC13, Aseptic Sampling, in the pre-requisite curriculum. This course is a significant upgrade in course content providing more relevant and up to date information.
  - xiv. IFPTI Course B26 Sanitation Practices (CC8032W): Replace MIC15, Cleaning & Sanitizing, in "pre" courses. This course is a significant upgrade in course content providing more relevant and up to date information.
  - xv. IFPTI Course B27 Traceability (CC8042W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - xvi. IFPTI Course B28 Transportation (CC8036W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
- c. Charge 2b: The committee reviewed the time frame for completion of Standard 2, Steps 1 through 4, for new hires or staff newly assigned to regulatory retail food protection programs. The committee voted on February 16, 2019 to increase the timeframe from 18 to 24 months to align with Standard 2 of the Manufactured Food Regulatory Program Standards and to provide adequate time for standardization of staff.
- d. Charge 3: The committee reviewed the twenty quality assurance program elements in Standard 4 of the VNRFRPS. It was determined that all but three elements are contained in the CFP Field Training Manual, Training Plan and Log. To better align with

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training in Standard 2 (attachment *PSC subcommittee #3 Charge 3 Quality Elements Cross-referenced*), the committee recommends adding the following three missing elements to the CFP Field Training Manual, Training Plan and Log:

- i.* Standard 4 Performance Element III: “Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met.” Add “Reviewed establishment file for documentation indicating the assigned risk category” to CFP Training Manual Section I Pre-inspection, #2. Reviews establishment file for previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance by the agency. Also add “Verified the establishment is assigned the correct risk category, and when necessary, informs the supervisor when the establishment is not in the proper risk category.” to CFP Training Manual Section II Inspection Observations and Performance, #3 Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.
- ii.* Standard 4 Performance Element IX: “Discuss options for the long-term control of risk factors with establishment managers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction’s policies. Options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans.” Add “Discussed options for the long-term control of risk factors with establishment managers when the same out-of-control risk factor occurs on consecutive inspections (e.g., risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans)” to CFP Training Manual Section II Inspection Observations and Performance, #6 Verifies correction of out of compliance observations identified during previous inspection.
- iii.* Standard 4 Performance Element XVIII: “Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.” Add “Documented that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections” to CFP Training Manual Section IV Written Communication, #1 Completes inspection form per jurisdiction’s administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).

### 3. Status of charges still PENDING and activities yet to be completed:

- a. N/A

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:  *No requested action at this time*

### ATTACHMENTS:

#### 1. Content Documents: None

#### 2. Supporting Attachments (OPTIONAL): Not applicable

- a.* See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #1 Minutes 12 19 2018
- b.* See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #2 Minutes 1 09 2019
- c.* See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #3 Minutes 1 23 2019
- d.* See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #4 Minutes 2 06 2019
- e.* See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #5 Minutes 3 13 2019
- f.* See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #6 Minutes 4 10 2019
- g.* See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #7 Minutes 5 8 2019
- h.* See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #8 Minutes 6 12 2019
- i.* See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #9 Minutes 7 17 2019

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- j.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #10 Minutes 8 14 2019
- k.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #11 Minutes 9 11 2019
- l.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #12 Minutes 10 2 2019
- m.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 1 Training Evaluation and Certification Initiatives
- n.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1st Draft
- o.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft
- p.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 IFPTI Course Review
- q.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 3 Quality Elements Cross-referenced
- r.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Integrated Food Safety System (IFSS) Food Protection Professionals Curriculum Framework
- s.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B2 Allergens IFPTI Course Profile
- t.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B17 Laws Regulations IFPTI Course Profile
- u.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B23 Public Health Principles IFPTI Course Profile
- v.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B25 Sampling IFPTI Course Profile
- w.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B26 Sanitation Practices IFPTI Course Profile
- x.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 2 Appendix B-1 (see <https://www.fda.gov/media/86752/download>)
- y.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B8 Environmental Hazards IFPTI Course Profile
- z.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B12 Integrated Food Safety System IFPTI Course Profile
- aa.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B15 Jurisdiction IFPTI Course Profile
- bb.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B16 Labeling IFPTI Course Profile
- cc.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B19 Pest Control IFPTI Course Profile
- dd.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B20 Plumbing IFPTI Course Profile
- ee.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B22 Professionalism IFPTI Course Profile
- ff.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B24 Recalls IFPTI Course Profile
- gg.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B27 Traceability IFPTI Course Profile
- hh.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B28 Transportation IFPTI Course Profile
- ii.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: VNRFRPS, Standard 2 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-december-2019>)
- jj.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: VNRFRPS, Standard 3 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-december-2019>)
- kk.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: VNRFRPS, Standard 4 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-december-2019>)
- ll.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: CFP Training Manual (see <http://www.foodprotect.org/guides-documents/conference-for-food-protection-cfp-field-training-manual-for-regulatory-retail-food-safety-inspection-officers-5-31-13-cfp-update/>)

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- mm.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Manufactured Food Regulatory Program Standards (see <https://www.fda.gov/MFRPS>)
- nn.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Draft CFP Training Manual Revision
- oo.** See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Draft Attachment A – CFP Training Plan and Log Revision (attached Word document)

## Conference for Food Protection – Committee FINAL Report

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

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**COMMITTEE NAME: Program Standards Committee subcommittee #4**

**DATE OF FINAL REPORT: October 23, 2019**      **Date amended: 12/3/2019**

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

**REPORT SUBMITTED BY: James Mack, Chair**

### COMMITTEE CHARGE(S):

Issue # 2018 II-020 PSC 8

1. Maintaining the "Crosswalk - Requirements for Foodborne Illness Training Programs" document as a resource for content baseline for foodborne illness training
2. Evaluating the following references for inclusion in the Crosswalk document
3. Reporting back any findings and recommendations to each biennial meeting of the Conference for Food Protection.

### COMMITTEE WORK PLAN AND TIMELINE:

1. See the Program Standards Committee Work Plan

### COMMITTEE ACTIVITIES:

1. **Dates of committee meetings or conference calls:** PSC subcommittee #4 (Issue # 2018 II-020) held a conference call on December 6, 2018. A second call was scheduled for January 23, 2019 but was postponed due to the federal government shutdown. The subcommittee chair reached out to team members individually to discuss progress on their assigned tasks throughout 2019.
2. **Overview of committee activities:** The subcommittee had discussions regarding the use of the Crosswalk – Requirements for Foodborne Illness Training Programs (Crosswalk) document for Standard #5. In addition, updating previous resources identified, such as CIFOR, occurred in 2019. EATS 102 was evaluated as a resource. EATS 101 is already a resource, so there was no need to review EATS 101. Subcommittee members continued to identify resources and report at the subcommittee meetings. Emphasis was on industry private sector courses. Four of the eight resources currently identified were reviewed for accuracy in order to maintain the Crosswalk document. Pending resources were reviewed against the Crosswalk document, to verify that the reference citations were still accurate. On February 11, 2019, the PSC committee chair reached out to FDA to request Pathlore access to non-regulatory subcommittee members for purposes of materials review related to the subcommittee charges. The subcommittee chair worked directly with the subcommittee members throughout the biennium as they worked on reviewing their assigned resources. The Crosswalk document was updated with the new resources that were reviewed.
3. **Charges COMPLETED and the rationale for each specific recommendation:**
  - a. Charge 1 – The Crosswalk document was revised to include updated information.
  - b. Charge 2 – Additional references were evaluated and included in the Crosswalk document.
  - c. Charge 3 – This report and associated Issue submission complete this charge.
4. **Charges INCOMPLETE and to be continued to next biennium:** None

### COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

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

### LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. PSC Committee Issue #3 Posting updated Crosswalk
  - a. **List of content documents submitted with this Issue: None**
  - b. **List of supporting attachments:**
    - (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Program Standards Committee subcommittee #4 final report* (see attached Word document)
    - (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Crosswalk-Requirements for Foodborne Illness Training Programs Based on Standard 5 2019* (see attached Word document)

## Conference for Food Protection – Committee FINAL Report

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**COMMITTEE NAME:** Program Standards Committee subcommittee #5

**DATE OF FINAL REPORT:** October 24, 2019      **Date amended:** 12/3/2019

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

**REPORT SUBMITTED BY:** Carrie Pohjola and Bridget Sweet, Co-Chairs

### COMMITTEE CHARGE(S):

Issue # 2018 II-021 Amend VNRFRPS-Standard 4-Uniform Inspection Program. The Program Standards Committee was charged to address the Voluntary National Retail Program Standards (VNRFRPS), Program Standard No. 4-Uniform Inspection Program to:

1. Research a new model, solution and/or recommendation that will allow large and small jurisdictions to have the same statistical compliance requirements
2. Amend audit requirements to include randomized selection of files to be reviewed
3. Report back to the 2020 Biennial meeting of the Conference for Food Protection its findings and recommendations.

### COMMITTEE WORK PLAN AND TIMELINE:

1. See the Program Standards Committee Work Plan

### COMMITTEE ACTIVITIES:

1. **Dates of committee meetings or conference calls:** PSC subcommittee #5 (Issue #2018 II-021) held conference calls on January 2, 2019, January 30, 2019, February 14, 2019, and February 28, 2019 with biweekly calls scheduled from this date on.

2. **Overview of committee activities:**

The committee has met via conference call twice (1-2-2019 and 1-1-30-2019). Conference calls are now scheduled bi-weekly beginning 2-14-2019. Time was spent reviewing Standard 4. Committee members reached out to larger jurisdictions who are enrolled in the standards and have indicated that they have met Standard 4 and the burden of conducting the 3 field exercises with applicable file review over the 5 years. Those agencies that responded were Tri-County Health in Colorado and Florida Dept. of Business and Professional Regulation. The committee is also reviewing the statistical methodology for Standard 4 as well as discussing with the FDA statistician the percentage of each quality element for compliance to be 75%. The committee also reached out to the original submitter, Veronica Bryant, for further clarification on the issue submitted which she provided. Finally, the committee will be reviewing the instructions for auditors and the possibility of random sampling and a randomly selected sample size as opposed to the auditor reviewing all records for each applicable field exercises. The committee met again via phone conference on 2-14-2019 and 2-28-2019 to further discuss the issue. Marc Boyer, CFSAN math statistician, joined the call on 2-14-19 and provided Statistical Methodology and Explanation of the Statistical Model for Standard 4 which is attached. It was decided at the 2/28/2019 meeting by Robert Sudler to submit the issue via questions to the Clearinghouse and to suspend meetings until the Clearinghouse was able to address the questions. The questions submitted can be found in the attached document, Clearinghouse Submission.

On 6/21/1019, further clarification of the Clearinghouse Submission questions were provided to Robert Sudler by Carrie Pohjola (Clearinghouse Submitter) to bring forth to the Clearinghouse group for consideration. Clarification provided for Question 1 was the requirements for the person completing the field exercises and applicable file review to assess the 20 Quality Elements. In addition, clarification for Question 2 was provided on file review of the auditor of an agencies self-assessment and the required file review involved assessing if Standard 4 is being met by an agency. Clarification was provided from the Clearinghouse on Standard 4 and the response is attached.

With regard to the issue of file review of all files during the self-assessment audit of Standard 4 the committee discussed and interpreted, after extensive review of the standard documentation, that file review is not required by the auditor but can be requested upon discretion.

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

- a. Charge 1 – Based on the information provided by the FDA Statistician, small and large jurisdictions already have the same statistical compliance requirements. (See Standard 4 – Statistical Methodology attached PDF)
- b. This charge was related to the review of files during an audit. This was discussed and interpreted, after extensive review of the standard documentation, that file review is not required by the auditor. The auditor can request a random number of files to review, upon their discretion.
- c. Charge 3 – this report serves as completion of this charge.

4. **Charges INCOMPLETE and to be continued to next biennium: None**

### COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

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

**LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:** None

## Conference for Food Protection – Committee FINAL Report

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### ATTACHMENTS:

1. Content Documents: No draft content documents submitted at this time
  
2. Supporting Attachments
  - a. See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: CFP PSC Subcommittee CWG Questions (see attached PDF)
  - b. See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: CWG Standard 4 Response (see attached PDF)
  - c. See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 4 – Statistical Methodology (see attached PDF)

## Program Standards Committee Online Supporting Documents

- (1) Issue 2018 II-018 (see page 27  
<http://www.foodprotect.org/media/biennialmeeting/council-ii-final-issue-recommendations-1.pdf>)
- (2) 2018 Program Standards Committee Final Report  
[http://www.foodprotect.org/issues/packets/2018Packet/issues/II\\_013.html](http://www.foodprotect.org/issues/packets/2018Packet/issues/II_013.html). See the Re-evaluation of VNRFRPS Standard 8 Subcommittee Report and supporting attachments for Standard 8.
- (3) Voluntary National Retail Food Regulatory Program Standards – Standard 8 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (4) CFP Plan Review Guide (see <http://www.foodprotect.org/media/guide/2016-plan-review-manual.pdf>)
- (5) Standard 2 Appendix B-1 (see <https://www.fda.gov/media/86752/download>)
- (6) VNRFRPS, Standard 2 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (7) VNRFRPS, Standard 3 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (8) VNRFRPS, Standard 4 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (9) CFP Training Manual (see <http://www.foodprotect.org/guides-documents/conference-for-food-protection-cfp-field-training-manual-for-regulatory-retail-food-safety-inspection-officers-5-31-13-cfp-update/>)
- (10) Manufactured Food Regulatory Program Standards (see <https://www.fda.gov/MFRPS>)

## Standard 8 Staffing Level

### Purpose of Standard 8 staffing level section:

*Standard 8 Section 1. Staffing Level* requires a health department (HD) to demonstrate that they have the staff “necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors known to contribute to foodborne illness”

### Current criteria to pass Standard 8:

A HD currently meets this standard if they demonstrate an inspection to FTE ratio range of 280-320 inspections per FTE. The Conference for Food Protection (CFP) developed an assessment tool and instruction guide that can be used by a HD if desired. If not the HD has to calculate their inspection to FTE ratio through their own method and see if it falls within the required range.

### Problem with inspection to FTE ratio range:

It has been agreed by upon by subcommittee that this range is problematic as it's based on the idea that every inspection should take 4 hours. The subcommittee has also agreed that a range is problematic as it allows for an adequately staffed health department to fail the standard as they could fall below the range.

### Recommendations:

We are recommending removing the range and allowing HDs to demonstrate to independent auditors that they are adequately staffed in a more appropriate way. The following are the 3 options we think are reasonable that a HD can use to demonstrate staffing levels.

1. A HD can use their own method they feel is appropriate for them to demonstrate adequate staffing levels
2. A HD can use the current assessment tool (with inspection to FTE section removed) developed by CFP to assess if they're adequately staffed
3. A health department can use the updated CFP assessment tool that calculates staffing levels by risk category
  - a. Using the updated vs. current assessment tool may make it easier for a HD to prove to their auditor that they are adequately staffed because:
    - i. It has a section that calculates how many FTEs a HD *should* have based on risk categories (current assessment does not do this)
    - ii. It then automatically compares how many FTEs a health department *currently* has with how many they *should* have (the current assessment only calculates *current* FTE, so it may be challenging to convince an auditor that a current calculated FTE # demonstrates a HD to be adequately staffed)

## Updated CFP Assessment Tool

The following is an example of how to use the updated assessment tool to calculate if a health department is adequately staffed.

Discussion on Table 1. The risk category column is broken into three categories, the minimum required by Standard 8. The number of establishments will be unique to each health department. The rows in the remaining columns show values that are based off of survey data of 100 local and state health departments throughout the country (see footnotes for more details). A HD should feel free to use these values or input ones that more appropriately fit their organization.

**Table 1.**

Risk Category	Number of Establishments	Inspection Frequency <sup>1</sup>	Average Inspection Time (does not include travel) <sup>2</sup>	Reinspection frequency <sup>3</sup>	FBI Inspection Frequency <sup>4</sup>	Other Frequency <sup>5</sup>
Low	1,000	1	45 minutes	15%	1%	10%
Medium	2,000	2	75 minutes	15%	1%	10%
High	1,000	3	120 minutes	15%	1%	10%

**Step 1. Calculate available annual inspection time per full time equivalent (FTE) using assessment tool.** 1200 hours a year will be used for this example.

**Step 2. Calculate number of FTE currently available at health department.** This # is calculated in the current and updated assessment tools.

**Step 3. Calculate total number of hours required to inspect each risk category.** Formula for calculating # of inspection hours per risk type below (low risk type used for example):

(1000 establishments x 1 inspection a year = 1000 inspections) + (1000 establishments x 15 % reinspections a year = 150 inspections) + (1000 establishments x 1% FBI inspections a year = 10 inspections) + (1000 inspections x 10% other inspections a year = 100 inspections) = 1260 inspections a year x 45 minutes an inspection = 945 hours a year

Medium risk = 4520 inspections a year x 75 minutes = 5650 hours

High Risk = 3260 inspections a year x 120 minutes = 6520 hours

Total inspection time = 945 + 5650 + 6520 = 13,115 inspection hours a year

**Step 4. Calculate number of FTE's required**

13,115 total inspection time hours /1200 inspection hours available per FTE = 10.93 FTEs

**Step 5. Calculate if health department is adequately staffed**

If FTEs currently available >= 10.93 FTEs that a HD should have then that HD is adequately staffed

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<sup>1</sup> Median inspection frequencies of 100 health departments from 2017 survey

<sup>2</sup> Median inspection times of 100 health departments from 2017 survey

<sup>3</sup> Median reinspection frequency %s of 60 health departments form 2017 survey<sup>2</sup>

<sup>4</sup> Median food borne illness inspection frequency %s of 60 health departments from 2017 survey<sup>2</sup>

<sup>5</sup> Final % value still being calculated, 10% being used for this demonstration

### **Appendix 8.2 Calculation for determining a required number of inspectors**

This appendix is *an example* of how to calculate the number of field staff required to conduct inspections<sup>21</sup> of food plants. The data in the following table will vary significantly based on local or regional conditions. The State program may use the risk categories and inspection frequencies found in the statement of work for the food contract as a basis for determining the required number of inspectors.

Risk category	Number in inventory	Inspection frequency	Average inspection time (includes travel) <sup>22</sup>	Reinspection frequency
High	1,000	12 months	7.2 hours	10%
Medium	2,000	18 months	5.7 hours	10%
Low	1,000	24 months	4.2 hours	10%

1. Calculate available annual inspection time per full time equivalent(FTE).

For example, the State agency determines that after allowances for annual leave, sick leave, holidays, training, administrative time, and other activities each State program FTE has 1200 hours available for conducting inspections.

2. Calculate the number of hours required to inspect establishments in each risk category.

Formula for high risk establishment inspection time:

1000 firms x 100% coverage = 1000 inspections + 10% reinspection = 1100 total inspections per year x 7.2 hours = 7920 hours

Formula for medium risk establishment inspection time:

2000 firms x 66.6% coverage = 1333 inspections + 10% reinspection = 1466 total inspections per year x 5.7 hours = 8356 hours

Formula for low risk establishment inspection time:

1000 firms x 50% coverage = 500 inspections + 10% reinspection = 550 inspection total inspections x 4.2 hours = 2320 hours

3. Calculate the number of FTE's required.

Formula:

7920 hours for high risk + 8356 hours for medium risk + 2320 hours for low risk = 18596 inspection hours required / 1200 inspection hours available per FTE = **15.5 FTEs**

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<sup>19</sup> Includes routine surveillance, reinspections, complaint or outbreak investigations, compliance follow-up investigations, risk assessment reviews, process reviews, and other direct establishment contact time such as on-site training.

<sup>20</sup> Inspection times based on calculations presented in "DHHS Office of Inspector General's FDA Oversight of State Food Firm Inspections" dated June 2000.

# Standard 8

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# Current Standard 8 Model

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- **Purpose regarding staffing levels:**

- Assesses the adequacy of a health department's staffing levels, by calculating if it has an *inspection to FTE ratio* within the specified FDA range
  - The range is **280 – 320 inspections per inspector**

- **Problem 1:**

- This range was created with the belief that every food inspection regardless of establishment type would take **4 hours**. This is problematic as health departments (HD) have establishments that vary by type and risk category making the required time to complete inspections also vary.

- **Problem 2:**

- The very existence of a range creates the possibility that a HD can appear to be **overstaffed**. This creates the potential for that HD to have an *inspection to FTE ratio* that goes below the bottom value of the 280-320 range (thus making the HD fail to meet the standard). Standard 8 is evaluating if a HD has the “necessary” staff to perform the required number of inspections. If a HD has a unique need and the resources available to hire more staff than Standard 8 would require, it is not consistent with the intent of this standard to fail them.

# The Logic Behind the 280-320 FTE Inspections Per Year Range

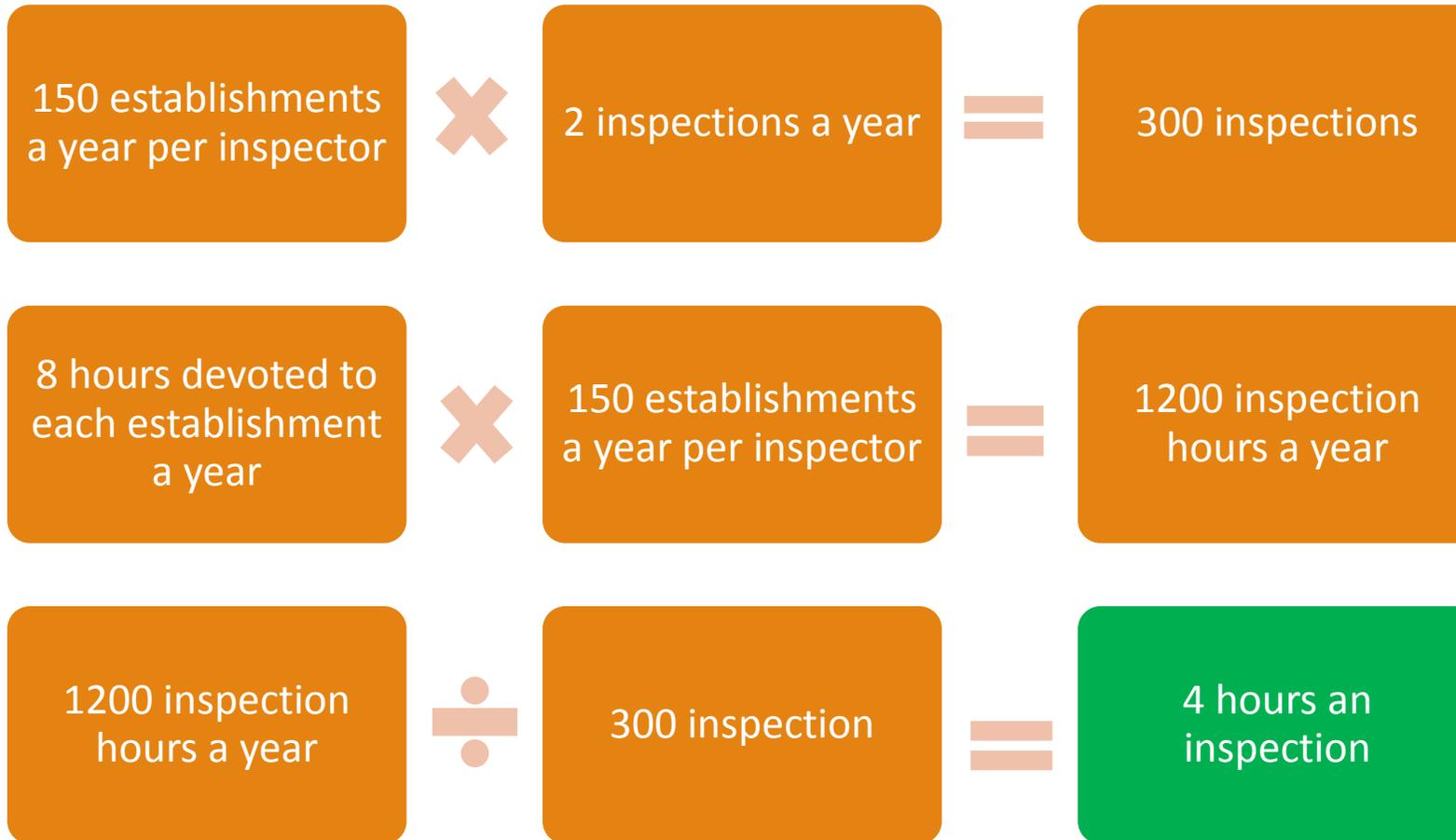
- VNRFRPS Clearinghouse Work Group agreed that **1,120 – 1,280 inspection hours a year** per one FTE “represents a reasonable range” of annual productive hours - [VNRFRPS 2019 https://www.fda.gov/media/86864/download](https://www.fda.gov/media/86864/download)



- This then “allows for the **same unit of measure** to be applied to all jurisdictions regardless of their procedures and processes” - [VNRFRPS 2019 https://www.fda.gov/media/86864/download](https://www.fda.gov/media/86864/download)

# The Logic Behind the 4 Hour Inspection

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# Potential Problem with these Figures

- **150 establishments a year per inspector** came from the 1961 International City Managers' Association the *Administration of Community Health Services* <https://babel.hathitrust.org/cgi/pt?id=mdp.39015072177739&view=1up&seq=177> book sharing that “there is no widely accepted formula on which to base the number of staff persons” but that “some local agencies” use 150
- **2 inspections a year** came from the *1976 Food Service Sanitation Manual* <https://babel.hathitrust.org/cgi/pt?id=umn.31951002840720j&view=1up&seq=29> that acknowledges the above 150 establishment number and adds without justification that “a minimum of two inspections of each establishment per year is required”
- **8 hours devoted to each establishment** comes from the *1997 FDA Food Code* <https://wayback.archive-it.org/7993/20170113023657/http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm054458.htm> which suggests “8 to 10 hours be allocated per establishment year” also without evidence or clear reasoning

**Conclusion:** There appears to be no strong justification for any of these values based on real data and research making it problematic that they are the criteria from which the 4 hour inspection time is based

# Our Solution

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- **It is more accurate to assess a health department's staffing levels by:**

1. categorizing establishments into **3 risk categories**: low, moderate, high
2. use a **standardized frequency** each risk type should be inspected a year
3. use a **standardized inspection time** required for each risk type
4. calculate how many FTEs it “should” take to complete all of these inspections.
5. calculate how many FTEs the health department “currently” has
6. If the health department currently has an equal or greater number of FTEs than our new standard would require they would be considered sufficiently staffed

*Note: The inspection to FTE ratio and the range which sets the standard would no longer be needed and would be removed from the Standard 8 Staffing Level assessment*

# Why Categorize Establishments

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- Standard 8 states that a “process should exist for the regulated food establishments to be grouped into at least 3 categories based on food safety risk” – [VNRFRPS 2019 https://www.fda.gov/media/86864/download](https://www.fda.gov/media/86864/download)
- The FDA recommends categorizing food establishments into risk categories because:
  - “By focusing inspections on the control of foodborne illness risk factors, inspectors can be assured that they are making a great impact on reducing foodborne illness” – [FDA Food Code 2017 https://www.fda.gov/food/fda-food-code/food-code-2017](https://www.fda.gov/food/fda-food-code/food-code-2017)
  - “Studies have shown that the types of food served, the food preparation processes used, the volume of food, and the population served all have a bearing on the occurrence of foodborne illness risk factors in retail and foodservice establishments” – FDA Food Code 2017
  - “With limited resources, creating a variable inspection frequency for each category will allow inspection staff to effectively spend more time in high risk establishments that pose the greatest potential risk of causing foodborne illness.” – FDA Food Code 2017

# Follow Other FDA Recommended Inspection Standards

- **FDA's *Manufactured Food Regulatory Program Standards 2016***

[Appendix 8.2: Calculation for determining a required number of inspectors  
https://www.fda.gov/media/100421/download](https://www.fda.gov/media/100421/download)

Risk category	Number in inventory	Inspection frequency	Average inspection time (includes travel)	Reinspection frequency
High		12 months	7.2 hours	10%
Medium		18 months	5.7 hours	10%
Low		24 months	4.2 hours	10%

- Formula: (high risk inspection hours + medium risk + low risk = total inspection hours required/**1200 inspection hours**) = **# FTEs required**
- Note: Average Inspection times came from [Department of Health and Human Services https://oig.hhs.gov/oei/reports/oei-01-98-00400.pdf](https://oig.hhs.gov/oei/reports/oei-01-98-00400.pdf) study of 37 states' inspection. 5.7 hours was the state average with a standard deviation of 1.5.

# How Our FTE Model Categorizes

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1. Following FDA recommendations it would require that a health department (HD) group their establishments into 3 risk categories: **low, moderate, and high risk**
2. If a HD is unsure how to put their current risk category scale into a 3 category model, refer to [Annex 5 – Risk Categorization of Food Establishments Table https://www.fda.gov/media/110822/download](https://www.fda.gov/media/110822/download). In this table there are 4 risk categories with descriptions. Risk category 1 would be low risk. Risk category 2-3 would be moderate risk. Risk category 4 would be high risk.
3. If a HD **only has 2 risk categories** put them in the most appropriate categories out of low, moderate, or high. E.g. low and high, moderate and high, etc

# Annex 5 Descriptions of Risk Categories

<p><b>Risk 1:</b> Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged, non- time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed, TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors.</p>	<p><b>Risk 2:</b> Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of TCS foods after preparation or cooking. Complex preparation of TCS foods requiring cooking, cooling, and reheating for hot holding is limited to only a few TCS foods. Establishments that would otherwise be grouped in Category 3 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne illness risk factors is achieved and documented.</p>
<p><b>Risk 3:</b> An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.</p>	<p><b>Risk 4:</b> Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.</p>

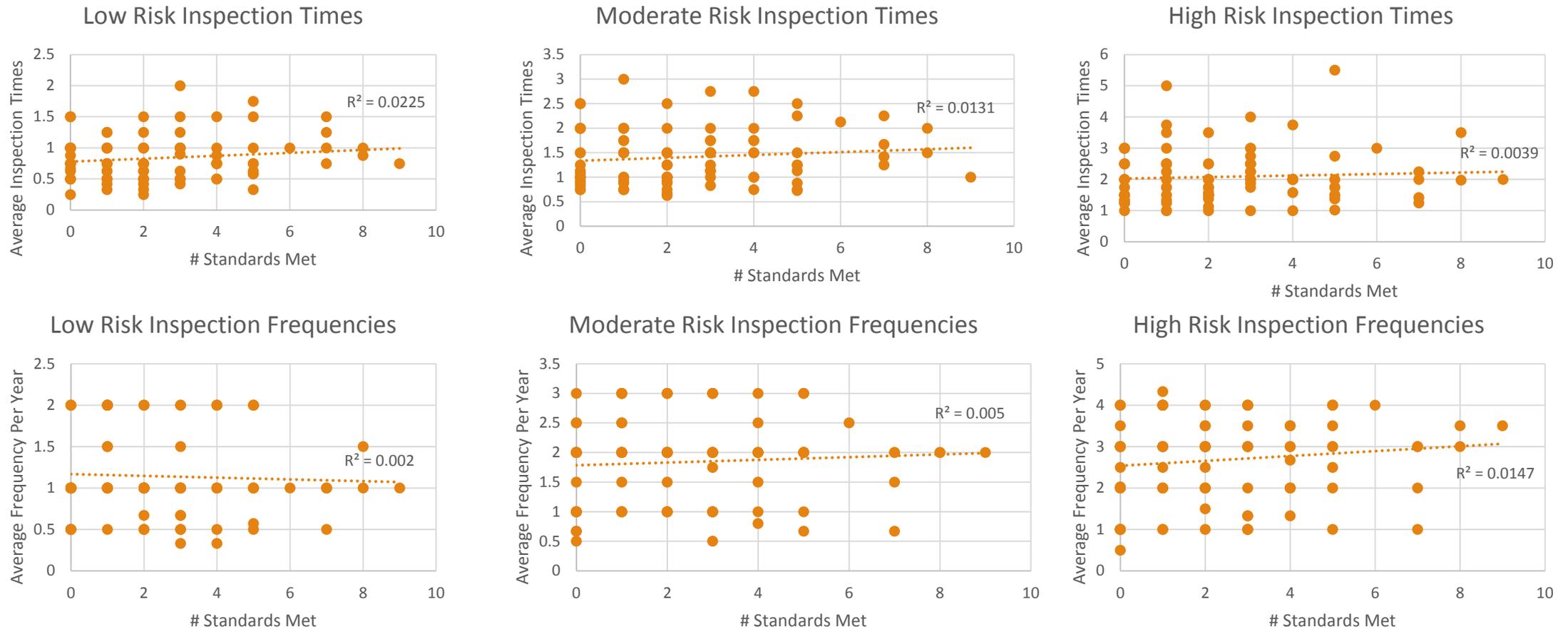
# Creating the Standard for Frequency and Inspection Time by Risk Category

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## Methodology:

- In 2017 HCPH surveyed 390 health departments (HD) across the country asking them for average inspection times and frequencies per the 3 risk categories. 100 complete responses were received.
- To create a standard we categorized these HDs by the # of standards they achieved and evaluated if HDs with more standards met had inspection times and frequencies different from HDs with less standards met.
- **Statistical techniques demonstrated** that there was **no relationship** between the # of standards a HD achieved and their times or frequencies
- Thus there is no rationale for emphasizing inspection times of HDs that passed more standards from the data we obtained
- Therefore it made the most sense to use the average or median inspection times and frequencies per risk category of all the HDs that responded as a standard. Now these values would be based on real data from a diverse group of HDs.

# Plots of # of Standards Met by Inspection Times and Frequencies Demonstrating no Relationship,



# Bivariate Linear Regression Results and Correlation Coefficients

Independent Variable	Dependent Variable	P-Value	Pearson's Correlation Coefficient
# Stds. Met	Low Risk Freq.	0.67	-0.05
# Stds. Met	Low Risk Time	0.15	0.15
# Stds. Met	Mod Risk Freq.	0.49	0.07
# Stds. Met	Mod Risk Time	0.27	0.11
# Stds. Met	High Risk Freq.	0.24	0.12
# Stds. Met	High Risk Time	0.54	0.06

Note:  
Statistically Significant Relationship = P-Value < .05

Pearson's Correlation Coefficient: Perfect positive relationship = 1, Perfect negative relationship = -1

# Creating Standard Inspection Times by Risk Category

## Median

Low Risk: 45 minutes

Mod Risk: 75 minutes

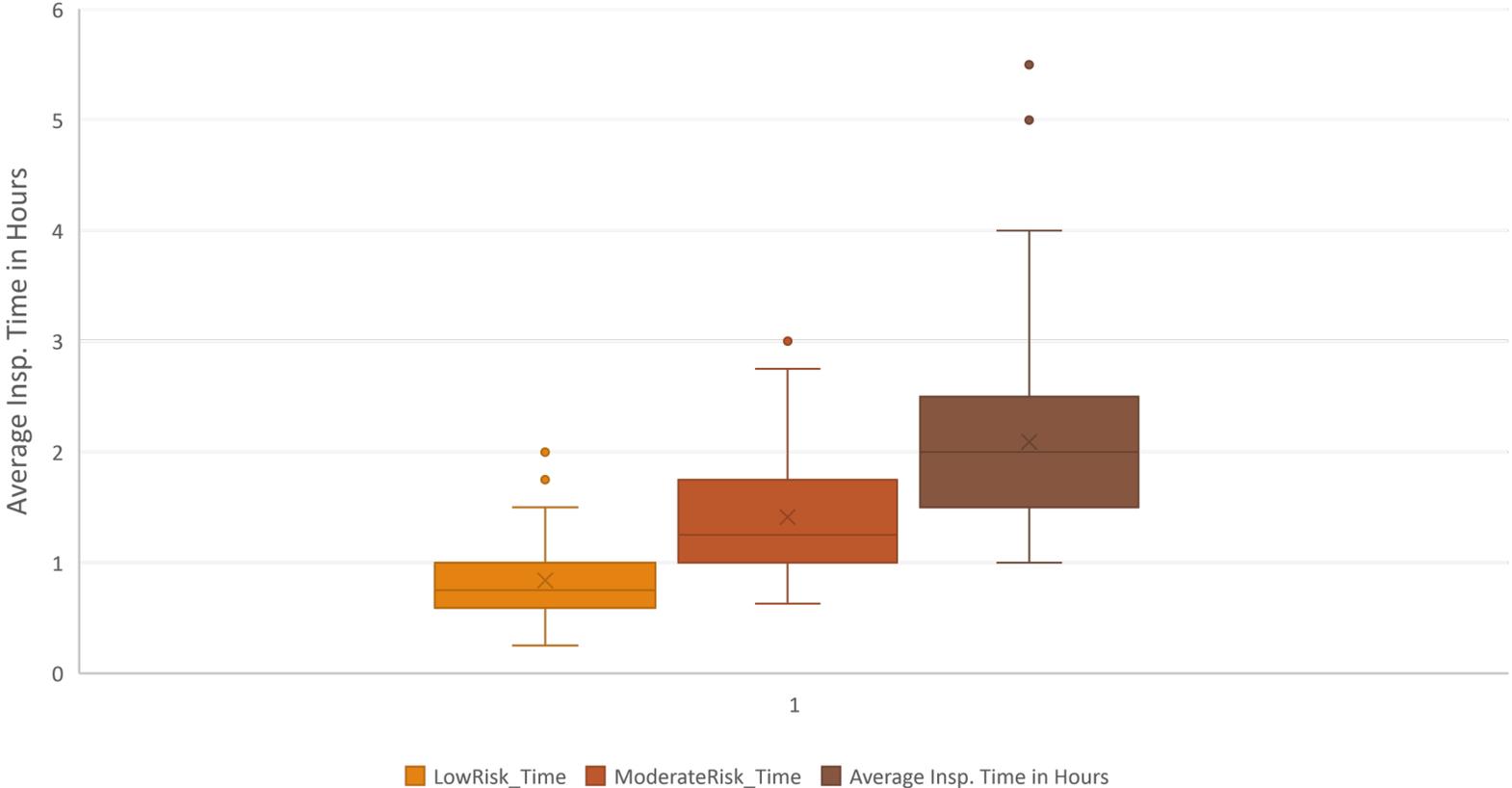
High Risk: 120 minutes

## Average

Low Risk: 50 minutes

Mod Risk: 85 minutes

High Risk: 125 minutes



# Creating Standard Inspection Frequencies by Risk Category

## Median

Low Risk: 1 insp.

Mod Risk: 2 insp.

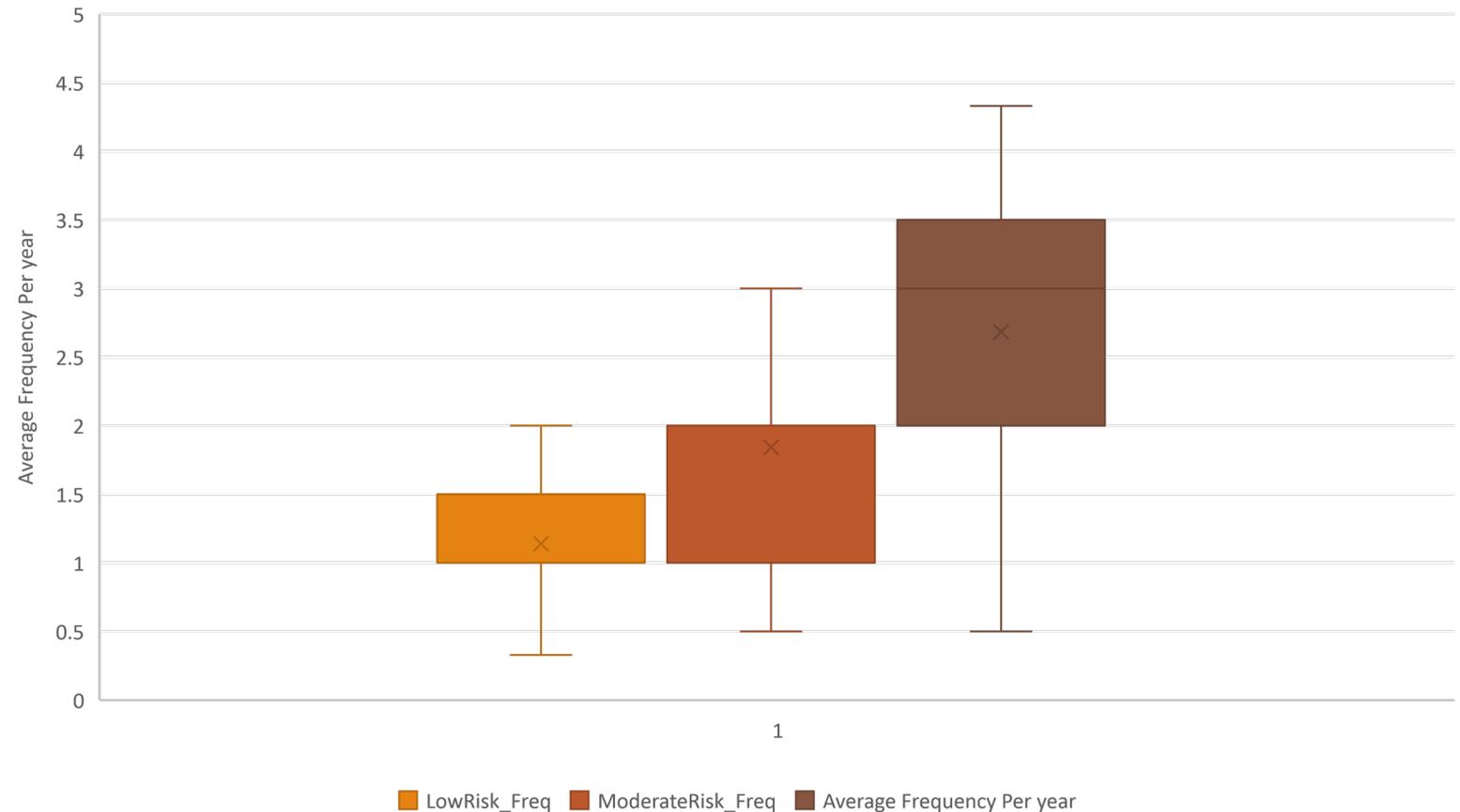
High Risk: 3 insp.

## Average

Low Risk: 1.14 insp.

Mod Risk: 1.84 insp.

High Risk: 2.68 insp.



# Calculating How Many FTEs a Health Department “currently” has

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- *Note: This process uses the current Standard 8 model developed by the FDA with the sections devoted to the **inspection to FTE ratio removed***
- **The model now only needs to:**
  1. calculate the annual productive hours of one FTE
  2. calculate the total food inspection hours the health department currently conducts
  3. divide the total food inspection hours by the annual productive hours of one FTE to calculate how many overall FTEs the health department “currently” has

$$\text{Total food inspection hours} / \text{one FTE's annual productive hours} = \text{Total FTEs}$$

# Calculating “current” FTEs

FTE DATA CALCULATION				
Calculate productive hours per year for an employee doing 100% food inspections				
Information For One Employee		Hours/Year	Hours/Day	Total Hours
<b>Annual FTE Hours Per Year: Industry Standard</b>			2080	
Local Holiday Hours Per Year		80		80
Local Vacation Leave Hours Per Year		104		104
Local Sick Leave Hours Per Year		78		78
Local Family-Personal Leave Hours Per Year		0		0
<b>Productivity Factoring Per Year</b>				
Travel Time For Inspection			1.5	1477
Administrative Work (in-office work)		192		1285
Training Time		20		1265
Others		0		1265
<b>Personal Development Time Per Year</b>				
Continuing Education Hours		12		1253
Others		0		1253
<b>Productive Annual FTE Hours Per Year (FTE Conversion Factor)</b>			<b>1253</b>	
FOOD SAFETY INSPECTION HOURS PER YEAR				
Position Category	Food Safety Inspection Hours	Number of Employees	Total Hours	
Food/NNA	1239	31	38397	
Food/Pool	831	2	1663	
Supervisors	42	3	126	
<b>Total Food Safety Inspection Hours</b>			<b>40186</b>	
<b>Total Local FTE</b>			<b>32.1</b>	

Actual working days	Actual working weeks
227.25	45.45

# Calculating How Many FTEs a Health Department “*should*” have

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- *Note: this process would be incorporated into the current Standard 8 model*
- **The steps of the new process are below:**
  1. A health department will input the number of establishments they have into each of the **3 risk categories** of the table
  2. The table will automatically calculate how many inspections should be conducted for each risk category using the **inspection frequency values** from the survey
  3. The table will then automatically calculate how many total hours are required to complete these inspections using the **inspection time values** from the survey
  4. The table will lastly divide these total inspection hours by the annual productive hours of one FTE (this value is already calculated in the previous section) to calculate how many overall FTEs the health department “*should*” have

# Calculating “required” FTE

STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION							
	Low Risk Establishment	Frequency of Low Risk Est Inspections Per Year	Moderate Risk Establishment	Frequency of Moderate Risk Est Inspections Per Year	High Risk Establishment	Frequency of High Risk Est Inspections Per Year	Total Inspections
Routine and Permitting	2090	1.00	6374	2.00	104	3.00	15150
Follow Up Inspections/Re-inspections (15%)							2550
Foodborne Illness Complaints (1%)							170
Other (10%)							1700
Median Hours Spent Per Inspection	0.75		1.25		2.00		
Total Inspection Time	1568		15935		624		24757
<b>Total Required FTE</b>							<b>19.76</b>
<b>Standard 8 Criteria</b>							<b>Standard met</b>
<b>Notes:</b>							
<ul style="list-style-type: none"> <li>• Frequency of inspections - 2017 HCPH Survey 1 (100 responses)</li> <li>• Median Hours Spent Per Inspection -2017 HCPH Survey 1 (100 responses)</li> <li>• Follow Up Inspections % (out of total # inspections) - 2017 HCPH Survey 2 (60 responses)</li> <li>• Foodborne Illness Complaints % (out of total # inspections)- 2017 HCPH Survey 2 (60 responses)</li> <li>• Other % (out of total # inspections) E.g. from <i>Standard 8 Staffing Level Assessment Workbook, pg. 10</i> - complaints, outbreak investigations, risk assessment reviews, process reviews, variance process reviews, final construction inspections and “other direct establishment contact time”</li> </ul>							

# Meet or Not Meet Standard 8

- As demonstrated on previous slide, once the Standard 8 model is completed it will automatically calculate if a health department meets or does not meet the standard. E.g. below.

Jurisdiction X *“should”* have 5 FTE  
Jurisdiction X *“currently”* has 4 FTE

should have > currently have



Jurisdiction Y *“should”* have 20 FTE  
Jurisdiction Y *“currently”* has 23 FTE

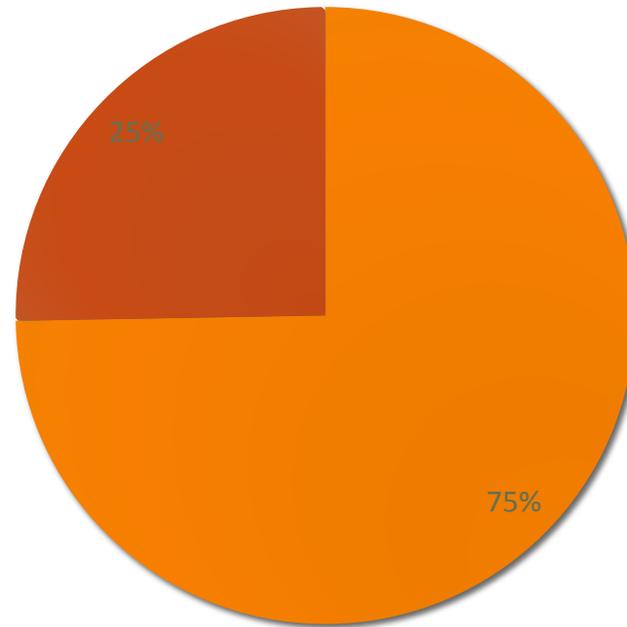
should have =< currently have



# How Do Our Surveyed HDs Do?

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Surveyed HDs, n=91



■ Meet Standard ■ Not Meet Standard

# Recommendation #1

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- A HD can use their own method
- A HD can use the current assessment tool
- A HD can use the new proposed assessment tool that calculates staffing levels by risk category

# Recommendation #2

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- Use the new proposed model to determine staffing level
  - Option 1: use the standardized values from the survey
  - Option 2: use values that the HD determines to be appropriate for their program

# Recommendation #3

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- Pilot the new proposed model among HDs for a period of time

# Conclusion

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- The standard 4 hour inspection time needs to be updated
- Our survey demonstrates that inspection times and frequencies vary by risk category
- An *inspection to FTE ratio* is not necessary to assess a HD's staffing levels, in fact it creates the potential for failing a health department that is sufficiently staffed

# **Standard 8 Re-Evaluation of Staffing Level Model**

## **Pilot Study Report**

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Subcommittee #2

Program Standards Committee

Conference for Food Protection

October 2019



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## Background

Regulatory food safety programs residing within health departments (State and Local) across the country are responsible for conducting food safety inspections for retail food establishments within their respective jurisdictions. These regulatory programs are required to abide by the regulations set forth, at a minimum, by the Food and Drug Administration (FDA) through the FDA Food Code. The FDA, in an effort to achieve uniformity, developed the Voluntary National Retail Food Regulatory Standards (VNRFRPS). The Retail Program Standards allow health departments to enroll and audit the effectiveness of their program. There are a total of 9 standards designed to assist regulatory food safety programs to improve and enhance the services they provide to protect the public.

### Issue #2016 II-020

In 2016, an issue (#2016 II-020) was submitted to the Conference for Food Protection (CFP), regarding the ineffectiveness of a model used to determine compliance for Standard 8 (Fig. 1). Standard 8 assesses the regulatory food safety programs' level of *Program Support and Resources*. There are 12 items by which a health department conducts self and verification audits to see if they comply with Standard 8. According to a survey from the National Association of County Health Officials (NACCHO), there is a low percentage of health departments (<10%), that are able to complete Standard 8. Usually the reason for not meeting the standard is due to *Item 8.1: Staffing Level*. This item evaluates if a food safety program has sufficient full-time equivalent (FTE) staff to conduct food inspections. The model calculates if a health department is fully staffed using an inspection-to-FTE ratio. In order to meet Standard 8, the health department must fall into a specific range of 280-320 inspections -per inspector per year. The problems regarding the logic behind the ratio have been explained previously (**see Appendix; Item A: Standard 8 Staffing Level**).

The charges addressed in the first issue #2016 II-020 were evaluated by Conference for Food Protection, 2016-2018 Program Standards Committee, Standard 8 Subcommittee. The goal was to propose a new model, focused on risk-based inspections that would more accurately assess a health department's staffing levels. In 2017, the subcommittee surveyed 390 health departments across the country and collected data on average inspection times and frequencies by risk category. In total, 105 complete responses were received which were used to create a new data-driven model.

## **Issue #2018 II-018**

In 2018, following the work of the Standard 8 Subcommittee, more recommendations were submitted to CFP regarding the initial issue (#2016 II-020). The proposed solutions were accepted by CFP in 2018 and a new issue and subcommittee were created, Issue #2018 II-018 evaluated by Subcommittee #2. The new subcommittee was responsible for addressing the following charges:

- (1) Continue to collaborate with the FDA internal Program Standards working group on modifying the “description of Requirements” for “Staffing Level” in Standard 8 of the VNRFRPS;
- (2) Use the supporting attachments listed in the 2016-2018 Program Standards Committee, Standard 8 Subcommittee report as the foundation to establish a more statistically sound logic model for the FTE/Inspection ratio and provide the new calculation/formula to be used by a VNRFRPS enrollee to assess the Standard 8 “Staffing Level”;
- (3) Propose amendments to Standard 8 of the VNRFRPS and the CFP guidance document titled “standard 8 Staffing Level Assessment workbook” and accompanying “Instruction Guide” to incorporate the outcomes of Charges 1 and 2; and
- (4) Report back committee findings and recommendations to the 2020 Biennial Meeting.

## **Pilot Study**

In August 2019, Subcommittee #2 met with the Program Standards Committee to discuss the work that had been completed on the new model development to date. A key decision made on the call was to pilot the proposed model with a pool of health departments across the nation. In September 2019, Subcommittee #2 conducted a pilot study of a proposed staffing level evaluation model as decided by the Program Standards Committee. The study consisted of sending a survey to health departments in order to obtain staffing level data and use the proposed model to analyze this data. A local health department led the study and the following report provides details on the Standard 8 Pilot Study.

**Figure 1: Timeline**



## Methodology

### Validation of the Proposed Model

In order to verify that the proposed model was statistically sound for the Pilot Study, Subcommittee #2 worked with Dr. Matthew Koslovsky, a Post-Doctoral Research Associate from Rice University focusing in Biostatistics. For his detailed C.V., **see Appendix; Item B: Dr. Koslovsky-CV**. He reviewed and approved the below methodology used to create the proposed model. This model was created by using data provided by 105 health departments. The logic behind the proposed model requires that food establishments be categorized by risk level (low, moderate, and high). The first step in creating the proposed model was to analyze if the inspection times and frequencies provided by the health departments were significantly related to the number of standards a health department had met. This was important, since the number of standards a health department met was the only information indicating their performance level. If health departments that met more standards had significantly different inspection times and frequencies than those that did not, it would have been better to only use those values. Statistical analysis demonstrated that there was no significant relationship between the number of standards a health department met and their responses related to inspection time and frequency. Due to this, it was considered sufficient to use either the average or median inspection time and frequency values of all respondents (Table 1). Further statistical analysis confirmed that the average and median inspection frequency and time values were significantly different for each risk category. In other words, inspection time and frequency was lower for low-risk establishments and was higher for high-risk establishments. Lastly, it was decided that the median, not the average, should be used to remove the effects of extreme values. Detailed data analysis including tests and p-values can be made available upon request.

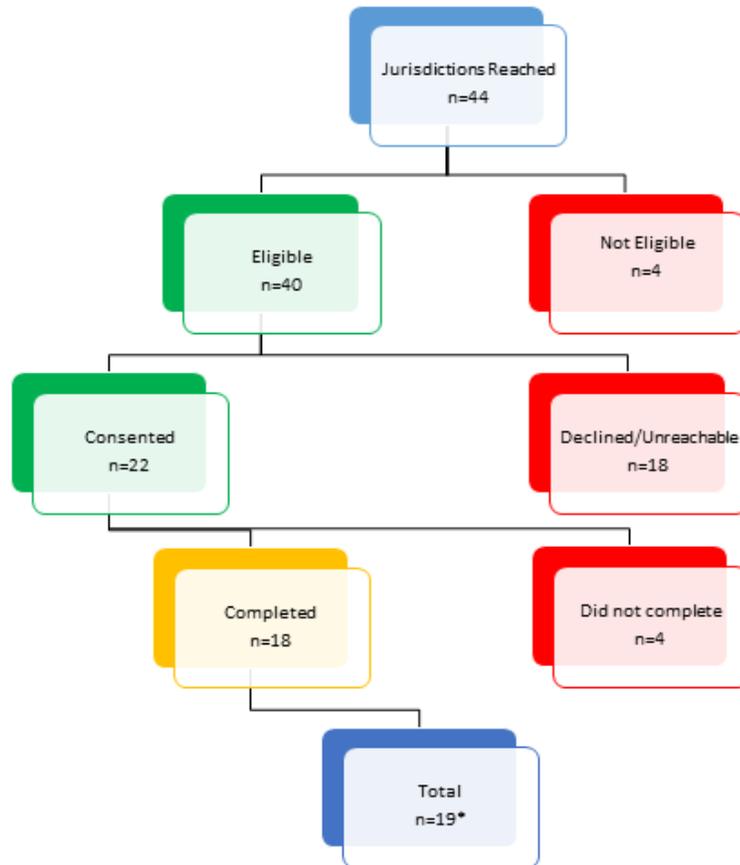
**Table 1: Median Inspection Times/Frequencies by Number of Standards Met**

# Standards Met		0	1	2	3	4	5	6 or more
Number of Jurisdictions		n = 22	n = 17	n = 19	n = 17	n = 11	n = 11	n = 8
Median Inspection Time in Hours	Low Risk	0.815	0.75	0.75	0.69	0.75	0.75	1
	Moderate Risk	1.105	1.5	1	1.375	1.5	1.25	1.585
	High Risk	1.875	2.5	1.75	2	2	1.75	2
Median Inspection Frequency per Year	Low Risk	1	1	1	1	1	1	1
	Moderate Risk	2	2	2	2	2	2	2
	High Risk	2	3	3	3	2.67	3	3

### Sampling & Recruitment

In order to include health departments already involved in the Program Standards Committee, a mixture of non-random and random sampling was used. As shown in Figure 2, a total of 44 health departments were contacted to participate in the pilot. Of the 44 jurisdictions contacted, 13 were already involved with the Program Standards Committee and were aware of the purpose of the Pilot Study, the remaining 31 were chosen randomly from the list of original participants of the 2017 survey or were referred by an ineligible jurisdiction. Of the 40 eligible health departments, 22 consented to participate. Of the 22 consented health departments, 18 provided data, and 4 were not able to complete the survey. A total of 19 jurisdictions were included in the study once the local health department leading the study added their own data

**Figure 2: Participation Flow-Chart**



\*Local health department leading Pilot Study added their own data

### Data Collection

Participating health departments were given the option of providing the requested staffing level data either via a 1) weblink to a SurveyMonkey questionnaire (**see Appendix; Item C: Survey**) or 2) phone call as a guided interview with one of the Pilot Study team members. SurveyMonkey was chosen as the platform for collecting data in order to have an organized database of participant’s responses. Participants were also provided a guidance document (**see Appendix; Item D: Guidance Document**) with useful definitions and descriptions to help interpret the questions and provide the appropriate data in the correct format. Upon recruitment, participating departments had one month (from August 30<sup>th</sup> until September 30<sup>th</sup>) to either complete the questionnaire on SurveyMonkey or schedule and complete through a phone call.

## Survey Details

The survey aimed to collect data necessary to determine the total productive hours per FTE, total inspection hours each health department currently conducts, the total inspection hours each health department should be conducting, the total current FTE and the total required FTE. To determine the total productive hours for each jurisdiction, the survey included questions about the time spent traveling to inspections, conducting administrative work, and professional development as well as time spent on breaks, holiday, and vacation. To have a better understanding of total productive hours, the survey asked each jurisdiction to list all types of Environmental Health Specialist (EHS) employees (such as managers, supervisors, and regular EHS staff) and include the average percent of time that each employee spends on food inspections. A second objective of the survey was to obtain data which would allow us to observe each jurisdiction's method of categorizing inspections, as well as the average time spent on food-borne illness, routine, and other types of inspections.

## Comparing Models

Participant data was taken from the SurveyMonkey database and moved to an Excel workbook where it was organized to review staffing levels for each health department. First, the data was run through the current Standard 8 model (**see Appendix, Item E: Standard 8 - Assessment Workbook**). By doing this, we obtained the current FTE and inspection-to-FTE ratio for each health department. If a health department falls above or below the ratio, then the health department does not meet Standard 8. We then determined which departments “passed” or “failed” to meet the staffing level requirements using the current Standard 8 model.

The data was then analyzed using the proposed Standard 8 model (**see Appendix, Item F: Standard 8 - Proposed Model Workbook**). The proposed model works by removing the inspection-to-FTE ratio and instead calculates how many FTEs a health department should have. It does this by first using a formula based on standardized inspection times and frequencies based on risk categories to calculate the total inspection hours for each jurisdiction. It automatically divides this total by the FTE productive hours calculated in the current model to obtain the number of FTEs the health department should have. Lastly, it “passes” the health department if the number of FTEs they currently has is greater than or equal to the number of FTES the HD should have. If the health department currently has an equal or greater number of FTEs, as calculated by the proposed model, then the health department would be considered sufficiently staffed; consequently, that health department would meet Standard 8. Finally, we checked which health departments “passed” or “failed” to meet the staffing level requirements using the proposed Standard 8 model.

## Pilot Results

### Jurisdiction Characteristics

A total of 16 States were represented in the Pilot Study. Of the 19 health departments, 16 jurisdictions were Local Health Departments, and the remaining 3 were State Health Departments or Agencies. After organizing the data, we observed each health department's characteristics such as total EHS employees, total inspections in a year, and total establishments in their jurisdictions (Table 2). Sizes of participating departments varied substantially, with the lowest number of EHS employees being 2 and the highest 99.

**Table 2: Employees, total inspections, and total establishments per jurisdiction**

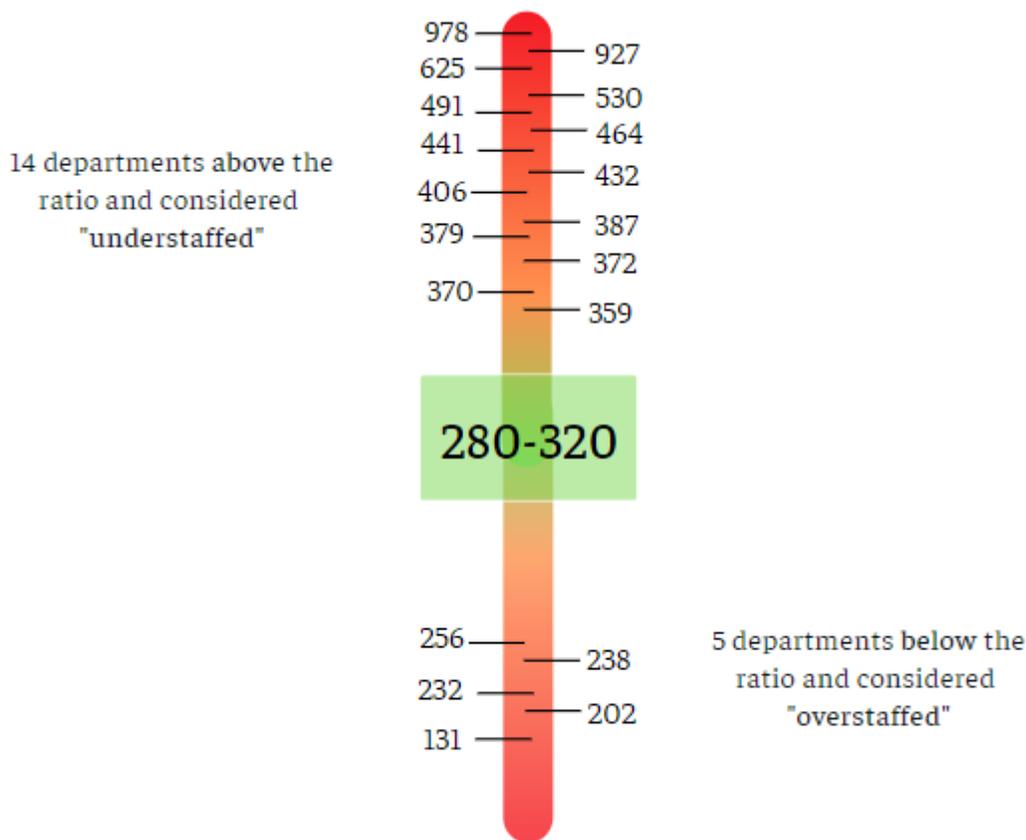
Total Employees	Total Inspections	Total Establishments
2	512	128
2	144	109
4.6	764	585
6	464	303
6	488	262
7	1889	1889
7	1065	606
9	1676	961
9	1627	1384
9	1321	648
10	5475	3618
16	4518	6629
21.1	9211	6363
22	4655	2599
25	9490	4508
29.75	8015	3753
36	17463	8568
56	12623	8830
99	47216	25300

### Current Model v Proposed Model

When analyzing the data using the current model, all (100%) of the participating health departments failed *Item 8.1: Staffing Level*. Of the 19 health departments, 5 fell below the established ratio of 280-320 inspections per FTE (Fig. 3). Falling below the ratio indicates that the health department is “overstaffed”; that is, each EHS is assigned too few

inspections per year. The remaining 14 health departments fell above the ratio and were considered “understaffed”; in other words, each EHS is assigned too many inspections per year. A major problem with the current ratio is that health departments who are “overstaffed” should actually be considered sufficiently staffed, with each EHS assigned an attainable number of inspections to complete per year. If the 5 health departments who were “overstaffed” were not restricted by the ratio, they would have “passed” Standard 8, indicating a compliance rate of about 26%. The ratio seems to penalize health departments who have too many EHS.

**Figure 3: “Understaffed” and “Overstaffed” departments based on current model**



When analyzing the data using the proposed model, 10 (52.6%) health departments “passed” *Item 8.1: Staffing Level*. The model was able to confirm that those 10 health departments currently had an equal or greater number of EHS employees required to complete the inspections in their jurisdictions. The remaining 9 (47.4%) health departments “failed” to meet item 8.1. The model was able to confirm that those 9 health

departments currently had a lower number of EHS employees required to complete the inspections in their jurisdictions.

When looking at the data more closely, there were a few interesting results that were observed between the jurisdictions that “failed” (n=9) and those who “passed” (n=10) the proposed model (Table 3). On average, jurisdictions who “passed” had less FTEs (8.6 vs 15.3), fewer employee position categories (3.2 vs. 4.2), and less food establishments categorized as high risk (24% vs 38%). Jurisdictions who “passed” also had, on average, more total productive hours (1337 vs. 1043) and more employees who dedicated a higher percent of their time to food inspections. Alternatively, jurisdictions that “failed” spent more time, on average, on travel (61 vs. 23 min/day) and administrative work (93 vs. 71 min/day). Another interesting observation was that of the 10 jurisdictions that “passed” in the proposed model, half (5) originally fell above the 280-320 ratio (overstaffed) and half fell below (understaffed).

**Table 3: Differences of Jurisdictions who “Passed” or “Failed” the Proposed Model**

	Total FTE	Total Productive Hours	Average travel time	Average administrative time	Average inspection/FTE ratio	Average "high-risk" establishments
Passing	8.6	1337	23 min/day	71 min/day	334	24%
Failing	15.3	1043	61 min/day	93 min/day	543	38%

## Discussion

When using the proposed model, the number of jurisdictions who met *Item 8.1: Staffing Level*, increased by half (0% to 52%). If the jurisdictions who were “overstaffed” (5) based on the current model were not limited by the inspection-to-FTE-ratio, the number of jurisdictions meeting *Item 8.1: Staffing Level* in the proposed model would have only increased from 26% to 52%. This shows that using the ratio to evaluate staffing levels severely limits the ability to meet Standard 8. Further, the increase in passing rate between the current and proposed models would not have been as high if the ratio was not used.

This provides additional evidence that the current inspection-to-FTE ratio is an inadequate method to assess staffing levels. According to a survey by NACCHO, health departments reported completing Standard 1 (55%), Standard 3 (51%), Standard 6 (46%), and Standard 7 (49%). Similarly, the completion rate based on the proposed model (52%) can be considered comparable to the rates for other Program Standards. The characteristics observed among the participating health departments demonstrate the variability between health departments. We acknowledge that the proposed model cannot take into consideration all of the different factors that can impact staffing level. However, we believe the proposed model is a more reasonable and logical method to calculate staffing level.

For detailed contact information on the Pilot Study team refer to **Appendix, Item G: Pilot Study Team Roster**. Refer any questions/comments on the Pilot Study to any of the team members. Data can be made available upon request.

## **Recommendations**

On October 21, 2019, the voting members from Subcommittee #2 voted to recommend a modification for Standard 8 to include adding the new proposed model assessment tool as an alternative method to determine compliance. Each jurisdiction that is completing a self-audit will have the option of either using the current or proposed model assessment tools. The intent of the recommendation is not to weaken the Standard, but to provide a secondary assessment tool that can measure practical performance of the enrollee against the Standard. This recommendation has been submitted as an issue for consideration in the Conference for Food Protection 2020 Biennial Meeting.

## Appendix

### **Purpose of Standard 8 staffing level section:**

*Standard 8 Section 1. Staffing Level* requires a health department (HD) to demonstrate that they have the staff “necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors know to contribute to foodborne illness”

### **Current criteria to pass Standard 8:**

A HD currently meets this standard if they demonstrate an inspection to FTE ratio inspection-to-FTE ratio range of 280-320 inspections per FTE. The Conference for Food Protection (CFP) developed an assessment tool and instruction guide that can be used by a HD if desired. If not the HD has to calculate their inspection to FTE ratio through their own method and see if it falls within the required range.

### **Problem with inspection to FTE ratio range:**

It has been agreed by upon by subcommittee that this range is problematic as it is based on the idea that every inspection should take 4 hours. There are two major problems we have identified with the inspection-to-FTE ratio:

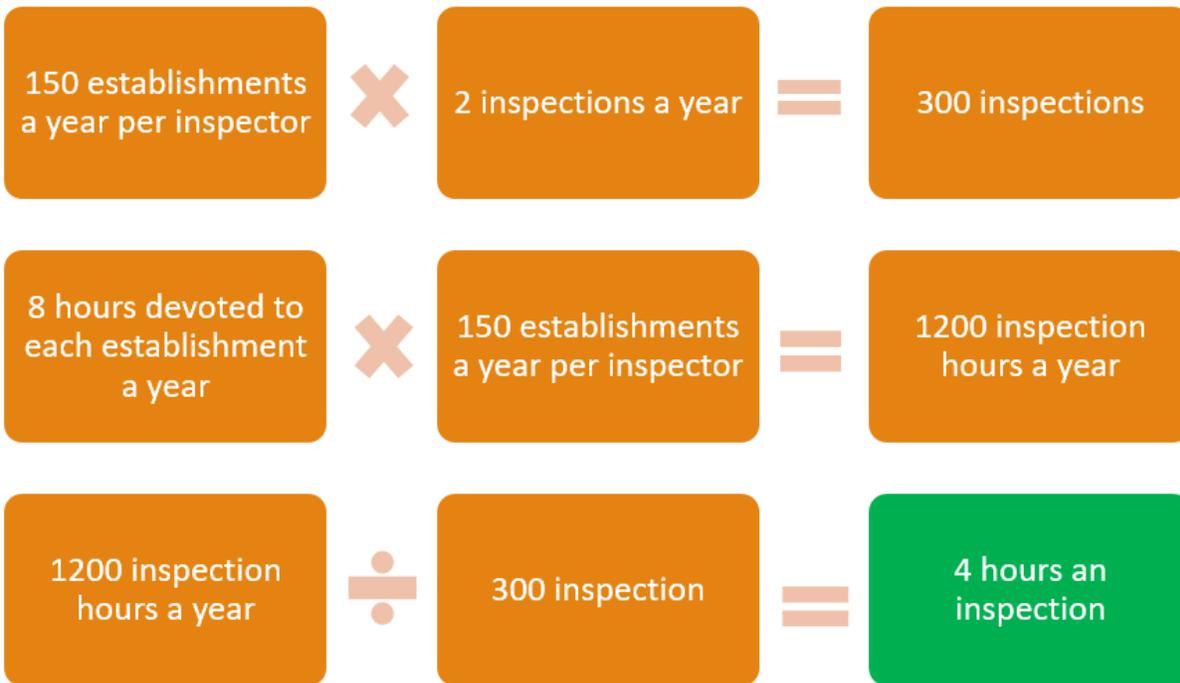
#### **Problem 1:**

- This range was created with the belief that every food inspection regardless of establishment type would take **4-hours**. This is problematic as health departments have establishments that vary by type and risk category making the required time to complete inspections also vary.

#### **Problem 2:**

- The very existence of a range creates the possibility that a HD can appear to be **overstaffed**. This creates the potential for that HD to have a ratio that goes below the bottom value of the 280-320 range (thus making the HD fail to meet the standard).

### The logic behind the 4-hour inspection



### Problems with these numbers

- **150 establishments a year per inspector** came from the 1961 International City Managers' Association the *Administration of Community Health Services* <https://babel.hathitrust.org/cgi/pt?id=mdp.39015072177739&view=1up&seq=177> book sharing that “there is no widely accepted formula on which to base the number of staff persons” but that “some local agencies” use 150
- **2 inspections a year** came from the *1976 Food Service Sanitation Manual* <https://babel.hathitrust.org/cgi/pt?id=umn.31951002840720j&view=1up&seq=29> that acknowledges the above 150 establishment number and adds without justification that “a minimum of two inspections of each establishment per year is required”
- **8 hours devoted to each establishment** comes from the *1997 FDA Food Code* <https://wayback.archive-it.org/7993/20170113023657/http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm054458.htm> which suggests “8 to 10 hours be allocated per establishment year” also without evidence or clear reasoning

**Conclusion:** There appears to be no strong justification for any of these values based on real data and research making it problematic that they are the criteria from which the 4-hour inspection time is based.

## Item A: Standard 8 Staffing Level

### Proposed Model Assessment Tool

The following is an example of how to use the updated assessment tool to calculate if a health department is adequately staffed.

Discussion on Table 1. The risk category column is broken into three categories, the minimum required by Standard 8. The number of establishments will be unique to each health department (HD). The rows in the remaining columns show values that are based off of survey data of 100 local and state health departments throughout the country (see footnotes for more details). A HD should feel free to use these values or input ones that more appropriately fit their organization.

**Table 1.**

Risk Category	Number of Establishments	Inspection Frequency <sup>1</sup>	Average Inspection Time (does not include travel) <sup>2</sup>	Reinspection frequency <sup>3</sup>	FBI Inspection Frequency <sup>4</sup>	Other Frequency <sup>5</sup>
Low	1,000	1	45 minutes	15%	1%	10%
Medium	2,000	2	75 minutes	15%	1%	10%
High	1,000	3	120 minutes	15%	1%	10%

**Step 1. Calculate available annual inspection time per full time equivalent (FTE) using assessment tool.** 1200 hours a year will be used for this example.

**Step 2. Calculate number of FTE currently available at health department.** This # is calculated in the current and updated assessment tools.

**Step 3. Calculate total number of hours required to inspect each risk category.** Formula for calculating # of inspection hours per risk type below (low risk type used for example):

$(1000 \text{ establishments} \times 1 \text{ inspection a year} = 1000 \text{ inspections}) + (1000 \text{ establishments} \times 15\% \text{ reinspections a year} = 150 \text{ inspections}) + (1000 \text{ establishments} \times 1\% \text{ FBI inspections a year} = 10 \text{ inspections}) + (1000 \text{ inspections} \times 10\% \text{ other inspections a year} = 100 \text{ inspections}) = 1260 \text{ inspections a year} \times 45 \text{ minutes an inspection} = 945 \text{ hours a year}$

Medium risk =  $4520 \text{ inspections a year} \times 75 \text{ minutes} = 5650 \text{ hours}$

High Risk =  $3260 \text{ inspections a year} \times 120 \text{ minutes} = 6520 \text{ hours}$

Total inspection time =  $945 + 5650 + 6520 = 13,115 \text{ inspection hours a year}$

**Step 4. Calculate number of FTE's required**

$13,115 \text{ total inspection time hours} / 1200 \text{ inspection hours available per FTE} = 10.93 \text{ FTEs}$

**Step 5. Calculate if health department is adequately staffed**

If FTEs currently available  $\geq 10.93$  FTEs that a HD should have then that HD is adequately staffed

<sup>1</sup> Median inspection frequencies of 105 health departments from 2017 survey

<sup>2</sup> Median inspection times of 105 health departments from 2017 survey

<sup>3</sup> Median reinspection frequency %s of 60 health departments from 2017 survey<sup>2</sup>

<sup>4</sup> Median food borne illness inspection frequency %s of 60 health departments from 2017 survey<sup>2</sup>

<sup>5</sup> Final % value still being calculated, 10% being used for this demonstration

## Matthew D. Koslovsky, PhD

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### RESEARCH INTERESTS

*Theory and Methods:* Bayesian modeling, variable selection, graphical models, nonparametric Bayes, statistical computing, multistate Markov models, R package development, varying-coefficient models, hidden Markov models, variational inference

*Application:* cancer prevention, smoking behaviors, mental health, addiction, physical activity, nutrition, microbiome, mHealth, ecological momentary assessment, intensive longitudinal data, environmental health, human health and performance in space

### EDUCATION

*The University of Texas Health Science Center*, Houston, TX  
Doctor of Philosophy, Biostatistics, GPA: 4.0/4.0 Dec 2016  
· Minor: Health Promotions and Behavioral Sciences  
· Title: Deterministic Bayesian variable selection developments for binary outcomes · Advisor: Michael D. Swartz, PhD

*The University of Texas*, Austin, TX  
Bachelor of Science, Mathematics Aug 2011  
· Concentration: Scientific Computation

### EXPERIENCE

*Rice University*, Houston, TX  
Post-Doctoral Research Associate March 2018 - Current  
· NSF/RTG Post-Doctoral Fellowship in Data Science  
· Advisor: Marina Vannucci, PhD

*KBRwyle*, Houston, TX  
Biostatistician July 2016 - March 2018  
· Human Health and Performance Contract  
· Johnson Space Center

*The University of Texas Health Science Center*, Houston, TX  
Pre-Doctoral Fellow Jan 2015 - Dec 2016  
· National Cancer Institute Pre-Doctoral Fellowship  
· Cancer Education and Career Development Program

Pre-Doctoral Trainee Aug 2013 - Jan 2015  
· National Institutes of Health Pre-Doctoral Traineeship

*Science Systems and Applications, Inc.*, Hampton, VA  
Summer Intern May 2014 - Aug 2014  
· DEVELOP National Program  
· Langley Research Center

*National Space Biomedical Research Institute*, Houston, TX  
Summer Apprentice May 2013 - Aug 2013  
· Biostatistics  
Laboratory · Johnson  
Space Center

*Cancer Prevention and Research Institute of Texas*, Austin, TX  
Summer Intern May 2010 - Oct 2010  
· University of Texas School of Public Health  
· Biostatistics Department

**TEACHING  
EXPERIENCE**

*University of Texas Health Science Center*, Department of Biostatistics and  
Data Science  
Lecturer (Ad Hoc), Foundations of Biostatistics (PH1690) Fall 2019  
Lecturer (Ad Hoc), Foundations of Biostatistics (PH1690) Summer 2019  
· Student evaluation of overall effectiveness - 4.86/5.0  
Teaching Assistant, Theory of Biostatistics II (PH1911) Spring 2016  
Teaching Assistant, Linear Models (PH1915) Fall 2015  
Teaching Assistant, Intermediate Biostatistics (PH1700) Fall 2015 Teaching  
Assistant, Applied Statistical Analysis I (PH1820) Summer 2015 Teaching  
Assistant, Applied Statistical Analysis II (PH1821) Spring 2013

**PUBLICATIONS**

**Submitted/In Progress**

1. **Koslovsky, M.D.** & Vannucci, M. DTMBvs: Dirichlet-tree multinomial regression models with Bayesian variable selection for microbiome Data - an R package. *BMC Bioinformatics*. (Revised)
2. **Koslovsky, M.D.**, Hoffman, K., Daniel-MacDougall, C., & Vannucci, M., A joint model for predicting phenotypic responses with human microbiome data. (Submitted)
3. **Koslovsky, M.D.**, H'ebert, E.T., Businelle, M.S., & Vannucci, M. An efficient Bayesian varying-coefficient modeling approach for behavioral mHealth data. (Submitted)
4. Rosenberg, M.J., **Koslovsky, M.D.**, Noyes, M., Reschke, M.F., & Clement, G. Tandem Walk in Simulated Martian Gravity and Visual Environment. (Submitted)
5. **Koslovsky, M.D.**, Liang, M.<sup>†</sup>, & Vannucci, M. A Bayesian hidden Markov model for accommodating social desirability bias in mHealth data. (In Progress)

6. Shaddox, E.<sup>†</sup>, **Koslovsky, M.D.**, & Vannucci, M. A Spiked Dirichlet Process Prior for Joint Network Inference. (In Progress)
7. H'ebert, E.T., **Koslovsky, M.D.**, & Businelle, M.S. Time-varying relations for smoking behaviors captured in a novel, smartphone-based just-in-time adaptive intervention. (In Progress)
8. Denti, F.<sup>‡</sup>, **Koslovsky, M.D.**<sup>‡</sup>, Guindani, M., Vannucci, M., & Whiteson, K.L. Bayesian models for understanding the modulating factors of microbiome data. In S. Datta & S. Guha (Eds.), *Statistical Analysis of Microbiome Data*. Springer Verlag. (In Progress)

<sup>†</sup> indicates PhD student in Dr. Vannucci's research group at Rice University <sup>‡</sup> indicates equal contribution

### Statistical Methodology

9. **Koslovsky, M.D.**, Swartz, M.D., Chan, W., Leon-Novelo, L., Wilkinson, A.V., Kendzor, D.E., & Businelle, M.S. (2018). Bayesian variable selection for multistate Markov models with interval-censored data in an ecological momentary assessment study of smoking cessation. *Biometrics*, **74(2)**, 636-644.
10. **Koslovsky, M.D.**, Swartz, M.D., Leon-Novelo, L., Chan, W., & Wilkinson, A.V. (2018). Using the EM algorithm for Bayesian variable selection in logistic regression models with related covariates. *Journal of Statistical Computation and Simulation*, **88(3)**, 575-596.

### Applications

11. Zwart, S.R., Rice, B.L., Dlouhy, H., Shackelford, L.C., Heer, M., **Koslovsky, M.D.**, & Smith, S.M. (2018). Dietary acid load and bone turnover during longduration spaceflight and bed rest. *The American Journal of Clinical Nutrition*, **107(5)**, 834-844.
12. Conkin, J., Sanders, R.W., **Koslovsky, M.D.**, Wear, M.L., Kozminski, A.G., & Abercromby, A.F. (2018). A systematic review and meta-analysis of decompression sickness in altitude physiological training. *Aerospace Medicine and Human Performance*, **89(11)**, 941-951.
13. **Koslovsky, M.D.**, H'ebert, E.T., Swartz, M.D., Chan, W., Leon-Novelo, L., Wilkinson, A.V., Kendzor, D.E. & Businelle, M.S. (2017). The time-varying relations between risk factors and smoking before and after a quit attempt. *Nicotine and Tobacco Research*, **20(10)**, 1231-1236.
14. Conkin, J., Wessel, J.H., Norcross, J.R., Bekdash, O.S., Abercromby, A.F., **Koslovsky, M.D.**, & Gernhardt, M.L. (2017). Hemoglobin oxygen saturation with mild hypoxia and microgravity. *Aerospace Medicine and Human Performance*, **88(6)**, 527-534.

## Proceedings

15. Meyers, J., Garcia, Y., Arellano, J., Boley, L., Goodenow D., Kerstman, E., **Koslovsky, M.D.**, Reyes, D., Saile, L., Taiym, W., & Young, M. (2018, September 16-21). Validation of the NASA Integrated Medical Model: A Space Flight Medical Risk Prediction Tool. Paper presented at *Probabilistic Safety Assessment and Management 14*, Los Angeles, CA.

- PRESENTATIONS**
- **Koslovsky, M.D.\***, Hoffman, K., Daniel-MacDougall, C., & Vannucci, M. "A Bayesian Model of Microbiome Data for Simultaneous Identification of Covariate Associations and Prediction of Phenotypic Outcomes." Joint Statistics Meetings, Denver, CO. Aug 2019. (contributed poster presentation)
  - **Koslovsky, M.D.\***, Hoffman, K., Daniel-MacDougall, C., & Vannucci, M. "A Bayesian Model of Microbiome Data for Simultaneous Identification of Covariate Associations and Prediction of Phenotypic Outcomes." BigDIA, Houston, TX. Dec 2018. (contributed poster presentation)
  - Yu, D., Sedory, A.C., Mohammadi, K., **Koslovsky, M.D.**, & Swartz, M.D.\*. "Trio RVEMVS: A fast Bayesian variable selection method for trios that identifies individual rare variants," International Genetic Epidemiology Society Meetings, San Diego, CA, Oct 2018. (platform presentation)
  - **Koslovsky, M.D.\***, Arellano, J., Schaefer, C., Feiveson, A., & Young, M. "CommClust: A network-based algorithm for clustering multivariate repeated measures data." NASA HuMan Research Program Investigators' Workshop. Galveston, TX. Jan 2018. (contributed poster presentation)

## AWARDS

- Dr. M. Stewart West Memorial Scholarship, 2015
- UTHealth Division of Biostatistics Travel Award, 2015
- Richard D. Remington Memorial Student Scholarship, 2014
- Robert. H Bigelow Endowed Scholarship, 2013

## Item B: Dr. Koslovsky - CV

- MENTORING**
- Yefei Zhang, UTHealth, PhD Biostatistics candidate, Dissertation Committee, 01/2017-Current
  - Scott Liang, Rice University, PhD Statistics student, Co-mentor, 03/2019Current
  - James Warner, Rice University, Rice Undergraduate Data Science Summer Program, 2018
  - Karan Adams, Rice University, Rice Undergraduate Data Science Summer Program, 2018
  - Stoyan Komitov, Rice University, Rice Undergraduate Data Science Summer Program, 2018
  - Alex Aguilar, Rice University, PhD Statistics candidate, NASA Summer Intern, 2018
  - Austin Vo, University of Central Florida, NASA Summer Intern, 2017
  - UTHealth New Student Mentor, Fall 2013
- COMPUTER SKILLS**
- Languages & Software:* R, C++, Rcpp, Shiny, L<sup>A</sup>TEX, STATA, SAS, WinBUGS
- PROFESSIONAL AFFILIATION**
- Member*
- American Statistical Association, 2015 – Current
- PROFESSIONAL SERVICE**
- Reviewer*
- Biometrical Journal, Biometrics, Biostatistics, Nature Communications
- Board Member*
- Johnson Space Center IRB
- Board Member*
- Conference for Food Protection: Program Standards Committee, KBRwyle, NASA
- CONTINUING SERVICE**
- HACASA - Short Course “Randomized Clinical Trials replacing Traditional Analyses with Better Alternatives,” Houston, TX, May 2018
  - Joint Statistical Meetings - Short Course “Network Meta-Analysis,” Baltimore, MD, Aug 2017
  - NASA Human Research Program Investigator’s Workshop - “A New Dawn: Enabling Human Space Exploration,” Galveston, TX, Jan 2017
  - Technology Collaboration Center - “Omics Workshop,” Houston, TX, Spring 2017
  - Tableau Conference 2016 - Tableau Classroom Training- “Tableau Desktop II,” Austin, TX, Fall 2016
-

## Item B: Dr. Koslovsky - CV

- ENAR - Short Course “An Introduction to Statistical Machine Learning,” Austin, TX, Spring 2016
- ENAR - Tutorial Session - “Data Visualizations in R with shiny and ggplot2,” Austin, TX, Spring 2016
- ENAR - Tutorial Session - “High Performance Computing with R,” Austin, TX, Spring 2016
- ASA Biopharmaceutical Section FDA - Industry Statistics Workshop - “Equivalence and Similarity Testing,” Washington, DC, Fall 2015
- ASA Biopharmaceutical Section FDA - Industry Statistics Workshop - “Designing Observational Comparative Studies Using Propensity Score Methodology in Regulatory Settings,” Washington, DC, Fall 2015
- Joint Statistical Meetings - “Adaptive Methods for Modern Clinical Trials,” Seattle, WA, Summer 2015
- UT Summer Statistics Institute - “Introduction to Mixed Models with Applications,” Austin, TX, Summer 2015
- UT Summer Statistics Institute - “Big Data Analytics,” Austin, TX, Summer 2015

**REFERENCES**

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Lead of Biostatistics Laboratory  
Johnson Space Center  
NASA

## Standard 8 Pilot Survey

Subcommittee #2 established by the Program Standards Committee is conducting a survey to pilot a model evaluating the staffing requirements as outlined by Standard 8 of the Voluntary National Retail Food Regulatory Program (FDA). The purpose of this survey is to collect the necessary data to conduct a staffing level audit for your Health Department.

You will need to use the guidance documented provided to assist you in filling out the information on the survey.

### 1. Please provide your name and jurisdiction

### 2. On average, how many hours per year do EHS (Environmental Health Specialist) employees spend on the following:

(If not applicable, please answer "N/A")

Holiday

Vacation

Sick leave

Family/Personal leave

### 3. On average, how many hours per year do your EHS employees spend on the following:

(If not applicable, please answer "N/A")

Traveling to/from inspections

Administrative work

Break time

Professional development (training, continuing education)

## Item C: Pilot Study Survey

4. Please list all employees who conduct food safety inspections using the following format:

**Title of position, % of time dedicated to food safety inspections, number of this type of employee in your health department**

Example: Environmental Health Specialist-Training, 60%, 12

(If less than 6 positions, please answer "N/A" for empty boxes)

Position 1

Position 2

Position 3

Position 4

Position 5

Position 6

5. Please provide the total number of inspections related to food safety conducted for your department's entire jurisdiction in one year.

6. How many of each of the following establishments does your department conduct inspections on?

(If not applicable, please answer "N/A")

Low-risk

Moderate-risk

High-risk

7. How many routine inspections were conducted in 2018?

8. How many permitting inspections were conducted in 2018?

\*9. What is the average time spent conducting each of the following inspections in your department?

(If not applicable, please answer "N/A")

\*Note: Please specify when using hours or minutes.

Follow-ups/reinspections	<input type="text"/>
Food-borne illness complaints	<input type="text"/>
Complaint investigations	<input type="text"/>
Outbreak investigations	<input type="text"/>
Compliance follow-up inspections	<input type="text"/>
Risk assessment reviews	<input type="text"/>
Process reviews	<input type="text"/>
Variance process reviews	<input type="text"/>
Final construction inspections	<input type="text"/>
Other	<input type="text"/>

### INSTRUCTIONS FOR PROVIDING DATA REQUESTED FOR PILOT

#### **Guidance Notes:**

These notes are intended to guide the survey process by providing you with definitions, examples, and instructions on how to answer the survey questions. We also suggest where you might find the information needed if you do not have it readily available. Use the checklist provided on Page 3 ensure you have all the information to fill this survey.

#### **Question 1:**

*“Holiday, Vacation, Sick Leave, Family Personal Leave”* - These hours may vary by seniority of staff or other factors, please provide the best average for a 100% full-time EHS staff. Your Human Resources department may be a good resource to obtain some of this information.

#### **Question 2:**

*“Traveling to/from inspections”* - Districts vary in size and therefore this number will be different across health departments. Please use a best estimate or average time for a full-time equivalent EHS staff.

*“Administrative work”* - This includes any office time and administrative work an EHS employee does outside of food inspection. This does **NOT** include completing the inspection report.

*“Professional development”* - This includes things like training and continuing education.

#### **Question 3:**

*“Employees who conduct food safety inspections”* - For this question, we ask that you take time to consider *all of the employees that conduct food safety inspections*. Most health departments have inspectors whose time is dedicated solely to food safety, but have others that may dedicate only a small percentage of their time to food. For example, supervisors may conduct inspections, but only dedicate about 10% of their time to this. Use as many rows as needed to list all types of employees who conduct food inspections, even if their job titles are similar. For example:

1. EHS I, 80%, 15
2. EHS II, 60%, 5
3. EHS Supervisor, 40%, 2
4. EHS Manager, 5%, 1

#### **Question 4:**

*“Total number of inspections”* - Inspections are defined as routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews, foodborne illness complaint response, final construction inspections and other direct establishment contact time

## Item D: Survey Guidance Document

such as on-site training that is performed by the field inspection staff. (Standard 8 Staffing Level Assessment Workbook: Instruction Guide, page 10).

### **Question 5:**

“*Low - Moderate - High Risk*” - Do your best to categorize all of your establishments into low, moderate, and high risk categories.

- If you have more than three categories, attempt to distribute your establishments into the categories provided.
- If you currently use fewer than three categories (Example: Low and High), then only provide the number of establishments for those categories and leave the unused one blank.
- If you do not already have a process in place to categorize food establishments in your jurisdiction, the FDA Food Code has a recommended guide to assist with categorizing, refer to Annex 5, Table 1 (Page 4 of this document). You can also review a recommendation of how to categorize your establishments below:
  1. **Low risk establishments** = Examples include most convenience store operations, or establishments that sell pre-packaged or non-TCS (temperature control for safety) food.
  2. **Moderate risk establishments** = Examples may include retail food store operations. They may have a limited menu. Most products are prepared/cooked and served immediately.
  3. **High risk establishments** = Examples include full service restaurants. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods.

### **Question 6 & 7:**

“Routine Inspections” - A full review and evaluation of a food establishment’s operations and facilities to assess its compliance with food safety law, at a planned frequency determined by the regulatory authority. This does not include re-inspections and other follow-up or special investigations.

“Permitting Inspections” - A review of a food establishment’s operations and facilities to determine if a permit will be issued for the establishment to operate.

### **Question 8:**

“Average time” - For each category determine the time spent on the activity from beginning to end, plus any writing and delivering reports if applicable. For example, for follow-up/re-inspections: average time = (inspection start to finish) + writing and delivering report. Leave blank if category is not applicable to your jurisdiction.

## **CHECKLIST**

Before starting the survey please gather all information mentioned on the below checklist. It is vital to the success of this pilot study that you try and obtain as accurate of information as possible.

*Note: Annual Non-Inspection Hours and Annual Productive Hours are for an EHS employee dedicated to 100% food inspections. While there may be some variation in these hours per employee please provide the best possible average.*

### **Annual Non-Inspection Hours**

- Holiday
- Vacation
- Sick Leave
- Family/Personal Leave

### **Annual Productive Non-Food Inspection Hours**

- Travel time to and from inspections
- Administrative work (not including inspection reports)
- Break time (lunch, break, etc.)
- Professional development (training, continuing education)

### **EHS or Related Positions**

- A list of all types of EHS personnel or related positions (ANYONE who conducts a food establishment inspection)
- % of time dedicated to food safety inspections for all above position types
- # of employees in each position

### **Other Inspection Data**

- Total number of food safety inspections conducted in 2018
- List of all food establishments in your jurisdiction
- How many routine/permitting inspections were conducted in 2018
- Average time spent conducting follow-up/re-inspections, food-borne illness complaints, and other

**Annex 5, Table 1. Risk Categorization of Food Establishments**

RISK CATEGORY	DESCRIPTION	FREQUENCY #/YR
1	Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged, non- time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed, TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors.	1
2	Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of TCS foods after preparation or cooking. Complex preparation of TCS foods requiring cooking, cooling, and reheating for hot holding is limited to only a few TCS foods. Establishments that would otherwise be grouped in Category 3 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne illness risk factors is achieved and documented.	2
3	An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.	3
4	Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.	4

# Item E: Current Standard 8 Assessment Workbook

AGENCY

## Standard 8: Staffing Levels FTE (Full-Time Employee) Data

DATE

<b>FTE DATA CALCULATIONS</b>			
Program Description and Supporting Information:			
<b>FOOD SAFETY PROGRAM FTE HOURS PER YEAR</b>			
Annual FTE Hours Per Year: Industry Standard		2080	
	Local Holiday Hours Per Year		
	Local Vacation Leave Hours Per Year		
	Local Sick Leave Hours Per Year		
	Local Family-Personal Leave Hours Per Year		
Annual FTE Hours Per Year: Local Inspector		2080	
	Productivity Factoring		
	Personal Development Time		
Productive Annual FTE Hours Per Year (FTE Conversion Factor): Local Inspector		2080	
<b>FOOD SAFETY INSPECTION HOURS PER YEAR</b>			
Position Category	Food Safety Inspection Hours	Number of Employees	Total Food Safety Inspection Hours
			0
			0
			0
			0
Total Food Safety Inspection Hours			0
Other Local Inspector EH Inspection Hours			0
Actual Food Safety Inspection Hours			0
Total Local FTE			0.0

AGENCY

## Standard 8: Staffing Levels Inspection-to-FTE Ratio

DATE

<b>INSPECTION-TO-FTE RATIO</b>	
In accordance with Standard 8 Self-Assessment Guidance provided in the January 2011 version of the Program Standards, the Inspection-to-FTE Ratio must fall between 280 and 320.	
Local program number of Food Safety Inspections	0
Local program number of FTEs	0.0
Inspection-to-FTE RATIO	#DIV/0!

## Item F: Proposed Standard 8 Assessment Workbook

<b>FTE DATA CALCULATION</b>				
Calculate productive hours per year for an employee doing 100% food inspections				
Information For One Employee		Hours/Year	Hours/Day	Total Hours
Annual FTE Hours Per Year: Industry Standard				2080
	Local Holiday Hours Per Year			0
	Local Vacation Leave Hours Per Year			0
	Local Sick Leave Hours Per Year			0
	Local Family-Personal Leave Hours Per Year			0
<b>Productivity Factoring Per Year</b>				
	Travel Time For Inspection			2080
	Administrative Work (in-office work)			2080
	Break time			2080
	Others			2080
<b>Personal Development Time Per Year</b>				
	Professional Development			2080
	Others			2080
<b>Productive Annual FTE Hours Per Year (FTE Conversion Factor)</b>				<b>2080</b>
<b>FOOD SAFETY INSPECTION HOURS PER YEAR</b>				
Position Title	Percent of time spent on food inspections	Number of Employees	Total Hours	
			0	
			0	
			0	
			0	
			0	
			0	
<b>Total Food Safety Inspection Hours</b>			<b>0</b>	
<b>Total Current FTE</b>			<b>0.00</b>	

<b>STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION</b>							
	Low Risk Establishments	Frequency of Low Risk Est Inspections Per Year	Moderate Risk Establishments	Frequency of Moderate Risk Est Inspections Per Year	High Risk Establishments	Frequency of High Risk Est Inspections Per Year	Total
Routine and Permitting		1.00		2.00		3.00	0
Follow Up Inspections/Reinspections							0
Foodborne Illness Complaints							0
Other							0
<b>Total Number of Required Inspections</b>							<b>0</b>
Median Hours Spent Per Inspection	0.75		1.25		2.00		
Total Inspection Time							0
<b>Total Required FTE</b>							<b>0.00</b>
<b>Standard 8.1 Staffing Level</b>							<b>Standard not met</b>
<b>Sources</b>							
-2017 Subcommittee # 2 - Survey 1 and 2							
-2019 Pilot Study							

### PILOT STUDY TEAM

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### ACKNOWLEDGEMENTS

The Pilot Study Team would like to thank all members from Subcommittee #2 and the Program Standards Committee for their feedback and suggestions. Their input and expertise was invaluable throughout the process to develop a recommended solution to the Standard. Special thanks to the 18 jurisdictions who took the time and effort to provide the data necessary to drive this Pilot Study.

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\*Riddhi Patel conducted the 2017 survey and originally developed the proposed model from which all this work was based on.

## Standard #4 Clearinghouse Questions

Submitted by Carrie Pohjola, WI DATCP

[Carrie.Pohjola@Wisconsin.gov](mailto:Carrie.Pohjola@Wisconsin.gov), 715-579-9487

An issue was submitted during the 2018 Biennial Conference for Food Protection with regard to individuals conducting field exercises. Background information regarding this issue submission is as follows:

When conducting a Standard 4 audit for jurisdictions; the auditor must ensure that the jurisdiction meets the applicable requirements. At this time, there is no consideration for performing an audit on larger jurisdictions. Jurisdiction sizes are only taken into consideration in calculating the program effectiveness. There are jurisdictions in the country that have over 100 inspectors not within their first 18 months of training as part of their food program. This means that an auditor will have to verify that at least 300 field reviews and the applicable file reviews are conducted and that they meet the requirements listed. This creates an undue hardship on the auditor and should be re-examined. In Standard 1, 2, and 6, there is a statistical model utilized to pull a random sampling of the content to be reviewed, with which the auditor can then use to determine whether the jurisdiction meets the requirements. It is recommended that for jurisdictions with over 20 inspectors performing foodservice or retail food inspection work, a similar statistical measure be provided or allowed to determine whether the jurisdiction meets the Standard.

Currently, there is no specification requiring an auditor to verify that the individual(s) performing the field reviews have been conducted by someone that has completed Steps 1-3 in Standard 2, and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.

Should the auditor then verify the training records, affidavits, certificates, etc... for those individual(s) that are performing the field reviews? If so, it is recommended that a field evaluator course, track, and/or certificate be established to demonstrate Steps 1-3 of Standard 2 have been completed. This will be especially beneficial when auditing large jurisdictions with many individual(s) performing the field reviews. Although the Retail Program Standards are voluntary, and auditors volunteer, performing an audit is highly time consuming and any means to make this process more efficient would be beneficial.

### Questions:

- 1. When conducting the field exercises and applicable file review for Standard #4, does the evaluator need to be trained in Standard #2, Trained Staff?**
- 2. Does an auditor need to review all field exercise files for all staff when conducting a verification of Standard #4?**

## **AUDITOR VERIFYING STANDARD 2 TRAINING**

Key Words: STD-02, STD-04, Field Exercises, Verification Audit, File Review

### **Issue Description**

#### **Background**

Currently there are no specifications that require an auditor to verify that the individual(s) performing the field reviews of other staff members has completed Steps 1-3 in Standard 2. Would this require the auditor to verify via training records, affidavits, and the like, that the individual(s) performing the field reviews has completed these steps? If so, is it recommended that a field evaluator course, track, and/or certificate be established to demonstrate Steps 1-3 of Standard 2 have been completed. This will be especially beneficial when auditing large jurisdictions with many individual(s) performing the field reviews.

#### **Rationale**

#### **Question/Problem**

When conducting the field exercises and applicable file review for Standard #4, does the staff member conducting the review need to be trained in Standard #2, Trained Staff? Does an auditor need to verify that this training has occurred?

#### **Response from Clearinghouse**

The Standard 4 Self-Assessment Instructions and Worksheet states that field reviews must be conducted by someone who has:

- A) Completed Steps 1-3 in Standard 2; and
- B) Recognized by the program manager as having the field experience and communication skills necessary to train new employees.

Currently there are no requirements that an auditor verify that staff members conducting field reviews with other employees have completed steps 1-3 in Standard 2. An auditor is not required to verify additional paperwork related to any Standard 2 criteria when conducting the Standard 4 verification audit.

## **Update: EXPLANATION OF THE STATISTICAL MODEL for STANDARD 4**

The criteria used for evaluating the inspectional performance of jurisdictions have changed resulting in the need to update the statistical model. Previously in large jurisdictions (jurisdictions with 10 or more inspectors) the evaluation is based on direct oversight of two inspections per inspector, with respect to 10 items of performance. There will now be 20 items on performance instead of 10.

Using the previous statistical model and assumptions, a team achieving 88 percent at each inspection would pass the evaluation 75 percent of the time. Therefore, this 88 percent level of performance was used as a simple representation of a team that is good enough that we want them to have a good chance of passing, but not so good that they would not find it advantageous to improve. But now with 20 items instead of 10 a jurisdiction with 88 percent level of performance would pass only 59% of the time. This would fail too many high performing jurisdictions.

Large jurisdictions (jurisdictions with 10 or more inspectors) the evaluation is based on direct oversight of three inspections per inspector, with respect to 20 items of performance. With the additional inspections evaluated the 88 percent performing jurisdiction will pass 75% of the time.

### Evaluation of performance of small jurisdictions

A statistical issue was to determine a reasonable standard for those jurisdictions with less than 10 inspectors. When the sample gets this small, the relative error in the estimated fractions gets so large that the “each of 20 items rule” will fail good programs too frequently. Therefore, the 88 percent level of performance at each inspection was the feature of the standard that was kept constant in designing the sample sizes for the smaller jurisdictions

In jurisdictions with less than 10 inspectors, the statistical solution is to group all of the individual ratings, disregarding the individual items. For 5 inspectors we would review  $5 \times 3 = 15$  inspections, with respect to all 20 items combined. This gives 300 observations. It is not possible to make a total observation test mimic exactly a 10 item test, but the minimum passing rates will be about as stringent as the 75 percent for each of 10 aspects test:

For 4 to 9 inspectors, conduct three co-inspections for each inspector. Chart 4-1 shows the lowest total passing score out of the complete set of combined items that would give at least a 75 percent chance of passing for a team with an 88 percent chance of getting any particular observation correct. For a team of three or less, it is recommended that extra oversight inspections be performed to produce a total of 12 inspections. This is an intuitive judgment call that any set smaller than 12 could randomly turn out to be odd enough to produce an unfair rating.

Standard 4: Uniform Inspection  
Program  
Self-Assessment  
Worksheet

Chart 4-1: Method of Calculation for Jurisdictions with Less Than Ten Inspectors

# of inspectors	# inspections needed	# of items needed to be marked IN compliance in order to meet Standard 4 criteria
<4	12 minimum	200 (out of 240 possible Items)
4-9	3 per inspector	4 inspectors = 200 (out of 240 possible Items) 5 inspectors = 252 (out of 300 possible Items) 6 inspectors = 303 (out of 360 possible Items) 7 inspectors = 355 (out of 420 possible Items) 8 inspectors = 407 (out of 480 possible Items) 9 inspectors = 459 (out of 540 possible Items)

NOTE:

1. These minimum inspection program assessment criteria are comparable to the 75% IN Compliance rate for each of the ten inspection program areas for jurisdictions with 10 or more inspectors.

Example:

*For 6 inspectors, there will be 3 field visits per inspector = 18 visits  
18 visits X 20 Items per visit = 360 Total Possible Items*

## Survey Metrics

### Date Metrics

Start Date	14-Mar-19
End Date	4-Mar-29

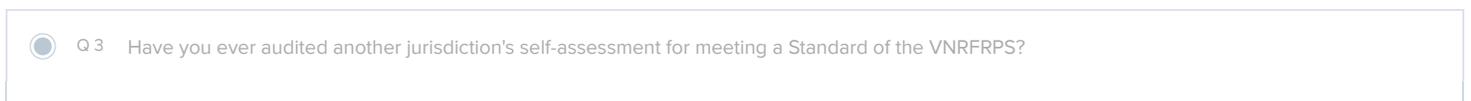
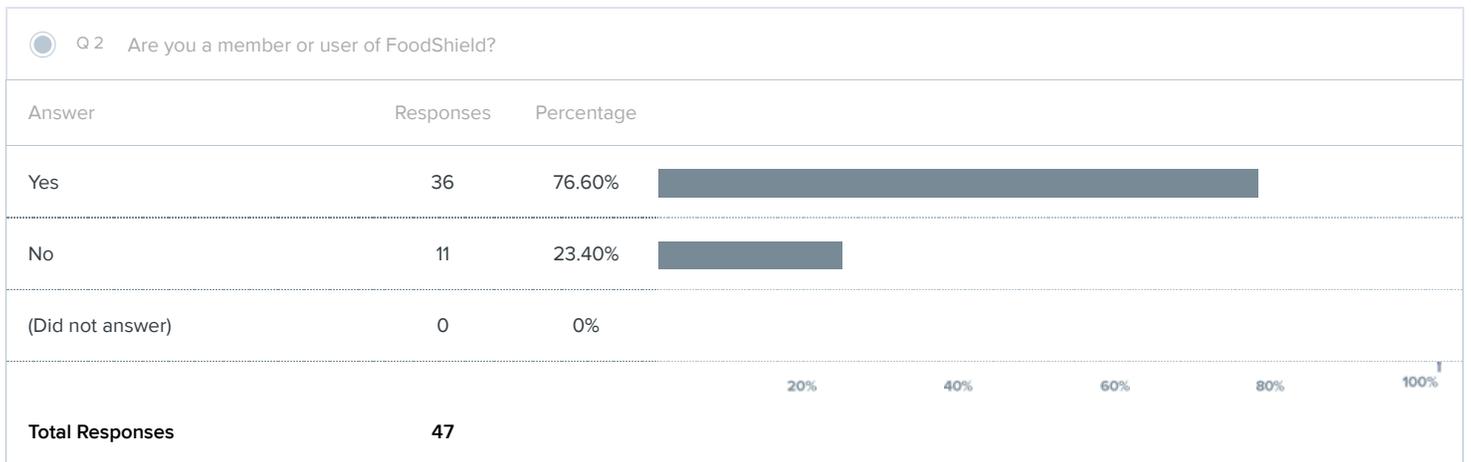
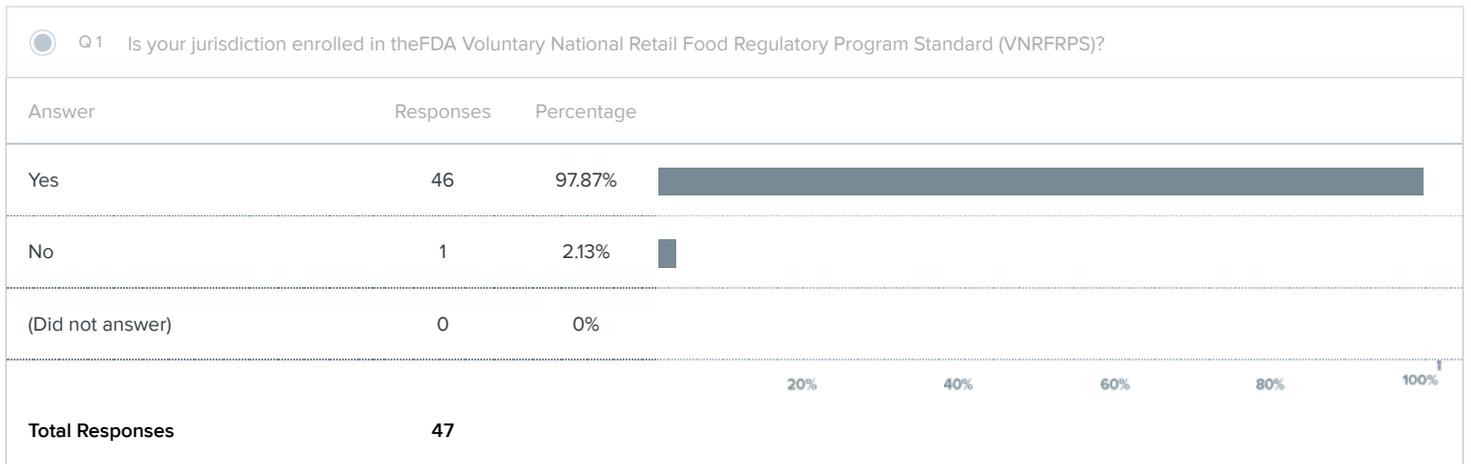
### Deployment Metrics

Sent	0
Delivered	0
Bounced	0

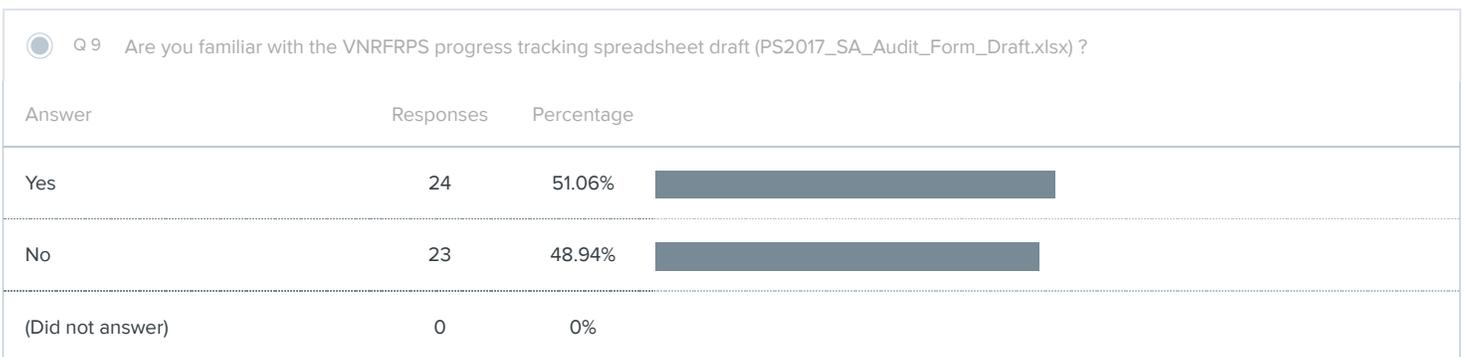
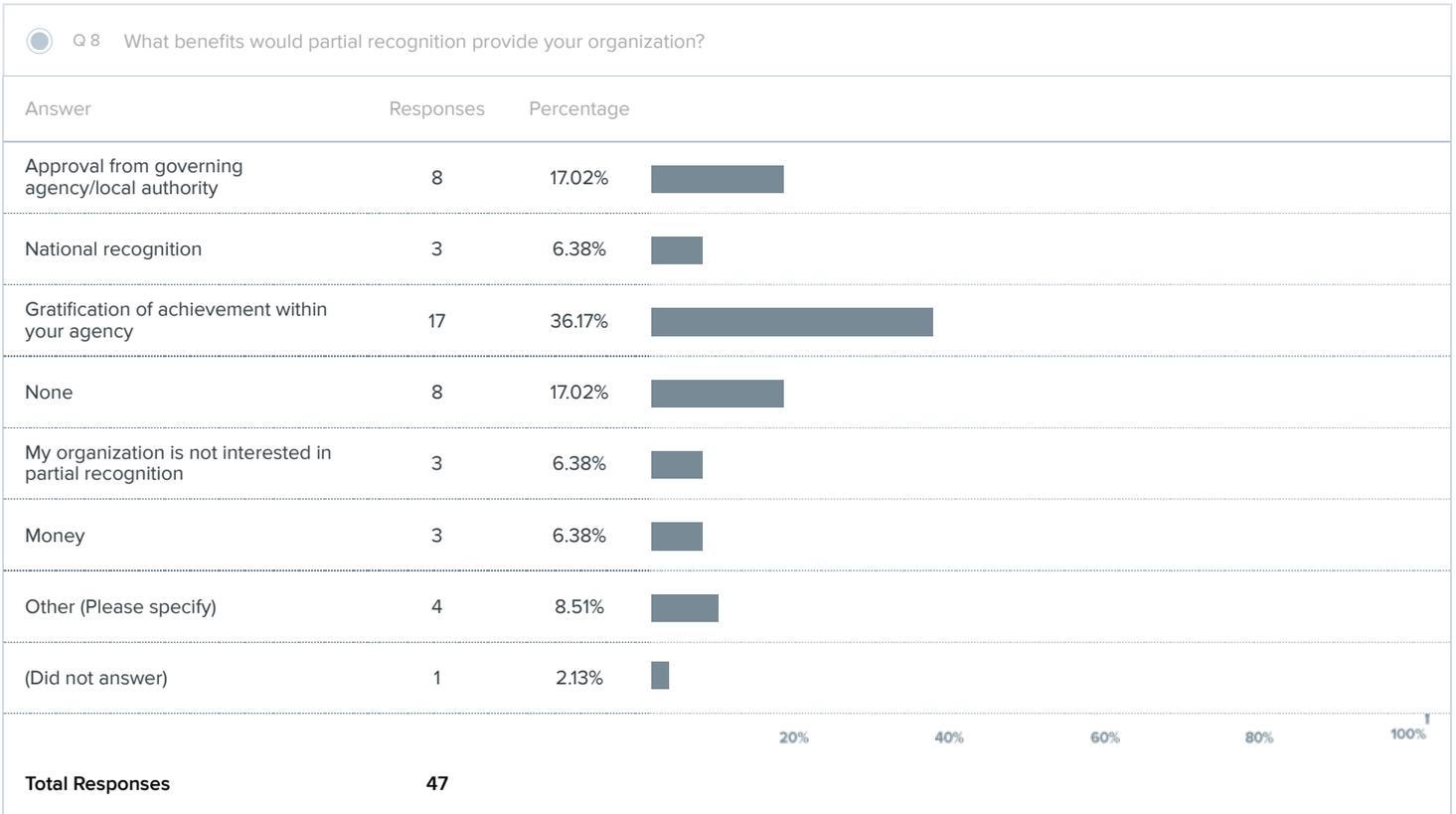
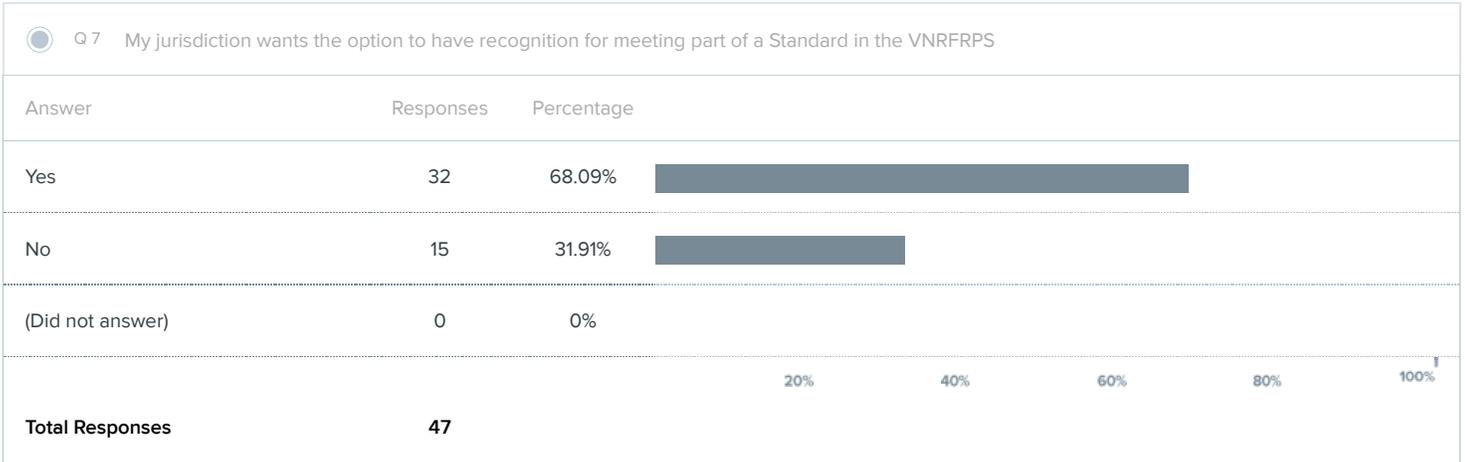
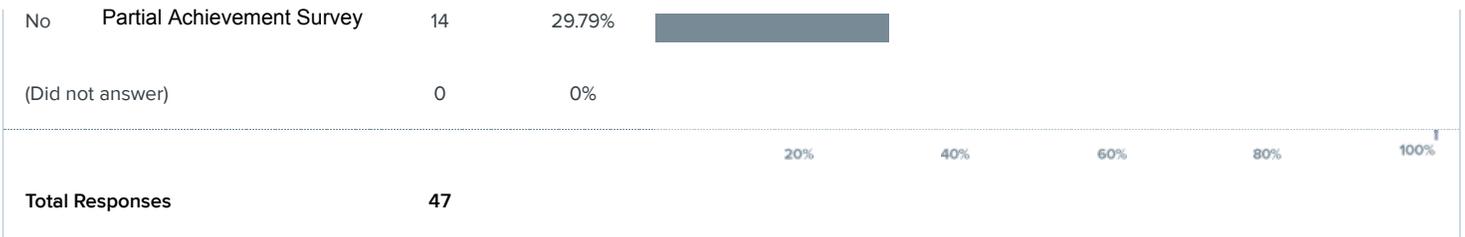
### Response Metrics

Completed	47
Unique Access Rate	0.00%
Incomplete	0
Incomplete Incl. in Report	0

## Bar Graph Report







Partial Achievement Survey



**Total Responses** 47

Q 10 Is your organization a state or local jurisdiction?

Answer	Responses	Percentage	
Local	43	91.49%	
Federal	1	2.13%	
Tribal	0	0%	
State/Territory (Please specify)	3	6.38%	
(Did not answer)	0	0%	
<b>Total Responses</b>		<b>47</b>	



## **Reasons for including plan review in Voluntary National Retail Food Regulatory Program Standards**

Programs standards exist to evaluate if the regulatory program is effectively controlling and/or reducing foodborne illness risk factors through periodic assessment of existing programs to identify if improvement is needed.

Plan review identifies if the proposed or remodeled establishment will have adequate facilities, systems, and equipment to safely store, prepare and serve food.

Lack of plan review or incomplete plan review may result in conditions that contribute to foodborne illness, such as a lack of proper equipment to properly store or hold food at safe temperatures, unsanitary conditions that promote pest infestation, contamination from employees, raw animal foods, unclean food contact surfaces, etc.

### **Requirement Summary:**

Food establishment plan review is recognized as an important food program component that allows:

- Regulatory agencies to ensure that food establishments are built or renovated according to current regulations or rules.
- Industry to establish an organized and efficient flow of food.
- Regulatory agencies to eliminate code violations prior to construction.

### **Description of Requirement:**

Competency of personnel conducting the plan review

- Training
- Continuing Education

For all new and substantially remodeled establishments [defined in program regulations]

### **Outcome:**

Regulatory agency reviews all plans for food establishments to determine compliance with applicable sections of the Food Code, or local regulations. If the regulatory program does not have resources to conduct plan review or if the agency does not have jurisdiction over plan review, indicate if there another agency within the jurisdiction that provides this service (such as when the inspecting agency does not issue the food safety license).

### **Documentation:**

Plan review process and required documentation requested from applicants

Subjects/areas reviewed for each plan, including but not limited to:

## PRELIMINARY PLAN REVIEW PROPOSAL

- Appropriate facilities to prepare food safely
- Systems to prevent foodborne illness and injury
- Adequate space and equipment for all CCPs in the flow of food
- Plumbing systems – safe water and waste water disposal; appropriate backflow prevention; adequate supply of hot water; size and location of dish washing sinks and machines; drain boards; removal of grease – trap or interceptor; sewage disposal; produce washing/food preparation sink; utility sink
- Prevention of cross-contamination (areas and/or time for preparation of raw and ready-to-eat foods)
- Adequate numbers and capacity of food storage and production equipment
- Proper hygiene – hand washing sinks are provided in all necessary areas and are easily-accessible
- Menu review to identify HACCP process flows
- Cleaning and maintenance of facilities, premises and equipment; equipment on legs or sealed to the floor
- Chemical storage locations
- Waste storage and removal
- Electrical system – capacity; adequate lighting and shielded
- HVAC – ventilation to remove grease, odors and moisture – kitchen and restrooms
- Prevention of conditions that contribute to pest infestation
- Approved food service equipment – NSF or similarly-approved
- Adequate storage for clean utensils, food, linens, single-service articles and equipment
- Adequate storage for employee personal belongings, locker rooms, restrooms

Documentation of all plan reviews (approval, conditional, denial) within specified time frame in standardized format.

Reviewer – checks x % for compliance.

Hello Group,

Here are the minutes from the kickoff call (12/19/2018):

- Greeting and antitrust statement.
  - > Attendance was taken at the start of the call.
- Proposed calendar for calls is 1/9, 1/23, 2/6 then second Wednesdays of the subsequent months (3/13, 4/10, 5/8, 6/12, 7/10, 8/14) which concludes on September 11<sup>th</sup>. We'd also like to ask for flexibility, as we may need to include additional calls in the coming months. If we are all in agreement with the proposed schedule of calls, calendar invitations will be sent out by the end of this week.
  - > 1/09 - Review Charge 1
  - > 1/23 - Review Charge 3
  - > 2/06 - Review Charge 2. David Read will review the IFPTI group work for Charge 2.
- Discuss procedures/Food Shield access and use. Meeting minutes will be posted on our Food Shield workgroup page within 48 hours of our calls.
  - > Angie Cyr sent out the Food Shield usernames and passwords from that website on November 5th. Confirmed successful access to the workgroup documents.
- Goals/Review the charges assigned to this subcommittee. Subcommittee reports will be prepared and submitted according to the CFP master calendar. The first of which is due by 2/09/2018.
  - > The charges under the issue 2018 II-019 were reviewed with the group and explained briefly.
  - > David Read gave an update on his work specifically reviewing the regulatory training program. He shared the website to reference his group work, <https://ifpti.org/retail-food-framework/>
  - > To prepare for the upcoming call, the group was asked to review the documents uploaded to Food Shield. Pages 2,3, 19-25 of the 2017 Program Standards Committee Report are pertinent to us, as we continue reviewing the issue.

Call Participants (8)

DeBrena Hilton  
Adam Kramer  
Amanda Douglas  
Christine Sylvis  
Matthew Walker  
Kenesha Williamson  
David Read  
Katey Kennedy

Hello Group,

Here are the minutes from the call (1/09/2019):

- **What are some current initiatives used for training food safety inspection officers?**

Mark – Standard 2 training curriculum, review of codes specific to Iowa, and all staff attend FD 218 risk based inspection methods, FD 312 special processes, and FD 215 managing retail food safety.

Matt – Compliance Wire for special processes training.

**What is the difference between Compliance Wire and Pathlore?**

David – FDA moved away from Compliance Wire and started using Pathlore going forward. They migrated their learning management system.

DeBrena – Tulsa uses their state agency partners to present the same FDA courses. Sometimes the FDA specialist will present and the State will present a portion of the course.

**Which of the FDA courses has the course in a box instructor material available?**

Christine - Several districts are burdened with the cost of hosting the instructor, paying the course fees, etc.

Some customized internal trainings are given on report writing and fine points of the inspection process. Modeled after the old FD 170 course.

FDA website does offer several additional online courses (food defense, allergens, basics of auditing, etc.) and Pathlore has some new courses which have just been added.

**What subjects do we feel the courses do not address?**

In-house trainings have been developed to train FSIOs on report writing, applying HACCP, etc. because it is difficult to receive the feedback on understanding from the online courses.

DeBrena – Tulsa has been doing some in-house consistency / standardization training activities to ensure the district is monitoring for uniformity of assessment and marking. They use the web-based Kahoot polling software for staff tabletop exercises.

Christine - In Southern Nevada, they also give their team more intense plumbing system training and review of HACCP principles.

Districts are also bringing in Meat and Poultry inspection bureau partners to cover cross-jurisdictional matters.

Food Safety Centers of Excellence offers foodborne illness training and EATS 101 and portions of 102.

DeBrena – Tulsa is currently working with Epi to develop some new training for foodborne illness exercises. They have developed a PowerPoint to present various scenarios the inspectors will encounter.

Adam – They gave the new staff approximately a dozen different mock scenarios and practice entering the report and role playing with retail operators.

Christine – Southern Nevada uses a similar method as part of the report writing training.

**What is meant by non-traditional food outlets on the retail food curriculum framework?**

It is the current verbiage used in place of “ethnic foods”.

DeBrena – To address non-traditional food outlets, they use the ethnic foods presentation from FDA. AFDO has some resources on ethnic foods, shared kitchens, cottage foods, catering, etc.

**How does everyone address temporary food events whether large scale or small scale? Are there formal training courses or materials offered?**

DeBrena – Tulsa has a temporary events coordinator to help with planning and permitting. Oklahoma has a full classroom setting training course and an on-site training.

Northern Arizona University has a public education course for food safety basics. Applications include camping and emergency situations.

- **What are the current initiatives for certification of FSIOs?**

Melissa – Uses both the managers and inspector HACCP certification programs available through the International HACCP Alliance. Environmental assessments team is sent to root cause analysis training from ASQ (American Society for Quality).

Christine – Southern Nevada uses the 40hr Haswoper trainings.

Melissa – Recommends inspectors take an ANSI approved food safety manager training to obtain CFPM certification. She would like to see consistency in the requirements for FSIOs maintaining CEUs.

(NCBRT) - National Center for Biomedical Research and Training Academy - Counterterrorist Course is available, as well as EHTER training for environmental health & emergency preparedness strike teams.

- **What are some current initiatives for the evaluation of food safety inspection officers?**

Districts are referencing the individual training logs, the CFP training manual, and using the assessment forms from Standard 4. There are several documents in Food Shield which have been developed by districts for general evaluations.

Call Participants (9)

DeBrena Hilton

Adam Kramer

Amanda Douglas

Christine Sylvis

Matthew Walker

Kenesha Williamson

David Read

Melissa Vaccaro

Mark Speltz

Hello Group,

Here are the minutes from the call (1/23/2019):

**The group discussed gaps and alignment between Standard 2 and Standard 4, using our workgroup's Standard 4 QA Elements and Training Courses table:**

Mark – Reviewed the CFP training plan to double check for elements which are not line items in the training log. Proposed updating the CFP training manual with our findings. We need the CFP manual to mirror those elements.

Christine – She asked four new staff members go through the elements to identify which areas were not part of the required training. Considers most jurisdictions to have an internal review of the basics of inspection.

Mark – Trying to address individualistic policies in a national curriculum will be difficult. Ultimately, how do we address individual procedural trainings?

Dave – Some of this looks like a best practices list. Much of these elements will be addressed during standardization.

Christine – FDA considers standardization to be a qualitative assessment of an inspector's training and not a training program itself.

**Do the districts approach new inspector training with standardization in view?**

Melissa – Yes. We make sure they will be able to pass standardization.

**Element 3 - How do the districts train staff to understand why risk type is assigned, how to recognize changes in the operation which affect risk type assignment, or identification of an incorrectly permitted facility?**

Mark – In alignment with Standard 3, Iowa uses customized training to address basics of inspection.

Melissa – Districts have custom training to support methods of risk-based inspection course.

DeBrena - Digital health department lists the facilities and their corresponding risk types.

Mark – We will need to proceed with caution on proposing that instructor led FD courses be included in the Standard 2 requirement. Some of the courses are not offered very frequently and some may be discontinued.

Dave – Recommends we refrain from listing names of courses or listing “equivalent courses”. He recommends we focus on the competency areas. He recalls changes to the standard 2 curriculum were discouraged during the last two conferences.

Mark – Maybe all we need to propose for standard 4 is that we create an addendum which lists optional courses.

Dave - Changes to the curriculum may not be worthwhile right now, given that the curriculum framework project is still underway.

**What if an inspector felt those trainings were not adequate? What other resources are used to support?**

Some of the digital health department systems call out repeat violations to the inspector. This element requires long term coaching and communication training as a support. Additional support is provided in having the inspector demonstrate competencies.

**Group assignment** – We reviewed the table of twenty quality elements with trainings identified in the right column. The regulatory members of the group were asked to provide the table to recently hired staff and obtain feedback for discussion on or before our next discussion of charge #3. Review the standard 2 curriculum.

**Resources – IFPTI page and Google FDA ORAU and Pathlore will provide access to the current curriculum.**

**Christine – David, how does the retail food framework fit into the food industry framework?**

David – It is still being built with the intention of making the introductory courses an adequate starting point for any individual working in food protection.

Christine will set up a WebEx and allow David to present the information during our discussion of charge #2.

Call Participants (9)

DeBrena Hilton

Christine Sylvis

Matthew Walker

Kenesha Williamson

Amanda Douglas

Mark Speltz

Melissa Vaccaro

Adam Kramer

David Read

Hello Group,

Here are the minutes from the call (2/06/2019):

- **WebEx presentation on the national curriculum framework from IFPTI:**

Dave provided the group some background information on how the integrated food safety system content was developed and updated us on current progress. There has been recurrent feedback from the food industry regarding the consistency and standardization of inspectors. The FDA website has some additional resources available to learn more about the Partnership for Food Protection. A set of competencies was created to ensure all food protection professionals have a robust foundation of knowledge to equip them to fulfill their job roles. The framework itself provides a way of organizing the collection of competencies across all learning experiences for the field of food protection. The base level of the framework contains the entry level or general competencies pertinent to all food protection professionals. The framework is also divided into food protection program areas such as retail food or manufactured food. The next level of the framework contains more specialized content areas or advanced knowledge. When using the framework (<http://incs.ifpti.org/>), more information on each competency can be accessed by clicking the icon directly below the title of the individual content area. There are assessments within the framework content areas which are currently do not have an established pass or fail rating.

**Can anyone set up an account on IFPTI's website? If regulators access the assessment from the Pathlore website, is there a certificate which can be generated from the activity?**

Yes, anyone within the regulatory field can access the assessments without cost through Pathlore. The framework is designed to allow a user to take the assessments without having taken the courses. The user may choose to retest.

- **The group discussed Charge #2:**

**Does the group consider the Standard 2 (steps 1-4) completion time frame of 18 months adequate?**

Matt - Yes. The time frame does seem generous. Perhaps we could recommend that the 90% could be scaled for jurisdictions of different staff sizes. Consider jurisdictions with less than 10 inspectors.  
DeBrena – Turnover does interfere with the standardization time frame. Steps 1 through 3 have been met within the eighteen months consistently within Tulsa.  
Katey – We need to consider the rationale for any recommendation that parameters be scaled for jurisdictions who serve smaller populations.

**What is the background or history as to whether the 18-month time frame was introduced to synchronize with the standard for manufactured food?**

For manufactured food standard, the time frame is 24 months.

DeBrena- The six-month differential between the manufactured food standard and the retail food standard may be an allowance for the small jurisdiction size.

Christine – The time frame issue could be separate from the staff size and may be attributed to the availability of the standardization official.

It seems we all agree to recommend increasing the completion time frame for steps 1-4 to 24 months. The motion will be forwarded to the voting members of this subcommittee via email.

**Are there gaps or recommendations for change(s) to the Standard 2 curriculum?**

Dave – FDA has been funding the development of the IFSS framework. There is a potential transition to supplementing or replacing the ORAU courses with the framework in the future. If we are considering changes to the curriculum, we may want to identify specific content areas and not courses themselves.

**The group is encouraged to explore the framework and complete some of the assessments, in preparation for our March meeting.**

Dave - If you want to use the INCS assessment process please click the link below, then click in one of the brown boxes to the right of the entry box on the lower part of the curriculum framework which brings up the detailed framework content areas. Then on the full framework page click on one of the basic brown color content areas to go to the course description and competencies, next click the blue Take Assessment button that takes you to the login page. Click on create account and fill in the requested information.

<http://incs.ifpti.org/Frameworks/Home>

Call Participants (7)

DeBrena Hilton

Amanda Douglas

Christine Sylvis

Matthew Walker

Kenesha Williamson

David Read

Katey Kennedy

Hello Group,

**Here are the minutes from the call (3/13/2019):**

We discussed the content areas below. To prepare for our future meetings, we asked that regulatory members access the assigned coursework through Pathlore, review the framework competencies, and complete (7) assessments each for the basic curriculum content areas. Industry members were asked to explore the competencies as well on the IFPTI website. Industry members now have a regulatory partner with whom they will share the assignments for the applicable content areas. As we're all reviewing the material, let's consider its usefulness, whether there is any missing content, and how it would be implemented as "pre" or "post" coursework to replace ORA U. Appendix B of Standard 2 was attached to the March meeting invitation. Partner discussions prior to meetings are encouraged. For our March 13<sup>th</sup> meeting, the top row assignments were reviewed.

	<u>Christine Sylvis w/ Kenesha Williamson</u>	<u>DeBrena Hilton w/ Melissa Vaccaro</u>	<u>Mark Speltz w/ Amanda Douglas</u>	<u>Matt Walker</u>
3/13	<b>B1 Regulatory Program Foundations</b>	<b>B8 Environmental Hazards</b>	<b>B15 Jurisdiction</b>	<b>B22 Professionalism</b>
4/10	B2 Allergens	B9 Food / Feed Defense Awareness	B16 Labeling	B23 Public Health Principles
5/8	B3 Biological Hazards	B10 HACCP	B17 Laws, Regulations, Policies, & Procedures	B24 Recalls
6/12	B4 Biosecurity	B11 Imports	B18 Personal Safety	B25 Sampling
7/10	B5 Communication Skills	B12 Integrated Food Safety System	B19 Pest Control	B26 Sanitation Practices
8/14	B6 Data & Information Systems	B13 Inspections, Compliance, & Enforcement	B20 Plumbing	B27 Traceability
9/11	B7 Emergency Response	B14 Investigation Principles	B21 Preventive Controls	B28 Transportation

### Having reviewed the initial courses assigned, what feedback do you have?

Amanda and Mark – B15 Jurisdiction. We thought the course gave a good overview of the subject and was well designed to provide the information in a logical order. The course does not have slide numbers, so as with regards to feedback we have provided the slide header:

- Unit 1 – Foundations State & Local Jurisdiction Authority. Suggest a change to a word in the paragraph that states food ‘consumed’, suggest changing to food ‘sold or distributed’. It would be inaccurate to describe food purchased at a retailer and then consumed at a home just across the state line as intrastate commerce.
- Unit 3 – Activities under the State Retail Food Program. It states FDA develops the Retail Food Program, we felt that the CFP process develops with input/oversight from FDA.
- The Exam at the end of the course only provides a score, it does not let you know which questions you got incorrect. This could help determine what part of the course you may need to retake etc.

Mark – On AFDO’s website, the courses are cross-referenced. There was not much interactive content within the course. The lack of interactive features seems like a step back considering the way that online coursework is developed today. The terminology is bridged from the manufacturing content. Violative is commonly used in manufacturing regulation. We scheduled an hour. However, we had to move through the content more quickly toward the end.

Christine and Kenesha – B1 Regulatory Foundations. Upon logging into Pathlore, it was a little confusing trying to determine which course was correct. So, having a cross-reference would be helpful. Slide numbers would have been helpful. The very first course was long. Providing a projected time frame would be helpful. The content includes a lengthy history on how the law and enforcement actions were developed. It was nice to see a great list of tips for training new inspectors on when to involve a supervisor and how to think critically during the inspection. Program standards were mentioned. There was some terminology which was concerning for new inspectors to be translating this knowledge to the retail food industry. For example: the word violative seems to have been used interchangeably with “hazardous” or “priority”. The coursework frames were not very interactive. Perhaps the relevant terminology could have been hyperlinked throughout the course instead of being featured at the beginning. The knowledge checks and final exam does not give a detailed performance summary. It just gives a score.

DeBrena – B8 Environmental Hazards. For someone just starting out, the course content is pretty basic. I agree with the comments that have been shared. I will contact Melissa to continue reviewing B8.

Matt – B22 Professionalism. The material was divided into six units. It was a lot of reading with a few pictures. They did provide a few good examples. It seems this would be a good fit for the “pre” courses. But, it would not be a replacement for the existing standard content. There was some overlapping content. Overall, the content was refreshing. It took around 45 mins to complete.

**How long did it take to complete the courses?**

Christine – The regulatory foundations course seemed to require approximately 1.5hrs be scheduled to complete it.

Katey – Within Appendix B of Standard 2, there are time estimates for completion of coursework.

**Do we recommend adding this content to the Standard 2 curriculum as a replacement or supplement?**

Mark – It is difficult to say. Is the new curriculum framework intended to replace the Standard 2 curriculum? If so, what is the intended time frame?

Katey – I will get those answers and update the group.

Call Participants (9)

DeBrena Hilton

Adam Kramer

Katey Kennedy

Christine Sylvis

Matthew Walker

Kenesha Williamson

Robert Sudler

Mark Speltz

Amanda Douglas

Hello Group,

Here are the minutes from the call (4/10/2019):

We discussed the content areas below. As we all continue reviewing the material, let's consider its usefulness, whether there is any missing content, and how it would be implemented as "pre" or "post" coursework to replace FDA ORA U.

	<u>Christine Sylvis w/ Kenesha Williamson</u>	<u>DeBrena Hilton w/ Melissa Vaccaro</u>	<u>Mark Speltz w/ Amanda Douglas</u>	<u>Matt Walker</u>
3/13	B1 Regulatory Program Foundations	B8 Environmental Hazards	B15 Jurisdiction	B22 Professionalism
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The group continued discussion on course reviews. Feedback is focused on making key comparisons between the IFPTI curriculum framework and standard 2 curriculum. Ultimately, we will need to make recommendations for replacement or supplement.

Christine and Kenesha – B2 Allergens. The course seemed much shorter than the initial course, B1. The U.S. recognized allergens and allergens recognized overseas were explained well. The link for the full list of tree nuts did not lead us to the correct FDA page. We had to google search the FALCPA list to access the correct FDA page. There is currently no allergens course in the standard 2 curriculum.

Dave – The courses are now under review to make improvements where needed. It has been determined that the courses will be made to be more interactive. We should also keep in mind that the courses are created to be introductory for regulators.

DeBrena – B8 Environmental Hazards. It was a good foundation for new regulatory staff. Again, it would be helpful to have slide numbers and a recap on the overall performance. It would be better for the module to provide a quick reference to the correct answer instead of just displaying the word “correct” when the right selection was chosen. The content seemed to be more geared toward manufacturing. In unit 2, it would be better to explain that Norovirus is the number one cause of viral foodborne illness cases. In unit 4, the photos do not match the content being discussed. The subject was food safety instead of workplace safety. The photos should support that.

DeBrena - B10 HACCP. The term validity. Videos in unit 4. FSMA. Recall information could have been more in depth versus the existing standard 2 HACCP content. The majority of standard 2 HACCP bullet points were covered. The course took roughly 1 hr. The two video clips were a nice inclusion. However, the videos did not adequately explain the concepts.

- Unit 1 – Foundations – is course content geared towards Retail Food or Manufacturing? Many of the examples and pictures emphasize manufacturing. We also suggest adding radiological hazard language in the opening slides. Also, be consistent with use of Radiological throughout if it is going to be used and mirror FSMA rules.
- Unit 2 – Virus slide. Suggest rewording or structuring slide so that it is clear that Norovirus is the #1 cause. Currently worded that viruses in general are the number one cause of illness in US.
- Unit 3 – Suggest adding more retail food pictures to balance out all the manufacturing pictures. Assessment Knowledge Check 1 – sampling question not covered very well in module.
- Unit 4 – Food Safety Plans: personnel safety pictures used instead of food safety symbolic pictures. Control Factors: expound more on why source is important as a control factor. GRAS definition clarification needed that explains that GRAS is a chemical or substance added to food.
- Course Assessment – Question 9: is the question asking about pre or post packaging. Needs to be reworded so that its clear.
- *Note:* B9 Food/Feed Defense Awareness. The course could not be found in Pathlore. On the IFPTI course list menu, no course number is listed. Dave checked into it and found that the course does exist. But, the course was not provided on Pathlore.

Amanda and Mark – B16 Labeling.

*Course Overall:*

- No slide numbers or time to complete course/sections.
- inconsistency on knowledge base confirmation on whether a question was answered correctly.
- There were a few videos (a little basic), but not sure if they were positioned correctly i.e. they seemed to introduce a new topic, would prefer an intro slide prior to the video.
- Some of the label images were too small to read, even on a large screen.
- The course did seem very long.

*Course Design:*

- The course design may benefit from being aligned under regulated areas i.e. Human Food – FDA / FSIS, Dietary Supplements, and Animal feed and then having the specific topics under each area i.e. regulations, label requirements, etc. this could help with repetition, flow and refresher training. It is a lot of information for a new employee, especially if they are not responsible for a certain regulated area i.e. animal feed, the information becomes irrelevant.
- The competency flow did not align with the course, so by having it aligned under regulated areas could help better align it.

*Specific Course Feedback:*

- Unit 1 – Label Vs Labeling Slide. Include supplement labeling on a website
- Unit 2 – Labeling components required allergy information is referencing ‘Produced in a facility that processes peanuts’ which is not required
- Unit 2 - Labeling components trail mix labeling confusing
- Unit 3 – Labeling laws referencing outdated FDA 2013 Food code

Dave – One of the reasons that the course covers both food and animal feed is because of the regulatory oversight for those areas. The course is more general education for anyone entering the food regulation field. The course is being revised as well.

Matt - B23 Public Health Principles. The course did a great job covering the content. I recommend it as a replacement for FDA36. It is lengthy at seven units in total. However, the content is relevant and interesting. The course gave a lot of good examples to explain the principles. While there is not much interactivity, it does not necessarily need it. Both courses have the same name and align well. Reviewed FDA36 and B23 side by side to gather feedback.

**To prepare for the next call, the group was asked to revisit the standard 2 online courses to better support analysis of content alignment.**

Call Participants (9)

DeBrena Hilton

Katey Kennedy

Christine Sylvis

Matthew Walker

Kenesha Williamson

Robert Sudler

Amanda Douglas

David Read

Adam Kramer

Hello Group,

**Here are the minutes from the call (5/08/2019):**

Call Participants (7)

Christine Sylvis  
 Matthew Walker  
 Ed Robinson (visitor)  
 Kenesha Williamson  
 Robert Sudler  
 David Read  
 Adam Kramer

We discussed the content areas below. As we all continue reviewing the material, let's consider its usefulness, whether there is any missing content, and how it would be implemented as "pre" or "post" coursework to replace FDA ORA U.

	<u>Christine Sylvis w/ Kenesha Williamson</u>	<u>DeBrena Hilton w/ Melissa Vaccaro</u>	<u>Mark Speltz w/ Amanda Douglas</u>	<u>Matt Walker</u>
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<b>5/8</b>	<b>B3 Biological Hazards</b>	<b>B10 HACCP</b>	<b>B17 Laws, Regulations, Policies, &amp; Procedures</b>	<b>B24 Recalls</b>
6/12	B4 Biosecurity	B11 Imports	B18 Personal Safety	B25 Sampling
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8/14	B6 Data & Information Systems	B13 Inspections, Compliance, & Enforcement	B20 Plumbing	B27 Traceability
9/11	B7 Emergency Response	B14 Investigation Principles	B21 Preventive Controls	B28 Transportation

**The group continued discussion on course reviews. Feedback is focused on making key comparisons between the IFPTI curriculum framework and standard 2 curriculum. Ultimately, we will need to make recommendations for replacement or supplement.**

Christine and Kenesha – B3 Biological Hazards. There was very little about thermal processing as a control for biological hazards. Standard 2 gave more detail on microbiology. We recommend splitting the course due to its length.

Unit 1 - Pathogens vs Spoilage Organisms slide mentions that off-flavors are a characteristic of food compromised by the outgrowth of pathogens. This should be included under the spoilage organism column.

Sampling slides mention the term “for-cause” sampling. Where does this wording come from? The message could be rephrased to better represent circumstances such as traceback investigations for foodborne illness or precautionary circumstances. Also, the regulatory sampling slide gives the impression that the regulator will be completing the sampling in manufacturing environments.

Unit 2 – Aflatoxins slide mentions some effects of carcinogens. But, the slide does not explain that aflatoxins are carcinogens. Perhaps the previous slides could have included a brief explanation that many aflatoxins are considered carcinogenic.

Other Mycotoxins slide mentions that fumonisin consumption can be fatal. But, it is unclear as to whether that fatality is found in humans or just horses and swine. Also, are humans becoming affected through consumption of swine or the rice and corn directly?

Toxin-Mediated Infection slide does not explain that the terms toxicoinfection and toxin-mediated infection are interchangeable.

Examples of Incubation Periods slide uses a bullet point format to provide the information. This may have been better as a data table.

Biofilm slide could have included a nice tie-in to the messages about sampling, as *L. monocytogenes* is difficult to remove from a facility due to biofilms.

Unit 3 – Food Packaging slide provides an explanation of MAP below the bullet points for both MAP and general ROP without connecting the explanation directly to MAP.

Vectors: Humans slide contains a photo of a food handler correctly wearing gloves and using a utensil to handle food. It would be better to show bare hand contact.

Unit 4 – Listeria slide shows a photo of a drain cover in a pool. This should be a floor drain photo within a food establishment.

Food Contact Surfaces slide uses the terms direct and indirect food-contact surfaces. This is not in alignment with the terms food-contact surface and nonfood contact surface used in retail food.

Unit 5 – Several slides continued to mention only MAP as a type of packaging which can aid in the control of pathogenic growth.

Controlling campylobacter slide has the bacteria name misspelled in two of the sentences.

Estimated time to complete the course: approx. 2 hrs.

Dave – The photos and graphics were done by persons who do not have a food safety background. The photos are still being reviewed. The special processes topic is explored further in the retail food section.

DeBrena – B10 HACCP. Unit 2: Record Review for Accuracy – consider changing “validity” wording. Too much like verification vs validation and makes you think you are talking about validations whereas the slide is discussing verification. Overall comment: Verification vs Validations needs better disused and language on slides needs to stay true their meaning.

Unit 4: Videos? Seem out of place, not necessary, too short if they are going to be used. Would be better if video clips provided snippet of each of the 7 steps of HACCP instead of just 2.

Unit 5: Laws Regulations and Guidance: suggest creating stand-alone paragraph to explain implementation of FSMA. Need better clarification of State Agriculture programs, USDA, FDA, State and local oversight and co-regulation. Also, better explanation of FSMA (food safety plans) vs HACCP.

Assessment question—there was a question for recall procedure. We felt this was not adequately covered in module for use as a question. Recall information could have been more in depth versus the existing standard 2 HACCP content. The majority of the standard 2 HACCP bullet points were covered. The course took roughly 1 hr. The two video clips were a nice inclusion. However, the videos did not adequately explain the concepts.

Dave – Most of the questions/issues have been addressed for the HACCP course. As for FDA 16, 17, and 18, some of the HACCP coursework was existing. So, the IFPTI course is intended to blend all three and replace them.

Amanda and Mark – B17 Laws, Regulations, Policies, & Procedures. We do not have any significant feedback. We thought the course was well aligned with the competencies and covered all the topics. As stated on previous calls the content is a little dry, and we believe in future the courses will have more interaction.

Matt - B24 Recalls. Basics of it were useful. The course included videos. Nice change. The use of subtitles was also great from an accessibility aspect. If we were to add it to the curriculum, it should be included in the post courses. It would be good for a new EHS to get this intro to recalls, though not all jurisdictions are involved in issuing recalls.

Dave – Some new EHS can be involved in recall verification checks via phone call or site visits.

**To prepare for the next call, the group was asked to revisit the standard 2 online courses to better support analysis of content alignment.**

Hello Group,

Here are the minutes from the call (6/12/2019):

We discussed the content areas below. As we all continue reviewing the material, let's consider its usefulness, whether there is any missing content, and how it would be implemented as "pre" or "post" coursework to replace FDA ORA U.

	<u>Christine Sylvis w/ Kenesha Williamson</u>	<u>DeBrena Hilton w/ Melissa Vaccaro</u>	<u>Mark Speltz w/ Amanda Douglas</u>	<u>Matt Walker</u>
3/13	B1 Regulatory Program Foundations	B8 Environmental Hazards	B15 Jurisdiction	B22 Professionalism
4/10	B2 Allergens	B9 Food / Feed Defense Awareness	B16 Labeling	B23 Public Health Principles
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7/10	B5 Communication Skills	B12 Integrated Food Safety System	B19 Pest Control	B26 Sanitation Practices
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Christine and Kenesha - B4 Biosecurity. Currently, there is no biosecurity in the currently curriculum. So, this content would be an addition. It's more in depth than we consider to be necessary. Overall, it seemed to have been designed for manufacturing instead of food service. Several case studies were included. That is beneficial for the learner.

#### Unit 1

At the beginning of the Unit 1, the definition of biosecurity is very broad. It seems to reference what we understand to be the basics of food protection within retail/restaurant environments. Is it the best definition? Is this term more widely used in manufacturing?

Three parts of a facility's biosecurity plan: exclusion, management, and containment. All of which should be SOPs for the facility.

#### Unit 2

The definition for fomite includes living and non-living matter. I understood fomites to be inanimate objects or materials which can become contaminated and transfer pathogens.

Explanations for food processing were nicely worded. Nice use of plain language to differentiate between harvest/slaughter and processing.

#### Unit 3

Biosecurity zone slide defines a controlled access point as the third point. However, it would be better suited as the first definition because personnel would have to enter controlled or restricted zones through this point of access.

The slides which describe the types of PPE need some additional wording to relate the subject to its significance in the prevention of contamination within a facility or operation.

Is the term enhanced inspection interchangeable with the term investigation as an inspection type? This was included on the slide which described how inspectors should protect themselves.

#### Unit 4

The slide which discusses the importance of planning for the regulatory visit includes a non-working link to the FDA Investigations Operations Manual. The distinction between disinfection and sanitizing needs to be better explained. The material did not include an explanation of communicating breaches within the sanitation chain as part of the recall protocol.

#### Unit 5

The FDA Investigation Operations Manual link at the beginning on unit 5 did not navigate to the correct webpage. The knowledge check question 2 seems to assess whether the learner has read the material at the provided links to both the FDA and USDA documents. The slide with those links could be improved by including a brief explanation of the main focuses of those two

documents. FDA being routine operations and USDA being emergency preparedness and response to adverse events.

DeBrena - B11 Terminology. – The slide which explains the term custom(s) broker includes the abbreviation CBP. The phrase CBP custody is used but is not explained until later slides. At which point, CBP is defined as Customs and Border Protection. The text under the example figure for Harmonized Tariff Schedule Code has very low resolution and is difficult to read. Unit 5 includes a “Real World Applications” video on investigations which took a very long time to load. Upon completing the final unit, there was no button available on screen to navigate to the actual course assessment. FD251 references imports. So, the material presented in the module is covered there. We do not recommend the material replace FD251. Course completion time was 47 mins.

Mark – B18 Personal Safety. It sounds like there is some redundant material in other courses regarding PPE. We noticed that the course provided specific instructions on how an inspector should execute personal safety rather than describing the types of PPE. It mentioned that an inspector should reach out to a facility in advance to determine what types of hazards to personal safety may be there. The buddy system for entering coolers and freezers was also mentioned for personal safety reasons. However, there may not always be more than one inspector conducting the inspection. Ladder safety was also included. We considered the content to be focused on more OSHA recommendations than necessary for the food protection field. Examples of hazard signage and PPE requirement signage was very useful. The content should be more of an overview and could be confusing. Basics of inspection course, FDA 38, includes a brief inclusion of personal safety by informing the inspector of appropriate clothing, shoes, head cover.

Christine – Our jurisdiction does not allow our inspectors to operate or disassemble the facility’s equipment such as a dish machine. So, we address it through internal training as well.

Mark – An overall awareness is helpful. In Iowa, we follow a similar approach. Our team are not OSHA specialists. So, recognizing signage is good.

Adam – If the module used the term MSDS was used, the information should be updated to SDS.

Amanda – One of the assessment questions was related to chemical safety. I believe it used the term SDS.

Matt – B25 Sampling. Aseptic sampling and chain of custody was explained. The FDA operations manual was referenced. Unit 3 includes a three-minute video with subtitles to demonstrate how to collect aseptic samples. The video is step by step and well done. The overall quality of the module is good. I recommend it being added to Standard 2 in the post coursework. I would not recommend it as a replacement because it is more comprehensive. FIO4, Foodborne Illness Investigations 4: Conducting a Food Hazard Review, covers the sampling content as post coursework. FIO4 does a better job of describing how prepare for sampling visit in advance. However, that component is not necessary for the IFPTI content. Approximately 60 mins to complete it.

**On the next meeting, we will review our workgroup's charges, progress, and timeline. Please review the tracking sheet and provide recommendations for the courses assigned.**

Call Participants (7)

Mark Speltz

Adam Kramer

Amanda Douglas

Matt Walker

DeBrena Hilton

Christine Sylvis

Kenesha Williamson

Hello Group,

Here are the minutes from the call (7/17/2019):

We discussed the content areas below. As we all continue reviewing the material, let's consider its usefulness, whether there is any missing content, and how it would be implemented as "pre" or "post" coursework to replace FDA ORA U.

	<u>Christine Sylvis w/ Kenesha Williamson</u>	<u>DeBrena Hilton w/ Melissa Vaccaro</u>	<u>Mark Speltz w/ Amanda Douglas</u>	<u>Matt Walker</u>
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**We started the call with review of our charges, progress, and timeline:**

Christine - We have a good start on charge 1. The updated list of charge 1 initiatives is being reviewed today on WebEx. What started as just a table has been changed to a list similar to Appendix B-1.

**FD 170, is the course available? While checking some of the course links listed on Appendix B-1, we found several non-working links.**

Robert – FDA is aware that several links on Appendix B-1 are no longer functional. Course numbers have also changed for a few of the listings. FD 170 is available. It just has a different path. The updated Appendix B-1 is not yet published.

**Epi-Ready, is this an online or instructor led course?**

Dave and Matt – Centers of Excellence administered the course in our jurisdictions. It was between 2 and 2.5 days of training.

**I-FIIT-RR, is this for regulators?**

Kenesha – The course is a free NEHA workshop online. Companies can host a self-funded workshop for their teams. It is a one-day training.

**Reviewed charge 2. In review of this charge, we discussed the course review worksheet relative to charge 2a.**

We will send out copies of the course review worksheet to everyone. The worksheet will be included in the final report. Each group of reviewers will need to make sure the recommendations column is accurate and complete. Forward the updates to Kenesha.

Charge 2b is complete. The timeline for completing Standard 2, Steps 1 through 4, was recommended to increase from 18 months to 24 months.

**With only two meetings left, we want to complete charges 2a and 3.**

To complete our charges within the remaining two meetings: (1) we will have brief recaps of course notes; (2) groups will send notes directly to Kenesha; (3) the August meeting will cover charge 2a; and (4) the September meeting will cover charge 3.

Amanda and Mark – B19 Pest Control. The course was not available for review. It is still under development.

Melissa – B12 Integrated Food Safety System. Our group did not have a chance to complete the course yet. We will have the notes before the next meeting.

Christine and Kenesha – B5 Communication. We did not have time to review the current Standard 2 course for comparison. We will cross reference it before the next meeting.

Dave – There is a new B20 Plumbing course that is currently being reviewed. The B20 course from the PFP workgroup is currently not available on the IFPTI website.

Dave will give the reviewers access to the new plumbing course. This will be Mark, Amanda, and Matt.

**Please continue reviewing the course review worksheet and provide recommendations for the courses assigned.**

Call Participants (8)

Robert Sudler

Christine Sylvis

Kenesha Williamson

Dave Read

Amanda Douglas

Melissa Vaccaro

Adam Kramer

Matt Walker

Hello Group,

Here are the minutes from the call (8/14/2019):

We started the call with a review of the recommendations we have so far, i.e. add, replace, or no action and indicating “pre” or “post”. The course review worksheet was displayed via WebEx.

	<u>Christine Sylvis w/ Kenesha Williamson</u>	<u>DeBrena Hilton w/ Melissa Vaccaro</u>	<u>Mark Speltz w/ Amanda Douglas</u>	<u>Matt Walker</u>
3/13	B1 Regulatory Program Foundations	B8 Environmental Hazards	B15 Jurisdiction	B22 Professionalism
4/10	B2 Allergens	B9 Food / Feed Defense Awareness	B16 Labeling	B23 Public Health Principles
5/8	B3 Biological Hazards	B10 HACCP	B17 Laws, Regulations, Policies, & Procedures	B24 Recalls
6/12	B4 Biosecurity	B11 Imports	B18 Personal Safety	B25 Sampling
7/17	B5 Communication Skills	B12 Integrated Food Safety System	B19 Pest Control	B26 Sanitation Practices
<b>8/14</b>	<b>B6 Data &amp; Information Systems</b>	<b>B13 Inspections, Compliance, &amp; Enforcement</b>	<b>B20 Plumbing</b>	<b>B27 Traceability</b>
9/11	B7 Emergency Response	B14 Investigation Principles	B21 Preventive Controls	B28 Transportation

Kenesha – Everyone’s updates were received and loaded into the master worksheet that we are reviewing today.

Christine – B1 Regulatory Program Foundations. We still need to go back and review the existing Standard 2 content for cross-reference. B2 Allergens does have an existing course in the post curriculum. FD 252. We will review it before adding our recommendations on these two courses. B4 Biosecurity is currently not in the curriculum. We recommend no action because it is very geared to manufacturing.

DeBrena – B8 Environmental Hazards. We added comments indicating adjustments we would like to see before recommending addition of the course. We will go back to take another look to see what the specific modifications would be. We will do so for B8 through B13.

Mark and Amanda – B16 Labeling. We recommended no action in its current condition. We like the topic of labeling to be included in curriculum. We'd consider recommending addition, if course is revamped. B20 Plumbing we found to be the same as the old course. We contacted Dave Read on this.

Matt – B20 Plumbing. Dave provided a link to some of the new frames which worked for me.

Mark – Since pest control and plumbing content are not currently in Standard 2, we recommend adding them.

Katey – Those content areas may have been excluded because there were no formal courses available. So, if they are available now, that will be helpful.

Matt – B24 Recalls. I recommended no action here because the content may not be very useful. Most jurisdictions do not handle recalls. B26 Sanitation Practices is a good replacement for MIC 15. It would be good to have inspectors seeing this before taking the plan review course.

Mark and DeBrena recommend including B24 Recalls as good information for exposure. Katey reminded that Standard 5 does include handling recalls.

**During the next meeting, we will complete our discussions of charge 2a and charge 3 and we will finalize our committee's recommendations by voting.**

Updated workgroup docs will be sent out before the next meeting: Workgroup Doc 3 – Updated IFPTI course review worksheet; Workgroup Doc 6 – Table of Standard 4 quality elements updated with CFP Training Manual references; Workgroup Doc 7 – CFP Training Manual with notes added on pages 7 and 8 identifying Standard 4 quality elements.

Call Participants (7)

Christine Sylvis  
Kenesha Williamson  
Mark Speltz  
Amanda Douglas  
Matt Walker  
DeBrena Hilton  
Katey Kennedy

Hello Group,

**Here are the minutes from the call (9/11/2019):**

**We continued discussing Charge 2a (identifying any gaps and recommendations for changes to Standard 2 curriculum)**

Christine – We were unable to access the FD252 allergens course and make our recommendation. The link on the FDA website is not valid. When word searching for allergens course, the search results only provide the Pathlore course. The link for the current Communication Skills for Regulators course in Appendix B is also no longer valid. We also could not find the emergency response course listed on AFDO's GenEds list.

Mark – In the 2015 Appendix B, there is different link. The link is class.ucanr.edu instead of class.ucanr.org. On the FDA site, there is a separate link for the Communication Skills course.

Dave – Given that many of the existing Compliance Wire courses are 10+ years old, it's not likely that FDA will continue those courses. The course review sheet includes several recommendations not to replace the existing curriculum. So, we will need to consider this. Also, it is uncertain whether FDA will continue with using Pathlore as its learning management system.

Christine – Perhaps we need to connect with FDA on the implications of our recommendations based on their ultimate plans for the courses.

Mark – Discussed the accessibility of the coursework. Many of the course names and numbers had to be cross-referenced back to the IFPTI site. The course names are often not consistent.

Dave – The update and release of the courses are being completed at a rate of one per month. The process involves a workgroup of subject matter experts who develop the courses for FDA. That work has been completed. Now the look and feel of the courses is being updated. Once that is complete, the courses are given to FDA. Be mindful to cite content areas instead of specific course numbers to be removed. Ultimately, the general education for all food inspectors will come into alignment with integrated food safety under FSMA. Exposure to the additional knowledge is good for all.

**Discussed Charge #3 and the updated Workgroup Doc 6 - Standard 4 Elements Table.**

Christine – The Basics of Inspection course really touches on majority of the quality elements. Many of the quality elements are drafted from the CFP training manual. Quality Element 3 is not.

Mark – Since risk type and inspection frequency are varied by jurisdiction, it seems appropriate to have this addressed by the inspector's training plan under additional jurisdictional competencies.

Christine – Element 7 would not be met by jurisdictions which do not use the IN/OUT/N/O/N/A format for their inspections, if we are just considering report writing.

All – Element 7 is really covered through the training plan parts 2 and 3 of Inspection Observations and Performance. We will update Workgroup Doc 6 to include our feedback from today's call for the quality elements table. The correlation between Standard 2 and 4 is in the CFP training manual. It has not been updated since 2008.

**Due to low participation on last week's call, we are setting up another call for the first week in October. Hopefully, everyone can attend. Our group needs to vote on the committee's suggested changes to Standard 2 and discuss issue submissions.**

Call Participants (4)

Christine Sylvis  
Kenesha Williamson  
Mark Speltz  
Dave Read

## Final Meeting

Here are the minutes from the call (10/02/2019):

During the meeting, the group discussed all pending items. We connected with Angie Cyr for some clarifications prior to the meeting. Dave Read cautioned the group to consider that courses which are not recommended become unavailable. CFP meets once every two years. Also, many of the new courses are designed with the intention to increase the learner's competency and not mimic the course design of the past. Christine reviewed the language of our charge as it relates to the standard 2 curriculum.

The 5 (out of 7) voting members on the call voted on the committee's suggested changes to Standard 2. Pending items for today's vote:

- Each topic/class added to Standard 2, Appendix B1 will require an individual issue submission with reasoning why it should be included (**Charge 2A**)
- Change in format of Standard 2, Appendix B1 will require an issue submission (**Charge 2A**)
- Change of date for Standard 2 post training will require an issue submission with reasoning why (**Charge 2B**)
- Changes to CFP Training Manual to align Standard 4 with Standard 2 – each addition will require an individual issue submission with reasoning why (**Charge 3**)

### Voted Actions for IFPTI courses

B8 Environmental Hazards (CC8024W) – Add to the pre-coursework

**Pending** B10 HACCP (CC8033W) – Additional feedback needed from reviewers; Vote via Survey Monkey

B12 Integrated Food Safety System (CC8018W) – Add to post-coursework

**Pending** B13 Inspections, Compliance, & Enforcement (CC8019W) - Additional feedback needed from reviewers; Vote via Survey Monkey

**Pending** B14 Investigation Principles (CC8020W) - Additional feedback needed from reviewers; Vote via Survey Monkey

B15 Jurisdiction (CC8037W) – Replace FDA 35 in the pre-coursework

**Pending** B16 Labeling (CC8038W) - Additional feedback needed from reviewers; Vote via Survey Monkey

B17 Laws, Regulations, Policies, & Procedures (CC8039W) – Add to pre-coursework

B19 Pest Control (under development) – Add to pre-coursework

B20 Plumbing CC8001W (under development) – Add to pre-coursework

B22 Professionalism (CC8025W) – Add to the pre-coursework

B23 Public Health Principles (CC8026W) – Replace FDA 36 in pre-coursework

B24 Recalls (CC8041W) – Add to post-coursework

B25 Sampling (CC8035W) – Replace MIC13 in the pre-coursework

B26 Sanitation Practices (CC8032W) – Replace MIC15 in the pre-coursework

B27 Traceability (CC8042W) – Add to post-coursework

B28 Transportation (CC8036W) – Add to post-coursework

Updates to the CFP Training Manual were reviewed. The group agreed to recommend that Traceability, Recalls, and Transportation be included with Integrated Food Safety System under a header of the same name in “post” coursework.

Christine Sylvis will be an issue submitter. We need volunteers to be co-issue submitters. Issue submitters will need to attend the biennial meeting to discuss the issue and answer any questions from Council. Also, we can have up to (2) issue submitters per issue. As of today, we will have approximately 20 issues.

**Next, we will complete our final report, vote on remaining items, and coordinate volunteers for issue submission through Survey Monkey.**

#### **Pending Vote**

1. B10 HACCP (CC8033W) course recommendation
2. B13 Inspections, Compliance, & Enforcement (CC8019W) course recommendation
3. B14 Investigation Principles (CC8020W) course recommendation
4. B16 Labeling (CC8038W) course recommendation
5. Add to CFP Training Manual Section 1 Pre-inspection, #2 Reviews establishment file for previous inspection report, complaints on file... (review current risk category) and Section II Inspection observations and performance #3 Uses a risk-based inspection methodology to correctly assess regulations... (verifies risk category is correct based on inspection observations)
6. Add to CFP Training Manual Section II Inspection Observations and Performance, #6 addresses violations on previous inspection being corrected
7. Add to CFP Training Manual Section IV. Written Communication, #1. Completes inspection form per jurisdiction’s administrative procedures addresses violations on previous inspection being corrected

#### Call Participants (8)

Kenisha Williamson<sup>v</sup>

Christine Sylvis<sup>v</sup>

Adam Kramer

Mark Speltz<sup>v</sup>

Dave Read

Amanda Douglas<sup>v</sup>

Matt Walker<sup>v</sup>

Katey Kennedy

Charge 1: Initiatives (existing, new, or under development) involving the training, evaluation and/or certification available to Food Safety Inspection Officers (FSIO):

### Training – Existing

#### ORAU Pre

- Public Health Principles FDA 36
- Overview of Microbiology MIC01
- Food Microbiological Control 2A: Gram-Negative Rods MIC02
- Food Microbiological Control 2A: Gram-Positive Rods and Cocci MIC03
- Food Microbiological Control 2A: Foodborne Viruses MIC04
- Food Microbiological Control 4: Foodborne Parasites MIC05
- Food Microbiological Control: Mid-Series Exam MIC16
- Food Microbiological Control 5: Controlling Growth Factors MIC06
- Food Microbiological Control 6: Control by Refrigeration and Freezing MIC07
- Food Microbiological Control 7A: Control by Thermal Processing MIC08
- Food Microbiological Control 7B: Control by Pasteurization MIC09
- Food Microbiological Control 10: Aseptic Sampling MIC13
- Food Microbiological Control 10: Cleaning and Sanitizing MIC15
- Basic Food Law for State Regulators FDA35
- Basics of Inspections: Beginning an Inspection FDA38
- Basics of Inspections: Issues and Observations FDA39
- An Introduction to Food Security Awareness FD251 (<https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness>) **NOTE: Required Exam is available via ([www.compliancewire.com](http://www.compliancewire.com))**
- Communication Skills for Regulators

#### ORAU Post

- An Introduction to Food Security Awareness MIC10
- Food Microbiological Control 8: Technology-based Food Processes MIC11
- Food Microbiological Control 9: Natural Toxins MIC12
- Basics of HACCP: Overview of HACCP FDA16
- Basics of HACCP: Prerequisite Programs and Preliminary Steps FDA17
- Basics of HACCP: Prerequisite Programs and Preliminary Steps FDA18
- Foodborne Illness Investigations 1: Collecting Surveillance Data FI01
- Foodborne Illness Investigations 2: Beginning an Investigation FI02
- Foodborne Illness Investigations 3: Expanding the Investigation FI03
- Foodborne Illness Investigations 4: Conducting a Food Hazard Review FI04
- Foodborne Illness Investigations 5: Epidemiological Statistics FI05
- Foodborne Illness Investigations 6: Final Report FI06
- Food Allergens FD252 (**Course must be accessed through <http://class.ucanr.edu/>**)

**FEMA courses can be accessed at: <http://training.fema.gov/IS/NIMS.asp>**

- Introduction to Incident Command System **IS-100.C**
- ICS for Single Resources and Initial Action Incidents **IS-200.C**
- NIMS an Introduction **IS-700.B**

#### FDA ComplianceWire

- Food Code Chapter 7: Poisonous and Toxic Materials FD112 Food Code (FDAFC01)
- Food Code Chapter 1: Purpose and Definitions FD112 Food Code (FDAFC02)
- Food Code Chapter 3: Part I FD112 Food Code (FDAFC03)
- Food Code Chapter 5: Water, Plumbing, and Waste FD112 Food Code (FDAFC04)
- Food Code Chapter 3: Part II FD112 Food Code (FDAFC05)
- Food Code Chapter 3: Part III FD112 Food Code (FDAFC06)
- Food Code Chapter 2: Supervision FD112 Food Code (FDAFC07)
- Food Code Chapter 4: Part I FD112 Food Code (FDAFC08)
- Food Code Chapter 6 FD112 Food Code (FDAFC09)
- Food Code Chapter 4: Part II FD112 Food Code (FDAFC10)
- Food Code Chapter 8: Enforcement and Annex 1 FD112 Food Code (FDAFC11)
- HACCP (CC8033W)
- Employee Hygiene: Food Service (FOOD1)
- HACCP (FOOD5)
- Preventing Microbial Cross-Contamination (FOOD3)

#### IFPTI Courses on ComplianceWire

- Regulatory Program Foundations (CC8021W)
- Allergens (CC8029W)
- Biological Hazards (CC8028W)
- Biosecurity (CC8023W)
- Communication Skills (CC8011W) **Course must be accessed through FDA Pathlore at: ([https://oraportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&mainmenu=ORA&top\\_frame=1](https://oraportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&mainmenu=ORA&top_frame=1))**
- Data & Information Systems (CC8017W)
- Environmental Hazards (CC8027W)
- HACCP (CC8033W)
- Imports (CC8034W)
- Integrated Food Safety System (CC8018W)
- Inspections, Compliance, & Enforcement (CC8019W)
- Investigation Principles (CC8020W)
- Jurisdiction (CC8037W)
- Labeling (CC8038W)
- Laws, Regulations, Policies, & Procedures (CC8039W)
- Personal Safety (CC8031W)

- Preventive Controls (CC8040W)
- Professionalism (CC8025W)
- Public Health Principles (CC8026W)
- Recalls (CC8041W)
- Sampling (CC8035W)
- Sanitation Practices (CC8032W)
- Traceability (CC8042W)
- Transportation (CC8036)

#### FDA Pathlore

- Fermentation at Retail (FD8009W)
- Curing, Smoking, Drying of Meat, Poultry and Fish and the Processing of Fermented Sausages (FD8005W)
- Reduced Oxygen Packaging at Retail (FD8004W)
- Juicing at Retail (FD8008W)
- Shellfish Tanks at Retail (FD8007W)
- Custom Processing of Meats at Retail (FD8006W)
- HACCP (CC8033W)
- Plumbing Controls for Commercial Food Establishments (CC8001W)
- Pest Control in Food Establishments (FD180W100)

#### Instructor Led Courses

- FD112 – Food Code
- FD218 - Risk-Based Inspection Methods in Retail
- FD204 - Temporary Food Establishments
- FD207 – Plan Review for Food Establishments
- FD312 - Special Processes at Retail
- FD215 - Managing Retail Food Safety
- ER310 - Food Safety Issues in the Event of Disasters
- EPI-Ready in person training through (NEHA/Centers of Excellence)
- AFDO – Environmental Sampling in Retail Food Facilities

#### Training – New

- CDC EATS 101
- CDC EATS 102

#### Training – Under Development

- FD170 – Application of Inspection and Investigation Techniques
- IFPTI Pest Control
- IFPTI Plumbing
- IFPTI Emergency Response

In-house training provided by State/Local Health Departments:

- Report writing
- State-specific
- Software
- Compliance and enforcement
- Risk-based inspection methods
- HACCP (application)
- Plumbing/backflow
- Consistency training (marking under same number)
- Meat/poultry inspection
- Scenario/mock inspection/role playing
- Ethnic Food Book
- Temporary Food Establishment training
- Mobile Vending training
- NAU Back Country Excursions
- Food Service During Disasters

Training Resources

- AFDO Ethnic Food CD/App
- AFDO Salvage Food
- AFDO Dented Cans
- AFDO Incubator (Community/Shared) Kitchens
- AFDO Cottage Food
- Centers of Excellence (COE) food safety tools

Evaluation

- CFP Training manual forms for new hires
- Standard 4 - 20 Quality Elements
- Standardization

Certification

- NEHA Registered Environmental Health Specialist/Registered Sanitarian (REHS/RS)
- NEHA Certified Professional - Food Safety (CPFS)
- NEHA Certified Foodborne Outbreak Investigator (CFOI)
- HACCP Alliance – Certified HACCP Manager
- NSF – Certified HACCP Manager
- ASQ (American Society for Quality) Root Cause Analysis Training
- 40 Hour HAZWOPER
- ANSI Food Safety Manager

## Program Standard #2

## APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers

For state, local & tribal regulators to register on-line for free access to web courses, go to:

<http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm>

**Pre-requisite (“Pre”) curriculum courses**

*(to be completed during the 25 joint inspection period AND prior to conducting any independent inspections)*

CURRICULUM TOPICS	COURSES WHICH FULFILL CURRICULUM TOPICS
<b>PUBLIC HEALTH PRINCIPLES</b>	
1. Public Health Principles	FDA36 (90)
<b>MICROBIOLOGY</b>	
1. Overview of Microbiology	MIC01 (60)
2. Gram-Negative Rods	MIC02 (60)
3. Gram-Positive Rods & Cocci	MIC03 (90)
4. Foodborne Viruses	MIC04 (60)
5. Foodborne Parasites	MIC05 (90)
6. Mid-Series Exam	MIC16 (30)
7. Controlling Growth Factors	MIC06 (90)
8. Control by Refrigeration & Freezing	MIC07 (60)
9. Control by Thermal Processing	MIC08 (90)
10. Control by Pasteurization	MIC09 (90)
11. Aseptic Sampling	MIC13 (90)
12. Cleaning & Sanitizing	MIC15 (90)
<b>PREVAILING STATUTES, REGULATIONS, ORDINANCES</b>	
1. Basic Food Law for State Regulators	FDA35 (60)
2. Basics of Inspection: Beginning an Inspection	FDA38 (90)
3. Basics of Inspection: Issues & Observations	FDA39 (90)
4. An Introduction to Food Security Awareness	FD251 (60) ( <a href="https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness">https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness</a> ) Note: Required exam is available via <a href="http://www.compliancewire.com">www.compliancewire.com</a> .
5. FDA Food Code	NOTE: Specific state/local laws & regulations to be addressed by each jurisdiction
<b>COMMUNICATION SKILLS</b>	
1. Communication Skills for Regulators	CC 8011W (60) Note: Course can be accessed through FDA Pathlore at: ( <a href="https://orauportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&amp;mainmenu=ORA&amp;top_frame=1">https://orauportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&amp;mainmenu=ORA&amp;top_frame=1</a> )

**Curriculum (“Post”) courses**

*(to be completed any time prior to Food Code Standardization AND within 18 months of hire or assignment to the regulatory retail food program)*

CURRICULUM TOPICS	COURSES WHICH FULFILL CURRICULUM TOPICS
<b>MICROBIOLOGY</b>	
1. Control by Retorting	MIC10 (90)
2. Technology-Based Food Processes	MIC11 (120)
3. Natural Toxins	MIC12 (90)
<b>HACCP</b>	
1. Overview of HACCP	FDA16 (60)
2. Prerequisite Programs & Preliminary Steps	FDA17 (60)
3. The Principles	FDA18 (60)
<b>ALLERGEN MANAGEMENT</b>	
1. Food Allergens	FD252 (60)
<b>EPIDEMIOLOGY</b>	
1. Collecting Surveillance Data	FI01 (90)
2. Beginning the Investigation	FI02 (90)
3. Expanding the Investigation	FI03 (90)
4. Conducting a Food Hazard Review	FI04 (90)
5. Epidemiological Statistics	FI05 (90)
6. Final Report	FI06 (30)
<b>EMERGENCY MANAGEMENT</b>	
FEMA – Incident Command System and National Incident Management System: Course available from FEMA web link <a href="http://training.fema.gov/IS/NIMS.asp">http://training.fema.gov/IS/NIMS.asp</a>	
1. Introduction to Incident Command System	IS-100.C, Introduction to Incident Command System, (180) ICS-100 or IS-100 for FDA
2. ICS for Single Resources and Initial Action Incidents	ICS-200.C, IS-200.C, ICS for Single Resources and Initial Action Incidents, (180) ICS-200
3. NIMS an Introduction	ICS 700.B, NIMS an Introduction, (180) ICS-700

( ) Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs

Estimated total hours for “Pre” courses are 42 hours.

Estimated total hours for “Post” courses are 26 hours.

Estimated total hours for completion of all Program Standard #2 coursework are 68 hours

## Program Standard #2

## APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officer

**Pre-requisite (“Pre”) curriculum courses**

*(to be completed during the 25 joint inspection period AND prior to conducting any independent inspections)*

CURRICULUM TOPICS	COURSES WHICH FULFILL CURRICULUM TOPICS
<b>ENVIRONMENTAL HEALTH FOUNDATIONS</b>	
1. Public Health Principles	CC8026W <sup>P</sup>
2. Environmental Hazards	CC8024W <sup>P</sup>
3. Jurisdiction	CC8037W <sup>P</sup>
4. Pest Control	[IFPTI Course under development]
5. Plumbing	CC8001W [IFPTI Course under development]
<b>MICROBIOLOGY</b>	
1. Overview of Microbiology	MIC01 <sup>C</sup> (60)
2. Gram-Negative Rods	MIC02 <sup>C</sup> (60)
3. Gram-Positive Rods & Cocci	MIC03 <sup>C</sup> (90)
4. Foodborne Viruses	MIC04 <sup>C</sup> (60)
5. Foodborne Parasites	MIC05 <sup>C</sup> (90)
6. Mid-Series Exam	MIC16 <sup>C</sup> (30)
7. Controlling Growth Factors	MIC06 <sup>C</sup> (90)
8. Control by Refrigeration & Freezing	MIC07 <sup>C</sup> (60)
9. Control by Thermal Processing	MIC08 <sup>C</sup> (90)
10. Control by Pasteurization	MIC09 (90) <sup>C</sup>
11. Sampling	CC8035W <sup>P</sup>
12. Sanitation Practices	CC8032W <sup>P</sup>
<b>PREVAILING STATUTES, REGULATIONS, ORDINANCES</b>	
1. Laws, Regulations, Policies, & Procedures	CC8039W <sup>P</sup>
2. Basics of Inspection: Beginning an Inspection	FDA38 <sup>C</sup> (90)
3. Basics of Inspection: Issues & Observations	FDA39 <sup>C</sup> (90)
4. An Introduction to Food Security Awareness	FD251 (60) ( <a href="https://www.fda.gov/training-and-continuing-education/officetraining-education-and-development-oted/introduction-food-security-awareness">https://www.fda.gov/training-and-continuing-education/officetraining-education-and-development-oted/introduction-food-security-awareness</a> ) NOTE: Required Exam is available via ( <a href="http://www.compliancewire.com">www.compliancewire.com</a> )
5. FDA Food Code (NOTE: Specific state/local laws & regulations to be addressed by each jurisdiction)	
6. Jurisdiction	CC8037W <sup>P</sup>
<b>COMMUNICATION SKILLS</b>	
1. Communication Skills for Regulators	CC8011W (60) NOTE: Course must be accessed through FDA Pathlore at: ( <a href="https://">https://</a>

	orauportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&main menu=ORA&top_frame=1)
PROFESSIONALISM	
1. Professionalism	CC8025W <sup>P</sup>

### Curriculum (“Post”) courses

*(to be completed any time prior to Food Code Standardization AND within 18 months of hire or assignment to the regulatory retail food program)*

CURRICULUM TOPICS	COURSES WHICH FULFILL CURRICULUM TOPICS
<b>MICROBIOLOGY</b>	
1. Control by Retorting	MIC10 <sup>C</sup> (90)
2. Technology-Based Food Processes	MIC11 <sup>C</sup> (120)
3. Natural Toxins	MIC12 <sup>C</sup> (90)
<b>HACCP</b>	
1. Overview of HACCP	FDA16 <sup>C</sup> (60)
2. Prerequisite Programs & Preliminary Steps	FDA17 <sup>C</sup> (60)
3. The Principles	FDA18 <sup>C</sup> (60)
<b>ALLERGEN MANAGEMENT</b>	
1. Food Allergens	CC8029W <sup>P</sup>
<b>EPIDEMIOLOGY</b>	
1. Collecting Surveillance Data	FI01 <sup>C</sup> (90)
2. Beginning the Investigation	FI02 <sup>C</sup> (90)
3. Expanding the Investigation	FI03 <sup>C</sup> (90)
4. Conducting a Food Hazard Review	FI04 <sup>C</sup> (90)
5. Epidemiological Statistics	FI05 <sup>C</sup> (90)
6. Final Report	FI06 <sup>C</sup> (30)
<b>INTEGRATED FOOD SAFETY SYSTEM</b>	
1. Integrated Food Safety System	CC8018W <sup>P</sup>
2. Imports	CC8034W <sup>P</sup>
3. Recalls	CC8041W <sup>P</sup>
4. Traceability	CC8042W <sup>P</sup>
5. Transportation	CC8036W <sup>P</sup>
<b>EMERGENCY MANAGEMENT</b>	
FEMA – Incident Command System and National Incident Management System: Course available from FEMA web link <a href="http://training.fema.gov/IS/NIMS.asp">http://training.fema.gov/IS/NIMS.asp</a>	
1. Introduction to Incident Command System	IS 100.C, ICS-100 or IS-100 for FDA (180)
2. ICS for Single Resources and Initial Action Incidents	IS-200C, ICS-200 (180)
3. NIMS an Introduction	IS-700.B, ICS 700 (180)

( ) Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs

<sup>P</sup>Course available on Pathlore

<sup>C</sup>Course available on ComplianceWire

Estimated total hours for “Pre” courses are XX hours.

Estimated total hours for “Post” courses are XX hours.

Estimated total hours for completion of all Program Standard #2 coursework are XX hours

### **B1 Regulatory Program Foundations (CC8021W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to the elements of feed and food regulatory programs.

- a) Goal: The student will be able to exhibit introductory knowledge, skills, and abilities related to the elements of feed and food regulatory programs.
- b) Scope: Topics covered in this course include foundations, laws and regulations, feed/food protection agencies, program standard areas, IFSS, mutual reliance (recognition and reciprocity).

Committee Review: Slide numbers would have been helpful. The very first course was long. Providing a projected time frame would be helpful. The content includes a lengthy history on how the law and enforcement actions were developed. It was nice to see a great list of tips for training new inspectors on when to involve a supervisor and how to think critically during the inspection. Program standards were mentioned. There was some terminology which was concerning for new inspectors to be translating this knowledge to the retail food industry. For example: the word violative seems to have been used interchangeably with “hazardous” or “priority”. The coursework frames were not very interactive. Perhaps the relevant terminology could have been hyperlinked throughout the course instead of being featured at the beginning. The knowledge checks and final exam does not give a detailed performance summary; it just gives a score.

Committee Recommendation: No action

### **B2 Allergens (CC8029W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to food allergens, controls and regulatory requirements.

- (a) Goal: Discuss the control of allergens in relation to food safety.
- (b) Scope: This course will cover introductory knowledge, skills, and abilities related to food allergens, controls, and regulatory requirements. Topics include foundations of allergens, labeling requirements, FSMA, control measures, and educational resources.

Committee Review: This course is currently under revision by IFPTI. The U.S. recognized allergens and allergens recognized overseas were explained well. The link for the full list of tree nuts did not lead us to the correct FDA page. We had to google search the FALCPA list to access the correct FDA page.

Committee Recommendation: We recommend replacing FD252, Allergen Management in “post” courses with this course.

### **B3 Biological Hazards (CC8028W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to biological hazards, focusing on sources of contamination, growth factors, and control methods.

Committee Review:

#### ***Unit 1***

- Pathogens vs Spoilage Organisms slide mentions that off-flavors are a characteristic of food compromised by the outgrowth of pathogens. This should be included under the spoilage organism column.

- Sampling slides mention the term “for-cause” sampling. Where does this wording come from? The message could be rephrased to better represent circumstances such as traceback investigations for foodborne illness or precautionary circumstances. Also, the regulatory sampling slide gives the impression that the regulator will be completing the sampling in manufacturing environments.

### **Unit 2**

- Aflatoxins slide mentions some effects of carcinogens. But, the slide does not explain that aflatoxins are carcinogens. Perhaps the previous slides could have included a brief explanation that many aflatoxins are considered carcinogenic.
- Other Mycotoxins slide mentions that fumonisin consumption can be fatal. But, it is unclear as to whether that fatality is found in humans or just horses and swine. Also, are humans becoming affected through consumption of swine or the rice and corn directly?
- Toxin-Mediated Infection slide does not explain that the terms toxicoinfection and toxin-mediated infection are interchangeable.
- Examples of Incubation Periods slide uses a bullet point format to provide the information. This may have been better as a data table.
- Biofilm slide could have included a nice tie-in to the messages about sampling, as *L. monocytogenes* is difficult to remove from a facility due to biofilms.

### **Unit 3**

- Food Packaging slide provides an explanation of MAP below the bullet points for both MAP and general ROP without connecting the explanation directly to MAP.
- Vectors: Humans slide contains a photo of a food handler correctly wearing gloves and using a utensil to handle food. It would be better to show bare hand contact.

### **Unit 4**

- Listeria slide shows a photo of a drain cover in a pool. This should be a floor drain photo within a food establishment.
- Food Contact Surfaces slide uses the terms direct and indirect food-contact surfaces. This is not in alignment with the term food-contact surface and nonfood contact surface used in retail food.

### **Unit 5**

- Several slides continued to mention only MAP as a type of packaging which can aid in the control of pathogenic growth.
- Controlling campylobacter slide has the bacteria name misspelled in two of the sentences. Estimated time: approx. 2 hrs.

Committee Recommendation: Standard 2 curriculum microbiology section covers these topics, no need to replace.

## **B4 Biosecurity (CC8023W)**

### FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to controlling disease transmission between people, animals, and plants. There are six modules in this course.

Committee Review:

**Unit 1**

At the beginning of the Unit 1, the definition of biosecurity is very broad. It seems to reference what we understand to be the basics of food protection within retail/restaurant environments. Is it the best definition? Is this term more widely used in manufacturing?

Three parts of a facility's biosecurity plan: exclusion, management, and containment. All of which should be SOPs for the facility.

**Unit 2**

The definition for fomite includes living and non-living matter. I understood fomites to be inanimate objects or materials which can become contaminated and transfer pathogens.

Explanations for food processing were nicely worded. Nice use of plain language to differentiate between harvest/slaughter and processing.

**Unit 3**

Biosecurity zone slide defines a controlled access point as the third point. However, it would be better suited as the first definition because personnel would have to enter controlled or restricted zones through this point of access.

The slides which describe the types of PPE need some additional wording to relate the subject to its significance in the prevention of contamination within a facility or operation.

Is the term enhanced inspection interchangeable with the term investigation as an inspection type? This was included on the slide which described how inspectors should protect themselves.

**Unit 4**

The slide which discusses the importance of planning for the regulatory visit includes a non-working link to the FDA Investigations Operations Manual. The distinction between disinfection and sanitizing needs to be better explained. The material did not include an explanation of communicating breaches within the sanitation chain as part of the recall protocol.

**Unit 5**

The FDA Investigation Operations Manual link at the beginning on unit 5 did navigate to the correct webpage. The knowledge check question 2 seems to assess whether the learner has read the material at the provided links to both the FDA and USDA documents. The slide with those links could be improved by including a brief explanation of the main focuses of those two documents. FDA being routine operations and USDA being emergency preparedness and response to adverse events.

Committee Recommendation: Currently, there is no biosecurity in the curriculum. It's more in depth than we consider to be necessary. Overall, it seemed to have been designed for manufacturing instead of food service. Several case studies were included. That is beneficial for the learner. We do not recommend addition.

**B5 Communication Skills (CC8030W)**

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to effective communication in the regulatory field.

- (a) Goal: Discuss the skills required for an effective communicator in the regulatory field.
- (b) Scope: Inspectors can expect to be introduced to the basic knowledge, skills, and abilities related to effective communication in the regulatory field. Topics discussed include foundations, specific communication skills (oral, written, effective listening, feedback, etc.), situational awareness, agency policies on communication, and educational resources.

Committee Review:

**Unit 1**

A slide mentions that an inspector may need to use the services of a translator. Should this say interpreter rather than a translator?

**Unit 2**

The slides which describe assertive communication as the preferred style for regulators contradict themselves. While assertiveness was described as a tool to achieve mutual respect and understanding, one of the slides gave a recommendation to use “I” statements. For example, “I would like begin the tour so that we can finish by 5 pm”.

**Unit 3**

Several of the situational awareness photos need to be replaced with photos which better suit the content.

Some of the course exam questions were poorly worded. For example, the question asks if one should contact a supervisor if the facility operators is perceived to be lying is poorly worded.

Committee Recommendation:

Covers many of the same topics as “Communication Skills for Regulators” currently required in “pre” courses which seems more applicable for retail food establishments. Recommend no action.

**B6 Data & Information Systems (CC8017W)**

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to systems used by regulatory agencies to store, process, and manage data and information.

Committee Review: Mostly a basic computer course hardware, software, data, database, mainframe, etc. The Unit 1 foundational information seemed largely irrelevant except for the distinction between data and information and the databases used by health departments and FDA.

Section 4, FDA 20.88 agreements provided useful information new inspectors may not be aware of. Section 2 also provided useful information on social media, but most jurisdictions have internal policies covering this for employees.

The “FOOD Tool” slide in Unit 1 is described as the CDC’s database for foodborne illness outbreak data. Food Outbreak Online Database (FOOD) Tool. Is this still used? Shouldn’t this be NORS (National Outbreak Reporting System)?

The Unit 3 and Unit 4 content does well in supporting the regulator's training on basics of inspection. These units provided good information on the knowledge a regulator must manage and the access and control of information: Freedom of Information Act, securing and updating passwords, etc. The bulk of the content seems to be common knowledge for new inspectors. Perhaps individuals who are unfamiliar with the internet and web-based applications would find the information beneficial.

Committee Recommendation: Overall, information not recommended to add to Standard 2. Most of this information is general knowledge of computers currently taught in school. Social media, malware, specific databases are usually often covered by jurisdictional internal policies. No action.

### **B7 Emergency Response**

FDA Pathlore Course Description: The course is still under development

Committee Review: N/A

Committee Recommendation: No action

### **B8 Environmental Hazards (CC8024W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to environmental hazards as sources of contamination, and associated control methods.

#### Foundations

1. Define relevant terminology
2. Give examples of food and feed products that may be affected by environmental hazards.
3. Describe where to find resources.
4. Describe the consequences of contamination by environmental hazards.
5. Discuss how sampling is used to detect environmental hazards.
6. Give examples of how a milestone event impacted public policy.
7. Give examples of illness caused by environmental hazards.

#### Environmental Hazards of Concern

1. Identify the categories of environmental hazards.
2. Give examples of each category of environmental hazard.
3. Associate environmental hazards with products or processes.

#### Sources and Pathways

1. Discuss how environmental hazards contaminate products and processes.
2. Describe vectors of contamination.
3. Give examples of food contamination sources.
4. Give examples of feed contamination sources.
5. Differentiate between intentional and unintentional contamination.

#### Control Factors

1. Explain the concept of acceptable levels of exposure.
2. Describe best management practices that are used to prevent spread of environmental hazards.
3. Give examples of preventive controls.
4. Describe control point monitoring.

5. Explain why source is important as a control factor.
6. Discuss response options for contamination

Duration

Unit 1: Foundations - 23 minutes

Unit 2: Environmental Hazards of Concern – 21 minutes

Unit 3: Sources and Pathways – 38 minutes

Unit 4: Factors – 11 minutes

Estimated time = 1 hour and 33 minutes

Committee Review:

**Unit 1**

Foundations – is course content geared towards Retail Food or Manufacturing? Many of the examples and pictures emphasize manufacturing. We also suggest adding radiological hazard language in the opening slides. Also, be consistent with use of Radiological throughout if it is going to be used and mirror FSMA rules.

**Unit 2**

Virus slide. Suggest rewording or structuring slide so that Norovirus is clearly the #1 cause. Currently worded that viruses in general are the number one cause of illness in US.

**Unit 3**

Suggest adding more retail food pictures to balance out all the manufacturing pictures. Assessment Knowledge Check 1 – sampling question not covered very well in module.

**Unit 4**

Control Factors Slide – Food Safety Plans: personnel safety pictures used instead of food safety symbolic pictures.

Control Factors: expound more on why source is important as a control factor. GRAS definition clarification needed that explains that GRAS is a chemical or substance added to food.

Course Assessment – Question 9: is the question asking about pre or post packaging. Needs to be reworded so that its clear.

Overall, we thought courses were good foundation for new regulatory staff. We also thought that it would be helpful for the modules to have slide number to be able to reference slides later. We concur with others that the exams at the end of the courses should provide feedback on questions that were missed so that the “student” learns the correct information. The assessments taken during each unit would also be better if the answer was reiterated why it was correct or why the answer chosen was incorrect. We like that a description pops up when hovering over photos.

Committee Recommendation: Good introduction to hazards, add to “pre” courses.

**B9 Food / Feed Defense Awareness**

FDA Pathlore Course Description: N/A

Committee Review: Unable to review this module because the course was not submitted by the course developer, is not on Pathlore or in the course catalog. Dave Read checked into it and found that the course does exist, but the course was not provided on Pathlore.

Committee Recommendation: No action

### **B10 HACCP (CC8033W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to the hazard analysis and critical control points (HACCP) system There are five modules in this course.

Committee Review:

#### ***Unit 2***

Record Review for Accuracy – consider changing “validity” wording. Too much like verification vs validation and makes you think you are talking about validations whereas the slide is discussing verification. Overall comment: Verification vs Validations needs better disused and language on slides needs to stay true their meaning.

#### ***Unit 4***

Videos. Seem out of place, not necessary, too short if they are going to be used. Would be better if video clips provided snippet of each of the 7 steps of HACCP instead of just 2.

#### ***Unit 5***

Laws Regulations and Guidance: suggest creating stand-alone paragraph to explain implementation of FSMA. Need better clarification of State Agriculture programs, USDA, FDA, State and local oversight and co-regulation. Also, better explanation of FSMA (food safety plans) vs HACCP.

Assessment question—there was a question for recall procedure. We felt this was not adequately covered in module for use as a question.

Committee Recommendation: Comparable to current “post” HACCP series (FDA16-18). If possible, merge with current courses. Recommend no action.

### **B11 Imports (CC8034W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to the regulation of feed and food products grown, produced or manufactured outside of or returned to the US.

- a) Goal: The student will be able to apply knowledge of import requirements.
- b) Scope: The topics in this course include foundations, acts and regulations, entry process, inspection, investigation, compliance and enforcement actions, import fraud.

Committee Review: The slide which explains the term custom(s) broker includes the abbreviation CBP. The phrase CBP custody is used but is not explained until later slides. At which point, CBP is defined as Customs and Border Protection. The text under the example figure for Harmonized Tariff Schedule Code has very low resolution and is difficult to read. Unit 5 includes a “Real World Applications” video on investigations which took a very long time to load. Upon completing the final unit, there was no button available on screen to navigate to the actual course assessment. FD251 references imports, so the material presented in the module is covered there. Course completion time was 47 mins.

Committee Recommendation: We do not recommend the material replace FD251, An Introduction to Food Security Awareness, but differing information is important; add to “post” courses to supplement FD251.

### **B12 Integrated Food Safety System (CC8018W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial feed and food protection agencies working in concert to protect the U.S. human and animal food supply.

(a) Goal: Describe how collaborative interrelationships of regulatory agencies promote and protect public health in a global environment.

(b) Scope: This course will cover introductory knowledge, skills, and abilities related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial feed and food protection agencies working in concert to protect the U.S. human and animal food supply. Topics include foundations of IFSS, stakeholders, mutual reliance, and program standards.

Committee Review:

Reading – reading description of images not helpful stating same thing as image that is presented.

“Example” images – throughout presentation – placeholders?

Module covered the basic foundations of an IFSS and identified the stakeholders. Also covered mutual reliance between stakeholders and covered the different program standards. 35 minutes to complete.

Committee Recommendation: Add to “post” course work.

### **B13 Inspections, Compliance, & Enforcement (CC8019W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to ensuring regulatory compliance through inspection and enforcement activities.

a) Goal: The student will be able to explain compliance activities as they relate to the safety of feed and food programs.

b) Scope: Topics in this course will include Foundations, Jurisdiction, inspection classifications, Inspection tools, Inspection techniques, Pre-inspection, Inspection process, post inspection, enforcement measures

Committee Review: Would be nice to be able to modify and brand to individual jurisdictional procedures.

Introductory knowledge, skills, and abilities related to ensuring regulatory compliance through inspection and enforcement activities. We have covered foundations, jurisdiction, inspection classification, inspection tools, inspection techniques, pre-inspection, inspection process, post-inspection, and enforcement measures.

Committee Recommendation: Only replace if the FDA 38, 39 & Communication can be merged with this course. No action.

### **B14 Investigation Principles (CC8020W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to conducting an investigation of a food safety-related event.

- a) Goal: The student will be able to describe an investigation.
- b) Scope: Topics covered in this course include foundations, communication, agency collaboration, investigation skills pre-investigation, investigation, post-investigation.

Committee Review: Example of Collaborating on Releasing Information, Released Early-

“EXAMPLE image” used – also on the following:

Unit 3- Examples of Potentially Involved Agencies

Unit 5 -Commodity Research Example One, two

Unit 6 -Observational Evidence Example

**Exam - Question 5**, not clarified in reading material:

The Incident Command System (ICS) is:

a) A flexible system that allows agencies the ability to innovate as necessary.

b) A rigid system.

After successful completion of exam, suggest providing a reference slide or information to inform learner of correct choices for the incorrect selections that were made.

Committee Recommendation: Some material covered in FDA38 – Basics of Inspection course; no action.

### **B15 Jurisdiction (CC8037W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to various regulatory agencies and their authority over feed and food.

- a) Goal: The student will be able to describe which agencies have authority to conduct specific regulatory activities.
- b) Scope: The topics covered in this course include foundations, law, crossing boundaries, inter-agency agreements.

Committee Review: We thought the course gave a good overview of the subject and was well designed to provide the information in a logical order. The course does not have slide numbers, so as with regards to feedback we have provided the slide header:

#### **Unit 1**

Foundations State & Local Jurisdiction Authority. Suggest a change to a word in the paragraph that states food ‘consumed’, suggest changing to food ‘sold or distributed’. It would be inaccurate to describe food purchased at a retailer and then consumed at a home just across the state line as intrastate commerce.

#### **Unit 3**

Activities under the State Retail Food Program. It states FDA develops the Retail Food Program, we felt that the CFP process develops with input/oversight from FDA.

The Exam at the end of the course only provides a score, it does not let you know which questions you got incorrect. This could help determine what part of the course you may need to retake etc.

On AFDO's website, the courses are cross-referenced. There was not much interactive content within the course. The lack of interactive features seems like a step back considering the way that online coursework is developed today. The terminology is bridged from the manufacturing content. Violative is commonly used in manufacturing regulation. We scheduled an hour. However, we had to move through the content more quickly toward the end.

Committee Recommendation: Add to "pre" courses.

### **B16 Labeling (CC8038W)**

#### FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to labeling requirements, and the components of feed and food product labels.

a) Goal: The student will be able to explain label requirements.

b) Scope: The topics covered in this course include foundations, labeling laws and regulations, labeling components, feed, food.

#### Committee Review:

##### *Course Overall:*

- No slide numbers or time to complete course/sections.
- inconsistency on knowledge base confirmation on whether a question was answered correctly or not.
- There were a few videos (a little basic), but not sure if they were positioned correctly i.e. they seemed to introduce a new topic, would prefer an intro slide prior to the video.
- Some of the label images were too small to read, even on a large screen.
- The course did seem very long.

##### *Course Design:*

- The course design may benefit from being aligned under regulated areas i.e. Human Food – FDA / FSIS, Dietary Supplements, and Animal feed and then having the specific topics under each area i.e. regulations, label requirements, etc. this could help with repetition, flow and refresher training. It is a lot of information for a new employee, especially if they are not responsible for a certain regulated area i.e. animal feed, the information becomes irrelevant.
- The competency flow did not align with the course, so by having it aligned under regulated areas could help better align it.

#### **Unit 1**

Label Vs Labeling Slide. Include supplement labeling on a website

#### **Unit 2**

Labeling components required allergy information is referencing 'Produced in a facility that processes peanuts' which is not required

- Labeling components trail mix labeling confusing

#### **Unit 3**

Labeling laws referencing outdated FDA 2013 Food code

**Committee Recommendation:** No action in current condition. Like the topic of labeling to be included in curriculum; consider addition if course is revamped.

### **B17 Laws, Regulations, Policies, & Procedures (CC8039W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to the system of federal, state, and local laws that provide the authority to regulate feed and food, and associated policies and procedures.

- a) Goal: The student will be able to employ legal authorities when conducting regulatory activities.
- b) Scope: The topics covered in this course include foundations, constitution, law, regulation, policy, procedures, guidance.

Committee Review: We do not have any significant feedback. We thought the course was well aligned with the competencies and covered all the topics. As stated on previous calls the content is a little dry, and we believe in future the courses will have more interaction.

Committee Recommendation: Replace FDA35, Basic Food Law for State Regulators in “pre” courses.

### **B18 Personal Safety (CC8031W)**

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to hazards encountered by regulators, and appropriate protective actions to mitigate hazards.

- (a) Goal: Choose safe practices based on assessment of risk.
- (b) Scope: This course will provide introductory knowledge, skills and abilities related to hazards encountered by regulators as well as appropriate protective actions to mitigate hazards. Specific topics include foundations of personal safety, chemical hazards, equipment hazards, physical/environmental hazards, miscellaneous hazards, safety equipment, and educational resources.

Committee Review: It sounds like there is some redundant material in other courses regarding PPE. We noticed that the course provided specific instructions on how an inspector should execute personal safety rather than describing the types of PPE. It mentioned that an inspector should reach out to a facility in advance to determine what types of hazards to personal safety may be there. The buddy system for entering coolers and freezers was also mentioned for personal safety reasons. However, there may not always be more than one inspector conducting the inspection. Ladder safety was also included. We considered the content to be focused on more OSHA recommendations than necessary for the food protection field. Examples of hazard signage and PPE requirement signage was very useful. The content should be more of an overview and could be confusing. Basics of inspection course, FDA 38, includes a brief inclusion of personal safety by informing the inspector of appropriate clothing, shoes, head cover.

Committee Recommendation: Given that the material is not covered, it would not replace the current curriculum; no action.

### **B19 Pest Control (under development)**

IFPTI Course Description: Explain how pest activity can impact food safety. Discuss pests of significance to human and animal health. Discuss the importance of facility design for pest control. Describe sanitation practices for pest control. Discuss detection of pests. Discuss how pest management is used to control pests.

Committee Review: This course is currently under development and unable to review. However, this topic is important for new inspectors.

Committee Recommendation: Recommend adding to “pre” courses.

### **B20 Plumbing (CC8001W - under development)**

FDA Pathlore Course Description: This one-hour online course provides information on plumbing controls used in commercial food establishments to protect the potable water supply from contamination. The course consists of 4 lessons: Course Introduction, Cross-Connection Fundamentals, Physical and Mechanical Backflow Prevention, Protection for Drains, Wells, and Septic Systems.

This online course is a prerequisite for several OTED face-to-face courses designed to increase knowledge in identifying plumbing issues in food manufacturing facilities when conducting food GMP inspections. The commodity specific face-to-face course will increase skills and ability to interpret industry situations related to conducting food GMP inspections by FDA investigators/State inspectors.

Committee Review: B20 Plumbing is still in development but appears to be largely complete; I was provided with PDFs of the storyboards and narration for this review. This course includes significant improvements over the other courses I reviewed, having expanded accessibility features, narration, and knowledge checks that include 4+ answers. Some knowledge checks had “choose all that apply” options or asked the participant to choose the correct diagram to match the concept described. The photos and diagrams are matched for backflow prevention devices and other fixtures, which is helpful. I would consider this course a big upgrade from CC8001W.

The course has 5 units: Foundations, Water Source, Wastewater Systems, Backflow Prevention and Jurisdictional Authority. It provides a rationale for proper plumbing, citing an example from the EPA Cross-Connection Control Manual. (Kool-Aid that got mixed with a now-banned pesticide; it would have been prevented with a backflow prevention device.) The material identifies the differences between public and private water supplies, informing the regulator as to which questions to ask. B20 also covers preventing cross-connections, air gaps, maintenance, transport, and so on.

Committee Recommendation: Add to the Standard 2 pre-requisite curriculum. As an aside, it could also replace CC8001W as the pre-requisite for FD207 Plan Review.

### **B21 Preventive Controls (CC8040W)**

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to measures implemented by feed and food manufacturing facilities to ensure feed and food safety.

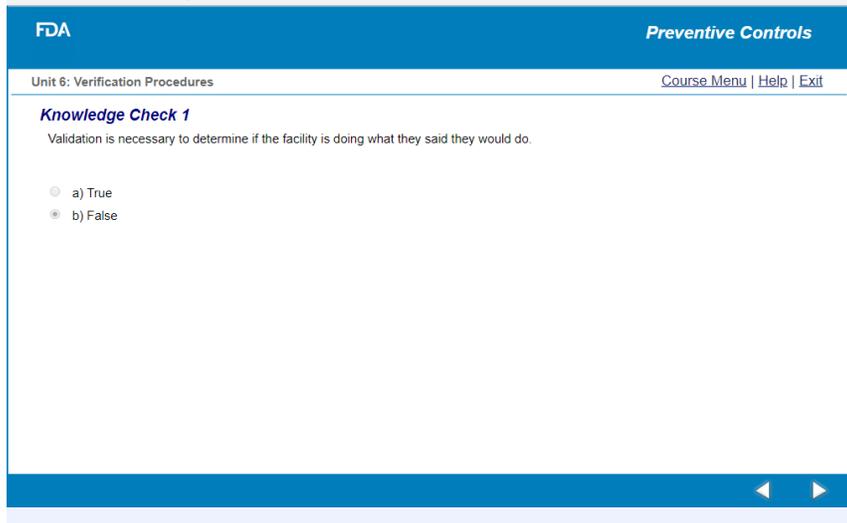
- a) Goal: The student will be able to describe the principles of preventive controls.
- b) Scope: Topics covered in this course include foundations, food safety plans, hazard

analysis, monitoring preventive control programs, corrective action plans, verification procedures, recordkeeping.

Committee Review: The course is geared towards manufacturing and could confuse if used for retail.

- Course flows well.
- Knowledge checks were good.

Unit 6 - Validation question incorrect. "Verification" should be the wording. Screenshot below:



- Final Exam – Q9 wording is confusing.
- Final exam does not state which question was answered incorrectly

Committee Recommendation: Not applicable to retail food; no action.

## **B22 Professionalism (CC8025W)**

### FDA Pathlore Course Description

Introductory knowledge, skills, and abilities related to ethics, integrity, and personal conduct during job-related activities.

- (a) Goal: The student will be able to exhibit the use of integrity and positive interpersonal conduct in the performance of professional and personal activities.
- (b) Scope: Topics covered in this course include foundations, ethics, conduct, personal management, communication, and interpersonal skills.

Committee Review: The coursework is divided into 6 units: Foundations, Ethics, Conduct, Personal Management, Communications and Interpersonal Skills. It defines professionalism, explains its value and the rationale for regulators to act with integrity and the accountability to the public.

The course includes straightforward and relevant scenarios for situations where a regulator could fail to conduct themselves appropriately and how to avoid even the perception of improper conduct. This content is largely text but includes illustrations and photos on most slides.

Each unit has a pair of questions at the end; they are not difficult, only requiring the participant to choose between 2 options. That said, they do underscore important concepts and prevent the participant from just clicking through the course on auto-pilot. The 10-question assessment at the conclusion is similar and provides a final percentage upon completion.

The course required about 45 minutes to complete.

Committee Recommendation: Add to the “pre” curriculum courses.

### **B23 Public Health Principles (CC8026W)**

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to how regulatory agencies promote health and prevent and control feed- and food-related illness.

- a) Goal: The student will be able to discuss basic public health concepts.
- b) Scope: Topics in this course include foundations, assessment, policy development, education and outreach, disease mitigation, emerging health issues, feed/food safety professional’s role in public health.

Committee Review: The course covers 7 units: Foundations, Assessment, Policy Development, Education and Outreach, Disease Mitigation, Emerging Health Issues and the Regulator’s Role in Public Health. I reviewed FDA36 and B23 side-by-side to compare the content between the courses. I recommend B23 as a replacement for FDA36; it covers the much of the same material but is designed to be more relevant to a regulator working in food safety.

The course provides good examples to explain each of the principles. Rather than recount the history of John Snow versus cholera (FDA36), B23 cites more contemporary examples, including “mad cow disease” in Great Britain and E. coli O157:H7 at Jack in the Box in 1993. These examples are used to describe subsequent changes in public policy.

The course required about 75 minutes to complete. It follows the same format as B22, with text, illustrations and photos on most slides. The 10-question assessment at the end includes questions binary questions similar to those found in B22.

Committee Recommendation: Replace FDA36, “Public Health Principles” in “pre” courses.

### **B24 Recalls (CC8041W)**

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to the process of removing a product from commerce.

- a) Goal: The student will be able to describe the recall process in regulatory programs.
- b) Scope: Topics covered in this course include foundations, risk assessment, documentation, communications, recall process, product disposition.

Committee Review: The course has 6 units: Foundations, Risk Assessment, Documentation, Communications, Recall Process and Product disposition. Units 1 and 2 each include a subtitled video, which is a nice addition and a nod to accessibility. Useful distinctions, like the difference between recalls and market withdrawals, and adulteration versus misbranding, are explained throughout the course. The information is relevant for state regulatory agencies that monitor recalls and notify local jurisdictions, and for those agencies that assist in verifying that a product is being removed. However, local jurisdictions are not always involved in recalls (and the course helpfully points out that local health departments don’t typically have the authority to initiate a

recall). As a newer state regulator, I felt the content was useful in many instances, and was my first exposure to some of the information.

I am tentatively recommending that B24 be added, unless we are finding that too many courses are being added and not enough are being removed or replaced. I am concerned about adding an unnecessary burden to inspectors by including this in the Standard 2 curriculum if it does not pertain to their normal duties. It required about 70 minutes to complete.

Committee Recommendation: Add to the “post” curriculum courses.

### **B25 Sampling (CC8035W)**

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to feed and food sample collection, and the role of the laboratory.

- a) Goal: The student will be able to employ sampling protocols when collecting samples.
- b) Scope: Topics covered in this course include foundations, sampling methodology, procedures, laboratory.

Committee Review: B25 has just 4 units: Foundations, Sampling Methodology, Procedures and Laboratory. It defines integrity and validity in regard to sampling, describing the rationale in collecting and documenting samples that are legally and scientifically defensible. Aseptic sampling and chain of custody is explained. The course references the FDA Inspections Operations Manual as a resource for determining how much of a sample is required to be representative. (Maybe include a link that to that manual?)

Unit 3 includes a three-minute video with subtitles to demonstrate how to collect aseptic samples. The shots throughout the video are framed well and allow the viewer to clearly see each step as it is demonstrated. FI04, Foodborne Illness Investigations 4: Conducting a Food Hazard Review, covers the some of this sampling content but is more focused on preparing (logistics and interviewing) for the site visit. B25 is more analogous to MIC13. It took approximately 60 minutes to complete.

Committee Recommendation: Replace MIC13, Aseptic Sampling, in the pre-requisite curriculum.

### **B26 Sanitation Practices (CC8032W)**

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to cleaning, sanitizing, and disinfecting, and the importance of facility and equipment sanitary design.

- (a) Goal: Describe the importance of sanitary design and practices.
- (b) Scope: This course will consist of introductory knowledge, skills and abilities related to cleaning, sanitizing and disinfecting as well as the importance of facility and equipment sanitary design. Topics include foundations of sanitation, cleaning, sanitizing, disinfecting, sanitary engineering, and educational resources.

Committee Review: The course consists of 6 units: Foundations, Cleaning, Sanitizing, Disinfecting, Sanitary Engineering and Sources/Routes of Contamination. It addresses construction materials, contact and non-contact surfaces, the distinction between cleaning and sanitizing, proper layout and so on. The material addresses the limitations and thresholds for different methods of sanitization (chemical, thermal, radiation). It also identifies barriers to

effective cleaning and sanitization. The course took about 75 minutes to complete, but it might be more like 90 minutes for someone new to the material.

Committee Recommendation: Replacing MIC15, Cleaning & Sanitizing, in the Standard 2 Pre-requisite curriculum; it's a significant upgrade across the board. Also, this course covers a lot of the fundamentals for FD207 Plan Review and may be a suitable pre-requisite for that course.

### **B27 Traceability (CC8042W)**

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to tracking feed and food throughout the supply chain.

- a) Goal: The student will be able to describe the role of traceability in feed and food programs.
- b) Scope: Topics covered in this course include foundations, preliminary review, supply chain, documentation, communications, technology.

Committee Review: This course has 6 units: Foundations, Preliminary Review, Supply Chain, Documentation, Communication and Technology. It serves as a primer for tracking human and animal foods through the supply chain. The traceback processes and necessary documentation are clearly defined, and the rationale is provided for when and why a traceback is conducted. (Or a traceforward...) It has some overlap with the Foodborne Illness Investigations series. But, it is distinct and focused enough that it would not replace any of them. It seems most relevant to epidemiologists; most of the local jurisdictions I work with have epidemiological staff and perhaps one inspector that is crossed-trained on epi.

**Unit 3:**

Supply Chain has a 2-minute video, subtitled, that describes a traceability study, followed by a traceback diagram. The diagram might be better served as a larger image (expandable or clicking to enlarge), as it is difficult to see at the current resolution. Some images have the option of clicking a line of text to read a description of the image.

Like B24 (Recalls), this course has useful information for all regulators, but I am unsure as to how necessary it would be for regulators that work on teams with trained epidemiologists. It took about 75 minutes to complete.

Committee Recommendation: Add to "post" curriculum.

### **B28 Transportation (CC8036W)**

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to preventing contamination of feed and food during transport.

- a) Goal: The student will be able to describe how transportation affects feed and food safety.
- b) Scope: Topics in this course include foundations, transportation methods, inspections, security, product safety.

Committee Review: The course contains 5 units: Foundations, Transportation Methods, Inspections, Security and Product safety. It required about 90 minutes to complete.

The first section includes a 4-minute video (subtitled) on the importance of transportation. Unit 2 includes a 2-minute video on a *Salmonella enteritidis* outbreak that sounds like it is referencing the Schwan's incident investigated in Minnesota. The video and header indicate the outbreak happened in 1984, but the well-known outbreak occurred in 1994. A minor detail; is this an error? Also found a typo in Unit: Product Safety on the Air Distribution Exchange slide in the heading.

The Security unit has useful information on chain of custody. The content is well-written and includes examples from relevant outbreaks. It appears to be more pertinent to manufactured foods and agriculture, rather than retail foods. Much of the content (pest control, HACCP, temperature control) that would be applicable to retail food inspections is covered in other courses.

Committee Recommendation: Add to "post" curriculum.

VNRFRPS Table-Standard 4

#	Performance Element	CFP Training Manual
1.	Has required equipment and forms to conduct the inspection.	Pre-inspection
2.	Reviews the contents of the establishment file, including the previous inspection report, reported complaints on file, and, if applicable, required HACCP Plans or documents supporting the issuance of a variance.	Pre-inspection
3.	Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met.	Needs to be added under Pre-inspection #2 (review current risk category) and Inspection observations and performance #3 (verifies risk category is correct based on inspection observations)
4.	Provides identification as a regulatory official to the person in charge and states the purpose of the visit.	Inspection observations and performance
5.	Interprets and applies the jurisdiction’s laws, rules, policies, procedures, and regulations required for conducting retail food establishment inspections.	Inspection observations and performance
6.	Uses a risk-based inspection methodology to conduct the inspection.	Inspection observations and performance
7.	Accurately determines the compliance status of each risk factor and Food Code intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).	Joint inspections during training process/ Section II Inspection Observations and Performance & Section III Inspection Observations and Performance
8.	Obtains corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction’s policies.	Inspection observations and performance
9.	Discuss options for the long-term control of risk factors with establishment managers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction’s policies. Options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans.	Section II Inspection Observations and Performance, #6 addresses violations on previous inspection being corrected, what if they were not

VNRFRPS Table-Standard 4

		corrected and long-term control is needed? Needs to be added to Inspection Observations and Performance, #6
10.	Verifies correction of out-of-compliance observations identified during the previous inspection.  In addition, follows through with compliance and enforcement in accordance with the jurisdiction's policies.	Inspection observations and performance
11.	Conducts an exit interview that explains the out-of-compliance observations, corrective actions, and timeframes for correction, in accordance with the jurisdiction's policies.	Oral communication
12.	Provides the inspection report and, when necessary, cross-referenced documents, to the person in charge or permit holder, in accordance with the jurisdiction's policies.	Written communication
13.	Demonstrates proper sanitary practices as expected from a food service employee.	Professionalism
14.	Completes the inspection form per the jurisdiction's policies (i.e. observations, public health reasons, applicable code reference, compliance dates).	Written communication
15.	Documents the compliance status of each risk factor and intervention (IN, OUT, NA, NO).	Implied in written communication?
16.	Cites the proper code provisions for risk factors and Food code interventions, in accordance with the jurisdiction's policies.	Written communication
17.	Documents corrective action for out-of-compliance risk factors and Food code interventions in accordance with the jurisdiction's policies.	Written communication
18.	Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.	Section IV. Written Communication, 1. Completes inspection form per jurisdiction's administrative procedures Needs to be added
19.	Compliance or regulatory documents (i.e. exhibits, attachments, sample forms) are accurately completed, appropriately cross-referenced within the inspection report, and included with the inspection report, in accordance with the jurisdiction's policies.	Written communication
20.	Files reports and other documentation in a timely manner, in accordance with the jurisdiction's policies.	



## B2 Allergens

**Definition:** An overview of food allergens, including labeling requirements, preventive controls, and societal impact.

**Topic Area TLO:** Discuss the control of allergens in relation to food safety.

**Topic Area ELOs:**

- Explain the risks of allergen exposure.
- Identify major food allergens.
- Describe potential routes of allergen cross-contact.
- Use agency resources to evaluate allergen controls.
- Explain allergen labeling requirements.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> Food allergens related to food programs.</p> <p><b>TLO:</b> Discuss foundational information related to major food allergens.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define relevant terminology.</li> <li>• Differentiate food allergy from food intolerance.</li> <li>• Discuss the prevalence of food allergy in the United States.</li> <li>• Identify major food allergens as recognized by FDA and USDA.</li> <li>• Give examples of foods deemed major allergens in non-U.S. countries.</li> <li>• Discuss the public health significance of food allergens.</li> <li>• Describe the symptoms of an allergic reaction.</li> <li>• Describe the treatment of an allergic reaction.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness of the existence of allergens.</li> <li>• The regulator can define what an allergen is.</li> <li>• The regulator has a knowledge or awareness of regulations tied to allergens.</li> <li>• The regulator has a knowledge or awareness that allergens have the potential to cause a health hazard.</li> <li>• The regulator can give examples of some of the major allergens:             <ul style="list-style-type: none"> <li>a. List the major food allergens</li> <li>b. 8 common allergens</li> </ul> </li> <li>• The regulator has a knowledge or awareness of regulations related to allergens:             <ul style="list-style-type: none"> <li>a. Name the regulation</li> <li>b. Undeclared allergens                 <ul style="list-style-type: none"> <li>▪ Recalls</li> </ul> </li> <li>c. Animal feed is exempt</li> <li>d. Labeling requirements</li> </ul> </li> <li>• The regulator can discuss the importance of regulating allergens.</li> <li>• The regulator has a knowledge or awareness of routes of exposure for allergens:             <ul style="list-style-type: none"> <li>a. Hygiene hypothesis</li> </ul> </li> </ul>

<ul style="list-style-type: none"> <li>• Discuss allergens in relation to recalls.</li> </ul>	
<p><b>Unit 2: Labeling Requirements</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Food labeling requirements pertaining to major food allergens.</p> <p><b>TLO:</b> Discuss allergen labeling requirements.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Discuss the purpose of the Food Allergen Labeling and Consumer Protection Act (FALCPA).</li> <li>• Give examples of allergen labeling options under FALCPA.</li> <li>• Give examples of scientific terms vs. plain language.</li> <li>• Give examples of allergen labeling for tree nuts, fish, and crustacean shellfish.</li> <li>• Discuss the placement of allergen provisions on food labels.</li> <li>• Discuss the use of allergen advisory (“may contain”) statements.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has knowledge or awareness that allergens must be declared on the label.</li> <li>• The regulator has a knowledge or awareness of which allergens must be declared on the label:             <ol style="list-style-type: none"> <li>a. Big 8 (USA)</li> </ol> </li> <li>• The regulator has a knowledge or awareness of different allergen labeling options.</li> </ul>
<p><b>Unit 3: FSMA</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> The provisions of FSMA specifically related to major allergens.</p> <p><b>TLO:</b> Discuss the allergen provisions of the Food Safety Modernization Act (FSMA).</p> <p><b>ELOs:</b></p>	<ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness that because of FSMA, allergens are considered health hazards.</li> </ul>

<ul style="list-style-type: none"> <li>• Discuss “adulterant” in relation to allergens under FSMA.</li> <li>• Discuss “hazard” in relation to allergens under FSMA.</li> <li>• Define “food allergen cross-contact”.</li> </ul>	
<p><b>Unit 4: Control Measures</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Measures by industry to prevent allergen cross-contamination.</p> <p><b>TLO:</b> Discuss control measures to prevent allergen cross-contact.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define “allergen threshold”.</li> <li>• Define “dedicated” in relation to allergen cross-contact.</li> <li>• Discuss cleaning methods to remove allergen residues.</li> <li>• Discuss the role of product changeover in relation to allergen cross-contact.</li> <li>• Discuss the scheduling of processing runs in relation to allergen cross-contact.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness of various control measures.</li> <li>• The regulator has a knowledge or awareness of control measures utilized to prevent cross-contact.</li> <li>• The regulator can name several control measures:             <ol style="list-style-type: none"> <li>a. Cleaning</li> <li>b. Sanitizing</li> <li>c. Physical separation</li> <li>d. Dedicated equipment</li> <li>e. Labeling</li> <li>f. Colored coding</li> <li>g. Dedicated facility</li> <li>h. Gloves</li> <li>i. Air flow controls</li> <li>j. Training</li> </ol> </li> <li>• The regulator can explain how control measures prevent cross-contact.</li> <li>• The regulator can recognize when control measures are not properly implemented.</li> </ul>

**B17 Laws, Regulations, Policies, & Procedures**

**Definition:** Introductory knowledge, skills, and abilities related to the system of federal, state, and local laws that provide the authority to regulate feed and food, and associated policies and procedures.

**Topic Area TLO:** Employ legal authorities when conducting regulatory activities.

**Topic Area ELOs:**

- Discuss legal authorities.
- Differentiate among law, regulations, and ordinances.
- Explain legal authorities to conduct activities.
- Describe administrative protocols.
- Apply authorities to determine compliance.

<p><b>Unit 1: Foundations</b></p> <p><b>Definition:</b> Base knowledge of laws, regulations, policies and procedures related to feed and food programs.</p> <p><b>TLO:</b> Differentiate between laws, regulations, policies, and procedures applicable to regulatory activities.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define relevant terminology.</li> <li>• Explain the significance of key laws.</li> <li>• Describe the relationship between laws and regulations.</li> <li>• Describe how administrative protocols support laws and regulations.</li> <li>• Describe how model codes can be adopted.</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can define key terms:             <ul style="list-style-type: none"> <li>a. Laws (acts, statutes, and ordinances), regulations, policies, procedures and authority</li> </ul> </li> <li>• The regulator can provide an example of each key term.</li> <li>• The regulator can identify laws, regulations, policies, and procedures applicable to your agency.</li> <li>• The regulator can list the laws, regulations, policies, and procedures pertinent to your position.</li> <li>• The regulator can describe how each is developed:             <ul style="list-style-type: none"> <li>a. Authority versus agency requirements (example: Congress gives FDA authority in FD&amp;C Act, FDA promulgates regulations to carry out the law)</li> <li>b. Have awareness of the difference between a law and regulation</li> </ul> </li> <li>• The regulator can describe the relationship of policies and procedures to laws and regulations.             <ul style="list-style-type: none"> <li>a. Support of regulatory activities (example: relationship of sampling to the law, regulation, policy and procedure)</li> <li>b. Describe when to refer to each one</li> <li>c. Identify regulatory actions your agency may take for non-compliant firms</li> </ul> </li> </ul>
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<p><b>Unit 2: Constitution</b></p> <p><b>Definition:</b> The system of</p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
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<p>fundamental principles according to which Federal, State and local agencies are governed.</p> <p><b>TLO:</b> Describe how constitutional law grants and limits authorities.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe how the federal constitution grants and limits agency powers.</li> <li>• Describe how state constitutions grant and limit agency powers.</li> <li>• Explain the difference between State and Federal rights and limits.</li> <li>• Explain due process.</li> <li>• Explain individual rights guaranteed by the constitution.</li> <li>• Describe the separation of powers between the executive, legislative, and judicial branches of government.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has a basic knowledge or awareness of the constitution:             <ul style="list-style-type: none"> <li>a. Define Constitutional law</li> <li>b. Constitution establishes fundamental principles of all laws</li> <li>c. 3 branches of the federal government</li> <li>d. Commerce clause (interstate commerce)                 <ul style="list-style-type: none"> <li>▪ Grants authority and accountability</li> </ul> </li> </ul> </li> <li>• The regulator has a knowledge or awareness of rights of the individual protected under the Constitution:             <ul style="list-style-type: none"> <li>a. Interpretation of rights example: FD&amp;C Act requires payment for some samples because of the Constitution, other agencies may not</li> <li>b. Food Law and regulations may require owner giving up rights</li> <li>c. Seizures, embargoes, stop sales, inspections</li> </ul> </li> <li>• The regulator has a knowledge or awareness of the Federal constitution versus state constitution.</li> <li>• The regulator has a knowledge or awareness of the delegation of authority.</li> </ul>
<p><b>Unit 3: Law</b></p> <p><b>Definition:</b> The foundational knowledge of the process by which laws are created and how authority is delegated.</p> <p><b>TLO:</b> Discuss how laws determine regulatory authority.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe legislative processes.</li> <li>• Explain how local</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can define regulatory authority.</li> <li>• The regulator can define a law, act/statute:             <ul style="list-style-type: none"> <li>a. Include enforcement authority</li> <li>b. Authority to write regulations</li> </ul> </li> <li>• The regulator has a knowledge or awareness of Laws establish and limit regulatory authority:             <ul style="list-style-type: none"> <li>a. Agencies are not able to exceed regulatory authority</li> </ul> </li> <li>• The regulator has a knowledge or awareness of which laws provide the authority to do the regulator’s job.</li> <li>• The regulator can find where in the law your authority is</li> </ul>

<p>ordinances differ from state and federal statutes.</p> <ul style="list-style-type: none"> <li>• Explain delegation of authority.</li> <li>• Differentiate between statutory and case law.</li> <li>• Explain how law authorizes enforcement actions.</li> </ul>	<p>derived from:</p> <ol style="list-style-type: none"> <li>a. Delegation of authority</li> </ol>
<p><b>Unit 4: Regulation</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> An administrative act or rule, based on law, prescribed by agency authority.</p> <p><b>TLO:</b> Explain how regulations assist agencies to implement laws.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Identify pertinent regulations that are applicable to regulatory programs.</li> <li>• Explain the general process by which regulations are developed.</li> <li>• Describe the FDA cooperative program model regulations.</li> <li>• Describe how regulations are published.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can explain the relationship between a law and regulation:             <ol style="list-style-type: none"> <li>a. What is the difference between a regulation and a law</li> <li>b. Regulations provide information about the implementation of laws</li> <li>c. Laws prevail over regulations</li> <li>d. Regulations are based on the law</li> </ol> </li> <li>• The regulator has a knowledge or awareness that your agency implements regulations.</li> <li>• The regulator can list regulations your agency implements.</li> <li>• The regulator can clarify enforcement authority:             <ol style="list-style-type: none"> <li>a. Discretion</li> </ol> </li> <li>• The regulator can list the information that regulations may provide about implementation of the law:             <ol style="list-style-type: none"> <li>a. Standards</li> <li>b. Who/what is regulated</li> <li>c. Required procedures</li> <li>d. Point of reference</li> <li>e. Minimum requirements</li> <li>f. Clarity</li> <li>g. Required process</li> </ol> </li> </ul>
<p><b>Unit 5: Policy</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Set of principles formulated or adopted by an agency to influence and determine actions.</p> <p><b>TLO:</b> Describe the purpose of</p>	<ul style="list-style-type: none"> <li>• The regulator can define a policy.</li> <li>• The regulator can give examples of policies.</li> <li>• The regulator can provide the basis for consistent implementation or application of the law.</li> <li>• The regulator can outline legal requirements in plain</li> </ul>

<p>agency policies.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe how policies are developed.</li> <li>• Differentiate between regulatory and administrative policies.</li> <li>• Give examples of when a regulatory policy is applicable.</li> <li>• Give examples of when an administrative policy is applicable.</li> <li>• Discuss the relationship between policy and procedures.</li> </ul>	<p>language.</p> <ul style="list-style-type: none"> <li>• The regulator can link policies to specific laws and regulations.</li> <li>• The regulator can give examples of what agency policies accomplish:             <ol style="list-style-type: none"> <li>a. Provide agency positions/strategy</li> <li>b. Correct an issue</li> <li>c. Address a need</li> <li>d. Emerging technology</li> <li>e. To provide a scientific basis</li> </ol> </li> <li>• Provide additional information about laws and regulations</li> </ul>
<p><b>Unit 6: Procedures</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Providing a standard method for conducting activities.</p> <p><b>TLO:</b> Explain the purpose of procedures used in federal, state, and local regulatory programs.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe the process of procedure development.</li> <li>• Describe the process of procedure implementation.</li> <li>• Explain the importance of following procedures.</li> <li>• Explain how procedures are used to obtain compliance.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can define a procedure:             <ol style="list-style-type: none"> <li>a. Series of steps to be followed</li> <li>b. Provides the instruction and/or paperwork to carry out an activity</li> <li>c. Describe how policies will be put into action</li> <li>d. Determines who will do what</li> <li>e. Step by step instructions/guidance</li> <li>f. More detailed than policy</li> <li>g. Identify specific forms or documents</li> </ol> </li> <li>• The regulator can give examples of procedures used in their agency.</li> <li>• The regulator can describe how procedures benefit the agency:             <ol style="list-style-type: none"> <li>a. Improve time efficiency</li> <li>b. Improves sharing of information</li> <li>c. Efficient use of resources</li> </ol> </li> </ul>

<ul style="list-style-type: none"> <li>• Give examples of when to use applicable procedures.</li> </ul>	
<p><b>Unit 7: Guidance</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can define what is a guidance document is:             <ol style="list-style-type: none"> <li>a. Interpretation of regulation</li> <li>b. Recommendations, not law or legally binding</li> <li>c. Recommendations or instructions on how to meet agency expectations</li> <li>d. Guidelines to assist in carrying out regulatory requirements</li> <li>e. Regulatory authorities current thinking on a subject or method</li> <li>f. Not mandatory</li> <li>g. Can be used by industry and regulators</li> </ol> </li> <li>• The regulator can give an example of guidance documents.</li> <li>• The regulator can recognize how their agency uses guidance documents.</li> <li>• The regulator can describe the relationship of a guidance document to a regulation.</li> <li>• The regulator can describe what guidance documents accomplish:             <ol style="list-style-type: none"> <li>a. Support a consistent application of laws, regulations, policies and procedures</li> <li>b. Provide additional clarity for vague or gray areas within the regulations</li> <li>c. Provides historical and scientific background to regulation and policy</li> <li>d. Standardize response to a defined situation</li> <li>e. Explain a complex subject or procedure</li> <li>f. Clarify laws, regulations, policy and procedures, etc.</li> <li>g. Guidance documents often point to additional resources</li> <li>h. Help implement best practices</li> <li>i. Additional information to support and/or complete an activity</li> <li>j. Provide information that can be used to attain and remain in compliance</li> </ol> </li> </ul>

**IFSS Framework – Basic Level Gen Eds  
B23 Public Health Principles**

**Definition:** Introductory knowledge, skills, and abilities related to how regulatory agencies promote health and prevent and control feed- and food-related illness.

**Topic Area TLO** (Terminal Learning Objective): Discuss basic public health concepts.

**Topic Area ELOs** (Enabling Learning Objective):

- Explain public health principles.
- Discuss how public health principles are applied to the food system to protect consumers.
- Explain the relationships among agent, host, and environment with respect to hazards in food.
- Explain the agency’s role to protect consumers.
- Apply public health principles while conducting regulatory activities.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> Base knowledge of public health principles and successes related to feed and food programs.</p> <p><b>TLO:</b> Discuss public health principles and successes.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define relevant terminology.</li> <li>• Locate resources.</li> <li>• State the goal of public health.</li> <li>• Describe the three components of public health.</li> <li>• Explain what actions public health professionals take to promote public health.</li> <li>• Provide examples of public health programs.</li> <li>• Provide examples of public health</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can describe the goal of public health:               <ul style="list-style-type: none"> <li>a. Promote population health</li> </ul> </li> <li>• The regulator can give an example of public health programs.</li> <li>• The regulator can list the three components of public health:               <ul style="list-style-type: none"> <li>a. Assessment</li> <li>b. Policy development</li> <li>c. Assurance</li> </ul> </li> <li>• The regulator can describe a public health success.</li> </ul>

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successes.

<p><b>Unit 2: Assessment</b></p> <p><b>Definition:</b> The evaluation of data to determine the impact from exposure to disease and the effects on public health.</p> <p><b>TLO:</b> Describe the best practices for public health assessments.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the importance of assessment.</li> <li>• Explain the role of epidemiology.</li> <li>• Explain the role of risk factors.</li> <li>• Discuss the purpose of data collection and analysis.</li> <li>• Explain the public health implications of a disease.</li> <li>• Differentiate active and passive surveillance.</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can discuss the role of epidemiology.</li> <li>• The regulator can explain the importance of data collection.</li> <li>• The regulator can discuss the importance of assessment.</li> <li>• The regulator can describe active surveillance.</li> <li>• The regulator can describe passive surveillance.</li> </ul>
<p><b>Unit 3: Policy Development</b></p> <p><b>Definition:</b> A basic knowledge of policy development.</p> <p><b>TLO:</b> Describe policy development and implementation.</p> <p><b>ELOs:</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can describe how incidents influence public health policy.</li> <li>• The regulator can discuss how political forces affect public health policy.</li> <li>• The regulator can give an example of public health policy implementation.</li> </ul>

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<ul style="list-style-type: none"> <li>• Explain how incidents drive policy.</li> <li>• Explain how research influences policy.</li> <li>• Explain how stakeholders influence policy.</li> <li>• Explain how the political process influences policy.</li> <li>• Explain how policy is implemented.</li> <li>• Give an example of the implementation of a public health policy.</li> </ul>	
<p><b>Unit 4: Education and Outreach</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can describe the importance of education and outreach in public health.</li> <li>• The regulator can give an example of a public health communication method.</li> </ul>
<p><b>Definition:</b> A description of how the public health professional can be proactive to educate and protect the community.</p> <p><b>TLO:</b> Describe the use of education and outreach in public health.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the importance of education and outreach.</li> <li>• Give examples of health communication methods.</li> <li>• Identify relevant public health issues for outreach.</li> <li>• Describe populations that would benefit from education and outreach.</li> <li>• Explain outreach methods for intended</li> </ul>	

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audience.	
<b>Unit 5: Disease Mitigation</b>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can discuss methods to prevent or control disease.</li> <li>• The regulator can describe a disease control strategy.</li> <li>• The regulator can list two means of disease transmission.</li> </ul>
<p><b>Definition:</b> Basic knowledge of disease mitigation.</p> <p><b>TLO:</b> Describe approaches to prevent, reduce, or control disease.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Discuss the importance of disease mitigation.</li> <li>• Discuss disease prevention strategies.</li> <li>• Explain modes of disease transmission.</li> <li>• List risk factors that increase susceptibility to disease in populations.</li> </ul>	
<b>Unit 6: Emerging Health Issues</b>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can give an example of an emerging health issue.</li> <li>• The regulator can describe how an emerging health issues impacts regulation.</li> </ul>
<p><b>Definition:</b> How emerging health issues can influence public health.</p> <p><b>TLO:</b> Identify how emerging health issues affect public health.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe the concept of emerging health issues.</li> <li>• Provide an example of how an emerging</li> </ul>	

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<p>health issue has impacted public health policy and regulation.</p> <ul style="list-style-type: none"> <li>• Provide examples of currently emerging health issues.</li> </ul>	
<p><b>Unit 7: Feed/Food Safety Professional’s Role in Public Health</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can describe the regulator’s role in promoting public health.</li> <li>• The regulator can provide an example of how a food safety regulator promotes public health.</li> </ul>
<p><b>Definition:</b> Basic knowledge of how food regulatory agencies promote public health.</p> <p><b>TLO:</b> Describe the role of the food safety professional in public health.</p>	
<p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe the contribution of feed/food safety activities to public health.</li> <li>• Discuss how feed/food safety is influenced by public health.</li> <li>• Describe the role of feed/food safety professionals in mitigation of public health threats.</li> <li>• Describe the role of feed/food safety professionals in promoting public health.</li> <li>• Give an example of how a feed/food safety professional promotes public health.</li> </ul>	

IFSS Framework – Basic Level Gen Eds  
**B25 Sampling**

**Definition:** Introductory knowledge, skills, and abilities related to feed and food sample collection, and the role of the laboratory.

**Topic Area TLO (Terminal Learning Objective):** Employ sampling protocols when collecting samples.

**Topic Area ELOs (Enabling Learning Objectives):**

- Discuss sampling techniques.
- Explain sampling protocols.
- Determine if sample collection is necessary.
- Employ authority to collect samples.
- Apply sampling procedures.

<p><b>Unit 1: Foundations</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Basic knowledge of sampling related to feed and food programs.</p> <p><b>TLO:</b> Collect a sample with documentation.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define sampling terminology.</li> <li>• Discuss sample collection methods.</li> <li>• Explain why samples are collected.</li> <li>• Record required information pertaining to a sample.</li> <li>• Describe the different types of samples.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can describe the agency’s policies for sample collection:             <ol style="list-style-type: none"> <li>a. Chain of custody</li> <li>b. Documentation</li> <li>c. Sampling techniques</li> </ol> </li> <li>• The regulator can describe the importance of correct documentation.</li> <li>• The regulator can independently demonstrate correct sample documentation.</li> <li>• The regulator can explain the importance of correct documentation:             <ol style="list-style-type: none"> <li>a. Identification</li> <li>b. Chain of custody</li> <li>c. Proper documentation of seal</li> <li>d. Sample technique documentation</li> <li>e. Shipping documentation</li> <li>f. Time</li> <li>g. Temperature</li> <li>h. Volume</li> </ol> </li> </ul>
<p><b>Unit 2: Sampling Methodology</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Knowledge needed to collect a sample.</p>	<ul style="list-style-type: none"> <li>• The regulator can describe considerations for sampling:             <ol style="list-style-type: none"> <li>a. Expiration</li> <li>b. Time restraints</li> <li>c. Staffing/team</li> </ol> </li> </ul>

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**B25 Sampling**

<p><b>TLO:</b> Discuss the factors to consider when collecting a sample.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Determine equipment to use when collecting samples.</li> <li>• Explain time related factors when collecting a sample.</li> <li>• Give examples of key factors used to determine what makes a sample.</li> <li>• Explain the difference between random and selective sampling.</li> </ul>	<ul style="list-style-type: none"> <li>d. Method of sampling             <ul style="list-style-type: none"> <li>▪ Representation of the lot</li> </ul> </li> <li>e. Equipment</li> <li>f. Sample type             <ul style="list-style-type: none"> <li>▪ Finished product</li> <li>▪ Environmental samples</li> <li>▪ Ingredients</li> <li>▪ Surveillance vs for cause</li> </ul> </li> <li>g. Safety</li> <li>h. Enclosed areas</li> <li>i. Aware of your sampling environment</li> <li>• The regulator can explain the ramifications if sampling factors are not considered:             <ul style="list-style-type: none"> <li>a. Product contamination</li> <li>b. cross contamination</li> <li>c. cross contact</li> <li>d. Enforcement action fails</li> </ul> </li> </ul>
<p><b>Unit 3: Procedures</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> A series of steps used to collect a sample.</p> <p><b>TLO:</b> Explain the procedures utilized when collecting a sample.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Apply official procedures when collecting samples.</li> <li>• Record information on proper forms.</li> <li>• Describe chain of custody.</li> <li>• Give examples of procedures to follow when collecting a sample.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can provide information to aid in decision making:             <ul style="list-style-type: none"> <li>a. To determine the scope of the recall</li> <li>b. To support the risk assessment</li> </ul> </li> <li>• The regulator can conduct recall audit checks:             <ul style="list-style-type: none"> <li>a. Verify unsafe products are off the market.</li> </ul> </li> <li>• The regulator can discuss the role of documentation in validation, tracking, and organization:             <ul style="list-style-type: none"> <li>a. Defensibility</li> <li>b. Evidence to support a recall</li> </ul> </li> <li>• The regulator can discuss procedures when collecting a sample.</li> <li>• The regulator can describe agency sampling policy.</li> <li>• The regulator can discuss personal safety in sampling.</li> <li>• The regulator can demonstrate sampling procedures.</li> <li>• The regulator can describe methods related to specific sample types.</li> <li>• The regulator can demonstrate safe sampling techniques.</li> </ul>

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**B25 Sampling**

<ul style="list-style-type: none"> <li>• Recognize the importance of expiration dates.</li> <li>• Discuss issues associated with transport of samples.</li> <li>• Describe the difference between an aseptic sample and a non-aseptic sample.</li> </ul>	
<p><b>Unit 4: Laboratory</b></p> <p><b>Definition:</b> Basic knowledge of laboratory functions pertaining to samples.</p> <p><b>TLO:</b> Discuss the role of the laboratory in feed/food safety.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the importance of the laboratory.</li> <li>• Describe lab receiving processes for samples collected.</li> <li>• Explain the lab results to the stakeholders.</li> <li>• Recognize the analytical capabilities of laboratories.</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can identify the laboratory’s function in feed/food safety:             <ol style="list-style-type: none"> <li>a. Receive</li> <li>b. Analyze</li> <li>c. Report results</li> <li>d. Interpret results</li> </ol> </li> <li>• The regulator can describe how laboratories use quality control to produce defensible results.</li> <li>• The regulator can discuss agency policy related to communication with the laboratory.</li> </ul>

**IFSS Framework – Basic Level Gen Eds**  
**B26 Sanitation Practices**

**Definition:** Introductory knowledge, skills, and abilities related to cleaning, sanitizing, and disinfecting, and the importance of facility and equipment sanitary design.

**Topic Area TLO (Terminal Learning Objective):** Describe the importance of sanitary design and practices.

**Topic Area ELOs (Enabling Learning Objective):**

- Discuss the principles of sanitary design and practices.
- Identify the appropriate use of cleaners, sanitizers, and disinfectants.
- Describe the use of cleaners and sanitizers in specific situations.
- Explain regulatory agency policies in regard to sanitation, design, and employee practices.
- Explain the use of cleaning and sanitizing to control adulterants.

<b>Unit 1: Foundations</b>	<b>TLO Behavioral Anchors - not all-inclusive</b>
<p><b>Definition:</b> Sanitation practices and sanitary design of facilities and equipment.</p> <p><b>TLO:</b> Discuss sanitation practices and sanitary design of facilities and equipment.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Discuss sanitary design of facilities and equipment.</li> <li>• Discuss the importance of GMPs, GRPs, and GAPs.</li> <li>• Describe principles of sanitation.</li> <li>• Describe the purpose of SSOPs.</li> <li>• Describe the importance of employee sanitation training.</li> <li>• Give examples of monitoring records.</li> <li>• Discuss water chemistry.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can identify three facility sanitary design principles:               <ol style="list-style-type: none"> <li>a. Exterior and upstream considerations</li> <li>b. Piping</li> <li>c. Facility plan review</li> <li>d. Airflow</li> <li>e. Clean ability</li> <li>f. No niches/harborages areas</li> <li>g. Facility design meets the needs of the food sector</li> <li>h. Traffic patterns</li> <li>i. Process flow considerations</li> <li>j. Food contact surfaces made of food compatible materials (Food Code 4-101.11)</li> <li>k. Vermin control</li> <li>l. Water source and quality</li> </ol> </li> <li>• The regulator can identify an equipment sanitary design principle:               <ol style="list-style-type: none"> <li>a. UL</li> <li>b. Cleanable to a microbiological level</li> <li>c. NSF International</li> <li>d. Facility plan review</li> <li>e. Cleanability</li> <li>f. No niches/harborage areas</li> <li>g. 3-A Sanitation Standards, Inc.</li> <li>h. Self-draining</li> <li>i. Accessible for inspection and maintenance</li> </ol> </li> <li>• The regulator can discuss a biological hazard related to sanitary design:               <ol style="list-style-type: none"> <li>a. Minimize bacterial growth</li> </ol> </li> </ul>

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**B26 Sanitation Practices**

	<ul style="list-style-type: none"> <li>b. Transportation as a hazard</li> <li>c. Biohazards</li> <li>d. Sanitation provides a five (5) log reduction</li> <li>e. Validation of cleaning and sanitizing protocols</li> <li>f. Environmental hazards</li> <li>• The regulator can identify cleaning and sanitizing protocols:             <ul style="list-style-type: none"> <li>a. Allergen control</li> <li>b. Food safety plan</li> <li>c. Sanitation Standards of Operation (SSOPs)</li> <li>d. Employee training</li> <li>e. Sanitary operational performance</li> <li>f. Cleaning vs sanitizing</li> <li>g. SOPs describe how sanitation is conducted</li> <li>h. Management oversight</li> <li>i. Current Good Manufacturing Practices (cGMP), current Good Retail Practices (cGRP), current Good Agriculture Practices (cGAP)</li> <li>j. Cross-contamination prevention</li> <li>k. Monitoring records</li> <li>l. Biofilms</li> <li>m. Types of sanitizers</li> <li>n. Labels</li> <li>o. Hot water</li> <li>p. Follow label instructions</li> <li>q. Heat</li> </ul> </li> <li>• The regulator can explain how clean ability impacts sanitization.</li> <li>• The regulator can describe how sanitary design, adequate cleaning and sanitizing lead to hazard reduction.</li> </ul>
<p><b>Unit 2: Cleaning</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> The process of removing visible material such as soil, dirt, and organic matter from facilities and equipment.</p>	<ul style="list-style-type: none"> <li>a. The regulator can describe two different types of cleaning:             <ul style="list-style-type: none"> <li>a. Cleaning vs sanitizing</li> <li>b. High pressure washing</li> <li>c. Dustless cleaning methods</li> </ul> </li> </ul>

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<p><b>TLO:</b> Discuss the process of removing visible material such as soil, dirt, and organic matter from facilities and equipment.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe the factors that affect the efficacy of cleaning agents.</li> <li>• Explain how water chemistry can affect cleaning agents.</li> <li>• Discuss types of cleaning agents and their function on soil.</li> <li>• Describe cleaning methods.</li> <li>• Explain the importance of following the manufacturer’s directions for use.</li> <li>• Explain the importance of breaking down equipment for cleaning.</li> </ul>	<ul style="list-style-type: none"> <li>d. Dry clean</li> <li>e. Flushing (dry feed)</li> <li>f. Rinsing (wet)</li> <li>g. Wet clean</li> <li>h. Clean-in-Place (CIP)</li> <li>i. Clean-out-of-Place (COP)</li> <li>j. Equipment teardown</li> </ul> <ul style="list-style-type: none"> <li>• The regulator can discuss two concerns with cleaning supply usage:             <ul style="list-style-type: none"> <li>• Types of detergents/soaps</li> <li>• Contact time</li> <li>• Concentration strengths</li> <li>• Appropriate cleaning supplies</li> <li>• Matching cleaners with intended use</li> <li>• Follow label instructions</li> <li>• Cleaning solution labeling</li> <li>• Material Safety Data Sheets (MSD)</li> <li>• Cleaning frequencies</li> <li>• Proper storage of chemicals</li> </ul> </li> <li>• The regulator can provide two examples of appropriate cleaning methods.</li> <li>• The regulator can discuss four concerns with cleaning supply usage.</li> </ul>
<p><b>Unit 3: Sanitizing</b></p> <p><b>Definition:</b> Reducing the presence of microorganisms.</p> <p><b>TLO:</b> Discuss the process of reducing the presence of microorganisms.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the importance of using approved food-grade sanitizers.</li> <li>• Describe the factors that affect the efficacy of sanitizers.</li> <li>• Describe the types of</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can list two considerations for microorganism control:             <ol style="list-style-type: none"> <li>a. Prescribed treatment matches threat</li> <li>b. Environmental hazards</li> <li>c. Importance of cleaning before sanitizing</li> <li>d. Pathogens of concern</li> <li>e. Cross contamination (sanitizer residue, overspray, etc.)</li> </ol> </li> <li>• The regulator can describe the concept of how sanitizers work for microorganism control:             <ol style="list-style-type: none"> <li>a. Types of sanitizers</li> <li>b. Label instructions</li> <li>c. Parts per million (PPM)</li> <li>d. Sanitizer concentrations</li> <li>e. Methods, chemical, and hot water</li> <li>f. Contact time</li> <li>g. Test strips</li> <li>h. Temperature effects on efficacy</li> <li>i. Drying</li> </ol> </li> </ul>

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<p>sanitizing agents.</p> <ul style="list-style-type: none"> <li>• Discuss the purpose of sanitizers.</li> <li>• Discuss sanitizers' requirements for use.</li> <li>• Describe sanitizing strategies.</li> <li>• Identify sanitizer test methods.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can describe three considerations for microorganism control.</li> <li>• The regulator can describe proper use of two sanitizers for microorganism control.</li> </ul>
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<p><b>Unit 4: Disinfecting</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can identify a specialized technique for disinfection:             <ol style="list-style-type: none"> <li>a. Oxidation</li> <li>b. Ozone</li> <li>c. Ultra violet (UV)</li> <li>d. Time/temperature/concentration</li> <li>e. Potential of hydrogen (pH) control</li> <li>f. Irradiation</li> <li>g. Membrane technologies</li> <li>h. Onsite disinfection generation</li> </ol> </li> <li>• The regulator can distinguish between sanitizing and disinfecting.</li> <li>• The regulator can discuss a specialized technique for disinfection.</li> </ul>
<p><b>Definition:</b> The use of specialized techniques to destroy or irreversibly inactivate pathogenic microorganisms but not necessarily their spores.</p> <p><b>TLO:</b> Discuss the use of specialized techniques to destroy or irreversibly inactivate pathogenic microorganisms but not necessarily their spores.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the importance of using approved food-grade disinfectants.</li> <li>• Describe the factors that affect the efficacy of disinfectants.</li> <li>• Discuss the purpose of disinfectants.</li> <li>• Discuss disinfectants' requirements for use.</li> <li>• Describe disinfecting strategies.</li> <li>• Identify disinfectant test methods.</li> </ul>	

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<p><b>Unit 5: Sanitary Engineering</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> The design and construction of facilities and equipment to reduce or prevent Contamination and facilitate cleaning and sanitizing.</p> <p><b>TLO:</b> Discuss how facility and equipment design impacts sanitation.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Discuss the concept of building envelope.</li> <li>• Discuss the importance of proper equipment layout.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can discuss three equipment design considerations:             <ol style="list-style-type: none"> <li>a. Appropriate materials</li> <li>b. Smooth, non-absorbent, easily cleanable construction</li> <li>c. UL or NSF International certified</li> <li>d. Non-corrosive and durable</li> <li>e. Self-draining</li> <li>f. Biofilms</li> <li>g. Non-toxic materials</li> <li>h. No niches</li> <li>i. Accessibility</li> </ol> </li> <li>• The regulator can describe three sanitary design principles:             <ol style="list-style-type: none"> <li>a. Appropriate wastewater disposal</li> <li>b. Biohazard areas</li> <li>c. Allergen control</li> <li>d. Employee movement</li> <li>e. Refuse storage/removal</li> <li>f. Loading dock design and maintenance</li> <li>g. Clean rooms</li> <li>h. Water source</li> <li>i. Water quality</li> <li>j. Upstream considerations</li> <li>k. Emerging pathogens of concern on building design</li> <li>l. Hygienic compatibility</li> <li>m. Facility flow, incoming to finished product</li> <li>n. Exterior considerations</li> <li>o. Airflow systems</li> <li>p. Condensation</li> <li>q. Negative airflow vs positive</li> <li>r. Pest control</li> <li>s. Hygienic design of maintenance enclosures</li> <li>t. Plumbing design and installation</li> </ol> </li> <li>• The regulator can discuss six equipment design considerations.</li> <li>• The regulator can describe six sanitary design principles.</li> </ul>
<p><b>Unit 6: Sources and Routes of Contamination</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Hazards, practices, and facility/equipment design that may lead to contamination.</p>	<ul style="list-style-type: none"> <li>• The regulator can list two improper activities that may lead to contamination:             <ol style="list-style-type: none"> <li>a. Splash may transfer pathogens (droplet or airborne)</li> </ol> </li> </ul>

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<p><b>TLO:</b> Discuss hazards, practices, and facility/equipment design that may lead to contamination.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Discuss potential hazards.</li> <li>• Explain routes of contamination.</li> <li>• Describe how people can be a source of contamination.</li> <li>• Describe how cleaning practices can contribute to contamination.</li> <li>• Explain the importance of vector control.</li> <li>• Discuss the water source.</li> </ul>	<ul style="list-style-type: none"> <li>b. Cross contamination</li> <li>c. Allergen cross contact</li> <li>d. Improper cleaning, sanitizing, and disinfecting</li> <li>e. Employee hygiene</li> <li>• The regulator can list facility/equipment design attributes that may lead to contamination:             <ul style="list-style-type: none"> <li>a. Improper design of facilities and equipment</li> <li>b. Improper maintenance of facilities and equipment</li> <li>c. Hidden niches</li> <li>d. Airborne contaminants</li> <li>e. Vector control</li> <li>f. Water management (standing water, drains)</li> </ul> </li> <li>• The regulator can identify three types of hazards:             <ul style="list-style-type: none"> <li>a. Chemical, Physical, Microbial hazards</li> </ul> </li> <li>• The regulator can explain how improper activities lead to contamination.</li> <li>• The regulator can explain how improper design of facility/equipment and maintenance may lead to contamination.</li> </ul>
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## IFSS Framework – Basic Level Gen Eds

### B8 Environmental Hazards

**Definition:** Introductory knowledge, skills, and abilities related to environmental hazards focusing on sources of contamination and associated control methods.

**Topic Area TLO:** Explain the properties of environmental hazards.

**Topic Area ELOs:**

- Discuss the characteristics of environmental hazards.
- Identify categories and examples of environmental hazards.
- Recognize impacts of environmental hazards on animal feed and human food.
- Differentiate among environmental hazards.
- Describe methods to control environmental hazards.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> Basic knowledge of environmental hazards related to feed and food products and processes.</p> <p><b>TLO:</b> Describe the effect of environmental hazards in feed and food products and processes.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define relevant terminology.</li> <li>• Describe where to find resources.</li> <li>• Give examples of feed and food products that may be affected by environmental hazards.</li> <li>• Give examples of how a milestone event impacted public policy.</li> <li>• Describe the consequences of contamination by environmental hazards.</li> <li>• Give examples of illness caused by</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can define environmental hazards.</li> <li>• The regulator has a knowledge or awareness of the effect of environmental hazards:               <ul style="list-style-type: none"> <li>a. Environmental hazards can cause injury, illness, or death in people and animals.</li> </ul> </li> <li>• The regulator has a knowledge or awareness of the effects of environmental hazards in food and feed:               <ul style="list-style-type: none"> <li>a. Short term and long term</li> <li>b. Name types of injury or illness caused by environmental hazards</li> </ul> </li> <li>• The regulator can explain the difference between environmental and biological hazards.</li> </ul>

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<p>environmental hazards.</p> <ul style="list-style-type: none"> <li>• Discuss how sampling is used to detect environmental hazards.</li> </ul>	
<p><b>Unit 2: Environmental Hazards of Concerns</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Basic knowledge of environmental hazards that can be a risk or threat.</p> <p><b>TLO:</b> Explain which environmental hazards can adulterate the feed and food supply.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Identify the categories of environmental hazards.</li> <li>• Give examples of each category of environmental hazard.</li> <li>• Associate environmental hazards with products or processes.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can name the three categories of environmental hazards that can adulterate feed and food:             <ol style="list-style-type: none"> <li>Physical</li> <li>Chemical/toxin                 <ul style="list-style-type: none"> <li>▪ Radiological</li> </ul> </li> <li>Biological</li> </ol> </li> <li>• The regulator can define adulteration.</li> <li>• The regulator can give examples for each of the three categories of environmental hazards that can adulterate feed and food:             <ol style="list-style-type: none"> <li>Physical - glass</li> <li>Chemical/toxin – rat poison</li> <li>Biological – salmonella, listeria</li> </ol> </li> <li>• The regulator has a knowledge or awareness that there may be allowable limits of various physical, chemical, and biological elements such as:             <ol style="list-style-type: none"> <li>Physical – insect parts</li> <li>Chemical/toxin– pesticides, aflatoxins</li> <li>Biological – coliforms</li> </ol> </li> </ul>
<p><b>Unit 3: Sources and Pathways</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Basic knowledge of the sources and pathways that environmental hazards can take in contaminating products and processes.</p> <p><b>TLO:</b> Explain how products and processes can become contaminated by environmental hazards.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Discuss how environmental</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can name the three categories of environmental hazards that can adulterate feed and food:             <ol style="list-style-type: none"> <li>Physical</li> <li>Chemical/toxin                 <ul style="list-style-type: none"> <li>▪ Radiological</li> </ul> </li> <li>Biological</li> </ol> </li> <li>• The regulator can define adulteration.</li> <li>• The regulator can give examples of each of the three categories of environmental hazards that can adulterate feed and food:             <ol style="list-style-type: none"> <li>Physical – glass</li> <li>Chemical/toxin – rat poison</li> <li>Biological – salmonella, listeria</li> </ol> </li> </ul>

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<p>hazards contaminate products and processes.</p> <ul style="list-style-type: none"> <li>• Differentiate between intentional and unintentional contamination.</li> <li>• Describe vectors of contamination.</li> <li>• Give examples of food contamination sources.</li> <li>• Give examples of feed contamination sources.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness that there may be allowable limits of various physical, chemical, and biological elements such as:             <ol style="list-style-type: none"> <li>a. Physical – insect parts</li> <li>b. Chemical/toxin – pesticides, aflatoxins</li> <li>c. Biological - coliforms</li> </ol> </li> </ul>
<p><b>Unit 4: Control Factors</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Basic knowledge of methods to control environmental hazards.</p> <p><b>TLO:</b> Discuss methods used to control environmental hazards.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the concept of acceptable levels of exposure.</li> <li>• Describe best management practices that are used to prevent spread of environmental hazards.</li> <li>• Give examples of preventive controls.</li> <li>• Describe control point monitoring.</li> <li>• Explain why source is important as a control factor.</li> <li>• Discuss response options for contamination.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness that methods exist to control environmental hazards.</li> <li>• The regulator can define the terms eliminate, prevent, and control for environmental hazards.</li> <li>• The regulator can identify methods that reduce, control, monitor, or eliminate environmental hazards:             <ol style="list-style-type: none"> <li>a. Proper cleaning and sanitation</li> <li>b. Environmental monitoring programs</li> <li>c. Sequencing or flushing</li> <li>d. Time and temperature controls</li> <li>e. Corrective actions</li> <li>f. Process flow</li> <li>g. Chemical control program</li> </ol> </li> </ul>

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### B12 Integrated Food Safety System (IFSS)

**Definition:** Introductory knowledge, skills, and abilities related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial feed and food protection agencies working in concert to protect the U.S. feed and food supply.

**Topic Area TLO:** Describe how collaborative interrelationships of regulatory agencies promote and protect public health in a global environment.

**Topic Area ELOs:**

- Discuss the IFSS elements.
- Explain the IFSS.
- Distinguish regulatory roles in a global environment.
- Explain responsibilities and roles that contribute to the IFSS.
- Describe the global food supply system.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> Basic knowledge of the IFSS concept, development, and sustainment.</p> <p><b>TLO:</b> Discuss the origins, mandates, and drivers of the IFSS.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define relevant terminology.</li> <li>• Discuss the concept of IFSS.</li> <li>• Discuss the development of the IFSS.</li> <li>• Explain IFSS sustainability.</li> <li>• Discuss the relationship between the IFSS and FSMA.</li> <li>• Describe the IFSS role throughout the global food/feed supply.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness of the origin of the IFSS:               <ul style="list-style-type: none"> <li>a. 50 state meetings                   <ul style="list-style-type: none"> <li>▪ Food and Feed Associations</li> <li>▪ FSLTT</li> </ul> </li> <li>b. PFP</li> </ul> </li> <li>• The regulator has a knowledge or awareness of the IFSS mandate:               <ul style="list-style-type: none"> <li>a. What is FSMA?                   <ul style="list-style-type: none"> <li>▪ Briefly describe FSMA</li> </ul> </li> </ul> </li> <li>• The regulator has a knowledge or awareness of the IFSS drivers:               <ul style="list-style-type: none"> <li>a. Collaboration to protect public health</li> <li>b. Uniformity</li> </ul> </li> <li>• The regulator can describe the timeline of IFSS development.</li> <li>• The regulator can give examples of FSMA rules.</li> <li>• The regulator has knowledge or awareness of the need to increase efficiency by leveraging resources across overlapping jurisdictions:               <ul style="list-style-type: none"> <li>a. Stakeholders</li> <li>b. Examples of collaboration                   <ul style="list-style-type: none"> <li>▪ Cooperative agreements / grant, contracts, MOUs                       <ul style="list-style-type: none"> <li>○ Joint work planning</li> <li>○ Rapid Response Team</li> </ul> </li> </ul> </li> </ul> </li> <li>• The regulator knows how the IFSS impacts public health.</li> </ul>

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Unit 2: Stakeholders	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> Government, non-government organizations, and industry with vested interest in the IFSS.</p> <p><b>TLO:</b> Describe the stakeholders within the IFSS.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Identify the types of stakeholders.</li> <li>• Describe how stakeholders influence public policy.</li> <li>• Discuss roles for each type of stakeholder.</li> <li>• Describe the relationship between the Partnership for Food Protection (PFP) and the IFSS.</li> <li>• Identify the associations that comprise the Council of Association Presidents (CAP).</li> <li>• Match feed/food trade associations within their primary target audience.</li> <li>• Describe the role of feed/food safety alliances.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness IFSS stakeholders:               <ul style="list-style-type: none"> <li>a. Industry                   <ul style="list-style-type: none"> <li>▪ Retail</li> <li>▪ Manufacturing</li> <li>▪ Unprocessed</li> <li>▪ Importers</li> </ul> </li> <li>b. Government                   <ul style="list-style-type: none"> <li>▪ FSLTT</li> <li>▪ Military</li> </ul> </li> <li>c. Laboratories</li> <li>d. Representative groups                   <ul style="list-style-type: none"> <li>▪ Alliances</li> <li>▪ Organizations</li> <li>▪ Associations</li> </ul> </li> </ul> </li> <li>• The regulator has a knowledge or awareness of additional IFSS stakeholders:               <ul style="list-style-type: none"> <li>a. Consumers                   <ul style="list-style-type: none"> <li>▪ Human Food</li> <li>▪ Animal Food</li> </ul> </li> </ul> </li> <li>• The regulator can discuss examples and roles of Industry Associations:               <ul style="list-style-type: none"> <li>a. NRA</li> <li>b. GMA</li> <li>c. AFIA</li> </ul> </li> <li>• The regulator can discuss examples and roles of regulatory associations:               <ul style="list-style-type: none"> <li>a. AAFCO</li> <li>b. AFDO</li> <li>c. NEHA</li> </ul> </li> <li>• The regulator can discuss examples and roles of laboratory associations:               <ul style="list-style-type: none"> <li>a. APHL</li> <li>b. Private vs government labs</li> </ul> </li> <li>• The regulator can give examples of collaborative partnerships:               <ul style="list-style-type: none"> <li>a. NCIMS</li> <li>b. ISSC</li> <li>c. FSPCA</li> <li>d. PSA</li> </ul> </li> <li>• The regulator can give examples of international and domestic partnerships.</li> <li>• The regulator can discuss examples and roles of laboratory and academia:               <ul style="list-style-type: none"> <li>a. Consulting</li> <li>b. Process authorities</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>c. Cooperative Extension Services</li> <li>d. Develop emerging technology</li> <li>e. Research</li> <li>• The regulator can describe your role as a stakeholder in the IFSS.</li> <li>• The regulator can describe how you interact with other stakeholders in the IFSS.</li> </ul>
<p><b>Unit 3: Mutual Reliance</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Government agency agreements that support mutual reliance.</p> <p><b>TLO:</b> Discuss how agreements support mutual reliance.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Discuss the use of funding vehicles to support mutual reliance programs.</li> <li>• Discuss the relationship between formal agreements and the IFSS.</li> <li>• Discuss the importance of third-party audit programs.</li> <li>• Describe mutual reliance conducted under cooperative programs.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can define mutual reliance:             <ul style="list-style-type: none"> <li>a. Sharing of resources</li> <li>b. Improved communication</li> <li>c. Utilizing partner strengths</li> </ul> </li> <li>• The regulator can define agreements:             <ul style="list-style-type: none"> <li>a. Contracts</li> <li>b. Compliance agreements</li> <li>c. Cooperative agreements</li> <li>d. MOUs</li> </ul> </li> <li>• The regulator can explain why mutual reliance is important:             <ul style="list-style-type: none"> <li>a. Efficiency                 <ul style="list-style-type: none"> <li>▪ Increased impact</li> <li>▪ Increase work output</li> </ul> </li> <li>b. Improved trust</li> <li>c. Share inspectional and lab results                 <ul style="list-style-type: none"> <li>▪ Equivalent data</li> </ul> </li> <li>d. Interagency cooperation</li> <li>e. Leveraging resources                 <ul style="list-style-type: none"> <li>▪ Joint work planning</li> <li>▪ Joint inspections</li> </ul> </li> </ul> </li> <li>• The regulator can describe how mutual reliance leads to comparability:             <ul style="list-style-type: none"> <li>a. Training</li> <li>b. Joint exercises</li> <li>c. Uniform enforcement of consumer laws</li> <li>d. Quality regulatory Systems</li> <li>e. Program standards</li> </ul> </li> <li>• The regulator can give examples of different types of agreements:             <ul style="list-style-type: none"> <li>a. Inter-agency</li> <li>b. Industry and agency</li> </ul> </li> <li>• The regulator can discuss how mutual reliance agreements support the IFSS.</li> </ul>
<p><b>Unit 4: Program Standards</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness of how program standards affect efficiency and uniformity.</li> </ul>

## IFSS Framework – Basic Level Gen Eds

	<ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness of the importance of building a quality management system.</li> <li>• The regulator has a knowledge or awareness of how the standards may help protect public health.</li> <li>• The regulator has a knowledge or awareness of the focus on prevention.</li> <li>• The regulator has a knowledge or awareness of whether your program is enrolled in program standards.</li> <li>• The regulator can explain increased efficiency and uniformity:             <ul style="list-style-type: none"> <li>a. Building infrastructure</li> <li>b. Mutual reliance</li> <li>c. Consistency between agencies</li> <li>d. Collaboration</li> </ul> </li> <li>• The regulator can explain the importance of a quality management system:             <ul style="list-style-type: none"> <li>a. Continuous improvement</li> <li>b. Known standards</li> <li>c. Focus on prevention</li> <li>d. Legally defensible regulatory system</li> </ul> </li> <li>• The regulator can discuss the impact of standards on the protection of public health:             <ul style="list-style-type: none"> <li>a. Faster incident response time</li> <li>b. Risk based inspections</li> <li>c. Consumer and industry confidence</li> </ul> </li> <li>• The regulator can explain the focus on prevention:             <ul style="list-style-type: none"> <li>a. Benefits of risk-based inspections</li> <li>b. Importance of sampling</li> <li>c. Benefits of uniform program standards (UPS)</li> <li>d. Reduction in foodborne illness</li> </ul> </li> </ul>
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## IFSS Framework – Basic Level Gen Eds

### B15 Jurisdiction

**Definition:** Introductory knowledge, skills, and abilities related to various regulatory agencies and their authority over feed and food.

**Topic Area TLO:** Discuss which agencies have authority to conduct specific regulatory activities.

**Topic Area ELOs:**

- Discuss authority for regulatory activities.
- Describe the importance of collaboration with other agencies.
- Determine which agency has authority to conduct specific regulatory activities.
- Identify agency responsibilities related to program area.
- Explain the statutory authority for jurisdiction.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> Base knowledge of jurisdiction authority related to feed and food programs.</p> <p><b>TLO:</b> Describe jurisdictional authority related to feed and food programs.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define relevant terminology.</li> <li>• Describe statutory authority for feed/food regulation.</li> <li>• Identify jurisdictional responsibilities for feed and food regulated products.</li> <li>• Discuss differences in federal, state, local, tribal, and territorial jurisdiction.</li> <li>• Discuss dual-agency jurisdictions.</li> <li>• Describe the relationships between agencies.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness of their agency’s statutory authority:               <ul style="list-style-type: none"> <li>a. Know what you regulate</li> <li>b. Know what law your authority comes from</li> </ul> </li> <li>• The regulator has a knowledge or awareness of state, local, and federal laws and rules associated with the regulator’s feed and food program.</li> <li>• The regulator can recognize the difference between a statute and a regulation</li> <li>• The regulator can discuss the regulatory implications of overlapping authority.</li> <li>• The regulator can differentiate between delegated and statutory authority.</li> <li>• The regulator has a knowledge or awareness of when you don’t have authority:               <ul style="list-style-type: none"> <li>a. Know where to refer what you don’t regulate                   <ul style="list-style-type: none"> <li>▪ Local</li> <li>▪ State</li> <li>▪ Federal                       <ul style="list-style-type: none"> <li>○ Interstate commerce</li> </ul> </li> </ul> </li> </ul> </li> <li>• The regulator can list state, local, and federal laws and rules associated with the regulator’s feed and food program:               <ul style="list-style-type: none"> <li>a. FD&amp;C Act</li> <li>b. State laws and regulations</li> <li>c. FSMA</li> <li>d. Local ordinances</li> </ul> </li> <li>• The regulator can cite where the regulator’s authority comes from.</li> </ul>

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<p><b>Unit 2: Law</b></p> <p><b>Definition:</b> Base knowledge of the statutes, regulations and ordinances related to feed and food products.</p> <p><b>TLO:</b> Discuss the creation of laws related to feed and food products.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe how laws are created.</li> <li>• Differentiate between statutes, regulations, and ordinances.</li> <li>• Describe the difference between interstate, intrastate and international commerce laws.</li> <li>• Describe statutory authority within each regulatory agency.</li> <li>• Describe the concept of due process.</li> <li>• Give examples of statutory limits of regulations.</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness of the origin of laws:             <ul style="list-style-type: none"> <li>a. History of FDA creation in 1906</li> <li>b. Reaction to emerging public health issues</li> <li>c. Special interest</li> </ul> </li> <li>• The regulator has a knowledge or awareness of the development of legislation:             <ul style="list-style-type: none"> <li>a. Different levels of government</li> <li>b. Branches of government</li> <li>c. Legislative process</li> </ul> </li> <li>• The regulator can discuss how science informs laws.</li> <li>• The regulator can give examples of an emerging health issue that resulted in a regulation change.</li> <li>• The regulator can discuss “adoption by reference”:             <ul style="list-style-type: none"> <li>a. Food Code</li> <li>b. PMO</li> <li>c. CFRs</li> </ul> </li> </ul>
<p><b>Unit 3: Crossing Boundaries</b></p> <p><b>Definition:</b> Base knowledge of interagency collaboration required for cross jurisdictional issues related to feed and food products.</p> <p><b>TLO:</b> Describe collaborative authority between agencies regulating feed and food products.</p> <p><b>ELOs:</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness of shared authority:             <ul style="list-style-type: none"> <li>a. More than one agency may have jurisdiction</li> </ul> </li> <li>• The regulator has a knowledge or awareness that one agency will be the lead.</li> <li>• The regulator can explain the concept of the delegation of authority.</li> <li>• The regulator can discuss a situation where another agency may also have jurisdiction over a firm that you regulate.</li> <li>• The regulator can explain that agreements may define</li> </ul>

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<ul style="list-style-type: none"> <li>• Discuss the IFSS concept.</li> <li>• Give examples of dual-agency jurisdictions.</li> <li>• Describe state cooperative programs.</li> <li>• Give examples of agency collaboration.</li> </ul>	<p>shared authority between agencies.</p> <ul style="list-style-type: none"> <li>• The regulator can give an example of delegated authority.</li> </ul>
<p><b>Unit 4: Inter-agency Agreements</b></p> <p><b>Definition:</b> Base knowledge of collaboration required for interagency issues related to feed and food products.</p> <p><b>TLO:</b> Describe formal agreements between agencies regulating feed and food products.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe the purpose of a MOU.</li> <li>• Discuss the purpose of delegated authority.</li> <li>• Describe the purpose of cooperative agreements.</li> <li>• Give examples of interagency agreements.</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness of the existence of formal agreements between agencies.</li> <li>• The regulator has knowledge or awareness that agreements may mandate additional performance requirements:             <ol style="list-style-type: none"> <li>a. Training</li> <li>b. Reporting</li> <li>c. Certifications</li> </ol> </li> <li>• The regulator can give examples of formal agreements:             <ol style="list-style-type: none"> <li>a. MOUs                 <ul style="list-style-type: none"> <li>▪ International</li> <li>▪ Associations</li> <li>▪ OGAs</li> </ul> </li> <li>b. FDA District policy</li> <li>c. State contract</li> <li>d. Cooperative agreements</li> <li>e. State audits</li> </ol> </li> </ul>

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### B16 Labeling

**Definition:** Introductory knowledge, skills, and abilities related to labeling requirements, and the components of feed and food product labels.

**Topic Area TLO:** Explain label requirements.

**Topic Area ELOs:**

- Describe the types of labels.
- Review product labels for regulatory compliance.
- Recognize product-specific label requirements.
- Describe product label requirements.
- Identify product label components.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> Basic knowledge of labeling.</p> <p><b>TLO:</b> Discuss labeling fundamentals.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>○ Define relevant terminology.</li> <li>○ Discuss regulatory requirements for labeling.</li> <li>○ Discuss the purpose of supplemental labeling.</li> <li>○ Locate available resources.</li> <li>○ Explain how labels provide consumer information.</li> <li>○ Explain the purpose for product labeling.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can discuss two purposes of labeling:               <ul style="list-style-type: none"> <li>a. Consumer knows what they are purchasing</li> <li>b. Comparison between similar products</li> <li>c. Deter purchase of undesirable ingredients (allergens)</li> <li>d. Advertising restrictions</li> <li>e. Public health rationale of labeling</li> <li>f. Triggers for recall</li> <li>g. Economically motivated adulteration</li> <li>h. Traceforward and traceback</li> <li>i. Highly susceptible population</li> <li>j. Misbranding</li> </ul> </li> <li>• The regulator can identify three regulatory labeling requirements:               <ul style="list-style-type: none"> <li>a. Jurisdiction specific requirements</li> <li>b. Additives</li> <li>c. Bulk labeling vs retail labeling requirements</li> <li>d. 21 Code of Federal Register (CFR) 101</li> <li>e. Specific instructions</li> <li>f. Specifics of graphics</li> <li>g. Labels should be legible</li> <li>h. All packaged foods should be labeled</li> <li>i. Making false health claims</li> <li>j. Standards of identity (common names)</li> <li>k. English</li> <li>l. Restrictions on product use (between animal species)</li> <li>m. Purpose of product (feed and pet food)</li> <li>n. Guaranteed analysis (feed and pet food)</li> </ul> </li> <li>• The regulator can discuss two requirements for a specific label:               <ul style="list-style-type: none"> <li>a. Principle display panel</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>b. Net weight in metric for imports</li> <li>c. Manufacturer/distributor</li> <li>d. Country of origin labeling (COOL)</li> <li>e. Supplemental labeling</li> <li>f. Affordable Care Act (ACA) Labeling</li> <li>g. Safe handling instructions</li> <li>h. Cooking/handling instructions</li> <li>i. Allergens</li> <li>j. Ingredients</li> <li>k. Information display panel</li> <li>l. Nutritional Labeling and Education Act (NLEA)</li> <li>m. Infant formula</li> </ul> <ul style="list-style-type: none"> <li>• The regulator can discuss four purposes of labeling.</li> <li>• The regulator can identify six regulatory requirements for a specific label.</li> </ul>
<p><b>Unit 2: Labeling Laws and Regulations</b></p> <p><b>Definition:</b> Basic knowledge of labeling laws and regulations.</p> <p><b>TLO:</b> Describe the authority for labeling.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Identify the agency that regulates a commodity.</li> <li>• Identify the labeling requirements for specific commodities.</li> <li>• Describe the process for verifying label compliance.</li> <li>• Identify commodities exempt from labeling requirements.</li> <li>• Distinguish between agency labeling requirements.</li> <li>• Explain the recall rationale for improperly labeled products.</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can list two labeling authorities:             <ul style="list-style-type: none"> <li>a. Federal trade commission</li> <li>b. Food and Drug Administration (FDA)</li> <li>c. U. S. Department of Agriculture (USDA)</li> <li>d. State</li> <li>e. Local</li> <li>f. Tribal</li> <li>g. Territorial</li> <li>h. Centers for Disease Control and Prevention (CDC)</li> <li>i. National Shellfish Sanitation Program (NSSP)</li> </ul> </li> <li>• The regulator can list two federal acts:             <ul style="list-style-type: none"> <li>a. Food, Drug and Cosmetic Act (FD &amp; C)</li> <li>b. Federal Meat Inspection Act (FMIA)</li> <li>c. Patient Protection and Affordable Care Act (PPACA)</li> <li>d. Poultry Products Inspection Act</li> <li>e. Egg Products Inspection Act</li> <li>f. Agricultural Marketing Act</li> <li>g. Fair Packaging and Labeling Act (FPLA)</li> <li>h. Nutrition Label Education Act (NLEA)</li> </ul> </li> <li>• The regulator can list five labeling authorities.</li> <li>• The regulator can list four federal acts.</li> </ul>
<p><b>Unit 3: Labeling Components</b></p> <p><b>Definition:</b> Basic knowledge of</p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can identify the two required panels:</li> </ul>

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<p>label requirements.</p> <p><b>TLO:</b> Describe the components of a label.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe required components of a label.</li> <li>• Discuss label claims.</li> <li>• Determine if ingredients are approved for use.</li> <li>• Describe accompanying labeling.</li> <li>• Explain labeling format requirements.</li> <li>• Explain the net weight / net quantity of contents requirements.</li> </ul>	<ul style="list-style-type: none"> <li>a. Principle display panel</li> <li>b. Information panel</li> <li>c. Accompanying information</li> <li>d. The regulator can list three requirements found on the principle display panel.</li> <li>e. Name of food</li> <li>f. Net quantity of contents</li> <li>g. Pictures</li> <li>h. Size of letters (font)</li> <li>i. English language</li> <li>• The regulator can list three requirements found on the information panel:             <ul style="list-style-type: none"> <li>a. Manufactured for/distributed by</li> <li>b. Ingredients in plain language</li> <li>c. Colors (Yellow #5, etc.)</li> <li>d. Ingredients listed in order by weight</li> <li>e. Nutrition fact panel</li> <li>f. Serving size</li> <li>g. Allergen declaration</li> <li>h. English language</li> </ul> </li> <li>• The regulator can list three examples of accompanying information:             <ul style="list-style-type: none"> <li>a. Country of Origin (COOL)</li> <li>b. Sulfites</li> <li>c. Organics</li> <li>d. Safe food handling</li> <li>e. Genetically modified organism (GMO) -may be required labeling in some states</li> <li>f. Claims</li> <li>g. Disclosure (dietary supplements and medical foods)</li> <li>h. Pamphlets (retail)</li> <li>i. Date marking (retail, egg, milk)</li> <li>j. Lot number</li> <li>k. Best if used by</li> <li>l. Keep refrigerated</li> <li>m. Refrigerate after opening</li> <li>n. Unpasteurized juice warning statement (retail)</li> </ul> </li> <li>• The regulator can explain the importance of three items found on the principle display panel.</li> <li>• The regulator can explain the importance of three of the items found on the information panel.</li> </ul>
<p><b>Unit 4: Food</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Basic knowledge of food labeling requirements.</p>	<ul style="list-style-type: none"> <li>• The regulator can describe an alternate principle display panel.</li> <li>• The regulator can identify safe handling label on</li> </ul>

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<p><b>TLO:</b> Describe the labeling requirements for food.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Identify the principle display panel of a food label.</li> <li>• Identify the alternate principle display panel.</li> <li>• Discuss when a handling/holding statement is required.</li> <li>• Identify food label requirements for susceptible populations.</li> <li>• Explain the labeling requirements for allergens.</li> <li>• Identify the labeling requirements for dietary supplements.</li> </ul>	<p>packaged raw meat and poultry, and shell eggs.</p> <ul style="list-style-type: none"> <li>• The regulator can identify the dietary supplement label:             <ol style="list-style-type: none"> <li>a. No unsubstantiated health claims</li> <li>b. Disclosure</li> <li>c. Supplemental facts</li> </ol> </li> <li>• The regulator can identify the allergen labeling requirements:             <ol style="list-style-type: none"> <li>a. Common name</li> <li>b. Contains statement</li> </ol> </li> <li>• The regulator can identify a labeling requirement for highly susceptible populations:             <ol style="list-style-type: none"> <li>a. Consumer advisory</li> <li>b. Label of unpasteurized juices</li> <li>c. Infant formula</li> </ol> </li> <li>• The regulator can list a component of the dietary supplement label.</li> <li>• The regulator can list the eight allergens that require allergen labeling.</li> <li>• The regulator can identify the three foods listed on a consumer advisory.</li> </ul>
<p><b>Unit 5: Feed</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can recognize the seven required components of a standard feed label:             <ol style="list-style-type: none"> <li>a. Product name</li> <li>b. Product purpose statement</li> <li>c. Guaranteed analysis</li> <li>d. Ingredient statement</li> <li>e. Manufacture name &amp; address</li> <li>f. Net weight</li> <li>g. Feeding directions</li> </ol> </li> <li>• The regulator can recognize the required components of a pet food label:             <ol style="list-style-type: none"> <li>a. Seven listed above PLUS:                 <ul style="list-style-type: none"> <li>▪ American Association of Feed Control Officials (AAFCO) Nutritional Adequacy Statement, or the AAFCO Nutrient Profile Statement</li> <li>▪ Calorie count</li> </ul> </li> </ol> </li> <li>• The regulator can recognize the required components of a pet treat label:             <ol style="list-style-type: none"> <li>a. Same as standard label – no American Association of Feed Control Officials (AAFCO) Nutrient Profile required</li> </ol> </li> <li>• The regulator can recognize required components of a medicated feed labels:             <ol style="list-style-type: none"> <li>a. Active drug ingredient (name and amount)</li> <li>b. Medical purpose</li> </ol> </li> </ul>

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	<ul style="list-style-type: none"><li>c. Caution statement</li><li>d. Warning statement</li><li>• The regulator has knowledge or awareness of the format (ordering) of the required components of a standard feed label.</li><li>• The regulator can give examples of optional claims/components on a pet food label e.g., claims, advertising).</li></ul>
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## IFSS Framework – Basic Level Gen Eds

### B19 Pest Control

**Definition:** The management of pests that can be perceived to be detrimental to the production of safe human food and food for animals.

**Topic Area TLO:** Explain how pest activity can impact food safety.

**Topic Area ELOs:**

- Describe integrated pest management.
- Describe a pest infestation.
- Recognize when to take regulatory action.
- Discuss agency options for dealing with pest issues.
- Describe pest control measures.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> Knowledge, skills, and abilities to recognize pests and their significance to human and animal health.</p> <p><b>TLO:</b> Discuss pests of significance to human and animal health.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Give examples of types of pests.</li> <li>• Differentiate between types of pests.</li> <li>• Discuss the public health significance of pests.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can give examples of pests:               <ol style="list-style-type: none"> <li>a. Birds</li> <li>b. Rodents</li> <li>c. Insects</li> <li>d. Animals</li> </ol> </li> <li>• The regulator can discuss pest infestation in a facility:               <ol style="list-style-type: none"> <li>a. Insects</li> <li>b. Rodents</li> </ol> </li> <li>• The regulator can discuss the origins of significant pests:               <ol style="list-style-type: none"> <li>a. Geography</li> </ol> </li> <li>• The regulator can discuss the public health significance of pests:               <ol style="list-style-type: none"> <li>a. Zoonotic diseases</li> <li>b. Pests as a vector</li> </ol> </li> <li>• The regulator can identify pests of public health significance:               <ol style="list-style-type: none"> <li>a. Insects</li> <li>b. Rodents</li> </ol> </li> <li>• The regulator can explain the public health significance of pests.</li> <li>• The regulator can give an example of a zoonotic disease:               <ol style="list-style-type: none"> <li>a. Bird flu</li> <li>b. Rabies</li> <li>c. Hanta virus</li> </ol> </li> </ul>

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<p><b>Unit 2: Facility Design</b></p> <p><b>Definition:</b> Knowledge related to facility design to control pests.</p> <p><b>TLO:</b> Discuss the importance of facility design for pest control.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Give examples of pest exclusion in facility design.</li> <li>• Discuss how plant and grounds maintenance will reduce harborage areas.</li> <li>• Discuss the importance of pesticide storage areas.</li> <li>• Discuss how pest control station layout would be used in a facility to control pests.</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can identify methods of pest exclusion:             <ol style="list-style-type: none"> <li>a. Screens</li> <li>b. Tight doors</li> <li>c. Air curtains</li> <li>d. Engineering controls</li> <li>e. Strip curtains</li> </ol> </li> <li>• The regulator can discuss the importance of plants and grounds maintenance:             <ol style="list-style-type: none"> <li>a. Harborage areas</li> <li>b. Weeds</li> <li>c. Standing water</li> <li>d. Dumpster</li> <li>e. Trash disposal</li> </ol> </li> <li>• The regulator can discuss why bait station layout is important.</li> <li>• The regulator can discuss the importance of proper pesticide storage:             <ol style="list-style-type: none"> <li>a. Labeling</li> <li>b. Dedicated areas</li> <li>c. Locked storage</li> </ol> </li> <li>• The regulator can recognize ineffective methods of pest exclusion:             <ol style="list-style-type: none"> <li>a. Torn screen</li> <li>b. Short curtains</li> <li>c. Improper door fit</li> </ol> </li> <li>• The regulator can recognize the improper placement/location of bait stations.</li> <li>• The regulator can explain how proper pesticide storage prevents adulteration.</li> </ul>
<p><b>Unit 3: Sanitation Program</b></p> <p><b>Definition:</b> Knowledge, skills, and abilities related to sanitation programs for pest control.</p> <p><b>TLO:</b> Describe sanitation practices for pest control.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Recognize regulations associated with pest management (GMPs, GAPs,</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can identify guidance documents, laws, and regulations to develop a sanitation program for pest management:             <ol style="list-style-type: none"> <li>a. GMPs</li> <li>b. GRPs</li> <li>c. GAPs</li> <li>d. Defect action levels (allowable limits: wings, legs)</li> <li>e. 8 points of sanitation (HACCP)</li> </ol> </li> <li>• The regulator can describe proper labeling and storage of chemicals used for pest control.</li> <li>• The regulator can describe sanitation methods to control pests.</li> </ul>

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<p>GRPs).</p> <ul style="list-style-type: none"> <li>• Discuss sanitation measures to prevent adulteration from pests.</li> <li>• Describe measures to eliminate sources that attract pests.</li> <li>• Identify approved chemicals for pest control.</li> <li>• Discuss importance of pesticide chemical labeling.</li> <li>• Discuss importance of pesticide chemical storage.</li> <li>• Recognize defect action level list.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can use guidance documents, laws, and regulations to develop a sanitation program for pest management:             <ol style="list-style-type: none"> <li>a. GMPs</li> <li>b. GRPPs</li> <li>c. GAPs</li> <li>d. Defect action levels</li> </ol> </li> <li>• The regulator can assess proper labeling and storage of chemicals used for pest control.</li> <li>• The regulator can give examples of sanitation methods for pest control:             <ol style="list-style-type: none"> <li>a. Cleaning schedule</li> <li>b. Monitoring</li> <li>c. Training (SSOP/prerequisite programs)</li> <li>d. Maintenance of grounds</li> </ol> </li> <li>• The regulator can recommend ways to prevent adulteration in a given scenario:             <ol style="list-style-type: none"> <li>a. Cross contamination</li> <li>b. Removing food sources</li> <li>c. Closed containers</li> <li>d. Waste removal</li> </ol> </li> </ul>
<p><b>Unit 4: Detection</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Knowledge, skills, and abilities to detect pests while conducting regulatory activities.</p> <p><b>TLO:</b> Discuss detection of pests.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Recognize evidence of presence of pests.</li> <li>• Determine what equipment is needed for detection of pests.</li> <li>• Discuss agency procedures for pest infestation.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can list equipment needed to detect pests:             <ol style="list-style-type: none"> <li>a. Black light</li> <li>b. Flashlight</li> <li>c. Tracking powder</li> </ol> </li> <li>• The regulator can list agency procedures for addressing pest infestation:             <ol style="list-style-type: none"> <li>a. Seizure</li> <li>b. Place product on hold</li> <li>c. Destruction of product</li> </ol> </li> <li>• The regulator can list evidence of pest activity.</li> <li>• The regulator can use equipment needed to detect pests.</li> <li>• The regulator can implement agency procedures for addressing pest infestation:             <ol style="list-style-type: none"> <li>a. Seizure</li> <li>b. Place product on hold</li> <li>c. Destruction of product</li> </ol> </li> <li>• The regulator can identify evidence of pest activity:             <ol style="list-style-type: none"> <li>a. Urine stains</li> <li>b. Rodent droppings</li> <li>c. Gnawing</li> <li>d. Nesting materials</li> <li>e. Odors</li> </ol> </li> </ul>

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<p><b>Unit 5: Integrated Pest Management</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can define integrated pest management.</li> <li>• The regulator can give examples of effective pest control measures:             <ul style="list-style-type: none"> <li>a. Prevention/exclusion</li> <li>b. Pesticide application</li> <li>c. Bait stations</li> <li>d. Fly strips</li> <li>e. Traps</li> <li>f. Bug zappers</li> </ul> </li> <li>• The regulator can describe why pest control is necessary.</li> <li>• The regulator can discuss how a pest control plan is used:             <ul style="list-style-type: none"> <li>a. Training</li> <li>b. Monitoring</li> <li>c. Scheduled treatment</li> </ul> </li> <li>• The regulator can identify some approved pesticides and application methods:             <ul style="list-style-type: none"> <li>a. Certified or trained pest control operator</li> </ul> </li> <li>• The regulator can explain how integrated pest management is used to control pests.</li> <li>• The regulator can recognize when an appropriate control measure is needed.</li> <li>• The regulator can explain benefits of a pest control plan:             <ul style="list-style-type: none"> <li>a. Prevent adulteration of human and animal food</li> <li>b. Reduction or prevention of economic loss</li> <li>c. Enhanced regulatory compliance</li> <li>d. Identify problem area</li> </ul> </li> </ul>
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**IFSS Framework – Basic Level Gen Eds  
B20 Plumbing**

**Definition:** Knowledge, skills, and abilities related to the delivery, distribution or storage of potable and non-potable water in a manufacturing food facility and retail food establishment.

**Topic Area TLO (Terminal Learning Objective): Discuss how plumbing affects public health.**

**Topic Area ELOs (Enabling Learning Objective):**

- Explain the significance of plumbing.
- Explain the regulatory significance of water systems.
- Consider water source
- Discuss agency authority related to plumbing.
- Identify plumbing issues.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> An introduction to plumbing systems to keep water and food safe.</p> <p><b>TLO:</b> Discuss key concepts in plumbing.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the public health significance of plumbing design.</li> <li>• Identify water source.</li> <li>• Describe the water system.</li> <li>• Describe the concept of backflow.</li> <li>• Differentiate between an indirect and direct connection.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can give examples of public health concerns related to poor or improper plumbing designs:               <ul style="list-style-type: none"> <li>a. Hazard</li> <li>b. Connection between safe and unsafe supplies</li> <li>c. Contaminating water source</li> <li>d. Contaminating food</li> </ul> </li> <li>• The regulator can distinguish between a public and a private water supply.</li> <li>• The regulator can distinguish between potable and non-potable water.</li> <li>• The regulator can list some components of a water system:               <ul style="list-style-type: none"> <li>a. Pipes</li> <li>b. Pumps</li> <li>c. Tanks</li> <li>d. Fixtures</li> <li>e. Source</li> </ul> </li> <li>• The regulator can describe the concept of backflow:               <ul style="list-style-type: none"> <li>a. Back siphonage</li> <li>b. Back pressure</li> <li>c. Prevention</li> </ul> </li> <li>• The regulator can recognize examples of public health concerns related to poor or improper plumbing design.</li> <li>• The regulator can discuss the significance of a public and private water supply.</li> <li>• The regulator can discuss the significance of potable and non-potable water.</li> <li>• The regulator can elaborate on the concerns of individual water system components.</li> <li>• The regulator can give an example of indirect and direct connections:               <ul style="list-style-type: none"> <li>a. Air gap</li> </ul> </li> </ul>

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**B20 Plumbing**

	<ul style="list-style-type: none"> <li>b. Air break</li> <li>c. Tight connections/Fixed connection</li> </ul>
<p><b>Unit 2: Water Source</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Knowledge related to water sources.</p> <p><b>TLO:</b> Recognize the public health significance of protecting a water source.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Differentiate between public and private water supply systems.</li> <li>• List well construction considerations.</li> <li>• Identify types of treatment systems.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can give examples of the public health significance of unprotected water sources:             <ul style="list-style-type: none"> <li>a. Hazard</li> <li>b. Connection between safe and unsafe supplies</li> <li>c. Contaminating water source</li> <li>d. Contaminating food</li> </ul> </li> <li>• The regulator can differentiate between public and private water supply systems:             <ul style="list-style-type: none"> <li>a. Municipal or Public</li> <li>b. Well or Private</li> <li>c. Other – Spring</li> </ul> </li> <li>• The regulator can list well construction considerations:             <ul style="list-style-type: none"> <li>a. Pitless adapter</li> <li>b. Diversion ditches</li> <li>c. Fencing</li> <li>d. Drainage</li> <li>e. Covers or housing</li> <li>f. Vent screen</li> <li>g. Dug</li> <li>h. Drilled</li> </ul> </li> <li>• The regulator can list different types of water treatment systems:             <ul style="list-style-type: none"> <li>a. UV systems</li> <li>b. Chlorinator</li> <li>c. Reverse Osmosis</li> </ul> </li> <li>• The regulator can recognize examples of public health concerns related to unprotected water sources.</li> <li>• The regulator can match terms with images of water supply systems.</li> <li>• The regulator can match terms with images of well construction considerations.</li> </ul>
<p><b>Unit 3: Wastewater System</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Knowledge related to wastewater systems.</p> <p><b>TLO:</b> Discuss wastewater systems.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Identify wastewater systems.</li> <li>• Differentiate between public and private wastewater systems.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can identify wastewater systems:             <ul style="list-style-type: none"> <li>a. Public/municipal</li> <li>b. Private (septic)</li> </ul> </li> <li>• The regulator can give examples of private wastewater systems:             <ul style="list-style-type: none"> <li>a. Septic</li> <li>b. Private wastewater treatment plants</li> <li>c. Holding tanks</li> </ul> </li> </ul>

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B20 Plumbing**

<p><b>Unit 4: Backflow Prevention</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Knowledge of backflow prevention methods.</p> <p><b>TLO:</b> Discuss methods for preventing contamination.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define cross connection.</li> <li>• Discuss methods for preventing cross connections.</li> <li>• Identify types of backflow prevention devices.</li> <li>• Discuss considerations for selecting a backflow prevention device.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can define cross connection:             <ol style="list-style-type: none"> <li>a. Water</li> <li>b. Waste</li> </ol> </li> <li>• The regulator can list methods for preventing cross connections:             <ol style="list-style-type: none"> <li>a. Air gap</li> <li>b. Air break</li> <li>c. Backflow prevention devices</li> </ol> </li> <li>• The regulator can give examples of backflow prevention devices:             <ol style="list-style-type: none"> <li>a. Hose bib vacuum break</li> <li>b. Dual check valve with an atmospheric vent</li> <li>c. Reduced pressure zone backflow preventer (RPZ)</li> <li>d. Check valves</li> <li>e. Pressure vacuum breakers</li> </ol> </li> <li>• The regulator can list considerations for selecting backflow prevention devices:             <ol style="list-style-type: none"> <li>a. Backflow                 <ul style="list-style-type: none"> <li>▪ Back pressure</li> <li>▪ Back siphonage</li> </ul> </li> <li>b. Continuous or non-continuous pressure</li> <li>c. Low or high hazard</li> </ol> </li> <li>• The regulator can recognize methods for preventing cross connections.</li> <li>• The regulator can differentiate between an air gap and an air break.</li> <li>• The regulator can recognize types of backflow prevention devices.</li> </ul>
<p><b>Unit 5: Jurisdictional Authority</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Knowledge related to agency authority over water, waste water, and plumbing systems.</p> <p><b>TLO:</b> Describe agency authority.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Identify agency’s authority pertaining to water systems.</li> <li>• Identify agency’s authority pertaining to wastewater systems.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can identify which agencies may have authority pertaining to water systems:             <ol style="list-style-type: none"> <li>a. Local</li> <li>b. State</li> <li>c. Federal</li> </ol> </li> <li>• The regulator can identify which agencies may have authority pertaining to wastewater systems:             <ol style="list-style-type: none"> <li>a. Local</li> <li>b. State</li> <li>c. Federal</li> </ol> </li> <li>• The regulator can identify which agencies may have authority pertaining to plumbing systems:             <ol style="list-style-type: none"> <li>a. Local</li> <li>b. State</li> <li>c. Federal</li> </ol> </li> <li>• The regulator can list which regulations are used by the</li> </ul>

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**B20 Plumbing**

<ul style="list-style-type: none"><li>• Identify agency's authority pertaining to plumbing systems.</li></ul>	<p>regulator's jurisdiction.</p> <ul style="list-style-type: none"><li>• The regulator can list which regulations are used by the regulator's jurisdiction.</li></ul>
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## IFSS Framework – Basic Level Gen Eds

### B22 Professionalism

**Definition:** Introductory knowledge, skills, and abilities related to ethics, integrity, and personal conduct during job-related activities.

**Topic Area TLO:** Exhibit the use of integrity and positive interpersonal conduct in the performance of professional and personal activities.

**Topic Area ELOs:**

- Explain standards for professional conduct.
- Demonstrate professional conduct.
- Distinguish between professional and unprofessional conduct.
- Observe the agency’s ethics and personal conduct policies.
- Apply professionalism to specific situations.

<p><b>Unit 1: Foundations</b></p> <p><b>Definition:</b> Base knowledge of professionalism related to feed and food programs.</p> <p><b>TLO:</b> Explain professionalism.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define relevant terminology.</li> <li>• Give examples of professional and unprofessional behavior.</li> <li>• Explain the legal principles of professionalism.</li> <li>• Explain moral principles of professionalism.</li> <li>• Discuss the concept of the “perception of impropriety”.</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator has a knowledge or awareness of their agency’s policies regarding conduct.</li> <li>• The regulator can describe professional appearance:             <ul style="list-style-type: none"> <li>a. Dress to conditions</li> <li>b. Personal hygiene</li> </ul> </li> <li>• The regulator can describe what professional communication is:             <ul style="list-style-type: none"> <li>a. Language usage</li> <li>b. Direct communicators</li> <li>c. Appropriate vocabulary</li> <li>d. Active listening</li> <li>e. Unbiased</li> </ul> </li> <li>• The regulator can list attributes associated with professionalism:             <ul style="list-style-type: none"> <li>a. Respectfulness</li> <li>b. Civility</li> <li>c. Character</li> <li>d. Dedication to human and animal health</li> </ul> </li> <li>• The regulator can recognize professionalism in others.</li> <li>• The regulator can calibrate professional behavior to working conditions and environment.</li> </ul>
<p><b>Unit 2: Ethics</b></p> <p><b>Definition:</b> Core knowledge of professional conduct that elicits trust and demonstrates integrity.</p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can discuss ethics:             <ul style="list-style-type: none"> <li>a. Treat people fairly and equally</li> <li>b. Transparency in motivations</li> <li>c. Make and sound and rational choices</li> </ul> </li> </ul>

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<p><b>TLO:</b> Discuss the principles of business and personal integrity within the work environment.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the importance of an agency code of conduct.</li> <li>• Discuss the components of a code of conduct.</li> <li>• Explain confidentiality.</li> <li>• Give examples of conflict of interest.</li> <li>• Discuss purpose of ethical behavior in a work environment.</li> <li>• Give examples of ethical and unethical behavior.</li> <li>• Explain the organization’s values.</li> </ul>	<ul style="list-style-type: none"> <li>d. Be unbiased</li> <li>e. Stay faithful in your personal value and ethics</li> <li>f. Follow the law</li> <li>• The regulator can describe professional behavior:             <ul style="list-style-type: none"> <li>a. Shouldn’t obstruct the work environment</li> <li>b. Don’t be selfish in your business relationships</li> <li>c. Be a team player</li> <li>d. Deliver on time</li> <li>e. Represent yourself in a positive way</li> </ul> </li> <li>• The regulator can describe professional credibility:             <ul style="list-style-type: none"> <li>a. Authenticity</li> <li>b. Honest trustworthy truthful</li> </ul> </li> <li>• The regulator sets a positive example for others.</li> <li>• The regulator can recognize integrity in ambiguous situations.</li> <li>• The regulator can demonstrate ethical consistency in actions.</li> </ul>
<p><b>Unit 3: Conduct</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Expectations of personal behaviors.</p> <p><b>TLO:</b> Discuss the profession’s expectations of behavior.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Differentiate between acceptable and unacceptable behaviors.</li> <li>• Give examples of acceptable and unacceptable behaviors.</li> <li>• Differentiate between objective and subjective behavior.</li> <li>• Give examples of objective and subjective behavior.</li> <li>• Differentiate between bias and unbiased behaviors.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can discuss agency’s expectation of behavior:             <ul style="list-style-type: none"> <li>a. Shouldn’t obstruct the work environment</li> <li>b. Don’t be selfish in your business relationships</li> <li>c. Be a team player</li> <li>d. Deliver on time</li> <li>e. Represent yourself in a positive way</li> <li>f. Etc.</li> </ul> </li> <li>• The regulator can distinguish between acceptable and unacceptable behavior.</li> <li>• The regulator has a knowledge or awareness of the regulator’s agency’s policies.</li> <li>• The regulator can demonstrate consistency in professional behavior.</li> <li>• The regulator can set a positive example for others.</li> </ul>

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<ul style="list-style-type: none"> <li>Identify societal customary behavior appropriate for the workplace.</li> <li>Explain the importance of recognizing differences in workplace customs.</li> </ul>	
<p><b>Unit 4: Personal Management</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> The individual's responsibility for their actions and behaviors.</p> <p><b>TLO:</b> Discuss the impact of subjective personal behaviors in the workplace.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>Explain subjective personal behavior.</li> <li>Give examples of subjective personal behaviors.</li> <li>Recognize the need to modify subjective personal behaviors.</li> <li>Identify resources to address negative subjective personal behaviors.</li> <li>Explain the importance of being accountable for actions.</li> <li>Identify the components to manage time in the workplace.</li> </ul>	<ul style="list-style-type: none"> <li>The regulator can provide examples of subjective behavior that would impact the workplace:             <ol style="list-style-type: none"> <li>Playing inappropriate music</li> <li>Offensive clothing</li> <li>Offensive jokes</li> <li>Offensive language</li> <li>Off color remarks</li> <li>Poor personal hygiene</li> <li>Offensive Tattoo</li> <li>Inappropriate media usage</li> <li>Bullying</li> <li>Body language</li> </ol> </li> <li>The regulator can provide examples of how those behaviors impact the workplace:             <ol style="list-style-type: none"> <li>Loss production</li> <li>Communication degradation</li> <li>Credibility</li> <li>Contributes to a hostile environment</li> </ol> </li> <li>The regulator can give examples of appropriate reactions to negative behaviors:             <ol style="list-style-type: none"> <li>Agency</li> <li>Personal</li> </ol> </li> <li>The regulator can give examples of appropriate action to negative behaviors:             <ol style="list-style-type: none"> <li>Agency</li> <li>Personal</li> </ol> </li> </ul>
<p><b>Unit 5: Communications</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Disseminating, receiving, or exchanging information with other individuals in a clear, concise, factual, and courteous manner.</p> <p><b>TLO:</b> Employ professional</p>	<ul style="list-style-type: none"> <li>The regulator can give examples of unprofessional communication:             <ol style="list-style-type: none"> <li>Bullying</li> <li>Sexual harassment</li> <li>Inappropriate nonverbal (body language)</li> <li>Etc.</li> </ol> </li> </ul>

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<p>communication skills while conducting work-related activities.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain professional communication skills.</li> <li>• Explain the importance of communicating in a clear, concise, factual, and courteous manner.</li> <li>• Give examples of communicating in a clear, concise, factual, and courteous manner in the workplace.</li> <li>• Give examples of unprofessional communications.</li> <li>• Determine the appropriate communication method for target audience.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can explain professional communication skills.</li> <li>• The regulator can give examples of professional communication:             <ul style="list-style-type: none"> <li>a. Active listening</li> <li>b. Report writing</li> <li>c. Etc.</li> </ul> </li> <li>• The regulator can discern what constitutes professional communications in varying conditions:             <ul style="list-style-type: none"> <li>a. Effective and clear communication                 <ul style="list-style-type: none"> <li>▪ Emails</li> <li>▪ Reports</li> <li>▪ Phone</li> <li>▪ Etc.</li> </ul> </li> </ul> </li> <li>• The regulator can identify different levels of vernacular appropriate for different audiences:             <ul style="list-style-type: none"> <li>a. Co-worker</li> <li>b. Management</li> <li>c. Regulated population</li> <li>d. Etc.</li> </ul> </li> </ul>
<p><b>Unit 6: Interpersonal Skills</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can identify interpersonal skills in the workplace:             <ul style="list-style-type: none"> <li>a. Team player</li> <li>b. Collaborative</li> <li>c. Appropriate language</li> <li>d. Etiquette</li> </ul> </li> <li>• The regulator can list elements associated with emotional intelligence:             <ul style="list-style-type: none"> <li>a. Social awareness</li> <li>b. Use appropriate behavior</li> <li>c. Cognizant of team morale</li> <li>d. Culture awareness</li> <li>e. Respect</li> <li>f. Play nice in the sand box</li> <li>g. Considerate of other</li> </ul> </li> <li>• The regulator can demonstrate interpersonal skills in the workplace:             <ul style="list-style-type: none"> <li>a. Problem solving</li> <li>b. Decision making</li> <li>c. Assertiveness</li> <li>d. Negotiation</li> </ul> </li> <li>• The regulator can discuss the importance of emotional intelligence:             <ul style="list-style-type: none"> <li>a. Relation to the development of interpersonal</li> </ul> </li> </ul>

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	skills b. For improving interpersonal skills
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**IFSS Framework – Basic Level Gen Eds  
B24 Recalls**

**Definition:** Introductory knowledge, skills, and abilities related to the process of removing a product from commerce.

**Topic Area TLO** (Terminal Learning Objective): Describe the recall process in regulatory programs.

**Topic Area ELOs** (Enabling Learning Objective):

- Explain the recall process.
- Explain why recalls are initiated.
- Determine when to recommend that a recall may be necessary.
- Explain agency roles in recalls.
- Identify components in the recall process.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> Basic knowledge of recalls related to regulatory programs.</p> <p><b>TLO:</b> Describe the importance of recalls.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define key terminology.</li> <li>• Give examples of what could initiate a recall.</li> <li>• Explain the differences between recall classifications.</li> <li>• Describe the importance of interagency and industry collaboration.</li> <li>• Explain the need for communication with stakeholders.</li> <li>• Explain agency’s plan for removing product from the distributions system.</li> <li>• Explain firm’s plan for removing product from the distribution system.</li> <li>• Explain the purpose of</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can discuss how recalls contribute to maintaining human and animal health.</li> <li>• The regulator can describe the regulator’s agency’s policies for recalls.</li> <li>• The regulator can explain the reasons to initiate a recall:               <ul style="list-style-type: none"> <li>a. Enforcement action to keep human and animal food safe</li> <li>b. Remove economic adulteration</li> </ul> </li> <li>• The regulator can explain the impact if the product isn’t removed.</li> <li>• The regulator can explain the reasons for a voluntary recall:               <ul style="list-style-type: none"> <li>a. Process for allowing the producer to take responsibility for not complying with the requirements</li> </ul> </li> </ul>

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<p>a market withdrawal.</p> <ul style="list-style-type: none"> <li>• Trace a product through the supply chain.</li> </ul>	
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<b>Unit 2: Risk Assessment</b>	<b>TLO Behavioral Anchors - not all-inclusive</b>
<p><b>Definition:</b> Process to evaluate information for potential health impact of the product if it remains on the market.</p> <p><b>TLO:</b> Discuss the importance of risk assessment in product safety assurance.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the importance of risk assessment to determine if a recall is needed.</li> <li>• Give examples of triggers that could initiate a recall.</li> <li>• Explain how the potential severity of the hazard affects risk.</li> <li>• Explain how probability of exposure affects risk.</li> <li>• Describe how recall classes I, II, III would affect a recall decision.</li> </ul>	

<b>Unit 3: Documentation</b>	<b>TLO Behavioral Anchors - not all-inclusive</b>
<p><b>Definition:</b> Records needed when conducting a recall.</p> <p><b>TLO:</b> Explain the importance of documents needed when conducting a recall.</p>	

- The regulator can provide information to aid in decision making:
  - a. To determine the scope of the recall
  - b. To support the risk assessment
- The regulator can conduct recall audit checks:
  - a. Verify unsafe products are off the market.
- The regulator can discuss the role of documentation in validation, tracking, and organization:

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<p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>Identify documents used to track product movement.</li> <li>Give examples of documents that should be reviewed.</li> <li>Identify the documents that need to be collected.</li> <li>Review documents used to determine the scope of the recall.</li> </ul>	<ul style="list-style-type: none"> <li>a. Defensibility</li> <li>b. Evidence to support a recall</li> </ul>
<p><b>Unit 4: Communications</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>The regulator can describe the communication process with stakeholders while conducting a recall:             <ul style="list-style-type: none"> <li>a. Articulate the chain of command</li> <li>b. Describe agency’s jurisdiction</li> <li>c. Describe agency’s communication policy</li> </ul> </li> <li>The regulator can inform stakeholders that there is a recall:             <ul style="list-style-type: none"> <li>a. Recall alerts</li> <li>b. Inform the regulated population of the necessity</li> <li>c. Adapt communication to the stakeholders</li> <li>d. List the steps to take a recall</li> </ul> </li> <li>The regulator can gather information for a recall:             <ul style="list-style-type: none"> <li>a. Ask the right questions and document</li> <li>b. Active listening</li> <li>c. To maintain a better understanding of the situation</li> </ul> </li> <li>The regulator can give examples of agency communication policies.</li> <li>The regulator can discuss the process of assembling a recall team.</li> <li>The regulator can explain regulations to substantiate a recall.</li> </ul>
<p><b>Definition:</b> Information sharing and messaging strategies between agencies and stakeholders.</p> <p><b>TLO:</b> Discuss the role of communication during a recall.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>Describe the importance of interagency and industry communication.</li> <li>Explain how communication is coordinated during a recall.</li> <li>Identify requirements related to information sharing.</li> <li>Describe the roles of regulatory agencies in issuing public communications.</li> <li>Explain the importance of sharing lessons learned from recalls.</li> <li>Describe media types used to inform stakeholders of a recall.</li> <li>Describe the criteria of</li> </ul>	

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<p>the messaging types that are used during a recall.</p> <ul style="list-style-type: none"> <li>• Explain the criteria for issuing a public health message during a recall.</li> <li>• Explain how sensitive communication should be shared with affected stakeholders.</li> <li>• Explain when sensitive communication would be shared with affected stakeholders.</li> <li>• Describe the agency internal communication process during a recall.</li> <li>• Explain how public health recall messaging would affect international distribution.</li> </ul>	
<p><b>Unit 5: Recall Process</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> The process of removing unsafe products from all points of production, distribution, manufacturing, processing, storage, retail, and consumer ownership.</p> <p><b>TLO:</b> Explain how the recall process is used to remove unsafe products.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe how the decision is made to initiate a recall.</li> <li>• Describe the process of implementing a recall.</li> <li>• Discuss the importance of notifying the public.</li> <li>• Describe the process of recall validation.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can name the conditions that trigger a recall.</li> <li>• The regulator can list steps necessary to remove unsafe product from the marketplace.</li> <li>• The regulator can identify recall information to share with stakeholders.</li> <li>• The regulator can explain how the scope of the recall impacts complexity.</li> <li>• The regulator can identify the actions associated with each recall classification.</li> </ul>

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<ul style="list-style-type: none"> <li>• Describe the process of determining if a recall should be initiated.</li> <li>• Describe the process of how a recall would be conducted.</li> <li>• Explain the process of how relevant stakeholders are notified of a recall.</li> <li>• Describe how to verify that a recall has been properly conducted by a firm.</li> </ul>	
<p><b>Unit 6: Product Disposition</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Ensuring that unsafe products do not reenter the marketplace.</p> <p><b>TLO:</b> Explain the role of product disposition during a recall.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the importance of product disposition.</li> <li>• Give examples of reconditioning products.</li> <li>• Explain when a product needs to be destroyed.</li> <li>• Describe coordination that may be needed between agencies for product disposition.</li> <li>• Describe the verification needed to ensure proper product disposition.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can define what disposition means.</li> <li>• The regulator can discuss the methods for holding a product.</li> <li>• The regulator can define methods of disposition.</li> <li>• The regulator can discuss the importance of documentation.</li> <li>• The regulator can explain recall effectiveness checks:             <ul style="list-style-type: none"> <li>a. Trace back trace forward</li> <li>b. Collect evidence for disposition validation</li> </ul> </li> <li>• The regulator can explain how to avoid the reintroduction of unsafe product back into the food chain:             <ul style="list-style-type: none"> <li>a. Identify the product and document storage of the product</li> <li>b. Witness and document destruction of product</li> <li>c. Describe the appropriate security measures</li> </ul> </li> </ul>

**IFSS Framework – Basic Level Gen Eds  
B27 Traceability**

**Definition:** Introductory knowledge, skills, and abilities related to tracking feed and food throughout the supply chain.

**Topic Area TLO (Terminal Learning Objective):** Describe the role of traceability in feed and food programs.

**Topic Area ELOs (Enabling Learning Objective):**

- Explain product traceforward/traceback concepts.
- Trace the source of a food.
- Explain a product traceback diagram.
- Explain agency roles in traceforward/traceback.
- Identify components of product traceforward/traceback.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p><b>Definition:</b> Basic knowledge of traceability related to feed and food programs.</p> <p><b>TLO:</b> Describe the importance of product tracing.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define key terminology.</li> <li>• Explain factors that would initiate a traceforward/traceback.</li> <li>• Explain the difference between traceforward and traceback.</li> <li>• Describe the importance of interagency and industry collaboration.</li> <li>• Describe when traceforward/traceback is utilized.</li> <li>• Describe the primary functions of CORE.</li> <li>• Describe the primary function of ICS.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can define what product tracing is:             <ol style="list-style-type: none"> <li>a. Difference between tracing (documentation) and tracking (following product)</li> <li>b. Define product (ingredient to finished product)</li> <li>c. Define trackback and traceforward</li> </ol> </li> <li>• The regulator has knowledge or awareness of the purpose of product tracing:             <ol style="list-style-type: none"> <li>a. Find product source, e.g. grower, manufacturer, importer</li> <li>b. To ensure safe product</li> <li>c. Locate product to remove from commerce</li> <li>d. Identifies responsible or accountable party</li> </ol> </li> <li>• The regulator has knowledge or awareness of why product tracing is important:             <ol style="list-style-type: none"> <li>a. Provides product manufacturing information</li> <li>b. Identify source of product to determine how adulteration occurred</li> <li>c. To gather information during outbreaks (jurisdiction, interstate violation responsibility)</li> <li>d. Provides information needed for tracking outbreak vehicles</li> <li>e. Establishes scope and depth of a situation</li> <li>f. Identifies potential impact zone or region</li> <li>g. Decreases response time in a recall</li> </ol> </li> <li>• The regulator can give examples of product traceback and traceforward.</li> <li>• The regulator has knowledge or awareness of the importance of communication in product tracing situations:</li> </ul>

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	<ul style="list-style-type: none"> <li>a. Allow for ease of communication throughout the supply chain</li> <li>b. Information sharing</li> <li>c. Dissemination of information</li> </ul>
<p><b>Unit 2: Preliminary Review</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Analysis of surveillance data to determine if a traceforward/traceback investigation is warranted.</p> <p><b>TLO:</b> Identify the critical information from the surveillance reports needed for a traceforward/traceback.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Describe routine surveillance activities that might trigger a traceforward/traceback.</li> <li>• Describe the importance of time frames when reviewing surveillance reports.</li> <li>• Identify the potential health risk indicated by surveillance data.</li> <li>• Describe the subject matter expertise needed to assess surveillance data.</li> <li>• Explain how the RFR contributes to conducting traceforward/traceback investigations.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has knowledge or awareness of the product tracing process.</li> <li>• The regulator has an awareness of how products are identified:             <ul style="list-style-type: none"> <li>a. Production records: date, run time:</li> <li>b. Labeling info (brand name, ingredients, net weight, etc.)</li> <li>c. Lot numbers or other identification</li> <li>d. Product distribution list</li> <li>e. Firm information (address, key personnel)</li> <li>f. Manufacturer or grower information</li> <li>g. Distributor information</li> <li>h. Shipper info, i.e. trucking company and date shipped</li> </ul> </li> <li>• The regulator has knowledge or awareness of the importance of firm history information:             <ul style="list-style-type: none"> <li>a. Inspection history</li> </ul> </li> <li>• The regulator has knowledge or awareness of the factors to consider for tracing:             <ul style="list-style-type: none"> <li>a. Pending imminent health hazards</li> <li>b. Epi findings or ties to foodborne outbreaks</li> <li>c. Product/environmental samples</li> <li>d. Vector and/or vehicle</li> <li>e. Analysis report</li> <li>f. Outbreak demographics</li> <li>g. Target customers</li> <li>h. Date and location of initial finding (a place to start)</li> <li>i. Hazard associated with the product</li> <li>j. Aware of the risk associated with the hazard</li> <li>k. Foodborne illness reporting</li> <li>l. Implicated product(s) and associated products</li> <li>m. Degree of certainty with product</li> <li>n. Consumer complaints</li> </ul> </li> <li>• The regulator can list factors to consider during product tracing:             <ul style="list-style-type: none"> <li>a. Process or treatment performed on product</li> <li>b. Packaging type or material</li> <li>c. Components of the product</li> <li>d. Intended use of the product</li> </ul> </li> </ul>
<p><b>Unit 3: Supply Chain</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>

IFSS Framework – Basic Level Gen Eds  
**B27 Traceability**

<p><b>Definition:</b> The system of moving raw or manufactured products and ingredients from growing/raising, harvesting, processing, and manufacturing and all distribution points to consumption.</p> <p><b>TLO:</b> Discuss the complexity of traceability throughout the supply chain.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Explain the farm to table concept.</li> <li>• Describe major transportation systems.</li> <li>• Describe industry best practices for product traceability.</li> <li>• Describe how foreign suppliers may affect traceability.</li> <li>• Explain how to use a traceback diagram to identify potential points of contamination in the supply chain.</li> <li>• Explain requirements for industry to disclose customer purchases to regulatory agencies.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator has knowledge or awareness of product flow through the food production chain:             <ul style="list-style-type: none"> <li>a. Define supply chain and give an example</li> <li>b. Give examples of food chains</li> <li>c. List stakeholders to the supply chain</li> <li>d. Growing, harvesting, packing/processing, shipping, distributing, manufacturing, point of sale</li> </ul> </li> <li>• The regulator has knowledge or awareness of the importance of records:             <ul style="list-style-type: none"> <li>a. Accurate</li> <li>b. Legible</li> <li>c. Accessible</li> <li>d. Incomplete or missing records (batch, production, shipping)</li> <li>e. One step forward, one step back</li> </ul> </li> <li>• The regulator has knowledge or awareness of the challenges of traceability:             <ul style="list-style-type: none"> <li>a. Incomplete or missing product identification</li> <li>b. An ingredient can be used in multiple products with multiple companies</li> <li>c. Distribution can be worldwide</li> <li>d. Language barriers</li> <li>e. The sheer volume of a production run</li> <li>f. Shelf life can vary between perishable and shelf stable</li> </ul> </li> <li>• The regulator has knowledge or awareness and knowledge of the challenges of traceability:             <ul style="list-style-type: none"> <li>a. Supply chain relations (including regulator)</li> <li>b. Diversity of operations (examples consolidators, repackers, warehouses, importers, shippers)</li> <li>c. Distribution can flow through multiple wholesale and retail chains</li> <li>d. Changing consumer trends                 <ul style="list-style-type: none"> <li>▪ Increase in farm to table</li> <li>▪ Increase consumption of raw product</li> <li>▪ Cottage foods</li> </ul> </li> <li>e. Identifying parties responsible for the product (broker, distributor, firm)</li> <li>f. Proprietary information</li> <li>g. Firm’s definition of the term “lot” (e.g. produce industry)</li> <li>h. Global product identification</li> </ul> </li> <li>• The regulator has knowledge or awareness of the jurisdictional issues.</li> </ul>
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IFSS Framework – Basic Level Gen Eds

**B27 Traceability**

	<ul style="list-style-type: none"> <li>a. Jurisdictional boundaries</li> <li>b. Awareness of changing authorities through the supply chain</li> </ul>
<p><b>Unit 4: Documentation</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> The records needed when doing a traceforward/traceback.</p> <p><b>TLO:</b> Explain key documents needed for tracing product movement.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Identify documents used to track product movement.</li> <li>• Describe document retention requirements for the industry.</li> <li>• Give examples of documents that should be collected.</li> <li>• Give examples of key information needed for product tracing.</li> <li>• Describe the importance of collecting documents for the timeframes of interest.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can give three examples of types of records for determining traceforward and traceback:             <ul style="list-style-type: none"> <li>a. Sanitary transport records</li> <li>b. Signatures</li> <li>c. Invoices/bills of lading</li> <li>d. Production log</li> <li>e. Receipts</li> <li>f. Shipping documents</li> <li>g. Certificates of analysis</li> <li>h. Hazard analysis</li> <li>i. Food safety plan</li> <li>j. Lot number</li> <li>k. Shelf life</li> <li>l. Product label</li> </ul> </li> <li>• The regulator can explain the importance of regulatory documentation:             <ul style="list-style-type: none"> <li>a. Regulatory notes</li> <li>b. Interview notes</li> <li>c. Photographs</li> <li>d. Product/Process flow diagram</li> <li>e. Sample receipts</li> </ul> </li> <li>• The regulator can locate relevant agency policies:             <ul style="list-style-type: none"> <li>a. Recall effectiveness checks</li> <li>b. Embargo</li> </ul> </li> <li>• The regulator can give six examples of records for determining traceforward and traceback.</li> <li>• The regulator can demonstrate the effective collection of regulatory documentation.</li> <li>• The regulator can describe relevant agency policies.</li> </ul>
<p><b>Unit 5: Communications</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Information sharing and messaging strategies between agencies and stakeholders during a traceforward/traceback.</p> <p><b>TLO:</b> Discuss requirements for communication during a traceforward/traceback.</p>	<ul style="list-style-type: none"> <li>• The regulator can give examples of status communication:             <ul style="list-style-type: none"> <li>a. Keep supervisor apprised</li> <li>b. Email/phone clarifications of assigned tasks</li> <li>c. Keeping firm apprised of progress</li> </ul> </li> <li>• The regulator has knowledge or awareness of the existence of agency policy:             <ul style="list-style-type: none"> <li>a. Proprietary information</li> <li>b. Communication restrictions</li> </ul> </li> </ul>

IFSS Framework – Basic Level Gen Eds

**B27 Traceability**

<p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>Describe the importance of interagency/industry communication.</li> <li>Explain how communication is coordinated during a traceback.</li> <li>Identify requirements related to information sharing.</li> <li>Explain how the ICS system is used to facilitate communications.</li> </ul>	<ul style="list-style-type: none"> <li>c. Affidavits</li> <li>d. Lab reports</li> <li>The regulator can identify three effective ways of communicating during traceforward and traceback:             <ul style="list-style-type: none"> <li>a. Interview techniques</li> <li>b. Memos</li> <li>c. Can ask clarifying/relevant questions</li> <li>d. Effective notetaking</li> <li>e. Speaking to the most responsible person</li> <li>f. Clear and concise</li> <li>g. Can follow instructions</li> <li>h. Logic model (timeline of steps)</li> </ul> </li> <li>The regulator can identify one record that must be maintained for accuracy:             <ul style="list-style-type: none"> <li>a. Transport records</li> <li>b. Supplier list</li> <li>c. Lot numbers</li> <li>d. Facility location</li> <li>e. Accurate contact list</li> <li>f. Regulatory notes</li> </ul> </li> <li>The regulator can explain the importance of status communication.</li> <li>The regulator can identify a traceforward and traceback communication policy.</li> <li>The regulator can role play an effective way of communicating during traceforward and traceback.</li> <li>The regulator can identify three records that must be maintained for accuracy.</li> </ul>
<p><b>Unit 6: Technology</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> The systems or devices used to enhance traceability.</p> <p><b>TLO:</b> Explain how technology is used to improve traceability.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>Give examples of technology used to track products.</li> <li>Describe how data systems can help identify patterns.</li> <li>Discuss advantages</li> </ul>	<ul style="list-style-type: none"> <li>The regulator can list two means of technology used in traceability:             <ul style="list-style-type: none"> <li>a. Wi-Fi access to real-time answers</li> <li>b. Global Positioning System (GPS)</li> <li>c. Electronic records</li> <li>d. Camera technology</li> <li>e. Cell phone apps</li> </ul> </li> <li>The regulator has knowledge or awareness of relevant traceability databases:             <ul style="list-style-type: none"> <li>a. Reportable food registry</li> <li>b. Radio-frequency identification (RFID) technology</li> <li>c. Shopper identification cards</li> </ul> </li> <li>The regulator can give an example of how technology improves traceability:             <ul style="list-style-type: none"> <li>a. Ease of exchange</li> </ul> </li> </ul>

## IFSS Framework – Basic Level Gen Eds

**B27 Traceability**

of using technology to enhance traceability.	<ul style="list-style-type: none"><li>b. Faster verification</li><li>c. Economically motivated adulteration</li><li>d. Finding documentation</li><li>e. Genome sequencing</li><li>• The regulator recognizes the impact of communication outlets on traceability:<ul style="list-style-type: none"><li>a. Radio/television reporting for consumer safety</li><li>b. Social media</li></ul></li><li>• The regulator can give an example of how to use technology in traceability.</li><li>• The regulator can give an example of a relevant database.</li><li>• The regulator can give three examples of how technology improves traceability.</li><li>• The regulator can identify communication outlets.</li></ul>
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**IFSS Framework – Basic Level Gen Eds  
B28 Transportation**

**Definition:** Introductory knowledge, skills, and abilities related to preventing contamination of feed and food during transport.

**Topic Area TLO (Terminal Learning Objective):** Describe how transportation affects feed and food safety.

**Topic Area ELOs (Enabling Learning Objectives):**

- Articulate the requirements for protection of product.
- Explain how transportation practices can lead to adulterated product.
- Evaluate whether mishandling of products has occurred.
- Describe jurisdictional authority over transported products.
- Evaluate whether mishandling has resulted in adulterated product.

<p><b>Unit 1: Foundations</b></p> <p><b>Definition:</b> Basic knowledge of transportation related to feed and food safety.</p> <p><b>TLO:</b> Describe basic information regarding the role of transportation.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Define relevant terminology.</li> <li>• Locate resources.</li> <li>• Describe the importance of transportation.</li> <li>• Give examples of stakeholders.</li> <li>• Demonstrate knowledge of transportation regulations.</li> <li>• Identify agency jurisdiction for transportation.</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can describe the role of safe transportation within the food chain.</li> <li>• The regulator can describe transportation equipment impact on food safety.</li> <li>• The regulator can discuss the sanitary transportation rule.</li> <li>• The regulator can discuss key requirements of the sanitary transportation rule:             <ul style="list-style-type: none"> <li>a. Discuss waivers and exemptions</li> </ul> </li> </ul>
<p><b>Unit 2: Transportation Methods</b></p> <p><b>Definition:</b> Description of transportation methods.</p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can identify the transportation modes used in food and feed.</li> </ul>

IFSS Framework – Basic Level Gen Eds

**B28 Transportation**

<p><b>TLO:</b> Discuss transportation options used for feed and food.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Identify transportation modes used in feed/food systems.</li> <li>• Recognize the mode of transportation suited for specific products.</li> <li>• Recognize hazards unique to specific modes of transportation.</li> <li>• Explain the importance of dedicated transportation equipment.</li> <li>• Discuss required identification of equipment.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can discuss considerations in the selection of a transportation mode.</li> </ul>
<p><b>Unit 3: Inspections</b></p> <p><b>Definition:</b> Basic knowledge necessary to conduct inspections of various conveyances.</p> <p><b>TLO:</b> Discuss the complexity of traceability throughout the supply chain.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Discuss required documentation.</li> <li>• Describe inspection role in transportation incidents.</li> </ul>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p> <ul style="list-style-type: none"> <li>• The regulator can discuss the elements of the inspection process:             <ol style="list-style-type: none"> <li>a. Design</li> <li>b. Sanitary conditions</li> <li>c. Controlled environment</li> <li>d. Etc.</li> </ol> </li> <li>• The regulator can explain how the inspection process ensures food transportation safety:             <ol style="list-style-type: none"> <li>a. Proper design</li> <li>b. Sanitary conditions</li> <li>c. controlled environment</li> <li>d. Properly maintained</li> <li>e. Properly equipped</li> <li>f. Stored</li> <li>g. Design</li> <li>h. Training</li> <li>i. Documentation</li> </ol> </li> </ul>

**IFSS Framework – Basic Level Gen Eds  
B28 Transportation**

<ul style="list-style-type: none"> <li>• Describe the disposition of damaged products.</li> <li>• Give examples of disposition of salvaged products.</li> <li>• Describe procedures for the inspection of specific transportation conveyances.</li> <li>• Discuss receiving procedures.</li> <li>• Discuss the importance of maintaining shipping documentation.</li> </ul>	
<p><b>Unit 4: Security</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Basic knowledge of how security measures maintain safe transportation.</p> <p><b>TLO:</b> Describe security measures designed to ensure safe transportation.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"> <li>• Discuss the importance of transportation security.</li> <li>• Identify areas of vulnerability.</li> <li>• Identify the importance of seals.</li> <li>• Give examples of security breaches.</li> <li>• Describe the importance of documentation.</li> </ul>	<ul style="list-style-type: none"> <li>• The regulator can demonstrate knowledge of securing product during transportation:             <ol style="list-style-type: none"> <li>a. Seals/padlocks</li> <li>b. Etc.</li> </ol> </li> </ul>
<p><b>Unit 5: Product Safety</b></p>	<p><b>TLO Behavioral Anchors - not all-inclusive</b></p>
<p><b>Definition:</b> Basic knowledge of how to maintain and protect product safety during transportation.</p>	<ul style="list-style-type: none"> <li>• The regulator can demonstrate knowledge of securing product during transportation:             <ol style="list-style-type: none"> <li>a. Seals/padlocks</li> </ol> </li> </ul>

IFSS Framework – Basic Level Gen Eds

**B28 Transportation**

<p><b>TLO:</b> Discuss the importance of protecting products during transportation.</p> <p><b>ELOs:</b></p> <ul style="list-style-type: none"><li>• Discuss the importance of sanitation practices in transportation.</li><li>• Give examples of safe handling methods in feed transportation.</li><li>• Discuss the importance of pest control.</li><li>• Discuss the importance of environmental control.</li><li>• Explain the importance of preventing cross contamination.</li></ul>	<p>b. Etc.</p> <ul style="list-style-type: none"><li>• The regulator can discuss the risks associated with loading, transportation and storage.</li></ul>
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# Retail Program Standards Ver 3.0 [Draft]

## Self-Assessment / Audit Verification Summary & Gap Analysis

**Jurisdiction Name:** \_\_\_\_\_  
**Report completed by:** \_\_\_\_\_  
**Full Self-Assessment Date:** \_\_\_\_\_  
**Program Standards Version:** 2017  
**Self-Assessment Period** \_\_\_\_\_

**Table 1 - Summary Table of Progress Towards Meeting the Retail Program Standards**

MET	NO.	STANDARD TITLE	PROGRESS	STANDARD ELEMENTS*
NO	1	REGULATORY FOUNDATION	No elements met	<u>1a</u> <u>1b</u> <u>1c</u> <u>2a</u> <u>2b</u> <u>3a</u> <u>4a</u>
NO	2	TRAINED REGULATORY STAFF	No elements met	<u>1a</u> <u>1b</u> <u>2a</u> <u>2b</u> <u>3a</u> <u>3b</u> <u>4a</u> <u>4b</u> <u>5a</u>
NO	3	INSPECTION PROGRAM BASED ON HACCP PRINCIPLES	No elements met	<u>1a</u> <u>1b</u> <u>1c</u> <u>2a</u> <u>3a</u> <u>4a</u> <u>4b</u> <u>4c</u> <u>5a</u> <u>6a</u>
NO	4	UNIFORM INSPECTION PROGRAM	No elements met	<u>1a</u> <u>1b</u> <u>1c</u> <u>2</u> <u>2i</u> <u>2ii</u> <u>2iii</u> <u>2iv</u> <u>2v</u> <u>2vi</u> <u>2vii</u> <u>2viii</u> <u>2ix</u> <u>2x</u> <u>2xi</u> <u>2xii</u> <u>2xiii</u> <u>2xiv</u> <u>2xv</u> <u>2xvi</u> <u>2xvii</u> <u>2xviii</u> <u>2xix</u> <u>2xx</u> <u>3a</u> <u>3b</u>
NO	5	FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE	No elements met	<u>1a</u> <u>1b</u> <u>1c</u> <u>1d</u> <u>1e</u> <u>1f</u> <u>1g</u> <u>1h</u> <u>1i</u> <u>2a</u> <u>2b</u> <u>3a</u> <u>3b</u> <u>4a</u> <u>5a</u> <u>5b</u> <u>5c</u> <u>6a</u> <u>7a</u> <u>7b1</u> <u>7b2</u> <u>7b3</u> <u>7b4</u> <u>7b5</u> <u>7b6</u> <u>7b7</u> <u>7b8</u> <u>7b9</u> <u>7c</u>
NO	6	COMPLIANCE AND ENFORCEMENT	No elements met	<u>1a</u> <u>1b</u> <u>2a</u> <u>2b</u>
NO	7	INDUSTRY AND COMMUNITY RELATIONS	No elements met	<u>1a</u> <u>1b</u>
NO	8	PROGRAM SUPPORT AND RESOURCES	No elements met	<u>1a</u> <u>2a</u> <u>2b</u> <u>3a</u> <u>3b</u> <u>4a</u> <u>4b</u> <u>4c</u> <u>4d</u> <u>4e</u> <u>4f</u> <u>4g</u> <u>4h</u>
NO	9	PROGRAM ASSESSMENT	No elements met	<u>1a</u> <u>1b</u> <u>1c</u> <u>2a</u> <u>2b</u> <u>3a</u> <u>3b</u>

\* Elements that are met are identified by strikethrough text.

Click the below hyperlink link for additional Program Standards guidance, instructions and PDF files located the FDA Retail Food website

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm245409.htm>

## Standard 1: Regulatory Foundation

### Program Self-Assessment and Verification Audit Form (January 2017)

Click the below hyperlink link to open the online PDF verison of Standard 1

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Click the below hyperlink link to open the online PDF verison with Instuctions

[Missing Link, Still in Draft Status](#)

#### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

<b>Printed Name of the Person who conducted the SA:</b>	
<b>Self-Assessor's Title:</b>	
<b>Jurisdiction Name:</b>	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
<b>Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Standard 1 Self-Assessment was Completed:</b>	
<b>SA indicates the Jurisdiction MEETS the Standard 1 criteria:</b>	NO

*I affirm that the information represented in the Self-Assessment of Standard 1 is true and correct*

**Signature of the Self-Assessor:** \_\_\_\_\_

#### VERIFICATION AUDIT (VA) SUMMARY

<b>Printed Name of the Person who conducted the VA:</b>	
<b>Verification Auditor's Title:</b>	
<b>Auditor's Jurisdiction Name:</b>	
<b>Auditor's Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Verification Audit of Standard 1 was Completed:</b>	
<b>VA indicates the Jurisdiction MEETS the Standard 1 criteria:</b>	

*I affirm that the information represented in the Verification Audit of Standard 1 is true and correct*

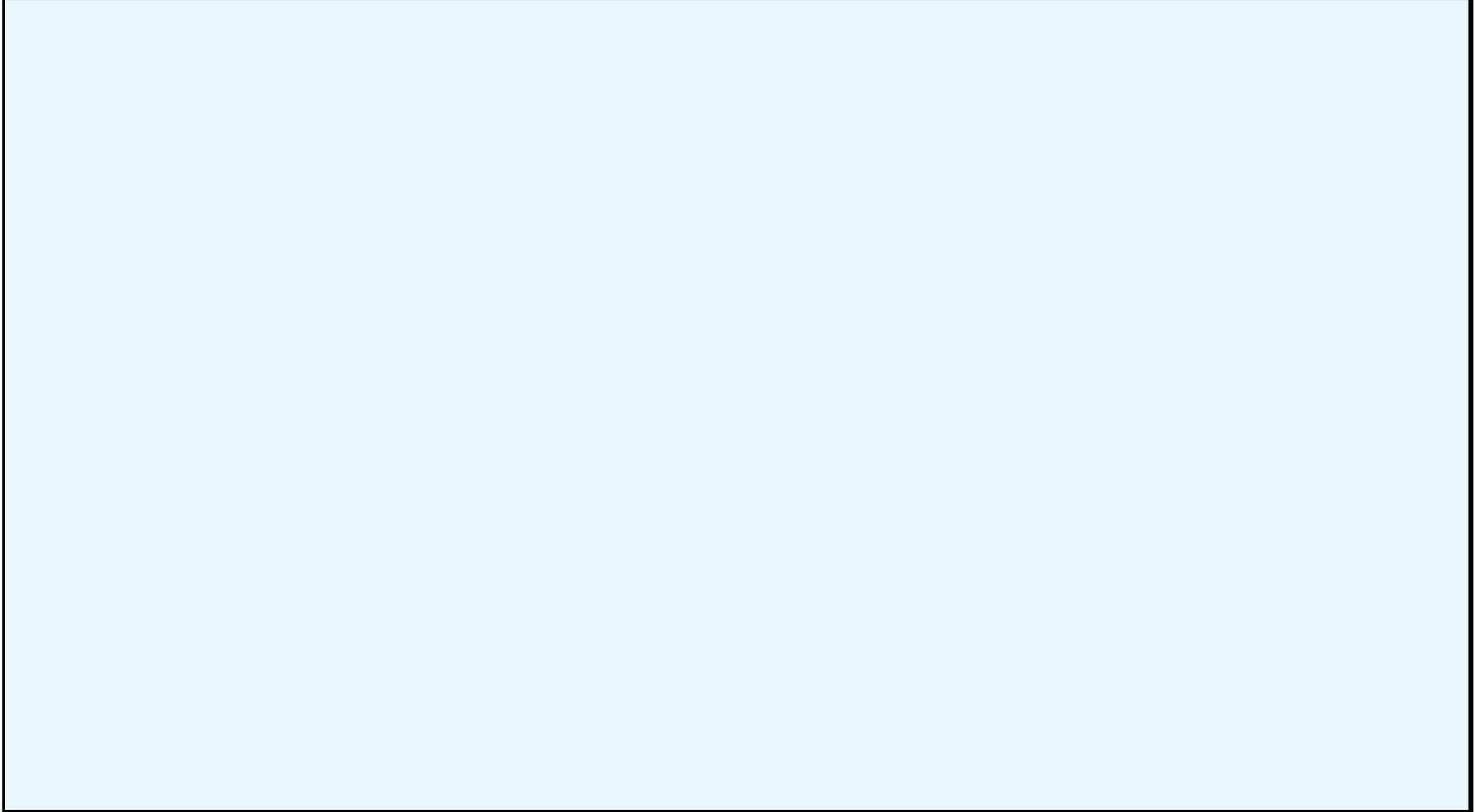
**Signature of the Verification Auditor:** \_\_\_\_\_

**Table 2 - Program Self-Assessment and Verification Audit Table for Standard 1**

Standard Sub-Elements Criteria	SA MET	Self-Assessor's Comments	VA MET	If NO, why criterion not met
<b>1. Assessment of the Program's Regulatory</b>				
a. The jurisdiction has documentation that it has performed a side-by-side comparison of its prevailing statutes, regulations, rules and other pertinent requirements against the current published edition of the FDA Food Code or one of the two most recent previous editions of the FDA Food Code.				
b. The jurisdiction's side-by-side comparison includes an assessment of major Food Code Interventions and Risk Factors, Good Retail Practices, and Compliance/Enforcement Administrative requirements.				
c. The regulatory foundation assessment clearly identifies the jurisdictions corresponding requirement to the applicable Code Section. The assessment provides a determination as to whether a specific provision in the jurisdiction's regulation meets the intent of the corresponding FDA Food Code Section.				
<b>2. Food Code Interventions and Risk Factors</b>				
a. The jurisdiction's initial Food Code assessment indicates that the agency's regulatory requirements contain at least 9 of the 11 FDA Food Code intervention and risk factor controls. By the third verification audit the jurisdiction's assessment indicated that the agency's regulatory requirement contain all 11 of the Food Code invention and risk factor controls. Documentation from: Part I – Self Assessment Worksheet and Part I – Verification Audit Worksheet				
b. The jurisdiction's Food Code assessment indicates that the agency has a corresponding requirement for ALL FDA Food Code provisions related to the interventions and risk factor controls. NOTE: Auditor's random selection of Food Code Intervention and Risk Factor Control Sections confirms the jurisdiction's assessment that a corresponding requirement is contained in the agency's rules, regulations, ordinances, code, or statutes.				
<b>3. Good Retail Practices</b>				

<p>a. The jurisdiction’s initial Food Code assessment indicates that regulatory requirements contain at least 95 percent of the FDA Food Code Good Retail Practices Sections. NOTE: Auditor’s random selection of Good Retail Practices Code Sections confirms the jurisdiction’s assessment that a corresponding requirement is contained in the agency’s code or statutes. Documentation from: Part II – Self-Assessment Worksheet and Part II – Verification Audit Worksheet</p>				
<p><b>4. Compliance and Enforcement</b></p>				
<p>a. The jurisdiction’s initial Food Code assessment indicates that regulatory requirements contain ALL the FDA Food Code Compliance and Enforcement Sections identified in the Standard. NOTE: Auditor’s random selection of Compliance and Enforcement Code Sections confirms the jurisdiction’s assessment that a corresponding requirement is contained in the agency’s code or statutes. Documentation from: Part III – Self Assessment Worksheet and Part III – Verification Audit Worksheet</p>				

**General notes Pertaining to the Program Self-Assessment or the Verification Audit**



## Standard 2: Trained Regulatory Staff

### Program Self-Assessment and Verification Audit Form (January 2017)

Click the below hyperlink link to open the online PDF verison of Standard 2

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Click the below hyperlink link to open the online PDF verison with Instuctions

[Missing Link, Still in Draft Status](#)

#### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

<b>Printed Name of the Person who conducted the SA:</b>	
<b>Self-Assessor's Title:</b>	
<b>Jurisdiction Name:</b>	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
<b>Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Standard 2 Self-Assessment was Completed:</b>	
<b>SA indicates the Jurisdiction MEETS the Standard 2 criteria:</b>	NO

*I affirm that the information represented in the Self-Assessment of Standard 2 is true and correct*

**Signature of the Self-Assessor:** \_\_\_\_\_

#### VERIFICATION AUDIT (VA) SUMMARY

<b>Printed Name of the Person who conducted the VA:</b>	
<b>Verification Auditor's Title:</b>	
<b>Auditor's Jurisdiction Name:</b>	
<b>Auditor's Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Verification Audit of Standard 2 was Completed:</b>	
<b>VA indicates the Jurisdiction MEETS the Standard 2 criteria:</b>	

*I affirm that the information represented in the Verification Audit of Standard 2 is true and correct*

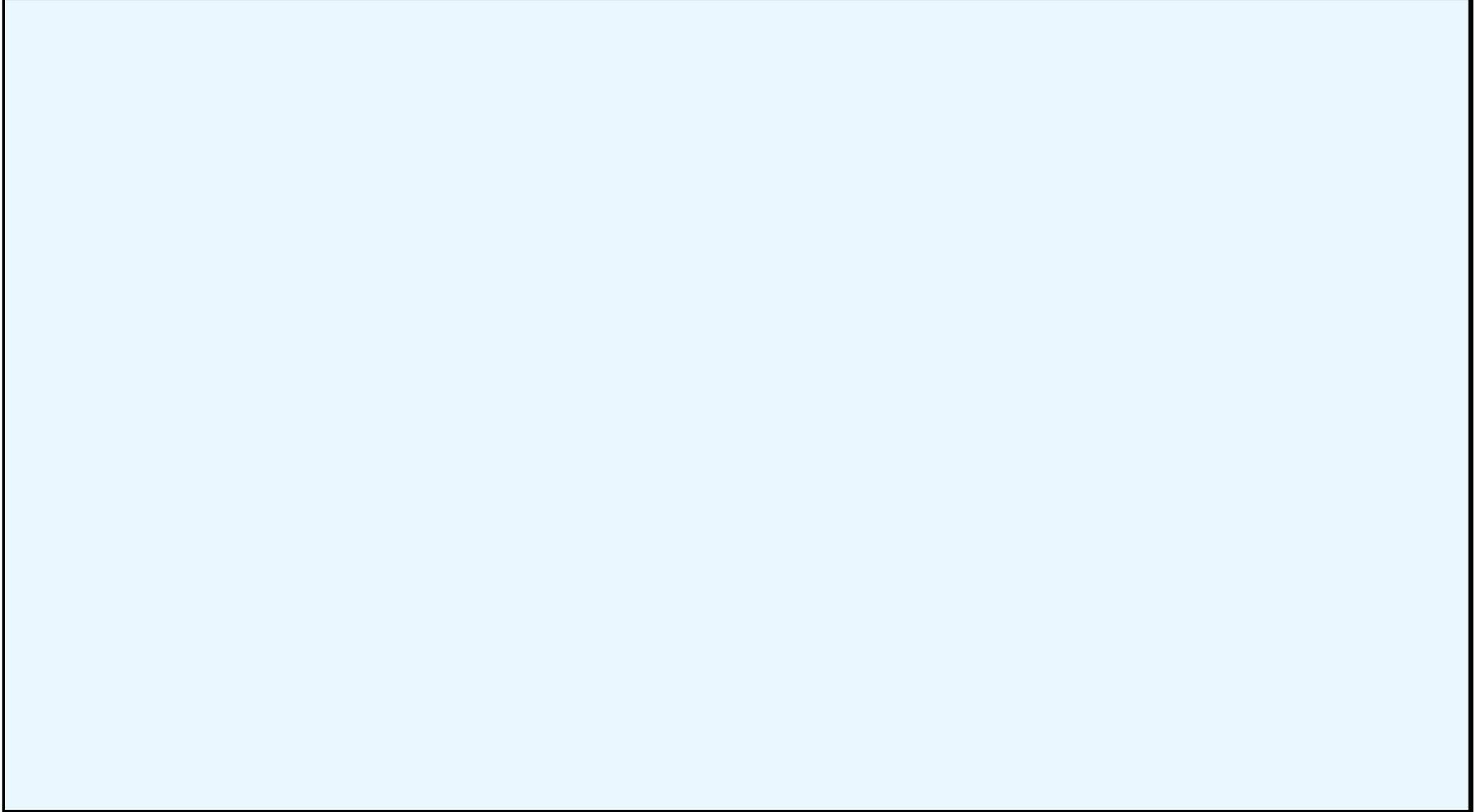
**Signature of the Verification Auditor:** \_\_\_\_\_

**Table 3 - Program Self-Assessment and Verification Audit Table for Standard 2**

Standard Sub-Elements Criteria	SA MET	Self-Assessor's Comments	VA MET	If NO, why criterion not met
<b>1. Employee Training Records</b>				
a. The jurisdiction maintains a written training record for each employee that includes the date of hire or assignment to the agency's retail food protection program.				
b. The jurisdiction written training record provides documentation that each employee has completed the Standard #2 pre-requisite ("Pre") training curriculum PRIOR to conducting independent retail food or foodservice inspections.				
<b>2. Initial Field Training</b>				
a. The jurisdiction maintains a written training record that provides confirmation that each employee completed a minimum of 25 joint field training inspections of retail food and/or foodservice establishments (if less than 25 joint field training inspections are performed, written documentation on file that FSIO has successfully demonstrated all required inspection competencies) PRIOR to conducting independent retail food or foodservice inspections				
b. The jurisdiction maintains a written training record that provides confirmation that each employee successfully completed a field training process similar to that contain in the CFP Field Training Manual provided in Appendix B-2, Standard 2, PRIOR to conducting independent inspections of retail food and/or foodservice establishments.				
<b>3. Independent Inspections / Completion of ALL</b>				
a. The jurisdiction maintains a written training record that provides confirmation that each employee completed a minimum of 25 independent retail food and/or foodservice inspections PRIOR to field standardization.				
b. The jurisdiction written training record provides documentation that each employee has completed ALL aspects of the Standard #2 training curriculum ("Pre") and ("Post") courses PRIOR to field standardization.				
<b>4. Field Standardization</b>				

<p>a. The jurisdiction maintains a written training record that provides documentation that each employee successfully completed a Standardization process similar to the ‘FDA Procedures for Standardization’ within 18 months of hire or assignment to the retail food protection program.</p>				
<p>b. The jurisdiction maintains a written training record that provides documentation that each standardized employee has maintained their standardization by performing a minimum of 4 joint inspections with a “training standard” every 3 years.</p>				
<p><b>5. Continuing Education and Training</b></p>				
<p>a. The jurisdiction maintains a written training record that provides documentation that each employee conducting retail food and/or foodservice inspections has accumulated 20 hours of continuing education every 36 months after the initial training (18) months is completed.</p>				

**General notes Pertaining to the Program Self-Assessment or the Verification Audit**



## Standard 3: Inspection Program Based On HACCP Principles Program Self-Assessment and Verification Audit Form (January 2017)

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### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

<b>Printed Name of the Person who conducted the SA:</b>	
<b>Self-Assessor's Title:</b>	
<b>Jurisdiction Name:</b>	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
<b>Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Standard 3 Self-Assessment was Completed:</b>	
<b>SA indicates the Jurisdiction MEETS the Standard 3 criteria:</b>	NO

*I affirm that the information represented in the Self-Assessment of Standard 3 is true and correct*

**Signature of the Self-Assessor:** \_\_\_\_\_

### VERIFICATION AUDIT (VA) SUMMARY

<b>Printed Name of the Person who conducted the VA:</b>	
<b>Verification Auditor's Title:</b>	
<b>Auditor's Jurisdiction Name:</b>	
<b>Auditor's Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Verification Audit of Standard 3 was Completed:</b>	
<b>VA indicates the Jurisdiction MEETS the Standard 3 criteria:</b>	

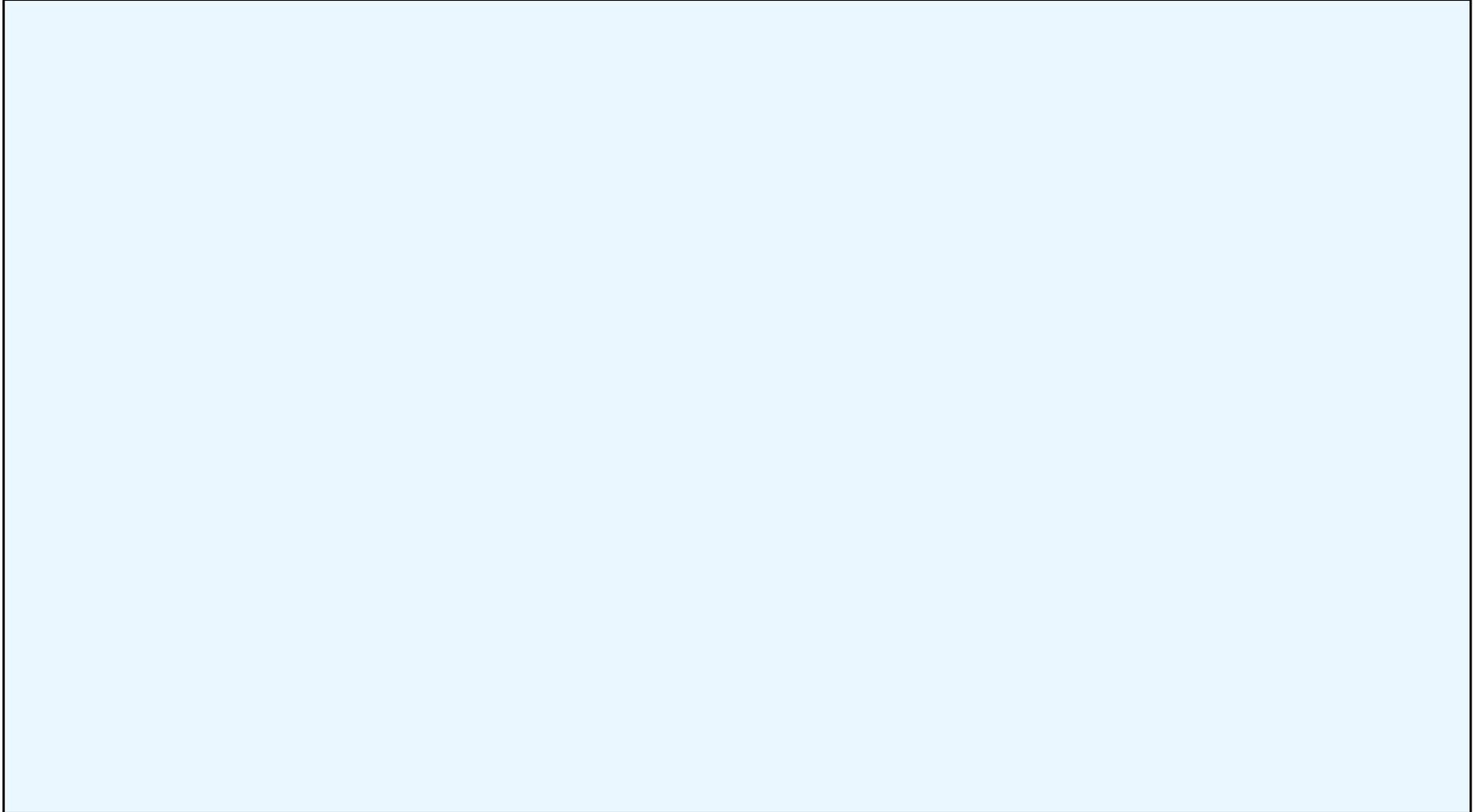
*I affirm that the information represented in the Verification Audit of Standard 3 is true and correct*

**Signature of the Verification Auditor:** \_\_\_\_\_

**Table 4 - Program Self-Assessment and Verification Audit Table for Standard 3**

<b>Standard Sub-Elements Criteria</b>	<b>SA MET</b>	<b>Self-Assessor's Comments</b>	<b>VA MET</b>	<b>If NO, why criterion not met</b>
<b>1. Inspection Form Design</b>				
a. The jurisdiction's inspection form identifies foodborne illness risk factors and Food Code interventions.				
b. The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.				
c. The jurisdiction's inspection form documents compliance and enforcement activities.				
<b>2. Risk Assessment Categories</b>				
a. A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.				
<b>3. Inspection Frequency</b>				
a. The jurisdiction's inspection frequency is based on the assigned risk categories.				
<b>4. Written and Implement Corrective Action Policy</b>				
a. The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.				
b. The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.				
c. The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.				
<b>5. Variance Requests</b>				
a. The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and Food Code interventions.				
<b>6. Verification and Validation of HACCP Plans</b>				
a. The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans when a plan is required by Code.				

**General notes Pertaining to the Program Self-Assessment or the Verification Audit**



## Standard 4: Uniform Inspection Program Program Self-Assessment and Verification Audit Form (January 2017)

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### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

<b>Printed Name of the Person who conducted the SA:</b>	
<b>Self-Assessor's Title:</b>	
<b>Jurisdiction Name:</b>	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
<b>Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Standard 4 Self-Assessment was Completed:</b>	
<b>SA indicates the Jurisdiction MEETS the Standard 4 criteria:</b>	NO

*I affirm that the information represented in the Self-Assessment of Standard 4 is true and correct*

**Signature of the Self-Assessor:** \_\_\_\_\_

### VERIFICATION AUDIT (VA) SUMMARY

<b>Printed Name of the Person who conducted the VA:</b>	
<b>Verification Auditor's Title:</b>	
<b>Auditor's Jurisdiction Name:</b>	
<b>Auditor's Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Verification Audit of Standard 4 was Completed:</b>	
<b>VA indicates the Jurisdiction MEETS the Standard 4 criteria:</b>	

*I affirm that the information represented in the Verification Audit of Standard 4 is true and correct*

**Signature of the Verification Auditor:** \_\_\_\_\_

**Table 5 - Program Self-Assessment and Verification Audit Table for Standard 4**

Standard Sub-Elements Criteria	SA MET	Self-Assessor's Comments	VA MET	If NO, why criterion not met
<b>1. Written Quality Assurance Program Document</b>				
a. The jurisdiction has a written quality assurance program that covers all regulatory staff that conducts retail food and/or foodservice inspections.				
b. The jurisdiction periodically conducts an analysis of the results of the quality assurance program to identify quality or consistency problems among the staff in the twenty quality elements.				
c. The jurisdiction's written quality assurance program describes corrective actions to address an individual retail food program inspector's performance quality or consistency issues when they are identified.				
<b>2. Twenty Quality Assurance Program Elements</b>				
The jurisdictions quality assurance program provides a method to review or monitor, either individually or programmatically, the concepts in the twenty quality elements. The twenty elements follow in I. through XX.				
I. The jurisdiction's quality assurance program assures that each inspector has the required equipment and forms to conduct the inspection.				
II. The jurisdiction's quality assurance program assures that each inspector reviews the contents of the establishment file, including the previous inspection report, reported complaints on file, and, if applicable, required HACCP Plans or documents supporting the issuance of a variance.				
III. The jurisdiction's quality assurance program assures that each inspector verifies that the establishment is in the proper risk category and that the required inspection frequency is being met, Informs the supervisor when the establishment is not in the proper risk category or when frequency is not met.				
IV. The jurisdiction's quality assurance program assures that each inspector provides identification as a regulatory official to the person in charge and states the purpose of the visit.				
V. The jurisdiction's quality assurance program assures that each inspector interprets and applies the jurisdiction's laws, rules, policies, procedures, and regulations required for conducting retail food inspections.				

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<p>VI. The jurisdiction’s quality assurance program assures that each inspector uses a risk-based inspection methodology to conduct the inspection.</p>				
<p>VII. The jurisdiction’s quality assurance program assures that each inspector accurately determines the compliance status of each risk factor and Food Code intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).</p>				
<p>VIII. The jurisdiction’s quality assurance program assures that each inspector obtains corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdictions policies.</p>				
<p>IX. The jurisdiction’s quality assurance program assures that each inspector discusses options for the long-term control of risk factors with establishment managers when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction’s policies. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.</p>				
<p>X. The jurisdiction’s quality assurance program assures that each inspector verifies correction of out-of-compliance observations identified during the previous inspection. In addition, follows through with compliance and enforcement in accordance with jurisdiction’s policies.</p>				
<p>XI. The jurisdiction’s quality assurance program assures that each inspector conducts an exit interview that explains the out-of-compliance observations, corrective actions, and timeframes for correction, in accordance with the jurisdiction’s policies.</p>				
<p>XII. The jurisdiction’s quality assurance program assures that each inspector provides the inspection report and, when necessary, cross referenced documents, to the person in charge or permit holder, in accordance with the jurisdiction’s policies.</p>				
<p>XIII. The jurisdiction’s quality assurance program assures that each inspector demonstrates proper sanitary practices as expected from a food service employee.</p>				

<p>XIV. The jurisdiction’s quality assurance program assures that each inspector completed the inspection form per the jurisdiction’s policies (i.e., observations, public health reasons, applicable code reference, compliance dates).</p>				
<p>XV. The jurisdiction’s quality assurance program assures that each inspector document the status of each risk factor and intervention (IN, OUT, NA, NO).</p>				
<p>XVI. The jurisdiction’s quality assurance program assures that each inspector cites the proper code provisions for risk factors and Food Code interventions, in accordance with the jurisdiction’s policies.</p>				
<p>XVII. The jurisdiction’s quality assurance program assures that each inspector documents corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction’s policies.</p>				
<p>XVIII. The jurisdiction’s quality assurance program assures that each inspector documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.</p>				
<p>XIX. The jurisdiction’s quality assurance program assures that each inspector accurately completes compliance or regulatory documents (i.e., exhibits, attachments, sample forms), appropriately cross-references them within the inspection report, and includes them with the inspection report, in accordance with the jurisdiction’s policies.</p>				
<p>XX. The jurisdiction’s quality assurance program assures that each inspector files reports and other documentation in a timely manner, in accordance with the jurisdiction’s policies.</p>				
<p><b>3. Demonstration of Program Effectiveness Using the Statistical Method in Standard 4: Self-Assessment Worksheet</b></p>				
<p>a. The program effectiveness measure documents that 2 self-assessment field reviews were conducted for each employee performing retail food and or foodservice inspection work during the five-year self-assessment period. [New staff who have not completed Steps 1 through 3 of Standard 2 are exempt from this field measurement.]</p>				

<p>b. Based on the self-assessment field reviews using the statistical method described in Standard 4: Self-Assessment Worksheet, the jurisdiction's regulatory staff achieves a rate of 75% on each quality element for jurisdictions with 10 or more inspectors. For jurisdictions with less than 10 inspectors, the achievement rate meets or exceeds the Table 4-1 calculation.</p>				
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**General notes Pertaining to the Program Self-Assessment or the Verification Audit**



## Standard 5: Foodborne Illness and Food Defense Preparedness and Response Program Self-Assessment and Verification Audit Form (January 2017)

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### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

<b>Printed Name of the Person who conducted the SA:</b>	
<b>Self-Assessor's Title:</b>	
<b>Jurisdiction Name:</b>	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
<b>Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Standard 5 Self-Assessment was Completed:</b>	
<b>SA indicates the Jurisdiction MEETS the Standard 5 criteria:</b>	NO

*I affirm that the information represented in the Self-Assessment of Standard 5 is true and correct*

**Signature of the Self-Assessor:** \_\_\_\_\_

### VERIFICATION AUDIT (VA) SUMMARY

<b>Printed Name of the Person who conducted the VA:</b>	
<b>Verification Auditor's Title:</b>	
<b>Auditor's Jurisdiction Name:</b>	
<b>Auditor's Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Verification Audit of Standard 5 was Completed:</b>	
<b>VA indicates the Jurisdiction MEETS the Standard 5 criteria:</b>	

*I affirm that the information represented in the Verification Audit of Standard 5 is true and correct*

**Signature of the Verification Auditor:** \_\_\_\_\_

**Table 6 - Program Self-Assessment and Verification Audit Table for Standard 5**

Standard Sub-Elements Criteria	SA MET	Self-Assessor's Comments	VA MET	If NO, why criterion not met
<b>1. Investigation Procedures</b>				
a. The program has written operating procedures for responding to and/or conducting investigations of foodborne illness and food-related injury that clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies. (The procedures may be contained in a single source document or in multiple documents.)				
b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illnesses, food-related injuries or contamination of food.				
c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.				
d. The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, food-related injury or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in, or linked to, the establishment record for retrieval purposes.				
e. Program procedures describe the disposition, action, or follow-up, and reporting required for each type of complaint or referral report.				
f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.				
g. The program has established procedures and guidance for collecting information on the suspect foods' preparation, storage or handling during on-site illness, food-injury, or outbreak investigations.				

<p>h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.</p>				
<p>i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency’s jurisdiction or has been shipped interstate.</p>				
<p><b>2. Reporting Procedures</b></p>				
<p>a. Possible contributing factors to the illness, food-related injury, or intentional food contamination are identified in each on-site investigation report.</p>				
<p>b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed disease outbreaks with CDC.</p>				
<p><b>3. Laboratory Support Documentation</b></p>				
<p>a. The program has a letter of understanding, written procedures, contract or MOU acknowledging that a laboratory(s) is willing and able to provide analytical support to the jurisdiction’s food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental, food, and/or clinical sample analyses.</p>				
<p>b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction’s primary laboratory(s).</p>				
<p><b>4. Trace-back Procedures</b></p>				
<p>a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The track-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.</p>				
<p><b>5. Recalls</b></p>				

a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak, or intentional food contamination.				
b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.				
c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.				
<b>6. Media Management</b>				
a. The program has a written policy and procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.				
<b>7. Data Review and Analysis</b>				
a. At least once per year, the program conducts a review of the data in the complaint log or database and the illness and food-related injury investigations to identify trends and possible contributing factors that are most likely to cause illness or injury. These periodic reviews of multiple complaints and contributing factors may suggest a need for further investigations and may suggest steps for illness prevention.				
b. The review is conducted with prevention in mind and focuses on but is not limited to, the following: 1) Multiple complaints on the same establishment;				
2) Multiple complaints on the same establishment type;				
3) Multiple complaints implicating the same food;				
4) Multiple complaints associated with similar food preparation processes;				
5) Number of confirmed foodborne disease outbreaks;				
6) Number of foodborne disease outbreaks and suspect foodborne disease outbreaks;				
7) Contributing factors most often identified;				
8) Number of complaints involving real and alleged threats of intentional food contamination; and				

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<p>9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.</p>				
<p>c. In the event that there have been no illness or food-related injury outbreak investigations conducted during the twelve months prior to the trend analysis, program management will plan and conduct a mock foodborne illness or food defense investigation to test program readiness. The mock investigation should simulate response to an actual illness outbreak and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no illness outbreak investigations occur.</p>				

**General notes Pertaining to the Program Self-Assessment or the Verification Audit**



## Standard 6: Compliance and Enforcement

### Program Self-Assessment and Verification Audit Form (January 2017)

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#### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

<b>Printed Name of the Person who conducted the SA:</b>	
<b>Self-Assessor's Title:</b>	
<b>Jurisdiction Name:</b>	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
<b>Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Standard 6 Self-Assessment was Completed:</b>	
<b>SA indicates the Jurisdiction MEETS the Standard 6 criteria:</b>	NO

*I affirm that the information represented in the Self-Assessment of Standard 6 is true and correct*

**Signature of the Self-Assessor:** \_\_\_\_\_

#### VERIFICATION AUDIT (VA) SUMMARY

<b>Printed Name of the Person who conducted the VA:</b>	
<b>Verification Auditor's Title:</b>	
<b>Auditor's Jurisdiction Name:</b>	
<b>Auditor's Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Verification Audit of Standard 6 was Completed:</b>	
<b>VA indicates the Jurisdiction MEETS the Standard 6 criteria:</b>	

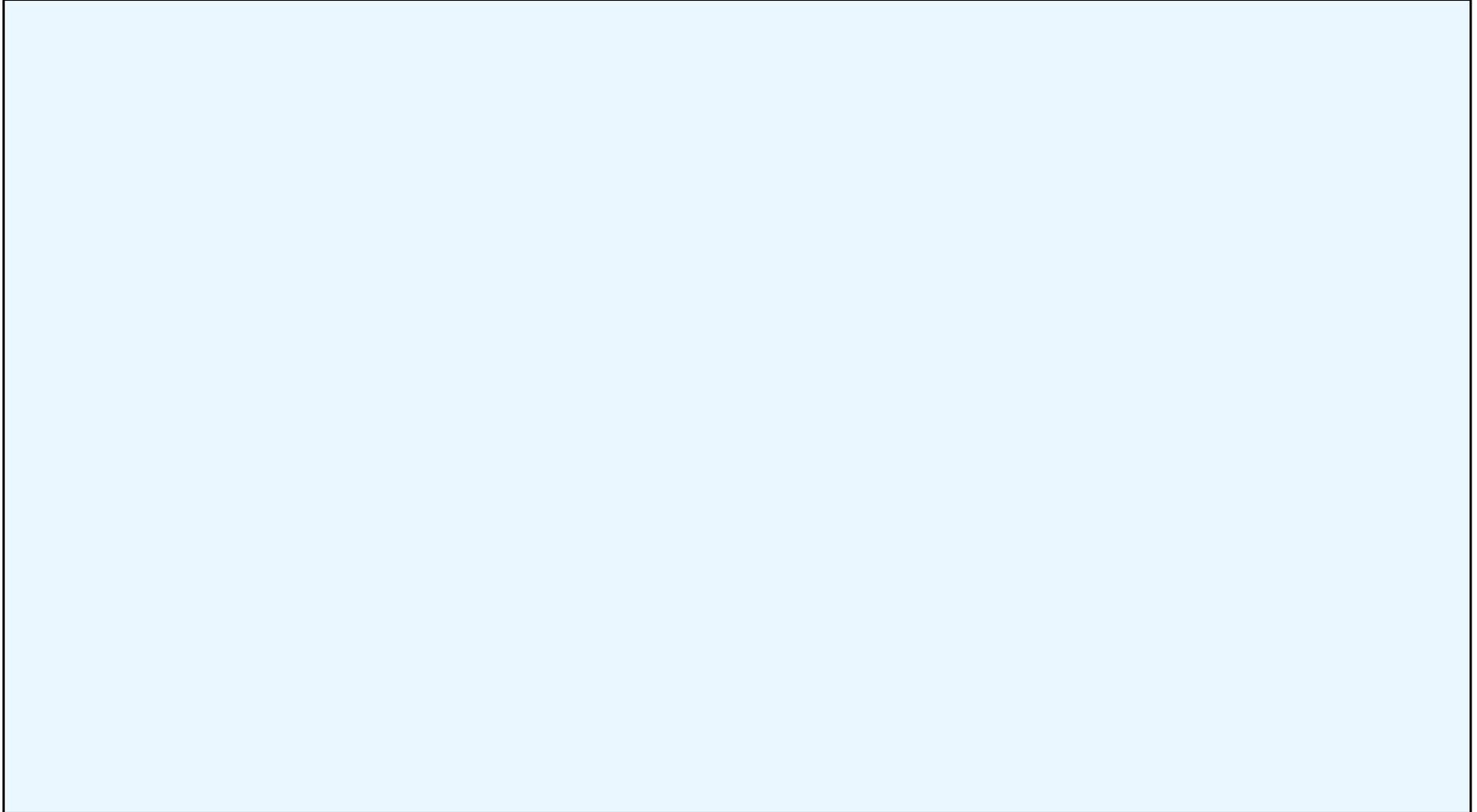
*I affirm that the information represented in the Verification Audit of Standard 6 is true and correct*

**Signature of the Verification Auditor:** \_\_\_\_\_

**Table 7 - Program Self-Assessment and Verification Audit Table for Standard 6**

Standard Sub-Elements Criteria	SA MET	Self-Assessor's Comments	VA MET	If NO, why criterion not met
<b>1. Compliance and Enforcement Procedure</b>				
a. The jurisdiction's has a written step-by-step compliance and enforcement procedure that describes what actions and tools (forms/documents/interventions) are to be used to achieve compliance.				
b. The jurisdiction's inspection form(s) record and quantify the compliance status of foodborne illness risk factors, <i>Food Code</i> interventions and other serious code violations.				
<b>2. Assessment of Effectiveness</b>				
a. The jurisdiction has written documentation that verifies the review of the effectiveness of the staff's implementation of the program's compliance and enforcement procedure that includes a selection of establishment files for review in accordance with the Standard criteria.				
b. The jurisdiction has written documentation verifying that at least 80 percent of the sampled files follow the agency's step-by-step compliance and enforcement procedures and actions were taken to resolve out-of-compliance risk factors recorded on the selected routine inspection in accordance with the Standard criteria.				

**General notes Pertaining to the Program Self-Assessment or the Verification Audit**



## Standard 7: Industry and Community Relations Program Self-Assessment and Verification Audit Form (January 2017)

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### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

<b>Printed Name of the Person who conducted the SA:</b>	
<b>Self-Assessor's Title:</b>	
<b>Jurisdiction Name:</b>	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
<b>Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Standard 7 Self-Assessment was Completed:</b>	
<b>SA indicates the Jurisdiction MEETS the Standard 7 criteria:</b>	NO

*I affirm that the information represented in the Self-Assessment of Standard 7 is true and correct*

**Signature of the Self-Assessor:** \_\_\_\_\_

### VERIFICATION AUDIT (VA) SUMMARY

<b>Printed Name of the Person who conducted the VA:</b>	
<b>Verification Auditor's Title:</b>	
<b>Auditor's Jurisdiction Name:</b>	
<b>Auditor's Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Verification Audit of Standard 7 was Completed:</b>	
<b>VA indicates the Jurisdiction MEETS the Standard 7 criteria:</b>	

*I affirm that the information represented in the Verification Audit of Standard 7 is true and correct*

**Signature of the Verification Auditor:** \_\_\_\_\_

**Table 8 - Program Self-Assessment and Verification Audit Table for Standard 7**

Standard Sub-Elements Criteria	SA MET	Self-Assessor's Comments	VA MET	If NO, why criterion not met
<b>1. Industry and Consumer Interaction</b>				
a. The jurisdiction maintains written documentation confirming that the agency has sponsored or actively participated in at least one meeting/forum annually, such as food safety task forces, advisory boards or advisory committees. Documentation confirms that offers of participation have been extended to industry and consumer representatives.				
<b>2. Educational Outreach</b>				
a. The jurisdiction maintains written documentation confirming that the agency has sponsored or coordinated at least one educational outreach activity annually directed at industry; consumer groups; the media; and or elected officials. Education outreach activities focus on increasing awareness of foodborne illness risk factors and control methods to prevent foodborne illness and may include industry recognition programs; web sites; newsletters; Fight BAC campaigns; food safety month activities; food worker training, consumer surveys, etc.				

**General notes Pertaining to the Program Self-Assessment or the Verification Audit**



## Standard 8: Program Support and Resources

### Program Self-Assessment and Verification Audit Form (January 2017)

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#### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

<b>Printed Name of the Person who conducted the SA:</b>	
<b>Self-Assessor's Title:</b>	
<b>Jurisdiction Name:</b>	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
<b>Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Standard 8 Self-Assessment was Completed:</b>	
<b>SA indicates the Jurisdiction MEETS the Standard 8 criteria:</b>	NO

*I affirm that the information represented in the Self-Assessment of Standard 8 is true and correct*

**Signature of the Self-Assessor:** \_\_\_\_\_

#### VERIFICATION AUDIT (VA) SUMMARY

<b>Printed Name of the Person who conducted the VA:</b>	
<b>Verification Auditor's Title:</b>	
<b>Auditor's Jurisdiction Name:</b>	
<b>Auditor's Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Verification Audit of Standard 8 was Completed:</b>	
<b>VA indicates the Jurisdiction MEETS the Standard 8 criteria:</b>	

*I affirm that the information represented in the Verification Audit of Standard 8 is true and correct*

**Signature of the Verification Auditor:** \_\_\_\_\_

**Table 9 - Program Self-Assessment and Verification Audit Table for Standard 8**

<b>Standard Sub-Elements Criteria</b>	<b>SA MET</b>	<b>Self-Assessor's Comments</b>	<b>VA MET</b>	<b>If NO, why criterion not met</b>
<b>1. Staffing Level – FTEs per Inspections Performed</b>				
a. The jurisdiction has written documentation, calculations, or a program resource assessment that demonstrated a staffing level of one full-time equivalent (FTE) for every 280-320 retail food program inspections performed.				
<b>2. Inspection Equipment</b>				
a. The jurisdiction can demonstrate through written records, equipment inventories, or actual observations that each retail food program inspector has a head cover, thermocouple, flashlight, sanitization test kit, heat sensitive tapes or maximum registering thermometer and necessary forms and administrative materials.				
b. The jurisdiction has a written procedure for obtaining the use of computers, cameras, black lights, light meters, pH meters, foodborne illness kits, sample collection kits, data loggers and cell phones should this equipment not be part of the agency's general equipment inventory.				
<b>3. Administrative Program Support</b>				
a. The jurisdiction has written documentation, calculations or a program resource assessment that demonstrates sufficient equipment is available to support the record keeping system utilized by the program.				
b. The jurisdiction has a system in place to collect, analyze, retain and report pertinent information required to manage and implement the retail food protection program.				
<b>4. Program Resource Assessment</b>				
a. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #1 – Regulatory Foundation.				
b. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #2 – Trained Regulatory Staff.				

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<p>c. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #3 – Inspection Program Based on HACCP Principles.</p>				
<p>d. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #4 – Uniform Inspection Program.</p>				
<p>e. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #5 – Foodborne Illness and Food Security Preparedness and Response.</p>				
<p>f. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #6 – Compliance and Enforcement.</p>				
<p>g. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #7 – Industry and Community Relations.</p>				
<p>h. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #9 – Program Assessment.</p>				

**General notes Pertaining to the Program Self-Assessment or the Verification Audit**



## Standard 9: Program Assessment

### Program Self-Assessment and Verification Audit Form (January 2017)

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#### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

<b>Printed Name of the Person who conducted the SA:</b>	
<b>Self-Assessor's Title:</b>	
<b>Jurisdiction Name:</b>	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
<b>Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Standard 9 Self-Assessment was Completed:</b>	
<b>SA indicates the Jurisdiction MEETS the Standard 9 criteria:</b>	NO

*I affirm that the information represented in the Self-Assessment of Standard 9 is true and correct*

**Signature of the Self-Assessor:** \_\_\_\_\_

#### VERIFICATION AUDIT (VA) SUMMARY

<b>Printed Name of the Person who conducted the VA:</b>	
<b>Verification Auditor's Title:</b>	
<b>Auditor's Jurisdiction Name:</b>	
<b>Auditor's Jurisdiction Address:</b>	
<b>Phone / Fax / E-mail:</b>	
<b>Date the Verification Audit of Standard 9 was Completed:</b>	
<b>VA indicates the Jurisdiction MEETS the Standard 9 criteria:</b>	

*I affirm that the information represented in the Verification Audit of Standard 9 is true and correct*

**Signature of the Verification Auditor:** \_\_\_\_\_

**Table 10 - Program Self-Assessment and Verification Audit Table for Standard 9**

<b>Standard Sub-Elements Criteria</b>	<b>SA MET</b>	<b>Self-Assessor's Comments</b>	<b>VA MET</b>	<b>If NO, why criterion not met</b>
<b>1. Risk Factor Study</b>				
a. A study on the occurrence of foodborne illness risk factors has been completed and includes data for each facility type regulated by the jurisdiction collected over the study cycle.				
b. The data collection form includes items pertaining to the following Center for Disease Control and Prevention (CDC) identified contributing factors to foodborne illness: 1) Food from Unsafe Sources, 2) Improper Holding/Time and Temperature, 3) Inadequate Cooking, 4) Poor Personal Hygiene, and 5) Contaminated Equipment/Protection from Contamination				
c. The data collection form provides for marking actual observations of food practices within an establishment (IN, OUT, NO, and NA).				
<b>2. Report of Analysis and Outcome</b>				
a. A report is available that shows the results of the data collection from the jurisdiction's foodborne illness risk factor study				
b. The report provides quantitative measurements upon which to assess the trends in the occurrence of foodborne illness risk factors over time..				
<b>3. Intervention Strategy</b>				
a. A targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their RISK FACTOR STUDY is implemented and the effectiveness of such strategy is evaluated by subsequent RISK FACTOR STUDIES or other similar tools				
b. Documentation is provided of performed interventions, action, or activities designed to improve control of foodborne illness risk factors.				

**General notes Pertaining to the Program Self-Assessment or the Verification Audit**



**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-018**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2016 II-020; new or additional information has been included or attached and the recommended solution has been revised.

**Title:**

PSC Issue #2 New assessment tool for Standard 8 Staffing Level Criteria

**Issue you would like the Conference to consider:**

The Program Standards Committee has addressed the charges outlined in Issue 2018 II-018: Continue Revision of Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard 8 Staffing Level Criteria. The Committee has proposed a recommendation that the FDA modify the Standard 8 "Staffing Level" criteria by including the proposed model assessment tool as a secondary option to assess compliance based on the findings of the 2018 - 2020 Program Standards Committee, Subcommittee #2.

**Public Health Significance:**

The VNRFRPS offer a systematic approach to, through a continuous improvement process, enhance retail food regulatory programs. The VNRFRPS define and provide a framework designed to accommodate both traditional and emerging approaches of regulatory programs operating within an integrated food safety system. The Program Standards Committee established a subcommittee to address the specific charges in Issue 2018 II-018. The subcommittee, with support from staff from Harris County Public Health, created a new proposed model assessment tool, ensured it to be statistically sound, and completed a pilot study among 19 jurisdictions to test the proposed model. The information collected provided the means to: (1) Improve the proposed model assessment tool that was initially created by the Standard 8 Subcommittee in Issue # 2016 II-020; (2) Validate the statistical soundness of the proposed model by confirming there was no relationship found between times and frequencies provided by "high" and "low" performing jurisdictions; (3) Determine if the proposed model assessment tool could be used in the real world setting by conducting a Pilot Study to assess the functionality of the model among varying jurisdictions; and (4) Utilize data from the study to recommend the proposed model assessment tool be included in the Standard 8 "Staffing Level" criteria as an alternative way to determine compliance.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends that a letter be sent to FDA asking them to modify the "Description of Requirements" for "Staffing Level" in Standard 8 by including the proposed model assessment tool as an alternative option to assess compliance for the VNRFRPS.*

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**Supporting Attachments:**

- "PSC Issue #2 list of supporting attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

## PSC Issue #2 list of supporting attachments

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 8 – Proposed Model
- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: 2018 Issue (see page 27 <http://www.foodprotect.org/media/biennialmeeting/council-ii-final-issue-recommendations-1.pdf>)
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: 2018 Program Standards Committee Final Report  
[http://www.foodprotect.org/issues/packets/2018Packet/issues/II\\_013.html](http://www.foodprotect.org/issues/packets/2018Packet/issues/II_013.html). See the Re-evaluation of VNRFRPS Standard 8 Subcommittee Report and supporting attachments for Standard 8.
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 8 Summary
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 8 PowerPoint
- (5) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Voluntary National Retail Food Regulatory Program Standards – Standard 8 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (6) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 8 Re-Evaluation of Staffing Level Model Pilot Study Report

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-019**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018 II-020; new or additional information has been included or attached.

**Title:**

PSC Issue #3 Posting updated Crosswalk - Requirements for Foodborne Illness

**Issue you would like the Conference to consider:**

Developing new and updated foodborne disease outbreak training programs will continue, and all target agencies could benefit from a process that updates a list of available training and reviews the programs. During the 2016-2018 CFP biennium, the Program Standards Committee (PSC) identified additional foodborne illness training resources but were unable to review them all for inclusion in the Crosswalk - Requirements for Foodborne Illness Training Programs Based on Standard 5 (Crosswalk) at that time. The 2018-2020 CFP PSC updated the Crosswalk with these additional resources. This document is posted on the CFP website; posting the updated Crosswalk will provide a tool that will facilitate the development of robust foodborne illness training programs.

**Public Health Significance:**

Delays in reporting or investigating a possible foodborne disease outbreak can prolong an outbreak event, potentially resulting in further illness or economic disruption. Adequate training of public health professionals, health agencies, universities, and industry in outbreak response can mitigate the negative impact of an outbreak. However, these entities may not be aware of the foodborne disease outbreak training that is currently available.

The Program Standards Committee believes that these opportunities provide the chance for the Conference for Food Protection to continue to influence the food and beverage community, health agencies, and universities through the review of their foodborne illness training programs to determine if their program is complete and meets the requirements as outlined in Standard 5 of the Voluntary National Retail Food Regulatory Program Standards.

**Recommended Solution: The Conference recommends...:**

1. Approval of the updated document titled "Crosswalk - Requirements for Foodborne Illness Training Programs" (Crosswalk) (revision date 10/24/19) and authorizing the Conference to make any necessary edits before posting the document on the CFP website.
2. Replace the existing PDF file on the CFP website with the updated Crosswalk document.

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**Supporting Attachments:**

- "PSC Issue #3 list of supporting attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

PSC Issue #3 list of supporting attachments

(1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Crosswalk-Requirements for Foodborne Illness Training Programs

(2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-020**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018 II-014; new or additional information has been included or attached.

**Title:**

PSC Issue #4 Maintenance and Posting of the Self-Assessment Tool (SA Tool)

**Issue you would like the Conference to consider:**

The Program Standards Committee recommends the SA Tool spreadsheet be maintained by FDA and posted on the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) web page as a resource for programs enrolled in the Retail Program Standards.

**Public Health Significance:**

Jurisdictions need tools to report progress on compliance with the Retail Program Standards to their boards, councils and other policy makers. The SA Tool is a spreadsheet created by FDA that mirrors the content of the Retail Program Standard forms, but is a single location to track each standard and summarizes the overall progress in a single table. Many enrolled jurisdictions are not aware of the existence of the SA Tool. Posting the SA Tool on the Retail Program Standards web page will make it accessible to enrolled jurisdictions. The SA Tool should be modified as the Program Standards are updated.

**Recommended Solution: The Conference recommends...:**

That a letter be sent to FDA asking them to:

1. Maintain the SA Tool that aligns with revisions of the Retail Program Standards
2. Post the SA Tool on the FDA Retail Program Standards web site under the "Information about Enrolling and Participating in the Retail Program Standards" section of the page with a notation that it is not a required form. <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>

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**Supporting Attachments:**

- "PSC Issue #4 list of supporting attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

PSC Issue #4 list of supporting attachments

(1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #1 final report

(2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Draft 2017 VNRFRPS Self-Assessment Audit Form

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-021**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Creation of a Digital Food Safety System Committee

**Issue you would like the Conference to consider:**

That a Digital Food Safety System Committee be created of members from all constituencies of the CFP.

**Public Health Significance:**

Technology platforms available to the foodservice industry today can provide levels of operational insights not previously possible. These systems provide real-time information that support a preventative approach to managing food safety. By establishing industry supported best practices focused on measuring and reporting on active managerial control foodborne illness incidents will be reduced.

**Recommended Solution: The Conference recommends...:**

The creation of a Digital Food Safety System Committee to complete the following charges and report it findings at the 2022 CFP Meeting.

The Committee will be charge with:

1. Identify best practices, existing guidance documents, and research that relate to the use of digital food safety management systems.
2. Develop a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for Digital Food Safety Management Systems.
3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 4 (Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors), Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance

document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.

4. Reporting the committee's findings and recommendations to the 2022 Biennial Meeting of the Conference for Food Protection.

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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-022**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Creation of a Digital Temperature Monitoring Equipment Committee

**Issue you would like the Conference to consider:**

That a Digital Temperature Monitoring Equipment Committee be created of members from all constituencies of the CFP.

**Public Health Significance:**

Digital Temperature Monitoring Equipment available to the foodservice industry today provide real-time information that support a preventative approach to managing food safety. By establishing industry supported best practices foodservice operators will be able to make better informed decisions and reduce unnecessary food waste due to temperature abuse.

**Recommended Solution: The Conference recommends...:**

The creation of a Digital Temperature Monitoring Equipment Committee to complete all charges and report back findings at the 2022 CFP meeting.

The Committee will be charge with:

1. Identify best practices, existing guidance documents, and research that relate to the use of digital temperature monitoring equipment.
2. Develop a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for Digital Temperature Monitoring Equipment.
3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 4 (Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors), Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance

document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.

4. Reporting the committee's findings and recommendations to the 2022 Biennial Meeting of the Conference for Food Protection.

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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-023**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018 II-014; new or additional information has been included or attached and the recommended solution has been revised.

**Title:**

PSC #5 Continuation of Issue 2018 II-014 PSC2

**Issue you would like the Conference to consider:**

The Program Standards Committee recommends continuation of Issue 2018 II-014, charge 1, to have the FDA work with the Program Standards Committee (PSC) to incorporate plan review in the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS).

**Public Health Significance:**

Plan review helps ensure retail food establishments are designed to have adequate facilities, systems, and equipment to safely store, prepare and serve food. The plan review function supports behaviors that reduce the occurrence of risk factors associated with foodborne illness.

Lack of plan review or incomplete plan review may result in conditions that contribute to foodborne illness, such as a lack of proper equipment to properly store or hold food at safe temperatures, unsanitary conditions that promote pest infestation, contamination from employees, raw animal foods, unclean food contact surfaces, etc.

**Recommended Solution: The Conference recommends...:**

1. The Program Standards committee and FDA staff continue to explore the feasibility of incorporation of plan review functions into the standards either as a stand-alone standard or inserted into the existing standards in the VNRFRPS.
2. Acknowledgement of the Preliminary Plan Review Proposal document to be utilized as a starting point for the 2020-2022 Program Standards Committee work on this issue.

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**Supporting Attachments:**

- "PSC Issue #5 list of supporting attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

PSC Issue #5 list of supporting attachments

(1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Preliminary Plan Review Proposal

(2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #1 final report

(3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: CFP Plan Review Guide (see <http://www.foodprotect.org/media/guide/2016-plan-review-manual.pdf>)

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-024**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This is a brand new Issue.

**Title:**

PSC Issue #6 Amend Standard 2 Appendix B-1 format

**Issue you would like the Conference to consider:**

The current formatting of Voluntary National Retail Food Regulatory Program Standards (VNRFRPS or Standards) Standard 2: Trained Regulatory Staff, Appendix B-1: Curriculum for Retail Food Safety Inspection Officers implies the course listed is the only course that will fulfill the training requirement.

There is the possibility of change in learning management system (LMS) platforms used by the FDA resulting in course availability issues and other comparable courses may be needed as substitutions. In addition, many of the courses listed in Appendix B-1 were developed over 10 years ago.

**Public Health Significance:**

Many health authority jurisdictions use Option 1 (the courses in Appendix B-1) to meet Step 1: Pre-Inspection Curriculum of Standard 2. If courses currently listed in Appendix B-1 are no longer available, jurisdiction will not be able to use Option 1.

The FDA has a contract with International Food Protection Training Institute (IFPTI) to develop a curriculum framework and associated coursework for food protection professionals as part of the Food Safety Modernization Act. The IFPTI courses, developed by subject matter experts, are more up to date than ComplianceWire courses and are being updated to include contemporary eLearning course design and technologies creating a more interactive experience for the learner resulting in better retention of the material. Many of these courses can be used to meet the curriculum requirements of Standard 2.

Reformatting of Appendix B-1 to change course titles to curriculum topics and listing courses which fulfill curriculum topics reinforces that alternate courses may be used to fulfill the topic.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting that Voluntary National Retail Food Regulatory Program Standards, Standard 2: Trained Regulatory Staff, Appendix B-1: Curriculum for Retail Food Safety Inspection Officers be reformatted into a table with curriculum topics in one column and courses which fulfill the curriculum topics in another column. Appendix B-1 Reformatted 1st Draft and 2nd Draft better show that other courses may be used if deemed equivalent by the regulatory jurisdiction.

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**Supporting Attachments:**

- "PSC Issue #6 list of supporting attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

PSC Issue # 6 list of supporting attachments

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1st Draft
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 2 Appendix B-1 (see <https://www.fda.gov/media/86752/download>)

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-025**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

PSC Issue #7 Amend Std 2 curriculum to replace select courses with updates

**Issue you would like the Conference to consider:**

FD252 Allergen Management, FDA 35 Basic Food Law for State Regulators, FDA36 Public Health Principles, MIC13 Aseptic Sampling, MIC15 Cleaning and Sanitizing, of the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Program Standard 2, Trained Regulatory Staff Appendix B-1, Coursework for Food Safety Inspection Officers (FSIO) all have outdated content and require replacement with upgraded course content that provides more relevant and up-to-date information.

**Public Health Significance:**

The updated course content was developed as part of a cooperative agreement between the International Food Protection Training Institute (IFPTI) and the FDA. In Standard 2, Trained Regulatory Staff, the VNRFRPS describe the training process for an FSIO to obtain the knowledge, skills and ability to adequately perform their duties. Standard 2 identifies allergen management as a required competency for individuals conducting regulatory inspections. As per the B2 Allergens IFPTI course profile, the course includes information that will assist an FSIO in discussing the control of allergens in relation to food safety, labeling requirements, and Food Safety Modernization Act (FSMA).

Standard 2 identifies statutes, regulation, and ordinances as a required competency for individuals conducting regulatory inspections. As per the B17 Laws, Regulations, Policies, and Procedures IFPTI course profile, the course includes information that will assist an FSIO in discussing foundations, constitution, law, regulation, policy, procedures, and guidance.

Standard 2 indicates that an understanding of public health principles is a required competency for individuals conducting regulatory inspections. FDA36 Public Health Principles covers this subject matter but is directed at public health professionals in a variety of program areas. As per the B23 Public Health Principles IFPTI course profile, the course is updated and focused more specifically on food protection professionals. B23

includes contemporary examples, such as the bovine spongiform encephalopathy (BSE) outbreak in the United Kingdom and the E. coli O157:H7 outbreak in the United States during 1993. These examples are used to describe subsequent changes in public policy and describe the methodology for disease mitigation.

Standard 2 identifies food microbiology and epidemiology as required competencies for individuals conducting regulatory inspections, including the collection of samples during foodborne illness investigations. As per the B25 Sampling IFPTI course profile, the course covers the same material as MIC13, but also includes a subtitled video demonstration of protocols for collecting aseptic samples. Additionally, the course describes the methods and rationale for collecting and documenting samples that are legally and scientifically defensible, including chain of custody.

Standard 2 identifies food microbiology as a required competency for individuals conducting regulatory inspections. As per the B26 Sanitation Practices IFPTI course profile, the course covers the same material as MIC15 but expands on that content to include construction materials, establishment layout and other principles relevant to sanitary engineering. It addresses the distinction between cleaning and sanitizing, barriers to accomplishing both activities, the limitations and thresholds for different methods.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting the replacement of the following courses with committee suggested courses as they contain material that is a significant upgrade in course content and provide more relevant and up-to-date information:

(1) the replacement of FD252 Allergen Management in Standard 2, Trained Regulatory Staff, "post" curriculum with coursework such as the International Food Protection Training Institute course B2 Allergens (CC8029W);

(2) the replacement of FDA35 Basic Food Law for State Regulators in Standard 2, Trained Regulatory Staff, "pre" curriculum with coursework such as the International Food Protection Training Institute course B17 Laws, Regulations, Policies, and Procedures (CC8039W);

(3) the replacement of FDA36 Public Health Principles with an updated course, such as the International Food Protection Training Institute Course B23 Public Health Principles (CC8026W) in the "pre" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards;

(4) the replacement of MIC13 Aseptic Sampling with an updated course, such as the International Food Protection Training Institute Course B25 Sampling (CC8035W) in the "pre" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards; and

(5) the replacement of MIC15, "Cleaning & Sanitizing," with an updated course, such as the International Food Protection Training Institute Course B26 Sanitation Practices (CC8032W) in the "pre-requisite" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards.

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**Supporting Attachments:**

- "PSC Issue #7 list of supporting attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

PSC Issue #7 list of supporting attachments

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B2 Allergens IFPTI Course Profile
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B17 Laws Regulations IFPTI Course Profile
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B23 Public Health Principles IFPTI Course Profile
- (5) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B25 Sampling IFPTI Course Profile
- (6) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B26 Sanitation Practices IFPTI Course Profile

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-026**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018 II-019 and 2016 II-015; new or additional information has been included or attached and the recommended solution has been revised.

**Title:**

PSC Issue #8 Amend Standard 2 to include additional "pre" and "post" topics

**Issue you would like the Conference to consider:**

Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Program Standard 2, Trained Regulatory Staff Appendix B-1, Coursework for Food Safety Inspection Officers (FSIO) is lacking courses on the following topics: environmental hazards, integrated food safety systems, jurisdiction, labeling, pest control, plumbing, professionalism, recalls, traceability, and transportation.

**Public Health Significance:**

In Standard 2, Trained Regulatory Staff, the VNRFRPS describe the training process for an FSIO to obtain the knowledge, skills and ability to adequately perform their duties. New coursework was developed as part of a cooperative agreement between the International Food Protection Training Institute (IFPTI) and the FDA. Standard 2 identifies public health principles as a required competency for individuals conducting regulatory inspections. As per the B8 Environmental Hazards IFPTI course profile, the course includes information that will assist an FSIO in developing knowledge, skills, and abilities related to environmental hazards as sources of contamination, and associated control methods.

Standard 2 identifies communication as a required competency for individuals conducting regulatory inspections. As per the B12 Integrated Food Safety System IFPTI course profile, the course includes information that will assist an FSIO in discussion of integrated food safety system foundations, stakeholders, mutual reliance, and program standards.

Standard 2 identifies statutes, regulations, and ordinances as a required competency for individuals conducting regulatory inspections. As per the B15 Jurisdiction IFPTI course profile, the course includes information that will assist an FSIO in gaining introductory knowledge, skills, and abilities related to various regulatory agencies and their authority over feed and food. The topics covered in this course include foundations, law, crossing

boundaries, inter-agency agreements. The student will be able to describe which agencies have authority to conduct specific regulatory activities.

Standard 2 identifies basics of inspection as a required competency for individuals conducting regulatory inspections. As per the B16 Labeling IFPTI course profile, the course includes information that will assist an FSIO in gaining introductory knowledge of labeling laws and regulations and components of feed and food labels. While conducting inspections, trained inspection staff will routinely encounter product labels and may need to interpret labeling for determination of compliance.

Pest Control is another key public health principle and required competency for individuals conducting regulatory inspections. As per the B19 Pest Control IFPTI course profile, the course includes information that will assist an FSIO in explaining how pest activity can impact food safety, discussing pests of significance to human and animal health, discussing the importance of facility design for pest control, describing sanitation practices for pest control, and discussing how pest management is used to control pests. While conducting inspections, trained inspection staff will need to rely on knowledge of how integrated pest management impacts food safety.

Adequate assessment of plumbing is also part of inspection basics. As per the B20 Plumbing IFPTI course profile, the course provides information on plumbing controls used in commercial food establishments to protect the potable water supply from contamination, citing contemporary examples where illness and injury could have been prevented with properly maintained plumbing devices. The course includes photos and diagrams that illustrate the function of plumbing devices that an inspector will be evaluating during inspections. The material also identifies the differences between public and private water supplies and how these differences inform the questions that should be asked by the regulator during an inspection.

Knowledge of professionalism standards also supports the required competency of communication for individuals conducting regulatory inspections. As per the B22 Professionalism IFPTI course profile, the course includes information that will assist an FSIO in communicating effectively, demonstrating professional conduct and avoiding the appearance of misconduct.

Knowledge of prevailing statutes, regulations and ordinances also includes recall procedures. As per the B24 Recalls IFPTI course profile, the course is an introduction to the process of removing products from commerce when they are adulterated or misbranded. It addresses important distinctions, such as the difference between product recalls and market withdrawals. B24 Recalls also covers the disposition of food products, assessing risk, documentation, and how to coordinate with other jurisdictions, state agencies and the FDA.

Standard 2 indicates that an understanding of food microbiology and epidemiology is required for regulators. As per the B27 Traceability IFPTI course profile, the course serves as a primer for tracking human and animal foods through the supply chain. The traceback processes and necessary documentation are clearly defined, and the rationale is provided for when and why a traceback is conducted. B27 Traceability builds on material presented in the Foodborne Illness Investigations series.

As per the B28 Transportation IFPTI course profile, the course introduces material pertaining to preventing contamination of food during transport. It addresses transportation

methods, security and product safety along the chain of custody. The course cites contemporary examples, such as a Salmonella enteritidis outbreak in Minnesota. B28 Transportation also includes information on pest control, HACCP and temperature control as it relates to transporting food. Regulators must consider the impact of a compromised supply chain on the flow of food.

**Recommended Solution: The Conference recommends...:**

That a letter be sent to the FDA requesting the following coursework be added as they are important topics that are not currently covered in the Standard 2 curriculum and are necessary for a new Food Safety Inspection Officer's baseline knowledge. :

(1.) The addition of coursework on environmental hazards, such as the International Food Protection Training Institute Course B8 Environmental Hazards (CC8024W) to the "pre" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards;

(2.) The addition of coursework on integrated food safety system, such as the International Food Protection Training Institute Course B12 Integrated Food Safety System (CC8018W) to the "post" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards;

(3.) The addition of coursework on jurisdictional authority, such as the International Food Protection Training Institute Course B15 Jurisdiction (CC8037W) to the "pre" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards;

(4.) The addition of coursework on labeling, such as the International Food Protection Training Institute Course B16 Labeling (CC8038W) to the "post" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards;

(5.) The addition of coursework on pest control, such as the International Food Protection Training Institute Course B19 Pest Control to the "pre" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards;

(6.) The addition of coursework on plumbing, such as the International Food Protection Training Institute Course B20 Plumbing (Course under development-upgrade from CC8001W) to the "pre" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards;

(7.) The addition of coursework on professionalism, such as the International Food Protection Training Institute Course B22 Professionalism (CC8025W) to the "pre" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards;

(8.) The addition of coursework on recalls, such as the International Food Protection Training Institute Course B24 Recalls (CC8041W) to the "post" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards;

(9.) The addition of coursework on traceability, such as the International Food Protection Training Institute Course B27 Traceability (CC8042W) to the "post" curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards; and

(10.) The addition of coursework on transportation, such as the International Food Protection Training Institute Course B28 Transportation (CC8036W) to the "post"

curriculum for Standard 2 in the Voluntary National Retail Food Regulatory Program Standards.

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**Supporting Attachments:**

- "PSC Issue #8 list of supporting attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

## PSC Issue #8 list of supporting attachments

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B8 Environmental Hazards IFPTI Course Profile (see attached PDF)
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B12 Integrated Food Safety System IFPTI Course Profile (see attached PDF)
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B15 Jurisdiction IFPTI Course Profile (see attached PDF)
- (5) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B16 Labeling IFPTI Course Profile (see attached PDF)
- (6) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B19 Pest Control IFPTI Course Profile (see attached PDF)
- (7) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B20 Plumbing IFPTI Course Profile (see attached PDF)
- (8) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B22 Professionalism IFPTI Course Profile (see attached PDF)
- (9) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B24 Recalls IFPTI Course Profile (see attached PDF)
- (10) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B27 Traceability IFPTI Course Profile (see attached PDF)
- (11) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: B28 Transportation IFPTI Course Profile

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-027**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

PSC Issue #9 Amend Std 2 to increase the time for completion of Steps 1-4

**Issue you would like the Conference to consider:**

The Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Standard 2: Trained Regulatory Staff requires that Steps 1 through 4 are completed within 18 months of hire or assignment to the retail food regulatory program. This timeframe can be difficult to meet and does not align with the time frame provided by Standard 2 - Training Program of the Manufactured Food Regulatory Program Standards (MFRPS).

**Public Health Significance:**

Standard 2 ensures that regulatory retail food program inspection staff shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency:

Step 1: Pre-Inspection Curriculum

Step 2: Initial Field Training and Experience

Step 3: Independent Inspections and Completion of All Curriculum Elements

Step 4: Food Safety Inspection Officer - Field Standardization

Step 5: Continuing Education and Training

Standard 2 requires that ninety percent of the regulatory retail food program inspection staff must have successfully completed the required elements of steps 1 through 4 within 18 months of hire or assignment to the retail food regulatory program.

In many regulatory jurisdictions, retail food inspection staff are generalists performing multiple environmental health functions. Upon hire or reassignment, staff must be trained in many disciplines including water, wastewater, air quality, on-site waste management, aquatic health, public accommodations, housing, and solid waste in addition to retail food.

Allowing for more time to steps 1-4 will make the retail food training requirements in Standard 2 more attainable.

One of the major hurdles for regulatory jurisdictions to meet the Standard 2 is the completion of a standardization process similar to the FDA standardization procedures. This process requires a Standardized Food Safety Inspection Officer who has been standardized by FDA to conduct standardization of inspection staff or to create State Standards to conduct standardization of inspection staff. Standardized Food Safety Inspection Officer are in short supply and high demand. In some states, local regulatory jurisdictions participate in VNRFRPS, but the state does not, and a Standardized Food Safety Inspection Officer is not available. In other states, travel is required for the Standardized Food Safety Inspection Officer to perform standardization for local regulatory jurisdictions resulting in financial concerns. Additionally, scheduling and conducting eight joint field inspections of food establishments is very time consuming. Allowing for more time to complete the field standardization process may not alleviate all obstacles, but it will make the requirement more attainable.

Many regulatory jurisdictions participate in both VNRFRPS and MFRPS. Standard 2 - Training Program of the MFRPS allows for 24 months to complete a basic food inspection training curriculum that consists of coursework and field training. Increasing the timeframe for VNRFRPS, Standard 2 to 24 months will align with the requirements of MFRPS, Standard 2.

#### **Recommended Solution: The Conference recommends...:**

The Conference recommends that a letter be sent to the FDA requesting the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Standard 2: Trained Regulatory Staff be amended to increase the timeframe for completion of Steps 1 - 4 to 24 months.

Amended language for VNRFRPS Standard 2:

#### ***Description of Requirement***

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection

Officers - FSIO) shall have successfully completed the required elements of the 5-step training and

standardization process:

- Steps 1 through 4 within ~~48~~ 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial ~~48~~ 24 months of training.

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**Supporting Attachments:**

- "PSC Issue #9 list of supporting attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

PSC Issue #9 list of supporting attachments

(1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report

(2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: VNRFRPS, Standard 2 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)

(3) Manufactured Food Regulatory Program Standards (see <https://www.fda.gov/MFRPS>)

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-028**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

PSC Issue #10 Amend CFP Training Manual to add Quality Program Elements

**Issue you would like the Conference to consider:**

Voluntary National Retail Food Regulatory Program Standards (VNRFRPS or Standards), Standard 4: Uniform Inspection Staff requires that Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and uniformity among the regulatory staff, in accordance with twenty quality assurance program elements:

Program Element III requires that inspection staff "Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met";

Program Element IX requires that inspection staff "Discuss options for the long-term control of risk factors with establishment managers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies. Options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans"; and

Program Element XVIII requires that inspection staff "Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans."

Ideally, all program elements of the quality assurance plan should be addressed during training of inspection staff. Program Elements III, IX, and XVIII are not currently addressed in Standard 2: Trained Regulatory Staff and should be added.

The Program Standards Subcommittee #3 was charged to assess if any changes will be needed in Standard 2 to provide better alignment with Standard 4. After detailed review and deliberation, it was determined that amending the CFP Training Manual and

Attachment A - CFP Training Plan and Log performance elements will result in better alignment of the Standard 2 with Standard 4. See *Draft CFP Training Plan Revision and Draft Attachment A - CFP Training Plan and Log Revision*.

**Public Health Significance:**

Program Element III - Standard 3 requires that regulatory jurisdictions assign inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk. With limited resources, creating a variable inspection frequency for each category will allow inspection staff to effectively spend more time in high risk establishments that pose the greatest potential risk of causing foodborne illness. To make the best use of inspection staff's time, it is important that food establishments are assigned the correct risk category. In addition, many jurisdictions use risk categories as a basis for permit fees, so it is important to both the food industry and the regulatory agency that the risk category is correct.

Standard 2 requires that regulatory retail food program inspection staff shall have the knowledge, skills, and ability to adequately perform their required duties. This includes successful completion of the jurisdiction's Field Training Plan similar to the process outlined in the Conference for Food Protection (CFP) Field Training Manual. As noted in the Program Standards Committee Subcommittee #3 Final Report, the CFP Field Training Manual does not address Standard 4 Program Element III: "Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met." To properly address Standard 4 Program Element III, two changes to the CFP Training Manual and Attachment A - CFP Training Plan and Log are needed.

Program Element IX - Foodborne illness risk factors are food handling practices and behaviors commonly identified by the CDC as contributing factors in foodborne illness in retail food establishments. Observation of the same out-of-control risk factor on consecutive inspections indicates a lack of active managerial control by the facility management. At this point the violation has been identified and control measures discussed the first time the violation was observed. At the time of the second consecutive violation of the same risk factor, additional remedies must be discussed with facility management to gain long-term control (options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans).

As noted in the Program Standards Committee Subcommittee #3 Final Report, the CFP Field Training Manual does not address Standard 4 Program Element IX: "Discuss options for the long-term control of risk factors with establishment managers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies..."

Program Element XVIII - Observation of the same out-of-control risk factor on consecutive inspections indicates the need for long-term behavior change that will result in a reduction in the occurrence of risk factor violations. Inspection staff should discuss with management the importance of correcting the risk factor and offer suggestions for long-term control measures such as the development of food safety management systems, equipment

and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.

Future violations of the same out-of-control risk factor may require compliance activities and it is important that options for the long-term control of risk factors discussed with establishment managers previously were documented in the establishment file. This documentation also demonstrates due diligence of the regulatory authority to work with establishment management to gain compliance and reduce the occurrence of out-of-control risk factors.

As noted in the Program Standards Committee Subcommittee #3 Final Report, the CFP Field Training Manual does not address Standard 4 Program Element XVIII: "Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans."

**Recommended Solution: The Conference recommends...:**

for better alignment of Standard 2 with Standard 2 that the CFP Training Manual and Attachment A - CFP Training Plan and Log (see *Draft CFP Training Plan Revision* and *Draft Attachment A - CFP Training Plan and Log Revision*) be amended to address:

(1) Quality Assurance Program Element III in Section I Pre-inspection, #2. Reviews establishment file for previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance by the agency by including "current risk category assigned." This will result in additional language for Section I performance element #2 on pg. 7 of the CFP Training Manual;

(2) Quality Assurance Program Element III in Section I Pre-inspection, #2. Reviews establishment file for previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance by the agency by including the statement "Reviewed establishment file for documentation indicating the assigned risk category." This will result in a total of five items under Section I performance element #2 in Attachment A - CFP Training Plan and Log;

(3) Quality Assurance Program Element III in Section II Inspection Observations and Performance, #3 Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food by including the statement "and verify the establishment is assigned the correct risk category." This will result in additional language for Section II performance element #3 on pg. 8 of the CFP Training Manual;

(4) Quality Assurance Program Element III in Section II Inspection Observations and Performance, #3 Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food by including the statement "Verified the establishment is assigned the correct risk category, and when necessary, informs the supervisor when the establishment is not in the proper risk category." This will result in a total of sixteen items under Section II performance element #3 in Attachment A - CFP Training Plan and Log;

(5) Quality Assurance Program Element IX in Section II, Inspection Observations and Performance, #6 Verifies correction of out of compliance observations identified during previous inspection by including the statement "Discussed options for the long-term control of risk factors." This will result in additional language for Section II performance element #6 on pg. 8 of the CFP Training Manual;

(6) Quality Assurance Program Element IX in Section II, Inspection Observations and Performance, #6 Verifies correction of out of compliance observations identified during previous inspection by including the statement "Discussed options for the long-term control of risk factors with establishment managers when the same out-of-control risk factor occurs on consecutive inspections (e.g., risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans)." This will result in a total of two items under Section II performance element #6 in Attachment A - CFP Training Plan and Log;

(7) Quality Assurance Program Element XVIII in Section IV Written Communication, #1 Completes inspection form per jurisdiction's administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates) by including the statement "options for the long-term control of risk factors." This will result in additional language for Section IV performance element #1 on pg. 8 of the CFP Training Manual; and

(8) Quality Assurance Program Element XVIII in Section IV Written Communication, #1 Completes inspection form per jurisdiction's administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates) by including the statement "Documented that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections." This will result in a total of eight items under Section IV performance element #1 in Attachment A - CFP Training Plan and Log.

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**Supporting Attachments:**

- "PSC Issue #10 list of supporting attachments"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

PSC Issue #10 list of supporting documents

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #3 final report
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: PSC Subcommittee #3 Charge 3 Quality Elements Cross-referenced
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Draft Attachment A – CFP Training Plan and Log Revision
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: VNRFPS, Standard 2 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (5) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: VNRFPS, Standard 4 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (6) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: CFP Training Manual (see <http://www.foodprotect.org/guides-documents/conference-for-food-protection-cfp-field-training-manual-for-regulatory-retail-food-safety-inspection-officers-5-31-13-cfp-update/>)
- (7) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Draft CFP Training Manual Revision

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-029**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

CFP Model Code

**Issue you would like the Conference to consider:**

The Conference on Food Protection should publish a model code document based on the 2017 Food Code but encompassing the recommendations of the CFP process solely. FDA would have a voice in the determination of the issues as does every member of the Conference.

**Public Health Significance:**

CFP makes recommendations, based on unanimous consent between the 50 states, to FDA. Often the recommendations for changes to the food code are ignored or discounted. There are many stakeholders that ensure safe food in the food regulatory sphere. Utilizing a system that is science-based and with strong emphasis on data driven risk analysis is a paramount to our mission. Many of FDA objections appear to be based on the principle that the absence of evidence is evidence of absence, which is a logic fallacy. This lends to the impression that the States do not feel they have a say in the code. CFP was "created to provide a formal process whereby members of industry, regulatory, academia, consumer, and professional organizations are afforded equal input in the development and/or modification of food safety guidance."

Two years ago, CFP recommended 26 changes. All 50 States voted in favor. These recommendations went to FDA and only 13 were accepted. Most recently 15 issue recommendations were submitted to FDA and only 5 were accepted. Note: The FDA Response letters from 2012, 2014, 2016, 2018 are included as attachments, although not in full due to size limitations. Full letters can be found on CFP website at [www.foodprotect.org](http://www.foodprotect.org) under Biennial Meetings.

Recent examples of such discounting include the storage within the restroom issue (2018-I-031) and the cedar plank (2018-I-032) issue. FDA looks at a rubric to determine if an item is a core, Pf, or Priority. The rubric is not available to the public.

While FDA is the paramount regulatory agency in the realm of food safety, it is an executive branch agency of the federal government and as such is not free from the influence of outside forces. The CFP, through its deliberative process can lay bare such influences and promote a regulatory structure based on the best science, the experience of the regulators and practical applicability.

The place for debate and determination of the content of the code is CFP. Not an opaque process at the federal agency.

**Recommended Solution: The Conference recommends...:**

The creation of a memorandum that allows the Conference to express their displeasure with the FDA regarding their recent disregard to State opinion.

Further, the CFP should publish a model code that consists solely of the modifications of the code adopted by the CFP.

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**Supporting Attachments:**

- "CFP 2018 FDA Response Letter"
- "FDA Response to CFP Recommendations 2016"
- "FDA Response to CFP 2014"
- "2012 FDA Response to CFP"

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August 21, 2018

David Lawrence, Chair  
Conference for Food Protection  
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Dear Mr. Lawrence:

Thank you for your letter of May 21, 2018, transmitting the recommendations made by the Conference for Food Protection (CFP) at its 2018 Biennial Meeting in Richmond, Virginia. The Food and Drug Administration (FDA) values the opportunity to fully participate in the CFP Biennial Meetings and to provide input to the Executive Board and the numerous CFP Committees.

The 2018 Biennial Meeting was productive, with a total of 93 Issues deliberated. FDA appreciates the efforts of all participants in the 2018 Meeting to develop recommendations intended to further food safety and foster cooperation among Federal, State, local, territorial, and tribal agencies and our partners in industry, academia, and consumer groups.

In accordance with the Memorandum of Understanding between FDA and the CFP, I am pleased to respond with FDA's current positions on the 2018 recommendations for changes to the FDA Food Code or requests for other action by FDA.

**Part 1 – 2018 Conference Recommendations for Changes to the FDA Food Code**

Your letter identified 25 recommendations by the Assembly of Delegates to change the FDA Food Code or the Annexes. As explained more fully below, FDA **conceptually agrees** with 14 recommendations and **partially concurs** with two recommendations. For nine recommendations, FDA either **non-concurs** or **will consider** the recommendation before deciding whether a Food Code modification is warranted.

**U.S. Food and Drug Administration**  
**Center for Food Safety & Applied Nutrition**  
5001 Campus Drive  
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[www.fda.gov](http://www.fda.gov)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

August 8, 2016

Mr. Patrick Guzzle, Chair  
Conference for Food Protection  
30 Elliott Court  
Martinsville, IN 46151-1331

Dear Mr. Guzzle:

Thank you for your letter dated May 27, 2016 in which you transmitted the recommendations made by the Conference for Food Protection (CFP) at its 2016 Biennial Meeting in Boise, Idaho. By all accounts, the 2016 Meeting was a productive one. The Food and Drug Administration (FDA) appreciates the efforts of all participants in the 2016 Meeting to develop recommendations intended to further food safety and foster cooperation between Federal, state, local, territorial and tribal agencies and our partners in industry, academia, and consumers. FDA values the opportunity to fully participate in the CFP Biennial Meetings and to provide consult to the Executive Board and the numerous CFP Committees.

In accordance with the Memorandum of Understanding between the FDA and the CFP, I am pleased to respond with FDA's current position on those recommendations that pertain to the FDA Food Code or otherwise recommend action on the part of FDA.

**Part 1 – Conference Recommendations for Changes to the FDA Food Code**

Your letter identified twenty-five recommendations accepted by the Assembly of Delegates to change the FDA Food Code or the Food Code Annexes.

FDA conceptually agrees with sixteen of the twenty-five final recommendations and anticipates making changes to the Food Code and its Annexes related to the following issues:

- 2016-I-007 IMC 3 – Amend Food Code 4-602.11 (E) (4) Equipment Cleaning Frequency**
- 2016-I-022 Update the definition of Vending Machines**
- 2016-I-023 Shellfish Retail Record Keeping**
- 2016-I-033 Thawing 3-501.13**
- 2016-I-035 Missing reference in 2013 FDA Food Code Section 3-501.19(A)(1)(a)**
- 2016-I-036 Clarifying Date Marking Disposition**
- 2016-I-042 Towel Drying Exception For Equipment Removed From High-Temp Dish Machines**
- 2016-II-004 Imminent Health Hazard: Modify Enforcement & PIC Duties**
- 2016-II-025 Mandatory Food Protection Manager Certification for Persons in Charge**
- 2016-III-002 LRG 2 - Approval of Listeria Retail Guidance Document**
- 2016-III-014 Bandage, Finger Cot, and Stall contamination**



September 5, 2014

Mr. John M. Luker, Chair  
c/o Conference for Food Protection  
30 Elliott Court  
Martinsville, Indiana 46151-1331

Dear Mr. Luker:

Thank you for your letter dated June 17, 2014, in which you transmitted the recommendations made by the Conference for Food Protection (CFP) at its 2014 Biennial Meeting in Orlando, FL. I apologize for the delay in responding.

The Food and Drug Administration (FDA or Agency) appreciates the efforts of meeting participants to develop recommendations intended to further food safety and foster cooperation among federal, state, local, territorial, and tribal agencies, our partners in industry and, academia, and consumers. FDA values the opportunity to fully participate in the CFP Biennial Meetings and to provide advice to the Executive Board and the numerous CFP Committees.

In accordance with the Memorandum of Understanding between FDA and the CFP, I am pleased to respond with FDA's current position on those recommendations that pertain to the FDA Food Code or otherwise recommend action on the part of FDA.

**Part 1 – Conference Recommendations for Changes to the FDA Food Code**

Your letter identified 13 recommendations accepted by the Assembly of Delegates to change the FDA Food Code or the Food Code Annexes.

FDA agrees with the final recommendations and anticipates making changes to the Food Code and its Annexes related to the following issues:

- 2014-I-014 Update Sec. 8-201.14 to better agree with NACMCF HACCP Definitions**
- 2014-I 020 Duties of Person In Charge- Hot and Cold Holding Monitoring**
- 2014-I-030 Equipment and Utensil Cleaning Agent, Availability**
- 2014-II-003 Align Competency of Inspectors (8-402.10) with Program Standard 2**
- 2014-II-009 Public Website Posting of Inspection Reports**
- 2014-III-002 Emergency Action Plan for Retail Food Establishments**
- 2014-III-028 Salmonella as a Reportable Illness**



JUL 31 2012

Ms. Lori LeMaster, Chair  
Conference for Food Protection  
2792 Miramar Lane  
Lincoln, California 95648-2070

Dear Ms. LeMaster:

Thank you for your letter dated May 29, 2012, in which you transmitted the recommendations made by the Conference for Food Protection (CFP) at its 2012 Biennial meeting in Indianapolis. In accordance with the Memorandum of Understanding between the Food and Drug Administration (FDA) and the CFP, I am pleased to respond with FDA's current position on those recommendations that pertain to the FDA Food Code or to otherwise recommend action on the part of FDA.

FDA appreciates the efforts of all participants in the 2012 Biennial Meeting who collaborated to develop the recommendations made to FDA that are intended to further food safety and foster cooperation among Federal, state, local, territorial, and tribal agencies and our partners in industry, academia, and consumers.

Part 1 of your letter identified 27 recommendations for changes to the FDA Food Code or the various Food Code Annexes. FDA agrees in principle with almost all of the 27 recommendations and plans to revise the 2013 edition of the Food Code to address those recommendations.

**The Part 1 recommendations to which FDA will be giving additional consideration before concurring with the recommendation made by the CFP are identified and discussed in detail below.**

Please note that there are additional Part 1 recommendations with which FDA agrees in principle but for which we may not agree with the specific proposed wording for the Food Code changes. In these cases, FDA may modify the recommended text, either to provide clarity or to achieve consistency with the structure or conventions of the Food Code.

**2012-I-036 – Designation of Water Temperature at Handwashing Sinks as a Core Item**

This recommendation contains two parts. The first part suggests FDA review the priority designation assigned to Section 5-202.12 of the 2009 Food Code based on current science.

The second part makes a specific recommendation to divide that section into subsections and to designate one subsection as a Priority Foundation Item and one subsection as a Core Item. FDA expressed its opinion at the 2012 meeting that, based on a preliminary review of the designations, the current designation is appropriate. Based on the CFP recommendation, FDA agrees to carefully reconsider the designation assigned to Section 5-202.12 using the established criteria for making such designations and to consider recent publications that may inform the process. FDA will make a decision regarding a change to the designation after it completes such a review.

**2012-III-08 – Addressing Non-Typhoidal Salmonella in the Food Code**

FDA agrees in principle with the CFP recommendation to modify the FDA Food Code to specifically address Non-Typhoidal Salmonella (NTS) and the steps food establishments should take to prevent its transmission by infected food employees. However, before modifying the Food Code to incorporate the suggested revisions, FDA needs to determine the status of NTS on CDC's "List of Infectious and Communicable Diseases which are Transmitted through the Food Supply," as CDC is in the process of updating that list. FDA will take into consideration additional information made available by CDC as the agency determines how best to modify the Food Code to address the inclusion of NTS among the pathogens that trigger the need for certain employee health-related preventive controls, as described in the Food Code. FDA will keep the CFP Executive Board and the membership informed on progress on this effort.

**2012-III-021- Determining the Disposition of Refrigerated Potentially Hazardous Food above 5°C (41°F)**

This recommendation also contains two parts – first to add language to Annex #4 and second to create a committee to review and update the *CFP Emergency Action Plan for Retail Food Establishments*. FDA supports CFP's intention to create a CFP Committee to review and update the *CFP Emergency Action Plan for Retail Food Establishments* to enhance the recommendations for determining the disposition of potentially hazardous foods that have been subject to limited temperature abuse due to the unanticipated interruption of adequate temperature control (such as during emergency power outages). FDA is prepared to participate on that Committee and will carefully consider the recommendations put forward with this CFP issue and subsequent revisions to the *CFP Emergency Action Plan* document. FDA recognizes the value of having sound recommendations for how food establishments should best manage the potential risks associated with disruptions of temperature control, especially in situations in which consumer access to food may be limited.

FDA is not ready at this time, however, to commit to incorporating the specific recommendations made by CFP into the FDA Food Code or its Annexes. FDA believes further consideration needs to be given to: 1) the various model predictions of microbial growth likely to be associated with unanticipated disruption of proper refrigerated food storage; and 2) what level of monitoring and documentation are appropriate to allow for limited temperature abuse without compromising public safety.

FDA believes the new CFP Committee discussions should closely examine the recommendations in 2012-III-021 and looks forward to assisting in development of enhanced guidance for the industry and public health officials.

**2012-III-025 - Dual Step Hand Cleanse-Sanitize Protocol without Water (Note: This title is derived from the original issue submission and is not relevant to the final recommendation.)**

This recommendation also contains two parts; one that suggests charges to a CFP committee and one that suggests a Food Code change. FDA agrees with the recommendation that the same CFP committee that is to consider revisions to the *CFP Emergency Action Plan for Retail Food Establishments* (as described in 2012-III-021 above), should also consider how that document can best address hand hygiene recommendations when natural or man-made disasters make normal handwashing stations impracticable. The recommendation also suggests that FDA modify the Food Code to capture the concept that under catastrophic disaster situations, handwashing requirements should be “in accordance with emergency guidance documents.” Since the Food Code is primarily intended to identify appropriate routine preventive controls at retail and does not specifically address all the various food safety implications of a catastrophic disaster situation, FDA does not agree that such recommendations specific to hand washing alone belong in the FDA Food Code. Further, it is not clear to FDA what, if any, “emergency guidance documents” the CFP had in mind when recommending that the Food Code reference such documents. FDA will wait for the new CFP Committee to complete its charge and update the *Emergency Action Plan* document to include hand hygiene recommendations before considering whether and where to reference those recommendations in the Food Code.

Part 2 of your letter identified 14 recommendations that request FDA take some action other than modification of the FDA Food Code. FDA agrees in principle with all the recommendations in Part 2 of your letter, including four recommendations for improving the National Voluntary Retail Food Regulatory Programs Standards. Your letter also requests FDA to work in various capacities to enhance the information and resources it makes available to the various stakeholder groups that participate in the CFP.

Page 4 – Ms. Lori LeMaster, Chair

We trust that the CFP membership will recognize that FDA does not have unlimited resources and so must consider each of these recommendations in the context of overall agency priorities. FDA will do its best to keep CFP leadership and its members informed on progress made toward delivering on these recommendations. Allow us to elaborate on a couple CFP Recommendations of note in Part 2 of your letter.

**2012-II-027 – Recommendations for Promoting the Field Training Manual**

FDA very much appreciates the support shown by CFP for the use of the *Field Training Manual for Regulatory Retail Food Safety Inspection Officers*. FDA welcomes the suggestions made by CFP to improve access to this resource by regulatory agencies. To be useful, the recommendations in this manual must be tailored to the individual jurisdiction and the priorities of the jurisdiction's program manager or training officer. Therefore, widespread distribution of the resource without guided instruction may not achieve the desired outcome. Improving inspector training programs and the resources available to them continues to be an important part of FDA's retail food safety initiative and a focus of activity of FDA's Regional Retail Food Specialists.

**2012-III-029 - Public Release of Food Allergy Resource Document**

FDA acknowledges CFP's renewed request that FDA disseminate useful materials on the control of food allergens at retail. FDA is developing such guidance, and we are considering options for making it available to the public for review and comment. We do so with the understanding that the CFP Food Allergen Committee is no longer an established committee.

We hope this letter provides sufficient information about our positions on the relevant 2012 CFP Recommendations. We look forward to continuing our cooperative relationship with the Conference.

Sincerely,

A handwritten signature in black ink that reads "Michael M. Landa". The signature is written in a cursive, flowing style.

Michael M. Landa  
Director  
Center for Food Safety  
and Applied Nutrition

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-030**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Creation of a Food Safety Management System (FSMS) Committee

**Issue you would like the Conference to consider:**

The FDA Food Code emphasizes the need for risk-based preventive controls and daily active managerial control (AMC) of the risk factors contributing to foodborne illness in food establishments. AMC is "the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors" (FDA, 2018). AMC involves the proactive identification and prevention of food safety hazards through a continuous system of monitoring and verification procedures for performing critical operational steps in a food preparation process. Two strategies supporting AMC efforts in food establishments have received growing attention: The presence of a Certified Food Protection Manager (CFPM) and the implementation of Food Safety Management Systems (FSMSs).

FSMS refers to the incorporation of a specific set of actions (e.g., procedures, training, monitoring, and verification) to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors in food establishments. While FSMS procedures vary across the retail and food service industry, purposeful implementation of procedures, training, and monitoring are consistent components of FSMSs. While several systems and tools are available internationally, including International Organization for Standardization (ISO 22000), Good Manufacturing Practices (GMP), Hazard Analysis and Critical Control Point (HACCP), British Retail Consortium (BRC) and Safe Quality Food Institute (SQF) (Codex, 2003; ISO 22000:2005, 2005; Luning et al., 2008), the ongoing prevalence and degree of implementation of these or similar systems within foodservice and retail food establishments in the United States remains understudied.

Inadequate FSMSs are thought to contribute to the worldwide burden of foodborne disease (Luning et al., 2008). For example, HACCP has been shown to have positive effects on food safety, but the poor implementation of HACCP has been described as a precursor to foodborne outbreaks (Cormier, 2007; Luning et al., 2009; Ropkins and Beck, 2000).

The 2013-2024 FDA Retail Food Risk Factor Study examines the occurrence of foodborne illness risk factors, food safety practices, and behaviors in food establishments. In the 2013-2014 Restaurant Data Collection study, the agency investigated the relationship between FSMSs, CFPM, and the occurrence of foodborne illness risk factors from 2013 to 2014. FSMSs were the strongest predictor of data items being out-of-compliance in both fast food and full-service restaurants. The average number of out-of-compliance data items was greatly reduced when there was a well-developed FSMS in place. This was true for both fast food restaurants and full-service restaurants. On average, restaurants with well-developed FSMSs had less than half as many risk factors and food safety practices that were out-of-compliance than restaurants with non-existent FSMSs.

The FDA has endorsed the voluntary development and implementation of documented food safety management systems in food establishments for many years:

1. *Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments* was first published in 1998 and has been endorsed by the Conference for Food Protection (CFP).
2. In the 2005 FDA Food Code, Annex 4, "Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors," was revised to further promote the voluntary development and implementation of documented FSMSs using HACCP principles as a tool to achieve AMC in food establishments. In June 2014, the restaurant members of the FDA-Restaurant Industry Partnership Group provided feedback to the FDA for updating Annex 4. Specifically, the group provided feedback on "what industry models are in use for AMC and are these in line with Annex 4?" and "what works in Annex 4 and what is not a fit?" In general, the industry members suggested that AMC should be viewed as a "system" for process management, as defined in Annex 4, to include HACCP as the approach. Other suggestions included: 1) To consider including "Demonstration of Knowledge" by the Person in Charge as a way to manage/control processes and qualify as AMC; 2) Consider including food handler training and the topic of food defense in the criteria for AMC; 3) Specific to "how can the occurrence of foodborne illness risk factors be reduced," suggest encouraging the following four topics/steps: instituting food safety standards, training to the standards, executing the standards, and verifying that the standards are being executed.
3. Following the October 2010 release of the *FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998-2008)*, the FDA launched its Retail Food Safety Initiative which further emphasized the need for industry to establish food safety management systems and actively monitor compliance with those systems to reduce the occurrence of risk factors in retail operations.
4. Recognizing the importance of FSMSs in managing food safety hazards, since 2005, USDA has required that all public schools have in place a food safety plan based on process HACCP principles. Schools that do not meet this mandate are in jeopardy of losing their federal funds. The FDA collaborated with USDA on the development of the food safety plan model.

Despite over 20 years of promotion of voluntary FSMSs, widespread adoption of the Food Code across the U.S., and other ongoing food safety prevention efforts at the retail level,

foodborne illness from retail establishments continues to be a substantial public health burden that must be addressed in novel ways.

FDA has announced a New Era of Smarter Food Safety that includes examining new retail models and retail modernization in an effort to reduce foodborne illness at the retail level. The agency intends to publish a blueprint for this effort early in 2020. To support this effort, the FDA is recommending the formation of a CFP committee to provide recommendations to the agency on how best to promote the universal development and implementation of documented, HACCP principles-based FSMSs in food establishments.

### **Public Health Significance:**

- Foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths each year (Scallan et al., 2011). Depending on the estimation model used, the annual economic burden from health losses due to foodborne illness ranges from \$51.1 billion to \$77.7 billion (Scallan, 2012).
- From 2015 - 2018, the incidence of foodborne infections remained largely unchanged.<sup>1</sup>
- Of the approximately 9.4 million illnesses each year in the United States traced to known foodborne disease agents, only a small subset of illnesses are associated with recognized outbreaks. During 2009-2015, the Foodborne Disease Outbreak Surveillance System (FDOSS) received reports of 5,760 outbreaks, resulting in 100,939 illnesses, 5,699 hospitalizations, and 145 deaths. A location of preparation was provided for 5,022 outbreak reports (87%), with 4,696 (94%) indicating a single location. Consistent with previous reporting periods, among outbreaks reporting a single location of preparation, restaurants were the most common location (2,880 outbreaks [61%]), followed by catering or banquet facilities (636 [14%]) and private homes (561 [12%]). Sit-down dining style restaurants (2,239 [48%]) were the most commonly reported type of restaurant. The locations of food preparation with the most outbreak-associated illnesses were restaurants (33,465 illnesses [43%]), catering or banquet facilities (18,141 [24%]), and institutions, such as schools (9,806 [13%]). The preparation location with the largest average number of illnesses per outbreak was institutions (46.5), whereas restaurants had the smallest (11.6) (Dewey et al., 2018).
- In 2017, 841 foodborne disease outbreaks were reported by 50 states, Washington, D.C., and Puerto Rico, resulting in 14,481 illnesses, 827 hospitalizations, 20 deaths, and 14 food recalls. Among the 761 outbreaks and 12,502 illnesses with a reported single location where food was prepared, 489 outbreaks (64%) and 5,533 associated illnesses (44%) were attributed to foods prepared in a restaurant. Among these single-location outbreaks, restaurants with sit-down dining were most commonly reported as the location where food was prepared (366 outbreaks, 48% of the outbreaks). (CDC, 2019)

In a study of restaurant-associated outbreaks in the United States from 1998-2013, Angelo, Nisler, Hall, Brown and Gould (2016) identified 9,788 restaurant-associated outbreaks, with a median of 620 outbreaks per year. Norovirus caused 46% of the 3,072 outbreaks associated with a single, confirmed etiology. Activities related to food handling and

preparation practices were the most commonly reported contributing factors within restaurant-associated outbreaks

**Recommended Solution: The Conference recommends...:**

A Food Safety Management System (FSMS) Committee be created to identify recommendations for developing and implementing documented, HACCP principles-based Food Safety Management Systems (FSMSs) in all food establishments to support FDA's blueprint for a New Era of Smarter Food Safety. The FSMS Committee should consider:

1. Identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.
2. Identifying solutions for overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions.
3. Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on: a) the hurdles/challenges involved in such a requirement; and b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.
4. Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.

The committee should report its findings and recommendations to the 2022 Biennial Meeting of the Conference for Food Protection. While FDA's efforts will be ongoing during this time, the findings and recommendations will continue to be useful to the agency as it continues to implement its blueprint on retail modernization.

**Submitter Information:**

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**Supporting Attachments:**

- "Reference Sheet"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

Marder, MPH EP, Griffin PM, Cieslak PR, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006–2017. *MMWR Morb Mortal Wkly Rep* 2018;67:324–328. DOI: [http://dx.doi.org/10.15585/mmwr.mm6711a3external\\_icon](http://dx.doi.org/10.15585/mmwr.mm6711a3external_icon)

Angelo KM; Nisler AL; Hall AJ; Brown LG; Gould LH. Epidemiology of restaurant-associated foodborne disease outbreaks, United States, 1998-2013. *Epidemiol Infect.* 2017; 145(3):523-534.

Tack DM, Marder EP, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2015–2018. *MMWR Morb Mortal Wkly Rep* 2019;68:369–373. DOI: [http://dx.doi.org/10.15585/mmwr.mm6816a2external\\_icon](http://dx.doi.org/10.15585/mmwr.mm6816a2external_icon).

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Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis.* 2011;17(1):7-15. <https://dx.doi.org/10.3201/eid1701.p11101>

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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>

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Ropkins, K., and Beck, A.J. (2000). Evaluation of Worldwide Approaches to the Use of HACCP to Control Food Safety. *Trends in Food Science & Technology*, 11(1), 10-12.

Cormier, R.J., Mallet, M., Chiasson, S., Magnusson, H., and Valdimarsson, G. (2007). Effectiveness and Performance of HACCP-based Programs. *Food Control*, 18(6), 665-671.

International Organization for Standardization (2005). ISO 22000:2005. *Food Safety Management Systems – Requirements for any Organization in the Food Chain*. Retrieved from: [http://www.iso.org/iso/home/store/catalogue\\_tc/catalogue\\_detail.htm?csnumber=35466](http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=35466).

Food and Drug Administration. Food Code 2017. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2018. [https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm595139.htmexternal\\_icon](https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm595139.htmexternal_icon).

Luning, P.A., Bango, L., Kussaga, J., Rovira, J., and Marcelis, W.J. (2008). Comprehensive Analysis and Differentiated Assessment of Food Safety Control Systems: A Diagnostic Instrument. *Trends in Food Science & Technology*, 19(10), 522-534.

Issue Title: Creation of a Food Safety Management System (FSMS) Committee  
Reference Sheet

Luning, P.A., Marcelis, W.J., Rovira, J., Van der Spiegel, M., Uyttendaela, M., and Jacxsens, L. (2009). Systematic Assessment of Core Assurance Activities in a Company-specific Food Safety Management System. *Trends in Food Science & Technology*, 20(6), 300-312.

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-031**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Standard 1 Update to Require 80% of Certain Provisions

**Issue you would like the Conference to consider:**

Many times policy makers such as state legislatures and others outside the retail food program make decisions that impact the ability of the retail food program to meet all of the interventions and risk factors. This proposes changing the evaluation component to eighty percent adopting a percentage standard similar to the Good Retail Practices and not requiring a full-adoption of all invention and risk factors after the second self-assessment. For example, a legislature may choose to not ban barehand contact of ready-to-eat foods and all regulatory programs with the state automatically do not meet one of the of the 11 areas and after the second self-assessment would no-longer meet the Standard 1, because of an action completed un-related to the conduct of the regulatory program.

**Public Health Significance:**

This Standard currently is evaluating not only the regulatory program, but also decisions policy makers are making outside the regulatory programs control. The revisions allows programs to conform to the Standard if 80% of currently 9 to 11 of the Foodborne illness risk factors and public health interventions are adopted. While we absolutely support full adoption of the Code, the Standards already allow for this lower number for the first two self-assessments and the amendment seeks to eliminate the subsequent requirement for 100% adoption.

**Recommended Solution: The Conference recommends...:**

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Standard 1 - Regulatory Foundation be amended as follows:

Many times policy makers such as state legislatures and others outside the retail food program make decisions that impact the ability of the retail food program to meet all of the interventions and risk factors. This proposes changing the evaluation component to eighty percent adopting a percentage standard similar to the Good Retail Practices and not requiring a full-adoption of all intervention and risk factors after the second self-assessment. For example, a legislature may choose to not ban barehand contact of ready-to-eat foods and all regulatory programs with the state automatically do not meet one of the of the 11 areas and after the second self-assessment would no-longer meet the Standard 1, because of an action completed un-related to the conduct of the regulatory program.

1. Amend Standard 1, Description of Requirement, lettered paragraph "A" as follows (language to be deleted is in strikethrough format; language to be added is underlined):

#### A. *Food Code* Interventions and Risk Factor Control Measures

The regulatory foundation contains provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code*. Jurisdictions that meet Standard 1 but who may become noncompliant due to the release of a new edition of the *Food Code* are considered to continue meeting the Standard for a period of two years from the release date of the new *Food Code* edition in order to complete the process of updating its regulations.

To meet this element of the Standard, regulations must have a corresponding requirement for the *Food Code* sections as listed and summarized in the *Standard 1: Self-Assessment Worksheet for Part I*, from #1 "Demonstration of Knowledge" through #11 "Highly Susceptible Populations." ~~For initial listing, the~~ The regulatory foundation must ~~contain~~ include at least ~~80%~~ 9 of the 11 interventions and risk factor controls. ~~In order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third audit.~~

1. Amend Standard 1 Instructions and Worksheet for Conducting a Self-Assessment as follows., Step 3, as follows (language to be deleted is in strikethrough format; language to be added is underlined):

#### STEP 3 - Document the Self-Assessment Results for Part I

A summary table is provided in Part I of the *Standard 1: Self-Assessment Worksheet* to document the results of the self-assessment for each of the 11 public health intervention and risk factor control measures. For~~80~~ each public health intervention and risk factor control measure, the self-assessor must record the findings from the self-assessment. If each *Food Code* section listed under an Intervention/ Risk Factor has a check in the "Full Intent is Met" column, the Standard criteria is met. Place an "X" in the Self-Assessment Results "YES" column.

If any of the *Food Code* sections are missing, or the jurisdiction's regulatory requirements only partially meet the intent of the language, place an "X" in the Self-Assessment Results "NO"

column for that intervention/risk factor control measure.

At the bottom of Part I of the *Standard 1: Self-Assessment Worksheet*, the self-assessor must record the jurisdiction's name and the number of interventions/risk factors that are

~~met. For initial participation and listing purposes, the jurisdiction's self-assessment must indicate conformance with at least 9 of the 11 80% of the intervention/risk factor categories. By the third verification audit, the jurisdiction must meet 11 of the 11 intervention/risk factor control categories in order to meet the Standard 1 criteria.~~

Examples of documents that may be reviewed:

Ø The jurisdiction's statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of its food establishments

Ø Version of the *Food Code* that was used for the self-assessment

Ø Completed *Standard 1: Self-Assessment Worksheet, Part I - Food Code Interventions and Risk Factor Controls*

Ø If applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

1. Amend Standard 1 Instructions and Worksheet for Conducting a Verification Audit as follows Step 4, as follows (language to be deleted is in strikethrough format; language to be added is underlined):

STEP 4 - Document the Verification Audit Results for Part I

Part I of the *Standard 1: Self-Assessment Worksheet*, included at the end of these instructions, contains 11 public health interventions and risk factor controls:

1. Demonstration of Knowledge
2. Employee Health
3. Consumer Advisory
4. Approved Source
5. Time/Temperature
6. Protection from Contamination
7. Control of Hands as a Vehicle of Contamination
8. Good Hygienic Practices
9. Chemical
10. Conformance with Approved Procedures
11. Highly Susceptible Population

To meet any one of the 11 public health intervention and risk factor controls identified under the self-assessment process, the self-assessment must indicate that the jurisdiction's regulatory requirements address all *Food Code* sections listed for that area. ~~For initial listing, the jurisdiction's regulatory foundation must contain~~ include at least 9 of the 11 80% of public health interventions and risk factor controls. ~~In order to fully meet the requirement of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third verification audit cycle.~~

If four or more of the 15 selected code sections reviewed during the audit process do not meet the stringency of language criteria, the Standard 1, Part I element fails to meet the criteria, and no further sampling is necessary. If one, two or three of the 15 selected code sections do not meet the stringency of the language criteria but the jurisdiction continues to meet the required number of interventions and risk factor controls to meet the Standard, then randomly select an additional 15 *Food Code* sections. No more than three total disagreements are acceptable in the thirty (30) Code sections drawn for comparison in

order for the audit to confirm the Part I element of Standard 1 as met. In addition, at least 9 out of the 11 (80%) interventions and risk factor controls must still be met at the end of the first audit after the disagreements are taken into account, ~~and the jurisdiction must meet 11 out of the 11 interventions and risk factor controls by the third regular audit in order to meet the Standard 1 criteria.~~

Examples of documents that may be reviewed:

ØThe jurisdiction's statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of its food establishments

ØVersion of the *FDA Food Code* that was used for the self-assessment Ø? Completed *Standard 1: Self-Assessment Worksheet, Part I - Food Code Interventions and Risk Factor Controls*

ØIf applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

d) Amend any forms and instructions as needed to conform with the above changes.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-032**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018-II-016; the recommended solution has been revised.

**Title:**

Amend VNRFRPS Standard 6, Compliance and Enforcement

**Issue you would like the Conference to consider:**

Allow jurisdictions to assess the effectiveness of their compliance and enforcement program using an alternative sampling method that provides the same level of statistical confidence as the prescribed method in VNRFRPS Standard 6.

**Public Health Significance:**

The VNRFRPS offers a systematic approach through a continuous improvement process, to enhance retail food regulatory programs. The primary role of the CFP Program Standards Committee is to indirectly assist enrolled jurisdictions in making progress towards meeting the VNRFRPS Standards. The Committee has identified that this alternative proposal will assist agencies that are dually enrolled in both the VNRFRPS and the Manufactured Food Regulatory Program Standards (MFRPS) to maintain conformance while protecting public health.

**Recommended Solution: The Conference recommends...:**

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Standard 6 - Compliance and Enforcement be amended as follows:

1. Allow jurisdictions to assess the effectiveness of their compliance and enforcement program using an alternative sampling method that provides the same level of statistical confidence as the prescribed method in VNRFRPS Standard 6.

a) Amend Standard 6, Documentation, by adding additional options #5 and #6 (language to be added is underlined):

5. If necessary, a copy of the jurisdiction's established written procedures used to measure the effectiveness of the compliance and enforcement program

6. If necessary, statistical confidence level documentation from a statistician

b) Amend Standard 6 Instructions and Worksheet for Conducting a Self-Assessment, Step 2, as follows (language to be deleted is in strikethrough format; language to be added is underlined):

STEP 2 - Assess the Effectiveness of the Compliance & Enforcement Program

~~Randomly selected establishment files will be reviewed to determine if documented violations were resolved satisfactorily in the establishment. The results of the review will be used to assess the success of the compliance and enforcement program. This section of the self-assessment process has been broken down into the following four parts:-~~

Each jurisdiction shall measure the effectiveness of their compliance and enforcement program by either reviewing each inspection when a FBI Risk Factor or Public Health intervention was marked out of compliance or by using a statistical method to determine if the jurisdiction has satisfactorily resolved FBI Risk Factor and Public Health Intervention violations. The jurisdiction shall establish written procedures that:

- Describe the compliance and enforcement review process;
- Include a review of the routine inspections that have at least one Foodborne Illness or Public Health Intervention Violation marked OUT of compliance. The number of inspections reviewed and method of selection must provide a statistical confidence level equal to or greater than the published Standard 6 statistical model; and
- Include supporting documentation and worksheets. If a jurisdiction does not wish to establish independent written procedures, the jurisdiction may use the method set forth in Parts I-IV

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 II-033**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Refer Standard 5 to Program Standards Committee for Review and Updating

**Issue you would like the Conference to consider:**

Recommended Solution: The Conference recommends...:

that the Program Standards Committee, a CFP standing committee, be charged with the following during the 2020-2021 biennium:

1. Conduct a thorough review of Standard 5 "Foodborne Illness and Food Defense Preparedness and Response of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS);
2. The review should include comparing the Standard to other similar FDA standards in food;
3. Review the "Description of Requirements" to ensure the requirements provide program flexibility and include items generally part of a retail food program;
4. Review Standard 5 "Data Review and Analysis" from a sampling of jurisdictions to determine if certain data analysis requirements typically have no or such limited data to make the information not valuable;
5. Review the Center for Disease Control and Prevention's National Environmental Assessment Reporting System (NEARS) to consider inclusion of specific components.
6. Propose amendments to Standard 5 of the VNRFRPS;
7. Report back committee findings and recommendations to the 2022 Biennial Meeting.

**Public Health Significance:**

Standard 5 on Foodborne Illness and Food Defense Preparedness should be completely reviewing to ensure the most current and important items related to illnesses investigation are included. Further, the review should ensure that data analysis requirements are possible and provide meaningful data for jurisdictions.

**Recommended Solution: The Conference recommends...:**

Recommended Solution: The Conference recommends...:

that the Program Standards Committee, a CFP standing committee, be charged with the following during the 2020-2021 biennium:

1. Conduct a thorough review of Standard 5 "Foodborne Illness and Food Defense Preparedness and Response of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS);
2. The review should include comparing the Standard to other similar FDA standards in food;
3. Review the "Description of Requirements" to ensure the requirements provide program flexibility and include items generally part of a retail food program;
4. Review Standard 5 "Data Review and Analysis" from a sampling of jurisdictions to determine if certain data analysis requirements typically have no or such limited data to make the information not valuable;
5. Review the Center for Disease Control and Prevention's National Environmental Assessment Reporting System (NEARS) to consider inclusion of specific components.
6. Propose amendments to Standard 5 of the VNRFRPS;
7. Report back committee findings and recommendations to the 2022 Biennial Meeting.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-001**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This is a brand new Issue.

**Title:**

SHC-RPC - 1 Report - Safe Handling and Cooking of Roaster Pigs Committee

**Issue you would like the Conference to consider:**

At the 2018 Biennial Meeting of the Conference for Food Protection, the Safe Handling and Cooking of Roaster Pigs Committee was created and charged (Issue: 2018-III-023) with:

1. Identifying best practices, or any existing guidance documents, that relate to proper handling and storage of roaster pigs of various sizes.
2. Developing a comprehensive guidance document for food handlers, particularly caterers, that include detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs.
3. Determining appropriate methods of sharing the committee's work.
4. Reporting the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**Public Health Significance:**

The 2017 Food Code (§3-401.11(A)(2)) recommends cooking non-intact pork products to 155°F for 17 seconds with additional options at lower temperatures for longer lengths of time. For stuffed pork products, the Food Code (§3-401.11(A)(3)) recommends that the product reach a temperature of 165°F. However, due to the unique nature of the product, *Salmonella* outbreaks associated with roaster pigs continue to occur and show no indication of decline.

Inadequate handling and cooking of roaster pigs is a reoccurring food safety hazard that is becoming more prevalent in recent years. In the past three years, at least four *Salmonella* outbreaks have been associated with roaster pigs at special events<sup>1,2,3</sup>. One of the outbreaks in 2015<sup>1,4</sup> infected 192 patients across 5 states. Investigation findings indicated inappropriate methods for cold storage prior to cooking that could lead to an outgrowth of bacteria that may not all be destroyed during the cooking process.

Cooking an entire animal has additional challenges not addressed by the currently available cooking guidelines. Current guidance<sup>5,6,7,8</sup> is not comprehensive for addressing the unique challenges of cooking a whole animal (large size, variation in bone and fat distribution which create temperate variances across the entire large animal, control of humidity during the cooking process, cross contamination of clothes when moving the animal to the cooking location, appropriate methods for thawing of a large animal, appropriate methods for maintaining cold temperatures prior to cooking). Inadequate cooking may occur because the whole animal is being cooked (instead of the parts). When cooking parts, it is much easier to control the temperature and humidity of the oven and subsequently ensure even cooking of the food. However, when cooking a whole animal, it is challenging to control the temperature and humidity, especially when cooked in an open pit or grill. Each part may heat up differently depending on the muscle type, thickness, and proximity to the bone<sup>8</sup>. By the time the stuffing in the center of the pig reaches the appropriate temperature, the outer layers of the pig may be scorched, dried out, and unpalatable. Guidance could include methods to increase the humidity. Adding humidity to the cooking process prevents the surface from drying out, facilitates cooking, prevents heat resistance in the pathogens, and improves palatability. The guidance would also provide methods to ensure all parts of the pig are cooked thoroughly, where to place the thermometer, factors that could influence temperature (e.g., near joints, thickness of product), and at what depth. If the pig is stuffed with additional meat, the stuffing could remain cooler than the rest of the pig (FoodSafety.gov, Food Poisoning Bulletin). Providing this guidance will give retailers additional information to achieve the time and temperature recommendations in the Food Code.

Cross contamination, although not specifically mentioned in the outbreak reports, could also be a factor leading to illnesses. While cross contamination could be associated with any product, roaster pigs present a unique situation due to the size of the product. For example, caterers may clean or change utensils after cooking the product, however, they may not consider changing the clothes they are wearing as they carry the pig to the roasting location. Such findings are likely applicable to other retail food establishments that produce roaster pigs.

The committee developed a guidance document on safe handling and cooking of roaster pigs that would provide a valuable resource for those caterers that infrequently prepare roaster pigs so they are aware of lessons learned from past outbreaks as well as best practices used throughout the industry. This guidance document provides best practices for properly thawing or maintaining at appropriate temperatures prior to cooking, cooking, and measuring the temperature of the product. It also includes information on avoiding cross contamination of the product. By following the information in the guideline, retailers can ensure that the roaster pigs are thoroughly cooked, thereby, decreasing the likelihood of foodborne illness to consumers.

## References

1. FSIS 2015 Public Health Alert:  
<https://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-transcripts/news-release-archives-by-year/archive/2015/pha-073115>
2. FSIS 2016 Public Health Alert:  
<https://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-transcripts/news-release-archives-by-year/archive/2016/pha-072016>

3. FSIS 2017 Public Health Alert:  
<https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/foodborne-illness-investigations/outbreaks-salmonella-pork-products-2015-2016>
4. CDC 2015 Recall and Alert: <https://www.cdc.gov/salmonella/pork-08-15/recall-advice.html>
5. Foodsafety.gov, Pig Roasting and Food Safety: PDF provided as part of Articles Reviewed
6. Food Safety Tech Sheet, Washington State Department of Health:  
<https://www.doh.wa.gov/Portals/1/Documents/Pubs/332-165.pdf>
7. Food Poisoning Bulletin, Pig Roasting and Food Safety:  
<https://foodpoisoningbulletin.com/2016/pig-roasting-and-food-safety/>
8. How to Roast a Pig: <http://www.esquire.com/food-drink/food/a29391/how-to-roast-a-pig/>

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

1. Acknowledgment of the 2018-2020 Safe Handling and Cooking of Roaster Pigs Committee report;
2. Thanking the members of the Committee for their work; and
3. That the Committee be disbanded; all charges have been completed.

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**Content Documents:**

- "Committee Report"
- "Committee Roster"
- "Committee Guidance Document"

**Supporting Attachments:**

- "Committee Meeting Minutes"
- "Articles Reviewed"

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

**COMMITTEE NAME: Safe Handling and Cooking of Roaster Pig Committee**

**DATE OF FINAL REPORT:** November 1, 2019

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

**REPORT SUBMITTED BY: Erika Stapp-Kamotani and Susan Shelton**

**COMMITTEE CHARGE(S):**

**Issue # 2018-III-023**

1. Identifying best practices, or any existing guidance documents, that relate to proper handling and storage of roaster pigs of various sizes.
2. Developing a comprehensive guidance document for food handlers, particularly caterers, that include detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs.
3. Determining appropriate methods of sharing the committee's work.
4. Reporting the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**Issue # \_\_\_\_\_**

- 1.
- 2.
- 3.

**COMMITTEE WORK PLAN AND TIMELINE:**

**1. Charge 1: October 10, 2018 - November 19, 2018**

- a) *The Literature Review Subcommittee conducted the literature review to identify existing materials related to Charge 1. Literature review included other countries and species, epidemiological findings from previous outbreaks, scientific reports on temperatures in roaster pigs, and non-expert opinions. The non-expert opinions provided background on what is done and knowledge on the intended audience's thought-process.*
- b) *Identified materials posted to FoodSHIELD page specific to committee for screen sharing and material repository.*
- c) *Dr. James Dickson (Iowa State University, Department of Animal Science) provided his review on roaster pigs and associated food safety issues.*

**2. Charge 2: November 19, 2018 - October 2019**

- a) *The committee divided into two subcommittees to review the articles. The Theoretical Aspects Subcommittee reviewed the articles to glean best practices "in theory," develop the "why this is important," and the "how this relates to the intended audience." The Practical Aspects Subcommittee reviewed the articles to determine what is really done in practice and document the key points (what they did right, what they did wrong).*
- b) *Develop of guidance document outline. Five additional subcommittees were created to draft the language for each section of the outline. These subcommittees are numbered for the section they will be working on. Subcommittee 1 and 2 will develop the purpose of the guideline and relate the document to the intended audience. Each section will comprise about 2% of the document. Subcommittee 3 will review the epidemiological findings associated with the outbreaks. This section will comprise about 24% of the document. Subcommittee 4 will discuss the special considerations of roaster pigs and will comprise approximately 70% of the document. The last Subcommittee will focus on where to go for additional information and will comprise about 2% of the document.*
- c) *Provide scientific basis for key points. In section 4, the Subcommittee will take key points from the literature review and expand on why those actions were good or bad, how those actions impacted food safety, and what are some things to consider if electing to perform certain actions (like resting the pig for an hour after cooking - monitoring the temperature needs to be considered).*
- d) *Draft guidance document created.*
- e) *Review and edit draft guidance document into a final version.*

**3. Charge 3: August 2019 - October 2019**

- a) Determine methods for sharing work.
- b) Develop accessory materials, if needed.

**4. Charge 4: November 2019 - March 2020**

- a) Provide final committee report and prospective committee issues to the Executive Board for review.
- b) Report committee findings at the 2020 Biennial Meeting of the Conference for Food Protection.

**COMMITTEE ACTIVITIES:**

**1. Dates of committee meetings or conference calls:**

- 1.a.** 10/10/18: Introductory Committee conference call: Introduction of members, charges, FoodSHIELD repository, and process; development of working timeline; develop subcommittees to conduct literature review
- 1.b.** 10/17/18: Conference call with Dr. James Dickson (Iowa State University) reviewing cooking handling, cooking, and common practices with preparing roaster pigs
- 1.c.** 11/19/18: Conference call to discuss literature review results and assign subcommittees (Theoretical and Analytical Aspects) to read literature to identify key points for guidance document outline
- 1.d.** 11/27/18 Technical Aspects Subcommittee teleconference to identify highlights from literature review related to outbreaks and historical references linked to food preparation practices of roaster pigs or similar cooking styles
- 1.e.** 12/4/18 Analytical Aspects Subcommittee teleconference to identify highlights from literature review related to the process for handling, preparing, and cooking roaster pigs from farm to fork
- 1.f.** 1/7/19: Conference call rescheduled for 1/28/19 due to federal work stoppage
- 1.g.** 1/28/19: Conference call to review subcommittee work on guidance document key points; Analytical Aspects subcommittee affected by federal work stoppage and was reformed
- 1.h.** 2/11/19: Conference call to adjust the draft outline to incorporate key points identified by subcommittees and new subcommittees formed to create Guidance Document Draft 1
- 1.i.** 3/11/19: Conference call to share rough draft of the guidance document and to create a subcommittee to initiate the review process.
- 1.j.** 4/23/19: Section 4 Subcommittee met to review the draft and provide preliminary comments before sending to the group.
- 1.k.** 5/28/19: Conference call to review Section 4 with the entire group and create subcommittee to perform initial edits to draft guidance document.
- 1.l.** 6/4/19: Guidance Review Subcommittee met to conduct the first review of the draft guidance document and decide on the style to be used.
- 1.m.** 9/23/19: Review complete document with the Committee and discuss edits and comments.
- 1.n.** 10/22/19: Brainstorm of various avenues for sharing and disseminating the guidance document.

**2. Overview of committee activities:**

Committee has used multiple subcommittees to complete a literature review of applicable materials, draft an outline of key points to be covered in final guidance, and begun drafting language. The committee appears to have an effective representation of stakeholders, knowledge, skills, and abilities to produce quality material.

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

- a.** Charge 1: Literature review complete and the committee identified existing guidance materials and epidemiological data related to roaster pigs.
- b.** Charge 2: Guidance document drafted and finalized.
- c.** Charge 3: Determined methods to share the document (included in the SHC-RPC 03 Issue).
- d.** Charge 4: Committee findings will be reported at the 2020 Biennial Meeting.

**4. Charges INCOMPLETE and to be continued to next biennium:**

- a.
- b.

**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.**

- 1.
- 2.

**LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:**

- 1. **Issue #1: Report - Safe Handling and Cooking of Roaster Pigs Committee**

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

**(a.1) Committee Final Report (see attached PDF)**

**(a.2) Committee Member Roster (see attached PDF)**

**(a.3) Other content documents: Committee Guidance Document - "Whole Roaster Pigs: Guidance for the Safe Handling and Cooking"**

**b. List of supporting attachments:  No supporting attachments submitted**

**(b.1) Committee meeting minutes**

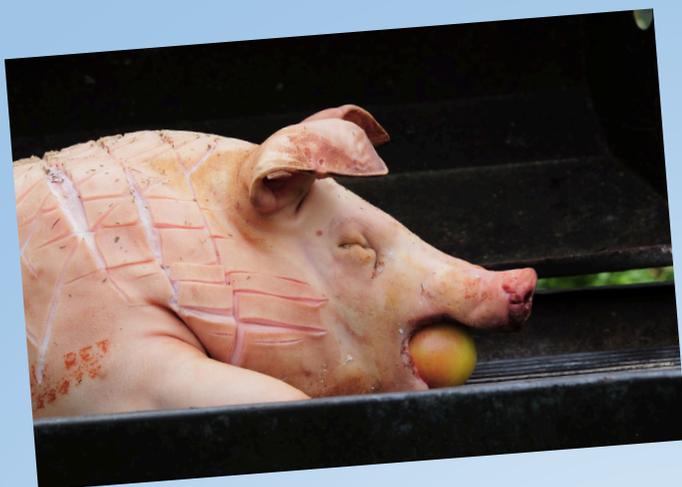
**(b.2) Articles, abstracts, and studies**

**2. Committee Issue #2 - Guidance Document for the Safe Handling and Cooking of Roaster Pigs Approval**

**3. Committee Issue #3 - Sharing of Guidance Document for the Safe Handling and Cooking of Roaster Pigs**

## Committee Roster

Committee Name: Safe Handling and Cooking of Roaster Pigs								
Last Name	First Name	Position	Constituency	Employer	City	State	Phone	Email
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This document is to help you safely prepare a whole roaster pig. Information is provided on how to safely purchase, store, and prepare this food that is served at events and celebrations to avoid spreading foodborne illness.



# Whole Roaster Pigs

Guidance for the Safe Handling  
and Cooking



Conference for Food Protection Safe Handling  
& Cooking of Roaster Pigs Committee

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## Introduction

This document includes data from past outbreaks from the United States and other countries, existing guidance, and currently accepted best practices to provide guidance for the retail food industry (chefs, caterers, and restaurant owners/employees), fundraiser organizers, community event sponsors, and the general public when handling, preparing, cooking, and serving whole roaster pigs. This document does not supersede any regulatory requirements. The recommendations in this guideline are not regulatory. The information is intended to assist individuals in meeting the FDA Model Food Code regulatory requirements and to produce a safe food.

In the United States, a whole pig is occasionally roasted to celebrate a holiday or special event. Unfortunately, there have been several foodborne illness outbreaks connected to these special events due to improper handling of the roaster pig. Between 2015 and 2017 there were three confirmed *Salmonella* outbreaks associated with roaster pigs in the United States. Public health investigations identified that inadequate handling and inappropriate cooking of the pig contributed to these illness outbreaks. Consumer and food handler preparation techniques are essential to prevent foodborne illness.

Pigs, like other livestock, are a known source of bacteria that can cause human illnesses. These bacteria may be transferred to the carcass during slaughter, processing, and handling. In addition to the presence of bacteria, roaster pigs are large. Ranging in size between 50 to 200 pounds, pigs require careful handling to reduce cross-contamination and proper monitoring of internal temperature to ensure thorough cooking. To address the size of the animal and the desired finished product, there is also a wide range of cooking methods from roasting on an open spit to using an imu pit in the ground, which presents multiple food safety challenges. Therefore, there are numerous opportunities for bacteria to multiply to dangerous levels and cause foodborne illness if mishandled.

## History of Associated Illnesses and Lessons Learned

There is an established history of foodborne outbreaks that have been attributed to events where roaster pigs were cooked and served. Suspected bacteria identified during the outbreak investigations as the likely sources of illness include *Clostridium perfringens*, *Bacillus cereus*, *Escherichia coli*, and *Salmonella*, with *Salmonella* being the most commonly reported cause. This document summarizes published outbreak investigations from several roaster pig outbreaks (Novotny, et al., 1987; Trotz-Williams, et al., 2012; Connecticut Department of Public Health (DPH), 2016; Todd, 2013). The investigations reported on interviews with food handlers regarding their roaster pig preparation and handling processes. The investigations identified concerns regarding handling of roaster pigs that may be contributing factors to these outbreaks, including storage, cooking, cooling, and cross-contamination. This section discusses each contributing factor in more detail, from the perspective of the outbreak. Guidance on how to control for these contributing factors is addressed in the [Preparing the Pig](#) section.

### Improper Storage

Food service workers and food handlers play a critical role in the receipt and storage of whole roaster pigs. Pigs were received a day or more before the event. The roaster pigs were generally between 45 and 65 pounds. The size of the pig presented a challenge for storage, particularly with events held in private homes. Proper storage can have a significant impact on control of these bacteria. Refrigeration units were often too small or not designed for holding a carcass of the size and shape of the roaster pig. In one outbreak, the pig was stored in a home refrigerator with the door partially open, which prevented adequate cold holding of

the pig and, thus, providing ideal temperatures to promote bacterial growth (Novotny, et al., 1987). In an outbreak in England, the pig was stored at room temperature for 38 hours (Todd, 2013). In other outbreaks, the pig was covered with bags of ice, but no indication as to completeness of coverage or monitoring of temperature to ensure the pig was kept at an appropriate temperature (Washington State Department of Health, unpublished, 2016).

Commercial facilities associated with outbreaks often had large mechanical coolers; however, these facilities were often used for storing other cooked or ready-to-eat foods, providing potential for cross-contamination. When roaster pigs were stored in someone's home, ice was commonly used and was found to be inconsistent as a method of temperature control, posing an increased risk of bacteria growth (Washington State Department of Health, unpublished, 2016).

### Inadequate Cooking

The lack of uniformity in pig size and shape presents another risk factor. This requires that temperatures are taken in multiple locations on the carcass to confirm that final cook temperatures are achieved. Most outbreak investigations demonstrated attempts to monitor temperatures with a thermometer. However, there were no records verifying the temperatures or the locations of where the temperature was collected. Due to the lack of records, it was unknown if all parts of the pig reached the minimum cooking temperature or how long it took to achieve the final temperature.

### Improper Cooling

Many of the outbreak investigations identified improper cooling of leftover meat as a likely contributor to the outbreak. In one outbreak, it was noted that food was left to cool on the counters and not placed into refrigeration quickly. Improper cooling exacerbated the growth of bacteria, causing rapid proliferation of the suspected agents *Clostridium perfringens* and *Bacillus cereus* (Trotz-Williams, et al., 2012). Another outbreak with *Clostridium perfringens* occurred in New Zealand. This outbreak was attributed to the 90-minute rest period between cooking and serving (Todd, 2013). Both of these bacteria may survive the cooking process and can produce toxins if the meat is not cooled properly. Reheating the meat will not destroy these toxins.

### Cross-Contamination

The most predominate bacteria noted in the outbreak investigations was *Salmonella* spp. Contributing factors included cross-contamination due to brining, mishandling of large carcasses, and lack of handwashing.

In situations where brining was a concern, large volumes of meat, both large and small cuts, were brined at the same time in the same brine solution, a common practice for large events. Mishandling of these large volumes of brine led to cross-contamination which was enhanced through the improper disposal of the brine solution into sinks that were then improperly cleaned and sanitized afterwards (Connecticut Epidemiologist, 2016). The contamination in the sinks then led to cross-contamination throughout the facility when the sinks were later used for other ready to eat product preparation as well. Ready-to-eat food products were implicated in the outbreak; however, their source of contamination was likely due to the mishandling of the brine and its disposal.

## Preparing the Pig

Roasting a whole pig is no small feat. From purchasing and storage to cooking and serving, the large size complicates every step of the process and provides ample opportunity for things to go wrong. Both USDA and FDA recommend to keep the pig 41°F or colder prior to cooking, to cook the pig to 145°F with a 4-minute rest time ([USDA Cooking Guide](https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/bacteria-guidance) [also known as Appendix A; under the *Salmonella* heading, <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/bacteria-guidance>], [FDA Model Food Code](https://www.fda.gov/food/retail-food-protection/fda-food-code) [<https://www.fda.gov/food/retail-food-protection/fda-food-code>] subparagraph 3-401.11(B)(1)), and to avoid cross-contamination. In reality, this is easier said than done. This section reviews some of the common practices in roasting whole pigs and how those practices relate to food safety.

## Purchasing and Receiving

There are several considerations when purchasing a whole pig, like where does one buy a whole pig? What age or size should be selected? Will the pig come already dressed (clean and eviscerated where the innards are removed)? How is the pig going to be transported?

Whole pigs may be purchased directly from a slaughter establishment, grocery store, butcher, or in some states, a local farmer. Most places will require one to three weeks' notice to ensure availability and often require special order. Grocery stores receive their pigs from a state or federally-regulated slaughter establishment. These processing facilities have the proper equipment to slaughter and eviscerate the pig to minimize fecal contamination. In a state or federally-regulated establishment, each carcass will also undergo inspection to ensure it is fit for human consumption. All food establishments must use a state or federally-approved source for customers.

Some pigs may have specific raising claims, such as antibiotic-free or naturally raised. These claims are consumer preferences and do not impact the food safety since all slaughtered animals are required to be free of antibiotics, achieved by either never giving the animal antibiotics or by observing an FDA-regulated withdrawal time (time for the body to eliminate the antibiotic).

Regardless of where the pig will be purchased, the seller will need to know the desired age and/or size. Some consumers prefer the suckling pig to the adult. Suckling pigs are still nursing off the mother. They are 2 to 6 weeks old and generally under 25 pounds, but some may be up to 50 pounds. When deciding on the size of the pig, the general rule is to estimate 1 to 2 pounds of dressed weight per person. Larger animals will have a higher meat to bone ratio, and therefore, may be on the low end of that estimate. Respectively, smaller animals will have a lower meat to bone ratio and may be on the higher end of that estimate. This estimate assumes a 25-50% meat yield after cooking and that each person will eat roughly half of a pound. The number of expected guests will greatly influence size determination, however, keep in mind that as the size of the pig increases, so do the risk factors of temperature abuse, improper cooking, and cross-contamination. Depending on the situation, it may be safer to select a smaller pig and offer more side dishes or alternate meat choices.

Some may ask what the term dressed weight means. Dressed weight is the weight of the pig after it has been slaughtered, cleaned, and eviscerated. Some places sell uneviscerated pigs, which would require the pig to be eviscerated by the buyer. For food safety reasons, pigs should not be eviscerated at home. Evisceration is a messy process and is critical for food safety. If not done properly, and with appropriate equipment, the intestinal contents can transfer to the work surface and onto the meat. This will increase the risk of cross-contamination and increase the number of bacteria that would need to be killed during cooking, thus increasing the possibility of bacteria surviving the cooking process and causing illness.

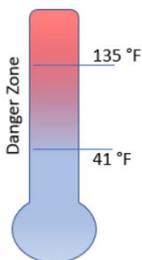
**Dressed weight** is the weight of the pig after it has been slaughtered, cleaned, and eviscerated.

**Evisceration** is the process of removing the internal organs from an animal.

As part of the dressing process, there may be the option to have the pig split so it will lay flat. This process is referred to as spatchcocking. The decision to split is based on the desired appearance of the end-product and whether the pig will be stuffed. With either option, there needs to be a method to ensure the hams and shoulders are cooked to the proper time and temperature to ensure food safety. Split pigs open up the hams and shoulders to allow for heat exposure, thus decreasing cooking time. If it is desired that the pig retains its roundness, then increasing the amount of coals in the area heating the hams and shoulders or applying a direct heat source, such as a hot rock, can provide better heat distribution.

Once the pig has been purchased, then the question is how to transport the pig. During the purchasing process, ask the seller if they will provide a food-grade plastic bag for transport. If not, then one should be purchased to prevent cross-contamination from the juices. The bag will need to be large enough to cover all parts of the pig, including the feet. Ask the seller about approximate length and girth so an appropriately-sized bag can be purchased. For larger pigs, consider searching for a food-grade 55-gallon barrel liner or box liner.

## Thawing and Storage



Depending on the seller, the pig may come fresh or frozen. Either option has significant food safety implications. Bacteria are capable of growing at temperatures between 41°F and 135°F (referred to as the danger zone; [FDA Model Food Code](#) paragraph 3-501.16(A) and corresponding Annex) and it only takes a couple hours for some bacteria to double in number. High bacterial numbers could overwhelm the cooking step and result in their survival. For this reason, it is necessary to keep all parts of the pig cold -- 41°F or below. Ideally, a fresh pig would be available for pickup right before the big event and the thawing and/or storage would not be necessary.

If the pig is frozen, it will need to be thawed completely before cooking. When done properly, this process can take a couple days to even a week, depending on the size of the pig. There are two safe options for thawing a whole pig – refrigeration and keeping the pig under ice cold water. These are also safe options for storing a fresh pig.

Of the two options, the best option is to place the pig in a refrigerator. As most home refrigerators are not large enough to accommodate anything larger than a small suckling pig, it may be necessary to keep the pig at a local grocery store, butcher, or restaurant that has a walk-in refrigerator. If a large refrigerator is not available, another option is to place the pig in a large, clean and sanitized cooler, bathtub, or other container filled with ice and water. The water will ensure even distribution of the ice. The maintenance of ice in the water ensures the water stays close to 32°F and the pig stays below 41°F as long as the pig is submerged.

Use a thermometer to determine if enough ice is present. If the temperature approaches 41°F, add more ice. The ice water should cover all parts of the pig. If part of the pig is sticking out, then that part could rise above 41°F and allow for bacterial growth. Likewise, just ice alone will not ensure that all parts of the pig are kept cold enough unless the pig stays completely buried by the ice at all times.

If the pig will be brined, then the brining solution can be added to the ice water. If the brining solution contains high amounts of salt, it could cause the ice to melt quicker. The salt lowers the freezing temperature of water. If this happens, then add more ice if the temperature of the brining solution starts approaching 41°F.

If the pig is not going to be brined, then it is recommended to keep the pig in its food-grade bag while it is in the ice water bath. Another option is to put the brine in the bag with the pig, then submerge the bag in the ice water. The bag will help reduce cross-contamination between the ice water bath and the pig.

If a container is used to thaw or store the pig, make sure the container is thoroughly cleaned and sanitized prior to use and again after the pig is removed. Since pigs can carry bacteria such as *Escherichia coli* (*E. coli*) and *Salmonella*, it is important to select an appropriate sanitizer, concentration, and contact time. Refer to the section on [Clean Up and Preventing Cross-Contamination](#) for more information.

## Cooking Methods Overview

There are numerous variations in cooking a whole pig, but most can be categorized into one of three methods: underground, open pit, or closed pit/oven. All three methods involve preparing a fire a couple of hours *prior* to transferring the pig to the heat source for cooking.

1. The **underground method** is most often used in Hawaii and the Polynesian Islands. Cooking a whole roaster pig underground begins with digging a hole into the ground, called an imu. The imu should be three times the width of the pig and twice as long. Rounding the corners aids in air circulation. Prepare the imu by starting a fire using untreated hard wood that burns hot. You may place river rocks on the firewood prior to lighting or wait and place the rocks on the bed of hot coals created from burning the firewood. Once the rocks are heated, they are spread out over the base of the imu. A few rocks will be removed from the imu and added to the pig's cavity near the hams and shoulders to provide extra heat to the thick muscles. (Cooking tip: Keep the pig on a grate throughout the cooking process to help with moving the pig around without disrupting the location of the hot rocks.) Green vegetative material with a high-water content (banana trunk, cabbage, corn husks) is layered on top of the coals. Aim to have the pit around 225°F to 250°F. The pig is lowered into the imu and covered with more vegetative material. Moistened burlap bags or gunny sacks are added on top. The imu is filled in with dirt. The moisture from the vegetative materials and moistened sacks will create steam to transfer heat to cook the pig. If any steam is leaking through, then more dirt is added to prevent the heat from escaping.



2. **Open pits** most commonly involve a spit or rotisserie-style of cooking. As with an imu, start a fire first. Either wood or coals can be used. The goal is to get a hot bed of coals that will provide the heat source for cooking the pig. Additional wood or coal will be needed periodically to maintain heat. The spit is placed between the thighs, along the inside of the body cavity, and out through the mouth. The pig is then secured to the spit to prevent it from falling off or rotating independently of the spit. There are several how-to videos and instructions on the internet for securing a pig to a spit, often referred to as trussing. Once done, the pig should not be able to move around the spit. The distance between the pig and the fire may vary depending on weather or individual circumstances. Most people aim to place the pig where it will be exposed to an air temperature of 225°F to 250°F. Rotate the pig frequently throughout the process to provide even heating and to keep the opposite side from cooling down. If rotation is performed manually, thermometers placed in each ham and shoulder can help gauge when the pig should be rotated. Rotation should occur at a frequency to keep the parts facing away from the fire from cooling down. Time intervals will vary based on ambient temperature, distance from the fire, and other contributing factors.



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- **Purchasing Equipment.** Specialized hog rotisserie equipment is available for purchase. If you are a food establishment, ensure the rotisserie equipment meets your local jurisdictional requirements before purchasing. Electric rotisseries are also available and can rotate the pig automatically and continuously.
- **Making Equipment.** If you create your own rotisserie out of Y-shaped sticks, spare lumber, or cinder blocks pay attention to the materials you use. This style typically uses a food-grade stainless steel rod for the spit. **Do not use galvanized material, because toxic zinc may leach into the meat and into the air around the fire.** Carbon steel may impart off flavors into the meat.

3. **Closed pits** can include an oven, caja china box, grill, smoker, or even a homemade pit using cinderblocks. Ovens are typically used for the small suckling pigs. Caja china boxes are specifically designed for roasting large amounts of meat, including whole pigs. Some of the larger roasting boxes can hold a 110-pound pig live weight (approximately 80 pounds dressed weight). Large grills may be available to rent from party suppliers, home improvement stores, or barbeque rental companies. If you prefer to create your own outdoor oven using cinderblocks and covered with metal, **do not use galvanized metal, as this may release toxic zinc into the air and into the meat.** Lining the inside of the pit with aluminum foil may help to hold in more radiant heat and decrease cooking time, but it is not required. Aim to have the pit around 225°F to 250°F prior to placing the roaster pig in the oven.



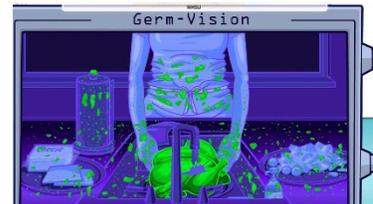
## Pig Preparation

Regardless of the cooking method chosen, the fire will need time to build up and get a bed of hot coals. Use that time to prepare the pig. Depending on cooking preferences and style, some pig preparation will take place before the fire is started, such as brining. But much of the pig preparation will take place after the fire is started. Whenever handling the pig, it is recommended to wear gloves and a plastic or disposable apron. This will make clean up easier and minimize cross-contamination.

Brining is done to increase the flavor and tenderness of the pig. As mentioned in the [Thawing and Storage](#) section, brining can be performed while thawing or storing the pig prior to cooking. If brining is done, the solution needs to be kept at 41°F or below to prevent bacteria from multiplying.

Other methods to increase flavor and tenderness include scoring, salt rubs, and injections. Scoring involves making partial thickness cuts through the skin. Salt rubs are applied directly to the skin, and if made, into the scored areas. Injections means injecting a marinade solution directly into the meat. If the marinade solution will be used for basting during the cooking, then it is important to thoroughly cook and properly cool the solution prior to using it as a baste. This will kill bacteria that are present in the solution, which is especially important if the solution is applied near the end of cooking. Properly refrigerate the solution between injection and basting applications to prevent bacteria from multiplying and potentially producing toxins.

At no point during the preparation is it appropriate to hose down or wash the pig. The act of hosing or washing the pig actually increases the risk of cross-contamination. Bacteria can be transferred to nearby surfaces through the water used to wash the pig. In addition, the bacteria can travel through the air on tiny water droplets, a process referred to as aerosolization. This aerosolization spreads the bacteria around the area where the pig is being washed and may not be visible due to the small size. Since these bacteria-contaminated droplets may not be visible, they may not get cleaned appropriately. Do not hose down or wash the pig.



BACTERIA AEROSOLIZATION AFTER WASHING A CHICKEN. WASHING A PIG WOULD CREATE GREATER AEROSOLIZATION OF BACTERIA. PICTURE FROM NEW MEXICO STATE UNIVERSITY AT: [HTTPS://ACES.NMSU.EDU/DONT WASHYOURCHICKEN/INDEX.HTML](https://aces.nmsu.edu/dontwashyourchicken/index.html)

Similar guidance is provided for chickens. As shown in the picture, bacteria (depicted by the green coloring) were splattered onto the counter and the person's clothing.

Some people choose to dry the pig prior to cooking. Drying can make the pig less slippery and easier to handle. It can also increase the browning of the skin during the cooking process. If drying is done, use disposable paper towels instead of a kitchen towel. Bacteria can survive on the kitchen towel and increase the risk of cross-contamination. Be sure to throw the paper towels in the trash immediately after use. Do not set them down on countertops or other food preparation surfaces where they could leave behind bacteria from the pig.

Another part of preparation includes wrapping the ears and snout in aluminum foil. If the eyes have been removed, then place crumbled aluminum foil into the eye sockets. While this is not a food safety hazard, these areas are prone to burning and creating a smoky, undesirable ash. The aluminum foil can be removed near the end of cooking.

An apple or wood block may be placed in the mouth. While this is not required, it keeps the mouth open and improves heat circulation through the thicker head regions.

### Special Considerations If Stuffing a Pig

Best practice is to cook the pig unstuffed to ensure proper cooking in the shortest time possible with minimal temperature variations and risk to safety. However, when feeding a large number of people, it is not uncommon for the pig to be stuffed with additional meat, vegetables, or grains if cooking multiple pigs is not possible due to space or availability.

Stuffing uncooked pigs with any food will increase the length of time it takes to cook. It also increases the food safety risk, as the stuffing is the slowest to cook and the hardest to get accurate temperatures. If the pig needs to be stuffed, then the safest method is to cook the stuffing to the appropriate temperature prior to stuffing the pig and place the stuffing inside the pig's abdominal cavity immediately before service and only after both the pig and the stuffing have been separately and thoroughly cooked.

If the pig will be stuffed prior to being cooked, loosely pack the pig's abdominal cavity. Overly packing the stuffing will slow down the heat disbursement. Regardless of the stuffing used, it should be moist, not dry, because heat destroys bacteria more rapidly in a moist environment ([USDA Stuffing and Food Safety, https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/poultry-preparation/stuffing-and-food-safety/ct\\_index](https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/poultry-preparation/stuffing-and-food-safety/ct_index)). Stuffed raw pigs must be cooked to an increased internal temperature of 165°F ([FDA Model Food Code 3-401.11 \(A\)\(3\)](#)). Refrigerate the cooked pig and stuffing within 2 hours. It is best to remove any stuffing when cooling to speed the cooling process.

### Cooking

Now that the fire is hot, and the pig is prepared, it is time to cook the pig. Depending on weight of the pig, it can take several hours for the pig to reach its final temperature. Most people estimate one hour of cook time per ten pounds of weight, but time will vary depending on the breed and size of the pig, type of heating element, distance from heat source, weather conditions, etc.

The amount of work required during cooking depends on the method of cooking. If cooking the pig underground in an imu, then once the pig has been properly covered to ensure minimal heat / steam loss, there is not much left to do until the pig comes to the proper temperature. If cooking in a closed oven, then it is imperative to maintain the heat in the oven. If cooking over an open fire, then it is imperative to maintain the fire and rotate the pig. Since the open fire utilizes a direct method of cooking, the pig will need to be rotated frequently so all parts of the pig are heated evenly and the parts facing away from the fire do not cool between rotations.

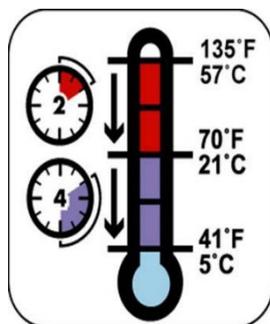
Some people prefer to baste the pig during the cooking phase. Basting is a preference and is not performed to meet any food safety criteria. Basting will help the skin retain moisture and provide brown color. However, it can also make the skin leathery. Ensure the basting solution has been properly cooked and cooled appropriately prior to use so that it does not contaminate the pig. Keep the basting solution in the refrigerator between applications. If the pig is not basted, then the fats in the skin will make it crispy. If using a closed pit to cook the pig, then opening the lid to apply basting solution will allow heat to escape and increase the cooking time.

For food safety purposes, the entire pig needs to reach a minimum temperature of 145°F and hold that temperature for at least four minutes (also known as a rest period). This will ensure the bacteria and parasites in the meat are destroyed, provided that the pig was not temperature-abused earlier. The challenging part, though, is that some areas of the pig will heat up faster than others. For that reason, it is necessary to take multiple temperature readings. The hams, shoulders, and in between the shoulders are the thickest portions and the last to heat up. If the pig was stuffed with meat or vegetables, the stuffing will heat up even slower than the hams and shoulders. To ensure appropriate depth, the thermometer should be placed all the way down to the bone and then pulled back just enough so that the thermometer is not resting on the bone. That way, the temperature is taken at the deepest part of the meat. If the thermometer is resting on the bone, the temperature will not be representative of the meat.

Many people will cook the pig to higher temperatures, such as 180°F to 200°F. The increased temperatures break down the collagen within the meat, especially in the hams and shoulders. This makes the meat more tender. It also helps to ensure all parts of the pig reach the minimum 145°F, just in case the thermometer missed a cold spot. And with higher temperatures, rest periods will be less or not necessary for food safety purposes, depending on the temperature achieved ([USDA Cooking Guide](#) (under *Salmonella*); [FDA Model Food Code](#) subparagraph 3-401.11(B)(1)). However, the rest period allows for the protein to break down and make the meat juicier.

## Serving and Leftovers

Once the pig has finished cooking, it is time to eat. But it is important to not forget about food safety while everyone is enjoying the meal. Bacteria can start to grow once the temperature of the pig drops below 135°F. It is recommended to place a thermometer into the pig to monitor temperature. Once the



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## Temperatures and Thermometers

- It is necessary to take multiple temperature readings.
- Hams, shoulders, in between the shoulders, and stuffing (if added) are the last to reach a proper cooking temperature.
- Stuffing the roaster pig with meat or vegetables will increase the needed cooking time.
- The thermometer should be placed all the way down to the bone and then pulled back just enough so that the thermometer is not resting on the bone.
- If possible, use a thermometer probe that can be left in the pig during the cooking process. This will help ensure the pig is being cooked appropriately throughout the process.



temperature drops to 135°F, the pig will either need to be consumed within four hours ([FDA Model Food Code](#) paragraph 3-501.19(B)) or be in the refrigerator to start its cooling process. If it appears there are going to be leftovers, start cutting up the pig into small pieces and place in small, shallow containers for placement in the refrigerator. Deeper dishes will slow the cooling process, which could allow bacteria to grow. In addition, it is better to place hot food directly into the refrigerator and leave the lid loose to allow for efficient cooling, as opposed to letting the food come to room temperature prior to placing in the refrigerator. If

the refrigerator is full or unavailable, then seal the food in food storage bags and immerse the bags in an ice bath. Full refrigerators can limit the cold air flow and slow the cooling process. In order to prevent bacteria from growing, the food needs to be cooled from 135°F to 70°F within 2 hours and from 70°F to 41°F within 4 hours ([FDA Model Food Code](#) paragraph 3-501.14(A)).

## Clean Up and Preventing Cross-Contamination

It is important to prevent cross-contamination and the spread of bacteria from raw meat to food preparation surfaces, equipment, and utensils. Cross-contamination is where contaminants are transferred from one object or food to another object or food. As discussed in [History of Associated Illnesses and Lessons Learned](#), cross-contamination is one of the major risk factors leading to foodborne illness. Cross-contamination can be prevented by maintaining good hygiene practices, separating raw foods from cooked foods, and properly cleaning equipment and food contact surfaces.

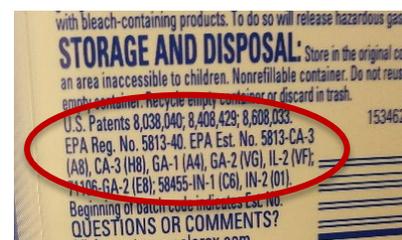
In food safety, good hygiene practices involve not working when sick, good handwashing practices, and the use of gloves or other tools to prevent hand contact with food. Wash hands in soap and water for at least 20 seconds with a full rinse. This will remove visible and invisible contamination from the hands. Dry hands with a clean towel or disposable paper towel to further remove contamination. Wash hands after handling raw product, prior to handling cooked product, and whenever the hands become dirty. After washing hands, wear gloves. Gloves will prevent bacteria from transferring to the hands when handling raw foods. They also prevent the transfer of bacteria from the hands to cooked foods. Waterless hand sanitizers do not remove contamination and may become inactivated when the hands are visibly contaminated and are not recommended to replace handwashing.

In addition, good hygiene practices also include handling of roaster pigs. Roaster pigs present a unique challenge in maintaining good hygiene practices because of the size and shape. It is recommended to wear clean or disposable aprons when preparing the pig for cooking. Once the pig is on the fire, it is recommended to remove the apron and gloves as well as change clothes if possible to prevent these objects from contaminating other food items or the cooked pig.

Separating raw foods from cooked or ready-to-eat foods will help prevent the raw food from contaminating the other food items. This includes refrigerating the raw pig in a separate location from other foods, using separate utensils and cutting boards for handling raw food, and cleaning all equipment and food contact surfaces between preparing raw and ready-to-eat foods.

When cleaning the equipment and food contact surfaces, be sure to clean all coolers, sinks, cutting boards, knives, countertops, roasting pans, or other equipment that come into contact with raw meat using these three steps:

1. Wash in hot, soapy water to remove all visible material.
2. Rinse in running water to remove all soap and visible material.
3. Sanitize with an EPA-registered sanitizer. EPA-registered sanitizers will have the EPA number and directions for use printed on the label. An effective sanitizer commonly used for food equipment is a solution of 1 teaspoon of plain bleach in 1 gallon of cold water.



When cleaning equipment and food contact surfaces, all visible material should be removed prior to applying a sanitizer. Sanitizers may become ineffective when organic material such as food, juices, and dirt is present. By not removing all visible material, the sanitizers may not be able to kill the bacteria, thereby increasing the risk of foodborne illness.

## General Safety

While not directly related to food safety, the roasting of a whole pig can present some physical safety hazards. Safety hazards should be considered when beginning the project of preparing, cooking and serving a roaster pig. Many roaster pigs are over 50 pounds, thus making handling difficult. Physical injuries can be prevented by having the proper equipment for lifting and handling the pig.

Most cooking methods use a form of open flame or charcoal. Precautions should be in place to prevent injuries or damage from open flames, especially if it is windy. Flame control may also become challenging if the fat from the pig is dripping onto the fire. Minimizing the amount of fuel supplied to the fire to minimize flame development, wind blocks, and use of a drip pan to catch the fat from the pig will help reduce accidents. Even with measures in place to control the flame, accidents can happen. Be prepared and have a water hose readily available with the water spigot already turned on (can have a nozzle on the end of the hose to prevent water from continuously running) or a fire extinguisher. Remember to aim at the base (bottom) of the flames and not the top.

Once the pig is fully cooked, it will be hot. Use tongs and knives to pull the meat from the bone to prevent burns to the hands. Using clean tongs and knives have the added benefit of minimizing cross-contamination from the hands to the food.

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# Roaster Pig Safety

Preparing roaster pigs takes special planning to prevent foodborne illness. Follow these safe handling and cooking tips to help ensure your special event is safe, happy, and healthy.



## PLAN

Roaster pigs have unique food safety risks.

- How big is the party?** Plan 1-2 pounds dressed weight per attendee.
- How big is the pig?** Big pigs are harder to keep cold, awkward to handle, difficult to fit in equipment, and take longer to cook.
- Fresh or frozen?** Frozen pigs take several days to thaw.
- To stuff or not to stuff?** Stuffing increases risk and cooking time.
- Cooking in a pit, a box, or on the grill?** Make sure the weather is right and you have enough fuel to keep the pig cooking for hours.

## WASH

Wash hands, utensils, and cutting boards with soap and water often.

- Cleanliness is key.** Stop the spread of germs by using soap, running water, and disposable towels.
- Cooking outside?** Be sure to take soap, water, and disposable towels where the action is to wash your hands and the food prep area.
- Step up your game.** After washing surfaces, you may also use a food-grade sanitizer to help reduce risk.

## SEPARATE

Take care! Bacteria can spread to you and your equipment.

- Will the store give you the pig in a water-proof bag?** A bag will help keep the pig juices from contaminating your equipment.
- Using a kitchen sink, an ice chest, counter, or bathtub?** Wash and sanitize the area after handling the pig to destroy illness-causing bacteria.
- Don't wash the pig!** Splashing water on the pig will spread germs around.
- Dress the part.** A raw pig can spread germs to your clothes. Consider wearing a disposable apron while preparing the pig.

## COOK

Roaster pigs cook unevenly. Make sure all parts get 145°F or hotter!

- Cooking time varies by the pig, the weather, and cooking method.** Plan for at least 1 hour of cooking for every 10 pounds of meat.
- You can't tell by looking.** Use a thermometer to check for doneness.
- Take several temperatures.** The hams, shoulders, stuffing, and between the shoulders take the longest to get fully cooked.

## COOL

Have leftovers? Get them cold to keep bacteria at bay.

- Shallow is better!** Shallow, uncovered containers cool faster than thick layers of food in the refrigerator.
- No refrigerator?** Serve or discard all of the food within 4 hours of cooking or immediately cool the foods in small containers with ice.

## CHECKLIST

### PURCHASE THE PIG

- Fresh or frozen
- Intact or eviscerated
- Water-tight bag for transport

### KEEP IT COLD (41°F OR COLDER)

- Keep at store until day of event
- Store in refrigerator
- Use ice chest/bathtub: Buy ice

### PREVENT CROSS-CONTAMINATION

- Keep pig away from other food and equipment (and don't wash the pig!)
- Wash hands and equipment with soap and water after handling the pig
- Use a sanitizer
  - Mix 2 Tsp unscented bleach in 1 gallon water
  - Buy EPA-labeled food-grade sanitizer

### GET IT HOT

- Imu/In Ground (Keep pig covered)
- Open pit (Rotate pig frequently)
- Closed pit/smoker (Make sure pig fits)

### KNOW IT'S HOT (AT LEAST 145°F)

- Buy a food-grade thermometer
- Measure the hams, the shoulders, between the shoulders, and in areas away from the heat source

### LEFTOVERS

- Cool in uncovered containers or ice immediately after cooking
- Plan to serve or discard food in 4 hours after cooking

# CFP Safe Handling and Cooking of Roaster Pigs Committee Conference Call

**Date:** October 10, 2018 (11:00-11:52 a.m. Eastern)

**Recording on:** Yes  No

**Reminder of Anti-trust Statement:** Yes  No

## Roll Call:

Baldwin, Tanja  
 Beyer, Nancy  
 Bush, Lauren  
 Cadet, Melissa  
 Hanson, Dana  
 Hilton, DeBrena  
 Jackson, Jeff  
 Johnson, Thomas  
 Martin, Dave

McGuire, Meg  
 Patel, Jaymin  
 Rivas, April  
 Seaman, Chuck  
 Sedlak, Mandy  
 Sparks, Christopher  
 Vaccaro, Melissa  
 Villareal, Rolando  
 Westbrook, Tim

## *Non-Voting Members*

Abley, Melanie  
 Idjagboro, Charles  
 Krzyzanowski, Becky  
 Moore, Veronica  
 Shelton, Susan  
 Stapp-Kamotani, Erika

**Quorum:** Yes  No  14/24 Members Present

**Vote on previous conference call's Roll Call and Summation:** Not Applicable.

APPROVE  DISAPPROVE  (document date and results of email vote, if applicable)

APPROVE AS AMENDED

**Agenda review:** Yes  No

## Summation of call proceedings:

Committee read the antitrust statement at the beginning of the call. The antitrust statement is additionally posted on the shared FoodSHIELD site.

Members on the call reviewed formation of the committee due to issue submittal (2018-III-023) from USDA for a CFP-developed guidance document for safe handling and cooking of roaster pigs following several outbreaks of Salmonella linked to unsafe preparation at retail/consumer level.

The committee reviewed the four charges for the committee:

1. Identifying best practices, or any existing guidance documents, that relate to proper handling and storage of roaster pigs of various sizes.
2. Developing a comprehensive guidance document for food handlers, particularly caterers, that include detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs.
3. Determining appropriate methods of sharing the committee's work.
4. Reporting the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

Each of the participants introduced themselves and included information about their strengths to offer the committee. Participants indicated substantial regulatory and industry experience with

several identifying strengths in food safety experience/knowledge, educational/training principles, policy development, and research as well as a desire to help prepare and provide competent, current guidance.

The members next discussed a work plan to complete each charge. The members stated that a literature review would be needed to better determine work plan, timeline, and any needed subcommittees.

- **Stage 1: October 10-November 19, 2018 (Charge 1)**

Literature review to be conducted by a small group of members that volunteered to identify existing materials related to Charge 1. Literature review will include other countries and species (such as Greece and goats). Materials need to be directed toward meeting charges of committee and intended audience (retail food handlers) and should include epidemiological data if possible. Members tasked with the literature review include Christopher Sparks, Rolando Villareal, April Rivas, Erika Stapp, and Susan Shelton. Identified materials will be posted to FoodSHIELD.

Committee voted to invite Dr. James Dickson (Iowa State University, Department of Animal Science) on call #2 to update committee on his research on roaster pigs and associated food safety issues (*Melissa Vacarro motioned; Dana Hanson seconded; vote unanimous*).

- **Stage 2: Begins November 19, 2018 (Charge 2)**

Committee call scheduled for 11/19/18. Committee will be presented materials identified during literature review to develop outline of guidance document and meeting charge 2. Subcommittees and tasks to be determined during stage 2.

- **Charges 3 and 4 will be addressed after completion of literature review and guidance document development.**

The final two charges to be addressed after completion of charge 2. By November 1, 2019, final committee report and prospective committee issues are due to the Executive Board for review.

**Action Items:**

- Erika Stapp to determine if Dr. Dickson is able to participate in call #2 or share literature resources.
- Subcommittee (Christopher Sparks, Rolando Villareal, April Rivas, Erika Stapp, and Susan Shelton) complete literature review by 11/19/18. Post materials in FoodSHIELD.

**Next conference call:** November 19, 2018 1:00 p.m. (Eastern)

## CFP Safe Handling and Cooking of Roaster Pigs Committee Conference Call

**Date:** October 17, 2018 (3:00-3:45 p.m. Eastern)

**Recording on:** Yes  No

**Reminder of Anti-trust Statement:** Yes  No

**Roll Call:** Not taken

**Quorum:** Yes  No  Informational call; no vote.

**Vote on previous conference call's Roll Call and Summation:** Not Applicable.

**Agenda review:** Yes  No

### **Summation of call proceedings:**

Dr. James Dickson (Iowa State University, Department of Animal Science) provided an update on recent research on the handling, cooking, and common practices with preparing roaster pigs. The work was done in response to an outbreak in 2015 associated with pork products.

See attached slide notes for more information. Call was recorded on FoodSHIELD.

### **Action Items:**

- Dr. Dickson will provide additional literature identified by his work on roaster pig guidance.

**Next conference call:** November 19, 2018 1:00 p.m. (Eastern)

Slide 1



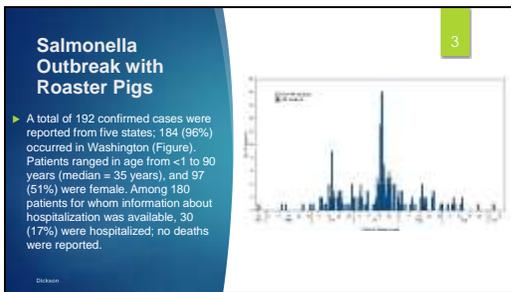
Presentation provided by Dr. James Dickson to CFP Safe Handling and Cooking of Roaster Pig Committee members on 10/17/18.

Slide 2



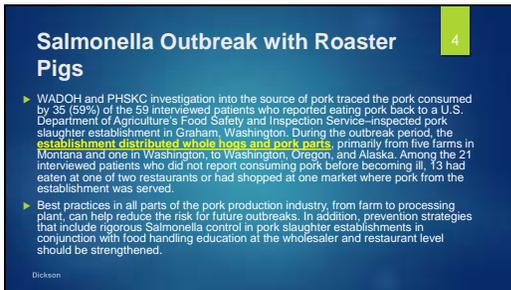
While this was a unique type of Salmonella for the state of Washington, the serotype is commonly identified in pigs in Iowa.

Slide 3



The peak in the epicurve is not uncommon due to the seasonality of roasting pigs at outdoor BBQ.

Slide 4



Information regarding the 2015 outbreak in Washington.

Slide 5



On the left of the slide is a commercially processed roaster pig. They are sorted by carcass weight and individually packaged. On right is a pig roasted for the project.

Slide 6

**Live Pig**

- ▶ Live weight may range from as low as 35-40 pounds to almost 200 pounds
- ▶ Smaller pigs (~80%; ~<120 pounds) are sourced from large scale operations, usually as "overflow" pigs
- ▶ Some pigs (~20%) sourced from sale barns

Dickson

Pigs in the 35-40 pounds size are likely newly weaned and about 3 weeks old.

"Overflow" pigs are young ones that can be sold because the establishment doesn't need the larger hogs these young pigs would become. Large establishments with efficient operations are the facilities most likely to have these 'overflows'— which is why they have the larger percentage of sales of the smaller pigs.

Slide 7

**Roaster Pigs**

- ▶ Processed differently from market hogs
  - ▶ Hung by head, not hind legs
  - ▶ Sternum not split
  - ▶ Carcass remains intact, with head
  - ▶ Carcass weight = 78% live weight
  - ▶ Meat (yield) = 30% carcass weight
  - ▶ (not all are processed under Federal Inspection)

Dickson

Although they are generally stunned and bled out the same way, roaster pigs have quite a few differences than the market hogs when processed:

- Because they're generally smaller than hogs, they're hung by their head instead of their hind legs.
- Consumers want the visual display of the whole pig, so the sternum isn't split down the middle of the pig.
- The carcass includes the head which increases the carcass weight but ultimately reduces the meat yield for a comparable carcass weight of a market hog.
- Ultimately, roaster pigs have very little meat yield so operators will possibly need to stuff them to feed a large gathering.
- The major processors are under FSIS, but smaller scale are under state oversight or likely custom/market exempt.

Slide 8

**Yield Comparison**

Live Weight	Carcass Weight	Meat (Yield)
35.0	27.3	8.19
40.0	31.2	9.36
45.0	35.1	10.53
50.0	39	11.7
55.0	42.9	12.87
60.0	46.8	14.04
70.0	54.6	16.38
80.0	62.4	18.72
90.0	70.2	21.06
100.0	78	23.4
110.0	85.8	25.74
120.0	93.6	28.08

Dickson

There's about a 1/3 of usable meat from a roaster pig. Again—this may drive people to stuff the carcass before cooking.

Slide 9

**Roaster Pig – Cooking Methods**

- ▶ Carcass are cooked under a variety of highly variable conditions
  - ▶ Pit
  - ▶ Open Grill
  - ▶ Closed grill
- ▶ May be stuffed with boneless pork or other protein

Dickson

There was a limitation of pig size in the study due to the size of the cooking grill available. They were only able to fit a carcass up to 45 pounds in the size of cooking chamber for their grill.

There is substantial the cooking variability of different cooking chambers—pit, closed metal case, grills too small to allow air flow, etc. This should be a point of discussion with end consumers, restaurants, caterers.

Slide  
10

**Roaster Pig – Cooking Methods** 10

- ▶ Carcass are cooked by a variety of individuals
  - ▶ Some operations and restaurants cook regularly (weekly)
  - ▶ Some are cooked by operations that cook infrequently (< 5/year)

Dickson

A key point is there is a range of experience from the cooks—they anecdotally figured that anyone that does it less than 5 times per year is potentially more likely to have errors due to the infrequency of process.

Slide  
11

**Experimental Data** 11

Dickson

Slide  
12

**Cooking Roaster Pigs** 12

- ▶ Maximum carcass weight 45 pounds; limited by size of cooker
- ▶ Range from 42-45 pounds
- ▶ Cooked 4 pigs on 4 different occasions
- ▶ Monitored temperature from cold (~32F) to end point (minimum 200F)

Dickson

Testing was conducted at Iowa State University meat lab (by a coworker that had won awards in numerous national BBQ championships).

Slide  
13

**Roaster pig stuffed with boneless pork** 13



Dickson

This pig is about 43 pounds and stuffed with boneless pork and tied back together.

Slide  
14

**Thermocouple Insertions** 14

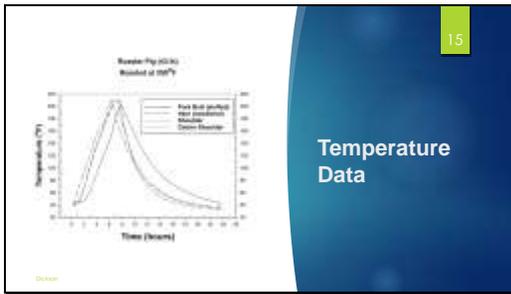


Dickson

The yellow boxes indicate thermocouple locations: right and left hams, the stuffing, right and left shoulders, and between the shoulder blades.

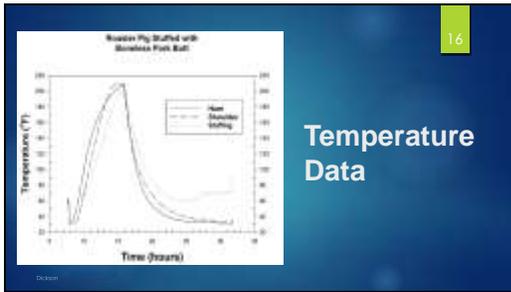
[Spoiler: the stuffing and between the shoulder blades were the slowest to get to cook temp.]

Slide 15



Note the right shift of the temperature/time with the stuffed product indicated by the solid line (it took longer to get to temp).

Slide 16



(Note: We didn't discuss cooling patterns—the products were planned to be rendered so proper cooling was not monitored.)

Slide 17

**Time to Specific Temperatures**

Location	Time to 145°F (hours)	Time to 160°F (hours)
Left Ham	3.11	3.53
Right Ham	2.73	3.14
Left Shoulder	2.79	3.4
Right Shoulder	3.42	4.18
Center Shoulder	4.12	4.89
Roast (Body Cavity)	4.83	5.33

Shoulder temp variation between right and left was likely due to the limitations of the cooking vessel. The center shoulder took longer to reach temps— likely a bit sheltered from the heat source. Clearly, the stuffed product in the cavity was routinely the longest to get to temp.

Slide 18



Here's what the pigs looked like when they are removed from the roaster. The data logger indicates the internal temperature exceeded 200°F.

Slide 19



Since this product is generally “pulled” most operators prefer to cook to 185°F or hotter for quality and yield.

Slide 20

Salmonella Typhimurium I 4,[5],12:i:-

Thermal resistance

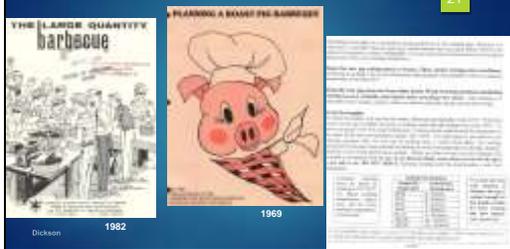
63C	6.5 log reduction (sec)			Appendix A	
	Min	Sec	Temp	Temp	6.5 log reduction (sec)
Mean	0.40	25.72	167.15	62.3	249
Std Dev.	0.22	13.03		63.3	169
68C				67.8	27
Mean	0.18	14.93	97.04	68.3	22
Std Dev.	0.07	4.23			

In the lab, six different isolates of the target organism were tested for thermal resistance from 6 different herds.

The reduction times were compared to the processing in the USDA Lethality Performance Standards for Salmonella listed in Appendix A. Ultimately, he said they were unable to identify any heat resistance with this strain.

Slide 21

Next Steps?



They identified very few materials available on whole roast pig cooking—he will provide the current material provided by some processors.

Slide 22

Next Steps?

- ▶ Information provided with Roaster pigs (information included in the box by processor)
- ▶ Iowa Meat Processor's Association – February 2018
  - ▶ Presentation on food safety, including roaster pigs
  - ▶ 1 page handout on basic food safety practices
  - ▶ Hand out thermometers with demonstration on calibration

They've provided outreach to industry.

Suggestions to focus on:

- Lack of thermometer usage
- Operators that run out of time/get behind/rush the cooking process
- Lack of taking temps in right portion of pig— between shoulders and stuffing are key
- Increasing cooking time if pigs are partially frozen (it takes about 4 days for a pig to thaw when distributed frozen)
- Lack of proper equipment/cooking chambers (some mentioned the metal box that's covered with charcoal might be a better cooking method than a pit or bbq grill)
- Obvious risk of cross contamination and potential Bare Hand Contact issues

Contact Information

- ▶ Jim Dickson
- ▶ 515.294.4733
- ▶ [jdickson@iastate.edu](mailto:jdickson@iastate.edu)

He's happy to answer emails if we have questions or provide additional input.

# CFP Safe Handling and Cooking of Roaster Pigs Committee Conference Call

**Date:** November 19, 2018 (1:00-1:45 p.m. Eastern)

**Recording on:** Yes  No

**Reminder of Anti-trust Statement:** Yes  No

<http://www.foodprotect.org/administration/policies/antitrust-policy/>

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## Roll Call

Baldwin, Tanja  
 Beyer, Nancy  
 Bush, Lauren  
 Cadet, Melissa  
 Hanson, Dana  
 Hilton, DeBrena  
 Jackson, Jeff  
 Johnson, Thomas  
 Martin, Dave

McGuire, Meg  
 Patel, Jaymin  
 Rivas, April  
 Seaman, Chuck  
 Sedlak, Mandy  
 Sparks, Christopher  
 Vaccaro, Melissa  
 Villareal, Rolando  
 Westbrook, Tim

### *Co-Chairs*

Shelton, Susan  
 Stapp-Kamotani, Erika

### *Non-Voting Members*

Abley, Melanie  
 Idjagboro, Charles  
 Krzyzanowski, Becky  
 Moore, Veronica

**Quorum:** Yes  No  11/20 Voting Members

**Vote on previous conference call's Roll Call and Summation (Initial Call Conducted 10/10/18):**

APPROVE  DISAPPROVE

APPROVE AS AMENDED

**Vote on previous conference call's Summation (Call with Dr. Dickson Conducted 10/17/18):**

APPROVE  DISAPPROVE

APPROVE AS AMENDED

**Agenda review:** Yes  No

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## Summation of conference call proceedings:

Committee read the antitrust statement at the beginning of the call. The antitrust statement is also posted on the shared FoodSHIELD site.

After roll call, a brief summary of the two conference calls conducted in October 2018 was provided for the committee to vote on the written meeting summations. The meeting summaries had been housed on FoodSHIELD, shared electronically with members immediately after the conference calls, and emailed with the current meeting agenda for committee review.

Conference call 1: The committee's initial conference call was conducted on 10/10/18 and the written meeting summation included committee member introductions, reviewed the committee charges, drafted the initial timeline for completion of charges, included a request to Dr. Dickson to present on roaster pigs at a future call, and identified the first

subcommittee to conduct a literature review. Committee voted to accept the roll call and summation as written (*Jeff Jackson motioned; Dave Martin seconded; vote unanimous*).

Conference call 2: The committee's second conference call was conducted on 10/17/18 and included a presentation by Dr. James Dickson regarding his research of roaster pig preparation. No roll call was conducted for this meeting and the meeting notes/summation included the slide set provided by Dr. Dickson. Committee voted to accept the summation as written (*Dana Hanson motioned; Jeff Jackson seconded; vote unanimous*).

Committee was reminded that the committee charges will be routinely included on shared committee materials to help ensure charges are met. The individual charges are included here but were not reviewed during the conference call.

1. Identify best practices, or any existing guidance documents, that relate to proper handling and storage of roaster pigs of various sizes.
2. Develop a comprehensive guidance document for food handlers, particularly caterers, that includes detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs.
3. Determine appropriate methods of sharing the committee's work.
4. Report the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

To begin Charge 2, the committee next reviewed a draft guidance document outline and divided the document topics into two sections (informally named Theoretical Aspects and Practical Aspects) to facilitate forming subcommittees. It was determined that the subcommittees would review the twenty-seven documents identified during the literature review in Charge 1 to identify key concepts/bullet points to include for each section in the guidelines. The subcommittees will report back to the committee at the next conference call to enable the committee to determine points to include in the guidelines.

The members self-selected to volunteer for either the Theoretical group or the Practical Aspects sections with the results posted below.

### **Theoretical Aspects:**

#### ***Topics to Cover:***

- Purpose of Guideline
- Intended Audience
- History of Associated Illnesses and Lessons Learned
- Where to go for more answers

#### ***Volunteers:***

- Jeff Jackson
- Nancy Beyer
- Susan Shelton

### **Practical Aspects:**

#### ***Topics to Cover:***

- Special Considerations & Equipment Rationale for Roasted Pigs
- Receiving, Thawing, and Holding

- Avoiding Cross-Contamination
- Preparing and Cooking
- Serving and Handling Leftovers

**Volunteers:**

- Dave Martin
- Erika Stapp-Kamotani
- Jaymin Patel
- April Rivas
- Tanja Baldwin
- Dana Hanson

**Action Items:**

- Erika Stapp and Susan Shelton will reach out to subcommittees to coordinate work on bullet points.
- Each subcommittee (Theoretical Aspects and Practical Aspects) volunteer will use literature review materials to develop key concepts for each of the listed topics listed

**Next conference call set:** Monday, January 7, 2019 at 1p.m. (Eastern). The purpose of the call will be for the committee to review the key concepts identified by the Theoretical and Practical Aspect subcommittees and to form next tasks to develop the guidance document.

CFP Safe Handling and Cooking of Roaster Pigs Committee  
Meeting Summary  
January 28, 2019 1:00 p.m. (Eastern)

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**Welcome and Roll Call**

- Baldwin, Tanja
- Beyer, Nancy
- Bush, Lauren
- Cadet, Melissa
- Hanson, Dana
- Hilton, DeBrena
- Jackson, Jeff
- Johnson, Thomas
- Martin, Dave

- McGuire, Meg
- Patel, Jaymin
- Rivas, April
- Seaman, Chuck
- Sedlak, Mandy
- Sparks, Christopher
- Vaccaro, Melissa
- Villareal, Rolando
- Westbrook, Tim

*Co-Chairs*

- Shelton, Susan
- Stapp-Kamotani, Erika

*Non-Voting Members*

- Abley, Melanie
- Idjagboro, Charles
- Krzyzanowski, Becky
- Moore, Veronica

**Quorum:** Yes  No

**Reminder of Anti-trust Statement:** [www.foodprotect.org/administration/policies/antitrust-policy/](http://www.foodprotect.org/administration/policies/antitrust-policy/)

**Vote on previous conference call's Roll Call and Summation:** N/A

**Reminder of Charges**

1. Identify best practices, or any existing guidance documents, that relate to proper handling and storage of roaster pigs of various sizes.
2. Develop a comprehensive guidance document for food handlers, particularly caterers, that includes detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs.
3. Determine appropriate methods of sharing the committee's work.
4. Report the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**Current Status of Charge 2**

Interim Reports from Theoretical and Practical Concepts.

Reviewed the outline developed from the Theoretical Aspects Subcommittee

Reviewed April's chart (Practical Aspects Subcommittee) that provided bullet points for 5 of the articles pertaining to each topic.

Three of the members for the Practical Aspects Subcommittee were not able to attend this meeting to provide an update – Jaymin, Dana, and Tanja. Mandy volunteered to check in with Jaymin to see if he needs assistance. Melissa V. is to check in with Dana. And Melissa C. is to check in with Tanja.

Committee will meet again in 2 weeks with the anticipation that the remaining articles will be reviewed for key concepts and important considerations.

**Set date and time for next conference call.**

February 11 at 1pm ET.

**CFP Safe Handling and Cooking of Roaster Pigs Committee**  
**Meeting Summary**  
February 11, 2019 1:00 p.m. (Eastern)

**Recording on:** Yes  No

**Reminder of Anti-trust Statement:** Yes  No

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**Welcome and Roll Call**

Baldwin, Tanja

Beyer, Nancy

Bush, Lauren

Cadet, Melissa

Hanson, Dana

Hilton, DeBrena (retired)

Jackson, Jeff

Johnson, Thomas

Martin, Dave

McGuire, Meg

Patel, Jaymin

Rivas, April

Seaman, Chuck

Sedlak, Mandy

Sparks, Christopher

Vaccaro, Melissa

Villareal, Rolando

Westbrook, Tim

**Co-Chairs**

Shelton, Susan

Stapp-Kamotani, Erika

**Non-Voting Members**

Abley, Melanie

Idjagboro, Charles

Krzyzanowski, Becky

Moore, Veronica

**Quorum:** Yes  No

**Vote on previous conference call's Roll Call and Summation:**

N/A. Please review meeting summaries from 1/28/19 and 2/11/19 fore vote at next conference call.

**Reminder of Charges**

1. Identify best practices, or any existing guidance documents, that relate to proper handling and storage of roaster pigs of various sizes.
2. Develop a comprehensive guidance document for food handlers, particularly caterers, that includes detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs.
3. Determine appropriate methods of sharing the committee's work.
4. Report the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**Committee Member Retirement**

Local Regulator, DeBrena Hilton, has retired from the committee. With three remaining local regulator representatives on the committee, we have been advised we do not need to find a replacement. We will provide official notification and a revised roster to the Executive Board via a periodic status report.

**Periodic Status Report**

We have two periodic reports updating on our progress toward the charges of our committee due to the CFP Executive Board. Our first status report is due by March 1, 2019 and the second will be due by July 1, 2019. A draft will be shared for committee review.

## Current Work on Charge 2

- The committee adjusted the draft outline to discuss key points from theoretical and practical concepts literature review. Several committee members volunteered to draft language for each of the sections (see Action Items below).
- USDA sees cross contamination as substantial concern and potential for pigs drying out could increase Salmonella resistance. Erika will reach out to food scientists at USDA to verify safety steps.

## Action Items:

- Erika and Susan to work with subcommittees to draft language:
  - Section 1 and 2: **Jeff Jackson** to draft language for the introduction to the document and intended audience.
  - Section 3: **Nancy Beyer, Melissa Vaccaro, and Jaymin Patel** to draft language for *History of Associated Illnesses and Lessons Learned 3* incorporating Theoretical Concepts.
  - Section 4: **Erika Stapp-Kamotani, Veronica Moore, Dana Hanson, and Susan Shelton** to draft language for *Special Considerations & Equipment Rationale for Roasted Pigs* incorporating Analytical Concepts.
- Draft language to be completed by 3/11/19 prior to next meeting

**Date and time for next conference call: 3/11/19 at 1:00 p.m. (eastern) to review draft language developed.**

**CFP Safe Handling and Cooking of Roaster Pigs Committee**  
**Meeting Summary**  
March 11, 2019 1:00 p.m. (Eastern)

**Recording on:** Yes  No

**Reminder of Anti-trust Statement:** Yes  No

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**Welcome and Roll Call**

Baldwin, Tanja

Beyer, Nancy

Bush, Lauren

Cadet, Melissa

Hanson, Dana

Hilton, DeBrena (retired)

Jackson, Jeff

Johnson, Thomas

Martin, Dave

McGuire, Meg

Patel, Jaymin

Rivas, April

Seaman, Chuck

Sedlak, Mandy

Sparks, Christopher

Vaccaro, Melissa

Villareal, Rolando

Westbrook, Tim

**Co-Chairs**

Shelton, Susan

Stapp-Kamotani, Erika

**Non-Voting Members**

Abley, Melanie

Idjagboro, Charles

Krzyzanowski, Becky

Moore, Veronica

**Quorum:** Yes  No

**Vote on previous conference call's Roll Call and Summation (Call Conducted 1/28/19):**

*Vote delayed due to lack of quorum.*

APPROVE  DISAPPROVE

APPROVE AS AMENDED

**Vote on previous conference call's Summation (Call Conducted 2/11/19):**

*Vote delayed due to lack of quorum.*

APPROVE  DISAPPROVE

APPROVE AS AMENDED

**Reminder of Charges**

1. Identify best practices, or any existing guidance documents, that relate to proper handling and storage of roaster pigs of various sizes.
2. Develop a comprehensive guidance document for food handlers, particularly caterers, that includes detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs.
3. Determine appropriate methods of sharing the committee's work.
4. Report the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**Periodic Status Report**

Our first periodic status report has been received and accepted by the Executive Board. A copy was provided to the committee. We plan to participate in the Executive Board meeting (April 3, 2019)

to present current activities of the committee. If you have suggestions for inclusion, please let Erika or Susan know.

### **Current Work on Charge 2**

Draft 1 of the guideline presented today. Currently, draft language from the three groups was combined into one document with minimal edits. Thank you Jeff Jackson, Nancy Beyer, Melissa Vaccaro, Jaymin Patel, and Erika Stapp-Kamotani for drafting several sections of the first version of the guidance document.

**Question:** Is there a preferred length of document? CFP committees have materials that range in length; the key is to meet the needs of the audience. We might want to consider preparing shorter sheets or infographics for changing audience needs.

**Question:** Does FSIS plan to take ownership of the document? No. While FSIS may link to the document if it is available, it will be a product of CFP and will not be owned by FSIS.

**Question:** Should we share this draft with others outside the committee for review? Discussed waiting until Draft 2 is available for review; current draft is not ready for an external audience and does not include full information.

### **Action Items:**

- March-April: Erika Stapp-Kamotani, Veronica Moore, and Susan Shelton will update Draft 1 with additional material to create Draft 2. Erika will forward to FSIS partners for continued food safety review.
- May: Draft 2 to be sent to committee members.
- Consider other partners you think would be able to provide a review of Draft 2. Also think about how to share the document with audiences—info sheets, infographics, etc.

**Date and time for next conference call: May 13, 2019 1:00 p.m.**

**CFP Safe Handling and Cooking of Roaster Pigs Committee**  
**Meeting Summary**  
May 28, 2019 1:00 p.m. (Eastern)

**Recording on:** Yes  No

**Reminder of Anti-trust Statement:** Yes  No

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**Welcome and Roll Call**

Baldwin, Tanja

Beyer, Nancy

Bush, Lauren

Cadet, Melissa

Hanson, Dana

Hilton, DeBrena (retired)

Jackson, Jeff

Johnson, Thomas

Martin, Dave

McGuire, Meg

Patel, Jaymin

Rivas, April

Seaman, Chuck

Sedlak, Mandy

Sparks, Christopher

Vaccaro, Melissa

Villareal, Rolando

Westbrook, Tim

*Co-Chairs*

Shelton, Susan

Stapp-Kamotani, Erika

*Non-Voting Members*

Abley, Melanie

Idjagboro, Charles

Krzyzanowski, Becky

Moore, Veronica

**Quorum:** Yes  No

**Vote on previous conference call's Roll Call and Summation:**

N/A

**Reminder of Charges**

1. Identify best practices, or any existing guidance documents, that relate to proper handling and storage of roaster pigs of various sizes.
2. Develop a comprehensive guidance document for food handlers, particularly caterers, that includes detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs.
3. Determine appropriate methods of sharing the committee's work.
4. Report the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**Review of Section 4 – the Practical Section**

The members on the call reviewed the common practices associated with roaster pig handling and cooking. With each practice, the document covered the potential food safety concerns and practical recommendations to mitigate those food safety concerns.

**Action Items:**

- Combine the various sections together and review

**CFP Safe Handling and Cooking of Roaster Pigs Committee**  
**Meeting Summary**  
September 23, 2019 11:00 a.m. (Eastern)

**Recording on:** Yes  No

**Reminder of Anti-trust Statement:** Yes  No

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**Welcome and Roll Call**

Baldwin, Tanja

Beyer, Nancy

Bush, Lauren

Cadet, Melissa

Hanson, Dana

Hilton, DeBrena (retired)

Jackson, Jeff

Johnson, Thomas

Martin, Dave

McGuire, Meg

Patel, Jaymin

Rivas, April

Seaman, Chuck

Sedlak, Mandy

Sparks, Christopher

Vaccaro, Melissa

Villareal, Rolando

Westbrook, Tim

**Co-Chairs**

Shelton, Susan

Stapp-Kamotani, Erika

**Non-Voting Members**

Abley, Melanie

Idjagboro, Charles

Krzyzanowski, Becky

Moore, Veronica

**Quorum:** Yes  No

**Vote on previous conference call's Roll Call and Summation:**

N/A.

**Reminder of Charges**

1. Identify best practices, or any existing guidance documents, that relate to proper handling and storage of roaster pigs of various sizes.
2. Develop a comprehensive guidance document for food handlers, particularly caterers, that includes detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs.
3. Determine appropriate methods of sharing the committee's work.
4. Report the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**Review of Edits to Current Draft**

The members on the call reviewed the tracked changes on the draft shared on 9/9/19. In addition to providing a few word changes or deletions, the participants identified the following suggestions for the next draft:

- Add specific language regarding outbreaks linked to retail food establishments to help apply to FDA Model Food Code.
- Still need to add missing sources for several outbreaks in *History of Associated Illnesses and Lessons Learned* section.
- Modify safe instructions for how to stuff a pig in the *Pig Preparation* section. Emphasize the increased cooking time and other considerations.

**Next Steps**

1. Compile changes into next draft. Share prior to next conference call.
2. Determine communication to stakeholders.
3. Draft CFP Issues.

**Action Items:**

- April to provide comments on safe stuffing of roaster pigs to Erika and Susan.
- Erika to add additional photos; work on edits.
- Susan to provide citations for Washington-associated outbreaks and provide image of EPA Registry Number for sanitizer. Also review outbreaks to identify commercial establishments. Provide one-pager infographic before next meeting.

**Date and time for next conference call: Tuesday 10/22/19 1:00 p.m. (eastern)**

**CFP Safe Handling and Cooking of Roaster Pigs Committee**  
**Meeting Summary**  
October 22, 2019 1:00 p.m. (Eastern)

**Recording on:** Yes  No

**Reminder of Anti-trust Statement:** Yes  No

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**Welcome and Roll Call**

Baldwin, Tanja

Beyer, Nancy

Bush, Lauren

Cadet, Melissa

Hanson, Dana

Hilton, DeBrena (retired)

Jackson, Jeff

Johnson, Thomas

Martin, Dave

McGuire, Meg

Patel, Jaymin

Rivas, April

Seaman, Chuck

Sedlak, Mandy

Sparks, Christopher

Vaccaro, Melissa

Villareal, Rolando

Westbrook, Tim

**Co-Chairs**

Shelton, Susan

Stapp-Kamotani, Erika

**Non-Voting Members**

Abley, Melanie

Idjagboro, Charles

Krzyzanowski, Becky

Moore, Veronica

**Quorum:** Yes  No

**Vote on previous conference call's Roll Call and Summation:**

N/A.

**Reminder of Charges**

1. Identify best practices, or any existing guidance documents, that relate to proper handling and storage of roaster pigs of various sizes.
2. Develop a comprehensive guidance document for food handlers, particularly caterers, that includes detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs.
3. Determine appropriate methods of sharing the committee's work.
4. Report the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**Review of Edits to Current Draft**

The members on the call brainstormed different ways the document could be shared. FDA recommended sharing during their partnership meetings with stores, restaurants, and institutions. The states that have a Food Protection Taskforce could make the document available on their websites. AFDO may be able to distribute directly to states and local jurisdictions. It may also be possible to work with NEHA, IAFP, and NAMI to have them share the document with their constituents. In addition, the Centers for Excellence may be willing to share the document.

April Rivas could not attend the meeting, but later emailed with her recommendations of press release, Food Safety News, NEHA (and to announce it in JEH/NACCHO), and ServSafe / NRFSP (and National Restaurant Association).

**Next Steps**

1. Finalize the draft.
2. Finalize CFP Issues.

**Action Items:**

- Erika to work on the final CFP Issues.
- Susan to provide citations for Washington-associated outbreaks and provide image of EPA Registry Number for sanitizer. Also review outbreaks to identify commercial establishments. Provide one-pager infographic before next meeting.

**Date and time for next conference call: N/A**

**Safe Handling and Cooking of Roaster Pigs Committee**  
**Articles and Studies Used to Develop Guidance**

A Beginner's Guide to Roasting a Whole Pig (PDF provided as some government computers block the link)

<http://globetrotterdiaries.com/recipes/a-beginners-guide-to-roasting-a-whole-pig>

Before Roasting a Pig, the Pros Advise Food Safety Homework (PDF provided)

Charcoal – How to Roast a Pig

<https://broadwaypartyrental.com/wp-content/uploads/Pig-Roasting-Charcoal.pdf>

Foodborne Illness Associated with a Pig Roast

<https://www.ncbi.nlm.nih.gov/pubmed/30978824>

Globalization and Epidemiology of Foodborne Disease (pages 4-7)

[https://books.google.com/books?id=KTA0AAAAQBAJ&pg=PA5&lpg=PA5&dq=todd+ewen+guide+to+foodborne+pathogens&source=bl&ots=Ovr-cr\\_NgFo&sig=ACfU3U3-8mcbxdc7yjSOe7\\_S8xGISJtf4Q&hl=en&sa=X&ved=2ahUKewjBv7T50L\\_IAhWouVkkHQ2oCOUO6AEwAnoECAkQAQ#v=onepage&q=todd%20ewen%20guide%20to%20foodborne%20pathogens&f=false](https://books.google.com/books?id=KTA0AAAAQBAJ&pg=PA5&lpg=PA5&dq=todd+ewen+guide+to+foodborne+pathogens&source=bl&ots=Ovr-cr_NgFo&sig=ACfU3U3-8mcbxdc7yjSOe7_S8xGISJtf4Q&hl=en&sa=X&ved=2ahUKewjBv7T50L_IAhWouVkkHQ2oCOUO6AEwAnoECAkQAQ#v=onepage&q=todd%20ewen%20guide%20to%20foodborne%20pathogens&f=false)

Going Whole Hog: What You Need to Know to Roast a Hog or Suckling Pig

<https://amazingribs.com/tested-recipes/pork-recipes/going-whole-hog-what-you-need-know>

How to Cook a Whole Pig

<https://www.wikihow.com/Cook-a-Whole-Pig>

How to Roast a Pig in the Ground, Hawaiian Style

<https://www.artofmanliness.com/articles/how-to-cook-a-pig-in-the-ground-hawaiian-style/>

How to Prep, Brine and Roast a Pig in a Caja China

<https://stevedolinsky.com/how-to-prep-brine-and-roast-a-pig-in-a-caja-china>

How to Roast a Pig on a Spit

<https://www.serious-eats.com/2010/06/how-to-roast-a-pig-on-a-spit.html>

How to Roast a Whole Pig: It's Easier Than You Think

<https://www.post-gazette.com/life/food/2011/09/01/How-to-roast-a-whole-pig-it-s-easier-than-you-think/stories/201109010430>

How to Roast a Whole Pig: You'll Need Time, Average Cooking Skills – And a Mop

<https://www.twincities.com/2017/10/17/how-to-roast-a-whole-pig-hog-grill-dry-rub-barbecue-sauce-carolina-vinegar/>

How to Roast a Whole Pig Over an Open Fire

<https://qizmodo.com/how-to-roast-a-whole-pig-over-an-open-fire-1725473541>

Investigation of Salmonellosis Among Attendees of a Pig Roast, Connecticut, 2016

[https://portal.ct.govhttps://www.foodsafety.gov/blog/categories/food-outside-home/-/media/Departments-and-Agencies/DPH/dph/infectious\\_diseases/CTEPINEWS/Vol36No5pdf.pdf?la=en](https://portal.ct.govhttps://www.foodsafety.gov/blog/categories/food-outside-home/-/media/Departments-and-Agencies/DPH/dph/infectious_diseases/CTEPINEWS/Vol36No5pdf.pdf?la=en)

Pig Roasting 101: How to Cook a Whole Pig

<https://www.fieldandstream.com/articles/hunting/2013/07/how-cook-whole-pig-your-backyard/>

Pig Roasting and Food Safety (PDF provided)

Planning a Roast Big Barbeque

[https://www.canr.msu.edu/resources/planning\\_a\\_roast\\_pig\\_barbecue\\_e1604](https://www.canr.msu.edu/resources/planning_a_roast_pig_barbecue_e1604)

Polynesian Cultural Center Luau: How to Cook a Pig in an Imu

<https://migrationology.com/polynesian-cultural-center-luau/>

Pork Implicated in a Shiga Toxin-Producing Escherichia coli O157:H7 Outbreak in Ontario, Canada

<https://www.ncbi.nlm.nih.gov/pubmed/23617981>

Salmonella enterica serotype I 4,[5],12:i:- Illness Outbreaks Associated with Pork Products, 2015-2016

[https://www.fsis.usda.gov/wps/portal/fsis/newsroom!/ut/p/a1/vVPLbslwEPyWHjha3jxlzBEh0fJOIhraklyQ7Thq5DgBu6jq19eUquKCABXVPnhXmp3dWY1xgRe40HQvV9TKRIN1yItoCTOlN4AxuC500qCLHwaJwFMlqfITwFpzs6wOssnQwGQJLgUv0bLnDBtW3tGueVkJuObxRluhbQe3dauKimUnfANq3kpgM7walSBIFdovadKcnRWIBI14qgsbMOUTVnyRpXi6RSWhiDpN4LY390mUPPlq5EKYxc6e-MyxLnxGclY7yLQj9gKKSxh1hYMUSEXxIW9hinV4rPnD5cpfjCzo6A8y1yN0N8wiCN-zAaQjYbKyATqEXB2o6gLhP69Cb2\\_EkI3DhxhmnzGHqQ3ntCcvOx1f8FbnZbou-c\\_zB5B8WL\\_7N8m39UpNNNY2eCQTddv85r-p6mSSoyB-AK\\_E7Fo!/?1dmy&current=true&uril=wcm%3Apath%3A%2FFSIS-Content%2Finternet%2Fmain%2Ftopics%2Frecalls-and-public-health-alerts%2Ffoodborne-illness-investigations%2Foutbreaks-salmonella-pork-products-2015-2016](https://www.fsis.usda.gov/wps/portal/fsis/newsroom!/ut/p/a1/vVPLbslwEPyWHjha3jxlzBEh0fJOIhraklyQ7Thq5DgBu6jq19eUquKCABXVPnhXmp3dWY1xgRe40HQvV9TKRIN1yItoCTOlN4AxuC500qCLHwaJwFMlqfITwFpzs6wOssnQwGQJLgUv0bLnDBtW3tGueVkJuObxRluhbQe3dauKimUnfANq3kpgM7walSBIFdovadKcnRWIBI14qgsbMOUTVnyRpXi6RSWhiDpN4LY390mUPPlq5EKYxc6e-MyxLnxGclY7yLQj9gKKSxh1hYMUSEXxIW9hinV4rPnD5cpfjCzo6A8y1yN0N8wiCN-zAaQjYbKyATqEXB2o6gLhP69Cb2_EkI3DhxhmnzGHqQ3ntCcvOx1f8FbnZbou-c_zB5B8WL_7N8m39UpNNNY2eCQTddv85r-p6mSSoyB-AK_E7Fo!/?1dmy&current=true&uril=wcm%3Apath%3A%2FFSIS-Content%2Finternet%2Fmain%2Ftopics%2Frecalls-and-public-health-alerts%2Ffoodborne-illness-investigations%2Foutbreaks-salmonella-pork-products-2015-2016)

Spit-Roasted Pig with Nona's Rub and Basting Sauce

<https://www.cookingchanneltv.com/recipes/spit-roasted-pig-with-nonas-rub-and-basting-sauce-3081106>

The Surprisingly Easy Way to Roast a Whole Pig

<https://www.mensjournal.com/food-drink/the-surprisingly-easy-way-to-roast-a-whole-pig-20150612/>

Tender, Crispy-Skinned Whole Suckling Pig

<https://www.chefsteps.com/activities/tender-crispy-skinned-whole-suckling-pig>

Time-Temperature Survey of Hawaiian-Style Foods

<https://foodprotection.org/doi/pdf/10.4315/0362-028X-45.5.430>

The Whole Pig Roast: How to Cook a Full-Sized Pig (PDF provided)

Whole Roast Suckling Pig

<https://www.food.com/recipe/whole-roast-suckling-pig-462315>

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# A Beginner's Guide To Roasting A Whole Pig

by Karen on ~~Monday, June 20, 2011~~

It all started like most of my conversations with people. One night I was at my friends Mike and Ofelia's house sitting around the kitchen chit-chatting about food. Mike, who has the job I only dream of (he's a chef), and I talked through the night about different methods of cooking a whole pig. Before the night was over, permission to destroy the lawn was given by my lovely friend Ofelia and a deal was struck. We were going to try what everyone aspires to do one day: roast a whole pig. Well, at least everyone I know.

Valerie was soon on board with us and we set the date, invited some people to help eat, and started our research. This was new territory for me and Mike so a lot of books, blogs and friends were consulted. Many methods of cooking were available to us as we realized that people around the world have discovered incredible and diverse ways to cook pig. However, one of the first options we nixed was the “buried pig” method. A large fire is burned in a deep pit lined with lava rocks or bricks for hours, heating the earth. The fire is put out, the pig is lowered and the hole is covered and sealed completely, using the residual heat to cook the pig through. Because of a seeming lack of control over the heat (which is extremely important when it comes to barbeque) we decided that this was not the best option for beginners. Besides, I'm not sure how the neighbors would've felt about an enormous bonfire one yard over.

The Caja China, a pre-made wooden box that produces [\*lechón\*](#)-style pork, was recommended many times but after considering the cost, we decided to forego the investment– they're not cheap. We decided to consider purchasing it if our first roast turned out well.

The third and best option for us was a cinder-block barbeque. A rectangular barbeque is built from cinder blocks and a sheet of expanded metal or grates holds the pig a few feet above the hot coals. It requires a bit of elbow

grease and sweat, but as someone put it before, it “builds character.”

When it comes to determining the size of the pig you choose it depends on how many people you are going to feed. We planned for roughly 30 people coming so we got a 50 pound pig (after it's been cleaned). Although, we had more guests arrive than planned for (about 45) and everyone was eager to eat so I would get a larger pig next time, about 70 pounds. I learned that at an all-day barbeque if you keep bringing out the pork, people will keep eating!

So, let's get this process started, shall we?

### **Building the Pit**

*Start this process at least one day before the roast.*

You'll need:

- 30 cinderblocks
- foil
- a shovel
- a level
- a sheet of expanded metal or metal grate about 36 by 54 inches\*
- Optional: about 10 heat resistant bricks

*\*Do not use galvanized metal. The fumes it releases will make you and everyone who eats the food sick.*

A few words on obtaining a sheet of expanded metal. After some research we found the best option (if you don't already have some lying around) is to get one custom made from shops that make oil drum barbeques. Not only is it much cheaper but you can design the grate as you want. We decided here to get it reinforced and with handles attached. Since you can reuse it, the effort to find a place that can do this is worthwhile.



Clear a patch of land about the size of the barbeque pit (about 4 feet by 6 feet). Start by forming a rectangle of cinderblocks, 2 cinder blocks wide and 3 cinder blocks long. Lay this first row on it's sides so air can run

through this bottom layer, which helps the coals to continue burning. We used heat resistant bricks to line the inside of the length of the bottom row so that there wouldn't be *too* much oxygen in the pit. However, you could seal up those holes using foil or any other barrier you can get your hands on.

Use a level tool to make sure the first row is even. If it isn't each brick thereafter will be off making your whole barbeque unstable and rickety.

Then stack the rest of the rows on top of the barbeque with the solid sides facing out. Line the bottom of the barbeque with tin foil.

### **Prepping the Pig**

*Start this process the day before the roast.*

If the idea of picking out a live animal that you will later eat creeps you out, I implore you to open your mind to this process. I too was reluctant about it, fearing that my love for meat would be stifled by the stark reality of being a human who kills living things for our consumption. However, after the process (in which Val was the brave one pointing the finger) I would say it made me, Mike, Ofelia and Val more conscientious consumers and more appreciative of the meat we eat.

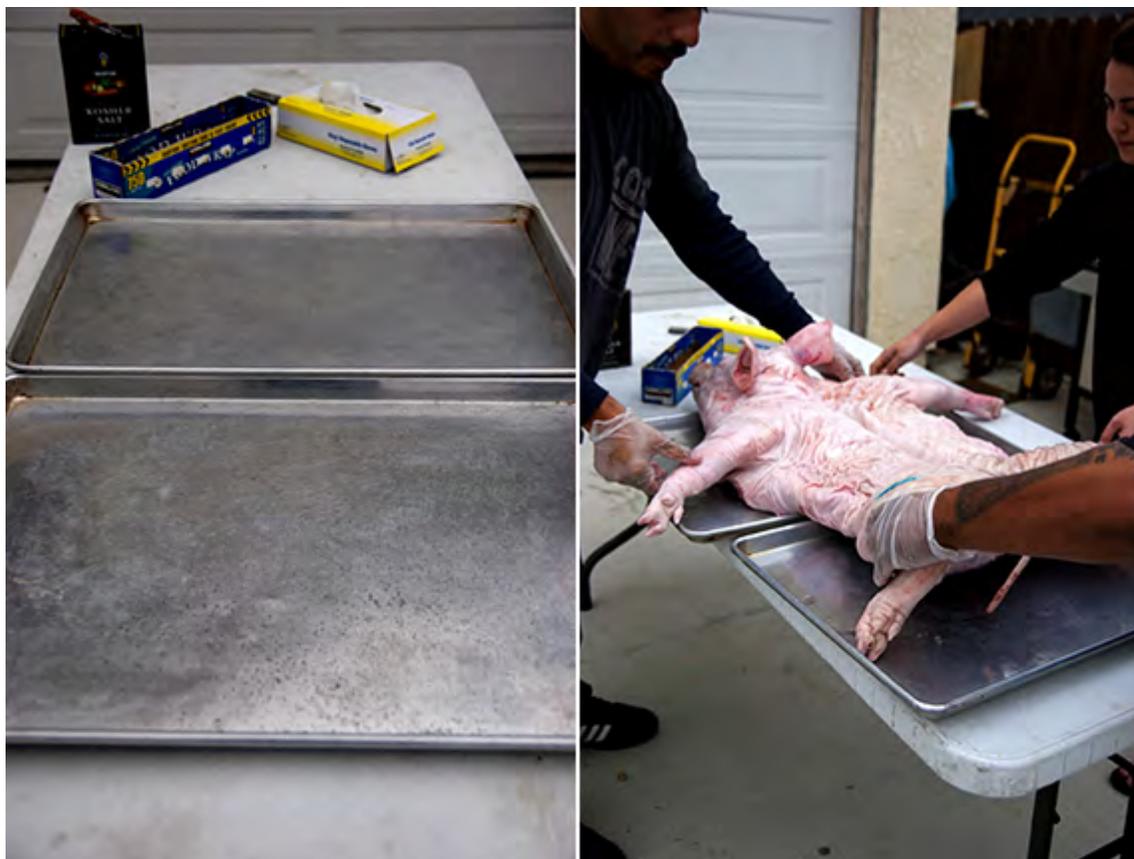
You'll need:

- 1 50-pound pig, gutted and cleaned
- Kosher salt
- a box cutter
- latex gloves
- Ice and cooler

Wherever you are able to source a whole hog, ask the butcher to crack the spine and head for you. This allows the pig to splay out flat over the grill. You can do this yourself but you will need a hammer, a small ax, and *very* careful hands.

When you get your pig, rinse it off very well and place it on a large clean surface. We used sheet pans on a table, and this is where latex gloves come in handy! Carefully score the surface of the pig with a box cutter in large

criss-crossing diagonals. Don't cut past the skin and layer of fat into the flesh. On a younger pig the skin will be much thinner and easier to cut through and on larger pig the skin will be thicker and tougher to penetrate.



With heaping handfuls of kosher salt, rub generous amounts all over the pig. Don't be concerned about over salting it; it is a lot of meat. We didn't measure the amount we used but I would say roughly 2 cups of kosher salt was used.

Place it in a cooler with bags of ice over it to rest overnight. We left the ice in the bag so it wouldn't melt and dilute the salt rub.

### **Starting the Grill**

*Start this early in the morning the day of the roast.*

You'll need:

- 60 pounds of charcoal
- 1 coal chimney
- a small rake or shovel
- BBQ tongs
- meat thermometer *(Use one that reads the external temperature as well as the meat temperature. Having this is absolutely critical to rookie BBQing!)*
- 6-8 sheet pans or a large sheet of metal
- \*Optional: meat syringe, BBQ mop, more heat resistant bricks

Start with one 20-pound bag of charcoal spread in two even piles on both ends of the barbeque. Light this and let it burn down until the coals are ashy and glowing. For our pig, we lowered the grate so it was resting on top of the second layer of cinder blocks about 16 to 18 inches from the ground. Layer the third row of cinder blocks on top of the grate. This provides a short wall around the pig so a sheet of metal can be placed over the pig while it cooks, trapping in the heat.

It will take a while for the initial coals to burn down, so in the meantime get the pig out of the chest and patted dry. We injected ours with a *mojo* of fresh pineapple juice (which has enzymes that helps break down protein), Seville orange juice, chillies, garlic, oregano, cumin and salt. We had a bowl of this on the side that we occasionally basted the pig with.



Getting the temperature right at the beginning is really the hardest part. After you have your pig ready, it's just about maintaining that temperature. Once the coals are ready, throw your pig on the grate belly-side down and stick your thermometer in the thickest part of the thigh. Cover with a sheet of metal or in our case a carefully arranged layer of sheet pans.

Once your pig is on, reserve a few coals to start a full chimney of coals (about 5 pounds) so that they're ready to add to the pit. From here it's all about keeping an eye on the temperature. You generally want the "oven" temperature to stay around 225 to 250 degrees. After adding coals to each side, just have another chimney full of coals burning so that they're ready any time you need them. It takes babysitting, but you can play cornhole in the meantime.

To add new coals, we just removed a couple of the corner cinder blocks and used a shovel and BBQ tongs to add to the pile. As ash starts to build up just push it carefully towards the center so that you're not putting new coals over a pile of ash. Just do this gently so the ash doesn't fly up all over the pig.

After about 1 hour (when the inside had gotten some good color on it) we flipped the pig onto its back and let it roast for another 2 hours or so before flipping it back onto its stomach again. We basted it a few times with the *mojo* we injected into it, but not a lot. We really wanted the results to be pure pork– just enhanced. It cooked the rest of the way like this until the internal temperature of the meat hit about 200 degrees and was served immediately.

There was one thing I would recommend doing differently. Get some oil on that skin– we thought there was enough fat to crisp up the skin, but while some parts were, others weren't.

### **Eating the Pig**

*(I think this is pretty self-explanatory.)*



Our group of friends is an adventuresome bunch so we decided to serve the pig as is, straight off the barbeque, and allow guests to pick what parts they wanted.

We made a finishing *mojo* with garlic slowly cooked in olive oil, Seville orange juice and spices to go with the pig. Rice, black beans, grilled plantains, grilled corn and a salad was a great way to finish off the meal!

# Before Roasting a Pig, the Pros Advise Food Safety Homework

By **Cookson Beecher** on July 31, 2015

While summer often conjures up mouth-watering thoughts of pig roasts, if you're actually contemplating tackling this culinary feat, some homework is in order. And that includes some homework about food safety. You certainly don't want to sicken your guests, which can be avoided if you play it safe. When you roast a whole pig, your first thought may be that since you'll be cooking the heck out of it, surely you'll also be killing any bacteria such as *Salmonella* or *E. coli* that might be on the meat. But that isn't always the case since some parts of the pig will cook more quickly than others, so a simple jab of the meat thermometer in just one part of the pig isn't going to tell you the whole story.

And you certainly can't base your decision of whether the pig is cooked enough by the length of time it's been cooking and how hungry your guests are. As with any type of cooking, what you do before and after preparing the roast is also important.

a last-minute decorative flourish.) **Ways to roast a whole pig** There are all manner of methods to roast a whole pig, among them burying it in a pit, boiling it in oil, cooking it over coals in a pit above ground, and using an electric rotisserie. The first of these, which originated in Hawaii, brings up thoughts of idyllic celebrations: A wild boar is wrapped in banana leaves and buried in a pit of hot lava stones. Many people who cook whole pigs in a pit have adapted this basic practice but use other “backyard” **techniques** that involve digging a pit and burning wood in it to build up a bed of coals. This method takes a lot of time, anywhere up to 12 hours in cooking time alone, not to mention the many hours (and often beers) it takes to build up that bed of coals. **Building** a pit above ground, usually of cinder blocks, is another popular method, with the pig turned every now and then. But care needs to be taken so the coals don’t flare up and touch the meat and that the equipment you’re using isn’t made of galvanized metal, which can exude toxic fumes. This takes care and diligence on the part of the person cooking the pig. (Important note: The temperature noted in the magazine article cited in the first sentence of this paragraph is lower than the pros in this article advise.) Perhaps the most popular method is using a rotisserie, which **SpitJack** prefers. The Massachusetts company specializes in “cooking with fire” equipment, not only because it’s “the easiest or tastiest way” to go, but also because it represents ‘the most authentic and entertaining way’ to do it. “There is nothing like watching a whole hog turn slowly over several hours, slowly browning and transforming into a delicious meal,” states SpitJack’s website. The site also refers to roasting a whole pig as “a great American tradition” that has come to symbolize “the essence of the community cookout and the shared work and pleasure that is involved.” Of course, this is not only an American culinary favorite. Chefs and backyard cooks around the globe also like to cook whole pigs this way. But, as those who have done it already know, it is not a simple or easy task and, as the SpitJack site notes, “there is much to be considered if everyone is to enjoy the feast.” In a sometimes humorous **article** about his experience roasting a whole pig, “Do Not Go Gently into That Pig Roast,” Ryan Tate warns of how “messy and inelegant it can get.”

site notes, “there is much to be considered if everyone is to enjoy the feast.” In a sometimes humorous **article** about his experience roasting a whole pig, “Do Not Go Gently into That Pig Roast,” Ryan Tate warns of how “messy and inelegant it can get.”

He also offers this advice: “Finally, remember that no enormous cooking project will be as simple as you imagine. You see a whole pig, and you imagine the roasting, and the eating, and the joy and camaraderie that goes along with it. But don’t forget the transportation, the setup, the fuel management, stray sparks and coal and ash, grease, estimating cooking progress and correcting your schedule, and of course the cleanup.” **A generous helping of food safety** Food safety must be kept in mind from start to finish, say those who roast whole pigs professionally or sell meat-roasting equipment. A good example of why this is so important can be seen in a **recent press release** from the Washington State Department of Health about an investigation into at least 56 *Salmonella* infections that department officials say “appear to be linked to eating pork.” The same release notes that the investigation “shows a potential exposure source of several cases was whole roasted pigs, cooked and served at private events.” (Important note: The temperature noted in the state’s press release is much lower than the temperature advised by the pros interviewed in this article.) Salmonellosis, the illness caused by *Salmonella* infection, can cause severe and even bloody diarrhea, fever, chills, abdominal discomfort, and vomiting. Serious bloodstream infections may also occur. That’s definitely not anything you want at your barbecue. SpitJack’s Bruce Frankel, a former chef/restaurantier, knows only too well

how many mistakes can be made along the way, especially when people don't follow basic food-safety practices. But he said that when roasted to the right temperature and served properly, a whole pig is perfectly safe to eat. But he warns that roasting a whole pig is not like cooking a pork roast that you put in the refrigerator until it's time to cook in the oven. To begin with, a whole pig is usually roasted for a lot more people than would be at a family meal. "If you're serving a lot of people, logistics demand more care," he told **Food Safety News**. "The bigger the event, the more care needs to be taken." He said that the cook should actually be thinking like a caterer and be well-versed in the food-safety practices that caterers are required to follow. The person or group doing the cooking needs to come into the venture well-prepared. To start with, the quality of the meat needs to be good, whether it's bought from a farm or a butcher shop. It also needs to be kept cold at the site. Even the USDA stamp can't ensure that it has been kept at the right temperature. That's something that needs to be verified. In most cases, the slaughtered whole pig is picked up and taken home. Being such a large "piece of meat," means you're going to have to have something to carry it in, Frankel said. His company sells "transport bags," which he likens to "body bags." They can be closed up so bloody water doesn't drip all over the car. You'll also need some bags of ice to keep the meat cold.

Where do you put the pig when you get home? Certainly not in the refrigerator; it's far too large for that. And most coolers aren't large enough either. "A large enough cooler is not easy to find," said Frankel. First things first, though. Hose the pig off and

salt it down to help prevent bacteria such as *Salmonella* and *E. coli* from growing on the surface. You can also wipe it down with towels soaked in a strong salt solution. Frankel said a common home practice is to put the pig in a bathtub with a lot of ice. Of course, the tub should be cleaned with a bleach solution once the pig is taken out. Leaving it out on the porch with a cover over it to keep the flies off won't work since the pig not only needs to be kept clean but also cold. And you don't want a dog to come along and gnaw off part of a leg. When it's time to get the cooking apparatus ready, Frankel advises using food-grade stainless steel (304 Or 316) for the **spit**. He warned that carbon steel can impart off-flavors to the meat. In addition, galvanized metal can leach toxic zinc and should not be used as a rotisserie spit. And forget using that old rusty galvanized pipe lying around out in the yard. "You don't want to poison the meat," he said, adding, "The entire system needs to be food-safe."

**Cooking the meat** Temperature, of course, is critical — not just the temperature of the meat but also the temperature of the air around the meat. Frankel advised keeping the air temperature around the meat to 225-250 degrees F and cooking the meat to 195 degrees F. "There's a culinary reason for that," he explained. "When meat is cooked this way, it becomes soft and pullable — fork-tender." While some federal and state agencies recommend cooking the meat to 165 or 170 degrees F, Frankel said at that temperature you'll get some bloody meat and blood at the joints. Barbecuing a whole pig is an entirely different way to cook pork," he said. "Every part of the animal should be at least 180 degrees." He also said that at 195 degrees F, there will be no food-safety problems with the meat, at least in the cooking process. When roasting a whole pig, Frankel said you need to keep an eye on what the temperature is in various parts of the pig since different sections, such as the shoulders and legs, are much thicker than other parts, such as the ribs, which means that some parts will take longer to cook.

That's why his company offers a package of three thermometers. Two provide not only a constant reading for the leg or shoulder but also a good indication of the ambient, or cooking, temperature. The third thermometer, an instant read thermometer, provides a quick read for any part of the roast. Frankel emphasized that someone needs to watch that the temperature is OK — at least 175 degrees F. — all the way through the cooking process. When using a smoker, he recommends cooking the whole animal to beyond the safe temperature. As for cooking a whole pig in a pit, he warns that there are a lot of variables in this method. "It's an ancient practice and can be a bit dangerous," Frankel said. **Serving the meat** For food safety's sake, the meat shouldn't go below 140 degrees F for any length of time once it comes off the spit. Frankel recommends quickly cutting up the meat and putting the pieces into containers placed over chafing dishes to keep it warm. "It's nice to have hot meat to serve," he said, pointing out that not only is the meat tastier that way, but it's also safer. There's no need to let the meat "rest" before serving it because it's been cooking the entire time at a reasonable temperature. Leftovers should be cooled down and packaged with ice for people to take home. **Challenging, but satisfying** Frankel describes cooking a whole pig as "a tricky thing" and not for the faint of heart. "But when it's done right, it's very satisfying," he said. "It's a great show to see the meat turning on the spit and a great feeling to know that you've done it right." He also said that providing people with the proper information about food safety pertaining to cooking a whole pig is an important issue that needs to be

pursued. “People should know how to make sure it’s safe all the way through — until the last leftover has been eaten,” Frankel said. **Another vote for food safety**

Lance Anderson of **Marv’s Marvius Pit BBQ Catering** also can’t stress enough the importance of food safety. “It’s our number-one priority,” he told **Food Safety News**. It’s important not to make people sick, plus a company’s reputation is based on word of mouth. “It can go two ways,” Anderson said. “Really good and customers will tell other people and you get more customers, or really bad and you can lose your business.” He said that roasting a whole pig to the proper temperature is standard practice for his business. “Our business model is to cook the fresh pork on site and serve it,” he said. Pointing out that *Salmonella* can’t live at temperatures higher than 160-165 degrees F, Anderson said that Marv’s cooks whole pigs they bring to a site to 200-205 degrees F. “We go way above and beyond,” he said, adding that if people want them to cook the pig to a lower temperature, they won’t go. “There’s just too much risk involved,” Anderson said. Marv’s also provides coolers with ice. And they won’t leave the leftovers behind unless they know the people will use the ice to keep it cold. “Most people are good about it,” he said, “although we rarely have leftovers.” Summing up some of the principles his company follows, Anderson said that using the proper equipment, making sure the cooking and serving temperatures are right, and working in a clean environment are critical. “The risks can be severe, especially for older people and children,” he said, referring to foodborne illnesses such as *Salmonella* and *E. coli*. Anderson compared the know-how required when roasting a

whole pig to services that other companies provide. “If your car needs to get fixed, you take it to a mechanic,” he said. “If you want a haircut, you go to a barber. Roasting a whole pig is similar — sometimes it’s better to leave it to the professionals.” **Some physical safety tips** When a pig is being cooked, it’s a jacket of hot fat, Frankel noted. This is why it’s so important to have a drip pan or sand for the drippings to fall into so the coals won’t flare up into flames. “It’s like a bomb when a pig catches fire,” he said. “It explodes. That’s why you need to have a fire extinguisher for grease fires handy.” In addition, since you’ll be working with very hot objects, you shouldn’t wear loose clothing that can catch on fire or shoes that are not fire-safe. Long, heavy leather gloves are also advised when handling hot objects and food-safe gloves for processing or transporting the meat. If you’re using an electric motor, make sure the power cord is away from the fire and that any extension cord used is properly rated and secured. Frankel also said that there should be nothing near the rotisserie that people can trip over and to make sure that kids are kept at a safe distance. It’s also important that the operator doesn’t drink alcohol. “If you’re managing an open fire, you should be sober,” he said.

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## Food Safety News

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## Pig Roasting and Food Safety

**Dec 21, 2016**

By: *Bridgette Keefe, Food Safety Education Staff, Food Safety and Inspection Service, USDA*

Roasting a pig is as exciting as it is delicious, but it is also a serious undertaking. If done incorrectly, people can get sick. It is critical that you safely handle and prepare the pig and choose the roasting method—grilling, rotisserie cooking, or roasting in a rock-lined pit—you are most comfortable with.

If you are unsure of the method or process for pig roasting, you may want to consider hiring a professional or breaking the animal down into individual cuts for easier cooking.

The first step before roasting the pig is food safety. That begins when the pig is picked up and ends when the last piece of pork is eaten or safely refrigerated. By following these basic food handling and food safety tips, you can reduce your risk of Salmonellosis caused by cross-contamination or eating undercooked pork.

### Ordering and Transporting

After choosing the roasting method, you need to determine the number of guests you plan to serve. Allow 1½ pounds of pre-cook weight per person; this will result in approximately six ounces of cooked meat per serving. You should buy the pig from a reputable supplier and order at least seven days in advance to ensure your pig is ready for pick-up. If your supplier also sells frozen swine, ask them to thaw the pig for you under refrigerated conditions at 40 °F or less. It is not safe to roast a frozen or partially frozen pig.

Be sure to ask the supplier to wrap the pig in food grade plastic or a large good grade plastic bag to contain the juices. It is strongly recommended you pick the pig up just before you are ready to cook it. Otherwise, as soon as you get home you will need to put it in a cooler (be sure to check that you have one large enough before you order the pig) or in a food grade plastic-lined bathtub full of ice to keep it cold at 40 °F or below. Use an appliance thermometer to continuously monitor the temperature. If you do put your swine on ice, don't forget to disinfect your tub afterwards.

### Preparing for the Big Event

In addition to whatever is required for your preferred roasting method, be sure to have the following items on hand: two food thermometers, a clean table for preparation and final carving, clean utensils and serving dishes, paper towels and disinfectant wipes, a clean apron, a box of disposable gloves, and most importantly, access to soap and warm water. Be sure to use clean utensils to remove and carve the roasted pig and not the dirty utensils you used during the cooking process to prevent cross contamination.

The station where you prepare and carve the pig must be clean at all times. Anything that comes into contact with the raw pig should be washed with warm water and soap immediately. Be sure to dispose of gloves after each use. It is important to prepare the pig for roasting completely separately from other food items—such as vegetables for salads and fruits that won't be cooked—to prevent cross contamination.

If you plan to stuff the pig, keep the stuffing to a minimum to reduce risk. The more you put inside the pig, the longer it will take to cook and the more difficult it will be to use your thermometer to check the internal temperature. It is important that the stuffing be cooked to at least 165 °F to destroy bacteria that may be present.

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## Roasting the Pig

Take your time and follow the roasting instructions carefully. Your pig can take anywhere from 4 to 12 hours to cook depending on the size and roasting method. It could take even longer if stuffed. Check the temperature in the deepest part of each shoulder and leg, several places along the loin area, and stuffed areas. For best flavor and quality, cook the meat to at least 195 °F. It will ensure that the meat near the joints is fully cooked since there may be parts that you can't reach to measure with a thermometer. Meat should be fork-tender, and falling off the bone. Replenish wood or coals often to make sure the fire stays hot.

## Feeding your Group and Packing Leftovers

Now that the pig is fully cooked, take extra care when transporting the pig from the heat source to the table using freshly cleaned utensils. You should expect to spend an hour or so on carving so be mindful of the 2-Hour Rule to refrigerate perishable food within 2 hours after cooking (or 1 hour if the weather is 90 °F or above). Serve meat on clean serving dishes as you carve. While serving, keep trays of the cooked pig on the heat to keep it warm.

Pack leftovers in shallow containers and refrigerate within 1-2 hours. It is not necessary to cool before you refrigerate it. Freeze for 4-12 months for optimal quality.

Follow these basic food safety tips and have fun roasting the pig!

For more information on cooking pork, visit [Fresh Pork from Farm to Table](#).

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# The Whole Pig Roast: How to Cook a Full Sized Pig

A whole pig roast is a wondrous event, but if you've read How to Cook a Whole Pig then you know there is a lot that goes into it. A whole hog can be quite large and therefore requires special equipment and skills to pull off. While you may know the basics so far, this page will go into more of the details of things to plan for to make your whole hog roast go off without a hitch.



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## Some things to consider and plan for when cooking a whole pig roast:

### Invite a Lot of Friends!

This may seem obvious, but most people do not realize just how much meat is on a large hog! Don't plan a hog roast without sufficient friends and family to help you devour the tasty goodness when it is done. You'd hate to see all your hard work go to waste wouldn't you!

### The Hog Rotisserie

1. A suckling pig is typically under 25 lb. Therefore, whole hogs are generally significantly larger than that. While many that you'll see roasted are 30 to 60 lb., larger adult hogs can easily weight from 100 to 200 lb. For this reason, you need a very heavy-duty and sturdy rotisserie, as seen above, to slowly and safely turn your pig roast over your fire.
2. Why do you need a rotisserie in the first place? Why not just support the pig over your fire pit on a rack? A whole pig is a large roast! If left in one position over a fire or charcoal, one side would be burnt and crispy while the other side would be raw. Just like any cut of meat, you need to turn it to be fully cooked throughout. However, turning a whole hog is not as easy as flippin' a burger! Just imagine trying to flip the hog, several times, while it is inches over hot embers. Think you could handle it? Well you're wrong, this is a set-up for disaster. Turning a large whole pig roast over a fire



by hand is next to impossible and you will end up with charred arms and eyebrows. A sturdy hog rotisserie is the only solution and in my opinion is critical to a successful pig roast.

3. Many companies make whole hog rotisseries. Whatever you use, make sure it is weight tested for more than your pig weights so you know it will hold, and turn, that weight.

### Buying a Whole Pig

1. Plan ahead for your pig roast! In most areas a whole fresh hog is not that easy to come by. Find a source for a whole hog well before you plan your party.
2. Talk to your butcher. Most can special order whole pigs. Ethnic markets and butchers, Latin and Asian particularly, are a good place to start. Check out my [Where to Buy a Whole Hog for Barbecuing](#) page.
3. When buying a whole pig, find out if it will come frozen or fresh. If frozen, be sure to leave sufficient time once you get it to defrost. An average sized hog will take at least 48 hours to defrost completely. If you are planning to marinate or brine it as well, this will take additional time before the whole pig roast so plan ahead and make sure you don't run out of time!
4. Also ask your butcher how the pig will come. Most are prepped for cooking, meaning their hair and internal organs have been removed. If they haven't been prepped, make sure you have someone who can clean and prep the hog for you before cooking.

### Prepping Your Whole Pig Roast: Marinating, Brining and Injecting

1. A whole pig needs to be flavored. If you just throw it on your rotisserie and cook it, the large cuts of meat will be rather bland. But do not fret, pork takes to marinating and brining like a fish to water!
2. There are many types of recipes for prepping a whole pig roast, but I particularly like brining. Brining uses a salt water solution to tenderize the meat and also to help the muscle fibers retain moisture. This helps infuse flavor and keep your roast succulent and moist. It will not dry out and become tough.
3. There are many options for brine or marinade mixtures. One brine that I particularly love and works beautifully with pork is an apple cider brine described on my [pork tenderloin barbecue recipe](#). The apple flavor and subtle sweetness really enhance and compliment the natural flavor of the meat. To add even more flavor, I like to add an abundance of herbs, onions, lemons, oranges and/or hot peppers to the brine solution.
4. A whole pig should be brined or marinated for at least 24 hours overnight, if not longer. Additionally, injecting the thickest parts of meat with the marinade or brine solution will help to be sure your brine penetrates all of the meat, not just the surface cuts.

### Prepping Your Whole Pig Roast: Trussing

1. Proper trussing of your whole pig roast to the rotisserie spit is critical. As your pig cooks it will loosen, move and shift. The muscle fibers will pull apart and away from the bone. The result? Your whole hog could fall off your spit! That would be disaster. Prevent this by trussing aggressively and tightly.



2. In general, the spit should go between the thighs, along the inside of the body just under the spine and out through the mouth. Because the spit is not really going through meat, this is not secured to the spit. A large trussing need and heavy-duty kitchen twine should be used to secure the spine to the spit every 6 inches along the length of the meat. This should be tied as tightly as

possible with the knots on the back. Cut off excess twine so that it will not burn.

3. The hips, thighs and legs should also be trussed securely to hold them tight against each other and the spit. Same goes for the head and shoulders. You don't want any wiggle or give in your pig, it should move as one with the spit.
4. A great demonstration of how to truss a whole hog to a spit with pictures is available at [SpitJack](#).

### Go Slow and Easy

1. A whole pig roast takes a long time, you cannot, and should not, rush it. Quickly grilled pork leads to burnt skin and dried out meat. Cook slowly over the fire pit on the rotisserie at lower temperatures (around 250 degrees or so at the surface of your roast is ideal).
2. Whole hogs can take from 4 to 24 hours to cook completely depending on their size and the cooking temperature. So plan ahead and take your time.
3. When you think the roast is nearing doneness, test the doneness with a [meat thermometer](#). All internal temperatures of the deepest meat (the hams and shoulders will be the last to cook thoroughly) should be at least 160 degrees and ideally about 165.

### Basting, Basting, and Then More Basting

1. Basting with a good basting mixture helps to develop a nice thick, dark caramelized glaze on the surface of the roast. It also helps prevent the skin and superficial meat from drying out.
  2. Baste frequently throughout the cooking period, particularly when you notice the surface getting dry.
  3. Basting mixtures vary and can use any number of flavoring ingredients. Some examples of things to include are olive oil, wine, fruit juices, herbs and lemon juice. Even a little honey or sugar can enhance the flavor and help the caramelization. Just be careful not to put too much sugar on the surface of your whole pig roast or it will burn if it gets too hot. Remember, you want caramelization, not charcoal!
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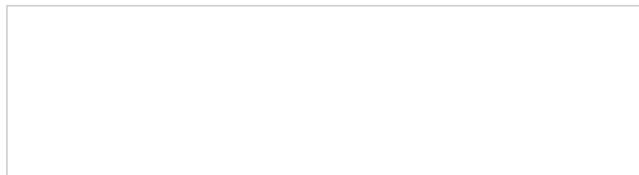
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2020 Issue Form**

**Issue: 2020 III-002**

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**Issue History:**

This is a brand new Issue.

**Title:**

SHC-RPC - 2 Approval of Guidance Document for Roaster Pig Cooking

**Issue you would like the Conference to consider:**

At the 2018 biennial meeting, Issue # 2018 III-023 charged the Safe Handling and Cooking of Roaster Pigs Committee with: "Developing a comprehensive guidance document for food handlers, particularly caterers, that include detailed best practices for roaster pig preparation. These recommendations would include proper handling, thawing, cooking, and temperature measurement of roaster pigs."

In addition, Issue # 2018 III-023 charged the Safe Handling and Cooking of Roaster Pigs Committee with: " Determining appropriate methods of sharing the committee's work."

The committee requests the Conference to consider approving the Safe Handling and Cooking of Roaster Pigs Committee's guidance document entitled "*Whole Roaster Pigs: Guidance for the Safe Handling and Cooking.*" The committee would also like the Conference to include the guidance document on the CFP website in a downloadable PDF format with functional hyperlinks.

**Public Health Significance:**

This guidance document provides practical recommendations for the safe handling, preparation, and cooking of roaster pigs. It contains a synopsis on lessons learned from previous outbreaks and a discussion on common handling and cooking practices of roaster pigs. This discussion describes the food safety risks associated with certain practices and practical recommendations to mitigate the food safety risks.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

1. Approval of the committee document entitled "*Whole Roaster Pigs: Guidance for the Safe Handling and Cooking*" (attached to Issue titled: Report - Safe Handling and Cooking of Roaster Pigs Committee);

2. Authorizing the Conference to make any necessary edits prior to posting the document to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
3. Posting the guidance document on the CFP website in a downloadable PDF format with functional hyperlinks.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-003**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

SHC-RPC - 3 Sharing of Guidance Document for Roaster Pig Cooking

**Issue you would like the Conference to consider:**

At the 2018 biennial meeting, Issue # 2018 III-023 charged the Safe Handling and Cooking of Roaster Pigs Committee with "Determining appropriate methods of sharing the committee's work." The Committee would like the Conference to request various organizations to make this document available to their respective constituents. The Committee would also like the Conference to develop a press release for major networks and develop an article for the Food Safety News announcing the availability of this document and its intended purpose.

**Public Health Significance:**

This guidance document provides practical recommendations for the safe handling, preparation, and cooking of roaster pigs. It contains a synopsis on lessons learned from previous outbreaks and a discussion on common handling and cooking practices of roaster pigs. This discussion describes the food safety risks associated with certain practices and practical recommendations to mitigate the food safety risks.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends...*

1. A letter be sent to the Food and Drug Administration (FDA) requesting:

that the most recent edition of the Food Code (Annex 2, Part 3 - Supporting Documents) be amended to include a reference to the CFP document titled "*Whole Roaster Pigs: Guidance for the Safe Handling and Cooking*" with phrasing similar to:

*Roaster pigs present unique challenges for handling and cooking due to their variable, and sometimes, large size. Improper handling and inadequate cooking of roaster pigs has contributed to several outbreaks. This guidance document provides practical recommendations for the safe handling, preparation, and cooking of roaster pigs. It*

*contains a synopsis on lessons learned from previous outbreaks and a discussion on common handling and cooking practices of roaster pigs. This discussion describes the food safety risks associated with certain practices and practical recommendations to mitigate the food safety risks; and*

2. That the document be shared through their partnership meetings with stores, restaurants, and institutions;

A. A letter be sent to the following organizations requesting that they inform their respective constituents of the document and make the document readily available to their constituents:

1. Association of Food and Drug Officials (AFDO),
2. National Environmental Health Association (NEHA),
3. International Association for Food Protection (IAFP),
4. North American Meat Institute (NAMI),
5. Association of American Meat Producers (AAMP),
6. National Pork Board,
7. National Restaurant Association and the National Registry for Food Safety Professionals (NRFSP),
8. Food Safety and Inspection Service (FSIS),
9. Centers for Disease Control and Prevention's (CDC) Integrated Food Safety Centers of Excellence, and
10. ServSafe;

B. A letter be sent to the States to make the document available on their applicable websites, such as the Food Protection Taskforce, and

3. The Conference develops a press release to the major networks announcing the availability of the document;

4. The Conference prepares an article for the Food Safety News regarding the availability of the document and its purpose.

*Note: Draft CPF guidance document is attached to Issue titled: Report - Safe Handling and Cooking of Roaster Pigs Committee (SHCRPC); approval of the document is requested in Issue titled: SHCRPC - Approval of Guidance Document the Safe Handling and Cooking of Roaster Pigs*

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-004**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Report of the Direct to Consumer Delivery Committee (DTCDC)

**Issue you would like the Conference to consider:**

The Direct to Consumer Delivery Committee requests acknowledgement of their final report and that the Conference thank the committee members for their efforts and hard work.

**Public Health Significance:**

This guidance document provides food safety best practices for managing or performing direct to consumer (DTC) or third-party delivery (TPD) services. This document includes parameters critical to preventive controls, mechanisms to assess risk, validation and verification practices, recommendations for proper packaging, temperature control, receiving and storage, physical and chemical contamination control, allergen control, general food safety information, and suggestion for return of compromised and abused products. The intent of the guide is primarily to provide best practices for preventing biological, physical and chemical contamination as well as the growth of harmful bacteria and/or the formation of toxins within the food being transported.

**Recommended Solution: The Conference recommends...:**

The Committee recommends that the Conference:

1. Acknowledge the committee final report.
2. Thank the voting members, at large non-voting members, federal consultants and observers for their tireless service.
3. Disband the committee.

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**Content Documents:**

- "Direct to Consumer Delivery Committee final report"
- "Committee Member Roster"
- "Guidance Document for DtC and TPD Service Food Delivery"

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

**COMMITTEE NAME:** Direct to Consumer Delivery Committee

**DATE OF FINAL REPORT:** November 6, 2019

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

**REPORT SUBMITTED BY:** Donald W Schaffner (chair). Albert Espinoza (vice chair)

**COMMITTEE CHARGE(S):**

**Issue # 2018-III-006**

1. Identify current recommended practices and existing guidance documents that relate to shipment directly to a consumer of perishable food items and for the safe delivery of food by Third Party Delivery Services (TPDS) entities.
2. Revise the Guidance Document for Mail Order Food Companies that includes recommended practices for transportation directly to a consumer of perishable products, to include proper packaging; temperature control during shipping, receiving, and storage; return of compromised and abused products; and other food safety related topics. Current guidance document to be revised to include food safety training for the TPDS entities, and information on all food delivery practices from food production, distribution, or retail food service facilities.
3. Determine appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the 2017 Food Code, Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.
4. Report the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

**COMMITTEE WORK PLAN AND TIMELINE:**

The committee met every two weeks on Tuesdays at 3 PM Eastern since it's formation. Two sub-committees also met on a by-weekly or more frequent basis since their formation. One subcommittee focused on foundational issues that apply to direct to consumer delivery as well as third-party delivery. The subcommittee also revised the direct to consumer delivery (previously called mail-order) text from the original document. The second subcommittee focused on third-party delivery specific issues.

The committee and sub-committees use the CFP supplied Pragmatic conference call service and a variety of screen sharing platforms. All committee calls and some subcommittee calls were recorded and available for listening afterward for those who could not attend, or for those that need a refresher.

Attendance was monitored after the end of the call using a Google survey. Vice-chair Albert Espinoza monitored responses and non-participating members were asked to step down from the committee.

The committee worked by reaching consensus. No votes were required, until the final vote on acceptance. The final vote was unanimous in favor of acceptance, with one abstention.

**COMMITTEE ACTIVITIES:**

1. **Dates of committee meetings or conference calls:** The committee almost every two weeks starting from Tuesday, Sep 18th, 2018, through the date of this report, with the exception of holidays.
2. **Overview of committee activities:** See work plan and timeline above.
3. **Charges COMPLETED and the rationale for each specific recommendation:**
  - a. Current recommended practices and existing guidance documents that relate to shipment directly to a consumer of perishable food items and for the safe delivery of food by Third Party Delivery Services (TPDS) entities were identified.
  - b. The Guidance Document for Mail Order Food Companies was revised. Additions include but are not limited to: addition of food safety training for the TPDS entities, and information on all food delivery practices from food production, distribution, and retail food service facilities.
  - c. The committee recommends a letter be sent to FDA requesting that the 2017 Food Code, Annex 2 (References, Part 3-Supporting Documents) be amended by adding reference to the new guidance document and the posting of information on the CFP website.
  - d. The committee's findings and recommendations will be presented at the 2020 Biennial Meeting of the Conference for Food Protection.

4. ***Charges INCOMPLETE and to be continued to next biennium:***
  - a. none

**COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:**

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

**LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:**

**Issue #1:** Report - Direct to Consumer Delivery Committee Acknowledge the 2018-2020 Direct to Consumer Delivery Committee final report, thank the committee members for their work, and disband the committee.

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

**(a.1)** *Committee Final Report (see attached PDF)*

**(a.2)** *Committee Member Roster (see attached PDF)*

**(a.3)** *Committee generated guidance document entitled Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery" (see attached PDF)*

**b. List of supporting attachments: x *No supporting attachments submitted***

**Issue #2:** Recommend acceptance of the Committee generated guidance document entitled "Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery" included in Issue #1: Report- Direct to Consumer Delivery Committee and; inclusion of the guidance document on the CFP website in a down-loadable PDF format.

**Issue #3:** Recommend a letter be sent to FDA requesting that the most recent edition of the Food Code be amended to include a reference to the "Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery".

## Committee Name: Direct to Consumer Delivery Committee

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# **Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery**

**Prepared by the  
Direct to Consumer Delivery Committee  
2018-2020 Conference for Food Protection**

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# *1. Preface*

Council III of the 2018 Conference for Food Protection (CFP) formed the Direct to Consumer Delivery Committee, in response to Issue 2018-III-006, which was charged to:

1. Identify current recommended practices and existing guidance documents that relate to shipment directly to a consumer of perishable food items and for the safe delivery of food by Third Party Delivery Services (TPDS) entities.
2. Revise the Guidance Document for Mail Order Food Companies that includes recommended practices for transportation directly to a consumer of perishable products, to include proper packaging; temperature control during shipping, receiving, and storage; return of compromised and abused products; and other food safety related topics. Current guidance document to be revised to include food safety training for the TPDS entities, and information on all food delivery practices from food production, distribution, or retail food service facilities.
3. Determine appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.
4. Report the committee's findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

This guidance replaces the 2016 “Guidance Document for Mail Order Food Companies”, which was produced by the former Mail Order Food Safety Committee in response to Issue 2016-III-037.

The 2016 Guidance was informed by “Industry Guide to Good Hygiene Practice: MAIL ORDER” in support of Regulation (EC) No 852/2004 on the Hygiene of Foodstuffs and the temperature control requirements of the Food Hygiene (England/ Scotland/ Wales/ Northern Ireland) Regulations 2006.”

## *2. Introduction and Scope*

This guidance document provides food safety best practices for managing or performing Direct to Consumer (DTC) or third-party delivery (TPD) services. This document includes parameters critical to preventive controls, mechanisms to assess risk, validation and verification practices, recommendations for proper packaging, temperature control, receiving and storage, physical and chemical contamination control, allergen control, general food safety information, and suggestion for return of compromised and abused products. The intent of the guide is primarily to provide best practices for preventing biological, physical and chemical contamination as well as the growth of harmful bacteria and/or the formation of toxins within the food being transported.

The methods by which foods reach the final consumer can vary significantly, and this guidance is not intended to provide a “one-size-fits-all” approach. This guidance aims to review some of the essential parameters that any company should consider in providing safe foods to the consumer. Companies should research, understand, and test the methods best suited to their specific operation.

This guidance recommends best practices and provides references that may help in this process. The use of this guidance is voluntary. It is not a regulatory document. Food companies, including food manufacturers and food establishments where food is held or prepared for DTC or TPD are subject to applicable federal, state and local food safety statutes and regulations. It is important that DTC and TDP companies understand all legal and regulatory requirements, as well as industry guidelines, governing the safety of food throughout production and distribution.

This guide does not specifically address (a) the delivery of foods intended for immediate consumption from food establishments where the delivery is under the control of the food establishment who prepared and delivered the food by the food establishment’s employee, since these companies are already regulated by state and local codes or (b) export requirements, tariffs or customs aspects of international deliveries. Although not covered by this document, the information provided here may contain useful advice for delivery of foods intended for immediate consumption from restaurants where the delivery is under the control of the restaurant who prepared the food and delivered by a restaurant employee.

### ***3. Definitions***

**Active Managerial Control:** The purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors.

**Best Practices:** Those practices that represent the “state of the art” or current best approaches of assuring food safety and quality based on state of the science and technology.

**Broker:** A food broker is an independent sales agent that works in negotiating sales for food manufacturers. Food brokers work for both manufacturers and buyers of food as they help “broker” deals to sell food products to a variety of buyers.

**Common Carrier:** A person or company that transports goods for any person or company.

**Coolant:** A coolant (also called a refrigerant) is defined in this document as a time-limited source of temperature reduction, such as an ice or gel pack. Coolants are often better used to maintain cold food at temperature rather than bring warm food down to a cold temperature.

**Direct to Consumer (DTC) Food Delivery:** Food that may be ordered through any non-face-to-face communication (e.g., via mail, phone, fax, email, or internet) and delivered to consumers through various channels (e.g., mail, common carrier, internal company logistics). DTC Food Delivery companies are generally not limited by specific geographic radii, unlike third-party delivery services which are defined below.

**Direct to Consumer (DTC) Food Delivery Company:** A business organized to promote, receive, prepare, fulfil, and transport orders of food directly to consumers. This term reflects an evolution of the term “Mail Order” used in prior versions of this document.

**Feed:** The Food, Drug, & Cosmetics Act (FD&C) defines feed as an article which is intended for use for food for animals other than man. Feed is intended for use as a substantial source of nutrients in the diet of the animal and is not limited to a mixture intended to be the sole ration of the animal. Feed safety (and thus pet food safety) is not specifically within the scope of the charge addressed by this document.

**First in First out (FIFO):** A method of inventory accounting in which the oldest remaining items are assumed to have been the first sold.

**Food Deliverer:** A person or unmanned transportation device (e.g. drone, robot, driverless car, etc.) which receives a food order that was placed via a Food Ordering Platform, retrieves the food order from a Food Establishment, and transports the order to the consumer’s designated location.

**Food Employee/Handler:** An individual working with unpackaged food, food equipment or utensils, or who handles open/exposed, wrapped or packaged food, packaging and other food equipment, including food contact surfaces.

**Food Establishment:** As per the Food and Drug Administration's (FDA) model Food Code an operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

**Food for Home Preparation:** Food that is delivered to a consumer where the consumer is expected to prepare/cook the food.

**Food for Immediate Consumption:** Prepared food that is delivered to a consumer where the expectation is that the food is going to be consumed without extensive preparation and consumed shortly after arrival.

**Food for Later Consumption:** Food that is delivered to a consumer where the expectation is that the food is going to be consumed without extensive preparation and may be stored for some time and/or consumed shortly after arrival.

**Food Ordering Platform:** An online marketplace that connects food establishments with consumers and food deliverers. The Food Ordering Platform does not manufacture or otherwise prepare the food, which is delivered, but instead facilitates the delivery of those items.

**Food Safety Plan:** This document uses the phrase food safety plan in a generic sense. This is not to be confused with a food safety plan that is required for compliance with the Food Safety Modernization Act (FSMA). The business entities discussed in this document may or may not be subject to compliance with FSMA.

**Food Shopper:** A person who receives an order that was placed on a Food Ordering Platform, selects food and/or non-food products from a Food Establishment on behalf of a consumer, bags/boxes the products for shipment/delivery, and places the bagged/boxed products in a staging area for future delivery to the consumer. A food shopper may also be a food deliverer and transport the order to the consumer's designated location.

**Food:** As noted in the FDA model Food Code and Code of Federal Regulations, "Food" means a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption or chewing gum.

**HACCP:** Hazard analysis and critical control points is a systematic preventive approach to manage risks from biological, chemical, and physical hazards in food processing or preparation. In some (but not all) cases HACCP is part of a regulatory framework (i.e. FDA Juice HACCP).

**Hazard:** A biological, chemical, or physical substance in a food that may cause an unacceptable consumer health risk.

**Mechanical Refrigeration:** The use of powered refrigerator units to cold-hold and/or cool foods to their required safe food temperatures, and often simply called refrigeration.

**Monitoring:** Defined as conducting a planned sequence of observations or measurements of control parameters to assess whether a process is under control.

**Passive Refrigeration:** A method of maintaining perishable foods at safe temperatures without the use of electrical-powered refrigerator units.

**Pathogen:** A microorganism of public health significance.

**Perishable Foods:** Foods that are required by law to remain at specific refrigerated food temperatures for product safety. See definition below for time/temperature control for safety foods or TCS foods. They have been historically called potentially hazardous foods (PHF). Guidance on applicable food products can be found later in this document.

**Preventive Controls:** Risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would use to minimize or prevent the hazards identified under the hazard analysis. These controls should be consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

**Provisioning System:** The means by which a third-party delivery service is connected with a food establishment.

**Ready-to-Eat (RTE):** Food in a form that is edible without additional preparation to render it safe for consumption.

**Records:** Documentation of actions taken or parameters recorded. Records may be hard copy or electronic in form. The appropriate record form may be impacted by the regulatory jurisdiction. Record retentions requirements are often related to the shelf life of the food and may also be subject to regulatory requirements.

**Regulatory Authority:** The local, state, or federal enforcement body or authorized representative having jurisdiction over the food establishment.

**Risk Control Plan:** A risk control plan is a systematic approach to identify and manage food safety risks.

**Risk:** The likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

**Shippers:** Parcel delivery services available in the United States, such as the US Postal Service (USPS), FedEx, or United Parcel Service (UPS).

**Slacking:** The process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -23 to -4°C (-10 to 25°F) prior to cooking. Thawing is different from slacking and details on thawing can be found in section 3-501.13 of the FDA Model Food Code.

**Staging:** Period of time after preparation and before pickup. May or may not include hot or cold holding.

**Standard Operating Procedures (SOP):** This term refers to standardized written procedures for performing various tasks. When used in a food safety context SOP's are designed to ensure food safety by following appropriate practices each time a given task is performed.

**Third-Party Delivery Service:** A food delivery where a consumer uses a Food Ordering Platform to place an order from a selection of Food Establishments and receives delivery of that order from a Food Deliverer. Third party delivery service is generally defined as offering consumers the option to place an order from Food Establishments within a defined geographic radius.

**Time/Temperature Control for Safety (TCS) Food:** A food that requires specific time and/or temperature requirements to limit pathogenic microorganism growth or toxin formation.

**Validate:** Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

**Verify:** The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

## ***4. Foundational concepts***

### **A. Regulatory Requirements**

There are requirements in federal, state and local laws and regulations that are relevant to the transportation and delivery of food. For example, state, territorial and local regulations modeled after the FDA model Food Code require retail food establishments to follow practices that prevent food from becoming adulterated or unsafe. These include establishing the maximum temperature at which TCS foods must be held during storage and display. For most TCS foods, the FDA model Food Code establishes a maximum cold-holding temperature of 5°C (41°F) to limit the growth of pathogenic bacteria during storage and display. For TCS foods prepared for hot holding, the FDA model Food Code establishes a minimum storage and display temperature of 57°C (135°F). Other temperature limits may be appropriate for foods that do not require temperature control for safety but that are kept cold to preserve quality and limit the growth of spoilage organisms.

While retail food establishments are generally governed by local regulations, food processing and manufacturing companies are also subject to a variety of food safety authorities, depending on the nature of their operations. For example, food facilities that are required to register with FDA must generally comply with the Preventive Controls for Human Food Rule under the FDA Food Safety Modernization Act (FSMA) as well as applicable Current Good Manufacturing Practices (CGMPs). DTC food companies subject to this rule are required to implement a food safety plan that addresses hazards and risk-based preventive controls for minimizing or preventing those hazards.

Any approach to controlling risk in DTC or TPD foods should be consistent with the federal, state, and/or local food safety laws and regulations that may apply to the various organizations involved in a particular food delivery model. Further resources regarding potentially applicable laws and regulations are provided in Appendix A.

### **B. Risk Management Overview**

#### **Identifying, assessing, and controlling risk in DTC or TPD foods**

DTC or TPD models can be complex and often involve several parties in the production and distribution chain. To ensure that food is delivered safely to the end consumer, the parties involved should work together to identify when food safety risks are reasonably likely to arise, what measures are needed to control those risks, and who is responsible for implementing those measures.

We encourage organizations involved in DTC and TPD to manage risk using a HACCP-based approach that accounts for all steps of a business model, including storage; packaging; repackaging; labeling; preparation; physical retail sale; selection (such as by a grocery delivery

service); transport and delivery by employees, independent contractors, third parties, or others; and consumer communication. The approach should reflect food safety parameters and controls for risks that may arise throughout the DTC or TPD processes. Delivery parameters may include delivery time, travel distance, number of orders per delivery, and take into consideration unplanned events such as gas, flat tires, and authorized breaks.

The various parties involved in a DTC or TPD operation may determine that existing approaches, such as a HACCP plan or a Food Safety Plan under the FSMA Preventive Controls Rule, are adequate to control risk. Alternatively, some parties may determine that they need to adopt new protocols for implementing the risk-control measures agreed upon by the various parties. Regardless, the parties should clearly communicate the necessary risk-control measures and agree upon who will implement each (see Section 5.H for further discussion).

### **Validation and verification**

Validation and verification are two critical but distinct elements of any food safety program. Validation involves obtaining and evaluating scientific and technical evidence that relevant risks have been detected and controlled. A validated control measure or a combination of control measures when properly implemented will effectively control identified risks. Examples of validation activities include identifying food safety parameters in scientific journals and/or regulatory guidance or rules and conducting studies using the company's products and packaging. A company should conduct validation before launching operations. Verification occurs after validation has been conducted and is intended to demonstrate whether validated measures are working as intended and are being effectively carried out. Validation is conducted before operations begin and perhaps annually thereafter. Verification should be conducted periodically as operations continue. Verification will occur more frequently than validation. Both validation and verification records should be maintained according to any applicable regulatory requirements.

*Validation.* Any business that intends to engage in DTC or TPD operations should identify and validate controls for the food safety risks it has identified. A company may perform validation activities in-house or may choose to have validation conducted by a reputable external entity. Given that multiple parties may be involved in processing, holding, handling, or transporting DTC or TPD food, these parties should work together to determine that end-to-end risk-control requirements are met. Risk-control requirements may include inputs that will enable control (e.g. thickness and insulative ability delivery packaging, number and positioning of gel packs, gel melting point) as well as outputs that demonstrate control (e.g. product inner temperature below 41°F upon delivery).

Validation data for DTC or TPD foods should be obtained both before launch and any time an essential component of the delivery model is modified, such as when the delivery area is expanded, or a packaging element is changed. Deliveries should not begin until the validation demonstrates that identified risks will be adequately controlled and deliveries do not exceed the validation parameters. Upon identification of chill chain systemic gaps or in the event previous validation records are no longer available, the company should perform a validation or re-validation as soon as possible.

Temperature controls may be the most important element in DTC or TPD to validate, but validation may also need to be conducted for other food safety measures. Companies should identify any other food safety risks that should be controlled in their operations and should determine the appropriate measures for controlling such risks.

*Verification.* Verification activities may include implementing and reviewing logs or checklists to ensure that validated food safety measures are implemented as required or conducting periodic internal or external audits of the company's food safety program. When verification shows that risk-control measures are not being adequately carried out, corrective actions should be identified and implemented. Corrective actions will vary and should be tailored to the identified deviation; examples may include conducting additional training, revising existing procedures, or developing new protocols. The parties involved in a DTC or TPD food operations should establish clear responsibilities for identifying and implementing corrective actions. Please refer to Section 5.H for a detailed discussion of best practices, including monitoring and strategies for managing noncompliance.

### **Risk Management Resources**

Both internal and/or external resources can be useful in managing risk, and each has its own specific attributes.

*Internal resources.* Dedicated internal staff provide a company with the flexibility to adjust food safety programs, conduct self-assessments, respond to food safety complaints/inquiries, and respond to emergencies (e.g., equipment failures, severe weather events potentially impacting transportation and product safety).

*External resources.* Employing external resources, such as a third-party auditing firm to assess food safety risks, can offer a number of benefits. Subject matter experts with food safety credentials and experience can offer added credibility. Professional evaluators dedicated to evaluating food safety risks typically can have specialized training in inspection techniques and root cause investigations. External experts can offer objectivity during assessments and consultations. External experts can offer an enhanced ability to collect data, generate insights, and make recommendations for improved food safety practices. Such experts can serve as important resources during emergencies (e.g., natural disasters, weather events, recalls, and outbreaks) when existing internal resources are saturated. External experts may offer services that are available more broadly, either locally, throughout the country or globally. Finally, external resources may supplement internal resources by helping with program design and updates to educational materials and SOPs.

## ***5. Direct to Consumer guidance***

### **A. Considerations Prior to Delivery**

A DTC food delivery company should implement procedures to ensure that food is produced under safe and sanitary conditions and address the food safety risks relevant to its operations. A starting place for this is to ensure the food is made by a company registered and/or approved by the appropriate regulatory authority. Company may also verify (with a documentation review or a physical audit performed internally or by a third party) additional qualifications such as implementation of Good Manufacturing Practices and HACCP. While this guidance focuses primarily on food safety considerations specific to DTC food delivery, a company should be familiar with general best practices and requirements relevant to receiving, storage, processing, and holding foods intended for delivery. For example, any DTC delivery food safety program must meet the regulatory requirements applicable to the company's operations, e.g., the state and local food codes, CGMPs, or the Preventive Controls for Human Food Rule under FSMA. Certain foods, including eggs, juice, milk products, meat, poultry, seafood, and low-acid canned foods, may be subject to specific regulatory requirements. Further resources are provided in Appendix A.

*Consumer information and notifications.* Companies should have systems in place to help ensure consumer names and delivery addresses are accurate because delivery delays may impact food safety. Depending on their product(s) and delivery model, companies may consider providing consumers with guidance on handling deliveries (e.g., refrigerating perishable food promptly if it is not intended to be used immediately). Companies may also develop protocols for notifying consumers of unanticipated disruptions, such as delays caused by labor shortages or extreme weather, and what to do if packages arrive late or if they have concerns regarding their deliveries.

### **B. Temperature Control During Transportation and Delivery**

Maintaining food at proper temperatures is critical to limiting the growth of pathogenic bacteria or the formation of microbial toxins in food. Thus, proper temperature control throughout production and delivery to the consumer should be an integral part of any DTC delivery operation. A DTC delivery company should identify required time and temperature parameters, validate and implement controls to meet these parameters, and verify that these controls are working effectively.

A DTC delivery company should identify the temperature requirements throughout transport and delivery based on regulatory requirements as well as the company's evaluation of its products, including their unique characteristics and uses. For example, a company that sells and delivers a variety of food types may require that its perishable refrigerated products remain at or below 41°F (5°C) and that its RTE hot-held foods remain at 135°F (57°C) or above to be consistent with the standards specified in the FDA Model Food Code. The company would then conduct validation activities to identify measures that will adequately maintain required

temperatures and control the microbiological risks posed by the product during all stages of production, transport, and delivery.

### **Conducting temperature-control validation**

Temperature requirements can be met using a combination of different controls at various stages of a company's operation. These controls can include limiting the maximum delivery time, using appropriate types and amounts of refrigerants or coolants, and requiring a specific initial product temperature. These controls can interact together to affect temperature, and it is critical that these controls be validated.

In conducting validation activities, a company should account for all possible variables that may compromise temperature control. With respect to transportation and delivery, for example, some businesses conduct same-day or overnight delivery and can control the longest possible delivery time (e.g., by restricting delivery ZIP code). Companies with less control over delivery times should account for this variability. Validation studies should also take into consideration the type of food, the organism(s) of concern, and the growth limit targeted. DTC delivery companies should also consider validating contingency measures for emergency situations that may compromise temperature control, such as power outages, refrigeration equipment breakdowns, or delivery-route disruptions. For further discussion of potential emergency considerations, see *Emergency Action Plan for Retail Food Establishment*, CFP 2014 (providing guidance for addressing emergency situations, including interruption of electrical service, floods and fire).

Examples of potential approaches for verifying temperature controls include testing temperature profiles and packaging configurations in a simulation chamber and conducting periodic shipment tests using data loggers and trained participants in various geographical areas. One recommended best practice is to simulate "worst-case scenarios" and show that product temperatures are lower than the targeted temperature at the end of the longest possible time to receipt by the final customer. A worst-case scenario should be based on the farthest, warmest locations to which food is shipped, accounting for historical temperature data and depending on where the food originates.

- *Example:* a company manufactures a variety of perishable, refrigerated products and delivers to consumers in all states and zip codes. The company determines that these products must not exceed 41°F at any time throughout transportation and delivery. In designing a study, the company identifies Phoenix, AZ; Dallas, TX; and Miami, FL; as the farthest, warmest locations from each of its respective distribution centers. The company then conducts a study to identify the packaging configurations and maximum delivery times that will maintain the required product temperature throughout delivery to each of these cities. This company conducts in-house testing and also elects to engage an external food safety laboratory to conduct several additional simulations to confirm its findings.

A company may determine that limited periods outside of required temperature parameters do not result in an increase in risk, but any such acceptable periods will depend upon the

combination of time and temperature and may require a variance from the regulatory authority. In establishing product temperature limits and any durations during which those limits may be exceeded, a DTC food delivery company should assess the microbiological risks posed by the product and ensure they are adequately controlled until delivery to the final consumer within the delivery period.

Validation studies should be supported by relevant scientific or technical literature, pathogen predictive growth models or actual pathogen growth experiments. Resources regarding temperature control and pathogen growth risk can be found in Appendix B.

## **C. Choosing Packaging**

A DTC delivery company should determine appropriate packaging elements based on the specific details of its products and delivery models.

While a company should consider all packaging possibilities that are appropriate for its products, in this section, we focus on three primary packaging elements: outer (i.e. tertiary) packaging, refrigerants/coolants, and dunnage.

### **Outer packaging**

Outer packaging can function as an insulator, keeping cold air in and warm air out. Any damage to the outer packaging could expose the contents to contamination or to loss of temperature control, so a company should ensure that the outer packaging maintains its integrity during transit and protects the contents from damage. A company may choose to conduct specific crush tests and may consider providing carriers with instructions for handling packages in transit.

Where a company determines that more sophisticated outer packaging is needed, solutions combining packaging and refrigerant systems are available. Before purchasing a solution, the company should ensure that their needs are covered by the validation of that solution, i.e. that the parameters (e.g. time, external temperature) used for the validation exceed those of the use case. Alternatively, the solution provider may have a computerized simulator to demonstrate the suitability of the solution for the company use case. In either case third-party validation is recommended.

*Reusable packaging.* Outer packaging can be disposable or re-usable. If re-usable, the collection logistics should be defined and communicated to consumers. Re-usable packaging should also be inspected, cleaned and/or sanitized before re-use to prevent contamination. Whatever contamination prevention process is chosen should be validated and verified to ensure effectiveness and suitability to the type of products carried.

### **Coolants**

The need for a coolant and the type/quantity used will depend on a variety of factors, including the outer packaging material, the presence of insulation or dunnage, the food's initial temperature at time of packing, transit time to consumer, and the temperature during transit. Coolant selection should be based on validated scientific principles and data. For example, a company may consider seasonality or temperature fluctuations in choosing a coolant (see Section 5.B for further discussion of considerations in temperature validation).

Coolant options include, but are not limited to, simple ice contained in plastic, frozen gel packs, plastic packs containing a freezable solution, or dry ice. The efficacy of a coolant depends in part on the temperature at which it changes physical state as well as the mass and coolant type.

- **Ice packs.** Only potable (drinking) water should be used to make ice packs or provide the liquid in gel packs. Ice packs thaw at 0°C (32°F) and thus may not always be able to maintain appropriate temperatures compared to frozen gel packs. If ice packs are reused or recycled, they should be adequately cleaned and sanitized.
- **Frozen gel packs.** Depending on their composition, gel packs can thaw at temperatures below 0°C (32°F). When considering such products, a company should ensure suitability for use with food. Companies may consider testing gel packs for quality and/or integrity before use. As above, reused or recycled gel packs should be adequately cleaned and sanitized.
- **Dry ice.** Dry ice is commonly used as a coolant in packages containing frozen food and sublimates at -79°C (-109°F). It may produce colder temperatures than ice or gel packs; however, since dry ice is so cold, it may also affect the quality of certain sensitive foods (e.g., produce). The use of dry ice requires extreme care for several reasons, including safety and environmental concerns, so companies using dry ice should inform workers of potential risks and best practices for handling dry ice. Companies may also consider including warnings for consumers related to the safe handling of dry ice. Shipping dry ice may be subject to specific regulatory requirements.

Companies should verify coolant packs will maintain their integrity and avoid compromising food safety. For example, if ice packs melt and leak, this may cause food to be submerged in water, potentially leading to cross-contamination or cross-contact.

Coolant packs are generally not appropriate for cooling of product but instead can be used to maintain product temperature at the time of packaging. Initial cold food temperature should ensure required temperatures are maintained throughout the transportation and delivery process. The placement of coolants within the packaging is equally important to ensure all parts of the food are kept at appropriate temperatures throughout the entire delivery process (see the discussion of validating temperature controls in Section 5.B).

## **Dunnage**

Dunnage refers to the extra packing materials used to fill the voids in the package and secure and protect its contents during transportation. Use of dunnage may be critical in packaging

foods for delivery because it replaces air in the package and may help with insulation. Food in a package containing a refrigerant and air will generally heat up faster than a similar package where dunnage (e.g., paper, bubble wrap) replaces much of the air. Dunnage should be placed so it does not insulate the food from the refrigerant and should be of adequate sanitary quality.

## **D. Preventing Contamination**

Preventing cross-contamination is a key aspect of food safety whether these are biological, physical, or chemical contamination risks. Biological risks are discussed elsewhere in this document in detail. Physical risks include materials that can injure the consumer such as glass fragments, metal shards or rocks. Chemical contamination risks include toxins and allergens as well as intentional contaminants. Individual components of a delivery need to be packaged so cross-contamination does not occur during transport. The outer container of the delivery must be able to maintain integrity during transport. Sealing may be a useful means to prevent intentional adulteration. Items being delivered need to be transported in a clean and sanitary manner and transported so the food product does not become contaminated.

Any materials used for wrapping and packaging should not to be a source of contamination. These materials should be stored so they do not become contaminated. Any wrapping and packaging operations should be carried out in a manner where contamination of the food is prevented. Where pre-packaged foods are delivered to the consumer, integrity of the container's construction should be assured (e.g. no dents in metal cans, no breakage of glass jars). When raw meats are present in a package, appropriate measures should be taken to prevent leakage and cross-contamination to other foods or packaging materials.

Proper packing also serves to prevent chemical and physical contamination of foods. Food delivery companies should be aware of the chemical and physical risks posed by delivering non-food items together with food items. Food delivery companies should be aware allergens constitute a chemical hazard to be managed. Companies should provide a mechanism for the consumer to identify any food allergies during ordering. Care should be taken by the company to ensure unpackaged food items do not come into contact with any potential allergen sources prior to, during, or after packaging the food items for delivery. More details on allergens and their risks can be found in the FDA model Food Code, Appendix 3 Food Allergen Labelling and Appendix 4, Food Allergens as Food Safety Hazards.

## **E. Other Delivery Considerations**

*Choice of carrier.* This will depend on a range of factors, including the size and weight of packages, availability of service, general reliability, historic performance, and commercial viability. Specialized delivery services utilizing refrigerated transport may be appropriate. Since some carriers may not deliver 7 days a week, some companies may choose to ship only certain days of the week to ensure timely delivery.

A DTC delivery company should be aware its packages are typically treated the same as any other package transported by the chosen carrier and will be stored and transported at the prevailing ambient temperatures. The DTC delivery company should not expect their package

to receive any “special treatment” unless it is part of their agreement with the carrier. The DTC delivery company should verify any enhanced level of service promised by a carrier before relying upon it or modifying any established temperature-control requirements, including packaging and cooling.

*Signature requirements.* Some carriers offer the option of signature release (i.e., requiring a signature for delivery). This has the advantage of ensuring someone is immediately available to receive and refrigerate the food upon receipt. It presents the challenge of delaying delivery in the case a signatory is not available.

*Non-delivery.* A non-delivery may occur if the carrier cannot find the delivery address or if other problems occur. Any process for non-deliveries should be agreed to by the carrier. Some carriers may have specific requirements regarding packaging and labeling related to non-deliveries.

## **F. Food Safety Training**

Food safety is a responsibility shared by everyone involved in handling, processing, storing, packing, or distributing foods for DTC delivery. A DTC delivery company should ensure adequate food safety training and supervision for all personnel handling food. A DTC delivery company should ensure personnel handling food are adequately supervised and instructed to ensure they work in sanitary conditions and in accordance with proper food safety procedures. Continuous supervision is critical to ensure compliance. Such supervision is typically performed by an individual designated as the Person in Charge (PIC) in a retail environment. The PIC should always be appropriately trained according to applicable regulations or internal requirements so as to ensure good food safety practices. Where an operation employs only one or two people, supervision may not be applicable.

Training involves an overview of food safety principles as well as specific instructions, commensurate with the trainee’s responsibilities, for promoting food safety in day-to-day operations. Companies should also ensure those responsible for developing and maintaining a company’s written food safety program have the necessary qualifications and experience (e.g., food protection manager certification).

### **General principles**

Training should be given by qualified and competent persons or provided using online or other resources. Companies should have a plan to (a) identify the training needed for everyone whose activities may impact food safety and (b) keep records which confirm this training was completed satisfactorily. These records can help a company demonstrate it has a satisfactory food safety management system, and evidence of training in personal hygiene and food safety management may be very important for substantiating compliance.

Training needs and effectiveness should be assessed regularly. Certain food safety training may need to be implemented annually and ongoing training may also be necessary. A training program should also be updated to reflect operational or business changes (e.g., new products

or packaging methodology which may raise new food safety issues and concerns). A company can develop its own program or incorporate existing established curricula. These curricula often have documented course instruction notes, which can help to ensure consistency.

A company may also determine personnel other than those who handle food may need to undergo training. For example, personnel such as custodians, sanitation crews, maintenance workers, and others with access to a company's operations may need training in certain food safety practices.

### **Conducting training**

DTC food delivery companies should ensure personnel handling food and packaging for direct food contact receive training in the food safety practices appropriate to their duties. The training provided should ensure that such personnel have appropriate knowledge to handle food safely. This knowledge can be obtained in various ways, including on-the-job training, self-study with recognized guidance materials, formal training courses, and prior experience. Arrangements should be made for persons whose first language is not English and/or persons with learning or literacy difficulties.

A training program should be based on the food safety practices relevant to a company's operations, e.g., preventing cross-contamination, using appropriate packaging, implementing temperature-control requirements, and managing health and hygiene.

A DTC delivery company should contact the relevant regulatory authorities to determine any applicable training requirements. For example, see Section 2-103.11 Person in Charge and Annex 3, Section 2-103.11 of FDA model Food Code for a discussion of the training requirements for a person in charge. The FDA model Food Code also requires the person in charge must be a Certified Food Protection Manager (CFPM). A CFPM is an individual who has demonstrated by passing a food safety certification examination from an accredited certifying organization that he or she has the knowledge, skills and abilities required to protect the public from foodborne illness.

## **G. Consumer Communication**

A DTC delivery company should identify the food safety information which should be included within a package and/or in other communication channels, including on a product website or via email. This may include product information as well as consumer instructions for communicating feedback and concerns.

If food safety labeling is included on the outside of a package, a DTC delivery company should ensure it is not obscured, including by any labels a third-party carrier may affix to the package.

### **Product information**

Products for DTC delivery should be labeled according to applicable regulatory requirements. This includes following federal, state, and local regulations for nutrition information and

allergen disclosure. All partners should work together to ensure all relevant food safety information provided at the point of sale, including on product websites or mobile applications where orders may be placed, is accurately communicated.

Companies should advise consumers of when to expect their orders and what to do upon delivery. If directions are not already specified on the product label, the company should advise the recipient that such contents are perishable and should be refrigerated or frozen upon receipt if not used immediately. This is especially important if the package is sent as a gift, if the recipient may not be aware of the contents, or if the outer packing obscures the product label.

Companies may also need to provide consumers with updated information relevant to food safety after their orders have been placed. For example, a delivery may arrive late due to unexpected transportation delays. Depending on the extent of the delay and the nature of the food, a company may decide to inform the consumer that certain perishable items should be discarded. Sourcing challenges may also require changes to the allergen information required for a product, so companies should ensure they have processes in place to communicate updated allergen information to consumers when needed.

Product information may also include instructions for safe use, such as information about any raw product or raw ingredients that may pose a health risk and are intended to be consumed raw (e.g., raw milk cheeses or sushi-grade fish). Companies may also choose to provide consumers with guidance on safe food storage, handling, and preparation.

### **Instructions for consumer feedback and concerns**

We recommend DTC delivery companies also provide consumers with information about what to do if they are concerned about the safety of the product, such as when a delivery appears to have been tampered with or if the packaging has otherwise been compromised. In most cases, consumers should be informed of how to contact the company directly to resolve concerns. Consumers also have the right to contact the appropriate regulatory agency if they have a concern. In such circumstances, companies can prepare to respond to any concerns by having standard operating procedures, process records, and other appropriate documentation in hand. These records will assist with reported alleged foodborne illness and potential regulatory investigations.

Some companies may choose to label certain items with the date and time packaged and/or the shipping date. If a product's package has been manipulated in any way, the label should be updated to reflect the repackaging date.

## **H. Best Practices for Managing a DTC Delivery Food Safety Program**

### **Responsibilities for implementing food-safety control**

To promote the implementation of food safety controls, a DTC company should assess its business model and supply chain, including partnerships and agreements with other parties. The parties involved at each stage of the production and distribution chain should collaborate

closely, and companies should also consider defining food safety responsibilities in formal agreements between parties. Clear procedures for communication between the DTC company and its partners will be helpful for sharing compliance information, food safety concerns, and relevant operational changes in a timely manner.

Examples of expectations that can be reflected in agreements include:

- Responsibility for conducting validation and/or verification
- Managing non-conformances, including communication and escalation requirements
- Conducting training
- Complying with applicable food safety laws/regulations
- Implementing various food safety measures (e.g., meeting time/temperature limits, preventing contamination)
- Implementing employee health policies
- Emergency protocols or contingency plans
- Personnel standards (e.g., selection criteria, health and hygiene requirements, background checks)

## **Monitoring**

As discussed in Section 4.B, a DTC delivery company should validate the measures necessary to control any food safety risks arising in the company's operations. The company should then conduct verification activities to demonstrate whether the validated measures are being effectively implemented.

As a critical component of a food safety program, a comprehensive monitoring system helps verify food safety policies and systems are being applied in a consistent and sustainable manner and identify continuous improvements or corrective actions.

In designing its monitoring approach, a DTC delivery company should consider the following:

- Which validated food safety measures should be monitored
- Where monitoring will occur, whether in production, transportation, and/or upon delivery
- How monitoring will be conducted for each food safety measure
- How the monitoring system will be described and communicated (e.g., in written policies and procedures)
- How often each monitoring tactic will be implemented
- Who will be responsible for conducting monitoring
- How deviations will be addressed
- How monitoring results will be recorded (e.g., including the signature of the person completing the monitoring)
- What consumer inquiries and complaints have been received

### *Developing a Monitoring Approach*

A monitoring system should be based on the validated measures a DTC delivery company has identified are needed to control its food safety risks. A company should evaluate each validated risk-control measure to determine the best approach for monitoring, considering the type of data to be gathered, how the data will be used, how frequently the control measure should be evaluated, who should gather and/or interpret data, which key performance indicators should be used, and how monitoring results should be reported.

There are multiple tools which DTC delivery companies can consider incorporating into a monitoring system. Examples include:

- *Process Self-assessments.* Regular internal assessments can help a company's personnel to proactively address food safety risks and prepare for external audits and regulatory inspections. These assessments can include daily checklists, shift-based logs, internal reviews, and third-party audits. The type and frequency of such assessments should be appropriate for the complexity of the company's operations and products.
- *Process Audits.* A process audit is a formal inspection usually conducted by a third party. A DTC company can partner with a food safety auditing firm to design and implement an audit to determine if food safety risks are being controlled throughout the supply chain and delivery.
- *Inspection upon delivery.* A DTC company can employ its own personnel or third parties to confirm whether delivery parameters are met. For example, a company may consider assigning an individual or group (e.g., company employees or third-party "mystery shoppers") to replicate the consumer experience and provide feedback on the delivered product. This person or group can examine parameters such as product labeling, temperature controls, transportation times, package integrity, and the effectiveness of packaging in preventing cross-contamination.

### **Using Internal and External Resources**

A DTC delivery company should consider the complexity and risks associated with its operations when using internal and/or external resources for monitoring its food safety system. Depending on the scope of the business, both options may be useful, and a DTC company should weigh the benefits of employing these resources when making decisions based on their program needs. Regardless of whether they are employees or third parties, all personnel selected should have the expertise and proper training necessary to correctly and consistently carry out their assigned tasks.

### **Technical Tools**

A variety of monitoring tools are available to help DTC delivery companies monitor compliance. Companies should identify the most current technologies available to aid with capturing and maintaining data. Companies may choose to use equipment, such as temperature monitoring devices for food products, hot and cold holding equipment, refrigerated compartments, insulated carriers, and other packages; geo-tracking devices, cameras, video recording devices, web platforms/portals, and other technological solutions.

Companies should ensure measurement methodology is precise and the correct tools are being used for both food products and equipment. For example, probe thermometers should be used to measure internal product temperatures, and appropriate equipment thermometers should be used to measure ambient temperatures of refrigeration and hot holding equipment. Waterproof thermometers are also available for dishwashing machines. Temperature indicators can also be used for packages during transport and delivery. For accuracy, thermometers should also be regularly calibrated, either daily or per the manufacturer's directions. For further resources, see Appendix A.

Companies should consider systematic approaches to assist with compiling data. Software programs can be custom designed to include a variety of hierarchies and data fields, such as menu items, delivery types, delivery times, product and equipment temperature readings, and regulatory checklists. Food safety experts and analysts can use the data to gain insights, evaluate root causes, determine if corrective action plans are effective, or make program adjustments as necessary.

### **Managing noncompliance and continuous improvement**

Once a system is in place to monitor the key components of a food safety program, companies should establish processes to address noncompliance and improve risk management. These processes should include expectations for communicating non-conformances and performance metrics (e.g., temperatures at various critical control points). For example, including an escalation process to relay non-conformances to the appropriate individuals and departments can help ensure issues are addressed promptly. Companies should ensure qualified individuals have the authority to take corrective actions.

As part of its efforts towards continuous improvement, a DTC company should also continually research the most current food safety innovations and technologies in the manufacturing and retail food industry. Remaining up-to-date on industry trends can assist an organization in having awareness of the best available food safety tools can help it be more efficient, more quickly respond to alerts, take corrective actions, and adjust food safety procedures.

### **Traceability and recalls**

In the case of a foodborne outbreak or recall, DTC companies should have processes that allow public health officials to request relevant traceback and trace forward information that would aid in their investigation. This information should be shared in accordance with relevant privacy laws. For more information of traceability and recalls see Appendix A.

### **Corrective and Preventive Action Plans**

Incorporating corrective and preventive action plans into food safety monitoring is essential for controlling food safety risks and preventing repeat occurrences. Corrective and preventive action plans are applicable regardless of whether internal and/or external personnel are involved in monitoring. The action steps and urgency assigned should be appropriate to the level of risk.

When SOPs are developed, a DTC company should identify 1) corrective actions for the disposition of the affected items and 2) separate preventive actions, tailored to potential root causes, to ensure the problem does not recur. For example, a company may determine a perishable food must remain at 41°F or below but finds an instance in which the food exceeds this temperature for several hours due to equipment failure. The company may decide the corrective action is to discard the food, and the preventive action is to install monitoring and alert sensors for refrigerated delivery equipment. An alert is used to notify appropriate parties when the air temperature exceeds 41°F for a designated period. The organization is then able to eliminate a food safety risk to the consumer and prevent product loss.

When developing corrective and preventive control plans, companies should consider the following:

- Engaging stakeholders (e.g., representatives from food manufacturer/food establishment, product delivery/transportation company, or external auditing firm)
- Establishing requirements for communicating non-conformances, including timing protocols based on potential risk
- Determining what parties must be notified and level of escalation based on risk
- Identifying who is responsible for implementing the plan
- Monitoring corrective and preventive actions to ensure they are effectively implemented
- Incorporating root cause analyses to assist with corrective actions and adjustment of protocols as needed
- Conducting targeted training for personnel to identify and correct errors in the food safety management program
- Using accountability models (e.g., number of higher risk occurrences triggering escalation)
- Reassessing studies or procedures to determine if improvements are needed to resolve operational or behavior-related occurrences (may be part of recurring re-validation activities)

## ***6. Third-Party Delivery guidance***

### **A. Food Safety Responsibilities**

All parties engaging in Third-Party Delivery Service should understand the relevant food safety risks and define roles for such parties to help minimize those risks. The parties to the business agreement should clearly identify the responsible party during each stage of the flow of food, from preparation, staging, and delivery.

### **B. Preventing Contamination**

Food contamination refers to the presence of biological, chemical, and/or physical contaminants in food which can cause foodborne illness or injury. Biological contamination can occur through improper food storage and lack of temperature control during preparation, packaging, and delivering of food. Chemical contamination can occur when non-food products, such as household cleaners, personal hygiene items, etc., are packaged with food products in the same delivery bag during packaging. Physical contamination can occur if food products are not packaged appropriately or protected from the external environment.

Preventing contamination is a key aspect of food safety. Food establishments and food shoppers should minimize contamination risks by determining which items will be segregated and how items should be packaged. An added challenge in third-party delivery from food establishments is that various food and non-perishable food products may be delivered together. Best practice is to (a) separate ready-to-eat foods from raw proteins; (b) separate chemicals and non-food products from food products; and (c) separate glass and other fragile food products to reduce breakage risks. Separation options may include separate bags or the use of another barrier.

The food establishment should have processes to determine whether food deliverers may prepare beverages, collect accompanying utensils, napkins, straws, or condiments, or package foods.

#### **Time/Temperature Control**

Temperature control should be considered when delivering food to the consumer through the use of a food deliverer. However, time as a public health control is also acceptable for limiting pathogenic bacterial growth. A wide variety of transportation vehicles are used to provide delivery services. A refrigerated or freezer vehicle may be ideal in maintaining temperature control. If the transport vehicle does not have a mechanism to control the ambient temperature of the vehicle, food deliverers should address all relevant food safety concerns and hazards when transporting the food. Food deliverer procedures may include the use of insulated delivery bags, containers, or coolers, or use of coolants to keep foods hot or cold.

Food ordering platforms should issue guidelines to food deliverers to deliver orders safely and in accordance with relevant safety standards, and to follow any food establishment delivery guidelines that are meant to promote food safety and compliance with applicable regulations.

The food ordering platform, food deliverer, and food establishments should work together to develop appropriate procedures to prevent pathogen growth during handling, transport, and delivery. Whereas time may be an appropriate control measure during short delivery periods, additional control measures should be considered for longer delivery periods or when food is not handed directly to the consumer to ensure perishable items remain at proper temperatures.

### **Temperature Monitoring for Staging Foods at Food Establishments**

Foods held in a staging area should be maintained by food establishments at proper product temperatures prior to pick-up and delivery by a food deliverer. A temperature monitoring process for staging foods at food establishments may be needed to ensure food is maintained at the proper temperature until ready for pick-up and delivery to the consumer.

### **Packaging**

Packaging protects and separates products from contamination, the external environment, and physical damage. Packaging design and using multiple layers of packaging, including primary, secondary, and tertiary, minimizes the risks associated with contaminants and food safety hazards. Primary and secondary packaging, such as foil wraps, direct food contact containers, and plastic bags, directly protect the food. Tertiary packaging or outer packaging, such as delivery bags or coolers, provide protection from the external environment including extreme temperatures, direct sunlight, weather (e.g. rain, snow), road debris, and animals and pests.

The primary and secondary packaging should not be re-used by food establishments. The tertiary or outer packaging should be constructed of durable and easily cleanable materials for re-use to transport food during deliveries.

Food establishments and food deliverers should determine correct storage (e.g. upright) and amount of food to be packaged during transportation to avoid crushing of food or damage to primary food containers that could potentially contaminate other food or lead to unclean delivery bags.

### **Food Tampering**

Prevention of food tampering activities occurs through packaging design and tamper-evident devices. Food establishments may utilize primary packaging that cannot be resealed, such as tear strips, and secondary packaging, such as bags or boxes, with tamper-evident tape, stickers, or seals to deter food tampering activities during food delivery and maintain food safety and integrity.

Food deliverers should not remove food products from the secondary or tertiary packaging until delivered to the consumer. Food deliverers and food shoppers should not open, alter, tamper with, or change the primary or secondary packaging.

### **Delivery Bag Usage, Maintenance, and Cleanliness**

Food deliverers may use insulated delivery bags that help minimize food temperature fluctuations and/or help maintain food temperatures during delivery to the consumer. In addition to insulated delivery bags, food deliverers can add other refrigerants or coolants, such

as ice and/or gel packs, which may help reduce the rise in product temperatures during extended delivery times.

Delivery durations, ambient temperatures and conditions, and intended food temperatures at delivery may assist food deliverers with identifying the need to use insulated delivery bags. Delivery bags can be designed and manufactured to support a variety of business needs. The materials, construction, and design of the delivery bag can be customized to maintain food hot or cold and can be designed with pouches to separate cold food from hot food.

Food ordering platforms or food establishments may set guidelines for food deliverer delivery bags, especially for extended delivery times, which may help maintain the food at safe temperatures during delivery to the consumer. Guidelines may include the appropriate choice of delivery bag or other packaging, as well as who will provide the bag or packaging, how to obtain new or replacement materials (e.g. methods, costs, etc.), and whether these materials are mandatory or whether food deliverers can choose to use alternative options.

Delivery bag durability and lifespan will vary depending on construction, materials, usage, and maintenance; however, delivery bags should be easily cleanable, kept clean, and maintained in good repair. Delivery bags should be cleaned daily, or more frequently if needed. Food deliverers should check the delivery bag condition for rips, tears, holes, and food debris that could lead to contamination and entry points for pests, etc. Recommended best practice is to check delivery bag condition after each consumer drop-off and prior to the next food delivery and to remove food debris and clean up spills or leaks. The food deliverer should be responsible in ensuring delivery bag condition and maintenance.

Some third-party delivery service entities offer personal shopping services in addition to delivery services. Food shoppers might also utilize bags during selection and packing of products and should ensure bags are clean and in good repair.

### **Vehicle Cleanliness and Inspections**

A variety of vehicles or transportation methods (e.g. walkers, cars, motorcycles, bicycles, autonomous vehicles, or drones) may be used to transport food depending upon the delivery location and accessibility. Vehicles should be clean and free from odors, pests, animals, and any other materials that could adversely impact food safety. Food deliverers should inspect vehicles frequently to ensure that vehicle interiors are clean and free from debris. Food ordering platforms should provide food deliverers with information on maintaining their vehicles in safe conditions, such as vehicle cleanliness and maintenance.

## **C. Food Safety Education and Training**

Food ordering platforms should make available or provide relevant food safety education or training to food deliverers and food shoppers. Food safety education or training may be offered internally or externally through an outside education or training program.

Food deliverers and food shoppers should have appropriate knowledge of basic food safety principles through the completion of a food safety education or training program. Food safety education and training programs for food deliverers and food shoppers may cover topics

including: (a) contamination prevention; (b) product segregation; (c) temperature management; (d) health, hygiene, and hand washing; (e) product tampering prevention; (f) allergens; (g) vehicle transportation cleanliness; and (h) proper selection and use of clean, insulated delivery bags.

Food shopper's education or training may also cover additional topics including: (a) proper order of product selection, such as picking shelf-stable items first, frozen items second, cold refrigerated items third, and hot, prepared items last; (b) proper selection of products with the farthest use-by-date code and intact packaging; and (c) final product handling and packaging.

Additional knowledge areas may include, but should not be limited to: (a) when to pick/pull perishable and non-perishable food products; (b) preparation time needed for food products to be assembled; (c) staging food products utilizing dry storage shelves, refrigerators/coolers, and/or freezers; (d) instructions on foods for delivery (e.g. perishable vs non-perishable); and (e) modes of transportation to be used for delivery (e.g. personal vehicle, bicycle, motorcycle, commercial vehicle, etc.).

### **Education and Training Topics**

Prevention of contamination, temperature control, and personal health and hygiene should be areas of focus for food safety education and training to prevent foodborne illness and minimize food safety risks.

#### *Contamination*

Food deliverers and food shoppers should be aware of any sources of potential contamination. Food contamination could occur from various sources, including but not limited to: (a) food deliverer or food shopper themselves; (b) bags, coolers, or other methods used to transport the food; (c) external environment; (d) animals and pests; and (e) mode of transportation.

#### *Temperature Control*

Food deliverers and food shoppers should know the correct hot and cold holding temperatures for food and understand the food safety implications of holding time temperature controlled food for safety (e.g. TCS foods) in the temperature danger zone for an extended period of time. Food deliverers and food shoppers should also have knowledge of the necessary equipment, such as insulated bags, coolers, and/or coolants that may be needed to safely hold food at proper product temperatures or help with temperature control. Familiarity with temperature measuring devices is also recommended when relevant.

#### *Personal Health*

Food deliverers and food shoppers should not work while ill. Viruses, bacteria, and parasites can all be potentially transmitted from an ill individual to food and/or the recipient of the food via direct contact and packaging. Food deliverers and food shoppers should not work with food if any of the following symptoms are present, including: (a) vomiting; (b) diarrhea; (c) jaundice (yellowing of the eyes and skin); (d) sore throat and fever; (e) infected skin lesion; or (f) have been diagnosed with Norovirus, Hepatitis A, *Shigella* spp., Shiga Toxin-Producing *Escherichia coli*, Typhoid fever (caused by *Salmonella* Typhi), or *Salmonella* (nontyphoidal). Food

deliverers and food shoppers who have been exposed to a foodborne pathogen from a household member with symptoms or diagnosis above should also not handle food.

### *Personal Hygiene*

Food deliverers and food shoppers should understand the importance of good personal hygiene, including wearing clean attire. Food deliverers and food shoppers should: (a) practice good personal hygiene; (b) know when hand washing is needed and how to effectively wash hands; (c) know how to avoid bare hand contact with ready-to-eat foods; and (d) know how to use provided utensils to handle food when necessary.

Food ordering platforms should have standards to address food deliverers and food shopper's behaviors that may pose food safety risks, such as eating, drinking, chewing gum, or utilizing tobacco and similar products during food selection and deliveries.

## **D. Management of Non-Compliance**

Food ordering platforms should have processes developed to address consumer feedback and issues of non-compliance as further described herein. Agreements between the parties and food ordering platforms can be used to outline the expectations of each party. Issues of non-compliance may include potential food safety concerns (e.g. reported incorrect food temperatures, allergens, foodborne illness, product adulteration, etc.), food quality concerns (e.g. broken, damaged, spoiled, etc.), wrong products (e.g. reported allergens), and delivery concerns (e.g. reports that deliveries were not delivered within specified timeframe). While product quality is outside the scope of this document, some consumers may perceive product quality issues as relating to food safety.

Food ordering platforms should determine (a) how issues of non-compliance and consumer feedback will be handled; (b) what guidance is provided to the consumer regarding any food products in question; (c) who receives the notification and/or feedback; and (d) who reviews reports and provides resolution.

Food ordering platforms may issue guidance to food deliverers for handling various logistical situations, including appropriate next steps, such as whether the food product can still be delivered, returned, or discarded. Some examples of situations that should be considered include (a) the food deliverer arrives to drop off the food order at the correct delivery time and location, but the consumer is not present for the delivery drop-off; (b) food products show evidence of tampering or alteration by someone other than the deliverer (e.g. loss of package integrity or seal); or (c) food products are damaged, spilled/leaked, or otherwise contaminated (e.g. hair, dirt, debris).

Processes should also include a mechanism for the consumer to contact the food ordering platform and provide feedback on the food order(s) or delivery service. The food ordering platform should monitor consumer reports and non-compliance issues as needed to determine whether their process is effective or if they should consider revisiting their process.

## **E. Other Food Safety Considerations**

### **Food Allergens**

Food establishments typically do not make claims or guarantees that their kitchen or prep areas are allergen-free environments or that cross-contact with allergens will not occur as food establishments may prepare products that contain allergens on similar surfaces and equipment. The food establishment may consider providing allergen awareness information through the food ordering platform. Food ordering platforms may include features to suggest substitutions when an ordered product is no longer available. When such features exist, consumers should be reminded about the allergen potential risk created by substitution options.

### **Traceability and recalls**

In the case of a foodborne outbreak or recall, food ordering platforms should have processes that allow public health officials to request relevant traceback and trace forward information that would aid in their investigation. This information should be shared in accordance with relevant privacy laws. For more information on traceability and recalls see Appendix A.

### **Technology and Innovation**

Incorporating and leveraging technology may be advantageous to provide notifications to consumers if deliveries have encountered unexpected or excessive delivery delays.

## ***7. Appendices***

### **A. Food regulation overview, labeling, and recalls**

#### **Regulatory overview**

Federal, state, and local agencies oversee the regulation of retail and manufactured food products. Most products sold in interstate commerce, or across state lines, will be regulated by both state or local and federal food regulatory agencies, with a few state-specific exceptions. Most products sold in intrastate commerce, or made and sold within the same state, will be regulated by state or local food regulatory agencies. Most facilities which handle food are licensed in some manner. DTC food delivery companies should contact the agency which issues their license or permit if they have questions about the food safety regulations which apply to their operation. If a DTC food delivery company is unsure who issues their license or permit or if one is required at all, the company should contact their state or local health department. The health department can assist or direct the company to the appropriate agency. DTC food delivery companies can also follow this link for state health department information: <https://www.foodsafety.gov/about/state/index.html>.

Food establishments and food ordering platforms may contact state, local, tribal, territorial or federal food regulatory agencies if questions or issues arise about food safety regulations which apply to their operation.

For additional information regarding the food products that federal agencies oversee, follow the links provided below:

Food and Drug Administration – What does FDA regulate?  
<https://www.fda.gov/aboutfda/transparency/basics/ucm194879.htm>

U.S. Department of Agriculture Food Safety Inspection Service  
<https://www.fsis.usda.gov/wps/portal/fsis/home>

#### **Food laws**

There are many laws which provide the basic framework for ensuring safety of foods in the US, including DTC delivery foods. These laws include but are not limited to the Food Drug and Cosmetic Act (FDCA), the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA). These laws prohibit the sale or distribution of adulterated foods. Foods can be deemed adulterated for many reasons including:

- (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; (FDCA 21 USC §342(a)(4), FMIA 21 USC §601(m)(4), PPIA 21 USC §453 (g)(4))

The FMIA specifically prohibits adulteration during transportation:

... any act while they are being transported in commerce or held for sale after such transportation, which is intended to cause or has the effect of causing such articles to be adulterated or misbranded.

Therefore, DTC delivery foods must always be transported in a way which minimizes the risk of contamination and potential adulteration of the food.

## **Food regulations**

Federal regulations also address sanitary situations which apply to transportation of foods. Some (but not all) of these regulations are provided below for reference.

The FDA Good Manufacturing Practice Regulations address warehousing and distribution as follows:

§117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions which will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

The USDA FSIS Sanitation Rules address shipping as follows:

9 CFR 416.4 Sanitary operations.

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

There is also the FDA Sanitary Transportation of Human and Animal Foods rule. See the following links for more information:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm>

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM553930.pdf>

The Sanitary Transportation of Human and Animal Food is designed to prevent transportation practices which create food safety risks (e.g. failure to properly refrigerate food, inadequate cleaning of vehicles between loads, etc.). The new FSMA Sanitary Transportation rule builds on the 2005 Sanitary Food Transportation Act (SFTA) and establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food. These requirements mandate a company to use sanitary practices to ensure the safety of food. The FSMA requirements do not apply to transportation by mail, air, or third-party delivery service because of limitations in the law.

For more information on FSMA Final Rule on Sanitary Transportation of Human and Animal Food, look here: <https://www.federalregister.gov/documents/2016/04/06/2016-07330/sanitary-transportation-of-human-and-animal-food>.

FDA has indicated several waivers from the Sanitary Transportation rule, which are detailed here: <https://www.federalregister.gov/documents/2017/04/06/2017-06854/waivers-from-requirements-of-the-sanitary-transportation-of-human-and-animal-food-rule>. DTC food delivery companies should contact the proper regulatory authority to determine if they are covered by the waiver. For specific questions regarding the Final Rule on Sanitary Transportation of Human and Animal Food or the waivers, contact the FDA Outreach and Information Center <https://cfsan.secure.force.com/Inquiry> or the FDA Center for Food Safety and Applied Nutrition: <https://www.fda.gov/Food/ResourcesForYou/ucm334249.htm>

FDA's Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions which address the safety and protection of food offered at retail and in food service. Most state and local codes are based on the FDA Model Food Code and provides rules which may be relevant to packing and shipping of DTC delivery foods. The FDA Food Code can be obtained here: <https://www.fda.gov/foodcode>.

USDA provides the following consumer information on Mail Order Food Safety (<https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/mail-order-food-safety/>) to help consumers determine if their perishable foods have been handled properly:

- Make sure your company sends perishable items, like meat or poultry, cold or frozen and packed with a cold source. Items should be packed in an appropriate container to ensure temperature control and protect the food(s) from contamination.
- The food should be mailed as planned, using mailing plans which have been validated to deliver appropriate temperature control. Make sure perishable items and the outer package are labelled appropriately (e.g. "keep refrigerated") to alert the recipient as to proper handling.
- The company should inform their consumers on how to handle foods on receipt. Your company may wish to include information on how to measure product temperature and what to do if foods are received outside the delivery window, at unacceptable temperatures, or in a damaged condition.
- The company should be aware of situations where a consumer is ordering food for another individual (e.g. as a gift). Your company should develop and implement a notification system appropriate for these situations.

## **Labeling**

As part of their obligations to comply with general legal requirements, proprietors of DTC food delivery companies need to ensure the labeling of food is correct and not misleading and the food's chemical composition and any materials and articles which come into contact with the food are not harmful to health.

Where a DTC food delivery company receives pre-packed foods (i.e. already in their primary packaging), such as canned, vacuum packed or pouch packed goods, from another company, the food should be correctly labelled by other business. Depending on the product, the labeling required can be extensive. However, where the proprietor of a mail order food company operation repackages individual items, they may have more limiting mandatory labeling to perform but should take care to ensure the requirements have been satisfied.

If a DTC food delivery company wishes to make a claim concerning its products, whether these claims relate to the origin, species or nature of the product, e.g. Alaskan salmon, vegan or organic, it would be advisable to take steps to substantiate these claims.

Some companies may choose to label certain items with the date and time packaged and/or the shipping date. If a product's package has been manipulated in any way, the label should be updated to reflect the repackaging date.

### **Traceability and recalls for direct to consumer and third-party delivery services parties**

A detailed discussion of the complexities of food recalls is beyond the scope of this document. However, an awareness of, and preparation for recalls is an important part of a food safety plan for all DTC food delivery companies and third-party delivery services (e.g. food ordering platforms and retail food establishments). Any DTC food delivery company and third-party delivery services should have four key aspects of their food safety system in place which relate to recalls:

- Means for tracking all recalls relevant to their business. The company should not rely upon their suppliers to inform them about the need for a recall but should actively seek out relevant information.
- Means to stop online sales once they learn of a relevant recall.
- Method to notify any consumers who have purchased a recalled product and inform them the product they purchased has been recalled.
- System to manage recalled inventory, to ensure any recalled product is appropriately tracked, controlled, and ultimately destroyed or reconditioned, and does not re-enter commerce.

DTC food delivery companies and third-party delivery services (e.g. food ordering platforms and retail food establishments) should be able to (a) provide trace-forward information to track where recalled product delivered to (e.g. consumer information) and (b) provide traceback information to track where recalled product originated from (e.g. distributor, supplier, manufacturer, farm).

Best practices for DTC food delivery companies and third-party delivery services (e.g. food ordering platforms and retail food establishments) are to have processes related to trace-forward and traceback actions developed and to have appropriate records to manage potential recalls.

More information regarding recalls is available on both FDA and USDA FSIS websites. A brief description of this information follows below.

### **FDA recalls**

Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under their statutory authority. FDA divides recalls into four categories:

- Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- Market withdrawal: when a product has a minor violation that would not be subject to FDA legal action it may be withdrawn from commerce. The firm removes the product from the market or corrects the violation.

For additional recall information, see recall Regulations in 21 CFR Part 7:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=7&showFR=1>

### **USDA FSIS recalls**

FSIS recalls are initiated by the manufacturer or distributor of the meat or poultry product, sometimes at the request of FSIS. All FSIS recalls are voluntary. However, if a company refuses to recall its products, then FSIS has the legal authority to detain and seize any products that are in commerce.

FSIS notifies the public through a Recall Release for Class I and Class II recalls, and issues a Recall Notification Report (RNR) for Class III recall issues. The definitions for FSIS Class I, II and III recalls are slightly different than for FDA products, and are summarized below:

- Class I: involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death.
- Class II: involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food.
- Class III: involves a situation in which eating the food will not cause adverse health consequences.

For more USDA FSIS information on recalls:

<https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts>

## B. Other resources

### Relevant resources regarding temperature control

- 2017 FDA Food Code Chapter 3 (Food), especially the section 3-5: Limitation of growth of organisms of public health concern  
<https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM595140.pdf>
- FDA Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food  
<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm>
- FDA Fish and Fishery Products Hazards and Controls Guidance  
<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm>
- USDA Food Safety Information: Mail Order Food Safety  
[https://www.fsis.usda.gov/wps/wcm/connect/9020369a-247f-423c-8486-7e31ca6bcfc3/Mail\\_Order\\_Food\\_Safety.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/9020369a-247f-423c-8486-7e31ca6bcfc3/Mail_Order_Food_Safety.pdf?MOD=AJPERES)
- Centers for Disease Control and Prevention: Tips for Meal Kit and Food Delivery Safety  
<https://www.cdc.gov/foodsafety/communication/food-safety-meal-kits.html>
- Some states may have specific requirements for DTC or TPD food temperature control. Contact the state department that has jurisdiction over food regulations for details. Contact information for state departments of health and agriculture can be found at  
<https://www.foodsafety.gov/about>

### Relevant resources regarding pathogen growth risk

- US FDA Hazard Analysis Critical Control Point (HACCP) guidance  
<https://www.fda.gov/Food/GuidanceRegulation/HACCP/default.htm>
- FSIS Compliance Guideline HACCP Systems validation April 2015  
[https://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP\\_Systems\\_Validation.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP_Systems_Validation.pdf?MOD=AJPERES)
- FDA Guidance for Industry: Control of *Listeria monocytogenes* in refrigerated or frozen ready-to-eat-food  
<https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm073110.htm>
- CFP Emergency Action Plan for Retail Food Establishments  
<http://www.foodprotect.org/media/guide/Emergency%20Action%20Plan%20for%20Retail%20food%20Est.pdf>
- USDA Pathogen Modeling Program  
<https://pmp.errc.ars.usda.gov/PMPOnline.aspx>
- ComBase Predictor  
[http://browser.combase.cc/ComBase\\_Predictor.aspx?model=1](http://browser.combase.cc/ComBase_Predictor.aspx?model=1)

### Procedures for taking food temperatures

The Food Code Annex 5, entitled “Conducting Risk-Based Inspections includes relevant information on temperature measurement in sections related to assessing temperatures (pages 608-612).

Several different types of thermometers are used to monitor the temperature of foods, including: bi-metal stemmed, digital, thermocouple and infrared types. Depending on their specific usage, these devices have advantages and disadvantages as described below.

<b>Type of Hand Held Thermometer</b>	<b>Advantages</b>	<b>Disadvantages</b>
Bi-Metal	Small – fits in pocket Inexpensive Can be calibrated	Requires frequent calibration Slow response time Not suitable for thin foods Narrow range (0 to +220°F) Less accurate Sensor located 2 ½” from tip
Digital	LCD display – easy to read Wide temp range (-50 to +300°F) Sensor located at tip Fast response time	Most require manufacturer calibration Require batteries
Thermocouple	Very wide temp range (-60 to +2000°F) Fast response time Very accurate Ideal for all food temp’s	Must be factory calibrated Expensive
Infrared	Fast response time Wide temp range (-25 to +900°F) Food contact not required Non-destructive	Measures surface temperatures only Used only as temperature indicator Not suitable for regulatory purposes

Employees preparing food within the DTC food delivery company prior to shipment should be trained on correct application, how to properly use and how to maintain the instruments to ensure they work properly. Thermometers need to be washed, rinsed, sanitized and air dried before and after use to prevent cross-contamination.

Any food temperature measuring devices should be readily accessible for use and stored in a clean manner. Regulatory guidance suggests food temperature measuring devices be calibrated in accordance with manufacturer's specifications (including frequency and method of calibration) to ensure their accuracy.

TCS food temperatures should be monitored and controlled in the following stages:

- Receiving

- Refrigerated storage
- Freezer storage
- Cooking
- Hot and cold holding
- Cooling
- Reheating
- Packing
- Mailing/Transport

Temperatures should be measured and recorded at appropriate frequencies and corrective actions should be taken when deviations are identified.

The FDA Model Food Code temperatures are given in Part 3-2, 3-4 and 3-5. However, mail order food companies should check with local jurisdictions for any local variations.

## C. Trading standards and imported food issues

Under the U.S. Federal Food, Drug and Cosmetic Act, importers and brokers of food products intended for introduction into U.S. interstate commerce are responsible for ensuring the products are safe, sanitary and labeled according to U.S. requirements. Both imported and domestically produced foods must meet the same legal requirements in the United States. FDA is not authorized under the law to approve, certify, license, or otherwise sanction individual food importers, product labels, or shipments. Importers can import foods into the United States as long as the facilities which manufacture, process, package, or hold the products are registered with FDA, and prior notice of incoming shipments is provided to FDA. It should be noted that some facilities are exempt from registration. Imported food products are subject to FDA inspection when offered for import at U.S. ports-of-entry. FDA may detain shipments of products offered for import if the shipments are not in compliance with U.S. requirements. For an overview of the U.S. Import Program, please see: <https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/default.htm>

Food imported into the United States directly to consumers by international mail is also subject to prior notice requirements (for more information see 21 CFR 1.279(c)). For an article of food sent by international mail, prior notice must be submitted and confirmed by FDA before the food is sent. The Prior Notice Confirmation Number must accompany the article of food and must appear on the Customs Declaration that accompanies the package. For further information about sending food to consumers through international mail, visit the following FDA link: <https://www.fda.gov/media/118190/download>

The FDA Food Safety Modernization Act gives FDA new tools and authorities to make certain imported foods meet the same safety standards as foods produced in the U.S. The following link outlines FDA's key new import authorities and mandates: <https://www.fda.gov/food/food-safety-modernization-act-fsma/background-fda-food-safety-modernization-act-fsma>

The USDA Food Safety and Inspection Service (FSIS) is responsible for ensuring domestic and imported meat, poultry, and egg products are safe, wholesome, and accurately labeled. In addition, the primary inspection responsibility for Siluriformes fish, commonly known as catfish, was transferred to FSIS on March 1, 2016, for domestic producers and on April 15, 2016, for importers.

Foreign countries which export meat, poultry, catfish, and egg products to the United States are required to establish and maintain inspection systems which are equivalent to those of the United States. The USDA FSIS provides detailed guidance on steps to ensure that these products are imported in compliance with the applicable statutes and regulations of the United States: <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/fsis-import-procedures-for-meat-poultry-and-egg-products/fsis-import-procedures>

Here is a link to the USDA FSIS website regarding Siluriformes information: <https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/siluriformes>

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-005**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

DTCDC #2 Approve/Post Guidance Document - DTC and TPD service food delivery

**Issue you would like the Conference to consider:**

Acceptance of the Direct to Consumer Delivery Committee guidance document entitled "Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery" and inclusion of the guidance document on the CFP website in a downloadable PDF format.

**Public Health Significance:**

This guidance document provides food safety best practices for managing or performing direct to consumer (DTC) or third-party delivery (TPD) services. This document includes parameters critical to preventive controls, mechanisms to assess risk, validation and verification practices, recommendations for proper packaging, temperature control, receiving and storage, physical and chemical contamination control, allergen control, general food safety information, and suggestion for return of compromised and abused products. The intent of the guide is primarily to provide best practices for preventing biological, physical and chemical contamination as well as the growth of harmful bacteria and/or the formation of toxins within the food being transported.

At the 2018 biennial meeting Issue # 2018-III-006 charged the Direct to Consumer Delivery Committee to "Revise the Guidance Document for Mail Order Food Companies that includes recommended practices for transportation directly to a consumer of perishable products, to include proper packaging; temperature control during shipping, receiving, and storage; return of compromised and abused products; and other food safety related topics. Current guidance document to be revised to include food safety training for the TPDS entities, and information on all food delivery practices from food production, distribution, or retail food service facilities."

Issue # 2018-III-006 also charged the committee to "Determine appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 2 (References, Part 3-Supporting

Documents) be amended by adding references to the new guidance document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website."

**Recommended Solution: The Conference recommends...:**

The Conference recommends:

1. Acceptance of the committee generated draft guidance document entitled "Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery". (See *document attached to Issue titled: Report of the Direct to Consumer Delivery Committee*)
2. Posting the guidance document on the CFP website in a down-loadable PDF format; and
3. Authorizing the Conference to make any necessary edits prior to posting the document to assure consistency of format and non-technical content; edits will not affect the technical content of the document.

**Submitter Information 1:**

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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-006**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

DTCDC #3 Request Food Code Annex be amended to include guidance document

**Issue you would like the Conference to consider:**

Inclusion of a reference to the committee generated "Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery" in the FDA Food Code Annex.

**Public Health Significance:**

This guidance document provides food safety best practices for managing or performing direct to consumer (DTC) or third-party delivery (TPD) services.

Issue # 2018-III-006 also charged the committee to "Determine appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance document.

**Recommended Solution: The Conference recommends...:**

The Conference recommends a letter be sent to FDA requesting that the most recent edition of the Food Code be amended to include a reference to the "Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery" as follows:

Annex 2-References, Part 3-Supporting Documents

W. Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery, 2019

Companies that engage in direct-to-consumer and third-party delivery service food delivery have increased in recent years. In 2018 the Conference for Food Protection recommended formation of a committee to revise the existing guidance for direct-to-consumer (mail order) food companies to include guidance for companies engaging in third-party delivery serviced for food delivery. This guidance document provides food safety best practices for managing or performing Direct to Consumer (DTC) or third-party delivery (TPD) services.

*Note: The guidance document referenced is attached to Issue titled: Report of the Direct to Consumer Delivery Committee.*

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-007**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

PWWC - Issue 1: Report of Produce Wash Water Committee (PWWC)

**Issue you would like the Conference to consider:**

The Produce Wash Water Committee was re-created at the 2018 Biennial Meeting. The Committee was charged to develop a Produce Washing and Crisping Guidance Document for Retail Food Establishments. This Committee completed the charges assigned. Since the charges assigned at the 2018 Biennial meeting have been fulfilled, the Committee is requesting for the Conference for Food Protection to disband the Produce Wash Water Committee. Additionally, the Produce Wash Water Committee requests acknowledgement of their Final Report and thanking the committee members for their hard work.

**Public Health Significance:**

Whole or fresh-cut produce may contain pathogenic microorganisms and at times have been associated with foodborne illness and outbreaks. Efforts have been undertaken by the produce industry and regulators (e.g., FSMA and the Produce Safety Rule) to minimize the risk of contamination of fresh produce. However, without a "kill step" a potential risk remains. In the event that contaminated product is received into a food establishment, washing and crisping practices introduce an additional risk. In food establishments, produce is washed before being cut, etc. as per the recommendation of the 2017 FDA Food Code, but it should be noted that washing has a limited effect on removing pathogens from the produce surface. When produce items are submerged in water the chance for cross-contamination presents a public health risk. Further, the practice of crisping could introduce an additional risk since contaminated water may internalize pathogens during the crisping process. When other procedures such as washing/sanitizing the sink before use are not followed, food contact surfaces can also contribute to cross-contamination. Taken together, these practices demonstrate the need to consider additional or alternative efforts to reduce the risks associated with fresh produce handling practices at food establishments

**Recommended Solution: The Conference recommends...:**

- a. Acknowledgement of PWWC Report and Roster
- b. Thank you and acknowledgement of Committee Members and their work
- c. Disbanding of the Committee.

**Submitter Information 1:**

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**Submitter Information 2:**

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E-mail: Jaime.Hernandez@dc.gov

**Content Documents:**

- "Committee Final Report"
- "Committee Member Roster"
- ""Guide for Washing and Crisping Whole Raw Fruits and Vegetables at Food"

**Supporting Attachments:**

- "Meeting notes"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

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

**COMMITTEE NAME:** *Produce Wash Water Committee (PWWC)*

**DATE OF FINAL REPORT:** 11/01/2019

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

**REPORT SUBMITTED BY:** *Anna Starobin, Jaime Hernandez*

**COMMITTEE CHARGE(S):**

**Issue # 2018-III-013: Re-Create - Produce Wash Water Committee**

1. *Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:*
  - a. *Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.*
  - b. *Describe the criteria for produce crisping vs. produce washing.*
  - c. *Clarify the types of chemicals and their use for washing and crisping.*
2. *Report findings and recommendations back to the 2020 Conference for Food Protection Biennial Meeting.*

**COMMITTEE WORK PLAN AND TIMELINE:**

1. Created subgroup will continue working on the guideline draft (Members: Amanda Garvin; Erich Hess; Jaime Hernandez; Janet Buffer; Jill Hollingsworth; Kris Zetterlund; Rick Barney; Todd Rossow; Anna Starobin) (**complete**)
2. The chapters of the future guideline will be created. (**complete**)
3. Washing and crisping methods, considerations, and comments will be listed in a table as an example of most commonly used produce washing methods and risk reduction associated with each of the methods. (**complete**)
4. Pre-requisite SOPs for produce washing and crisping will be prepared and included into the guideline. (**Outside of the committee charge, per CFP Board members Keith Jackson and Christine Applewhite**)
5. Diagram/decision tree for using various chemicals used in produce washing with jurisdictions regulated those chemicals will be created. (**complete**)
6. After developing the guidance document, said document will be peer-reviewed between Committee members and FDA consultants to ensure that all details from the charge have been fulfilled. June-July 2019 (**complete**)
7. After completion of the charge, the Committee will report back to the 2020 Conference for Food Protection Biennial Meeting. (**complete**)
8. Issues identified during the committee work will be prepared and submitted to CFP (September-December 2019) (**complete**)

**COMMITTEE ACTIVITIES:**

**1. Dates of committee meetings or conference calls:**

- a. 9/25/18; 10/23/18; 11/26/18; 12/17/18; 1/28/19; 2/25/19; 3/25/19; 4/22/19; 5/20/19; 6/24/19; 7/29/19; 8/26/19; 10/3/19
- b. Working group had conference calls at least every other week, as well as multiple e-mail communications.

**2. Overview of committee activities:**

- a. Committee member roster approved.
- b. Issued a guideline which covered most common methods for produce washing and crisping in retail. Risk reduction for each method recommended. Relevant references are searched and included.
- c. The types of chemicals and their use for washing and crisping clarified.
- d. Periodic reports submitted.
- e. Final report submitted.

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

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:

- a. Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.
- b. Describe the criteria for produce crisping vs. produce washing.
- c. Clarify the types of chemicals and their use for washing and crisping.

2. Report findings and recommendations back to the 2020 Conference for Food Protection Biennial Meeting.

4. **Charges INCOMPLETE and to be continued to next biennium:**

None

**COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:**

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

**LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:**

1. **Committee Issue #1:** PWWC 1- Acknowledgement of the 2018-2020 Produce Wash Water Committee Final Report and disbanding the 2018-2020 Produce Wash Water Committee

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

- (1) **Committee Final Report (see attached PDF)**
- (2) **Committee Member Roster (see attached PDF)**
- (3) **Guide for Washing and Crisping Whole, Raw Fruits and Vegetables at Retail Food Establishments**

**b. List of supporting attachments:**

(1) **Meeting Notes. All meeting notes were approved by the majority of the voting members via e-mail responses.**

2. **Committee Issue #2:** PWWC 2 - Posting of the Guidance Document of the 2018-2020 Produce Wash Water Committee to the Conference for Food Protection website.

**List of supporting attachments:**

- (1) **Guide for Washing and Crisping Whole, Raw Fruits and Vegetables at Retail Food Establishments**

3. **Committee Issue #3:** PWWC 3 - 4-302.15 Fruit and Vegetable Wash Solutions, Testing Devices

**List of supporting attachments: x No supporting attachments submitted**

Committee Name: Produce Wash Committee - 20 Voting Members 41 total members 9 Industry: 9 Regulatory: 2 Academia)

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Starobin	Anna	CHAIR	Industry - Support	Ecolab	Greensboro	NC	336-931-2185	anna.starobin@ecolab.com
Hernandez	Jaime	VICE CHAIR	Regulator - Local	DC Department of Health	Washington	DC	202-535-2180	jaime.hernandez@dc.gov
Baroudi	Al	Voting Member	Industry - Service	The Cheesecake Factory	Calabasas Hills	CA	818.871.5890	abaroudi@thecheesecakefactory.com
Culbert	Carol	Voting Member	Regulator - Local	Southern Nevada Health District	Las Vegas	NV	702-759-1110	culbert@snhd.org
Copeland	Deanna	Voting Member	Regulator - Local	Harris County Public Health	Pasadena	TX	(713) 274-6300	Deanna.Copeland@pchs.hctx.net
Dickhaut	Jason	Voting Member	Industry - Service	BJ's Restaurants & Brewhouse	Huntington Beach	CA	214-674-1341	jdickhaut@bjsrestaurants.com
Garvin	Amanda	Voting Member	Regulator - State	Michigan Department of Ag & RD	South haven	MI	616-265-9985	garvina1@michigan.gov
Hess	Erich	Voting Member	Industry - Retail	Jewel-Osco	Itasca	IL		erich.hess@jewelosco.com
Hollingsworth	Jill	Voting Member	Industry - Support	Chemstar Corp	Lithia Springs	GA	843-341-6640	jillh@chemstarcorp.com
Karlicek	Dianna	Voting Member	Regulator - Local	Washoe County Health District	Reno	NV	(775) 328-2614	dkarlicek@washoecounty.us
Ingham	Barbara	Voting Member	Academia	University of Wisconsin	Madison	WI	608-263-7383	bingham@wisc.edu
Jordan	Josh	Voting Member	Regulator - Local	NC Department of Health	Raleigh	NC	336-596-9537	josh.jordan@dhhs.nc.gov
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Thesmar	Hilary	Voting Member	Industry - Retail	FMI	Arlington	VA	202-220-0658	hthesmar@fmi.org
Rossow	Todd	Voting Member	Industry - Retail	Publix Super Market	Lakeland	FL	863-688-1188	todd.rossow@publix.com
Peasley	Chris	Voting Member	Regulator - State	Georgia Department of Agriculture	Atlanta	GA	404-656-3627	chris.peasley@agr.georgia.gov
Zetterlund	Kris	Voting Member	Industry - Service	Darden	Orlando	FL	407 2456095	kzetterlund@darden.com
Barney	Rick	At-Large Non-Voting	Industry - Retail	Southeastern Grocers	Jacksonville	FL	813-857-7122	rickbarney@segrocers.com
Buffer	Janet	At-Large Non-Voting	Industry - Retail	Amazon	Seattle	WA	206-508-9597	ilbuffer@amazon.com
Craig	Betsy	At-Large Non-Voting	Industry - Support	MenuTrinfo	Fort Collins	CO	970 295-4370	betsy@menutrinfo.com
Geller	Todd	At-Large Non-Voting	Industry - Service	Sodexo	Fredericksburg	VA	540-207-8610	todd.geller@sodexo.com
Manuel	Chip	At-Large Non-Voting	Industry - Support	GOJO	Atlanta	GA	704-458-9546	ManuelC@GOJO.COM
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Mikeska	B. J.	At-Large Non-Voting	Industry - Retail	Diversey	Bellville	TX	215-238-6892	barry.mikeska@diversey.com
Miller	Ashley	At-Large Non-Voting	Industry - Support	National Restaurant Association	Chicago	IL	312-715-6754	acmiller@restaurant.org
Nakamura	George	At-Large Non-Voting	Industry - Retail	State Food Safety	Sunnyvale	CA		gmlnaka@comcast.net
O'Donnell	Kathleen	At-Large Non-Voting	Industry - Retail	Wegmans Food Markets	Rochester	NY	585 429 3623	kathleen.odonnell@wegmans.com
Oswald	Steve	At-Large Non-Voting	Industry - Retail	Wakefern Food Corp.	Elizabeth	NJ	908-527-3624	steve.oswald@wakefern.com
Patel	Jaymin	At-Large Non-Voting	Industry - Service	Hardees / Carls Jr.	Nashville	TN	919-559-7093	jpatel@ckr.com
Patton	Travis	At-Large Non-Voting	Regulator - State	Kentucky Department for Public Health	Garrison	KY	314-298-4778	travist.patton@ky.gov
Reighter	Matthew	At-Large Non-Voting	Industry - Retail	Starbucks Coffee Corp	Seattle	WA	206 200-2581	mreighte@starbucks.com
Romo	Nela	At-Large Non-Voting	Industry - Service	El Pollo Loco	West Covina	CA	949-689 3101	nromo@elpolloloco.com
Seaman	Chuck	At-Large Non-Voting	Industry - Retail	Hy-Vee, Inc.	West Des Moines	IA	515-559-5736	cseaman@hy-vee.com
Walker	Matthew	At-Large Non-Voting	Regulator - State	Idaho Food Protection Program	Boise	ID	208-334-5946	matthew.walker@dhw.idaho.gov
Westbrook	Tim	At-Large Non-Voting	Industry - Retail	Publix Super Market	Eustis	FL	352-989-7314	tim.westbrook@publix.com
Willis	Richard	At-Large Non-Voting	Industry - Service	Mandalay	Las Vegas	NV	702-632-9485	rwillis@mandalaybay.com
Woodbury	Thomas	At-Large Non-Voting	Industry - Support	ComplianceMate	Holladay	UT	801-330-9511	twoodbury@compliancemat.com
Yoo	Woojin	At-Large Non-Voting	Industry - Service	Compass Group USA	Charlotte	NC	704-328-5708	woojin.yoo@compass-usa.com

asked to be removed from the committee

# Guide for Washing and Crisping Whole Raw Fruits and Vegetables at Food Establishments

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### Prepared for submission to:

2020 Biennial Meeting of the Conference for Food Protection

## **I. Disclaimer**

(Need CFP legal review)

The guidance in this document does not create or confer any rights for, or on, any person and does not operate to bind public health officials or the public. This guide does not have the force and effect of law and thus is not subject to enforcement. This guide encourages food establishments to use the general recommendations in the guidance to tailor food safety practices appropriate to their operations.

## **II. Preamble**

In response to Issue #2018-III-013 presented at the 2018 Conference for Food Protection (CFP) Biennial Meeting, Council III voted, and it was subsequently approved, to recreate the Produce Wash Water Committee. The following charges were given to the Committee:

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:
  - a. Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.
  - b. Describe the criteria for produce crisping vs. produce washing.
  - c. Clarify the types of chemicals and their use for washing and crisping.
2. Report findings and recommendations back to the 2020 Conference for Food Protection Biennial Meeting.

## **III. Introduction**

Fresh fruit and vegetable risk control measures, such as those detailed in the Food Safety Modernization Act (FSMA), the Produce Safety Rule, Food and Drug Administration (FDA) Guidance Documents and industry best practices guides, have enhanced the implementation of preventive controls during growing, harvesting, packing, holding and processing. However, despite these efforts, since there is no kill step for pathogens on whole, raw fruits and vegetables they may be contaminated when they enter commerce. Food establishment operators should be aware of potential risks associated with fruits and vegetables that may be washed at retail and consider appropriate risk control steps when handling fresh produce.

In food establishments, "... raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in READY-TO-EAT form" as per the 2017 FDA Food Code 3-302.15(A).<sup>1</sup>

As per the FDA Food Code Annex #3, “It was assumed that washing removes the majority of organisms and/or chemicals present; however, more recent studies have demonstrated washing to fall short of their complete removal.”<sup>2</sup>

In food establishments, different methods are used to wash different types of produce, including submersion, spray, rinsing, or a combination of these. Each method has advantages and risks that should be considered.

Spraying or rinsing with water, rather than submerging in water, may be less likely to cross-contaminate produce or result in infiltration of water. However, care must be taken with spray washing to prevent contamination by splashing or by aerosol. In a food establishment, this method may not be practical for large quantities of product.

Submersion in water is a common method used for washing whole, raw fruits and vegetables in food establishments. This method can present a risk of cross-contamination if pathogens present on the surface of the produce subsequently contaminate the water. Studies have shown that under certain conditions, pathogens washed off the produce surface into the water may be internalized into the produce via water infiltration.<sup>3, 4, 5</sup>

Regardless of wash method used, retail food establishments should be aware of the potential risks and control measures to minimize those risks. This guide seeks to assist food establishments that wash whole, raw produce by providing risk control steps for washing methods when using water alone, chemical treatments, and/or antimicrobial treatments. In practice, the differences in methods and treatments are not always understood or well differentiated. This guide provides information that should be considered when selecting a method for washing produce.

#### **IV. Definitions**

**Antimicrobial Pesticide (Treatment):** An antimicrobial pesticide [also called an antimicrobial treatment] is intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.<sup>6</sup>

Antimicrobial products are divided into two categories based on the type of microbial pest against which the product works:

- **Public health antimicrobial pesticide products** are those products that bear a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including but not limited to, microorganisms infectious to humans in any area of the inanimate environment, including water.<sup>6</sup>

- **Nonpublic-health antimicrobial pesticide products** are those products that bear a label claim to control microorganisms of economic or aesthetic significance, where the presence of the microorganism would not normally lead to infection or disease in humans.<sup>6</sup> Examples include fungi or lactic acid bacteria that can cause spoilage.

**Food Additive:** Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. Includes any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use if such substance is not GRAS or sanctioned prior to 1958 or otherwise excluded from the definition of food additives.<sup>7</sup>

**Fresh-Cut Produce:** Any fresh fruit or vegetable or combination thereof that has been physically altered from its whole state after being harvested from the field (e.g., by chopping, dicing, peeling, ricing, shredding, slicing, spiralizing, or tearing) without additional processing (such as blanching or cooking).<sup>8</sup>

**Infiltration (Internalization):** As it relates to fresh produce, the process of a liquid, usually water, permeating the internal structure by penetrating its pores [stoma], cut surfaces or other openings.<sup>5</sup> Infiltration of microorganisms can occur through stem scars, cracks, cuts, or bruises in certain fruits and vegetables during washing.<sup>2</sup> Microorganisms in water have been shown to enter produce through various pathways available due to the natural structure of certain produce. Various factors such as type of commodity, age, condition of the item (e.g., wounds, cracks, stem removal), water temperature, time in the water, and hydrostatic pressure can play a role in the internalization of microorganisms into fruits and vegetables.<sup>4</sup>

**On-Site Generators:** Devices that produce antimicrobial pesticides (chemicals), and which are located at the retail facility. On-site generators produce the antimicrobial chemical (usually a gas or liquid) via a chemical reaction and should not be confused with equipment that mixes, dilutes, or delivers chemicals that have been manufactured elsewhere. Refer to the FDA Food Code for details on using antimicrobials generated by on-site devices.<sup>9</sup>

- Whole, raw fruits and vegetables can be washed using antimicrobial treatments generated on-site.
- The EPA does not require the registration of the chemicals produced on-site from generating devices.
- The device must be manufactured in a registered establishment.
- Because there is no EPA registration of solutions generated and used on-site, the user of the equipment should look to the equipment manufacturer for data to validate the efficacy of the solution as well as the conditions for use.

**Potable Water:** Water that meets criteria as specified in 40 CFR 141 National Primary Drinking Water Regulations; referred to in the 2017 FDA Food Code as *drinking water*. (2017 FDA Food Code 1-201.10)<sup>1</sup>

**Produce:** Any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).<sup>10</sup>

**Raw Agricultural Commodity (RAC):** Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.<sup>11</sup> Certain activities such as refrigeration, washing, trimming, and waxing do not transform a RAC into a new or distinct commodity. Transforming a RAC into a processed food involves altering the general state of the commodity, sometimes referred to as transformation of a RAC. Examples of activities that may be manufacturing/processing without transforming a RAC into a processed food include coloring, washing, and waxing. Examples of activities that change a RAC into a processed food include chopping, cooking, cutting, homogenization, irradiation, and pasteurization.

**Ready-to-Eat (RTE) Food:** Food that is in a form that is edible without additional preparation to achieve food safety. (2017 FDA Food Code 1-201.10)<sup>1</sup> For this Guide, RTE includes raw fruits and vegetables [RACs] that are washed as specified under FDA Food Code § 3-302.15.<sup>1</sup>

**Risk Factors:** Food preparation practices and employee behaviors most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks. Risk factors include: Food from Unsafe Sources, Improper Holding Temperatures, Inadequate Cooking, Contaminated Equipment, and Poor Personal Hygiene. (2017 FDA Food Code, Annex 7, Guide 3-B)<sup>1</sup>

**Sanitizer:** Product [or substance] used to reduce, but not necessarily eliminate, microorganisms from the inanimate environment to levels considered safe as determined by public health codes or regulations.<sup>12</sup> Sanitizers can be designated for use on food-contact and/or nonfood-contact surfaces.

## **V. Information to Assist the User**

### **(A) Scope**

- This guidance is specific to whole, raw fruits and vegetables (also called raw agricultural commodities or RACs) that are washed at food establishments.
- This guidance does not apply to further processed fruits and vegetables, such as fresh-cut produce.
- In addition to washing, another common retail practice, known as crisping, involves produce-to-water contact. Therefore, this guide also provides information regarding the risks and controls that should be considered when selecting a method for crisping produce. (See Section VII)

### **(B) Understanding/Clarifying Sanitizers and Disinfectants**

The words cleaner, sanitizer, disinfectant, pesticide and antimicrobial treatment are often misused, which can lead to confusion. This section attempts to provide an explanation and clarification of these terms as used by the US Environmental Protection Agency (EPA) and FDA.

#### **Pest, Pesticide, and Antimicrobial Pesticide**

The term "pest" means: "(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals)..."<sup>13</sup>

A "pesticide" is any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating pests. A product is likely to be a pesticide if the labeling or advertising "makes a claim to prevent, kill, destroy, mitigate, remove, repel or any other similar action against any pest."<sup>14</sup>

Antimicrobial pesticides [also referred to as antimicrobial treatments] are substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms such as bacteria, viruses, or fungi on inanimate objects and surfaces.<sup>12</sup> Antimicrobial pesticides are intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.<sup>12</sup>

#### **Sanitizers and Disinfectants**

Food-contact surface sanitizers are EPA-registered products that are used to reduce, but not necessarily eliminate, microorganisms from the inanimate environment to levels considered safe as determined by public health codes or regulations.<sup>12</sup> They may not totally eliminate

microorganisms from hard, nonporous inanimate surfaces, but they reduce them to levels considered safe from a public health standpoint.

The FDA Food Code 1-201.10 describes sanitization as the “...application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.”<sup>1</sup>

Disinfectants are also EPA-registered products that can be used on hard, non-porous surfaces to destroy or irreversibly inactivate infectious bacteria and fungi, but not necessarily their spores.<sup>12</sup>

The efficacy testing, performance standards, and label claims required by EPA for food-contact surface *sanitizers* are different than those of hard surface *disinfectants*, as well as the intended purpose for these two types of products.

Likewise, the efficacy testing, performance standards, and label claims required by EPA for *surface sanitizers* are different than those required for *produce antimicrobial treatments*. EPA registered antimicrobial produce washes (treatments) must demonstrate antimicrobial efficacy in the wash water, but not on the produce surface. There are also different requirements for the substances allowed for treatment of food-contact surfaces vs. produce treatments. Not all substances approved as hard surface sanitizers can be used for produce wash antimicrobial treatments. For example, quaternary ammonium compounds (Quats) are commonly used as active ingredients for food-contact surface sanitizers but currently they are not allowed for use as produce antimicrobial wash treatments.

Substances for use as produce treatments are listed in 21 CFR §173 as additives permitted for human consumption<sup>15</sup> and in 21 CFR §184 as substances Generally Recognized As Safe.<sup>16</sup>

Substances cleared for use in antimicrobial formulations as hard surface sanitizers are listed in 40 CFR 180.940.<sup>17</sup>

## **VI. Methods and Risk Controls for Washing Whole Raw Fruits and Vegetables**

The following general principles apply to all the methods for washing whole, raw produce in food establishments included in the following chart titled:

### WASHING Whole Raw Fruits and Vegetables – Methods and Risk Reductions

In general:

- This guidance is specific to whole, raw fruits and vegetables (RACs) and does not apply to processed produce.
- Use only potable water when washing produce.
- All chemical treatments should meet the requirements of the FDA Food Code, Section 7-204.12. <sup>1</sup> Unless otherwise stipulated in 21 CFR 173, chemicals used to wash or peel fruits and vegetables should not exceed the minimum amount required to accomplish the intended effect, need to be accurately tested for proper concentration, and must adhere to any indications as dictated on the product label. (2017 FDA Food Code Annex 3-302.15) <sup>1</sup>
- A food establishment should consider developing a written procedure (such as a Standard Operating Procedure, job aid, or instructional wall chart) for washing produce. Controls for risk factors such as sourcing, receiving, holding temperatures, product handling, cleaning and sanitizing surfaces and equipment including the sink where produce will be washed, employee health, and personal hygiene can be found in the FDA Food Code and may be considered as part of the procedure or as pre-requisites prior to produce washing.
- This guide does not provide specific recommendations for how to comply with the FDA Food Code or state/local requirements. Because this guide does not repeat the full text of all requirements, users should familiarize themselves with the applicable requirements.

Different methods are used for washing whole, raw fruits and vegetables at food establishments. The following chart lists recommended risk reductions for each of the most commonly used produce washing methods.

## WASHING Whole Raw Fruits and Vegetables – Methods and Risk Reductions

Method	Risk Reductions	Comments
(W1) Washing fruits and vegetables by rinsing or spraying under continuous running and draining water	<ul style="list-style-type: none"> <li>• Rotating produce items so that all surfaces are washed/rinsed thoroughly</li> <li>• Providing sufficient water velocity to loosen soil and particles from the surface</li> <li>• Washing individual pieces or small batches of produce</li> </ul>	<ul style="list-style-type: none"> <li>• When produce is not submerged in water the risk of cross-contamination and microbial infiltration may be reduced.</li> <li>• This method could cross-contaminate if multiple pieces are rinsed at the same time.</li> <li>• Do not allow water to splash onto other product or food-contact surfaces.</li> <li>• This method may not be practical for large volumes of produce.</li> </ul>
(W2) Washing fruits and vegetables by rinsing or spraying in a container under a continuous stream of running water with a continuous overflow	<ul style="list-style-type: none"> <li>• Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration</li> <li>• Providing sufficient water velocity to loosen soil and particles from the surface and to float off loose particles in the overflow</li> <li>• Stirring the produce in the container to ensure equal exposure to the water flow</li> <li>• Washing small batches of produce</li> </ul>	<ul style="list-style-type: none"> <li>• The use of continuously flowing and draining water may reduce the potential risk of cross-contamination.</li> <li>• This method could cross-contaminate if multiple pieces are rinsed at the same time.</li> <li>• Do not allow water to splash onto other product or food-contact surfaces.</li> <li>• This method may not be practical for large volumes of produce.</li> </ul>

Method	Risk Reductions	Comments
<p>(W3) Washing fruits and vegetables by submerging or by spraying or rinsing under running water using an EPA registered antimicrobial treatment in the water</p> <p>Note: The treatment may be provided in a concentrated form that has to be diluted for use as per label instructions.</p>	<ul style="list-style-type: none"> <li>• Following all manufacturer’s instructions and the registered EPA label instructions for use</li> <li>• Using the concentration of the antimicrobial indicated by the manufacturer's use directions included in the EPA registered label</li> <li>• Agitating the produce to loosen soil and surface contaminants and to ensure all produce is exposed to the treated water</li> </ul>	<ul style="list-style-type: none"> <li>• Consult the EPA registered product label to determine if the product controls pathogens in the wash water, e.g., a 3-log reduction of <i>Salmonella</i>, <i>Listeria monocytogenes</i>, and <i>E. coli</i> O157:H7.</li> <li>• By reducing pathogens introduced into the water by contaminated produce, the risk of cross-contamination via the water and pathogen infiltration is reduced.</li> <li>• When it is not practical to reduce the temperature differential between the water and the produce, using an antimicrobial product in the wash water helps to mitigate the risk of pathogen contamination from wash water via infiltration.</li> <li>• Decreasing produce soaking time has been shown to reduce water infiltration rate.</li> <li>• The treated water should be prepared, and the concentration verified, following manufacturer label instructions.</li> </ul>
<p>(W4) Washing fruits and vegetables by submerging in water using a produce wash that is an approved food additive, or generally recognized as safe (GRAS), or is the subject of a food contact notification (FCN) as per FDA Food Code 7-204.12, but is <u>not</u> registered as an antimicrobial by EPA</p>	<ul style="list-style-type: none"> <li>• Following the manufacturer’s instructions</li> <li>• Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration</li> <li>• Developing a policy for the frequency of changing the water</li> <li>• Agitating the produce to loosen soil and surface contaminants</li> </ul>	<ul style="list-style-type: none"> <li>• These wash products may help loosen and remove soil and other contaminants on the surface of produce, but they have limited antimicrobial properties on pathogens introduced into the water by contaminated produce.</li> <li>• These wash products are <u>not</u> EPA registered, and do not make any pathogen kill or reduction claims.</li> <li>• Decreasing produce soaking time has been shown to reduce water infiltration rate.</li> <li>• The treated water should be prepared, and the concentration verified, following manufacturer label instructions.</li> </ul>

Method	Risk Reductions	Comments
(W5) Washing fruits and vegetables by submerging in water without adding anything to the water	<ul style="list-style-type: none"> <li>• Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration</li> <li>• Developing a policy for the frequency of changing the water</li> <li>• Agitating the produce to loosen dirt and contaminants</li> </ul>	<ul style="list-style-type: none"> <li>• This method provides the fewest preventive controls.</li> <li>• Water may loosen soil and some pathogens from the surface but will not reduce pathogens in the water; this increases the risk of pathogen cross-contamination and infiltration of pathogens via the water.</li> <li>• Decreasing produce soaking time has been shown to reduce water infiltration rate.</li> </ul>

## **VII. Methods and Risk Controls for Crisping Whole Raw Fruits and Vegetables**

Certain types of whole, raw fruits and vegetables may come in contact with water during a process known as crisping. Other terms used for this practice are re-crisping, hydrating, re-hydrating, and conditioning. Because washing and crisping may use the same produce-to-water contact methods, this guide also provides information regarding the risks and controls that should be considered by food establishments when selecting a method for crisping produce.

Crisping is the process of rehydrating produce with water for the primary purpose of maintaining quality and appearance. The process of crisping may also incorporate a method for chilling such as holding the produce under refrigeration. “Crisping typically involves the submersion of commodities in water (with or without sanitizers) followed by refrigeration, which gives products a fresh look and crisp texture.”<sup>18</sup> Crisping may also have the added benefit of contributing to sustainability initiatives such as reducing food waste and maintaining the produce quality appearance.

A primary risk factor that needs to be considered when crisping certain types of produce is internalization of pathogens. “Enteric pathogens have been shown to enter plant tissues through natural apertures (stomata, lateral junctions of roots, flowers), damaged tissue (wounds, cut surfaces),”<sup>5</sup> and purposeful openings such as stem trimming. Studies have shown that under certain conditions, pathogens washed off the produce surface may be internalized into the produce via water infiltration.<sup>4,5,8</sup> Pathogen internalization can occur at any time including pre-harvest, post-harvest processing and food establishment handling. Various factors such as type of commodity, age, condition of the item (e.g., wounds, cracks, stem removal), water temperature, time in the water, and hydrostatic pressure can play a role in the internalization of water which could contain pathogens if microbiological water quality is not maintained.

Crisping and washing have different objectives, however they share similar risks and controls. Washing is performed to clean produce surfaces and to remove surface soil and potential contaminants. The 2017 FDA Food Code 3-302.15(A) states “... raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form.”<sup>1</sup> Crisping is an optional practice, intended to maintain the quality and appearance of raw fruits and vegetables, and is not addressed in the FDA Food Code.

The information in this Guide regarding crisping reflects industry practices, published references (see Section IX), and input from subject matter experts. Because the FDA Food Code does not address crisping, this Guide is for use at the sole discretion of the food establishment and State/local regulators.

The following general principles apply to all the methods for crisping whole, raw produce in food establishments included in the following chart titled:

#### CRISPING Whole Raw Fruits and Vegetables – Methods and Risk Reductions

In general:

- This guidance is specific to whole, raw fruits and vegetables (RACs) and does not apply to processed produce.
- Use only potable water when crisping produce.
- When used, all chemical treatments should meet the requirements of the 2017 FDA Food Code 7-204.12.<sup>1</sup>
- A food establishment should consider developing a written procedure (such as a Standard Operating Procedure, job aid, or instructional wall chart) for crisping produce. Controls for risk factors such as sourcing, receiving, holding temperatures, product handling, cleaning and sanitizing surfaces and equipment, employee health, and personal hygiene can be found in the FDA Food Code and may be considered as part of the procedure or as pre-requisites prior to produce crisping.
- This guide does not provide specific recommendations for how to comply with the FDA Food Code or state/local requirements. Because this guide does not repeat the full text of all requirements, users should familiarize themselves with the applicable requirements.

Different methods are used for crisping whole, raw fruits and vegetables at food establishments. The following chart lists recommended risk reductions for each of the most commonly used crisping methods.

## CRISPING Whole Raw Fruits and Vegetables – Methods and Risk Reductions

Method	Risk Reductions	Comments
<p>(C1) Produce is submerged in water containing an EPA registered antimicrobial</p> <p>Note: The treatment may be provided in a concentrated form that has to be diluted for use as per label instructions.</p>	<ul style="list-style-type: none"> <li>• Following all manufacturer’s instructions and the registered EPA label instructions for use</li> <li>• Using the concentration of the antimicrobial indicated by the manufacturer's use directions included in the EPA registered label</li> <li>• Minimizing the time produce remains in the water</li> <li>• Holding the produce under refrigeration to complete the crisping process</li> </ul>	<ul style="list-style-type: none"> <li>• Consult the EPA registered product label to determine if the product controls pathogens in the wash water, e.g., a 3-log reduction of <i>Salmonella</i>, <i>Listeria monocytogenes</i>, and <i>E. coli</i> O157:H7.</li> <li>• By reducing pathogens introduced into the water by contaminated produce, the risk of cross-contamination via the water and pathogen infiltration is reduced.</li> <li>• When it is not practical to reduce the temperature differential between the water and the produce, using an antimicrobial product in the wash water helps to mitigate the risk of pathogen contamination from wash water via infiltration.</li> <li>• The treated water should be prepared, and the concentration verified, following manufacturer label instructions.</li> </ul>
<p>(C2) Produce is submerged in water with an added treatment that is an approved food additive, or generally recognized as safe (GRAS), or is the subject of a food contact notification (FCN) as per FDA Food Code 7-204.12, but is <u>not</u> registered by EPA as an antimicrobial</p>	<ul style="list-style-type: none"> <li>• Following the manufacturer’s instructions</li> <li>• Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration</li> <li>• Developing a policy for the frequency of changing the water</li> <li>• Minimizing the time produce remains in the water</li> <li>• Holding the produce under refrigeration to complete the crisping process</li> </ul>	<ul style="list-style-type: none"> <li>• These treatments are <u>not</u> EPA registered, and do not make any pathogen kill or reduction claims.</li> <li>• These treatments have limited antimicrobial properties on pathogens introduced into the water by contaminated produce; therefore, there is a risk of cross-contamination and pathogen infiltration.</li> <li>• Decreasing produce soaking time has been shown to reduce water infiltration rate.</li> <li>• The treated water should be prepared, and the concentration verified, following manufacturer label instructions.</li> </ul>

Method	Risk Reductions	Comments
(C3) Produce is submerged only in water, without adding anything to the water	<ul style="list-style-type: none"> <li>• Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration</li> <li>• Developing a policy for the frequency of changing the water</li> <li>• Minimizing the time produce remains in the water</li> <li>• Holding the produce under refrigeration to complete the crisping process</li> </ul>	<ul style="list-style-type: none"> <li>• This method provides the fewest preventive controls.</li> <li>• Pathogens on the surface of produce may be introduced into the water which can then cross-contaminate other produce items in the same water.</li> <li>• It has been shown that submerging some produce in water that is colder than the produce can increase the risk of pathogen infiltration.</li> <li>• Decreasing produce soaking time has been shown to reduce water infiltration rate.</li> </ul>
(C4) Produce is submerged in water in a container under a continuous stream of running water with a continuous overflow.	<ul style="list-style-type: none"> <li>• Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration</li> <li>• Crisping small batches to minimize cross-contamination</li> <li>• Minimizing the time produce remains in the water</li> <li>• Holding the produce under refrigeration to complete the crisping process</li> </ul>	<ul style="list-style-type: none"> <li>• The use of continuously flowing and draining water may reduce the potential risk of cross-contamination.</li> <li>• This method may not be practical for large volumes of produce.</li> </ul>

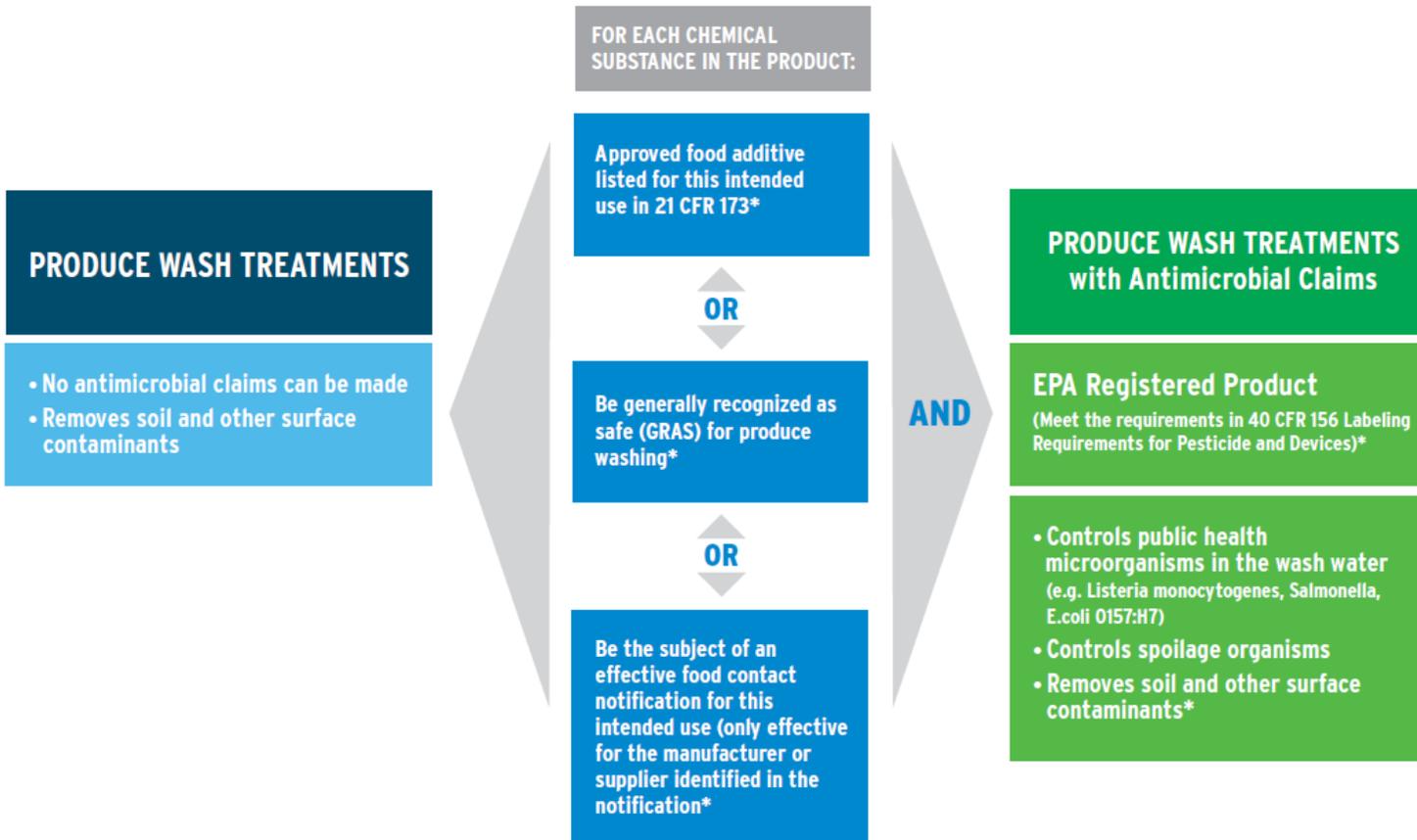
## **VIII. Chemical Use and Regulations**

Chemicals used for washing and crisping produce and/or to reduce microbial cross-contamination via wash water should be formulated from ingredients that are approved for this application and must be used in accordance with FDA and EPA regulations.

The following charts describe the approval process for chemicals, with and without antimicrobial claims, used for washing or crisping whole, raw fruits and vegetables.

Antimicrobial pesticide products are categorized by EPA as either "public health" or "non-public health," depending on the specific claims made on each product's labeling. Registrants of public health antimicrobial pesticide products must submit efficacy data to EPA to support their application for registration or amendments to add public health claims. The chemical producer or supplier is responsible for obtaining the appropriate approvals and assuring that the label provides instructions on proper use of the chemical for the intended purpose.

# WASHING WHOLE RAW FRUITS AND VEGETABLES (RACS) USING CHEMICALS



\*Reference Food Code §7-204.12

Note: This diagram does not include chemicals designed for the treatment of further processed produce

## Washing Whole Raw Fruits and Vegetables (RACs) Using Chemicals

All chemicals used for washing fruits and vegetables should meet Food Code 7-204.12 requirements

Treatment Types	Intended Use	Food Code Compliance	Comments
Antimicrobial EPA registered chemicals	To control pathogens or spoilage organisms in wash water.	Could be used for Washing Fruits and Vegetable as specified in FDA Food Code 3-302.15	Consult the product label to determine if the chemical controls pathogens in the wash water (e.g., a 3-log reduction of <i>Salmonella</i> , <i>Listeria monocytogenes</i> , <i>E. coli</i> O157:H7) and/or reduces non-public health organisms (e.g. spoilage organisms).
Chemicals with no antimicrobial claims (not EPA registered)	To help loosen soil from the produce surfaces.	Could be used for Washing Fruits and Vegetable as specified in FDA Food Code 3-302.15	No antimicrobial efficacy claims are made. Cross-contamination via water is not addressed.

**This table does not include chemicals designed for treatment of further processed produce**

## **IX. References**

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## **X. Acknowledgements**

Prepared by the Produce Wash Water Committee created at the CFP 2018 Biennial Meeting.

Chair: Anna Starobin

Vice-Chair: Jaime Hernandez

Working group members: Amanda Garvin; Erich Hess; Jaime Hernandez; Janet Buffer; Jill Hollingsworth; Kris Zetterlund; Rick Barney; Todd Rossow

Committee members: Barbara Ingham; Carol Culbert; Jaime Hernandez; Chris Peasley; Deanna Copeland; Anna Starobin; Ata (Al) Baroudi; Erich Hess; Hillary Thesmar; Jason Dickhaut; Jennifer Nord; Jill Hollingsworth; Josh Jordan; Karl Mathew; Dianna Karlicek; Ki Straughn; Kris Zetterlund; Todd Rossow; Tom McMahan, Amanda Garvin

Federal consultants: Laurie Williams; Kenya Moon

At-large, non-voting members: Rick Barney; Janet Buffer; Betsy Craig; Todd Geller; Chip Manuel; Carol McInnes; B.J. Mikeska; Ashley Miller; George Nakamura; Kathleen O'Donnell; Steve Oswald; Jaymin Patel; Travis Patton; Matthew Reighter; Nela Romo; Chick Seaman; Matthew Walker; Tim Westbrook; Richard Willis; Thomas Woodbury; Woo Jin Yoo;

Council III chair: Keith Jackson

Council III vice-chair: Christine Applewhite

The Committee wishes to thank all persons and organizations who provided input and assistance in the creation of this document.

## PWWC Conference Call Notes

9/25/2018

### Attendees:

- Voting Members:  
Al Baroudi, Carol Culbert, Deanna Copeland, Jason Dickhaut, Amada Garvin, Erich Hess, Jill Hollingsworth, Barbara Ingham, Josh Jordan, Dianna Karlicek, Karl Matthews, Jennifer Nord, Hilary Thesmar
- At-Large Members:  
Betsy Craig, Todd Geller, Chip Manuel, Carol McInnes, B.J. Mikeska, Jaymin Patel, Travis Patton, Nela Romo, Todd Rossow, Matthew Walker, Richard Willis, Woo Jin (Joey) Yoo

### Committee Charges:

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:
  - a. Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.
  - b. Describe the criteria for produce crisping vs. produce washing.
  - c. Clarify the types of chemicals and their use for washing and crisping.
2. Report findings and recommendations back to the 2020 Conference for Food Protection Biennial Meeting.

### Notes:

- 2018-2020 PWWC is continuation from 2016-2018 committee work
- Keith Jackson and Christine Applewhite are board representatives overlooking committee
- Committee charges from 2018 Biennium were reviewed
- Roll Call: Tom McMahan (excused), Chris Peasley (excused), and Kris Zetterlund (excused) were voting members that were absent from the call.
- Anna Starobin discussed the Antitrust Statement; this statement is to be read by all committee members and acknowledged, via email.
- Conference call frequency will be scheduled monthly; the frequency may be changed if needed.
- Attendance rules for the conference call were discussed; per an email sent by Keith Jackson, "The general guideline is that "excused" absences are acceptable, which means the committee Chair and Vice Chair receive notice of the absence. Two unexcused calls then requires for a counseling session, which I can do, and a third means they can no longer hold a voting position." Please notify both Anna Starobin ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime Hernandez ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) beforehand, if unable to be present for a scheduled conference call in order for absence to be excused.
- As a data storage platform for the committee, it was decided that Google Docs will be used, as it is user-friendly and the majority of members have access to said platform. Member Betsy Craig noted that she can assist in setting-up the platform. When using Google Docs, be sure to use Google Chrome browser in order to avoid any compatibility issues.
- Jill Hollingsworth noted that based on the survey results which were collected, it seems like produce washing/crisping practices for the retail and restaurant sectors are not the same. She proposed to work on them separately. It was decided that process flow diagrams for produce washing and crisping will be created for two sectors individually and later merged together, since both are governed by the same set of regulations. Hilary Thesmar, working together with several retailers will draft a diagram for the retail sector. Committee members that are involved in the restaurant industry will be recruited and draft a diagram for the restaurant sector. These diagrams will be presented at the next Conference Call, to determine if there is a significant difference between washing and crisping in the retail sector versus the restaurant sector. These diagrams will also be used as a

## PWWC Conference Call Notes

9/25/2018

foundation to create the produce washing and crisping guidance document requested for the 2020 Biennium. With this “framework” in place, sub-committees will be formed at the next conference call.

- All the supporting documents generated during the committee work were emailed to the members to inform them on the outcome and recommendations of the 2016-2018 committee work.

### Action Items:

- Jaime Hernandez will email Keith Jackson regarding being unable to record the conference calls.
- All members must read the Antitrust Statement that Anna Starobin sent via email and acknowledge that they read and understood the statement through sending an email to both Anna Starobin ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime Hernandez ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov))
- Anna Starobin will send an email to all members in the following weeks to set a date and time for the next conference call.
- Betsy Craig will assist both Chair and Vice Chair in setting-up the Google Docs data storage platform; all members should verify that they are able to access Google Docs, and to email both Anna Starobin ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime Hernandez ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) if they encounter any issues
- Hilary Thesmar, along with any other interested members will create the produce washing and crisping process flow diagram for the retail sector, to be presented at the next conference call
- Committee members that are involved in the restaurant industry along with any other interested members will be recruited and create the produce washing and crisping process flow diagram for the restaurant sector, to be presented at the next conference call



## *Conference for Food Protection Antitrust Statement*

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CFP functions, be they conferences, board or committee meetings, by their very nature, bring competitors together. To avoid antitrust allegations it is necessary to avoid discussions of sensitive topics. Agreements to engage in product boycotts, restrictive market allocations, refusal to deal with third parties and price-restraining activities are automatically illegal under antitrust laws.

An antitrust violation does not require proof of a formal agreement. There need not be written or verbal agreement to collude. Also, conversations regarding any of these sensitive areas may be construed as implicit violations. As a result, those attending CFP-sponsored functions should remember the importance of avoiding not only unlawful activities but even the appearance of unlawful activity.

The antitrust laws – the Sherman Act, Clayton Act, and the Federal Trade Commission Act – are intended to ensure free and open competition. Violations of these laws can have serious consequences for CFP and its members. Violations are felonies that can result in severe penalties and significant litigation expenses for CFP and its members. Even if a government or private suit is successfully defended, the cost and disruption of the litigation can be overwhelming. Taking antitrust precautions, therefore, is not only advisable but imperative.

For your protection, the Conference for Food Protection recommends that, should one of these subjects be brought up, it would be in your best interest to voice your objection and disassociate yourself from the discussion if it continues.

PWWC Conference Call Notes  
10/23/2018

**Attendees:**

- Voting Members:  
Al Baroudi, Carol Culbert, Jason Dickhaut, Amada Garvin, Erich Hess, Josh Jordan, Dianna Karlicek, Tom McMahan, Jennifer Nord, Hilary Thesmar, Chris Peasley, Kris Zetterlund, Anna Starobin, Jaime Hernandez
- At-Large Members:  
Rick Barney, Janet Buffer, Betsy Craig, Carol McInnes, Kathleen O'Donnell, Travis Patton, Matthew Reighter, Nela Romo, Todd Rossow, Matthew Walker, Woo Jin (Joey) Yoo

**Committee Charges:**

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  - a. Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.
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**Notes:**

- All conference calls are recorded. To request a recording of the conference call, please email either Anna Starobin ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) or Jaime Hernandez ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) and either will send you the recording.
- Roll Call: Deanna Copeland (excused), Jill Hollingsworth (excused), Barbara Ingham (excused) and Karl Matthews (excused) were voting members that were absent from the call.
- Anna Starobin presented a summary of 2016-2018 committee work
  - The presentation is saved in GoogleDrive. Please use the link above to access the PWWC folder within the drive. Once in the PWWC folder in GoogleDrive, the path for the presentation slides is as follows: **'16-'18 Committee Work > CFP Produce Committee 2016-2018 Summary.pdf**
- Jaime Hernandez discussed accessing the PWWC folder in GoogleDrive. With committee member Betsy Craig as lead, the GoogleDrive was created last week as a storage platform for all documents pertaining to our committee. Additionally, it was determined that the GoogleDrive could be accessed through clicking a link by anyone in the committee without the need to create and/or log into a Google account. Per committee members on the call, there were no issues in accessing the PWWC folder through using the link.
- A table for detailing steps for produce washing was created by Anna Starobin and Jaime Hernandez. This table is a consolidation of produce washing steps, from both the retail and restaurant sectors, that several committee members sent to the chair and vice chair within the last couple of weeks. During the call, the table was discussed with the committee members, and edited, in real time, by both Anna and Jaime. The path for the table within the PWWC folder in GoogleDrive is as follows: **'18-'20 PWWC Docs > Committee Charge > a. Guideline > Retail Produce Washing Steps**

PWWC Conference Call Notes

10/23/2018

**Action Items:**

- For those of you that have not done so, please read the Antitrust Statement (a copy of it is below) and acknowledge that you have read and understood the statement through sending an email to both Anna Starobin ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime Hernandez ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov))
- Anna Starobin will send an email to all members in the following weeks to set a date and time for the next conference call. Per an emailed suggestion by committee member Amada Garvin, an email with a poll for different days/times will be sent to determine what hours/days are best for the majority of committee members.
- Since the produce washing procedures table was not reviewed in its entirety (due to time constraints), please review the table. If you have any comments for the table, please download the document from the GoogleDrive, as a word document, comment, and email a copy of the commented table to both Anna Starobin ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime Hernandez ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)). As noted earlier, the path for the table within the PWWC folder in GoogleDrive is as follows: '18-'20 PWWC Docs > Committee Charge > a. Guideline > Retail Produce Washing Steps
- Committee members that have not already done so, are encouraged to email both Anna Starobin ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime Hernandez ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) SOPs / instructions for produce washing and produce crisping used by your organization.



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For your protection, the Conference for Food Protection recommends that, should one of these subjects be brought up, it would be in your best interest to voice your objection and disassociate yourself from the discussion if it continues.

PWWC Conference Call Notes  
11/26/2018

**Attendees:**

- Voting Members:  
Al Baroudi, Carol Culbert, Deanna Copeland, Jason Dickhaut, Amada Garvin, Erich Hess, Jill Hollingsworth, Barbara Ingham, Josh Jordan, Dianna Karlicek, Tom McMahan, Karl Matthews, Jennifer Nord, Hilary Thesmar, Kris Zetterlund, Anna Starobin, Jaime Hernandez
- At-Large Members:  
Rick Barney, Janet Buffer, Todd Geller, Chip Manuel, Carol McInnes, B.J. Mikeska, Kathleen O'Donnell, Matthew Reighter, Nela Romo, Matthew Walker, Thomas Woodbury

**Committee Charges:**

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:
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**Notes:**

- All conference calls are recorded. To request a recording of the conference call, please email either Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) or Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) and either will send you the recording.
- Roll Call: Chris Peasley (excused) was a voting member that was absent from the call.
- The Retail Produce Washing Steps table that was created last month was discussed with the committee members, and edited, in real time. The path for the table within the PWWC folder in GoogleDrive is as follows: '18-'20 PWWC Docs > Committee Charge > a. Guideline > \*Updated\* Retail Produce Washing Steps (Just in case, attached to the conference call notes email is a Word document of the table)

**Action Items:**

- For those of you that have not done so, please read the Antitrust Statement (a copy of it is below) and acknowledge that you have read and understood the statement through sending an email to both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)); currently, only eight (8) committee members have read and acknowledged the statement via email.
- Review the Retail Produce Washing Steps table, specifically the comments/questions in *red italics*, and populate with references and comments that are scientifically supported. Please provide comments in the Word document and email to both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- From the poll Anna sent via email, the **next conference call will occur on Monday, December 17, 2018, from 3:00 PM – 4:00 PM EST**. Jaime will be sending a calendar invite.
- Provide scientifically-based comments with references on any time limitations for produce washing, especially if produce is washed by submerging in water. Email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) with this information.

PWWC Conference Call Notes

11/26/2018

- Since crisping will be discussed in the next conference call, please review the crisping definition from 2016-2018 committee work and email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) with any comments. The crisping definition (CFP PWWC 2016-2018) is included in the Retail Produce Washing Steps table.
- Contact organizations outside of the committee (Ex. FMI, Nat'l Restaurant Assoc., Nat'l Produce Assoc., FDA, etc.) in order for them to provide their input on the following question (**If crisping produce is accomplished by submersion, is washing the produce necessary beforehand?**). Carbon Copy both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) on these emails.
- Email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) if interested in being a member of the subgroup for subcharge 1c (Clarify the types of chemicals and their use for washing and crisping).



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PWWC Conference Call Notes  
12/17/2018

**Attendees:**

- Voting Members:  
Al Baroudi, Carol Culbert, Erich Hess, Jill Hollingsworth, Barbara Ingham, Dianna Karlicek, Karl Matthews, Jennifer Nord, Hilary Thesmar, Anna Starobin, Jaime Hernandez
- At-Large Members:  
Rick Barney, Janet Buffer, Betsy Craig, Chip Manuel, Carol McInnes, Kathleen O'Donnell, Matthew Reighter, Todd Rossow, Chuck Seaman, Matthew Walker, Woo Jin Yoo

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- Roll Call: Deanna Copeland (excused), Jason Dickhaut (excused), Amanda Garvin (excused), Josh Jordan (unexcused), Tom McMahan (unexcused), Chris Peasley (unexcused), Kris Zetterlund (unexcused) were voting members that were absent from the call.
- Laurie Williams, the FDA consultant for this committee, provided FDA feedback on crisping. She mentioned that since there is no current FDA definition for crisping, it is important to distinguish between produce washing and produce crisping, as defined in our committee charge. She also mentioned that the FDA has recently created a guide to minimize food safety hazards in fresh-cut produce for industry. This guide includes parameters for produce washing, involving soaking and submerging, which we can reference for our guidance document.

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623718.pdf>

Laurie stated that Food Code does not have any details on the process of produce washing, while the Annex of the code advises against produce soaking, due to potential infiltration issues. Hillary Thesmar commented on the fact that the guide document addresses produce for the fresh cut industry, while the FDA Food Code covers produce washed at retail establishments. Laurie agreed with the comment, but stated that some information from the new guide could be useful.

- Crisping methods were discussed with the committee members, and edited, in real time in the table. Currently, four (4) crisping methods were discussed and noted in the table. These methods include:
  - A. Prechilled produce placed in warm water, and placed in a clean container into a cooler

PWWC Conference Call Notes

12/17/2018

- B. Submerging pre-washed produce in cold water; ice made from potable water could be added to maintain the temperature
- C. Submerging unwashed produce in cold water with antimicrobial; ice made from potable water could be added to maintain the temperature
- D. Holding produce under cold, running water for a time sufficient for rehydration

Misting was discussed as a potential crisping option, however, it was decided that misting is to **maintain** hydration of the produce (prevent dehydration/browning) and that soaking is not involved in the misting process, a “single-pass spray system” with potable water is being used. The path for the table within the PWWC folder in GoogleDrive is as follows: **18-'20 PWWC Docs > Committee Charge > a. Guideline > \*Updated\* Retail Produce Washing Steps** (Just in case, attached to the conference call notes email is a Word document of the table)

- Creation of a subgroup for subcharge 1c: “Clarify the types of chemicals and their use for washing and crisping” was discussed. Committee members interested in working this subgroup include Janet Buffer, Jill Hollingsworth, Todd Rossow, Anna Starobin, and Jaime Hernandez.
- Jill Hollingsworth volunteered to begin drafting the format for the Produce Washing and Crisping guidance document. Committee members Erich Hess, Todd Rossow, Anna Starobin, and Jaime Hernandez are interested in assisting Jill.

**Action Items:**

- For those of you that have not done so, please read the Antitrust Statement (a copy of it is below) and acknowledge that you have read and understood the statement through sending an email to both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)); currently, only ten (10) committee members have read and acknowledged the statement via email.
- Laurie Williams provided a link (<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623718.pdf>) to view a recently created FDA guide to minimize food safety hazards in fresh-cut produce for industry. Please take the time to read this guide, as it can be a great reference document for when we write-up our produce washing and crisping guideline.
- Review the four (4) crisping methods in the table. Please provide comments regarding the 4 methods, provide any other crisping processes not listed, and email to both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) so that our table can be updated.
- The **next conference call will occur on Monday, January 28, 2019, from 3:00 PM – 4:00 PM EST**. A calendar invite for this call will be sent shortly.
- Email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) if interested in being a member of the subgroup for subcharge 1c (Clarify the types of chemicals and their use for washing and crisping).
- Email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) if interested in aiding Jill Hollingsworth in drafting the format for the Produce Washing and Crisping guidance document.



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PWWC Conference Call Notes  
1/28/2019

**Attendees:**

- Voting Members:  
Al Baroudi, Carol Culbert, Deanna Copeland, Amanda Garvin, Erich Hess, Jill Hollingsworth, Barbara Ingham, Josh Jordan, Dianna Karlicek, Tom McMahan, Karl Matthews, Jennifer Nord, Todd Rossow, Anna Starobin, Jaime Hernandez
- At-Large Members:  
Carol McInnes, B.J. Mikeska, Kathleen O'Donnell, Matthew Reighter, Nela Romo, Chuck Seaman, Matthew Walker, Woo Jin Yoo
- FDA Consultants:  
Kenya Moon, Laurie Williams

**Committee Charges:**

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:
  - a. Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.
  - b. Describe the criteria for produce crisping vs. produce washing.
  - c. Clarify the types of chemicals and their use for washing and crisping.
2. Report findings and recommendations back to the 2020 Conference for Food Protection Biennial Meeting.

**PWWC GoogleDrive link:** (no need for Google Account or Google login)

[https://drive.google.com/drive/folders/158-NUmDMYs3eZ\\_5WXIcbslm8qLR3TbpP?usp=sharing](https://drive.google.com/drive/folders/158-NUmDMYs3eZ_5WXIcbslm8qLR3TbpP?usp=sharing)

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- Roll Call: Jason Dickhaut (excused), Hilary Thesmar (unexcused), Chris Peasley (unexcused), Kris Zetterlund (unexcused) were voting members that were absent from the call.
- Anna and Jaime recently completed the CFP Spring Progress Report for this committee. The report was submitted to both Keith Jackson and Christine Applewhite for review. Keith verified that he had received the report and will review said report this week. If any committee members are interested in viewing the progress report, please email Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) or Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) and they will send the report after it is approved by Keith and Christine.
- Jill Hollingsworth discussed progress made in the Draft Guideline subcommittee working group. Other members of this group include Amanda Garvin, Jaime Hernandez, Erich Hess, Todd Rossow, and Anna Starobin. Communication within this subgroup has been accomplished through emails and calls. Jill mentioned that an outline of the guidance document has been made. Sections within this document include an Introduction, Definitions, FDA Food Code References, Prerequisites, and detailed sections on the procedures of Produce Washing and Produce Crisping; Washing and Crisping are split into separate sections because the procedures for each process serve different purposes. For the Washing and Crisping sections, different procedures are stated for each process, including manners to mitigate the potential risks that are inherent for each procedure. In other words, these sections will have a significant emphasis on risk analysis, which will include a table of all procedures for each process, with an accompanying "decision tree" for each process.

## PWWC Conference Call Notes

1/28/2019

- Crisping methods were discussed with the committee members, and edited, in real time in the table. Jill mentioned that in some cases, submersion in cold water and crisping are performed without prewashing produce. This generated a discussion of the permissibility of crisping without prewashing, as this method has potential infiltration implications. Erich Hess mentioned that infiltration is temperature-dependent; produce has to maintain cold throughout the chain to minimize infiltration. Dr. Karl Matthews, stated that infiltration rates are commodity-specific; cut produce has a higher propensity for infiltration than uncut produce. He stated that in a limited research his group has done, the water uptake measured ranged from 5-15%. No micro work was done in this testing.
- Anna and Jill are contacting an academia expert to talk with the group on crisping, water uptake research.
- Laurie Williams asked if leafy greens are the only produce, we are covering. Anna responded that crisping applies to all produce, but most often used for leafy greens.
- Crisping methods were further discussed and the table was updated as listed below:
  - (A1)Prechilled produce placed in warm water, and placed in a clean container into a cooler
  - (A2)Prechilled produce placed in warm water with antimicrobial, and placed in a clean container into a cooler
  - (B1)Submerging pre-washed produce in cold water, ice made from potable water could be added to maintain the temperature.
  - (B2)Submerging pre-washed produce in cold water with a/m, ice made from potable water could be added to maintain the temperature.
  - (C1)Submerging unwashed produce in cold water with antimicrobial, ice made from potable water could be added to maintain the temperature.
  - (C2)Submerging unwashed produce in cold water, ice made from potable water could be added to maintain the temperature
  - (D)Hold the produce under the running cold water for time sufficient for rehydration.

### Action Items:

- For those of you that have not done so, please read the Antitrust Statement (a copy of it is below) and acknowledge that you have read and understood the statement through sending an email to both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)); currently, only ten (10) committee members have read and acknowledged the statement via email.
- Review the listed crisping methods in the table. Please provide comments regarding the methods, provide any other crisping processes not listed, and email to both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) so that our table can be updated.
- Since the next call is scheduled on Monday, February 18, 2019 (President's Day), the **next conference call will occur on Monday, February 25, 2019, from 3:00 PM – 4:00 PM EST.**
- Email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) if interested in being a member of the subgroup for subcharge 1c (Clarify the types of chemicals and their use for washing and crisping).
- Email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) if interested in aiding Jill Hollingsworth in drafting the format for the Produce Washing and Crisping guidance document.



## *Conference for Food Protection Antitrust Statement*

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PWWC Conference Call Notes  
2/25/2019

**Attendees:**

- Voting Members:  
Carol Culbert, Deanna Copeland, Jason Dickhaut, Amanda Garvin, Erich Hess, Jill Hollingsworth, Josh Jordan, Tom McMahan, Karl Matthews, Jennifer Nord, Hilary Thesmar, Kris Zetterlund, Jaime Hernandez
- At-Large Members:  
Rick Barney, Janet Buffer, Betsy Craig, Carol McInnes, Jaymin Patel
- FDA Consultants:  
Kenya Moon, Laurie Williams

**Committee Charges:**

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:
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- Roll Call: Al Baroudi (excused), Barbara Ingham (excused), Dianna Karlicek (excused), Todd Rossow (excused), Chris Peasley (unexcused), Anna Starobin (excused) were voting members that were absent from the call.
- Jill Hollingsworth discussed progress made in the Draft Guideline subcommittee working group. Other members of this group include Amanda Garvin, Jaime Hernandez, Erich Hess, Todd Rossow, and Anna Starobin. The subcommittee has compiled a washing and crisping methods chart that was discussed during the call.
  - Jill mentioned that food establishments may hold whole or fresh-cut produce in either cold or ice water for extended periods of time to maintain its crisp quality and asked if this practice is permissible per FDA Food Code. FDA consultant Laurie Williams mentioned that 3-302.12(c) of the Food Code states that raw produce, both whole and cut, may be immersed in ice water. She also stated that there are no specific time parameters for such practice delineated in the Food Code; this may be a topic to address in the guidance document.
  - Karl Matthews questioned the term “tepid water” that is used in the washing and crisping methods chart. Jill stated that tepid water is used with cold produce in order to minimize infiltration. Although acceptable for produce washing, this is ineffective for produce crisping as crisping requires the produce to uptake water. There was also a discussion regarding the wording in the term “tepid water.” Deanna Copeland mentioned that the temperature of water from the cold water tap will greatly differ nationwide. For example, during Texas summers, water from the cold water tap may be around 90°F, whereas in a northern state, water may be around 70°F. Due to this high variability in water temperatures from the cold tap, it was decided that “lukewarm” and “tepid” should both be used. There was another discussion regarding the crisping of cut produce, however, it was decided that the guidance

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2/25/2019

document that we are charged to complete should only relate to whole, uncut produce. Jaime mentioned that this statement should be noted in the introduction section of the guidance document.

- Deanna Copeland discussed that she edited the Retail Produce Product flowchart that was created months ago. She reorganized said flow chart so that it would be easier to follow. Jaime mentioned that this flowchart will be incorporated in our guidance document, to be used as a “decision tree” in conjunction with the washing and crisping methods chart.

**Action Items:**

- For those of you that have not done so, please read the Antitrust Statement (a copy of it is below) and acknowledge that you have read and understood the statement through sending an email to both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- Review the washing and crisping methods chart discussed during the call. Please provide edits/ comments and email to Jill Hollingsworth ([jillh@chemstarcorp.com](mailto:jillh@chemstarcorp.com)), Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- Review the flowchart Deanna Copeland edited and send an email with any comments to Deanna Copeland ([Deanna.Copeland@phs.hctx.net](mailto:Deanna.Copeland@phs.hctx.net)), Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- **The next conference call will occur on Monday, March 25, 2019, from 3:00 PM – 4:00 PM EST.**
- Email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) if interested in being a member of the subgroup for subcharge 1c (Clarify the types of chemicals and their use for washing and crisping).
- Email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) if interested in aiding Jill Hollingsworth in drafting the format for the Produce Washing and Crisping guidance document.



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PWWC Conference Call Notes  
3/25/2019

**Attendees:**

- Voting Members:  
Al Baroudi, Carol Culbert, Jason Dickhaut, Erich Hess, Jill Hollingsworth, Dianna Karlicek, Tom McMahan, Karl Matthews, Hilary Thesmar, Kris Zetterlund, Anna Starobin, Jaime Hernandez
- At-Large Members:  
Rick Barney, Chip Manuel, B.J. Mikeska, Kathleen O'Donnell, Nela Romo, Matthew Walker
- FDA Consultants:  
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**Committee Charges:**

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:
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- Roll Call: Deanna Copeland (absent), Amanda Garvin (excused), Barbara Ingham (absent), Josh Jordan (excused), Jennifer Nord (excused), Chris Peasley (absent) were voting members that were absent from the call.
- Anna Starobin had a question directed toward CFP Board members Christine Applewhite and Keith Jackson regarding whether or not SOPs of produce handling, from receiving to storage prior to produce washing, falls within the scope of our committee charges. Christine stated that based on the way the charges are written, some of the precursory info at the beginning of the SOP is outside the scope of the charges, specifically statements on approved sources and supplier. Christine also stated that information, like employee health and hygiene, could be mentioned, if desired, but in a very brief format with relevant FDA Food Code references.
- Jill Hollingsworth discussed progress made in the Draft Guideline subcommittee working group. Other members of this group include Rick Barney, Janet Buffer, Amanda Garvin, Jaime Hernandez, Erich Hess, Todd Rossow, and Anna Starobin. The subcommittee has compiled a washing and crisping methods chart that was discussed during the call.
  - FDA consultant Laurie Williams will review the chart and send feedback to Anna.
  - Al Baroudi asked if using ozone for produce washing applies to the chart, specifically W3. Anna suggested adding "on-site generation" wording to the table, in order to be inclusive with other chemicals that may be generated on-site for washing. Jill requested Al to provide language for on-site generated chemical use to be added to the chart.
  - Kris Zetterlund had a concern regarding the "crisping of unwashed produce" that is stated in the crisping section of the chart. Jill remarked that washing and crisping produce is sometimes performed in one-step; for this reason, the "crisping of unwashed produce" is stated in the chart. Erich Hess noted that the

PWWC Conference Call Notes

3/25/2019

washing and crisping distinction depends on the end-use of the produce, meaning if the produce will be on display for sale versus produce being further processed for direct consumption. Jill responded that in the crisping section of the chart, it is noted that crisping unwashed produce will require frequent change of the crisping water, due to the accumulative organic load within said water. In order to address Kris' concern, Jill recommended to state the frequent water change for the considerations sections related to the crisping of unwashed produce and to potentially merge the unwashed with the prewashed sections.

- Hilary Thesmar had concerns regarding the lack of a distinction in the chart of whole produce versus cut produce and the lack of specific produce-type commodities in the chart. Anna stated that this committee's charges are only regarding whole, uncut produce. Jaime stated also that Hilary's concerns will be addressed in the introduction section of this guidance document.
- Kris Zetterlund volunteered to join the Draft Guideline subcommittee working group.

**Action Items:**

- For those of you that have not done so, please read the Antitrust Statement (a copy of it is below) and acknowledge that you have read and understood the statement through sending an email to both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- Review the washing and crisping methods chart discussed during the call. Please provide edits/ comments and email to Jill Hollingsworth ([jillh@chemstarcorp.com](mailto:jillh@chemstarcorp.com)), Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- **The next conference call will occur on Monday, April 22, 2019, from 3:00 PM – 4:00 PM EST.**
- Email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) if interested in aiding Jill Hollingsworth in drafting the format for the Produce Washing and Crisping guidance document.



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## PWWC Conference Call Notes

4/22/2019

### Attendees:

- Voting Members:  
Al Baroudi, Deanna Copeland, Jason Dickhaut, Amanda Garvin, Erich Hess, Jill Hollingsworth, Josh Jordan, Dianna Karlicek, Tom McMahan, Karl Matthews, Todd Rossow, Hilary Thesmar, Kris Zetterlund, Anna Starobin, Jaime Hernandez
- At-Large Members:  
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- FDA Consultants:  
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### Committee Charges:

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- Roll Call: Carol Culbert (excused), Barbara Ingham (excused), Jennifer Nord (excused), Chris Peasley (excused) were voting members that were absent from the call.
- Jill Hollingsworth discussed progress made in the Draft Guideline subcommittee working group. Other members of this group include Rick Barney, Janet Buffer, Amanda Garvin, Jaime Hernandez, Erich Hess, Todd Rossow, Kris Zetterlund, and Anna Starobin. The subcommittee has compiled a washing and crisping methods chart that was discussed during the call.
  - On-site generated antimicrobials was the major topic of discussion related to the chart during this call. Jill mentioned the distinction between on-site generated antimicrobials versus systems that use EPA approved concentrated chemicals diluted with water; such methods are mutually exclusive. Anna mentioned that the risk reduction step of using on-site generated antimicrobials is the same as using other antimicrobials; the only difference is how the product is registered. Stating this, Anna questioned whether adding on-site generated antimicrobials as a separate method is redundant. Al Baroudi commented that on-site generated antimicrobials should be mentioned in the chart, however, it could be combined with other methods already listed. Jill was hesitant about combining such methods because other methods that use antimicrobials discussed in the table already emphasizes their specific intended use, which may be different than the specific intended use of on-site generated antimicrobials. Amanda Garvin noted that since on-site generated antimicrobials are often not encountered in the field in retail food establishments, this topic should not be too in-depth in the chart, as it may cause

## PWWC Conference Call Notes

4/22/2019

confusion to its intended audience. Laurie Williams agreed that it may cause confusion, and that on-site generated antimicrobials should maybe be added as a footnote in the chart.

- Anna discussed progress made in the chemicals document related to sub charge 1c. She mentioned that based on the feedback from regulators in the subcommittee, this document needs to be simplified so that it can be easily understood by its intended audience. Erich Hess agreed that the intended audience has to be kept in mind when creating this document and that the current document does not meet the sub charge. Specifically, this document should specifically address what are the chemical options and how to use them. Hilary Thesmar, noted that Food retail employees developing such programs are highly educated and well versed in regulations related to the chemical use and their choices. Therefore, comprehensive information needs to be kept in this document. Anna noted that two versions for different audiences could be created.
- FDA Consultant Laurie Williams provided an update related to the FDA reviewing the washing and crisping chart. She mentioned that CFSAN Produce Safety has two branches- one branch has already reviewed the document and has recommended that the other branch review the document as well. With that said, she wants to send back he comments to the committee once both branches have reviewed the chart and that she is expecting to send the comments in the next two weeks.

### Action Items:

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- Review the washing and crisping methods chart discussed during the call. Please provide edits/ comments and email to Jill Hollingsworth ([jillh@chemstarcorp.com](mailto:jillh@chemstarcorp.com)), Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- Review the chemicals document discussed during the call. Please provide edits/ comments and email to Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- **The next conference call will occur the week of May 20, 2019, from 3:00 PM – 4:00 PM EST (exact day still pending)**, since the regular call was scheduled for May 29 (Memorial Day).
- Email both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)) if interested in aiding Jill Hollingsworth in drafting the format for the Produce Washing and Crisping guidance document.



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PWWC Conference Call Notes  
5/20/2019

**Attendees:**

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- At-Large Members:  
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- FDA Consultants:  
Kenya Moon, Laurie Williams
- CFP:  
Keith Jackson

**Committee Charges:**

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:
  - a. Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.
  - b. Describe the criteria for produce crisping vs. produce washing.
  - c. Clarify the types of chemicals and their use for washing and crisping.
2. Report findings and recommendations back to the 2020 Conference for Food Protection Biennial Meeting.

**PWWC GoogleDrive link:** (no need for Google Account or Google login)

[https://drive.google.com/drive/folders/158-NUmDMYs3eZ\\_5WXlcbSlm8qLR3TbpP?usp=sharing](https://drive.google.com/drive/folders/158-NUmDMYs3eZ_5WXlcbSlm8qLR3TbpP?usp=sharing)

**Notes:**

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- Roll Call: Deanna Copeland (absent), Barbara Ingham (excused), Karl Matthews (absent), Hilary Thesmar (excused), Jaime Hernandez (excused) were voting members that were absent from the call.
- Jill Hollingsworth discussed the draft of the guidance document compiled by the subcommittee. During her discussion, she provided details to each section within said document.
- Amanda Garvin provided her feedback of the document. Her main feedback point was related to the generated on site (GOS) antimicrobial chemicals. As a Regulator, she noted that GOS are rarely used and it might be unnecessary to include this option into the table. She suggested to remove W6 and C5. Since this is an uncommon practice, she suggested to mention on-site generated antimicrobial treatments in the preface of the charts. Voting members of this committee will vote on this issue during the next call. Dr. Baroudi, who uses GOS, commented that keeping this method in the document would inform readers who are not familiar with this technology.
- Anna explained the differences between Food Contact (FC) sanitizers vs. produce washing antimicrobial treatments. She reiterated that both have different uses, different test methods and microorganisms to show antimicrobial efficacy. FC sanitizers have to achieve a 5-log reduction in 1 minute, while registered antimicrobial treatments are tested against the pathogens most commonly implicated in produce related outbreaks (*E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*) and need to provide a 3-log reduction in wash water. She also restated that this guidance document only pertains to RACs, not for fresh-cut or further processed produce. Tom

## PWWC Conference Call Notes

5/20/2019

McMahan stated that a clarifying statement noting that the guidance document is not intended for fresh-cut produce should be added, since fresh-cut produce is defined in the document and suggested to remove any references relevant to fresh-cut produce.

- Anna mentioned that she has submitted the chemical charts to the FDA for review. Laurie Williams will follow-up on this during the next conference call.
- Keith Jackson reminded the committee that all committee work needs to be approximately 75 – 95% complete by August.

### Action Items:

- For those of you that have not done so, please read the Antitrust Statement (a copy of it is below) and acknowledge that you have read and understood the statement through sending an email to both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- Review the draft guidance document. Please provide edits/ comments **by June 7th** and email to Jill Hollingsworth ([jillh@chemstarcop.com](mailto:jillh@chemstarcop.com)), Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- **The next conference call will occur Monday, June 24, 2019, from 3:00 PM – 4:00 PM EST.**



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## PWWC Conference Call Notes

6/24/2019

### Attendees:

- Voting Members:  
Al Baroudi, Carol Culbert, Deanna Copeland, Jason Dickhaut, Amanda Garvin, Erich Hess, Jill Hollingsworth, Barbara Ingham, Dianna Karlicek, Tom McMahan, Jennifer Nord, Anna Starobin, Jaime Hernandez
- At-Large Members:  
Rick Barney, Chip Manuel, Carol McInnes, Matthew Reighter, Nela Romo, Chuck Seaman, Matthew Walker
- FDA Consultants:  
Kenya Moon
- CFP:  
Christine Applewhite, Keith Jackson

### Committee Charges:

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:
  - a. Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.
  - b. Describe the criteria for produce crisping vs. produce washing.
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- Roll Call: Josh Jordan (excused), Karl Matthews (excused), Todd Rossow (excused), Hilary Thesmar (excused), Chris Peasley (absent), Kris Zetterlund (excused) were voting members that were absent from the call.
- Jill Hollingsworth discussed the draft of the guidance document compiled by the subcommittee. This draft contains comments made by FDA and responses to those comments. During her discussion, she provided details regarding changes/updates to each section within said document. Changes to the document include adding a section on sanitizers versus disinfectants, revising the definitions, and separating the washing and crisping tables into two separate sections.
  - Barbara Ingham suggests being consistent with language used in the document (ex. washing and rinsing)
- Anna discussed changes that were made to the chemicals diagram/chart. Changes include consolidating the chemical diagrams for produce wash treatments and produce was treatments with antimicrobial claims into one diagram.
- Anna shared the feedback provided by FDA, in which they stated that FDA does not support crisping or washing produce by soaking in water. Advice on further committee steps was sent to CFP.
- Anna mentioned that both she and Jaime created a draft of the Fall Committee Progress Report and sent the draft to both Keith Jackson and Christine Applewhite for review. Keith mentioned that he will provide comments by the end of the week.

PWWC Conference Call Notes  
6/24/2019

**Action Items:**

- For those of you that have not done so, please read the Antitrust Statement (a copy of it is below) and acknowledge that you have read and understood the statement through sending an email to both Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- Review the draft guidance document and chemicals diagram/chart. Please provide edits/ comments and email to Jill Hollingsworth ([jillh@chemstarcorp.com](mailto:jillh@chemstarcorp.com)), Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- **The next conference call will occur Monday, July 29, 2019, from 3:00 PM – 4:00 PM EST.** Initially, the next conference call was scheduled for Monday, July 22, 2019, however, several committee members will be attending the IAFP Conference that week.



## *Conference for Food Protection Antitrust Statement*

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PWWC Conference Call Notes  
7/29/2019

**Attendees:**

- Voting Members:  
Al Baroudi, Carol Culbert, Jason Dickhaut, Amanda Garvin, Erich Hess, Jill Hollingsworth, Barbara Ingham, Dianna Karlicek, Jennifer Nord, Todd Rossow, Hilary Thesmar, Chris Peasley, Kris Zetterlund, Anna Starobin, Jaime Hernandez
- At-Large Members:  
Rick Barney, Chip Manuel, Carol McInnes, Nela Romo

**Committee Charges:**

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:
  - a. Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.
  - b. Describe the criteria for produce crisping vs. produce washing.
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2. Report findings and recommendations back to the 2020 Conference for Food Protection Biennial Meeting.

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- Roll Call: Deanna Copeland (absent), Josh Jordan (absent), Tom McMahan (absent), Karl Matthews (absent) were voting members that were absent from the call.
- Anna discussed submitting the Fall Committee Report to the CFP Board. The report was submitted and within this report, a request was made for the CFP Board to advise the Produce Wash Water Committee group on the best manner of pursuing with the guidance document to ensure that it is both meaningful and that it aligns with our committee charges.
- Anna also mentioned that both Jill and she had an opportunity to meet with the Director of CFP, Dave McSwane, and CFP Board member Brenda Bacon during the IAFP meeting held last week. They discussed the challenges related to the guidance document. A conference call with CFP Board members, Anna, Jaime, and FDA consultants will be held on Wednesday, July 31, 2019, in order to follow-up on what was discussed during IAFP. The CFP Board members also invited Anna to attend the CFP Board meeting on August 13; Anna will be representing the work that this committee has done thus far during the Board Meeting.
- Jill Hollingsworth discussed the draft of the guidance document compiled by the subcommittee. Specifically, she reviewed comments made by FDA and responses to those comments. Several of the comments were provided by FDA representatives that deal with processed produce.
- Laurie Williams reviewed the 5 Steps for Retail Policy Debate. They are as follows... (1) Clearly define the problem that needs to be addressed, (2) Clearly describe the cause of the problem (3) Clearly describe why the status quo is not addressing the problem (4) Clearly present your recommended policy solution and explain why it should be preferred over possible alternatives (5) Clearly state the potential consequences of implementing the recommended policy solution. She mentioned that the 5 Steps will be made available shortly on the FDA website and will discuss with the group at a later conference call.
- Jill asked the group if they had any suggestions related to formatting of the guidance document. She mentioned that CFP has no preference, as long as consistency is being maintained throughout the document.

PWWC Conference Call Notes  
7/29/2019

**Action Items:**

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- Review the draft guidance document. Please provide edits/ comments and email to Jill Hollingsworth ([jillh@chemstarcorp.com](mailto:jillh@chemstarcorp.com)), Anna ([Anna.Starobin@ecolab.com](mailto:Anna.Starobin@ecolab.com)) and Jaime ([Jaime.Hernandez@dc.gov](mailto:Jaime.Hernandez@dc.gov)).
- **The next conference call will occur Monday, August 26, 2019, from 3:00 PM – 4:00 PM EST.**



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PWWC Conference Call Notes  
8/26/2019

**Attendees:**

- Voting Members:  
Al Baroudi, Carol Culbert, Deanna Copeland, Jason Dickhaut, Amanda Garvin, Erich Hess, Jill Hollingsworth, Josh Jordan, Dianna Karlicek, Tom McMahan, Jennifer Nord, Todd Rossow, Hilary Thesmar, Chris Peasley, Anna Starobin
- At-Large Members:  
Carol McInnes, Nela Romo

**Committee Charges:**

1. Develop a Produce Washing and Crisping Guidance document for Retail Food Establishments which includes the following:
  - a. Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.
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- Roll Call: Barbara Ingham (absent), Karl Matthews (absent), Kris Zetterlund (excused), Jaime Hernandez (excused) were voting members that were absent from the call.
- Anna attended the CFP Board meeting in August. She attended the meeting so that the Board could provide clarification for the next steps of this committee, based on FDA's position on crisping.
- Keith Jackson provided updates from the CFP Board. He mentioned that the Board accepted the PWWC Fall Report as submitted. The CFP Board understands the situation of the PWWC Committee in relation to fulfilling the crisping-related charges and FDA's position on crisping. Due to this situation, all mentions of crisping within the guidance document have been "compartmentalized" so that the committee can easily edit the document if the Council decides to edit or redact crisping during deliberation.
- Christine Applewhite mentioned that a CFP Board member stated that the PWWC guidance document is in response to the charges to CFP- in other words, the committee is ultimately responding to CFP; as long as the charges are fulfilled, CFP will have no conflicts with the document, with the understanding that FDA does not condone crisping. Amanda Garvin added that in the past, CFP has accepted documents and placed them on the CFP website that were not accepted by the FDA.
- Glenda Lewis (FDA) re-iterated that FDA supports the CFP process, however, still does not support the practice of crisping. She recommends to continue with creating the guidance document; Anna agrees.
- Anna reviewed the chemical diagram and table. There are currently two versions- one version is the initial document and the other is one that addresses comments provided by the FDA.
- Jill Hollingsworth reviewed on the progress made in the guidance document. Progress includes editing the disclaimer, citing references, clarifying definitions, "compartmentalizing" crisping within the document for easy extraction, if necessary.

PWWC Conference Call Notes  
8/26/2019

**Action Items:**

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PWWC Conference Call Notes  
10/3/2019

**Attendees:**

- Voting Members:  
Al Baroudi, Carol Culbert, Deanna Copeland, Jason Dickhaut, Amanda Garvin, Erich Hess, Jill Hollingsworth, Barbara Ingham, Josh Jordan, Jennifer Nord, Todd Rossow, Hilary Thesmar, Chris Peasley, Anna Starobin, Jaime Hernandez
- At-Large Members:  
Nela Romo, Matthew Walker

**Committee Charges:**

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- Roll Call: Diana Karlicek (excused), Tom McMahan (absent), Karl Matthews (absent), Kris Zetterlund (absent) were voting members that were absent from the call.
- Keith Jackson discussed deadlines for submitting our committee work and issues. Specifically, he mentioned that everything has to be complete and submitted with committee consensus to the CFP Council by **November 1, 2019**. Anna and Jaime will complete a Committee Report for this submission. Keith and Christine Applewhite will then review said report and supporting documents, to be submitted to the CFP Board by **December 1, 2019**. Keith also recommended to begin writing issues to be submitted. The issue submission process will begin in **December 2019**; CFP will send out an announcement regarding this shortly. Keith also mentioned that the Committee will have to submit an issue for the Council to acknowledge the report.
- Anna mentioned that Laurie Williams has contacted her, stating that FDA will review the latest version of the guidance document; comments made by the FDA will be sent next week.
- Jill Hollingsworth mentioned that the comments received regarding the guidance document were suggested word changes and clarifications. She also mentioned that the guidance document was reorganized to have a better flow. For example, the definitions section was placed after the introduction. Also, the "Sanitizers vs. Disinfectants" section was restructured to provide better clarification. Additionally, the document was reorganized to have "washing" and "crisping" as separate sections. Also, citations were verified and inserted into the document using the American Medical Association (AMA) method.
- Anna summarized our current status/plans based on FDA objection to crisping and washing by submersion. Committee will submit the document as-is (with crisping and washing by submersion), in order to address the committee charges. Laurie Williams confirmed this understanding between the CFP committee and FDA.
- Amanda Garvin suggested an issue to submit to CFP. The issue to be submitted relates to requirements for testing the concentration of EPA-registered produce wash chemicals in water. Currently, there are no such parameters delineated in the 2017 FDA Food Code. Anna suggested to clarify that this issue only applies for EPA-

PWWC Conference Call Notes

10/3/2019

registered chemicals. Jill suggested we do not include additional burdens on retailers and not be prescriptive about the frequency of monitoring or record keeping.

**Action Items:**

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-008**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

PWWC - Issue 2: Approval and Posting of Guidance Document.

**Issue you would like the Conference to consider:**

The Produce Wash Water Committee was re-created at the 2018 Biennial Meeting. The Committee was charged to develop a Produce Washing and Crisping Guidance Document for Retail Food Establishments. This Committee completed the charges assigned. The Committee is requesting for the Conference for Food Protection to post the created "Guide for Washing and Crisping Whole, Raw Fruits and Vegetables at Retail Food Establishments" guidance document on their website.

**Public Health Significance:**

Whole or fresh-cut produce may contain pathogenic microorganisms and at times have been associated with foodborne illness and outbreaks. Efforts have been undertaken by the produce industry and regulators (e.g., FSMA and the Produce Safety Rule) to minimize the risk of contamination of fresh produce. However, without a "kill step" a potential risk remains. In the event that contaminated product is received into a food establishment, washing and crisping practices introduce an additional risk. In food establishments, produce is washed before being cut, etc. as per the recommendation of the 2017 FDA Food Code, but it should be noted that washing has a limited effect on removing pathogens from the produce surface. When produce items are submerged in water the chance for cross-contamination presents a public health risk. Further, the practice of crisping could introduce an additional risk since contaminated water may internalize pathogens during the crisping process. When other procedures such as washing/sanitizing the sink before use are not followed, food contact surfaces can also contribute to cross-contamination. Taken together, these practices demonstrate the need to consider additional or alternative efforts to reduce the risks associated with fresh produce handling practices at food establishments.

**Recommended Solution: The Conference recommends...:**

1. Approval of the committee document entitled "*Guide for Washing and Crisping Whole, Raw Fruits and Vegetables at Retail Food Establishments*" (attached to Issue titled: PWWC - Issue 1 Report of Produce Wash Water Committee);
2. Authorizing the Conference to make any necessary edits prior to posting the document to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
3. Posting the guidance document on the CFP website in a downloadable PDF format.

**Submitter Information 1:**

Name: Anna Starobin  
Organization: ECOLAB  
Address: 8300 Capital Dr  
City/State/Zip: Greensboro, NC 27409  
Telephone: 336 931 2185  
E-mail: Anna.Starobin@ecolab.com

**Submitter Information 2:**

Name: Jaime Hernandez  
Organization: DC Health  
Address: 899 North Capitol St NW  
City/State/Zip: Washington, DC 20002  
Telephone: 202-535-2180  
E-mail: Jaime.Hernandez@dc.gov

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-009**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

PWWC- Issue 3: Amend Food Code to include Produce Wash Testing Devices

**Issue you would like the Conference to consider:**

Inclusion of a new section: "4-302.15 Fruit and Vegetable Wash Solutions, Testing Devices" into the next edition of the FDA Food Code which would require establishments who utilize chemicals to wash fruits and vegetables to have a test kit for such chemicals available for use in the establishment.

**Public Health Significance:**

2017 FDA Food Code section 3-302.15 (B) states, "Fruits and vegetables may be washed by using chemicals as specified under § 7-204.12." In the 2017 FDA Food Code Annex 3, 3-302.15, it explains that, "Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations. Unless otherwise stipulated in 21 CFR 173.315, chemicals used to wash or peel fruits and vegetables should not exceed the minimum amount required to accomplish the intended effect, need to be accurately tested for proper concentration, and must adhere to any indications as dictated on the product label."

Currently there is no FDA Food Code requirement to test or verify the concentration of chemicals used to wash fruits and vegetables when listed on the product label. Chemical produce washes which specify concentrations or ranges have been thoroughly reviewed and vetted by FDA and EPA for safety and efficacy. Concentrations exceeding or used at lower concentrations than listed on the product label, would not be appropriate for the intended use of the product. For EPA registered products, lower concentrations may not provide the desired and claimed product efficacy. Produce wash concentration verification is therefore necessary and recommended to prevent usage outside labeled use limits.

In order to assist both users of the chemical and regulators who want to verify proper use of the chemical as per label instructions, a method to verify concentrations for antimicrobial products used for fruit and vegetable washing should be available.

**Recommended Solution: The Conference recommends...:**

Amend the 2017 Food Code by adding a new section: "4-302.15 Fruit and Vegetable Wash Solutions, Testing Devices" as follows:

4-302.15 Fruit and Vegetable Wash Solutions, Testing Devices.

A test kit or other device that accurately measures the concentration of fruit and vegetable wash solution shall be provided if specified on the product label. <sup>Pf</sup>

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-010**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Report–Product Assessment Committee (PAC)

**Issue you would like the Conference to consider:**

The Product Assessment Committee requests acknowledgement of their final report and thanking the committee members for their efforts and hard work.

**Public Health Significance:**

Retail food establishments often want to hold foods that meet the definition of time/temperature control for safety (TCS) food outside of time and temperature parameters within the FDA Food Code. In order to do this, food establishments must do a product assessment or challenge study using the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) protocol. This protocol can be difficult for both operators and regulators to understand. This committee's final report contains a guidance document to help operators and regulators understand retail food establishment challenge studies which in turn will increase compliance with FDA Food Code and help to ease the burden for operators and regulators.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

1. Acknowledgement of 2018-2020 Product Assessment Committee Report;
2. Thank committee members for their work;
3. Committee be disbanded.

**Submitter Information 1:**

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**Submitter Information 2:**

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**Content Documents:**

- "Committee Final Report"
- "Committee Roster"
- "Committee Generated Guidance Document"
- "Checklist for Retail Establishment Challenge Study"
- "Worksheet to Determine Microbiological Stability of Food"

**Supporting Attachments:**

- "PAC Meeting Minutes"

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

**COMMITTEE NAME: Product Assessment Committee**

**DATE OF FINAL REPORT: October 29, 2019**

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

**REPORT SUBMITTED BY:** Veronica Bryant, Product Assessment Committee Chair and Jon Freed, Vice Chair

**COMMITTEE CHARGE(S):**

**Issue # III-024**

The Product Assessment Committee was created to leverage the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) challenge study guidelines document to create tools that are easier for the end users to understand and implement. Charges for this committee include creating:

1. A standardized template and checklist of appropriate criteria to consider when reviewing a challenge study, including directions for use.
2. A tool to assist in selecting appropriate organisms.
3. Standardized guidance on how to interpret results.
4. Direction on when it is appropriate to use computer modeling to either support or replace an inoculation study.
5. Report the committee's findings and recommendations back to the Conference at the 2020 Biennial Meeting.

**COMMITTEE WORK PLAN AND TIMELINE:**

During initial committee meeting September 21, 2018, it was determined that committee work would be accomplished as follows:

1. Committee work will be split into two subcommittees. Subcommittee #1 will handle charges, 2 (create a tool to assist in selecting appropriate organisms) and 4 (direction on when it is appropriate to use computer modeling to either support or replace an inoculation study). Subcommittee #2 will handle the charges 1 (create a standardized template and checklist of appropriate criteria to consider when reviewing a challenge study) and 3 (direction on how to interpret results).
2. Subcommittees will be allowed to do work concurrently and will work on charges subsequently.
3. Subcommittee #1 will be led by chair Veronica Bryant and will consist of Bryant, Burgess, Burns-Savage, Bush, Krzyzanowski, Willis, Bongo-Box, Derr, Karlicek, Mers, and Schaffner. Phone conferences will be held monthly on the first Friday of each month at 2:00 PM EST to discuss progress on charges.
4. Subcommittee #2 will be led by co-chair Jon Freed and will consist of Freed, Boyer, Curtis, Gordon, Pelech, Romo, Touhey, Wijesekera, Craig, Crownover, Shelton, and Thesmar. Phone conferences will be held monthly on the first Wednesday of each month at 2:00 PM EST to discuss progress on charges.
5. The chair and co-chair will monitor attendance of voting and non-voting members and voting members of the full committee will vote to excuse members if unexcused absence of the voting member becomes a pattern.
6. It is anticipated that work will be completed as follows:
  - a. March 1: Overall guidance document outline completed
  - b. May 1: Guidance document sections for charges 2 and 3 to be completed
  - c. July 1: Product Assessment evaluation checklist completed
  - d. Example challenge study using checklist will be completed by October 1
7. Periodic reports were submitted by March 1, 2019 and July 1, 2019 to the Council III Chair.
8. Final guidance document to be submitted to Council III Chair by November 1, 2019.

## **COMMITTEE ACTIVITIES:**

1. Dates of committee meetings or conference calls: The entire committee met on 9/21/18, 2/15/19, 4/26/19, 8/27/19, and 9/26/19. A smaller workgroup met on 9/11/19.

Sub-Committee #1 met on 11/2/18, 12/7/18, 1/4/19, 2/1/19, 3/1/19, 4/5/19, 5/3/19, 6/7/19.

Sub-Committee #2 met on 12/5/18, 1/2/19 and 2/6/19. There were additional smaller group meetings with section owners on 1/9/19, 1/23/19, 4/17/19 and 5/8/19.

### **2. Overview of committee activities:**

#### **a. Overview of committee activities:**

At the 9/21/18 meeting we decided to break out into two distinct sub-committees with each sub-committee working on two charges. Each of the sub-committees is also splitting work into smaller groups to accomplish charges. Documents are being shared via email, and software programs with shared editing capabilities. At the entire committee meeting on 2/15/19 we aligned to add additional sections to our guidance document (Introduction, definitions and laboratory qualifications). The committee aligned to our timelines with a target date for document completion of 10/1/19.

At the Sub-Committee #1 meeting on 11/2/18 we agreed to start with Charge #2 and move to work on Charge #4 when finished. During the meetings on 11/2/18, 12/7/18, and 1/4/19, it was determined that organism selection needs to highlight Table 2 and Appendix C already in the document, and this information could not be distilled into a flow chart. During the meeting on 2/1/19, final terminology for the outline was discussed and drafted and the committee moved to discuss Charge #4 during the next meeting.

At the Subcommittee #1 meetings on 3/1/19, 4/5/19, and 6/7/19, resolution of the two charges for the subcommittees were completed. Information regarding these charges will be included in the guidance document. The determination was made that computer modeling alone is not a suitable replacement for a challenge study.

At the Sub-Committee #2 meeting on 12/5/18 we agreed on a work strategy to address our charges. By the 1/2/19 meeting we aligned on creating content based on the NACMCF sections 1, 3 and 8 - 11. Our sub-committee assigned out section owners and began to create content. At the 2/6/19 meeting we reviewed first drafts of each section and aligned on a checklist format.

Draft versions of the guidance document were reviewed by all members and discussed during 4/17 and 5/8 committee meetings. A subgroup consisting of Todd Mers, Robert Curtis, Jon Freed and Veronica Bryant met to make final edits to the guidance document and incorporate all changes from the group.

At the 9/11/19 meeting, a group of committee members, FDA representatives, and FSIS representatives met to discuss final document edits. In attendance was Susan Shelton, Jon Freed, Veronica Bryant, Robert Curtis, Charles Idjagboro, and Meryl Silverman. FSIS and FDA concerns with the document were discussed, and edits were made in advance of the final vote.

At the meeting on 9/26/19, the full committee met to discuss the final versions of the documents. There were not enough voting members present at the time of the meeting to have quorum. An email vote was called to vote on the worksheet and the final document. The vote was 9-0 in favor to approve the document. We had 5 voting members who did not vote.

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

- A.a.** Charge #1 Create a standardized template and checklist of appropriate criteria to consider when reviewing a challenge study, including directions for use. *Template is included in Guidance Document and attached as a "content document."*
- A.b.** Charge #2 Create a tool to assist in selecting appropriate organisms. *Tool is included in Section 4.0 of the Guidance Document and attached as a "content document."*
- A.c.** Charge #3 Create standardized guidance on how to interpret results. *Guidance is included as Checklist for Retail Challenge Study and Challenge Testing Worksheet to Determine Microbiological Stability of Formulation and attached as a "content document."*
- A.d.** Charge #4 Provide direction on when it is appropriate to use computer modeling to either support or replace an inoculation study. *Guidance is included in the Section 11.0 of the Guidance Document and attached as a "content document."*

**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. Issue #1: Report - Product Assessment Committee** Acknowledgement of 2018-2020 Product Assessment Committee Report, thank the committee members for their work, and disband the committee.

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

- (a.1)* Committee Member Roster
- (a.2)** Guidance Document entitled, "*Using NACMCF Parameters for Challenge Study Protocols for Retail Food Operators and Regulators*" (see attached PDF).
- (a.3)** Checklist for Retail Establishment Challenge Study
- (a.4)** Challenge Testing Worksheet to Determine Microbiological Stability of Formulation

**b. List of supporting attachments:**  **No supporting attachments submitted**

*Product Assessment Committee Meeting Minutes*

*FSIS Report, Establishment Guidance For the Selection of a Commercial or Private Microbiological Testing Laboratory - <https://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651-b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab-062013.pdf?MOD=AJPERES>*

*Evaluation and Definition of Potentially Hazardous Food - <https://www.fda.gov/downloads/food/foodborneillnesscontaminants/ucm545171.pdf>*

*Parameters for Determining Inoculation Pack/Challenge Study Protocols - [https://www.fsis.usda.gov/wps/wcm/connect/3b52f9c0-0585-4c0a-abf2-b4fc89a9668c/NACMCF\\_Inoculated\\_Pack\\_2009F.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/3b52f9c0-0585-4c0a-abf2-b4fc89a9668c/NACMCF_Inoculated_Pack_2009F.pdf?MOD=AJPERES)*

- 2. Committee Issue #2:** Recommend acceptance of the committee generated guidance document entitled, "*Using NACMCF Parameters for Challenge Study Protocols for Retail Food*"

*Operators and Regulators*” included in Issue #1: Report- Product Assessment Committee and; inclusion of the guidance document on the CFP website in PDF form

**3. Committee Issue #3:** Recommend acceptance of the *“Checklist for Retail Establishment Challenge Study”* included in Issue #1: Report-Product Assessment Committee and; inclusion of the checklist on the CFP website in editable Word and in PDF form.

**4. Committee Issue #4:** Recommend acceptance of the *“Challenge Testing Worksheet to Determine Microbiological Stability of Formulation”* included in Issue #1: Report-Product Assessment Committee and; inclusion of the worksheet in editable Word and in PDF form.

**5. Committee Issue #5:** The Committee recommends a letter be sent to FDA requesting the Food Code, Annex 3 be amended to include the *“Using NACMCF Parameters for Challenge Study Protocol for Retail Food Operators and Regulators”* guidance document reference.

**Committee Name: Product Assessment Committee 14 Voting Members**

<b>Last Name</b>	<b>First Name</b>	<b>Position (Chair/Member)</b>	<b>Constituency</b>
Bryant	Veronica	CHAIR	Regulator - State
Freed	Jonathan	VICE CHAIR	Industry - Retail
Boyer	Renee	Voting Member	Academic
Burgess	Victoria	Voting Member	Industry - Retail
Burns Savage	Nikki	Voting Member	Regulator - Local
Bush	Lauren	Voting Member	Consumer
Curtis	Robert	Voting Member	Industry - Retail
Gordon	Tammy	Voting Member	Regulator - State
Krzyzanowski	Rebecca	Voting Member	Regulator - State
		Voting Member	Regulator - State
Pelech	Todd		
Romo	Nela	Voting Member	Industry - Service
Touhey	Michael	Voting Member	Regulator - Local
Willis	Richard	Voting Member	Industry - Service
Bongo-Box	Christina	At-Large Non-Voting	Industry - Service
		At-Large Non-Voting	
Craig	Betsy		Industry - Support
Crownover	David	Voting Member	Industry - Support
Karlicek	Dianna	At-Large Non-Voting	Regulator - Local
		At-Large Non-Voting	Regulator - State
Mers	Donald Todd		
Schaffner	Don	At-Large Non-Voting	Academia
		At-Large Non-Voting	Regulator - State
Shelton	Susan		
Thesmar	Hilary	At-Large Non-Voting	Industry - Retail
Wijsekera	Dilshika	At-Large Non-Voting	Industry - Retail

22 Total Members (5Industry:5Regulatory:0Academia:1Consumer)

Employer	City	State	Telephone	Email
NC DHHS	Gastonia	NC		<a href="mailto:veronica.bryant@dhhs.nc.gov">veronica.bryant@dhhs.nc.gov</a>
Amazon	Seattle	WA		<a href="mailto:jonfreed@amazon.com">jonfreed@amazon.com</a> ;
Virginia Tech University		VA		<a href="mailto:rraidn@vt.edu">rraidn@vt.edu</a> ;
Publix Super Market	Boynton Beach	FL		<a href="mailto:Victoria.Burgess@Publix.com">Victoria.Burgess@Publix.com</a> ;
Southern Nevada Health District	Las Vegas	NV	702-759-1634	<a href="mailto:ntburns@cox.net">ntburns@cox.net</a> ;
Stop Foodborne Illness	New York	NY		<a href="mailto:lauren31@gmail.com">lauren31@gmail.com</a> ;
Starbucks Coffee Corp	Seattle	WA	415-542-6064	<a href="mailto:rcurtis@starbucks.com">rcurtis@starbucks.com</a>
SCDHEC	Columbia	SC	803-896-0640	<a href="mailto:gordontl@dhec.sc.gov">gordontl@dhec.sc.gov</a> ;
Michigan Department of Ag & RD	Roscomm on	MI	517-719-7919	<a href="mailto:krzyzanowskir@michigan.gov">krzyzanowskir@michigan.gov</a> ;
Arizona Department of Health Services	Phoenix	AZ	602-364-3122	<a href="mailto:todd.peelch@azdhs.gov">todd.peelch@azdhs.gov</a> ;
El Pollo Loco	West Covina	CA	949-689-3101	<a href="mailto:nromo@elpolloloco.com">nromo@elpolloloco.com</a> ;
Washoe County Health District	Reno	NV	775-328-2698	<a href="mailto:mtouhey@washoecounty.us">mtouhey@washoecounty.us</a> ;
Mandalay	Las Vegas	NV		<a href="mailto:rwillis@mandalaybay.com">rwillis@mandalaybay.com</a> ;
Little Caesars Enterprises, Inc	Detroit	MN		<a href="mailto:christina.bongo-box@lcecorp.com">christina.bongo-box@lcecorp.com</a> ;
MenuTrinfo	Fort Collins	CO	970-295-4370	<a href="mailto:menu@menutrinfo.com">menu@menutrinfo.com</a> ;
Microbac Laboratories Inc	Pittsburgh	PA	412-699-0919	<a href="mailto:david.crownover@microbac.com">david.crownover@microbac.com</a> ;
Washoe County Health District	Reno	NV	775-328-2614	<a href="mailto:dkarlicek@washoecounty.us">dkarlicek@washoecounty.us</a> ;
Ohio Department of Agriculture	Reynolds burg	OH		<a href="mailto:tmers@agri.ohio.gov">tmers@agri.ohio.gov</a> ;
Rutgers University	New Brunswick	NJ		<a href="mailto:don.schaffner@rutgers.edu">don.schaffner@rutgers.edu</a> ;
Washington State Department of Health	Olympia	WA	509-212-1206	<a href="mailto:susan.shelton@doh.wa.gov">susan.shelton@doh.wa.gov</a> ;
FMI	Arlington	VA	202-220-0658	<a href="mailto:hthesmar@fmi.org">hthesmar@fmi.org</a> ;
Instacart	Seattle	WA		<a href="mailto:Dilshika.wijesekera@instacart.com">Dilshika.wijesekera@instacart.com</a>

# CFP Guidance Document on Using the NACMCF Parameters for Challenge Study Protocols For Retail Food Operators And Regulators

## Introduction

This document summarizes important points from the NACMCF document to assist retail food operators and regulators to use the document more easily. This document provides practical guidance to retail food facility operators looking to submit a food product for a challenge study, as well as to retail food regulators looking for assistance in reviewing a challenge study for approval. This CFP guidance document will primarily focus on extended holding of food products at room temperature, and extended date marking beyond 7 days, as these are the challenge studies primarily seen at retail. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Parameters for Determining Inoculated Pack/Challenge Study Protocols is the accepted reference for conducting and reviewing challenge studies. The NACMCF document is detailed and comprehensive but may be difficult for some end users to apply without more training. Laboratories conducting challenge studies should have a complete and working understanding of the NACMCF document.

Different parts of this CFP guidance document are applicable to different stakeholders. Much of the NACMCF document is intended for use by the laboratory conducting the challenge study, specifically sections 3.0 through 12.0. Retail food operators should familiarize themselves with sections 1.0 through 3.0, but they should also understand sections 8.0 and 10.0 as their input is required. Retail food safety regulators working for agencies who approve variances within a jurisdiction should be familiar with sections 10.0 and 11.0 as they, along with their respective expert food microbiological laboratory personnel, are the ones reviewing challenge studies for approval.

The section numbers referenced in the NACMCF document were maintained in this guidance document to provide ease of reference between this document and the original NACMCF document.

## Definitions

(Note: These definitions were adapted from standard dictionary definitions, using the context of the NACMCF document, and were written by the CFP committee.)

**Anaerobic environment:** An environment where little or no free oxygen exists. Certain microorganisms, such as *Clostridium botulinum* (the organism that causes botulism), can grow in anaerobic environments.

**Challenge test/study:** Microbiological testing performed to determine if a particular food requires time and/or temperature control to prevent pathogenic bacterial growth.

**Competitive microflora:** Yeasts, molds, and/or bacteria naturally or normally present in a food that can alter the behavior of the pathogen of concern. Competitive microorganisms can come from starter cultures, excessive inoculation, or typical or atypical spoilage organisms present in the food or introduced during the study. A challenge study food sample should be collected from fresh product (i.e. within the first 10% of its normal shelf-life).

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**Control limit:** A maximum and/or minimum value needed to control a biological, chemical or physical factor to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

**Gas permeability:** The state or quality of a material that allows gases to pass through it.

**Headspace volume:** Headspace is the internal volume of a package that is not occupied by the product.

**Inactivation:** To make or render something not active; to disable or cause not to function.

**Indigenous microflora:** The naturally occurring microorganisms in food in its natural state.

**Inoculate:** Intentionally introducing microorganisms into food or other substrate to see the extent to which they will grow, decline or survive.

**ISO/IEC:** The International Organization for Standardization/ International Electrotechnical Commission; a joint technical committee that sets standards for lab testing and calibration.

**Multi-component product:** A product, such as a chocolate chip cookie or a pizza, composed of distinct ingredients with varying fat, water, salt, or other constituents. A component can shield other ingredients from lethality during processing or alter the environment, such as by adjusting water activity ( $A_w$ ) or pH, to allow microbial growth not generally expected with the ingredient.

**Pathogen:** A microorganism, such as *Salmonella*, that can cause illness or disease.

**Product variability:** The difference between batches (lots) of food in terms of specific properties such as color, texture, pH, water activity, etc.

**Sampling interval:** The timeframe that determines how often measurements will be taken during a challenge study.

**Spoilage organisms:** Bacteria, yeasts, and molds, that when present in a food in high concentrations, causes food to spoil or become otherwise unfit for eating.

**Starter culture:** Bacteria yeasts or mold, deliberately used during food production to cause specific changes in a food (carbon dioxide production, acid production, etc.).

**Surrogate organisms:** A nonpathogenic microorganism with similar growth or inactivation characteristics to a pathogenic microorganism

**Worst-case formulation:** A worst-case food formulation should have acidity, moisture, salt,  $A_w$ , etc. at extreme values identified for the product variability that are closest to those optimal for pathogen growth.

## **NACMCF section commentary**

As noted above, the section numbers referenced below refer to the original numbering in the NACMCF document and have been retained in this to provide easy cross-referencing between this CFP guidance document and the original NACMCF document. In some case numbers appear to be missing if a section of the NACMCF document is not referenced in this CFP guidance document.

### **1.0 Obtaining expert advice and identifying a laboratory**

The study should<sup>1</sup> be designed, conducted and evaluated by expert food microbiologists with knowledge of food products, food pathogens, and statistics. Personnel performing the study should have a combination of education, such as a B.S. in Microbiology, evidence of knowledge of basic microbiological techniques, and at least 2 years of challenge study experience or supervision by a microbiologist with that expertise.

A laboratory selected for challenge testing should be able to demonstrate prior experience in conducting or validating challenge studies and should meet laboratory standards for capacity and capability. Certifications (such as *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories*) help identify laboratories capable of testing, but don't necessarily qualify a laboratory to design and conduct challenge studies. To conduct challenge studies, labs should also have approval and capacity to handle the organism(s) of concern as well as ensure appropriate microbial strains are used.

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Note: The committee uses the word should instead of must throughout the document as there may be instances where a scientifically valid study does not have all required components in order to be valid.

### **3.0 Factors related to test product**

#### **3.1 Product preparation.**

## CFP Guidance Document on Using the NACMCF Parameters for Challenge Study Protocols For Retail Food Operators And Regulators

The test product should be prepared under conditions most conducive to growth or survival based on the intended conditions of use and expected product variability (i.e. worst-case formulation). This includes ensuring the product is at equilibrium for physical properties (water activity, moisture, temperature, and pH) and that it is inoculated in areas most likely to become contaminated and/or where organisms would grow. The critical physical properties should be at worst-case limits for the finished product.

Multi-component products may take longer to equilibrate and should be inoculated prior to equilibration. Studies to determine growth, inactivation or survival of a pathogen present due to recontamination should be inoculated after equilibration.

### *3.2 Product variability.*

Knowledge of the product variability over several product lots is needed to determine the appropriate testing parameters for a challenge study. The greater the variability, the more samples of product should be evaluated to identify the worst-case limits. Wherever possible, food should be processed to mimic conditions used during commercial operations and be representative of normal production. Adjustments to acidity, moisture, salt, water activity, etc. should be made to test a “worst case scenario”.

### *3.3 Competitive microflora.*

Inoculated product should contain typical levels of competitive microflora, including starter cultures, but take care not to introduce atypical spoilage microorganisms. The study should ensure that the product evaluated was obtained and inoculated within the first 10% of its shelf life; for example, a product with a 30-day shelf-life should have the sample obtained and inoculated within 3 days of production.

## **4.0 Target Organisms**

### *4.1 Identifying Pathogens of Concern*

Organism selection is an important part of study design. A qualified study designer will determine what organism(s) to select. The organism(s) chosen will depend on a variety of factors, including the food storage temperature, pH, and aw. For example, consider *Clostridium botulinum* as a selected organism when evaluating foods held in anaerobic environments.

There are tables included in the NACMCF document that discuss organism selection that should be used to determine the proper organism for the challenge study. These tables are labeled as Table 2, and Appendix C [4] [5] of the original NACMCF document. Both tables should be used together to select the proper organism for test. Preliminary testing on product for pH and water activity may be needed to help select organism(s) of concern.

## *4.2 Surrogate Organisms*

There are certain circumstances in challenge testing that allow for the use of non-pathogenic surrogate organisms. If surrogates are to be used, their choice should be justified and valid for the food and the process being tested. The use of surrogate organisms may be most helpful to reduce cost and risk in product formulation design prior to conducting the challenge study.

## **8.0 Storage Conditions**

### *8.1 Packaging*

Products should be testing using the same conditions used for commercial packaging, including packaging materials and the process used for actual packing of the product. Attributes to consider include gas permeability, headspace volume, vacuum levels, and headspace gas composition. The conditions of the environment for packaging should also match the environment for commercial packaging.

### *8.2 Storage and Shipping temperatures*

Storage and shipping temperatures should take into consideration product temperature variation. Humidity should also be taken into consideration for these tests.

NACMCF recommends that refrigerated foods be tested at 44.6°F (7 °C) to account for expected consumer storage temperature in the United States but may also be tested at other temperatures for a better understanding of microbial growth patterns. If a product may be subject to variation of temperatures during its shelf life, the product should be tested using these temperature variations.

Products being tested to determine their safety at ambient temperature should be tested using the expected storage room temperatures (typically 24 to 35°C or 75.2 to 95°F).

## **Reference 9.0 Sample Considerations**

### *9.1 Sampling*

The number of samples analyzed at each time interval should be at least two and any studies should be replicated at least twice with different batches of product and inocula. The number of replications depends on the product and the inoculum.

## **10.0. Duration of study and sampling intervals**

For study duration parameters based on product shelf life, see chart 10.1.

*Chart 10.1*

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Product type	Proposed Shelf Life	Additional Safety Margin
Sold for Immediate Service	7 to 10 days	50%
Sold for Immediate Service	10 days to 3 months	25% to 50%*
Sold for Immediate Service	3 to 6 months	25%
Packaged for Retail Sale at the food establishment	Any	50%

\* at the discretion of the study designer

Food packaged at the retail establishment should use the most conservative additional safety margin provided in the NACMCF document, which is an additional 50%. Since the NACMCF document does not provide information on safety margin beyond 6 months, it is recommended that the proposed shelf life for a packaged product be determined by the microbiologist conducting the study, and should be between 7 days and 6 months.

Samples, including controls, should be analyzed initially after inoculation (*or after a short equilibration period at the direction of the study designer*) and then at least five to seven times over the duration of the study. For longer-shelf-life products, it may be necessary to have more than seven sampling points.

A study may be terminated when growth of the target pathogen exceeds 1 log for two or more consecutive sampling intervals, except in the case of *S. aureus*, *B. cereus* or *C. perfringens* where NACMCF recommends 3-log. Studies may also be terminated when gross spoilage occurs.

### 11.0. Interpreting test results

The results of a microbiological growth study must be interpreted and evaluated by an expert microbiologist who will consider all relevant factors and the thresholds in the chart below. Smaller increases may be significant depending upon the enumeration methods, number of samples and replicates used, and the variability among data points. The regulatory authority can use more restrictive pass/fail criteria for a specific challenge study based on the intended use of the product and the target consumer population (i.e. highly susceptible population).

The Pass/Fail criteria for test pathogens are listed below.

**Chart 11.1**

Pathogen	Pass	Fail
----------	------	------

CFP Guidance Document on Using the NACMCF Parameters for Challenge Study Protocols For  
Retail Food Operators And Regulators

<i>C. botulinum</i>	No toxin detected for the duration of the study.	Any toxin detected during the study.
<i>S. aureus</i> , <i>B. cereus</i> or <i>C. perfringens</i> (if applicable)	In lieu of toxin testing, less than 3-log CFU/g growth above the initial inoculum level across all replicates.	Equal to or greater than 3-log CFU/g growth above the initial inoculum level in any replicates.
All other pathogens	Less than 1-log CFU/g growth above the initial inoculum level across all replicates.	Equal to or greater than 1-log CFU/g growth above the initial inoculum level in any replicates.

**\*A product does not support pathogen growth if growth has not exceeded the initial inoculum level by the limits listed above throughout the intended shelf life of the product and across replicate trials.**

When publishing the final report, ensure that the lab specifically states that the challenge study was conducted following the NACMCF Protocols.

### Computer Modeling

The use of computer modeling for product assessment and pathogen growth in the absence of any laboratory data is limited. Only experimentally validated models for the specific pathogen(s) of concern should be used. Modeling can usually be used in excluding specific organisms of concern from consideration in challenge studies, (e.g., modeling shows than one pathogen grows faster, so the slow grower is excluded from subsequent laboratory studies).

### Reference Documents:

1. *FSIS Report, Establishment Guidance For the Selection of a Commercial or Private Microbiological Testing Laboratory* - <https://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651-b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab-062013.pdf?MOD=AJPERES>
2. *Evaluation and Definition of Potentially Hazardous Food* - <https://www.fda.gov/downloads/food/foodborneillnesscontaminants/ucm545171.pdf>
3. *Parameters for Determining Inoculation Pack/Challenge Study Protocols* - <https://www.fsis.usda.gov/wps/wcm/connect/3b52f9c0-0585-4c0a-abf2->

CFP Guidance Document on Using the NACMCF Parameters for Challenge Study Protocols For  
Retail Food Operators And Regulators

[b4fc89a9668c/NACMCF\\_Inoculated\\_Pack\\_2009F.pdf?MOD=AJPERES](https://www.fda.gov/oc/ohrt/b4fc89a9668c/NACMCF_Inoculated_Pack_2009F.pdf?MOD=AJPERES)

Sample Checklist for Retail Establishment Challenge Study for Extended Shelf Life or Holding Outside Temperature Control – Product not to be packaged

**Section 1.0 – Laboratory Selection**

YES	NO	Does laboratory selection meet appropriate criteria from Section 1.0 of NACMCF document? (See Table 1 in the NACMCF document)
-----	----	--

**Section 3.0 – Factors related to tested product**

Critical Physical Property	Range for Product (indicate NA if not applicable)
Water activity ( $a_w$ )	
pH	
Salt content	
Moisture	
Other (including nitrites or inhibitors):	
Intended Conditions for Storage	Range for Product (indicate NA if not applicable)
Storage temperature	
Storage shelf life	
Shelf life duration during challenge study	

YES	NO	Was product prepared and tested at intended conditions of use?
-----	----	--

**Section 4.0 – Organism Selection**

Use Table 2 and Appendix C from NACMCF document to determine answers

Pathogen (Expand rows as needed)	Growth in the $a_w$ of food being tested?	Growth in the pH of food being tested?	Concern in the food product category?
	YES   NO	YES   NO	YES   NO
	YES   NO	YES   NO	YES   NO

**Section 9.0 – Sample Considerations**

How many samples were analyzed initially and at required time intervals? _____		
YES	NO	Was sample replicated as required (2+ for most pathogens, 5+ for <i>C. botulinum</i> )
YES	NO	Does lab provide sample preparation information that is appropriate for food being tested?
YES	NO	Does lab provide information on enumeration of pathogens/measurement of toxins conducted using validated methods in a qualified lab? (NACMCF Appendix A)?



**DRAFT CFP Challenge Testing Worksheet to Determine Microbiological Stability of a Formulation**

<b>Protocol</b>	<b>Actual</b>
<p>Appropriate Study Design, Data Collection, and Data Interpretation Conducted by a Qualified Individual? (See Table 1 of the NACMCF Executive Secretariat. 2010 Parameters for Determining Inoculated Pack/Challenge Study Protocols. J. Food Prot. 73(1):140-202) as well as Institute of Food Technologists. 2001. Evaluation and Definition of Potentially Hazardous Foods. (IFT/FDA Contract No. 223-98-2333. Task Order No. 4 December 31.)</p>	
<p>Appropriate Challenge Microorganisms Selected? See Tables 4-1/6-1 of the (IFT Report and Table 2 and Appendix C of the NACMCF Report</p>	
<p>Proper Inoculum Level Used to Meet Objective? Typically, Between 2 and 3 log CFU/g</p>	
<p>Does Study Describe Preparation of Inoculum Using Appropriate Media and Under Conditions to Optimize Growth?</p>	
<p>Was Inoculation Method Used That Does Not Change the Critical Parameters of the Product Formulation Undergoing Challenge?</p>	
<p>Was Study Conducted for a Duration That Being at Least the Desired Shelf Life of the Product, plus an Additional Time of the Intended Shelf Life to Provide for Expected Consumer Consumption? See Section 10.0 Duration of Study and Sampling Intervals NACMCF Report (25-50%) as Well as NIST Handbook 130 E. Uniform Open Dating Regulation 3.3.1. Reasonable Period for Consumption. (30%).</p>	
<p>Was Each Key Factor Variable Tested that Controls a Product's Microbiological Stability Under Worst-Case Conditions?</p>	
<p>Did the Analysis Include the Supporting Data (Information Regarding the Product's Formulation, Types of Ingredients, Processing, and Final Packaging)?</p>	
<p>Did the Product Study Represent and Support the Conditions (Temperature, Packaging, Humidity, etc. ) the Product Will Go Through at the Retail Level?</p>	
<p>Sample Analysis Were Duplicate and, Preferably, Triplicate Samples of Each Lot (at least two) Used? Were the Levels of Live Challenge Microorganisms Enumerated at Each Sampling Point?</p>	
<p>Was Appropriate Toxin Testing Performed at Each Time Point using the Most Current Validated Method? Were Uninoculated Control Samples Analyzed for Background Microflora at Each or Selected Sampling Points?</p>	
<p>Data Interpretation Once the Study is Completed, Was the Data Analyzed to See How the Pathogens Behaved Over Time (Died, Remained Stable, or Increased)? In the case of Toxin-Producing Pathogens, was any Toxin Detected Over the Designated Challenge Period?</p>	
<p>Pass/Fail Criteria Note: The Significance of a Population Increase Varies with the Hazard Characterization of Each Microorganism. See IFT Report, Part 9 of Chapter 9 Microbiological Challenge Testing. The Exclusive Use of Computer Models are Not Recommended as they Address and Model only Certain Pathogens, and Do Not Mimic the Environmental Conditions at Retail or the Growth of Bacteria in Real Food Systems.</p>	

Note: This worksheet does not address the implementation of the product's handling once approved, as the local regulatory authority will likely require that procedures from the establishment also be submitted and implemented regarding the handling of the product as part of a variance or other approval.

First Meeting 9/21

Friday, September 21, 2018

Call Recap:

1. We have a very small committee with only a few At-large members who can become voting members (ie not voting members on other committee's). PLEASE let Veronica or I know if you change roles so we can make arrangements.
2. Everyone volunteered to be on this committee and we commit to treating everyone with respect, dignity and assume positive intent.
3. Our committee will break up into four sub-committees and begin working on each of the charges concurrently. Rank each subcommittee in order of preference. Respond back by 9/28. Subcommittee work will begin in October on a monthly cadence.
4. Committee meetings will be every 3-4 months.
5. Share with the Committee any relevant guides, templates or work that you currently use. Thank you Todd for sharing your work.

Readings and Courses:

1. Sign up for Don Schaftner's course on microbial challenge studies in 2019. Put yourself on the waitlist below:  
<https://www.foodprotection.org/events-meetings/workshops-conferences/microbial-challenge-testing-for-foods-workshop/>
2. Read and review the attached three documents:
  - a. NACMCF Challenge Study Document
  - b. IFT PHF Document
  - c. Todd's Challenge Study Process Flow

Subcommittee signup based on Charging Document:

Subcommittee	Preference
<b>Template / checklist for reviewing challenge study</b>	
<b>Organism selection tool</b>	
<b>Interpreting Results Guidance tool</b>	
<b>Computer modeling appropriateness</b>	

Nov 2. 2018 Notes

Introductions

Review of Charges

1. **A tool to assist in selecting appropriate organisms.**
2. **Direction on when it is appropriate to use computer modeling to either support or replace an inoculation study.**

Strategy to Complete Charges

Page 20, Appendix C, Table 2

Start with Appendix C, Next Step: pH and water activity, narrow down organisms

If food isn't on the list, go to table 2

Don provided historical information about the NACMCF document and said that it started as an idea of a decision tree, but it was too complicated.

Who is the end user of these tools? What kind of tool and for who?

**Common pitfalls, what are the things that are show mistakes, failures, etc of studies that have been looked at**

**Difference between HACCP validation and challenge study: Two projects that confuse people, good for industry to see comparison. Examples: processing facility, validate piece of equipment, no challenge study on final product.**

**Criteria for lab selection: Component of the NACMCF document needs to be highlighted for both industry and regulatory**

Resource Review

Next Steps

For next call, everyone should think about

December 2018 Subcommittee #1 12/7/18

Discussion Items

- Opened meeting with review of action items from last meeting and action items. Main action item was discussion of what causes challenge studies to be turned down from experience.
- Discussion began with Nikki; challenge studies submitted for processes, i.e. Peking duck that does did not include actual scientific data. Wanted to use anecdotal information of lack of outbreaks to get challenge study passes. **All agreed that this is important information and would cause a challenge study to be denied.**
- **Second discussion item from Dr. Schaffner; challenge studies that use the incorrect pathogens for the study. Not necessarily choosing the wrong organism completely but using stand ins or surrogates incorrectly.** For example, people choosing *Clostridium sporogenes* instead of *C. botulinum*. Tests with *C. sporogenes* are significantly cheaper than *C. botulinum*, but it will not properly predict growth of *C. botulinum*. Another example is doing a challenge study using generic *E. coli* instead of pathogenic *E. coli*. Pathogenic *E. coli* is more acid tolerant and so does not react the same way as generic *E. coli*.
- Third discussion item was from Veronica; discussion of choosing incorrect parameters for the challenge study. For example, if the study was extending holding at room temperature and the

study is conducted at 50°F. **All agreed choosing wrong parameters would lead to challenge study denial.**

- Discussion was had about laboratory selection. Victoria asked if local regulatory jurisdictions deny challenge studies based on “wrong lab” used. Regulators on the call agreed that they cannot require or suggest one lab over another. Accreditation of the lab is not required, but specific parameters must be met. Study must be designed by a PhD and must use validated methods. **All agreed information from Appendix B needs to be highlighted in report.**
- There is a list of university laboratories that are process authorities that was put together by Purdue University in 2011. Discussed if list could be updated by a university. Also discussed university labs may be used for challenge studies even though they are not good for routine testing. Also, same laboratory that does routine L. monocytogenes testing probably not able to do challenge studies. Any lab that does the challenge study needs to understand challenge studies and how they work.
- Committee members discussed that definitions are necessary early on to determine the scope and make sure information and recommendations are clear. Some terms that require definitions are process authority, challenge study, product assessment, HACCP validation, etc. Dr. Schaffner stated that some terms won't be able to be clearly defined. Example is a product assessment for a process deviation. Universities are contacted to validate a process deviation, which could require a challenge study, sometimes Dr. Schaffner stated that deviation can be validated via computer modeling in some cases. This item will be important for Charge 2 of subcommittee.
- **Committee agreed that for Charge 1, A tool to assist in selecting appropriate organisms, information is already available in chart format in Table 2 and Appendix C. Committee's job is to market and organize information so that people know where to find it.** Report will be written to help point people to the information in the document. Dr. Schaffner stated that as a writer of the original document, he is willing to help explain some of the technical language if there are items that are difficult to understand.

Action item for January Meeting:

- Review NACMCF document and determine questions about technical language and items that need to be further explained. Decision was made to split the document into sections for review. **All committee members must review document and record questions or items that need clarification. These items must be submitted to Veronica Bryant by January 3, 2019.** The assignment is split by the bold headings within the JFP version of the document. Assignments for document review are as follows:

Victoria Burgess and Nikki Burns-Savage

- Types of challenge studies
- Determining when a challenge study is needed
- Obtaining expert device and identifying a laboratory
- Type of study

Lauren Bush and Rebecca Krzyzanowski

- Factors related to the test product

- Target organisms
- Inoculum levels

Richard Willis and Dianna Kerlicek

- Inoculum preparation
- Method of inoculation
- Storage conditions
- Sample considerations

Todd Mers and Samuel Derr

- Duration of study and sample intervals
- Interpreting test results
- Elements to include in the report

Veronica Bryant and Christina Bongo-Box

- Appropriate uses of mathematic modeling
- Limitations of applying results to similar foods
- Existing protocols for applying to wide varieties of foods

SubCommittee #2 December 5 Notes:

1. Defining the scope of when this should be used (ie when the pH and water activity call for a product assessment OR anytime a product assessment is done)
  - a. We will define this as only when the pH and water activity call for a product assessment
2. Process and timeline: We should define the directions for assessing the challenge study first and then come up with template and checklist.

Next Steps:

1. Use the NACMAS document and formatting
2. Robert/Susan/Todd to come up with sections/steps for directions when assessing a PA.
3. We will assign out the sections from there.

Important Dates:

1. I am going to push our 1/2 call to 1/9 and reserve the 1/2 call for Robert Susan Todd and I to come up with the Sections that we will discuss and assign out on the 1/9 call.

Share with the Group ANY Product assessments:

1. Veronica - NACMAS does have an example in the appendix.
2. Tammy Gordon can pull a few PA's

January 2019 Meeting

Discuss follow-up from previous meeting. Continued to work on the charges related to developing a tool for computer modeling.

Most of the discussion was around the idea that the two charts already exist in the NACMCF document. Trying to rewrite these items and charts that already exist in Table 2 and Appendix C are going to be challenging. Most of the discussion surrounded around how to repackage the information already in the NACMCF document to be more accessible.

Discussed whether tables should be put into the guidance document or just referenced. No consensus reached.

Notes:

We used the NACMCF doc outline listed below to determine what sections would be applicable to our charging documents and our sub-committee. These include:

1.0 Obtaining expert advice and identify a lab.

3.0 Factors related to the test product

8.0 Storage condition

9.0 Sample considerations

10.0 Duration of study and sampling intervals

11.0 Interpreting results

On our 1/9 call we will be aligning these with the broader sub-committee and then forming groups to write instructions regarding their sections for use.

Section 1 & 3 - Susan Shelton

Sections 8 & 9 - Todd Pelech

Sections 10 & 11 - Robert Curtis

Currently we are tracking but do not intend to include in our write up the following:

1. Ongoing product verification
2. Humidity control during tests (not mentioned in NACMCF)
3. Non-pathogen surrogates selection
4. Self-Testing/Certification of results (pH & water activity)

**Notes for the call:**

The below Google Doc will be used to collaborate on our outlines.

<https://docs.google.com/document/d/1HKyuoVvFNNJiAja6Ztr4lajZ4buPF4KqNYXbAmdIG6g/edit?usp=sharing>

We reviewed the Committee Spring Report and agreed that:

- Looks good
- Timelines are reasonable
- Checklist might be hard

I have made the following updates to the report:

1. Moved the Report submittal deadline to 3/1 vs. 2/1. This gives us time to get everyone's outline into the google doc in our agreed upon formatting. Goal is to have this done by 2/18.
2. Included our caveat in the Spring Report that we are only looking at challenge studies that determine if a product is TCS or ones that extend the shelf life of TCS products.

We aligned that we will follow the outline created by Robbie (Attached) that is in line with the NACMFS doc and we will go relevant chapter by chapter and include information in our instructional assessment doc.

Veronica is working to get approval to use a Pizza Sauce Example which we can use as a sample assessment to evaluate.

[Our next All-Committee Meeting will be week of 2/11.](#)

February 2019 minutes  
Notes from PAC February 1, 2019

Chili Challenge Study discussion – Michigan only saw listeria, not bacillus or salmonella  
Some cyclospora  
Should consider abuse situations – in NACMCF

Guidance document may need to address regulator concerns with conditions

Can we give guidance on categories of products?  
Parameters that would be necessary for complex processes

Cannot be reduced to a flow chart

Job Aid – designing a study from start to finish  
Where can we add value  
Can we copy the table into our document? Needs to point to a table  
Point to the document with a few examples

**Action Items for Committee:**

**Come up with talking points on organism selection that needs to be included**

## **Come up with rea world examples that have been submitted**

Situations where you can use surrogates, but they must be validated for the food and for the process that you are developing.

Rule out formulations versus rule in

2/6/19

1. All work product is attached.
2. We will upload/combine all work into the Google Doc
3. Send out the Committee report prior to 2/15 call

Writing Style:

- When writing the section remember that the audience is the regulator
- Pull out relevant information from the NACMCF doc

Full Committee Meeting:

### **Overall:**

General Comments on the Committee Report - None

Don will check the entire doc for any plagiarism via his plagiarism software.

No issues with using the NACMCF titles.

### **Timeline:**

Doc to be completed 10/1 which will leave use one month for committee review

### **Action Items for Document:**

1. Add a definitions section - Any volunteers?
2. Add an introduction / who is the audience / how to use this doc section - Any volunteers?
3. Add a section around how to select a lab, what questions to ask, vetting a labs capability. Reference the FSIS doc here. - Any Volunteers?
4. Along with our doc submit a recommendation that CFP create a national group to review challenge studies - We need to understand what this looks like (ie add it to the doc, a separate doc?)

### **Overall Meeting:**

1. Susan Shelton presented sections 1 & 3
2. Nikki presented section 4
3. Todd presented sections 8 & 9
4. Nela presented sections 10 & 11

Aligned to using the Pizza Sauce example (need to attach it) throughout the document.

Volunteers please contact Veronica or Jon.

March 1, 2019

The following items were discussed in relation to Charge #4 – when to use computer modeling. Becky K discussed that Michigan used a group to discuss how computer modeling can be used and the following were some of the factors related to their decision.

- Some of the language used by FSIS is Non refrigerated shelf stable
- Data from salt, pH and water activity to show shelf life
- Refrigerated perishable, more than seven days
- More extensive than just modeling, must show they meet modeling requirements
- Technical advisory committee, what organisms, MSU, OSU, USDA, meat association
- Specific program for cured meat
- Deviation from code, use modeling
- Part of full haccp and variance, but modeling is just shelf life extending

April 5, 2019

Discussion continued around use of computer modeling. Need to add this information into the already in process guidance document. Difficult to use modeling alone.

Discussion continued on the best way to complete this charge. Consensus beginning around writing statement to be included in guidance document. Computer modeling might be available for use like being used in Michigan. Michigan documents were not able to be reviewed prior to this meeting.

Action items are for committee members to review documents and determine best steps to move forward.

FDA Rep Introductions – And thank you for your participation in our sub-committee group. We look forward to your contributions.

Reminders: Please review the [google doc](#) and put all comments feedback by 4/19 (tomorrow)

Volunteers:

Final Doc Editor - Robbie

"Sample Review" - Hilary Thesmar

Comments/Ideas to make the doc purpose more clear/easier to use are to:

Break it up into sections:

1. Food service relevant items
2. Labs - Remove the Lab components as this is not the intended audience (See Robbies comment below)
3. Regulator relevant items

Robbie - remove the lab components as it is not part of our introduction.

Call out the exclusion of manufacturing processes.

I will compile the above into the google doc.

#### June 2019 Notes

1. Jon to “clean” doc and repaste edited version in Google doc. Veronica will include this link to the committee. The FSIS folks will get the word docs separately. Google doc [here](#). The current version is at the top of the doc and the old version at the bottom. Format is not 100% but I am not going to fix it.
2. Veronica send out the edited version of the whole report to the whole committee. Don will run through plagiarism software and everyone can comment. Pull off all the checklist stuff and only send the doc. Accept all changes and send a “clean” copy.
3. Veronica we are seeking 1-2 more volunteers on the developing the checklist/example. We already have Hilary Thesmar but want at least one more regulator to support this
4. Checklist and Sample group to meet in July.

#### August 2019 Notes

- Draft document has been completed. All members have had ability to review document and make changes.
- Document was submitted to FDA reps in word format since Google Doc is not allowed for them.
- All discussion has been completed on the document, final vote will be taken at final meeting.
- Discussion around how to proceed with checklist. Current format is long.
- Workgroup will continue to work towards a better format for this checklist and will present at the final meeting.
- Unsure if example document will be able to be created due to limited time and no finalized checklist format.

#### September 2019 Notes

- Number of voting members present does not constitute quorum of voting members.
- Asked Becky K who is familiar with Board procedure if email vote could be called, it was decided that it was allowable to conduct votes via email.
- Email vote will be sent out on guidance document, document in final format that all are comfortable with.
- Checklist format still not finalized. Worksheet to compare protocol with actual submitted was created. Discussion on this format with mixed feelings.
- Some feel that it does not give enough guidance on how to move forward with a challenge study.
- Checklist in current format too long with too much information on lab selection.
- Determination was for Veronica to work on checklist to condense and send out to members for review.
- After meeting – email vote was sent out on guidance document and worksheet. Vote was 9-0 with several members not completing vote.
- Veronica sent out revised checklist for vote, vote was 11-0 with 2 members not voting.
- Discussion via email about keeping all documents separate for ease of council deliberation.

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-011**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

PAC 2–Approval of guidance, “Using NACMCF Parameters for Retail Food...”

**Issue you would like the Conference to consider:**

Acceptance of the Product Assessment Committee's guidance document entitled "Using NACMCF Parameters for Food Service" and inclusion of the guidance document CFP website in PDF format

**Public Health Significance:**

In order to meet the charges given to the Product Assessment Committee, a guidance document was developed to help provide clarification on the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Challenge Study Protocols as it relates to retail food service establishments. Using the NACMCF protocol can be difficult for both operators and regulators to understand. This leads to challenges for regulatory authorities, to provide approval for challenge studies, and retail food establishments, to know how to move forward with completing a challenge study. Providing guidance for retail food establishment challenge studies will increase compliance with FDA Food Code and help to ease the burden for operators and regulators.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends...*

1. Acceptance of the committee generated guidance document entitled "Using NACMCF Parameters for Challenge Study Protocols for Retail Food Operators and Regulators" (attached as a content document to Issue titled: Report - Product Assessment Committee); and
2. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
3. Posting the final document on the CFP website in PDF format

**Submitter Information 1:**

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-012**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

PAC 3–Approval of Checklist for Retail Establishment Challenge Study

**Issue you would like the Conference to consider:**

Acceptance of the Product Assessment Committee's checklist entitled "Checklist for Retail Establishment Challenge Study" and inclusion of the checklist on the CFP website in a down-loadable PDF format.

**Public Health Significance:**

Using the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) protocol can be difficult for both operators and regulators to understand. This leads to challenges for regulatory authorities, to provide approval for challenge studies, and retail food establishments, to know how to move forward with completing a challenge study. Providing this checklist of appropriate criteria for operators and regulators to consider when reviewing a challenge study, and directions for using it, will help to ease the burden for operators and regulators.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

1. Acceptance of the Checklist for Retail Establishment Challenge Study (attached as a content document to Issue titled: Report - Product Assessment Committee).
2. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document.
3. Posting the final document on the CFP website in PDF and editable Word format

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-013**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

PAC 4– Approve Challenge Testing Worksheet

**Issue you would like the Conference to consider:**

Acceptance of the "*Challenge Testing Worksheet to Determine Microbiological Stability of Formulation*" and; inclusion of the worksheet in editable Word and PDF format.

**Public Health Significance:**

Using the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) protocol can be difficult for both operators and regulators to understand. This leads to challenges for regulatory authorities, to provide approval for challenge studies, and retail food establishments, to know how to move forward with completing a challenge study. Providing tools for retail food establishment challenge studies will increase compliance with FDA Food Code and help to ease the burden for operators and regulators. This worksheet was created by the committee to help provide clarification on the NACMCF Challenge Study Protocols as it relates to retail food service establishments.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

1. Approval of the ***Challenge Testing Worksheet to Determine Microbiological Stability of Formulation*** (attached as a content document to Issue titled: Report - Product Assessment Committee).
2. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document.
3. Posting the final document on the CFP website in PDF and editable Word format

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-014**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

PAC 5–Amend Food Code Reference Approved Documents in FDA Food Code Annex 3

**Issue you would like the Conference to consider:**

Inclusion of the committee generated guidance document entitled, "Using NACMCF Parameters for Challenge Study Protocols for Retail Food Operators and Regulators", the "Checklist for Retail Establishment Challenge Study", and the "Challenge Testing Worksheet to Determine Microbiological Stability of Formulation" in the FDA Model Food Code Annex 3.

**Public Health Significance:**

Using the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) protocol can be difficult for both operators and regulators to understand. This leads to challenges for regulatory authorities, to provide approval for challenge studies, and retail food establishments, to know how to move forward with completing a challenge study. Providing tools for retail food establishment challenge studies will increase compliance with FDA Food Code and help to ease the burden for operators and regulators. Three documents were created by the Product Assessment Committee. Inclusion these documents in Annex 3 of the FDA Food Code will assist retail food establishment operators and regulators in accessing this information.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

A letter be sent to FDA requesting that the most recent edition of the Food Code be amended to include a reference to all of the approved documents/tools from the Product Assessment Committee at the end of the section as follows:

1-201.10 Statement of Application and Listing of Terms.

(B) Terms Defined

Time/Temperature Control for Safety Food

When a "Product Assessment" is indicated in the chart, a challenge study may be done to determine the shelf life of the product, or the time a product can be maintained at room temperature. Documents have been developed through the Conference for Food Protection (CFP) Product Assessment Committee to assist operators and regulators with the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Parameters for Determining Inoculated Pack/Challenge Study Protocols. These documents include Guidance Document on Using NACMCF Parameters for Challenge Study Protocols for Retail Food Operators and Regulators, Checklist for Retail Establishment Challenge Study, and Challenge Testing Worksheet to Determine Microbiological Stability of Formulation. These documents can be found on the CFP website.

*Note: All documents are attached to "Report - Product Assessment Committee (PAC)" and submitted for CFP approval and posting in Issues "PAC 2-4".*

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-015**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Committee to Update CFP Guidance on Beef Ground at Retail

**Issue you would like the Conference to consider:**

This Issue proposes creating a committee to update the "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments."<sup>1</sup> Outbreaks continue to be associated with beef ground at retail that was not intended for grinding (e.g., trim from intact steaks or roasts, and "pull backs"). In addition, FSIS surveillance has shown that 54%<sup>2</sup> of retailers have no records associated with beef grinding in violation of 9 CFR 320.1(b)(4).<sup>3</sup> These records help facilitate traceback in outbreak investigations and may be used to recall potentially injurious products from commerce. CFP's current guidance does not address intended use or the new grinding records requirement. Updating the guidance document would help increase awareness of record-keeping requirements and promote the adoption of safe grinding practices to help prevent illness from raw beef ground at retail food establishments.

**Public Health Significance:**

Shiga toxin-producing *Escherichia coli* (STEC) is estimated to cause 265,000 illnesses in the US annually, including 3,600 hospitalizations and 30 deaths.<sup>4</sup> Outbreaks continue to be associated with beef ground at retail that was not intended for grinding (e.g., trim from intact steaks or roasts, and "pull backs"). In many outbreak investigations, inadequate grinding records and insufficient sanitation between source lots at retail have hindered investigators' ability to determine the ultimate source of the implicated beef.

CFP developed the "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments"<sup>1</sup> (2012 I-014) to share best practices for grinding beef, including a record keeping template. In 2015, FSIS issued the "Records to be Kept by Official Establishments and Retail Stores that Grind Raw Beef Products" rule.<sup>5</sup> The rule requires grinders to maintain records on supplier names, establishment numbers, lot numbers, and production dates of the raw beef components used to make ground beef products (9 CFR 320.1(b)(4)<sup>3</sup>). Since CFP published the guidance and FSIS finalized the

grinding records requirement, there have been three outbreaks associated with food establishments grinding beef that was not intended for non-intact use.

As presented at the CFP Pre-meeting Workshop in 2018,<sup>6</sup> federally inspected meat processing plants that produce beef, identify the products' "intended use." Two common intended uses are: "intact" such as steak and roasts, or "non-intact" such as ground or mechanically tenderized beef.<sup>7,8</sup> Intact steaks may be considered a ready-to-eat food by searing without being fully cooked because contamination with pathogenic bacteria would only occur on the surface of the product (Food Code (§3- 401.11(C)(3)).<sup>9</sup> However, grinding causes STEC to move to the interior of the beef, which may increase risk of foodborne illness if consumed undercooked (e.g., rare or medium rare). For this reason, meat processing plants implement more stringent process controls for beef intended for non-intact use.<sup>8</sup>

Per FSIS routine ground beef sampling<sup>10</sup>, 83% (248/298) of retail food establishments reported grinding individually vacuum packaged whole muscle beef (a product intended for intact use). Retail food establishments can reduce risk of STEC when grinding raw beef by: (1) applying antimicrobial intervention to the beef intended for intact use before grinding, or (2) purchasing beef intended for non-intact use.<sup>6,8</sup> However, of the 248 retail food establishments who ground vacuum packaged beef, only 21 (8%) implemented additional food safety steps to eliminate STEC before grinding.<sup>10</sup>

The 2014 CFP guidance<sup>1</sup> does not include information on how the beef source material and its intended use affects food safety. Additionally, the CFP guidance document does not mention that retailers are required to keep grinding records since it was developed prior to the issuance of the Grinding Record Keeping Rule.

#### References (noted above with superscript numerals)

1. Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments. URL: <http://www.foodprotect.org/media/guide/CFP%20Beef%20Grinding%20Log%20Template%20Guidance%20Document%20-%208-8-2014.pdf>
2. USDA-FSIS Enforcement Records: October 1, 2016 - September 30, 2019
3. 9 CFR 320.1(b)(4) - URL: [https://gov.ecfr.io/cgi-bin/text-idx?SID=64ec97c3205d4b15340b3577e35c22d5&mc=true&node=se9.2.320\\_11&rgn=div8](https://gov.ecfr.io/cgi-bin/text-idx?SID=64ec97c3205d4b15340b3577e35c22d5&mc=true&node=se9.2.320_11&rgn=div8)
4. Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et al. Foodborne illness acquired in the United States---major pathogens. *Emerg Infect Dis* 2011;
5. 80 FR 79231, Records to be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products. URL: <https://www.fsis.usda.gov/wps/wcm/connect/6bb824d5-70ce-4c1d-8801-b18346fa595c/2009-0011F.pdf?MOD=AJPERES>
6. Sherri (Jenkins) Williams. *Intended Use of Non-Intact Products*. Pre-Meeting Workshop, Conference for Food Protection (CFP) 2018. Richmond, VA. (slides attached)

7. 2017 Food Code Section 1-201.10(B) Terms Defined "Intact Meat" and "Meat". URL: <https://www.fda.gov/media/110822/download>.
8. FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef (including Veal) Processing Operations. URL: <https://www.fsis.usda.gov/wps/wcm/connect/c1217185-1841-4a29-9e7f-8da6dc26d92c/Compliance-Guideline-STEC-Beef-Processing.pdf?MOD=AJPERES>.
9. 2017 Food Code §3- 401.11(C)(3). URL: <https://www.fda.gov/media/110822/download>
10. FSIS Directive 8010.1 Methodology for Conducting In-Commerce Surveillance Activities. URL: <https://www.fsis.usda.gov/wps/wcm/connect/66a3ae47-3a55-426e-8bab-ea7b2175c9be/8010.1.pdf?MOD=AJPERES>

**Recommended Solution: The Conference recommends...:**

The Conference recommends that a Committee be convened of members from all constituencies in the CFP. The Committee will be charged with:

1. Reviewing the available guidance and recommend changes to update and address continuing issues, such as:
  1. Low compliance with grinding records requirements,
  2. Grinding beef intended for intact use,
  3. Lack of sanitation (including records of sanitation) throughout the production day, and
  4. What to do if inadequate grinding records are found
2. Determining appropriate mechanisms for sharing the committee's work,
3. Reporting the committee's findings and recommendations to the 2022 Biennial Meeting of the CFP.

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**Supporting Attachments:**

- "CFP Presentation on Intended use of Non-Intact Products"

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WORLD'S LEADING ANIMAL PROTEIN PRODUCER

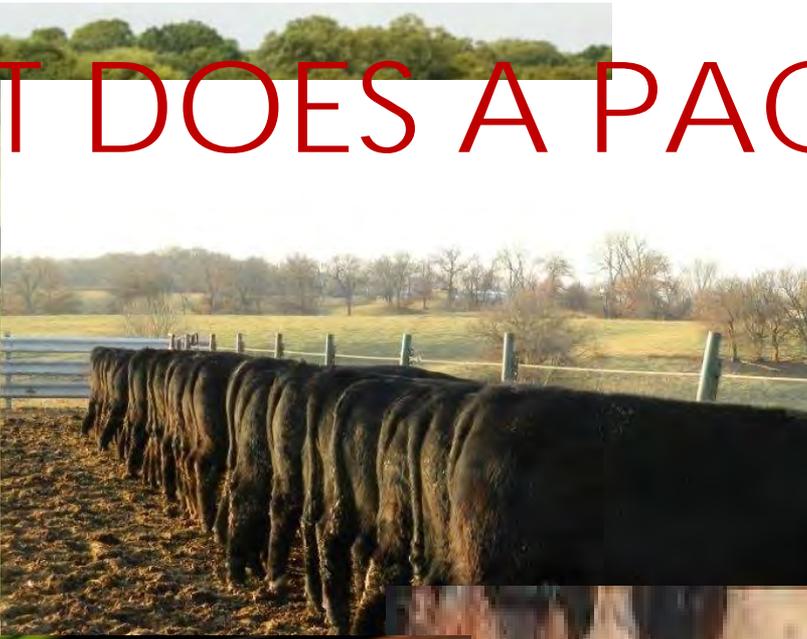


# Intended Use of Non-Intact Products

CFP April 16, 2018

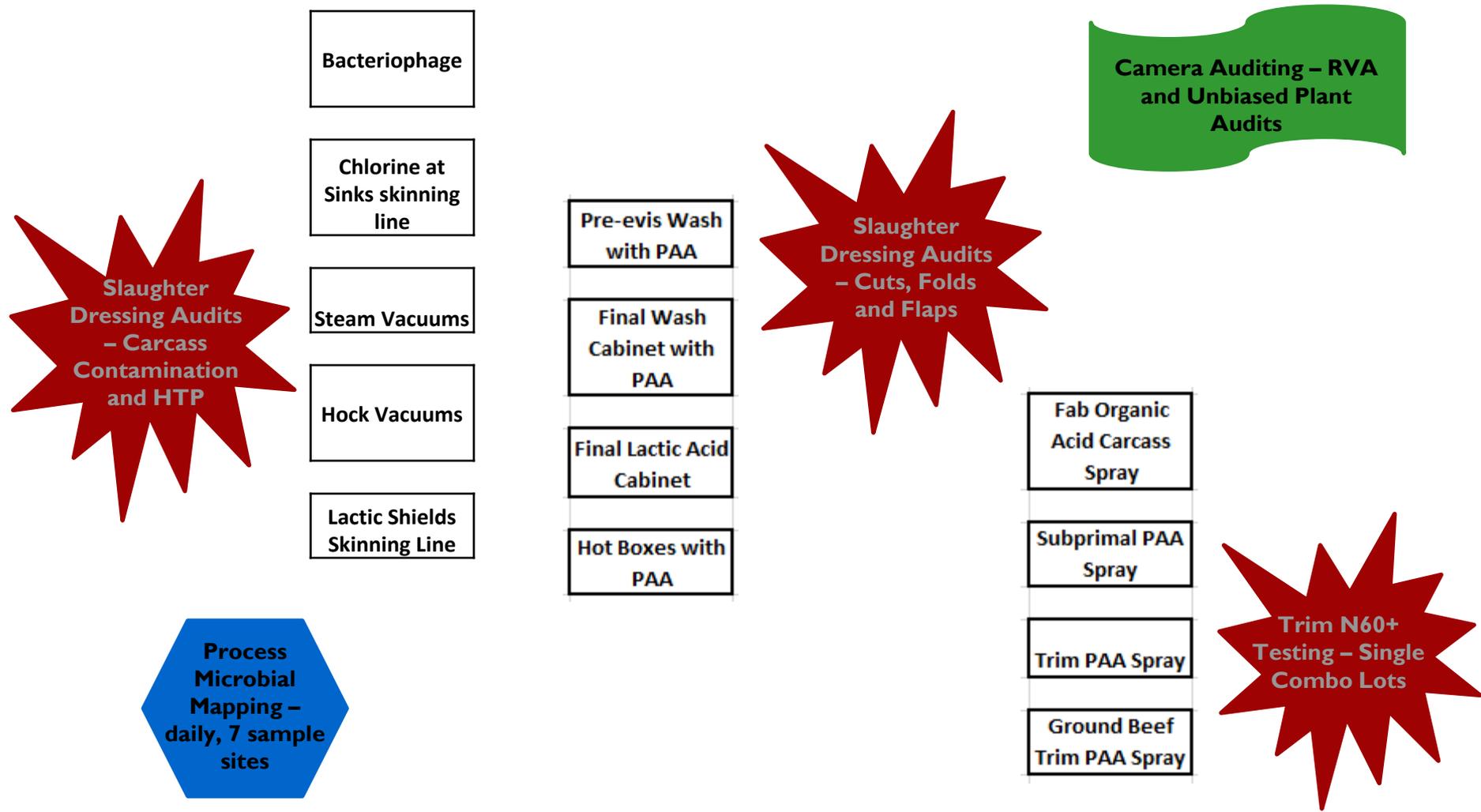
Sherri Jenkins, JBS USA Food Company

# WHAT DOES A PACKER DO?



MAKING YOUR WORLD STRONGER

# JBS Beef Food Safety Intervention System



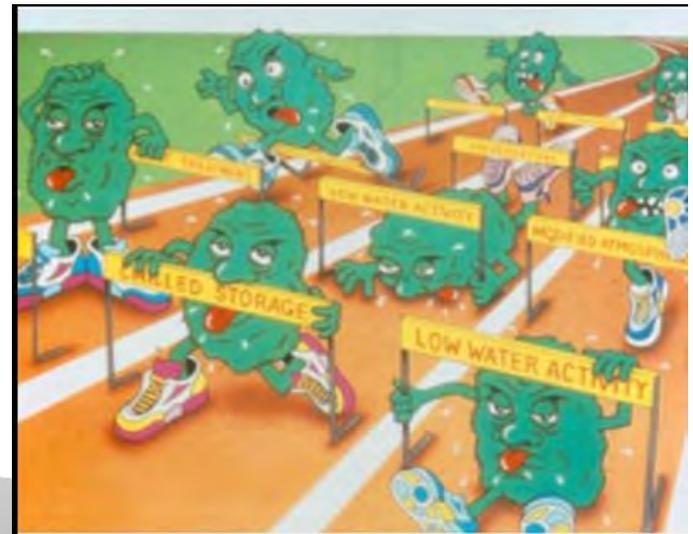
# What do interventions look like?



MAKING YOUR WORLD STRONGER

# Why are different interventions utilized?

- ❑ Multiple hurdle approach – stacking different types of antimicrobial solutions or systems throughout the production process to make it difficult for microorganisms to survive the process.
  - Types of interventions – thermal, pH, chilling, combinations



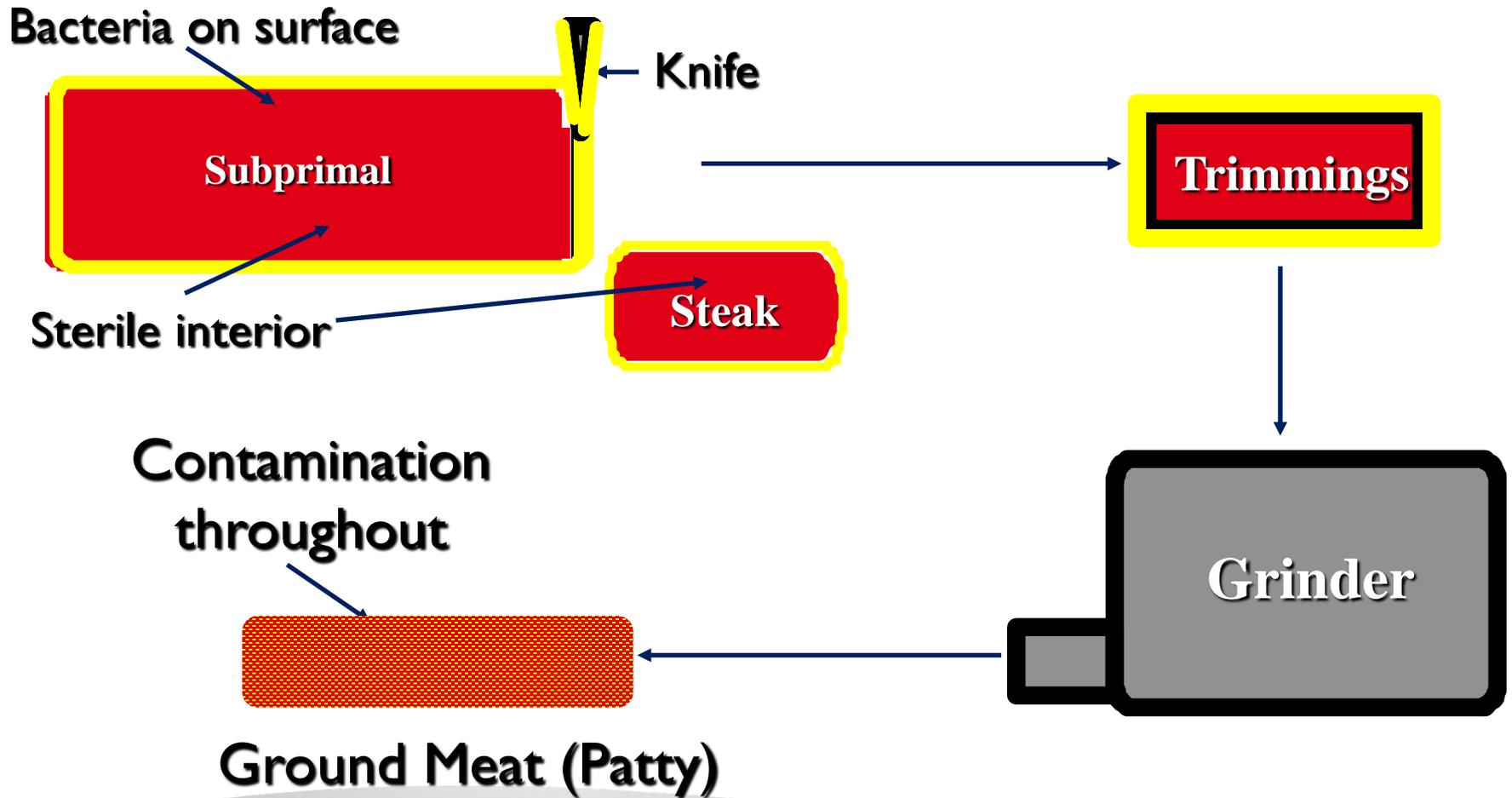
# What is a 'non-intact' product?

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- ❑ FSIS Directive 10,010.1, Revision 4
  - Raw, non-intact product – i.e., ground, mechanically tenderized, needled, and vacuum marinated.



# Why is non-intact different?



# Non-intact or Intact Product



MAKING YOUR WORLD STRONGER

# HACCP and Non-intact Products

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- ❑ Hazard analysis – addresses the likelihood of occurrence for pathogens.
- ❑ Antimicrobial interventions to reduce potential contamination may be applied as a processing aid or as a CCP prior to producing non-intact products.



# Why is intended use important?

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- ❑ What does JBS intend to be for non-intact versus intact products?
  - Intact – any vacuum packaged product(s) whether in a box or a combo.
  - Non-intact – naked (not vacuum packaged) product(s) in a box or a combo.
- ❑ What happens when customers use the product for non-intact when it was not intended for that use?
  - The 'lot' is unknown and not able to be controlled.



# Lotting and Testing product destined for ground beef

- ❑ Beef trimmings are destined to be raw, ground beef; therefore, they are **ALL** tested.
- ❑ Lots are typically 1 combo up to 5 combos.
- ❑ Lots should never be divided between use.



# Labeling of non-intact

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- ❑ On May 18, 2015, FSIS published a final rule that established labeling requirements for raw or partially cooked mechanically tenderized beef products.
- ❑ Does not apply to ground beef, hamburger patties, or beef patties.
- ❑ Does not apply to cubed steaks – visually able to tell it is tenderized.
- ❑ Does not apply to fully cooked products.



# Bench Trim

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- ❑ Occurs when a processor or retailer utilizes INTACT products to make smaller portions and the TRIM that comes from this process is termed 'bench trim'.
  
- ❑ Hazards of using Bench Trim –
  - Multiple suppliers with different food safety systems.
  - The lot of the product is unknown and therefore not able to be controlled.



# Bench Trim

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- ❑ If the processor is an FSIS inspected establishment, this process **MUST** be addressed in their HACCP plan.
  - Supplier approval program
  - Apply an antimicrobial intervention
  - Lot and test the bench trim





Questions?

MAKING YOUR WORLD STRONGER

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-016**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Creation of a Committee: Intended use STEC hazards in retail environment

**Issue you would like the Conference to consider:**

Retail food establishments with in house grinding operations are commonly not aware of the potential presence of Shiga Toxin-producing E. coli (STEC) associated with beef cuts that are intended for intact use. It is a very common practice for firms to use intact meats "intended for intact use", including boxed primal cuts or in-house generated 'bench trim' from the processing of primal and/or subprimal to make non-intact finished products such as ground beef. This practice exposes consumers to STEC hazards that are controlled at the primary processing facility. The inclusion of controls and education in the retail business environment will reduce the incidence of STEC illnesses and mitigate the liability firms unwittingly assume when violating the Intended Use policy.

**Public Health Significance:**

STEC may cause illness of varying severity from diarrhea (often bloody) and abdominal cramps to, rarely, kidney disorders. In some instances, the toxin produced by the organism can bind to tissues in the kidneys and cause hemolytic uremic syndrome (HUS), leading to kidney failure and death. Cattle have been identified as a reservoir for pathogens including STEC. The intestinal tract, mouth, hide, and hooves of cattle can contain these pathogens. Contamination can be transferred to the carcass during the slaughter process. Slaughter establishments typically employ a variety controls to prevent, eliminate or reduce these pathogens during the slaughter process. USDA policies do not consider the presence of STEC to be an adulterant in beef products that are intended for intact consumer use, but often these beef products are used at retail establishments to manufacture non-intact products. This practice is common in the retail food industry and often conducted without the firm being aware of the need for controls as evidenced by historically common frequency of outbreaks.

**Recommended Solution: The Conference recommends...:**

That a Committee for the Evaluation of Intended Use Hazards during Retail Meat Processing be created. This committee should include members of all constituencies in the CFP, including USDA personnel. The committee will be charged with:

1. Implement a variance with HACCP based controls requirement in the model food code for firms using Intact Intended Use meats to manufacture non-intact products. Elements of the variance must include:

A.) Pre-requisite program including supplier guarantee for beef products intended for non-intact products,

B.) Control measures related to STEC Reduction, specifically, methods to reduce STEC on the meat surface to below a detectable level before non-intact processing, such as an antimicrobial intervention, another lethality treatment, or treat or wash the product and trim the entire outer surface,

C.) Supporting recordkeeping, monitoring, and verification.

D.) Establishments must properly design and fully validate the method used to reduce STEC to below detectable levels. This is necessary to address the activity of retail establishments using primal and/or subprimal meats or bench trim from meats that are "intended for intact use" to make non-intact products, such as ground beef.

2.) Edit and revise prior developed 'CFP Beef Grinding Log Template Guidance Document' to include:

A.) Reference to "Intended Use" controls, such as supplier guarantees or certificates of analysis,

B.) STEC hazard controls and industry best practices as modeled by USDA inspected facilities.

3.) Develop educational materials to support grinding log assessment by facility management and state / local regulatory authorities, including:

A.) Educational fact sheets detailing STEC hazards represented by the non-intact handling of beef intended for whole intact use for public distribution,

B.) Inclusion of supporting information into the model food code Annex

4.) Determining appropriate methods of sharing the committee's work, such as:

A.) Posting to state and local health department websites or resource libraries,

B.) Incorporating into CFP training programs, posting to the CFP website, and

C.) Sending a letter to the FDA requesting that the Food Code, Annex be amended by adding references to the amended guidance document as well as any existing guidance documents that the committee recommends.

5.) Sending a letter to the USDA requesting that inspected facilities improve the critical control point of communication as related to the "Intended Use" policy to downstream customers.

6.) Reporting the committee's findings and recommendations to the 2022 Biennial Meeting of the Conference for Food Protection.

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**Supporting Attachments:**

- "USDA AskFSIS website detailing gaps in current notifications of hazards"
- "1999 Federal Register"
- "FSIS Compliance guideline for minimizing STEC in raw beef"
- "CFP Guidance document for the production of raw ground beef at retail"

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## Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts

Published 02/07/2014 08:37 AM | Updated 12/05/2019 03:51 PM

How can an establishment adequately support that the primal and subprimal cuts' intended use is for raw intact product and, as a result, would not be sampled as beef manufacturing trimmings or bench trim?

[FSIS Home](#) | [USDA.gov](#) | [FoodSafety.gov](#) | [USA.gov](#) | [Whitehouse.gov](#) | [Site Map](#) | [Policies & Links](#) | [Significant Guidance](#) | [FOIA](#) | [Accessibility Statement](#) | [Privacy Policy](#) | [Non-Discrimination Statement](#) | [Civil Rights](#) | [No FEAR](#) | [Information Quality](#)

In order to fully support the primal and subprimal cuts' intended use is for raw intact product, the establishment should identify establishment controls, along with supportable evidence, that ensure the primal and subprimal cuts are used as intended ([FSIS Directive 10,010.1](#), Section I.A.9.). On-going verification, at a frequency sufficient to be credible, that the receiving establishment or facility is using the product as intended need to be part of the supportable evidence. Establishments do not need to conduct lot-by-lot verification that their controls are effective to adequately support their assertion that primal and subprimal cuts are used as intended for raw intact product.

Some acceptable ways that the establishment can support that primal and subprimal cuts are intended for raw intact product include:

- The establishment communicates the intended use to the receiving establishment or facility by making the letter of intended use available on the producing establishment's company website and references the letter of intended use on bills of lading.
- The establishment receives letters of guarantee showing that all product is used in raw intact product only and maintains on-going communication with the receiving establishment or facility to verify that all its product is being processed as raw intact product only.
- The establishment has a contractual agreement with the receiving establishment or facility so the producing establishment has knowledge of the receiving establishment or facility's production process.

Some examples of when the primal and subprimal cuts' intended use is unclear include:

- An establishment that identifies that the product is intended for use in raw intact products in its hazard analysis, but does not have any controls and supportable evidence that demonstrate the product is used as intended.
- A producing establishment that maintains a letter from the receiving establishment or facility that says the receiving establishment or facility only produces raw intact product, without the producing establishment gathering additional information to verify that all product is only used in raw intact product on an on-going basis.
- An establishment identifies the product's intended use for raw intact products and ships the product through a broker or to retail but does not have controls to ensure product is used as intended and does not have supporting documentation showing the product is used as intended.
- An establishment makes the letter of intended use available on the producing establishment's company website but does not maintain on-going communication with the receiving establishments or facilities to ensure they are aware of the letter.

It is the establishment's responsibility to maintain sufficient supporting documentation that the primal and subprimal cuts in question are used as intended for raw intact product only. If the establishment cannot adequately support its assertion that primals and subprimal cuts are used as intended for raw intact products, FSIS will collect the sample.

**Paperwork Reduction Act**

The **Federal Register** information collection notice was published in the proposed rule on September 29, 1998 (63 FR 51864). A revised information collections package was submitted to the Office of Management and Budget and approved under OMB control number 0560-0148.

**Discussion of Comments**

Five comments, all in favor of the proposed change, were received from tobacco importers and brokers in response to the proposed rule which was published in the **Federal Register** at 63 FR 51864 (September 29, 1998). There were no unfavorable comments. Accordingly, for the reasons given when the proposed rule was published, it has been determined to adopt the proposed rule as a final rule.

**List of Subjects in 7 CFR Part 1464**

Imports, Loan programs—agriculture, Tobacco.

For the reasons set forth in the preamble, 7 CFR 1464 is amended as follows:

**PART 1464—TOBACCO [Amended]**

1. The authority citation for 7 CFR 1464 continues to read as follows:

**Authority:** 7 U.S.C. 1421, 1423, 1441, 1445, 1445-1 and 1445-2; 15 U.S.C. 714b, 714c.

2. Section 1464.101(b) is amended by revising the definition of “de minimis special entries” to read as follows:

**§ 1464.101 Definitions.**

\* \* \* \* \*

(b) Terms. \* \* \*

*De minimis special entries.* Imports of unmanufactured tobacco when the total importation at any time or on any date is 100 kilograms or less and such tobacco is imported segregated from other tobacco for use as samples, for research, or other use approved by the Director.

\* \* \* \* \*

Signed at Washington, DC, on January 11, 1999.

**Keith Kelly,**

*Executive Vice President, Commodity Credit Corporation.*

[FR Doc. 99-1134 Filed 1-15-99; 8:45 am]

**BILLING CODE 3410-05-P**

**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

**9 CFR Chapter III**

[Docket No. 97-068N]

**Beef Products Contaminated With *Escherichia Coli* O157:H7**

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Policy on beef products contaminated with *E. coli* O157:H7.

**SUMMARY:** In 1994, the Food Safety and Inspection Service (FSIS) notified the public that raw ground beef products contaminated with the pathogen *Escherichia coli* O157:H7 are adulterated under the Federal Meat Inspection Act unless the ground beef is further processed to destroy this pathogen. FSIS is publishing this notice to provide the public with information about its policy regarding beef products contaminated with *Escherichia coli* O157:H7 and to afford the public an opportunity to submit comments and recommendations relevant to the Agency’s policy, and any regulatory requirements that may be appropriate to prevent the distribution of beef products adulterated with this pathogen.

**DATES:** Comments must be received by March 22, 1999.

**ADDRESSES:** Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 97-068N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700. All comments submitted in response to this notice will be available for public inspection in the Docket Clerk’s office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, Washington, DC 20250-3700; (202) 205-0699.

**SUPPLEMENTARY INFORMATION:**

**Introduction**

The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) to protect the health and welfare of consumers by preventing the distribution of meat and meat food products that are unwholesome, adulterated, or misbranded. This notice explains the Agency’s policy governing beef products that contain the pathogen

*Escherichia coli* O157:H7 (*E. coli* O157:H7). Interested parties are encouraged to submit their views, relevant information, and suggestions regarding this policy or any regulatory requirements that the commenters believe may be appropriate to prevent the distribution of products contaminated with *E. coli* O157:H7.

**Beef Products of Concern**

In 1994, FSIS notified the public that raw ground beef products contaminated with *E. coli* O157:H7 are adulterated within the meaning of the FMIA unless the ground beef is further processed to destroy this pathogen. Exposure to *E. coli* O157:H7 has been linked with serious, life-threatening human illnesses (hemorrhagic colitis and hemolytic uremic syndrome). Raw ground beef products present a significant public health risk because they are frequently consumed after preparation (*e.g.*, cooking hamburger to a rare or medium rare state) that does not destroy *E. coli* O157:H7 organisms that have been introduced below the product’s surface by chopping or grinding (*e.g.*, ground beef, veal patties, and beef pattie mix).

The public health risk presented by beef products contaminated with *E. coli* O157:H7 is not limited, however, to raw ground beef products. Given the low infectious dose of *E. coli* O157:H7 associated with foodborne disease outbreaks and the very severe consequences of an *E. coli* O157:H7 infection, the Agency believes that the status under the FMIA of beef products contaminated with *E. coli* O157:H7 must depend on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed.

In evaluating the public health risk presented by *E. coli* O157:H7-contaminated beef products, FSIS has carefully considered the deliberations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and its Meat and Poultry Subcommittee. Last year, the Food and Drug Administration (FDA) requested recommendations, for use in the 1999 edition of its Food Code, on appropriate cooking temperatures for, among other foods, intact beef steaks for the control of vegetative enteric pathogens. In discussing intact product, the Committee stated that:

Due to a low probability of pathogenic bacteria being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed

to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. . . .

The Committee's definition of "Intact Beef Steak" limited the applicability of this conclusion to "[a] cut of whole muscle(s) that has not been injected, mechanically tenderized, or reconstructed."<sup>1</sup> For purposes of FDA's current Food Code (1997, Subpart 1-201.10(B)(41)), "injected" means:

manipulating a MEAT so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the MEAT such as with juices which may be referred to as "injecting," "pinning," or "stitch pumping."<sup>2</sup>

FSIS believes that in evaluating beef products contaminated with *E. coli* O157:H7, intact cuts of muscle that are to be distributed for consumption as intact cuts should be distinguished from non-intact products, as well as from intact cuts of muscle that are to be further processed into non-intact product prior to distribution for consumption. Intact beef cuts of muscle include steaks, roasts, and other intact cuts (e.g., briskets, stew beef, and beef "cubes for stew,"<sup>3</sup> as well as thin-sliced strips of beef for stir-frying) in which the meat interior remains protected from pathogens migrating below the exterior surface).

Non-intact beef products include beef that has been injected with solutions, mechanically tenderized by needling, cubing,<sup>4</sup> Frenching, or pounding devices, or reconstructed into formed entrees (e.g., beef that has been scored to incorporate a marinade, beef that has a solution of proteolytic enzymes applied to or injected into the cut of meat, or a formed and shaped product such as beef gyros). Pathogens may be introduced below the surface of these products as a result of the processes by which they are made. In addition, non-intact beef products include those beef products in which pathogens may be introduced below the surface by a comminution process such as chopping, grinding, flaking, or mincing (e.g., fresh veal sausage and fabricated beef steak).

<sup>1</sup> The NACMCF-adopted minutes of the Subcommittee on Meat and Poultry are available for viewing in the FSIS docket room.

<sup>2</sup> A copy of the 1997 FDA Food Code is available for viewing in the FSIS docket room. In addition, an electronic version of the Code is linked on line through the FSIS web page located at <http://www.fsis.usda.gov>.

<sup>3</sup> The phrase "cubes for stew" generally refers to meat hand-cut into uniform squares.

<sup>4</sup> The term "cubing" generally refers to the process of flattening and knitting together meat into outlet size products by means of a machine.

Intact cuts of beef that are to be further processed into non-intact cuts prior to distribution for consumption must be treated in the same manner as non-intact cuts of beef, since pathogens may be introduced below the surface of these products when they are further processed into non-intact products. Manufacturing trimmings (i.e., pieces of meat remaining after steaks, roasts, and other intact cuts are removed) are an example of this type of product. Although manufacturing trimmings may be intact, they are generally further processed into non-intact products.

The Agency believes that with the exception of beef products that are intact cuts of muscle that are to be distributed for consumption as intact cuts, an *E. coli* O157:H7-contaminated beef product must not be distributed until it has been processed into a ready-to-eat product—i.e., a food product that may be consumed safely without any further cooking or other preparation. Otherwise, such products (i.e., non-intact products and intact cuts of muscle that are to be further processed into non-intact products prior to distribution for consumption) must be deemed adulterated. Intact steaks and roasts and other intact cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with *E. coli* O157:H7 when consumed. Consequently, such intact products that are to be distributed for consumption as intact cuts are not deemed adulterated.

#### **E. coli O157:H7 Sampling and Testing Program**

FSIS currently samples and tests various raw ground beef products (including veal products) for *E. coli* O157:H7.<sup>5</sup> The program sampling is done at inspected establishments and retail stores. The Agency has limited the sampling and testing program to beef products because foodborne illness from *E. coli* O157:H7 has not been associated, to date, with other types of livestock or poultry subject to federal inspection.

The sampling and testing program does not cover intermediate products, such as beef derived from advanced meat/bone separation machinery and recovery systems, since these products are generally further processed to formulate products such as hamburger, but they are not themselves distributed to consumers. Additionally, the

<sup>5</sup> For the Agency's current sampling and testing program instructions, see FSIS Directive 10,010.1, Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef, February 1, 1998. A copy of this document is available for viewing in the FSIS docket room.

sampling and testing program does not cover multi-ingredient products that contain beef, as well as other livestock or poultry ingredients (e.g., sausage that contains both fresh beef and pork).

If FSIS confirms the presence of *E. coli* O157:H7 in a raw ground beef product sampled in the sampling and testing program, it takes regulatory action (coordinating with State officials for products found at retail). The action taken by FSIS is based on the facts of the particular case (e.g., the quantity of product that the sample represents; whether the product is associated with an outbreak of foodborne illness), but in all cases it reflects the Agency's determination that, unless further processed in a manner that destroys this pathogen (e.g., into ready-to-eat beef patties), the product involved that is contaminated with *E. coli* O157:H7 is adulterated.

At this time, FSIS is not expanding its sampling and testing program to include all types of non-intact beef products or intact cuts of muscle that are to be further processed into non-intact products prior to distribution. The Agency may reconsider its sampling and testing program, as well as the scope of products deemed adulterated, in response to any comments received on the Agency's position regarding application of the FMIA's adulteration standards.

#### **Other FSIS Activities**

FSIS's effort to reduce the risk of foodborne illness associated with beef products has included development of a guidance document to assist processors of ground beef in developing procedures to minimize the risk of *E. coli* O157:H7, and other pathogens, in their products. Draft Agency guidance, along with materials developed by two trade associations, was made available to the public and was the subject of an April 22, 1998, public meeting (63 FR 13618, March 20, 1998).<sup>6</sup> The Agency has reviewed the comments received on the draft materials and is publishing a notice of the availability of the revised guidance in this issue of the **Federal Register**.

FSIS is participating in a risk assessment regarding *E. coli* O157:H7. A public meeting regarding the risk assessment was announced in an earlier

<sup>6</sup> Copies of the comments received on the guidance document (Docket #98-004N), along with the transcript of the public meeting and the draft guidance document are available for viewing in the FSIS docket room. In addition, an electronic version of the FSIS and industry guidance documents are available on line through the FSIS web page located at <http://www.fsis.usda.gov> (see the link for HACCP guidance documents).

Federal Register notice and was held on October 28, 1998 (63 FR 4432, August 18, 1998).<sup>7</sup>

FSIS is now reviewing its regulations to determine what changes the Agency should make to increase consumer protection against meat and poultry products adulterated with *E. coli* O157:H7, or other pathogens. Therefore, FSIS is soliciting input from the public about regulatory requirements that may be appropriate to prevent the distribution of products adulterated with *E. coli* O157:H7. Any changes that the Agency would make in the regulations would have to be consistent with the Agency's view expressed in this notice that beef products, other than surface-contaminated intact cuts that are to be distributed for consumption as intact products, that contain *E. coli* O157:H7 are adulterated unless conditions of transportation and other handling ensure that they will not be distributed until they have been processed into ready-to-eat products.

Because FDA has amended its regulations to permit the use of ionizing radiation for refrigerated or frozen uncooked meat, meat byproducts, and certain meat food products to control foodborne pathogens (62 FR 64107, December 3, 1997), FSIS is preparing a proposed rule on procedural and labeling requirements for irradiated products. Interested persons will have the opportunity, in that rulemaking, to submit comments to the Agency on irradiation treatment of *E. coli* O157:H7-contaminated products as an option for effectively eliminating this one specific pathogen.

Done at Washington, DC, on January 13, 1999.

**Thomas J. Billy,**

*Administrator.*

[FR Doc. 99-1123 Filed 1-15-99; 8:45 am]

**BILLING CODE 3410-DM-P**

<sup>7</sup> Copies of the comments received on the risk assessment process (Docket #98-037N), the transcript of the risk assessment public meeting, and a preliminary scoping document are available for viewing in the FSIS docket room. In addition, an electronic version of the preliminary scoping document is available on line through the FSIS web page located at <http://www.fsis.usda.gov> (see the link for the Office of Public Health and Science, *E. coli* risk).

## DEPARTMENT OF THE TREASURY

### Office of Thrift Supervision

#### 12 CFR Parts 563, 563b

[No. 99-1]

RIN 1550-AA72

#### Capital Distributions

**AGENCY:** Office of Thrift Supervision, Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Office of Thrift Supervision (OTS) is issuing a final rule revising its capital distribution regulation. Today's rule updates, simplifies, and streamlines this regulation to reflect OTS's implementation of the system of prompt corrective action (PCA) established under the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA). The final rule also conforms OTS's capital distribution requirements more closely to those of the other banking agencies.

**EFFECTIVE DATE:** April 1, 1999.

**FOR FURTHER INFORMATION CONTACT:** Edward J. O'Connell, III, Project Manager, (202) 906-5694; Evelyne Bonhomme, Counsel (Banking and Finance), (202) 906-7052; Karen Osterloh, Assistant Chief Counsel, (202) 906-6639, Regulations and Legislation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street NW., Washington, D.C. 20552.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On January 7, 1998, the OTS published a proposed rule adding a new subpart E to part 563 to govern capital distributions by savings associations.<sup>1</sup> The proposal was intended to update, simplify, and streamline the existing capital distribution rule to reflect OTS's implementation of the system of prompt corrective action (PCA) established under the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA). Consistent with section 303 of the Community Development and Regulatory Improvement Act of 1994 (CDRIA), the proposed rule was also designed to conform the OTS capital distribution regulation to the rules of the other banking agencies, to the extent possible.

<sup>1</sup> 63 FR 1044 (Jan. 7, 1998).

## II. Summary of Comments and Description of Final Rule

### A. General Discussion of the Comments

The public comment period on the proposed rule closed on March 9, 1998. Four commenters responded: one federal savings bank, one savings and loan holding company, one law firm representing a federal savings bank, and one trade association. Two commenters supported the proposed rule with certain modifications and clarifications. One commenter, the savings and loan holding company, opposed the proposed changes. Another commenter addressed coverage of capital distributions by operating subsidiaries. The issues raised by the commenters are addressed in the section-by-section analysis below.

### B. Section-by-Section Analysis

#### *Proposed § 563.140—What Does this Subpart Cover?*

Section 563.140 of the proposed rule described the scope of the regulation. Proposed subpart E would apply to all capital distributions by savings associations. The OTS specifically requested comment on whether the capital distribution rule should also apply to capital distributions by operating subsidiaries of savings associations. This issue is addressed below under § 563.141.

#### *Proposed § 563.141—What is a Capital Distribution?*

Proposed § 563.141 defined the term "capital distribution" as a distribution of cash or other property to a savings association's owners, made on account of their ownership. The proposed definition, at § 563.141(a), excluded dividends consisting only of a savings association's shares or rights to purchase shares, and excluded payments that a mutual savings association is required to make under the terms of a deposit instrument.

Capital distributions would also include a savings association's payment to repurchase, redeem, retire, or otherwise acquire any of its shares or other ownership interests, any payment to repurchase, redeem, or otherwise acquire debt instruments included in total capital, and any extension of credit to finance an affiliate's acquisition of those shares or interests. Proposed § 563.141(b). Additionally, a capital distribution would include any direct or indirect payment of cash or other property to owners or affiliates made in connection with a corporate

# FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef (including Veal) Processing Operations

## 2017 Compliance Guideline

This guideline is designed to assist establishments producing non-intact and intact cuts intended for raw non-intact beef products so they may:

- Understand the adulterant status of STEC in beef products.
- Design supportable control measures for STEC.
- Develop ongoing verification measures to ensure that STEC control measures are functioning as intended.
- Develop grinding logs that identify and track source materials and products produced.
- Respond when the HACCP system failed to prevent, or reduce STEC to below detectable levels

## Preface

### What is the purpose of this Compliance Guideline?

The Food Safety and Inspection Service (FSIS) published this guideline to assist small and very small processing establishments that produce raw non-intact beef products (e.g., ground beef and mechanically tenderized beef), raw intact beef products intended for non-intact use, or raw intact beef products where the intended use is not clear. This guideline is designed to help establishments understand the adulterant status of STEC in beef products, design supportable control measures for STEC, develop ongoing verification measures to demonstrate that the HACCP system is functioning as intended to reduce STEC to below detectable levels, develop grinding logs to track products, and respond to positive STEC sample results.

This document provides guidance to assist establishments in meeting FSIS regulations. This guideline represents FSIS' best practice recommendations, based on the best scientific and practical considerations, and does not necessarily represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline. This guideline represents FSIS' current thinking on this topic and should be considered usable as of the issuance date.

This guideline is focused on small and very small establishments in support of the Small Business Administration's initiative to provide small and very small establishments with compliance assistance under the Small Business Regulatory Enforcement and Fairness Act (SBREFA). It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective HACCP systems. However, the recommendations in this guideline apply to all FSIS regulated meat establishments, regardless of their size.

FSIS posts policy guidance to the [askFSIS](#) Website and publishes directives and notices that provide Agency personnel with instructions for testing and other verification activities related to STEC. This guideline brings together the most current policy material and guidance on STEC in beef products, and aids small and very small establishments in understanding the features and preventive measures that are necessary to address STEC in non-intact beef product and product components when designing a HACCP system.

For the purpose of this document:

- When the document references beef; veal is also included
- When the document references non-intact products, also included are:
  - non-intact product components (e.g., as head meat, cheek meat, and weasand meat);
  - products intended for non-intact use; and
  - products where the intended use is unclear.
- Products that are intended for intact use (that will not be ground or otherwise rendered non intact either at Federally Inspected establishments or retail) are not covered by this document, because STEC is not an adulterant in these products (see page 4 for more information).
- The procedures described in this document to reduce STEC will also assist establishments in reducing *Salmonella*.

## What changes have been made to the guideline from the last version?

This single guideline updates and combines information from the following guidance documents, which will now be considered retired and replaced.

- *Draft Guidance for Small and Very Small Establishments on Sampling Beef Products for Escherichia coli O157:H7* (August 12, 2008)
- *Sanitation Guidance for Beef Grinders* (January 2012)

FSIS has made policy changes since issuing the previous guidelines. FSIS has also issued new revisions of [FSIS Directive 10,010.1, Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli \(STEC\) in Raw Beef Products](#), and [FSIS Directive 10,010.2, Verification Activities for Shiga Toxin-Producing Escherichia Coli \(STEC\) in Raw Beef Products](#), to inspection program personnel. This guideline incorporates current Agency thinking on the use of antimicrobial treatments, establishment sampling programs, and other measures in the establishment's HACCP system.

## How can I comment on this guideline?

FSIS is seeking comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days after the date of publishing November 6, 2017 and the document will be updated in response to the comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at [regulations.gov](http://www.regulations.gov): This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Mail, including CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: *FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations*. Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Although FSIS is requesting comments on this guideline and may update it in response to comments, FSIS encourages establishments to utilize the information contained in this guideline as it reflects FSIS's current position.

## Is this version of the guideline final?

FSIS will update this guideline in response to comments as necessary.

## What if I still have questions after I read this guideline?

If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the [askFSIS](#) database or submit questions through [askFSIS](#). Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter: **FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef (including Veal) Processing Operations**

Question Field: Enter question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Sampling** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue**.

# FSIS Compliance Guideline for Minimizing the Risk of STEC in Raw Beef (including Veal) Processing Operations

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## Why was this guideline developed?

As stated in the *Federal Register* ([76 FR 58157](#)), *E. coli* O157:H7 and six non-O157 serogroups (O26, O45, O103, O111, O121 and O145) are adulterants in raw non-intact beef and intact beef products intended for non-intact use. Although there are many other Shiga Toxin-producing *E. coli* (STEC), this document only refers to the 7 serogroups listed above, which are collectively referred to as STEC.

FSIS is revising this document because it has seen that many small and very small establishments have had difficulty in designing and supporting their HACCP system (e.g., HACCP plan, Sanitation Standard Operating Procedure, or other prerequisite program) in a manner to prevent, eliminate, or reduce STEC to an acceptable level. Consequently, FSIS continues to receive questions related to STEC and HACCP systems. In addition, FSIS continues to take enforcement actions at processing establishments for HACCP systems that inadequately address STEC. This guideline combines past compliance guidelines, incorporates guidance posted to [askFSIS](#), and serves as a comprehensive source of information for small and very small establishments when developing a sound HACCP system that address STEC in raw non-intact beef processing operations.

“STEC” is an acronym for **S**higa **T**oxin-producing **E. coli**. Some strains of STEC may cause severe illness due to the presence of Shiga toxin and other virulence factors. STEC includes *E. coli* O157:H7 and six non-O157 serogroups: O26, O45, O103, O111, O121, and O145. Raw non-intact beef products and beef products intended for non-intact use may be injurious to the public’s health if contaminated with STEC. Therefore, all seven serogroups above are considered adulterants in raw non-intact beef and beef intended for non-intact use under the Federal Meat Inspection Act (21 U.S.C. 601(m)(1)).

As required by the HACCP regulations contained in [9 CFR 417](#), each establishment must conduct a hazard analysis for its production process to determine the hazards that are reasonably likely to occur (RLTO). STEC contamination is a food safety hazard during the slaughter and processing of raw beef products. Establishments producing raw non-intact beef product should address STEC in their HACCP systems. This guideline applies to a wide range of production practices at both beef processing establishments and combination beef slaughter-processing establishments, and provides establishments with the comprehensive framework to understand and control STEC, and verify those controls are effective in reducing STEC to below detectable levels. This guideline provides small and very small establishments with the information necessary to make well-informed decisions regarding the adequacy of the controls in place for STEC and methods used to verify that the controls are functioning as intended. FSIS recognizes that extensive, high frequency sampling and testing may be cost prohibitive for small and very small establishments. Therefore, designing and implementing an effective HACCP system for minimizing the risk of STEC is outlined in this document.

Non-intact products include: ground beef; beef that an establishment has injected with solutions; beef that is vacuum tumbled with solutions; beef that an establishment has mechanically tenderized by needling, cubing, pounding devices (with or without marinade); beef that an establishment has reconstructed into formed entrees; and diced beef less than ¾ inch in any one dimension.

## Where does STEC come from?

Cattle have been identified as an important reservoir for pathogens including STEC and *Salmonella*. The intestinal tract, mouth, hide, and hooves of cattle can contain these pathogens. Contamination can be transferred to the carcass during the slaughter process. Slaughter establishments typically employ a variety of controls to prevent, eliminate or reduce these pathogens during the slaughter process.

The effectiveness of any slaughter process to control STEC begins with effective sanitary dressing procedures to minimize contamination in conjunction with methods to maximize decontamination. For more information on STEC control at pre-harvest and in slaughter establishments see the following guidance documents:

- [Sanitary Dressing and Antimicrobial Implementation at Veal Slaughter Establishments: Identified Issues and Best Practices](#) (Aug. 2015)
- [Pre-Harvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing \*Escherichia coli\* Shedding in Cattle: An Overview of Current Research](#) (Aug 2014)
- [FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin producing \*E.coli\* \(STEC\) and \*Salmonella\* in Beef \(including veal\) Slaughter Operations 2017.](#)

FSIS considers controls that are validated to control *E. coli* O157:H7 are also effective against non-O157 STEC. Therefore, a hazard analysis may specifically list each of the 7 STEC individually, or *E. coli* O157:H7, or STEC, etc. These are all considered the same adulterant (i.e., STEC) ([76 FR 58157](#)).

Since STEC contamination has historically occurred in the production of raw non-intact beef products, FSIS recommends that processing establishments incorporate additional procedures into their HACCP systems to support that STEC is not a hazard in the finished product(s). This document discusses measures processing establishments may implement to ensure that STEC has been reduced below detectable limits on products intended for raw non-intact use.

## What HACCP regulatory requirements apply to STEC?

[9 CFR 417.2\(a\)\(1\)](#) states, “Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the measures that can be applied to prevent, eliminate or reduce those hazards to an acceptable level. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment...” [9 CFR 417.5\(a\)\(1\)](#) requires establishments to maintain all supporting documentation for decisions made in the hazard analysis.

From the HACCP perspective, these two regulations work collaboratively. In short, [9 CFR 417.2\(a\)\(1\)](#) requires establishments to determine the hazards associated with the process and [9 CFR 417.5\(a\)\(1\)](#) requires them to support the adequacy of the HACCP system to address the hazards. STEC contamination of non-intact beef products has historically occurred and caused human health illnesses. Therefore, as explained in the *Federal Register* ([76 FR 58157](#)), establishments need to consider both the potential presence and potential outgrowth of STEC in the product, as they both play a critical role in ensuring STEC has been reduced to below detectable levels in raw non-intact beef products.

Temperature controls can inhibit the growth of STEC, but even freezing would not reduce STEC to below a detectable level. Establishments need to control both the presence and outgrowth of STEC, to ensure the products are not adulterated.

## Is STEC considered an adulterant in all beef?

No, STEC is not considered an adulterant on raw beef products “intended” for intact consumer use (e.g., steaks and roasts). That is because when STEC is present on the meat’s exterior surfaces and the product remains intact (intended use), normal consumer cooking will destroy any STEC that may be on the outer surface, even if the product is cooked to a rare or medium internal state. STEC is considered an adulterant in raw non-intact beef products and intact beef products intended for non-intact use (e.g., ground or needle tenderized) or when the intended use is not clearly defined or supported. In order to make supportable decisions in a hazard analysis, establishments need a thorough understanding of the characteristics of STEC and the final product’s intended use. As is discussed below, the establishment is required to identify the intended use or consumers of the product ([9 CFR 417.2\(a\)\(2\)](#)). When STEC is present on the meat’s exterior and the product does not remain intact, STEC may be translocated to the interior of the product during the non-intact process (e.g., grinding, tenderizing). In this case, normal cooking to a rare or medium rare internal state may not be sufficient to destroy STEC throughout the product. Understanding this key concept is crucial to understanding the adulterant status of STEC and evaluating the adequacy of the STEC controls in place in the HACCP system.

[9 CFR 417.2\(a\)\(2\)](#) requires each establishment to identify the intended use or consumers of the finished product. The product’s intended use may affect the STEC controls in place at both the shipping and receiving establishments. Establishments that purchase beef from slaughter establishments should be aware of the slaughter establishment’s intended use for the specific products they receive. Slaughter establishments should have a system in place to communicate the product’s intended use to its customers. Not all products produced by a slaughter establishment are intended for non-intact use, and in some cases, primals and subprimals may be designated for intact use only. When the receiving establishment plans to use the product in a manner that conflicts with the supplier’s intended use for that product, the receiving establishment would need to implement additional controls for STEC. The communication of the intended use of the product, identified at each level of the distribution chain including retail, is an important component for each establishment to consider when addressing STEC and developing a supportable HACCP system.

An establishment may receive and grind source materials that were not intended for grinding. However, the receiving establishment must address that specific use in its hazard analysis.

## Are customary cooking practices or validating cooking instruction labels enough to address STEC in raw non-intact beef products?

No. Validated cooking instructions cannot serve as a control or critical control point to address STEC in the production of raw non-intact products. Because of the history of severe outbreaks and illness associated with the consumption of undercooked non-intact beef products, FSIS

concluded in the *Federal Register* ([64 FR 2803](#)) that many non-intact raw beef products present a significant public health risk because STEC may be introduced below the product's surface. [9 CFR 317.2\(e\)\(3\)\(iii\)](#) requires that labels on raw or partially cooked needle or blade tenderized beef products destined for household consumer, hotels, restaurants, or similar institutions contain validated cooking instructions, because these non-intact products do not always appear non-intact to the consumer. If non-intact beef products (including partially cooked needle or blade tenderized products) are found to be adulterated, validated cooking instructions on the label do not prevent the product from being recalled nor do they provide a means of product disposition. That is because the label is a measure to inform the consumer of the need to cook the product thoroughly. However, these labels do not replace for need for establishment to address STEC in its HACCP system to ensure that the product is safe and wholesome before being distributed into commerce.

The customary preparation of raw ground beef and non-intact steaks (i.e., cooking to a rare or medium state) does not destroy STEC throughout the product or render the product safe. However, FSIS recognizes that there are some non-intact raw beef products that are customarily cooked by the consumer to a well done state (i.e., cooking the product to a time and temperature combination sufficient to destroy STEC throughout the product). These products include:

- Raw corned beef;
- Thinly sliced raw beef derived from reconstructed beef products used in "philly" style cheese steaks;
- Multi-ingredient raw ground meat or poultry products in which the ground meat block other than beef is more predominant by weight than is ground beef;
- Shaped and formed ground beef products other than patties (e.g., meatballs, meatloaf); and
- Raw beef sausages (e.g., fresh sausages, beef chorizo).

Establishments electing to use customary cooking practices as a means to support their hazard analysis decisions for certain non-intact products described above, must maintain all the supporting documentation described below that supports the products are customarily thoroughly cooked. Failure to maintain sufficient supporting documentation could implicate these products as adulterated if produced from the same source material of other STEC positive products without any other evidence of microbiological independence. Therefore, in the absence of this additional support, FSIS may request that the product may be recalled, even if consumers are likely to cook the product.

As part of the establishment's decision making regarding STEC in the hazard analysis, establishments need to clearly state the intended use of the product ([9 CFR 417.2\(a\)\(2\)](#)). Establishments also need to have documentation on file supporting their decisions, [9 CFR 417.5\(a\)\(1\)](#), which may include describing the customary preparation practices for the safe consumption of the product and the basis for the establishment's determination that these practices constitute customary preparation. The establishment also needs to document in the hazard analysis or decision-making documents any contractual controls the establishment may have in place to ensure their customers will prepare the non-intact product in a manner whereby STEC would not be a significant health risk. This may include decisions associated with having additional special handling instructions (not just the required safe handling instruction label per [9 CFR 317.2\(l\)](#)) or more descriptive cooking instructions on the product label to assist consumers in safely preparing the product, and why the establishment has

concluded that these instructions will be effective. Finally, as with any raw meat process, the establishment needs to also document in the hazard analysis necessary controls that must be maintained (e.g., purchase specification information, cold chain maintenance, other sanitary controls throughout the process) to minimize microbial growth or to prevent re-contamination to a level such that customary cooking practices would not be sufficient to render the product safe.

## **What controls are needed to address STEC for non-intact products?**

There is no one, absolute way for an establishment to prevent or control STEC. The primary factors that guide the development of effective food safety measures are the source of the beef and the product's intended use. Since STEC is primarily associated with cross-contamination during slaughter, each processing establishment must develop its own measures to address STEC based on knowledge and level of assurance of the STEC controls applied at slaughter.

Establishments that conduct raw non-intact processing typically receive beef source materials in two distinct ways: from an outside slaughtering establishment or directly from their own in-house slaughter operations. In establishments that use beef from both sources, the establishment would have to consider and address STEC for both aspects of its operation. [Attachment 1](#) includes a flow diagram to guide a decision-making process for STEC control in each of the pathways.

### **Combination Slaughter-Processing or “Self-Supplier”**

In establishments that conduct both slaughtering and processing, knowledge of the slaughter controls for STEC are readily available within the establishment and are self-contained within the HACCP system. To reduce STEC to below detectable levels, the HACCP system's decision-making process typically uses a multi-hurdle approach, including:

- Properly implemented and verified sanitary dressing procedures;
- Zero tolerance carcass examinations;
- Application of a validated antimicrobial intervention CCP to reduce any incidental nonvisible STEC contamination; and
- Proper cold chain management to prevent STEC growth.

If an establishment has a validated HACCP plan that is functioning as intended, and the establishment controls its process through properly monitoring sanitation and product temperature, the establishment may be able to support that STEC has been reduced to below detectable levels by its antimicrobial CCP in the slaughter process. In addition, verification (e.g., sampling) must be in place to demonstrate the system continues to function as intended, on an ongoing basis. [On-going verification](#) is discussed later in this document. In other words, the establishment's raw non-intact HACCP program may be able to support that STEC was reduced to below detectable levels by the STEC multi-hurdle approach contained in its slaughter HACCP program.

### **Receiving Establishment or “Outside-Supplier”**

In establishments that receive product from suppliers, knowledge of the STEC controls at slaughter is not self-contained within the receiving establishment's HACCP system. The establishment either needs detailed information that the supplier is meeting necessary purchase specifications or needs to apply additional procedures to address STEC. The receiving establishment's ability to support whether STEC has been reduced to below

detectable levels in the products received will determine whether the establishment is able to address STEC using purchase specifications or use in-house controls. Establishments may use a combination of prerequisite programs and CCPs to address STEC presence and growth during the production of raw non-intact products from beef products received from an outside supplier.

To address STEC in products at receiving, a purchase specification prerequisite program often can be used to provide the additional knowledge and support for the controls previously applied to demonstrate STEC is below detectable levels in the products received. If the establishment determines that STEC is NRLTO at receiving, FSIS recommends a three component approach:

- A Letter of Guarantee (LOG) from each supplier that describes the CCP(s) that address STEC, the monitoring of the CCP(s), and the use of any antimicrobial interventions. An LOG should be maintained for each establishment's meat used, and be updated routinely at a frequency sufficient to be credible;
- A Certificate of Analysis (COA) or similar information should be received from the supplier to demonstrate that STEC has been reduced to below detectable levels in each lot of product received. The information received should include the actual test result, the sampling method (e.g., N-60), the testing method, amount analyzed, and product description to match the purchased product. The COA or similar information should be received for each lot of product received, on a lot-by-lot basis.
- A method of ongoing verification in accordance with [9 CFR 417.4](#) (e.g., product testing) must be in place at the receiving establishment to demonstrate its HACCP system continues to function as intended, on an ongoing basis. [On-going verification](#) is discussed later in this document.

A Letter of Guarantee from a supplying establishment alone would not be considered meaningful ongoing communication with the supplier.

In situations where an establishment receives beef and is unable to receive COAs or similar information supporting that STEC is NRLTO in the product the establishment has the following options to demonstrate that STEC is below detectable levels:

- **Product Testing** – This method functions by demonstrating STEC is already below detectable levels in the product received and produced. Establishments have the option of testing either incoming product or finished product. Due to the lack of knowledge concerning the controls applied during slaughter and lack of a microbial reduction applied in-house, when sampling is selected as the only measure to address STEC, it should occur on a lot-by-lot basis, and establishments should be aware that sampling and testing is not a control; sampling and testing are verification activities. This option can be very cost prohibitive, and FSIS does not recommend it alone, as it relies on the detection or non-detection of STEC on a lot-by-lot basis rather than a systematic control for STEC.
- **STEC Reduction** – These methods function by reducing STEC on the meat surface to below a detectable level before non-intact processing. Establishments can apply an antimicrobial intervention, another lethality treatment, or treat or wash the product and trim the entire outer surface. Ideally, the STEC reduction method would be a CCP

Determining that STEC is RLTO does not mean that the specific product is positive for STEC. It means the establishment has to address the hazard in its HACCP plan.

because the recordkeeping, monitoring, and verification make it the strongest approach. However, it may be acceptable to create a validated pre-requisite program that includes recordkeeping, monitoring, and verification procedures to ensure STEC is below detectable levels in the product produced. Establishments must properly design and fully validate the method used to reduce STEC to below detectable levels regardless of whether it is a CCP or a prerequisite program. More information on validation is in:

[FSIS Compliance Guideline HACCP Systems Validation](#) (April 2015).

**NOTE:** Establishments that receive ground beef and repackage the ground beef without reducing the particle size or adding other source materials (i.e., portioning), should address STEC in their hazard analysis as STEC is a potential hazard in raw non-intact beef products. However, portioned ground beef products are not subject to FSIS verification testing.

A list of antimicrobial interventions and supporting documentation is in the [Resources and References](#) section of this guideline. The list is not all encompassing, but includes common interventions and operational parameters for developing STEC controls in small and very small operations. FSIS encourages multiple interventions where possible, as part of the systematic approach. The application of multiple interventions (or “hurdles”) has shown to be more effective than using a single intervention alone. Establishments should be aware that use of certain antimicrobial interventions may impact the product’s export eligibility to some countries. Eligibility requirements for export to other countries can be found in the [FSIS Export Library](#).

[FSIS Directive 7120.1](#) does not describe a specific level of STEC reduction and is not sufficient scientific supporting documentation for an antimicrobial’s effectiveness.

There is not one “superior” antimicrobial intervention against STEC.

When searching for an antimicrobial treatment, establishments should review the supporting documentation available and choose an intervention based on the HACCP system, available equipment, facility requirements, product type, and financial situation. Establishments should review [FSIS Directive 7120.1](#), *Safe and Suitable Ingredients in the Production of Meat, Poultry and Egg Products*, to verify the chemical intervention is being applied in a safe and suitable manner, and does not violate any applicable concentration or labeling requirements. [FSIS Directive 7120.1](#) does not support a chemical’s efficacy; additional scientific supporting documentation is needed to show that the substance is effective against STEC.

A temperature control program is necessary to prevent STEC outgrowth during the production process. Temperature controls can inhibit the growth of STEC, but even freezing would not reduce STEC to below a detectable level. As is noted above, establishments need to control both the presence and outgrowth of STEC, to ensure the products are not adulterated. Maintaining a proper product temperature during storage and processing ensures STEC will not grow from a previously undetectable level to a detectable level.

### **What is ongoing verification and how does it differ from initial validation?**

As is fully explained in the validation guidance (see link below), initial validation, ongoing verification, and reassessment are three distinct components of [9 CFR 417.4](#). These HACCP principles are relevant not only to a CCP; they apply to the entire HACCP system.

The purpose of validation is to demonstrate that the HACCP system, as designed, can adequately control identified hazards to produce a safe, unadulterated product. The purpose of ongoing verification is to demonstrate that the HACCP system continues to function as intended. It is common for establishments to measure the critical operational parameters or conduct product testing during initial validation to show the HACCP system addresses the hazard. However, doing so does not negate the need for frequent ongoing verification activities, such as testing, for appropriate pathogens and program evaluation, to support that the HACCP system continues to function as intended. More information on validation is in [FSIS Compliance Guidelines for HACCP Systems Validation](#).

### **Why does FSIS recommend testing as a verification activity?**

A common question posed to FSIS personnel by establishment owners is, “where in the regulations does it say I have to test for STEC?” To be clear, there is not a specific requirement for product testing. However, understanding why product testing is so common and why it is so important for a sound HACCP system relates to the complexity of the hazard itself.

Per [9 CFR 417.4](#), establishments perform verification procedures such as, calibrating process monitoring instruments, directly observing monitoring and corrective actions, and reviewing the records. This list is not all encompassing, and does not include all ongoing verification activities necessary for every HACCP system. For non-intact beef products and beef products intended for non-intact use, the HACCP system needs to reduce STEC below detectable levels. Because microbial contamination is not visible, establishments often perform microbiological testing to verify the HACCP system is functioning as intended to reduce STEC to below detectable levels. Each establishment must develop its own approach to controlling STEC and develop a method of ongoing verification. Sampling and testing can play a critical part in that systematic approach. Testing of product provides a statistical confidence that the product is not contaminated with STEC. However, negative test results do not provide 100% certainty that the product is not contaminated. For that reason, testing is a verification activity that demonstrates that a HACCP system is functioning as intended rather than a control for pathogens.

### **How often does ongoing verification need to be conducted?**

Ongoing verification should be designed to ensure that the HACCP system is functioning as intended. Knowledge of individual controls applied to address STEC, the number and types of products produced, the intended and final actual use of the product, the production volume, past HACCP system failures, and other factors should be considered when developing ongoing verification procedures and frequencies.

Each establishment needs to evaluate if the selected verification procedures and associated frequency provides meaningful data about the HACCP system and are adequate to show that the system continues to function as intended to ensure STEC is below detectable levels. As discussed above, establishments that produce beef intended for raw non-intact use or raw non-intact beef products must develop measures to ensure STEC is reduced to below detectable levels on a lot-by-lot basis, such as receiving COAs, applying an antimicrobial and testing product. These measures are separate from ongoing verification. Ongoing verification

is the HACCP principle responsible for verifying that the HACCP system measures are functioning as intended. When testing is used for ongoing verification, FSIS recommends the following minimum frequencies for establishments conducting sampling as an ongoing verification activity for either products intended for raw non-intact use or for finished raw non-intact products (based on volume of production):

- >250,000 lb weekly - sample at least once per month (12 times annually);
- 5,000-250,000 lb weekly - sample at least once every 2<sup>nd</sup> month (6 times annually);
- <5,000 lb weekly - sample at least once every 3<sup>rd</sup> month (4 times annually)

Studies have shown that cattle shed STEC more during the warmer months. Establishments electing to follow the above minimum frequencies should increase the recommended frequencies during the high prevalence months (April through October) by at least a factor of 2. These minimum frequencies are recommended when sampling is the only ongoing verification method selected, and may change as more information becomes available to FSIS. Establishments that receive products from numerous sources or have a history of HACCP system failures (i.e., positive results or high event periods) should consider increasing the ongoing verification frequency and include in their written decision-making documentation rationale justifying why the selected ongoing verification procedure and frequency are adequate to ensure the system continues to function as intended.

Example: An establishment producing 150-lb of non-intact beef daily would be in the “<5,000-lb per week” category for ongoing verification, and FSIS recommends at least “quarterly” sampling during the winter months (October to April) and conduct “twice-per-quarter” sampling during the summer months (April to October), for a total of 6 samples annually.

Establishments need to collect ongoing verification data to verify that its HACCP system is addressing STEC. Frequent on-going communication with suppliers, third party audits, and testing can all be incorporated into a well-designed ongoing verification process. FSIS encourages establishments to conduct verification testing at the minimum frequencies based upon product volume listed above, but also recognizes that the expenses associated with frequent testing can be cost-prohibitive.

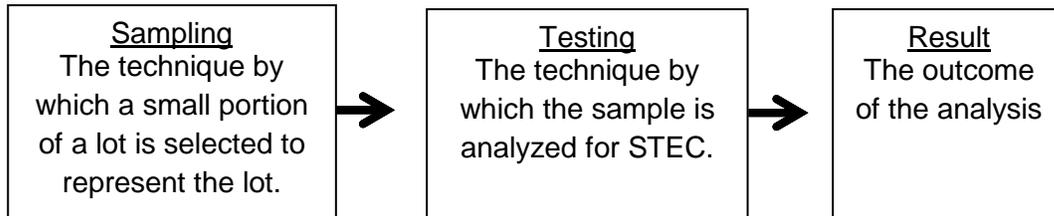
In the absence of a control or prevention measures, it is not appropriate for establishments to apply the recommended minimum frequencies. Without a control or preventive measure in place, sampling should occur on a lot-by-lot basis.

Focus and thought should be placed on the design of the ongoing verification procedures, frequencies, and the data generated to show how the HACCP system is functioning as intended, instead of where any given data point comes from (establishment or FSIS result). For that reason, FSIS does not prohibit establishments from using FSIS test results when documenting the establishment's sampling plan implementation, as the results can provide meaningful process control verification data. The frequency with which FSIS conducts sampling is not designed to support each individual HACCP system, and establishments should not rely solely on FSIS results. However, if an establishment elects to use an FSIS sample result in lieu of collecting its own in-house sampling, the establishment's written

ongoing verification program must provide detailed decision-making outlining how the FSIS result meets the established design of its written program, rather than simply relying upon FSIS testing.

## How do I design supportable “sampling” and “testing” protocols?

Frequently, the terms “sampling” and “testing” are used interchangeably. However, as explained below, they are two distinct processes, and the establishment should maintain adequate support for both the sampling protocol and testing protocol.



FSIS recommends frequent sampling at multiple points in the process (e.g., before and after the non-intact processing). A negative test result on a sampled lot does not imply, with 100% certainty, that a given lot is free of STEC for the following reasons:

- the sampling may have missed isolated pockets of contamination;
- the product may have become cross-contaminated after it was sampled; or
- the STEC population may grow from below a detectable level to a detectable level.

As previously discussed, STEC initially contaminates the meat’s exterior surface during slaughter. When large muscle cuts are ground, the grinding process mixes the exterior surface and any potential contamination with the internal muscle portions. Due to the sporadic low-level nature of STEC contamination, the sampling plan selected should be robust and focus on collecting thin pieces of the exterior surface (e.g., N60 method) throughout the production lot to maximize the likelihood of detecting any STEC contamination, if present. FSIS continually assesses advancements in sampling methodologies and may adopt innovative approaches or other methods other than incision and grab sampling (e.g., surface sampling). More information on sampling beef for STEC is in FSIS [Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing \*Escherichia coli\* \(STEC\) Organisms or Virulence Markers](#).

STEC illness can be caused the consumption of only a few cells. Therefore, when evaluating and selecting a testing method, it is important that the method is validated and includes the appropriate enrichment time and temperature to allow for injured cells to recover. Through enrichment, very low levels of STEC contamination can be identified during testing. Changing the incubation time, temperature, or excluding parts of the sample portion from analysis, without proper validation, can result in a lack of support for the sampling and testing methods. Alternatively, situations may arise when the testing occurs on multiple individual sub-samples (e.g., 65-g portions) rather than the entire sample all at once. In both situations, the testing methodology should be validated for the test portions selected and the entire sample portion should be analyzed. More information on testing methods validated for STEC is in [Foodborne Pathogen Test Kits Validated by Independent Organizations](#).

- Regardless of whether the testing occurs in-house, or at an external laboratory, the method of analysis should be equivalent to that used by FSIS laboratories. More information on FSIS methods and external laboratories is in [FSIS Microbiology Laboratory Guidebook](#) (MLG) and [Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory](#)

Establishments should have procedures in place to hold or control the product that is represented by the test result to prevent adulterated product from entering commerce. Establishments are required to hold or control the product pending FSIS, State, or other Federal test results. FSIS recommends that establishments hold or control the product pending establishment results to complete pre-shipment review on tested product. The amount held would include all products from the sampled and tested lot that are intended for non-intact use or when the product's intended use is not clearly defined. More information on production lot criteria is in the next section.

### **How do establishments determine a production “lot”?**

A production lot can be defined in many ways. FSIS does not recognize “clean-up to clean-up” alone as a supportable basis for distinguishing one portion of production of raw beef product from another portion of production. This is because STEC are generally not environmental contaminants and, therefore, would not be completely addressed through cleaning and sanitizing.

Common criteria used to determine microbiological independence between products include, but are not limited to:

- robust sampling and testing data;
- antimicrobial interventions applied;
- source material used;
- production equipment used; and
- equipment sanitation.

Raw non-intact beef products that are positive or presumptive positive (not confirmed negative) for STEC are adulterated unless they are further processed to destroy STEC. When a sample is positive for STEC, all product represented by the sample (i.e., the lot) is considered positive. When a STEC positive occurs, the establishment must demonstrate what product is affected by the positive result, on a case-by-case basis.

When positive product or an illness outbreak occurs and the recall committee is convened to determine the amount of adulterated product in commerce, additional factors may be assessed other than those specifically outlined in this document when determining the scope of a recall. While following the guidance in this document is a best practice, it may not necessarily guarantee microbiological independence in every situation as the guideline cannot encompass all the possible scenarios that are unique to each individual recall case.

While each lot of ground beef does not have to be from a single supplier, using a single supplier for each lot can be very beneficial for tracing the product back to the supplier during an investigation. For that reason, commingling product from multiple suppliers is not considered to be a best practice. Product that contains meat from only one supplier but is mixed with other non-meat ingredients (e.g., soy, spices) is still considered “sole source” product for lotting, recalls and traceback.

FSIS defines commingling as direct meat-to-meat contact in a package, vat, or other container. Meat exposed to common food contact surfaces does not constitute commingling. Most of the STEC present on meat is the result of cross-contamination events during the slaughter and dressing processes. Unlike *Listeria monocytogenes*, STEC does not persist and multiply to significant levels in the production environment. Therefore, provided the sanitation procedures are sufficient, food contact surfaces are typically not a significant source of STEC contamination in raw beef products.

Individually cryovaced products are not routinely commingled. FSIS recognizes that there may be rare situations when individually cryovaced product becomes commingled at the supplier establishment or further processor. The further processor's reconditioning procedures should address situations when unavoidable commingling occurs within its establishment. An example of acceptable reconditioning procedures at the supplier establishment or further processor includes running product that may have been accidentally commingled individually through a validated antimicrobial treatment and ensuring that no commingling occurs after this antimicrobial treatment. If a further processor wants to demonstrate that individually cryovaced primals or subprimals are a lot, they would need to be able to demonstrate the individually cryovaced product was not commingled at the supplier establishment (as represented through a purchase specification or some other form of documentation) and is not commingled or cross-contaminated before sample collection. If the further processor is not able to obtain information about the prior history of the cryovaced product regarding commingling by the supplier establishment, or if the individually cryovaced product is commingled before sample collection, then the establishment likely would not be able to support a lot definition consisting of one individually cryovaced product. If a single cryovaced package is the source material for finished non-intact product and the non-intact positive tests positive for STEC, FSIS will carefully evaluate the product's intended use and whether the product was commingled during the traceback investigation, to ensure the establishment's lot definitions are supportable and no other product injurious to human health was released into commerce.

FSIS discourages establishments from mixing source materials from different raw meat suppliers in order to allow for better tracking and identification of product, up and down the distribution chain.

More information on sanitation and lotting is in:

- [Resources and References](#) section of this guideline
- [Beef Processing Best Practices: Grinders Sanitation, Lotting, and Sampling.](#)
- [FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results.](#)

**Do establishments and retailers that grind beef have to keep a “Grinding Log”?**

As part of any well-designed HACCP system, detailed records are important when documenting the production process. In addition, the regulations require that retailers and establishments that grind or chop beef keep certain records listed below. Records tracking each product lot and its source material(s) can serve a vital public health purpose. When there is reason to believe products are adulterated or misbranded, FSIS and establishments track affected products up and down the distribution chain to remove them from commerce. These production records can serve as a roadmap to provide the establishment and the Agency with the information necessary to limit the scope of affected product and promptly remove the product from commerce.

In the case of raw ground beef products in official establishments and retail stores, [9 CFR 320.1\(b\)\(4\)\(iii\)](#) defines a lot as: the amount of raw ground beef produced during particular dates and times, following clean up and until the next clean up, during which the same source materials are used. These production records are necessary for traceback investigation if source material is implicated by positive test results or illness investigations. This lot definition is separate from FSIS sampling of STEC, where, pending test results, official establishments must define and hold the sampled lot on the basis of microbiological independence from other production lots. A “lot” of product, in the context of microbiological independence, is not necessarily limited to the ground beef produced between cleanings.

It is important to keep accurate records that contain all the necessary information to conduct traceback investigations. If the supplier lot number on the received product is missing or not legible, official establishments and retail stores should contact the supplier to obtain that lot number. If no lot number is available, FSIS recommends that the grinder write down any other available supplier material information, such as bar code numbers, invoice numbers, etc.

FSIS explained in the *Federal Register* ([80 FR 79231](#)), [9 CFR 320.1\(b\)\(4\)](#) requires all official establishments and retail stores that grind beef for sale in commerce to maintain the following records:

- The unique identifying number of each establishment supplying the materials used to prepare each lot of raw ground beef product;
- All supplier lot numbers and production dates;
- The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;
- The date and time each lot of raw ground beef product is produced; and
- The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

The above records need to be kept onsite where the product was ground, for at least one year from the grinding date. This rule applies strictly to establishments and retail stores that grind beef. It does not apply to other raw non-intact beef processing (mechanically tenderizing, cubing, injecting, etc.) nor does it apply when ground beef is only portioned or repackaged. This rule only applies to the beef component of the product; it does not apply to any non-meat ingredients added. If the ground product is fully cooked before being sent into commerce and the businesses maintains necessary records for FSIS to verify the final use, FSIS does not enforce these recordkeeping requirements.

Each establishment's production process and lotting system is unique. Detailed records are crucial when attempting to track affected product associated with an outbreak or limit the scope of a recall. The recordkeeping system should be able to track product forward (*from source material, through production, and into the final product produced*) and backwards (*from the final product, back through production, and to the source material used*) throughout the production process. An example of a single-page tracking record is included in [Attachment 2](#). During traceback investigations other non-intact products may be linked to the positive product if there is no evidence of microbiological independence between products. Therefore, FSIS may request that the establishment recall additional product.

### **How will the new “Grinding Log” rule be verified and enforced?**

FSIS will use different personnel to verify the new requirement, depending on whether the ground beef is produced in an official establishment or in a retail store. When produced in an official establishment, FSIS Inspection Program Personnel (IPP) will verify the official establishment meets these new requirements as part of their routine inspection activities. If IPP find that the establishment failed to maintain the required records, FSIS may issue a noncompliance record (NR), a Letter of Warning, or request the Department of Justice to initiate a civil processing in Federal court to enjoin the defendant from further violations of the applicable law and regulations.

When produced in a retail operation, FSIS Compliance Investigators verify the retail store meets these new requirements as part of their surveillance activities. When Investigators observe recordkeeping violations of the new recordkeeping requirements the Investigators are to inform the management official, designee, owner, or product custodian of the violation, and obtain supporting evidence in accordance with [FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal](#) and prepare a Report of Investigation for the violation in accordance with [FSIS Directive 8010.4 Report of Investigation](#).

### **What actions are required in the event of a STEC positive?**

If the product tests presumptive positive on a screening test, only a confirmatory test (culture) method that isolates STEC from the product can be used as an additional test to confirm or negate the presumptive positive test. If the confirmatory test is not conducted, the presumptive positive results will be considered the same as a confirmed positive result. Additional non-confirmatory testing of the same lot of product is not sufficient to show that the product is not adulterated. For example, if the first screening test is positive for STEC but a second screening test is negative, FSIS still considers the entire lot of product adulterated.

Following the identification of the affected lot, the establishment is required to ensure that no product that is injurious to health or otherwise adulterated enters commerce. Once the lot has been determined to be presumptive positive or positive, adding additional product to the lot only increases the affected lot size and does not provide any microbiological independence. The implemented corrective actions will depend on whether the positive result represents a CCP deviation requiring corrective actions per [9 CFR 417.3\(a\)](#), or the positive result represents an unforeseen hazard requiring corrective actions per [9 CFR 417.3\(b\)](#).

Establishments are required to maintain records evidencing proper disposal of beef product that is adulterated because the product is positive or presumptive positive for STEC. Specifically, [9 CFR 417.3](#) requires that establishments take corrective actions and [9 CFR 417.5\(a\)\(3\)](#) requires that they maintain records documenting their corrective actions. [9 CFR 417.3\(a\)\(4\) and \(b\)\(3\)](#) require that establishments' corrective actions ensure that no product that is injurious to health or otherwise adulterated enters commerce. As part of preshipment review, [9 CFR 417.5\(c\)](#) requires establishments to review the records associated with the production of adulterated product to ensure corrective actions were taken, including proper disposition of product, before signing the preshipment review. Additionally, if the establishment does not address STEC in its HACCP plan, the positive result represents an unforeseen hazard per [9 CFR 417.3\(b\)](#), and the establishment must perform the required reassessment and make any necessary changes to its HACCP system to ensure that no additional adulterated products are produced. In addition, the establishment needs to address STEC in its HACCP plan as a hazard reasonably likely to occur.

When a positive occurs, the establishment needs to determine the amount of product that is implicated by the positive result. Criteria to support microbiological independence between positive product and other product are explained on [page 12](#). Due to the process used to produce the non-intact product, the pathogen may have already been translocated into the product or comminuted within the product by the time the positive result is received. As a result, the typical options for handling positive STEC products include:

- Cooking the product in-house (at the official establishment that produced it) to a time and temperature combination adequate to eliminate STEC;
- Sending the product to another official establishment to cook the product to a time and temperature adequate to eliminate STEC;
- Sending the product to receive an adequate lethality treatment to eliminate STEC (e.g., High Pressure Processing (HPP) or irradiation);
- Sending the product to a renderer; or
- Sending the product to a landfill operation.

Records showing that the positive or presumptive positive product was received by an inspected establishment that ordinarily cooks the product is not sufficient to demonstrate that the product actually received a proper disposition. The establishment that produced the product must obtain records evidencing that the entire lot of product was appropriately processed.

Product that is positive or presumptive positive (and not confirmed negative) for STEC is adulterated and cannot move into commerce until it receives a treatment sufficient to destroy the pathogen in an FSIS inspected establishment. If the product is shipped off-site for lethality treatment, the shipping establishment must maintain control of the product until the pathogen is destroyed (under company seals or FSIS form 7350-1). The shipping establishment must receive and maintain sufficient documentation from the receiving establishment that shows each lot of positive product received a lethality treatment.

Product that is positive or presumptive positive for STEC cannot be denatured and sent to a pet food manufacturer. For guidelines on FDA's authorization for salvage of food considered to be adulterated for its intended use by diverting that food to an acceptable animal feed use, access [Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use](#).

Any movement of products that tested presumptive positive or positive for pathogens should be under documented company control (such as company seals or FSIS control). If such

product is going to another official establishment, it may move under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1). Products going to a landfill or off-site renderer need to be denatured before shipment, and include the appropriate controls in place (e.g., seals). Establishments are not to send these products to a broker or independent warehouse facility unless they are able to demonstrate how they control the product when it is at the facility.

Whether positive for STEC or not, it is not appropriate to divert raw non-intact products, products that may be intended for non-intact use, or products with an unknown intended use from an inspected process to a retail exempt process to address STEC. The retail exempt processing requirements of [9 CFR 303](#) specifies that only inspected and passed product sources are to be used. If the products are not produced by a validated HACCP system to address STEC, the products are not fit for use in retail exempt processing.

### Should grinding establishments address lymph nodes?

Recent publications, cited in the [Resources and References](#) section of this guideline, have identified major peripheral lymph nodes (identified below) as a potential source of pathogenic bacteria, including *Salmonella*, for ground beef products. Slaughter and dressing processes and/or typical interventions used to reduce pathogens on carcass surfaces may not be effective at reducing the pathogens, including *Salmonella*, which may be contained within the lymph nodes. Comprehensive systematic control of *Salmonella* should include addressing the potential presence of *Salmonella* from the inclusion of lymph nodes.

Slaughter and processing establishments may want to develop lymph node removal procedures and incorporate them into their HACCP system to ensure the beef products produced do not contain certain lymphatic tissue. Establishments that receive beef products for further processing may want to request documentation, such as an LOG, from their suppliers to support that their suppliers have procedures in place to ensure the removal of lymph nodes that are not incidental to the process. More information on lymph node removal is in:

- [FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin producing E.coli \(STEC\) and Salmonella in Beef \(including veal\) Slaughter Operations 2017](#)

## Scenarios

As a whole, this document includes guidance to small and very small establishments for minimizing the risk of STEC in raw non-intact beef operations by covering multiple topics, including: the adulterant status of STEC in beef products; intended use; developing and designing supportable control measures for STEC; and development of ongoing verification measures to ensure STEC is reduced to below detectable levels. The following scenarios cover common HACCP program decisions observed when establishments attempt to address STEC.

### **Scenario #1:** *Inadequate use of Purchase Specifications; Letters of Guarantee (LOG) only*

A processing establishment receives boxed subprimals from a variety of different establishments through a broker, to produce two non-intact products (i.e., tenderized steaks and ground beef). The boxed beef is received from different slaughter establishments each week based on distributor prices, and the receiving establishment does not have a direct relationship with any of the slaughter establishments. The establishment made the decision that STEC is NRLTO at the receiving step based on the LOG received from each slaughter establishment, updated every 6 months. The establishment is not able to receive a Certificate of Analysis (COA), and is unable to show that any of the product received has ever been tested for STEC, nor does the establishment apply any further interventions to reduce STEC. The establishment samples the finished ground beef six (6) times annually, as outlined in the ongoing verification recommendation for establishments producing <5,000 lb of non-intact beef each week.

*Analysis - The establishment's approach to STEC is inherently flawed because the establishment has failed to appropriately address STEC at the receiving facility. The LOG required by the receiving establishment does not provide adequate support that STEC is below detectable levels in the incoming beef that will be processed into non-intact product. The sampling conducted by the establishment would not be considered adequate verification of the establishment's HACCP system by itself, because the establishment does not have an actual control measure for STEC. Subsequently, the 6 results generated annually would not provide adequate meaningful information about the system's ability to control STEC, because the establishment does not conduct sampling and testing on a lot-by-lot basis. The establishment must request from the supplying establishment evidence that the source materials were tested and found negative for STEC (purchase specifications) or would need to develop and validate its own control measures for STEC (in-house controls), such as lot-by-lot testing of product or application of an antimicrobial treatment. When an actual control is in place, the 6 annual samples could serve as the ongoing verification data necessary to demonstrate the system is functioning as intended. The above HACCP system, as designed, is inadequate to address STEC.*

### **Scenario #2:** *Non-intact processor not adequately addressing hazards*

A low volume processing establishment (<500 lb weekly) does not slaughter but instead receives boxed beef manufacturing trimmings, along with an LOG and a COA for each lot. In addition, the establishment receives boxed beef primals, and produces various steaks, roasts, and bench trimmings to fill daily orders. The establishment is unable to receive COAs for the primal products (indicating that they are not intended by the supplier for non-intact use). In the grinding operation, the establishment combines the two types of trimmings and samples the finished ground beef 6 times annually.

*Analysis - In this instance the establishment has adequately addressed STEC in the purchased trimmings; the establishment maintains an LOG, receives a COA for each lot, and conducts product sampling and testing as part of its ongoing verification. However, the establishment has not adequately addressed STEC in the bench trimmings created from the primals received. That is because the establishment has changed the intended use of the product, but not applied additional controls for STEC to the product. The establishment must request from the supplying establishment evidence that the primal source materials were tested and found negative for STEC (purchase specifications) or would need to develop and validate its own control measures for STEC (in-house controls), such as lot-by-lot testing of product or application of an antimicrobial treatment. When an actual control is in place, the 6 annual samples could serve as the ongoing verification data necessary to demonstrate the system is functioning as intended. The above HACCP system, as designed, is inadequate to address STEC.*

**Scenario #3: Slaughter-Processing Operation – Self-Supplier Only**

A beef slaughter-processing establishment slaughters 5-10 cattle each week and produces various raw intact and raw non-intact beef products (including ground beef and vacuum-marinated steaks), per customer orders. The establishment uses sanitary dressing procedures to limit cross-contamination during slaughter, monitors carcasses for dressing failures, implements a zero tolerance examination CCP for fecal control, and applies a validated antimicrobial treatment at a CCP to reduce STEC to below detectable levels on the carcass before chilling, and maintains the product at temperatures that inhibit pathogen outgrowth. The establishment collects trim samples at the recommended quarterly frequency (6 samples annually) as part of its ongoing verification. No outside beef is received or processed into non-intact product.

*Analysis - In this example, the establishment uses a systematic approach to address STEC in the Slaughter HACCP plan by using measures to prevent carcass contamination, conduct zero tolerance examinations of carcasses for contamination, and reduce STEC with an antimicrobial treatment. Proper cold chain management following slaughter would support that STEC outgrowth would be prevented. The ongoing verification sampling would provide adequate support that the Slaughter HACCP plan and temperature controls are functioning as intended to reduce STEC to below detectable levels in the raw non-intact beef products.*

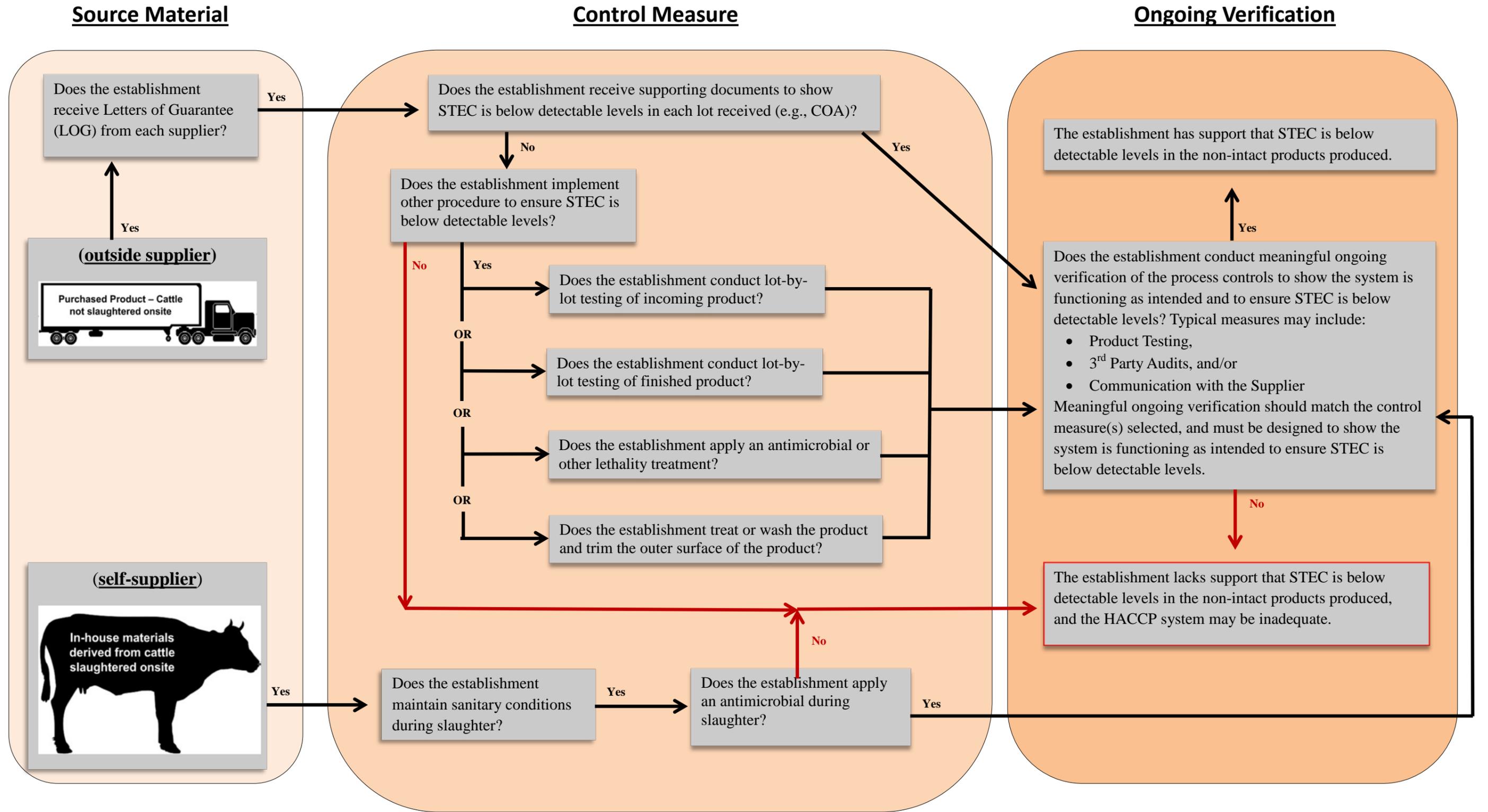
**Scenario #4: Tested product without lot-by-lot COA**

A small establishment receives 2,000 lb. of coarse ground beef daily to produce various ground beef products and beef patties. The program requires an LOG from each supplier that describes the controls in place for STEC, including one or more validated treatments and product sampling. The receiving establishment is not able to receive a traditional “lot-by-lot” COA, but does maintain the LOG and shipping invoices or other similar support documents, stating that each lot of product was produced from negative lots of beef trim. The documents include the sampling and testing method, amount analyzed, and a description of how the test results show STEC has been reduced below detectable levels in the product received. The receiving establishment conducts ongoing verification sampling of the finished product at the “every two months” frequency (total of 9 samples annually) to verify the purchase specifications. The establishment has a CCP in place to prevent growth by maintaining proper product temperature during processing and storage.

*Analysis - The receiving establishment is able to obtain a LOG, but is unable to obtain a traditional "lot-by-lot" COA. However, the receiving establishment is able to gain knowledge of the supplier's slaughter process, STEC controls, and is able to gain an understanding of the supplier's test-and-hold procedures and maintains such supporting documentation (e.g., statement on the invoice or other document on file). The receiving establishment is able to show that the product received was derived from tested negative source materials, and it has received specific information concerning each lot of incoming product that is equivalent to a lot-by-lot COA. This information provides the receiving establishment with necessary support that STEC is reduced to below detectable levels in the products received. The ongoing verification sampling results (9 samples annually) provide adequate ongoing verification to show the program is functioning as intended and continues to reduce STEC to below detectable levels in the raw non-intact beef products. In addition, the establishment has a CCP in place to effectively address cold chain maintenance of the product. The above HACCP system is adequate.*

### Attachment 1 – STEC Decision-Making Flow Chart Guide

This flow chart can be used as the framework to understand how the source materials, control measures, and ongoing verification work together to ensure the HACCP system functions as intended to prevent or control STEC to below detectable levels in the products produced. Typically, changes from the flow diagram or supplying a “no” answer with no further options indicates a flaw in the HACCP system. It is acceptable to follow different pathways for different source materials and different non-intact products produced, so long as all source materials used and every non-intact beef product produced is accounted for within the HACCP system. In addition to the below control measures and ongoing verification, the appropriate temperature controls must be in place throughout the process to ensure STEC does not grow from a non-detectable level to a detectable level.



**Attachment 2 – Grinder’s Log**

This log template is designed to track the source materials used, the products produced, and any microbiological independence between lots. Establishments are encouraged to use the below template as a guide, and include any additional information to the record to fit their unique production processes.

NEW WAVE STORE

123 Main Street

Anytown, USA, Zip Code

FRESH|GROUND BEEF PRODUCTION LOG/TRACKING LIST

Employee Name \_\_\_\_\_ Today’s Date \_\_\_\_\_

Date and Time of Grind	Manufacturer Name of Source Material Used for Product Produced	Supplier Lot #s, Product Code and/or Pack Date of Source Material Used	Est. Number(s) of Est. providing source material	Date and Time Grinder and Related FCSs Cleaned and Sanitized	Comments

\_\_\_\_\_  
Signature of Store Management Reviewer

\_\_\_\_\_  
Date

## Resources and References

Below is a list of published studies and reference materials that may be useful for small and very small establishments when developing STEC preventive measures. The list includes various reference materials outlining industry best practices for beef operations, and numerous publications on antimicrobial treatments common to industry. FSIS does not approve or recommend any one particular antimicrobial treatment over another. Under the HACCP regulations, establishments are required to select the antimicrobial treatment or treatments that best fits the establishment's unique operations, identify the critical factors applicable to the production process, and implement the treatment in a manner consistent with the support.

### Organic acids

- Geornaras, I, Yang, H, Moschonas, G, Munnely, MC, Belk, KE, Nightingale, KK, Woerner, DR, Smith, GC, and Sofos, JN. 2012. Efficacy of chemical interventions against *Escherichia coli* O157:H7 and multidrug-resistant and antibiotic-susceptible *Salmonella* on inoculated beef trimmings. *J. Food Prot.* 75: 1960-1967.
- Schmidt, JW, Bosilevac, JM, Kalchayanand, N, Wang, R, Wheeler, TL, and Koohmaraie, M. 2014. Immersion in antimicrobial solutions reduces *Salmonella enterica* and Shiga toxin-producing *Escherichia coli* on Beef cheek meat. *J. Food Prot.* 77: 538-548
- Wheeler, T. L., Kalchayanand, N., and Bosilevac, J.M. (2014) Pre- and post-harvest interventions to reduce pathogen contamination in the U.S. beef industry. *Meat Science.* 98: 372-382.
- Wolf, M. J., Miller, M. F., Parks, A.R., Loneragan, G. H., Garmyn, A. J., Thompson, L. D., Echeverry, A., and Brashears, M. M. 2012. Validation comparing the effectiveness of a lactic acid dip with a lactic acid spray for reducing *Escherichia coli* O157:H7, *Salmonella*, and Non-O157 Shiga toxigenic *Escherichia coli* on beef trim and ground beef. *J. Food Prot.* 75: 1968-1973.

### Oxidizer antimicrobials

- Penney, N., Bigwood, T, Barea, H., Bulford, D. LeRoux, G, Cook, R., Jarvis, G., Brightwell, G. 2007. Efficacy of peroxyacetic acid formulation as an anti-microbial intervention to reduce levels of inoculated *Escherichia coli* O157:H7 on external carcass surfaces of boned beef and veal. *J. Food Prot.* 70: 200-203.

### Hide-on carcass wash:

- Schmidt, J. W., R. Want, N. Kalchayanand, T. Wheeler, and M. Koohmaraie. 2012. Efficacy of hypobromous acid as a hide-on carcass antimicrobial intervention. *J. Food Prot.* 75(5):955-958.
- Bosilevac, J. M., X. Nou, M. S. Osborn, D. M. Allen, and M. Koohmaraie. 2005. Development and evaluation of an on-line hide decontamination procedure for use in a commercial beef processing plant. *J. Food Prot.* 68:265–272.
- Arthur, T. M., J. M. Bosilevac, D. M. Brichta-Harhay, N. Kalchayanand, S.D. Shackelford, T.L. Wheeler, and M. Koohmaraie. 2006. Effects of a Minimal Hide Wash Cabinet on the Levels and Prevalence of *Escherichia coli* O157:H7 and *Salmonella* on the Hides of Beef Cattle at Slaughter *J. Food Prot.* 70: 1076–79.

### Steam vacuum systems:

- Kochevar, S. L., J. N. Sofos, R. R. Bolin, J. O. Reagan, G. C. Smith. 1997. Steam Vacuuming as a Pre-Evisceration Intervention to Decontaminate Beef Carcasses. *J. Food*

Prot. 60: 107-113.

- Castillo, A., L. M. Lucia, K. J. Goodson, J. W. Savell, and G. R. Acuff. 1999. Decontamination of beef carcass surface tissue by steam vacuuming alone and combined with hot water and lactic acid sprays. *J. Food Prot.* 62(2), 146-151.

#### Organic acid Rinses:

- Gastillo, A, L. M. Lucia, K. J. Goodson, J. W. Savell, G.R. Acuff. 1998. Comparison of Water Washing, Trimming, and combined Hot Water and Lactic Acid Treatment for Reducing Bacteria of Fecal Origin on Beef Carcasses. *J. Food Prot.* 61: 823-828.
- Hardin, M.D., G. R. Acuff, G.R., L. M. Lucia, J. S. Oman, and J. W. Savell. 1995. Comparison of Methods for Decontamination from Beef Carcass Surfaces. *J. Food Prot.* 58: 368-374.
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- Bosilevac, J. M., X. Nou, G. A. Barkocy-Gallagher, T. M. Arthur, and M. Koohmaraie. 2006. Treatments using hot water instead of lactic acid reduce levels of aerobic bacteria and Enterobacteriaceae and reduce the prevalence of *Escherichia coli* O157: H7 on previsceration beef carcasses. *J. Food Prot.* 69(8), 1808-1813.
- Kalchayanand, N., T. M. Arthur, J. M. Bosilevac, D. M. Brichta-Harhay, M. N. Guerini, S. D. Shackelford, T. L. Wheeler, and M. Koohmaraie. 2009. Effectiveness of 1,3-Dibromo-5,5 Dimethylhydantoin on reduction of *Escherichia coli* O157:H7- and *Salmonella*-inoculated fresh meat. *J. Food Prot.* 72(1): 151-456.

#### Hot water rinses:

- Castillo, A., L. M. Lucia, K. J. Goodson, J. W. Savell, G. R. Acuff. 1998. Comparison of Water Wash, Trimming, and Combined Hot Water and Lactic Acid Treatments for Reducing Bacteria of Fecal Origin on Beef Carcasses. *J. Food Prot.* 61: 823-828.
- Bosilevac, J. M., X. Nou, G. A. Barkocy-Gallagher, T. M. Arthur, and M. Koohmaraie. 2006. Treatments using hot water instead of lactic acid reduce levels of aerobic bacteria and Enterobacteriaceae and reduce the prevalence of *Escherichia coli* O157: H7 on previsceration beef carcasses. *J. Food Prot.* 69(8), 1808-1813.
- Smith M. G. 1992. Destruction of bacteria on fresh meat by hot water, *Epidemiol. Infect.* 109: 491-496
- Kalchayanand, N., T. M. Arthur, J. M. Bosilevac, D. M. Brichta-Harhay, M. N. Guerini, R. T. L. Wheeler, and M. Koohmaraie. 2008. Evaluation of Various Antimicrobial Interventions for the Reduction of *Escherichia coli* O157:H7 on Bovine Heads during Processing, *J. Food Prot.*, 71(3):621–624.

#### Steam pasteurization:

- Davey, K. R. and M.G. Smith. 1989 A laboratory evaluation of a novel hot water cabinet for the decontamination of sides of beef. *Int. J. Food Sci Tech.* 24: 305-316.
- Dorsa, W.J., C. N. Cutter, G. R. Sirgusa, and M. Koohmaraie. 1996. Microbial Decontamination of Beef and Sheep carcasses by Steam, Hot water Spray Washes, and a Steam-vacuum Sanitizer. *J. Food Prot.* 59: 127-135.
- AMI Lethality model, demonstrating lethality at 160°F at carcass surface.
- Nutsch, A. L., R. K. Phebus, M. J. Riemann, J. S. Kotrola, R. C. Wilson, J. E. Boyer, and T.L. Brown. 1998. Steam pasteurization of commercially slaughtered beef carcasses: evaluation of bacterial populations at five anatomical locations. *J. Food Prot.* 61:571-577.

- Nutsch, A. L., R. K. Phebus, M. J. Riemann, D. E. Schafer, J. E. Boyer, R. C. Wilson, J. D. Leising, and C. L. Kastner. 1997. Evaluation of a Steam Pasteurization Process in a Commercial Beef Facility. *J. Food Prot.* 60:485-492.

#### Electrolyzed oxidizing (EO) water

- Hsu, SY. 2005. Effects of flow rate, temperature and salt concentration on chemical and physical properties of electrolyzed oxidizing water. *J. Food Eng.* 66: 171-176.
- Huang, YR, Hung, YC, Hsu, SY, Huang, YW. Amd Hwang, DF. 2008. Application of electrolyzed water in the food industry. *Food Control.* 19:329-345.
- Jadega, R, and Hung, Y. 2013. Influence of nalidixic acid adaptation on sensitivity of various Shiga toxin-producing *Escherichia coli* to EO water treatment. *Food Science and Technology.* 54: 298-301.

#### High Pressure Processing (HPP)

- Alpas, H, Kalchayanand, N, Bozoglu, F, and Ray, B. 2000. Interactions of high hydrostatic pressure, pressurization temperature and pH on death and injury of pressure-resistant and pressure-sensitive strains of foodborne pathogens. 60: 33-42.
- Black, E.P., K.A. Hirneisen, D.G. Hoover, and K.E. Knier. 2010. Fate of *Escherichia coli* O157:H7 in ground beef following high-pressure processing and freezing. *J. App. Microbiol.* 108: 1352-1360.
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- Ma, H., D.A. Ledward. 2013. High pressure processing of fresh meat — Is it worth it? *Meat Science.* 95: 897-903.
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#### Lymph Nodes

- Arthur, T. M., D. M. Brichta-Harhay, J. M. Bosilevac, M. N. Guerini, N. Kalchayanand, J. E. Wells, S. D. Shackelford, T. L. Wheeler, and M. Koochmaria. 2008. Prevalence and Characterization of *Salmonella* in Bovine Lymph Nodes Potentially Destined for Use in Ground Beef. *J. Food Prot.* 71:1685-1688.
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- Brown, T. R., T. S. Edrington, G. H. Loneragan, D. L. Hanson, K. Malin, J. J. Ison, and D. J. Nisbet. 2015. Investigation into Possible Differences in *Salmonella* Prevalence in the Peripheral Lymph Nodes of Cattle Derived from Distinct Production Systems and of Different Breed Types. *J. Food Prot.* 78:2081-2084.

## Beef Processing Best Practices: Grinders Sanitation, Lotting, and Sampling

- Comprehensive guide meat ground at retail recordkeeping and sanitation (2013),
  - <http://www.fmi.org/docs/default-source/food-safety-best-practice-guides/sample-ground-meat-record-for-retail-stores.pdf?sfvrsn=6>
- Best practices for processing raw ground beef products (2009),
  - [http://www.bifsc.org/CMDocs/BIFSCO2/Best%20Practices/Raw\\_Ground\\_Products\\_Best\\_Practices\\_2015.pdf](http://www.bifsc.org/CMDocs/BIFSCO2/Best%20Practices/Raw_Ground_Products_Best_Practices_2015.pdf)
- Guidance Document for Sampling and Lotting of Beef Products and Sample Analysis for Pathogens,
  - [http://www.bifsc.org/CMDocs/BIFSCO2/Best%20Practices%20New/Lotting\\_and\\_Sampling\\_of\\_Beef\\_Products\\_for\\_Pathogen\\_Analysis\\_Final\\_2016.pdf](http://www.bifsc.org/CMDocs/BIFSCO2/Best%20Practices%20New/Lotting_and_Sampling_of_Beef_Products_for_Pathogen_Analysis_Final_2016.pdf)
- Guidance for minimizing impact associated with food safety hazards in raw ground meat and other FSIS regulated products, (2002), <http://www.haccpalliance.org/sub/food-safety/BeefGrindGuide.pdf>



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**2017**



# Conference for Food Protection

## Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments

Council 1 of the Conference for Food Protection (CFP) formed the Beef Grinding Log Committee with the directive to:

- a) Review the United States Department of Agriculture, Food Safety Inspection Service's (FSIS) grinding log template and provide feedback to FSIS for consideration into the future FSIS compliance guide on retail grinding logs and on its use at retail food establishments;
- b) Provide recommendations for supplier provided labels to accomplish record keeping within retail food establishments; and
- c) Report back to 2014 Biennial Meeting.

The CFP Beef Grinding Log Committee recommended that this information be placed on the CFP website for use as a guidance document. This document contains a recommended set of practices and procedures for the production of raw ground beef at various types of retail food establishments.

The Committee reviewed the current United States Department of Agriculture, Food Safety Inspection Service's (USDA/FSIS) guidance and proposed the following templates and instructions, best practices, and guidelines for beef grinding practices at retail:

**Beef Grinding Log Template** - The *Sample Ground Meat Record for Retail Establishments* on page three shows the committee's conclusion of the minimum data points necessary on a beef grinding record log to successfully conduct a complete product traceback and recall. The basic components are:

- Production Date;
- Name of Source Product Ground (Trim, Chub, "Pull backs", etc.);
- Supplier Packed Date or Use by Date;
- Establishment number of supplier;
- Lot Number from supplier;
- Retail label or menu description;
- Quantity in lbs. of product being ground;
- Time grinder cleaned and sanitized; and
- Verification sign-off

Note: It is very important that each product ground be recorded on the template in sequential order for traceability purposes.

When feasible, the Committee highly encourages all retailers to adopt electronic recordkeeping along with scan technology to collect and maintain this important data as we feel scan technology will be more accurate and timely in the event of a “trace back”. We also recognize that smaller retailers will be challenged with financial and human resources to move to this standard today. In either event, being able to quickly provide accurate data is the requirement.

**Production Logs** - A Beef Grinding Log may be used in conjunction with a company’s beef production log (or cutting list) log. Production logs are used by retailers to project and produce specific types and amounts of steaks and roasts needed in a production cycle. A fall-out benefit of production logs is that they collect the source material of any bench trim that may have been produced by the retailer while fabricating steaks and roasts for the refrigerated display case. For those retailers grinding bench trim, this becomes the easiest way to collect the necessary data. Production logs or cutting lists will need to contain the supplier establishment number, manufacturer’s name of the primal, and pack date and lot number of the primal. (Note: Beef packers will reuse lot numbers. However, documenting *both* the lot number and pack date or use by date for a source material would make the lot number generally unique.) Retailers will then need to file together both the production log and grind log for record keeping. The *Sample Primal Production Log for Retail Food Establishments* on page three shows the pertinent information that must be tracked on a production log if an establishment is grinding in-store produced bench trim and/or pull back material.

Except for those records that relate to in-store ground products that are under current investigation or could be considered a possible cause of illness, completed grinding and production logs need to be maintained for a minimum of 90 days. All such records should be accessible within 24 hours but do not have to be maintained on-site.

## Sample Templates:

### Template 1 Sample Ground Meat Record for Retail Food Establishments

Retail Establishment Name: Store #55

Retail Establishment Production Date: 8/9/2013

Name of Source Product Ground  (Trim, chub, cut, pull-back, bench trim, etc.)	Source Material Pack Date or Use by Date  (From Supplier Label)	Establishment Number of Supplier	Lot Number of Product from Supplier	Retail Name  (Name of Product on Retail Label or Menu)	Quantity Ground  (in batch)	Time Equipment Cleaned & Sanitized  (Either Before or After Batch)	Associate Initials
BEEF COARSE GROUND 73/27	7/18/2013	M354	771007180001	GROUND BEEF	30 LBS	7:13 AM	JTM

#### Sample Ground Meat Record for Retail Food Establishments - Use Instructions

This document has eight columns titled: Name of Source Product Ground; Source Material Pack Date or Use by Date/Pull Backs Included (Yes/No)?; Establishment Number of Supplier; Lot Number of Product from Supplier; Retail Name; Quantity Ground; Time Equipment Cleaned & Sanitized, and Associate Initials The first four columns relate directly to the source material. The last four columns are food establishment functions.

This form will allow every ground product produced in food establishments to be associated to the day it was produced (as internally correlated to each establishment's sell-by date on the label, etc.). However, if an establishment is grinding in-store produced bench trim and/or pull back material, then a production log (in addition to the beef grinding log) will need to be maintained to correlate the sources of the bench trim and/or pull back material.

## Template 2 Sample Primal Production Log for Retail Food Establishments\*

Store Location: Store #55			Production Date: 8/8/2013	
Primal Product Name as Listed on the Box	Vendor/Supplier Name	Establishment #	Lot Number	Pack Date
BEEF KNUCKLE	Swift	3D	7846515	7/24/2013

\*Note: This sample production log is being provided as an example to visually provide the pertinent information that must be tracked (in addition to a beef grinding log) if an establishment is grinding in-store produced bench trim and/or pull back material. This document must not be misconstrued to prohibit an establishment from keeping this information in a different manner or format.

**The example shows the data points needed in tracking ground beef production from trim, which are...**

- **Retail Establishment Name**
- **Date of Production**
- **Common Name of Primal**
- **Supplier Name**
- **Establishment Number of Beef Supplier**
- **Lot Number of Primal**
- **Pack Date of Primal**

### **Best Practices for Grinding Beef at Retail**

Using sanitation standard operating procedures (SSOPs) to address the cleaning of food contact surfaces, equipment, utensils, implements, and the processing areas is a best practice. The SSOPs should specify how frequently everything will be cleaned and include a verification procedure for the process.

Furthermore, it is a best practice that each retailer also is able to convey to the USDA/FSIS their standard operating procedures (SOP's) for grinding product. Examples include policies and procedures regarding product sources, product dating, and the firm's meat handling/rework policies. All these factors will be necessary and useful in determining the extent of a product recall.

## **Employee Training and Employee Health and Hygiene**

Proper training of all employees with access to the meat case, packaging area, and grinding areas is essential. Only properly trained employees should be allowed to work in the meat department, handle meat, and operate equipment.

The Food Code and/or local and state regulations have guidelines for employee health and hygiene including illness procedures, and policies for hand washing, proper clothing, coverings, hair restraints, gloves, etc. Make sure all local regulations are followed by all retail employees.

Retailers should develop effective training procedures for the employees responsible for collecting; recording, and maintaining grind log data during their daily job duties. The best training programs utilize a “tell, show, allow practice/observe and praise/correct” component. Employees should understand the importance of the entire scope and need for the work.

## **Cleaning and Sanitation of Equipment**

Section 4-602.11 of the FDA Food Code states that all food contact surfaces should be cleaned at least every four hours. The food code provides for cleaning less frequently than every four hours if the utensils and equipment are held in a refrigerated room and cleaned according to the frequencies provided in the food code.

## **Importance of “Breaks” in the production cycle**

Breaks in the production cycle are critical and should not be overlooked. **A break in the production cycle is a combination of a complete cleaning and sanitation step in conjunction with no carryover of product.** *This can be the difference between needing to recall product from one day or from several months.* Therefore, documenting cleaning and sanitation is very important.

## **Significance of avoiding carryover of trim**

Avoid mixing product ground on one day with product made on subsequent days. If product is carried over from one day to the next, the two days of production are now linked even if the equipment is cleaned. Therefore, if this practice is done day after day and there is no break in production, the entire product becomes one huge lot. This can lead to rolling recalls and there are many examples in the meat industry of months of product being recalled because of carry-over and no breaks in production. On the other hand, there are also examples of very small recalls because the retailer utilized clean breaks in production and maintained appropriate processing and cleaning records.

## **Pull-Backs**

“Pull-backs” are retail packaged cuts, such as steaks or roasts, removed from the self-service refrigerated display cases and either reworked into smaller cuts, such as stew beef or cube steak, or ground product. “Pull-backs” can be ground separately but are normally co-mingled with in-store produced bench trim.

The determining factors for pulling and reworking a steak or roast vary greatly. An operator may or may not use the company's "sell-by" date on the retail cut to determine "pull-back". At times quality issues such as the visual appearance of the steak (trim standard, marbling, excessive bone per internal standards, loss of bloom, or eye appeal) will create the need to pull back a specific cut. Optionally, an operator may cut multiple roasts expecting to leave them for no more than one day and re-cut them the following day into steaks. There are many possible-determining factors for the timing or number of "pull-backs" on any one-day.

Large and small operators may use "pull backs" as part of normal Standard Operation Procedure (SOP). While this practice may present additional risks (temperature fluctuation of product and public handling of the packaged product) with proper food handling processes currently there is no known food safety risk.

To provide information necessary trace back, information such as source material, establishment numbers, pack date, lot code, etc. must be captured for "pull-backs" from the previous days' production (primal usage) logs. A retail operator utilizing "pull backs" would, therefore, be able to provide production logs from several proceeding days in the event of a trace back or recall of a particular batch of grinds. Retail operators will be required to establish, follow, and articulate internal SOPs related to the "pull back" process to FSIS in the event of a trace back recall process.

When a batch of ground beef contains "pull-back" product, the retail operator will indicate this on the grinding log under the "Source Product Ground" column of the Beef Grinding Log Template (see Appendix 1). The "Retail Label, Quantity Ground, and Time Equipment Cleaned Sanitized" blocks will be completed per normal procedures.

Note: Trace back becomes increasingly difficult when a retailer purchases from multiple suppliers. Trace back will become even more difficult when a retailer opts to do "pull backs" as the amount of data will be multiplied over four or five days of production. Having multiple possible sources of product will make pinpointing a particular beef supplier extremely challenging.

### **Points to consider**

In the case of outbreak investigations, certain practices make it very difficult to piece together information and can halt investigations. Examples of these include:

- Product from several suppliers combined in the grinder that is not recorded.
- Trim mixed with other product that is not recorded (for example, bench trim mixed with chubs and not recorded as such).
- Recording the supplier name but having no other identifying information, such as the establishment number which is a true identifier of the processing plant. (Many suppliers have multiple processing plants differentiated only by a different letter after the assigned establishment number.)
- Incomplete or inaccurate forms.
- Carryover without true breaks in the production cycle.

## **Lotting at Retail**

The package produced at retail must be linked to the lot of product from which it was made, i.e., the source product. The simplest way to do this is by placing an identifiable code, product name and date on the product label that links the package to the lot of meat ground for which there is a record. The retail-ground lot should have a supportable definition and should link the packaged product to the source material. Most companies produce multiple types of ground product throughout the day that should be labeled differently. Some companies will make several lots of the same product a day because they clean and sanitize frequently, and some only have one lot per day.

## **Recommended Product Handling Practices**

Store-generated trimmings should be segregated from other products. A full, documented cleaning and sanitizing of the entire grinder is then needed to create a “break” in the production cycle.

When grinding chubs or tubes, start with the highest lean percentage. All lean points will be considered the same “lot” unless the retailer completes a full cleaning and sanitizing between the lean points.

- **Rotate supply first-in first-out and pay attention to sell-by dates.**
- **Avoid mixing species unless intentional and clearly labeled. Clean and sanitize equipment between species.**
- **Store trim in clean and sanitized lugs and hold under refrigeration.**
- **Properly label all trim lugs with the primal source, date, time and employee.**
- **Avoid mixing products from different suppliers.**
- **Avoid mixing chubs and trim.**
- **Minimize grinding re-work or pull-backs (if they are ground, make sure they are clearly documented in the records).**

## **Recommendations for Beef Suppliers**

The CFP Beef Grinding Log Committee supports global traceability efforts such as adoption of the voluntary GS1 mpXML guidelines to standardize the information contained within barcodes. Furthermore, the Committee also recognizes that human readable data is also required in these efforts to allow collection of data by small retailers who may not have access to the bar scan readers of larger retailers.

Collecting data by hand is difficult, costly and subject to human error. The CFP – Grinding Log Committee recommends that the beef suppliers attach a sufficient number of “peel off” labels containing the needed trace back data either in the boxed beef or attached to the outside of the box. These “peel off” labels would be required on all primal-boxed beef as well as chubs or tubes.

A smart phone application or other system could be developed by each beef producer for deciphering the information contained within the barcodes that are currently applied to their products. This would make the information readily available for the grocer to

use. The application could also be used to collect and store the above needed data points in a web application. The ability to download this phone application would be given to any buyer of the establishment's meat products.

Note: We want to acknowledge and thank FMI for allowing sections of their report titled, "*Comprehensive Guide Meat Ground at Retail Recordkeeping and Sanitation - June 2013*" to be utilized in this report.

## 2012-2014 CFP Beef Grinding Log Committee Member Roster

Last Name	First Name	Position (Chair / Member)	Constituency	Employer	City	State	Telephone	Email
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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-017**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Create Committee – Standardization of HACCP Plans for Sushi at Retail

**Issue you would like the Conference to consider:**

The production of sushi at retail is considered a special process requiring a variance due to the acidification of rice to render it as a non-TCS food. In order to obtain this variance, a HACCP plan must be submitted and approved by the regulatory authority. The requirements of these HACCP plans vary widely between regulatory authorities, ranging from one CCP monitoring the pH of acidified rice to five or more CCPs in jurisdictions requiring that sushi kiosks be regulated under 21 CFR 123. These requirements are frequently not anchored in scientific references and are subject to the interpretation of risks by the regulatory authority. The wide variety of interpretations for what is required in a HACCP plan to safely produce sushi at retail highlights the need for a standardized, science-based HACCP plan to regulate sushi kiosks nationwide.

**Public Health Significance:**

The creation of a standardized, science-based HACCP plan for the production of sushi at retail would provide a variety of benefits for both retailers and regulators. The current process to obtain a variance requires a lengthy review process that may result in undue burden to the operator in the form of unnecessary critical control points not based in scientific fact. This can force for operators to maintain many versions of HACCP books for the same production process that must be updated on an annual basis or whenever individual regulatory authorities make changes. A standard plan would not only shorten plan review and approval times but would greatly reduce the number of HACCP plans that must be maintained. Currently, regulatory authorities must vary inspection criteria between operator and location. A standardized HACCP plan would allow for more consistent oversight and would allow for inspectors to be trained on established critical control points across all facilities. This benefit would also extend to operators who could be trained to follow a single plan that would control hazards across all jurisdictions.

## **Recommended Solution: The Conference recommends...:**

*The Conference recommends...*

that a Committee for the Standardization of HACCP for Sushi at Retail be created. This committee shall be composed of industry, academic, and regulatory stakeholders and charged with the following:

- Determining best practices and collecting available guidance documents pertaining to the production of sushi prepared at retail stores.
- Identifying and quantifying the array of current regulatory requirements for HACCP plans pertaining to the production of sushi prepared at retail stores.
- Developing a science-based HACCP plan and guidance document for the production of sushi prepared at retail stores.
- Referencing the guidance document in the Food Code or Annex, or wherever the committee deems appropriate.
- Identifying the best methods to disseminate the committee's findings.
- Reporting the committee's findings at 2022 CFP Biennial Conference.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-018**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018-III-022, 2014-III-025; new or additional information has been included or attached.

**Title:**

Creation of a Rotisserie Chicken Food Safety Committee

**Issue you would like the Conference to consider:**

There were three reported *Salmonella* outbreaks involving rotisserie chicken cooked at retail food establishments during 2013 - 2019<sup>2,3,4</sup>. Investigations in two of the outbreaks identified that inadequate cooking and cross contamination contributed to the outbreaks<sup>1,5</sup> and that written procedures did not adequately address these contributing factors. Since multiple whole chickens are often cooked at one time in retail food establishments, maintaining and measuring appropriate temperature during cooking can be challenging. Findings from the outbreak investigations, and best practices developed to address these findings, could apply to any retail food establishment preparing whole rotisserie chickens as well as products such as chicken salad that use meat harvested from rotisserie chickens. Therefore, FSIS recommends that the Conference for Food Protection (CFP) create a committee to develop guidance for retailers that addresses the unique challenges associated with cooking rotisserie chickens. This information could also be used to develop training materials, of which could be used by Food Safety Managers as a reference in their Active Managerial Control Program.

**Public Health Significance:**

The Food Code recommends that raw poultry be cooked to 165°F for 15 seconds per §3-401.11(A)(3). However, there have been outbreaks related to rotisserie chicken not reaching the recommended temperature and cross-contamination that needs to be addressed in existing guidance. These challenges, such as ensuring temperature measurement is taken on the coldest part of the largest bird and controlling traffic within the raw and ready-to-eat areas of the retail establishment, were identified as contributing factors in the two outbreaks in 2013 and 2016-2017<sup>1,5</sup>. The firm's procedures and training programs did not adequately address the food safety vulnerabilities unique to this product, such as variability in bird size, loading and unloading dozens of birds at a time into the rotisserie, taking temperatures at the proper location and depth, and preventing cross

contamination between the raw and RTE foods being prepared in the same space. The 2013 outbreak investigation involved at 32 case-patients that ate at a single retail food establishment. The 2016-2017 outbreak investigation involved 24 case-patients who reported consuming items containing rotisserie chicken at multiple stores of a single retail chain. In 2019, FSIS, CDC, and public health partners investigated a multistate *Salmonella* outbreak associated with chicken. Investigators identified a sub-cluster of 15 case-patients who had purchased rotisserie chicken or products made with harvested rotisserie chicken from a single grocery store location. In addition, in this 2019 outbreak investigation, a sample of leftover rotisserie chicken collected from a case-patient's home yielded the outbreak strain.

FSIS submitted issues to the 2014 CFP Biennial Meeting (2014 III\_025) as well as to the 2018 CFP Biennial Meeting (2018 III\_022) to create a Committee for Safe Cooking of Rotisserie Chicken. The focus was to develop further instructions to ensure that all poultry is cooked thoroughly, and that cross-contamination is avoided. No action was taken in response to either issue because it was felt that the cooking recommendations in the Food Code were sufficient. After each of the 2014 and 2018 CFP Biennial Meetings, an outbreak associated with rotisserie chicken occurred. Investigations following two of the outbreaks identified common challenges associated with ensuring rotisserie chickens are cooked to the recommended temperature. These challenges are not addressed by current recommendations in the Food Code. Specifically, investigation findings from two of the outbreaks indicated a potential for inadequate cooking of rotisserie chicken both because of the cooking procedures and inappropriate temperature monitoring. This can be attributed to the temperature of the largest bird not being monitored, variability of the location of temperature monitoring (e.g., breast, thigh, or both), variation in the depth of temperature measurement (surface and internal temperature measurements), and thermometers not properly calibrated. In addition, investigations noted handling practices provided opportunities for cross-contamination<sup>1,5</sup>. Contact between smocks and aprons used for ready-to-eat production and those used for raw production and employee traffic between raw and ready-to-eat areas were not controlled. While cross contamination could be associated with any product, cooking of rotisserie chicken at retail food establishments presents a unique situation due to the handling of whole birds while skewering, loading, and unloading the rotisserie and handling during harvesting of leg, breast, and thigh meat. These unique issues are likely applicable across retail food establishments that produce rotisserie chicken.

Forming a committee to develop a guidance document on the safe handling and cooking of rotisserie chicken would provide a valuable resource for retailers. The committee would further identify lessons learned from past outbreaks and provide guidance to the retail industry. While FSIS can share best practices for cooking poultry products in federal establishments, collaborating with retail industry and state and local regulators will ensure the guidance will provide practical recommendations for proper handling and preparation of raw rotisserie chicken, cooking procedures to achieve lethality, temperature measurement protocols, and post-processing handling. By following the recommendations in the guideline, retail food establishments would be better able to ensure that Food Code recommendations related to cooking and cross-contamination of chicken are followed. This in turn should decrease the likelihood of foodborne illness being attributed to such products.

## References (noted above with superscript numerals)

1. FSIS After Action Report (2019):  
<https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/foodborne-illness-investigations/outbreaks-salmonella-rotisserie-chicken-products-2016-2017>.
2. FSIS Recall Release (058-2013):  
<https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive/archive/2013/recall-058-2013-release>
3. FSIS Recall Release (058-2013 Expanded):  
<https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive/archive/2013/recall-058-2013-expanded>
4. FSIS 2016 Public Health Alert:  
<https://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-transcripts/news-release-archives-by-year/archive/2016/pha-100916>
5. Kissler, B. 2017. Assessing Contributing Factors for *Salmonella* I 4,[5],12, I:- Outbreak Investigations Associated with Pork and Rotisserie Chicken. International Association for Food Protection, July 10-12, 2017, Tampa, FL. Available at:  
[https://www.fsis.usda.gov/wps/wcm/connect/a59f7d39-0bd1-4ce1-8561-df3824b08dea/IAFP-slides-kissler\\_071217.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/a59f7d39-0bd1-4ce1-8561-df3824b08dea/IAFP-slides-kissler_071217.pdf?MOD=AJPERES).

## **Recommended Solution: The Conference recommends...:**

The Conference recommends that a Rotisserie Chicken Food Safety Committee be convened of members from all constituencies in the CFP. The Conference recommends FSIS support this committee with agency resources, including active engagement from advisory members and FSIS subject matter experts. The Committee will be charged with:

1. Identifying best practices and existing guidance documents that relate to the preparation of rotisserie chicken at retail,
2. Developing a comprehensive guidance document for retail food establishments with best practices specific to rotisserie chicken preparation to ensure general Food Code recommendations are followed. These recommendations would include proper handling during preparation, cooking procedures to achieve lethality, temperature measurement protocol, and post-processing handling,
3. Determining appropriate mechanisms for distributing the guideline and related outreach, such as:
  1. Posting to state and local health department websites or resource libraries;
  2. Incorporating into CFP training programs and posting to the CFP website, and
  3. Requesting through FDA that the Food Code Annex be amended by adding a reference to the new guidance document and posting this information on the CFP website, and
4. Reporting the committee's findings and recommendations to the 2022 Biennial Meeting of the CFP.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-019**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code – Frozen Food Cook Requirements for HSP

**Issue you would like the Conference to consider:**

A recommendation is being made to require a final cook temperature for frozen food products that are not considered ready-to-eat by the manufacturer, when served to a highly susceptible population (HSP).

**Public Health Significance:**

According to the website of the Centers for Disease Control and Prevention, frozen food products have been the source of multiple outbreaks in recent years, including an outbreak of *Listeria monocytogenes* linked to frozen vegetables that killed four people between 2013-2016.

Since 2008, the FDA draft Compliance Policy Guide (CPG) has allowed ready-to-eat food products that do not support the growth of *Listeria monocytogenes* to contain up to 100 CFU/g of the organism. Products that fall within this tolerance level are intended by the manufacturer to be thoroughly heated before consuming<sup>1</sup>. However, there has been an increase in the inclusion of frozen foods, such as berries and kale, in food products that are not heated. Currently, there is no regulatory requirement for these products to reach any temperature for lethality before service.

Research has confirmed that *Listeria* spp. will grow in thawed, frozen food without long lag phases. For example, lag phase duration was 48 hours for foods stored at 4°F, and freezing does not cause an increase in lag phase as had been previously hypothesized<sup>2</sup>. During the allowable 7 days holding for foods such as peas and corn, there is potential for a 3-log growth in *Listeria monocytogenes*, according to Kataoka et al<sup>2</sup>. This growth, with no required lethality step, could lead to illness.

An endpoint temperature of 135°F is being recommended to provide lethality for *Listeria monocytogenes* for highly susceptible populations. The listeriosis outbreak in 2015 linked to Blue Bell ice cream showed that even low doses of listeria ingestion can cause illness and death. While FDA and the frozen food industry work to find a solution to *Listeria* spp. in

frozen food for the general public, it is important to acknowledge additional care should be taken for highly susceptible populations.

#### References

1. Compliance Policy Guide, CFSAN, ORA, February 2008
2. Kataoka et al, *Journal of Food Protection*, Vol. 80, No. 3 (2017) 447-453
3. Pouillot et al, *Emerging Infectious Diseases*, Vol. 22, No. 12 (2016) 2113-2119

#### **Recommended Solution: The Conference recommends...:**

That a letter be sent to the FDA recommending the most recent version of the FDA Food Code , Section 3-801.11 be amended as follows (language to be added is underlined; language to be deleted is in strikethrough format):

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(E) Plant foods purchased in frozen form which contain validated cooking instructions and are not considered ready-to-eat by the manufacturer must be cooked to 135°F.

~~(E)~~(F) Time only, as the public health control as specified under ¶ 3-501.19(D), may not be used for raw EGGS.

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#### **Supporting Attachments:**

- "Compliance Policy Guide"
- "Growth of Listeria in Thawed Frozen Food"
- "Infectious Dose of Listeria Monocytogenes"

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**COMPLIANCE POLICY GUIDE (CPG)****CPG Sec. 555.320 *Listeria monocytogenes***

Final
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**Contains Nonbinding Recommendations  
Draft - Not for Implementation**

**Compliance Policy Guide  
Guidance for FDA Staff  
Sec. 555.320  
*Listeria monocytogenes***

**DRAFT GUIDANCE**

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-1400.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Regulatory Affairs  
February 2008**

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## Compliance Policy Guide Guidance for FDA Staff Sec. 555.320 *Listeria monocytogenes*

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

### I. INTRODUCTION:

The purpose of this Compliance Policy Guide is to provide guidance to FDA Staff on FDA's enforcement policy for *Listeria monocytogenes* (*L. monocytogenes*) in foods.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are

cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## II. BACKGROUND:

*L. monocytogenes* is a pathogenic bacterium that is widespread in the environment and may be introduced into a food processing facility. *L. monocytogenes* can contaminate foods and cause a mild illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, illness (called invasive listeriosis). Foods that have been implicated in outbreaks of invasive listeriosis have been foods that are ready-to-eat (RTE).

RTE foods can be contaminated if ingredients in the foods are contaminated with *L. monocytogenes* and are not treated to destroy viable cells of this pathogen, or if *L. monocytogenes* is allowed to contaminate the RTE food because of improper sanitary conditions or practices. Most RTE foods do not contain detectable numbers of *L. monocytogenes*. For many RTE foods, contamination with *L. monocytogenes* can be avoided – *e.g.*, through the application of current good manufacturing practice requirements that establish controls on ingredients, listericidal processes, segregation of foods that have been cooked from those that have not, and sanitation. Sanitation controls include effective environmental monitoring programs designed to identify and eliminate *L. monocytogenes* in and on surfaces and areas in the plant.

In 2003, FDA and the Food Safety and Inspection Service of the United States Department of Agriculture, in consultation with the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, released a quantitative assessment (the Risk Assessment) of relative risk associated with consumption of certain categories of RTE foods that

had a history of contamination with *L. monocytogenes*, or that were implicated epidemiologically with an outbreak or a sporadic case of listeriosis. The Risk Assessment estimated that the risk of listeriosis would vary widely among these food categories.

According to the Risk Assessment, foods estimated to pose the highest risk of being associated with listeriosis are RTE foods that support the growth of *L. monocytogenes*. Examples of RTE foods that support the growth of *L. monocytogenes* include:

- Milk;
- High fat and other dairy products (*e.g.*, butter and cream);
- Soft unripened cheeses (greater than 50 percent moisture) (*e.g.*, cottage cheese and ricotta cheese);
- Cooked crustaceans (*e.g.*, shrimp and crab);
- Smoked seafood (*e.g.*, smoked finfish and mollusks);
- Raw seafood that will be consumed as sushi or sashimi;
- Many vegetables (such as broccoli, cabbage, and salad greens);
- Non-acidic fruit (such as melon, watermelon, and papaya); and
- Some deli-type salads and sandwiches (particularly those containing seafood and those prepared at retail establishments without acidification and/or the addition of antimicrobial substances).

In contrast, the foods estimated to pose the lowest risk of being associated with listeriosis are foods that, because of intrinsic factors, extrinsic factors, and/or processing factors do not support the growth of *L. monocytogenes*. Intrinsic factors include chemical and physical factors

that are normally within the structure of the food, *e.g.*, pH and water activity. Extrinsic factors are those that refer to the environment surrounding the food, *e.g.*, storage temperature. Processing factors include substances added to adjust the pH of food (*e.g.*, acids) and substances that, alone or in combination with other substances, have antimicrobial properties (*e.g.*, sorbates and benzoates). It is well established that *L. monocytogenes* does not grow when:

- The pH of the food is less than or equal to 4.4;
- The water activity of the food is less than or equal to 0.92; or
- The food is frozen.

Foods may naturally have a pH or water activity that prevents growth of *L. monocytogenes* or processing factors may be deliberately used to achieve those characteristics (*e.g.*, by adding acid to deli-type salads to bring the pH to less than or equal to 4.4). At pH values above 4.4, processing factors generally are used in combination to prevent the growth of *L. monocytogenes* (*e.g.*, sorbates or benzoates may be used in combination with organic acids such as acetic acid, lactic acid, and citric acid in foods such as deli-type salads). The effectiveness of a particular listeristatic control measure in preventing growth in a particular RTE food generally is determined case-by-case, for example, using the results of growth studies specific to the food matrix.

Examples of RTE foods that generally are considered to not support the growth of *L. monocytogenes* include:

- Fish that are preserved by techniques such as drying, pickling, and marinating;
- Ice cream and other frozen dairy products;
- Processed cheese (*e.g.*, cheese foods, spreads, slices);

- Cultured milk products (*e.g.*, yogurt, sour cream, buttermilk);
- Hard cheeses (less than 39 percent moisture) (*e.g.*, cheddar, colby, and parmesan);
- Some deli-type salads, particularly those processed to a pH less than 4.4 and those containing antimicrobial substances such as sorbic acid/sorbates or benzoic acid/benzoates under conditions of use documented to be effective in preventing the growth of *L. monocytogenes*;
- Some vegetables (such as carrots); and
- Crackers, dry breakfast cereals, and other dry foods.

Fruits, vegetables, and cheeses (*e.g.*, soft and semi-soft cheeses) not listed in this CPG may include some products that support growth as well as other products that do not support growth.

### III. **POLICY:**

FDA will review the available evidence on a case-by-case basis to determine if a food is a RTE food that supports growth or a RTE food that does not support growth.

#### A. **Ready-to-Eat Food**

"Ready-to-eat food" (RTE food) means a food that is customarily consumed without cooking by the consumer, or that reasonably appears to be suitable for consumption without cooking by the consumer.

A food may be considered to be suitable for consumption without cooking by the consumer, and thus a RTE food, even though cooking instructions are provided on the label. For examples, fresh and frozen crabmeat and individually quick frozen (IQF) peas and corn

may be RTE foods. Some consumers eat such products without cooking, because they appear to be ready-to-eat.

## **B. Ready-to-Eat Foods that Support Growth of *L. monocytogenes***

Generally, we intend to consider that a RTE food will support the growth of *L. monocytogenes* if it does not meet the characteristics of a RTE food that does not support growth, as indicated in section III.C.

FDA may regard a RTE food that supports growth of *L. monocytogenes* to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act; the FD&C Act) (21 U.S.C. 342(a)(1)) when *L. monocytogenes* is present in the food based on the detection method indicated in section IV.A.

## **C. Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes***

A RTE food does not support the growth of *L. monocytogenes* if the food:

- Has a pH that is less than or equal to 4.4; or
- Is customarily held and consumed in a frozen state; or
- Has a water activity that is less than 0.92; or
- Is processed using an effective listeristatic control measure (e.g., an antimicrobial substance or a combination of factors such as pH, water activity, and antimicrobial substances).

FDA may regard a RTE food that does not support the growth of *L. monocytogenes* to be adulterated within the meaning of section 402(a)(1) of the Act (21 U.S.C. 342(a)(1)) when *L. monocytogenes* is present at or above 100 colony forming units per gram of food (cfu/g)

## IV. REGULATORY ACTION GUIDANCE:

### A. Ready-to-Eat Foods that Support Growth of *L. monocytogenes*

The following represents criteria for recommending legal action to CFSAN/Office of Compliance/Division of Enforcement (HFS-605):

- *L. monocytogenes* is detected in one or more subsamples of a RTE food that supports the growth of *L. monocytogenes*.

Use Bacteriological Analytical Manual Online, Chapter 10 - "*Listeria monocytogenes*," "Detection and Enumeration of *Listeria monocytogenes* in Foods" as the method for detecting and confirming presence of *L. monocytogenes* (available at <http://www.cfsan.fda.gov/~ebam/bam-10.html> (<http://www.cfsan.fda.gov/~ebam/bam-10.html>)).

### B. Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes*

Consult with CFSAN/Office of Compliance/Division of Enforcement (HFS-605) before recommending legal action for RTE foods that do not support the growth of *L. monocytogenes*. Use ISO 11290-2:1998(E) "Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of *Listeria monocytogenes* - Part 2: Enumeration method" as the method for enumerating *L. monocytogenes*. (ISO 11290-2:1998/Amd. 1:2004(E) "Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of *Listeria monocytogenes* - Part 2: Enumeration method AMENDMENT 1: Modification of the enumeration medium" amends ISO 11290-2:1998(E). The amendment uses ALOA agar instead of PALCAM agar. If ALOA agar is not commercially available in the United States, use PALCAM according to ISO

11290-2:1998(E)). ISO methods are available from the International Organization for Standardization at <http://www.iso.org/iso/en/ISOOnline.frontpage> (<http://www.iso.org/iso/en/ISOOnline.frontpage>) ↗ (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).

Use rapid biochemical test kits according to the Bacteriological Analytical Manual Online, Chapter 10 – "Detection and Enumeration of *Listeria monocytogenes* in Foods" Section E-11 (available at <http://www.cfsan.fda.gov/~ebam/bam-10.html> (<http://www.cfsan.fda.gov/~ebam/bam-10.html>)), instead of ISO 11290-2:1998(E) Section 9.5, for confirmation of *L. monocytogenes* isolates.

### C. Foods that are Not RTE Foods

Consult with CFSAN/Office of Compliance/Division of Enforcement (HFS-605) when *L. monocytogenes* is present in a food that is not a RTE food.

### D. Other Considerations

The criteria in this guidance do not establish an acceptable level of *L. monocytogenes* in food. FDA may choose to take legal action against adulterated food that does not meet the criteria for recommending legal action to CFSAN.

Further, the criteria in this guidance do not excuse violations of the requirement in section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)) that food may not be prepared, packed, or held under insanitary conditions or the requirements in FDA's good manufacturing practices regulation (21 CFR part 110). As set out in 21 CFR 110.80, food manufacturers must take "[a]ll reasonable precautions ... to ensure that production procedures do not contribute contamination from any source."

## V. SPECIMEN CHARGES:

### A. Domestic Seizure

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce within the meaning of the Act, 21 U.S.C. 342(a)(1), in that it bears and contains a poisonous or deleterious substance, namely *Listeria monocytogenes*, which may render it injurious to health.

### B. Import Detention

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears and contains a poisonous or deleterious substance, *Listeria monocytogenes*, which may render it injurious to health.

Issued: [insert date]

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## Research Paper

# Growth of *Listeria monocytogenes* in Thawed Frozen Foods

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### ABSTRACT

The growth characteristics of *Listeria monocytogenes* inoculated onto frozen foods (corn, green peas, crabmeat, and shrimp) and thawed by being stored at 4, 8, 12, and 20°C were investigated. The growth parameters, lag-phase duration (LPD) and exponential growth rate (EGR), were determined by using a two-phase linear growth model as a primary model and a square root model for EGR and a quadratic model for LPD as secondary models, based on the growth data. The EGR model predictions were compared with growth rates obtained from the USDA Pathogen Modeling Program, calculated with similar pH, salt percentage, and NaNO<sub>2</sub> parameters, at all storage temperatures. The results showed that *L. monocytogenes* grew well in all food types, with the growth rate increasing with storage temperature. Predicted EGRs for all food types demonstrated the significance of storage temperature and similar growth rates among four food types. The predicted EGRs showed slightly slower rate compared with the values from the U.S. Department of Agriculture Pathogen Modeling Program. LPD could not be accurately predicted, possibly because there were not enough sampling points. These data established by using real food samples demonstrated that *L. monocytogenes* can initiate growth without a prolonged lag phase even at refrigeration temperature (4°C), and the predictive models derived from this study can be useful for developing proper handling guidelines for thawed frozen foods during production and storage.

Key words: Frozen and thawed foods; Growth model; *Listeria monocytogenes*; Modeling; Ready-to-eat food

*Listeria monocytogenes* is a gram-positive, rod-shaped bacterium that causes the foodborne disease listeriosis in humans. Listeriosis can manifest as an invasive disease that can result in meningitis, pneumonia, septicemia, and death. Listeriosis mainly affects the elderly, the immunocompromised (20, 23, 27), and pregnant women, who may develop flulike symptoms and experience miscarriage or stillbirth (20, 23, 27). Although listeriosis is relatively rare, the mortality rate is high, and most patients are hospitalized. Scallan et al. (33) estimated that 1,600 cases of listeriosis occur annually in the United States, of which 250 cases are fatal. Although this pathogen is ubiquitous in the environment (32), it can be readily inactivated by pasteurization and cooking (5). *L. monocytogenes* can grow at refrigeration temperatures, and refrigerated ready-to-eat foods that support the growth of *L. monocytogenes* have been associated with listeriosis outbreaks (6, 14, 17, 20, 21, 40, 42). In the 1980s, the U.S. Food and Drug Administration and U.S. Department of Agriculture (USDA) Food Safety and Inspection Service established a “zero-tolerance” policy for *L. monocytogenes* in ready-to-eat foods (35). Since then, several risk assessments have been conducted to better understand the risk of consuming food contaminated with *L. monocytogenes* (14, 29, 39, 42).

Freezing is an effective control to prevent the growth of pathogens, including *L. monocytogenes*. However, once a frozen food is thawed, it may be able to support the growth of *L. monocytogenes*, if present. Cooked and frozen shrimp and crabmeat, along with frozen green peas and corn, may be thawed and held refrigerated before consumption, and some consumers may eat them without cooking or reheating. Because *L. monocytogenes* can grow at refrigeration temperatures, holding these foods for extended periods may allow this pathogen to grow to levels that represent a public health concern. A survey of frozen vegetables conducted in Portugal showed that 14.8 to 22.6% of frozen vegetable samples were positive for *L. monocytogenes* (24). Another investigation demonstrated that 26% of frozen seafood samples, including frozen cooked shrimp, cooked crabmeat, and raw seafood, were positive for *L. monocytogenes* overall (43).

There is a gap in the knowledge concerning the growth kinetics of *L. monocytogenes* in frozen foods that are then thawed and held at refrigeration temperatures. The 2013 Food Code requires that foods that fall under the category of “time-temperature control for safety” be stored at <5°C for up to 7 days, based on limiting the growth of *L. monocytogenes* (to an increase of no more than 10-fold or 1 log) (41). However, refrigerated temperature control can present a challenge in both retail and the consumer home setting. In a survey of product temperatures at retail locations, it was shown that 30.7% of products in retail

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display and 9.4% of backroom refrigerators had temperatures higher than 5°C (9). Cold salad bar settings may provide further opportunity for temperature abuse. For example, one study showed that the food surface of potato salad had temperatures of 13 to 16°C at salad bars, even though the units were set to the coldest setting (37). The same study also showed food handling practices that might lead to prolonged display and storage of food items: for example, mixing fresh food into old batches of leftover food on the salad bar (37). This study highlights the difficulties of controlling the food temperature in salad and food bar settings and in monitoring how long food products have been exposed to potential temperature abuse. Temperature abuse can also occur within the home; the abovementioned study showed that 16.8% of products tested within consumers' homes were stored at temperatures exceeding 5°C (9).

The objective of this study was to investigate the growth kinetics of *L. monocytogenes* in thawed frozen foods (corn, green peas, crabmeat, and shrimp) stored at 4, 8, 12, or 20°C. The temperatures reflect recommended refrigeration temperature (4°C), elevated "abuse" refrigeration temperature (8 or 12°C), and room temperature (20°C). Furthermore, the growth curves derived were used to develop predictive models for the lag-phase duration (LPD) and the exponential growth rate (EGR) in those food types at 4 to 20°C. Knowledge of the length of the lag phase of this organism could provide more accurate handling guidance for frozen foods that are thawed and, subsequently, held at refrigeration temperatures.

## MATERIALS AND METHODS

***L. monocytogenes* strains and culture conditions.** Twelve strains of *L. monocytogenes* from the Grocery Manufacturers Association culture collection (Washington, DC) were used in this study: N-7351 (1/2b, isolated from deli meat), N-7389 (1/2b, isolated from deli meat), N-7391 (1/2c, isolated from deli meat), N-7427 (4d, isolated from deli meat), N-7292 (4b, clinical isolate), N-7293 (4b, clinical isolate), N-7447 (1/2c, isolated from seafood salad), N-7497 (4b, isolated from seafood salad), N-7503 (1/2a, isolated from seafood salad), N-7601 (1/2b, isolated from seafood salad), N-7295 (4b, clinical isolate), and N-7296 (4b, clinical isolate). Working cultures were made from glycerol-frozen or lyophilized stocks stored in a -80°C freezer and maintained on tryptic soy agar (TSA; Difco, BD, Sparks, MD) with 0.6% yeast extract (YE; Difco, BD) slants at 4°C and transferred every 6 months. Before inoculation, a loopful of each strain was transferred in 10 mL of tryptic soy broth (TSB; Difco, BD) with 0.6% YE (TSB+0.6% YE) and grown aerobically at 35°C for 24 h (stationary-phase culture).

**Preparation of inocula.** One hundred microliters of each stationary-phase culture, approximately  $10^9$  CFU/mL, was transferred to an individual test tube containing 10 mL of sterile TSB+0.6% YE and incubated at 4°C for 7 days for cells to adapt to the cold (32). After the 7-day incubation, each culture reached approximately  $10^8$  CFU/mL. All 12 strains of refrigeration temperature-adapted cultures were combined into a cocktail (2 mL of each culture) in a centrifuge tube. The cocktail, containing approximately  $10^8$  CFU/mL of *L. monocytogenes* cells, was

serially diluted in 0.1% peptone water (pH 7.0; Fisher Scientific, Fair Lawn, NJ) to a desired inoculation level.

**Source and inoculation of food.** Four types of frozen food samples, blanched individually quick frozen corn, individually quick frozen green peas, cooked snow crabmeat, and cooked peeled shrimp, were obtained from a local grocery store and by mail order. Food samples were obtained frozen and held at -18°C prior to and during inoculation. Crabmeat from frozen cooked snow crab with shell was aseptically removed from shell as a part of sample preparation before the weighing process. Prior to each individual growth experiment, random samples from the four types of thawed frozen foods were tested for being *L. monocytogenes* negative by using VIDAS LMO2 (bioMérieux, Marcy l'Etoile, France). Aerobic plate counts were also performed with TSA plates incubated at 35°C for 48 h to obtain counts for background microflora in each product, and the pH was determined by using a pH meter (Accumet Research AR 20, Fisher Scientific).

Test samples were weighed (25 g) into stomacher bags (Whirl-Pak, Nasco, Fort Atkinson, WI) while they were still frozen and inoculated with 100- $\mu$ L aliquots of the culture cocktail that was distributed over the product surface by using a pipette. The initial inoculation level was approximately  $10^3$  CFU/g (confirmed immediately after the inoculation by plating, as described in the following). The inoculated product was stored frozen at -18°C for 7 days. Following frozen storage, the inoculated food samples were taken out of the freezer and transferred to air incubators set at 4, 8, 12, or 20°C. The initiation of the growth curves (time zero) was the time the food sample was transferred to 4, 8, 12, or 20°C (i.e., not the time the food sample reached temperature) as imitating consumer practices or practices potentially seen at food bars.

**Enumeration of *L. monocytogenes*.** At predetermined time intervals (established by preliminary experiments), samples were removed from incubation, and the samples were enumerated for *L. monocytogenes*. Samples were diluted 1:10 in buffered peptone water (3M, St. Paul, MN) and pulsed for 30 s (Pulsifier, Microgen Bioproducts, Ltd., Camberley, UK). If required, further decimal dilutions of samples were made with peptone water. The diluted samples were plated onto polymyxin-acriflavin-lithium chloride-ceftazidime-aesculin-mannitol agar (PALCAM; Difco, BD) by using a spiral plater (model AP 4000, Spiral Biotech, Norwood, MA). Preliminary experiments indicated that resuscitation steps for injured cells were not necessary. Plates were incubated for 48 h at 35°C. Cell counts were obtained by using a Q count system (model 510, Spiral Biotech). Three independent growth experiments, with one sample per replicate, were conducted for each food type at each storage temperature.

**Curve-fitting and primary model.** Data for each replicate were converted to log CFU per gram and iteratively fit to the two-phase linear growth equation (4, 36) to generate LPD and EGR by minimizing the residual sum of squares using the Solver function in Microsoft Excel, Version 1997 (Microsoft Corporation, Redmond, WA; worksheet provided by Dr. Richard Whiting [Exponent, Inc., Knoxville, TN]), in which an if-then statement defines the model:

$$N = N_0 + \text{IF}[t < \text{LPD}, N_0, \text{EGR} \times (t - \text{LPD})] \quad (1)$$

where  $N$  is the log CFU/g at time  $t$ ,  $N_0$  is the initial log CFU/g, LPD is the lag-phase duration (h), EGR is the exponential growth rate ([log CFU/g]/h), and  $t$  is the elapsed time (h).

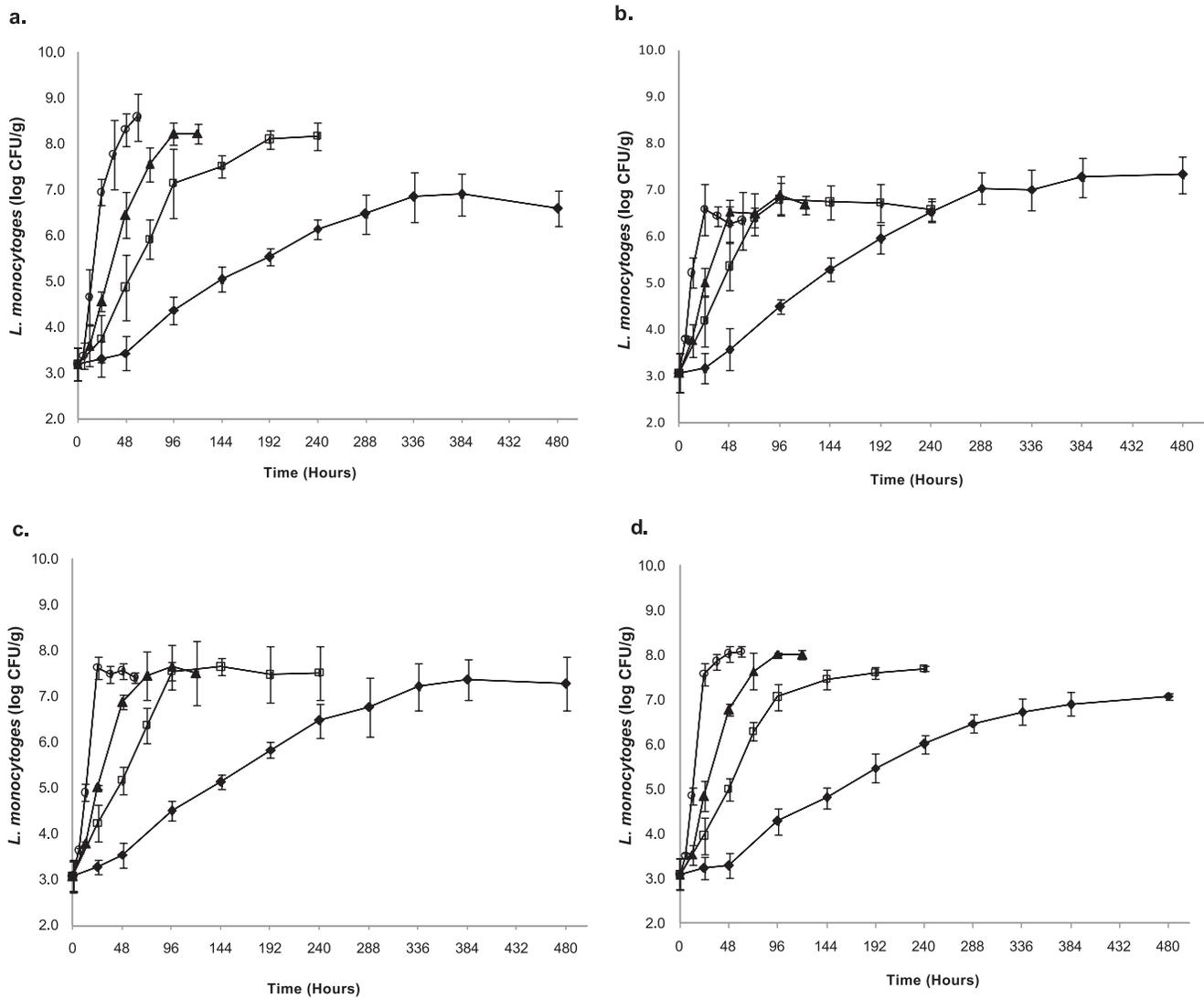


FIGURE 1. *L. monocytogenes* growth curves of thawed frozen food samples, (a) crabmeat, (b) corn, (c) green peas, and (d) shrimp, performed in triplicate at four storage temperatures (◆, 4°C; □, 8°C; ▲, 12°C; ○, 20°C). The error bars indicate standard deviation.

**Secondary model for EGRs.** To integrate the effect of storage temperature, EGRs were further calculated using data from the primary model (equation 1) with the square root model (8, 30). The curve fitting was performed with the Excel Solver.

$$\sqrt{\text{EGR}} = a(T - T_{\min}) \quad (2)$$

where  $a$  is the constant,  $T$  is the temperature, and  $T_{\min}$  is the theoretical minimum temperature at growth that no growth is possible.

**Secondary model for LPDs.** To incorporate the effect of storage temperature on the LPD, the quadratic model was used to calculate LPD predictions (31). LPDs were calculated by using data from the primary model (equation 1) with the quadratic model.

$$\text{LPD} = p_1 + p_2T + p_3T^2 \quad (3)$$

$p_i$  ( $i = 1, \dots, 10$ ) are coefficients to be estimated and  $T$  is the temperature.

**Data analysis.** The fit of models was evaluated by the residual mean squares ( $R^2$ ) based on regression analysis (15, 44). LPDs and EGRs derived from the secondary model were compared

against a calculation on predictions made from the USDA Pathogen Modeling Program (PMP) (38) by using pH (7.0), NaCl (0.5%), and NaNO<sub>2</sub> (0%). These parameters were selected based on sample characteristics. For NaCl (percentage) and NaNO<sub>2</sub> (percentage), nutrient descriptions on the product label of each product were used.

## RESULTS

**Growth of *L. monocytogenes* in four types of thawed frozen foods.** Frozen corn, green peas, crabmeat, and shrimp were obtained, and the pH values of the products were 7.2, 6.8, 7.2, and 7.5, respectively. Representative uninoculated samples were tested for *L. monocytogenes*, which was not detected. The products were inoculated with a cocktail of *L. monocytogenes* and held at -18°C for 7 days. Then, the inoculated samples were incubated at 4, 8, 12, or 20°C, and growth was monitored for up to 20 days.

*L. monocytogenes* grew to stationary phase in all products at all temperatures, as shown in Figure 1a through 1d. Growth of *L. monocytogenes* occurred much more

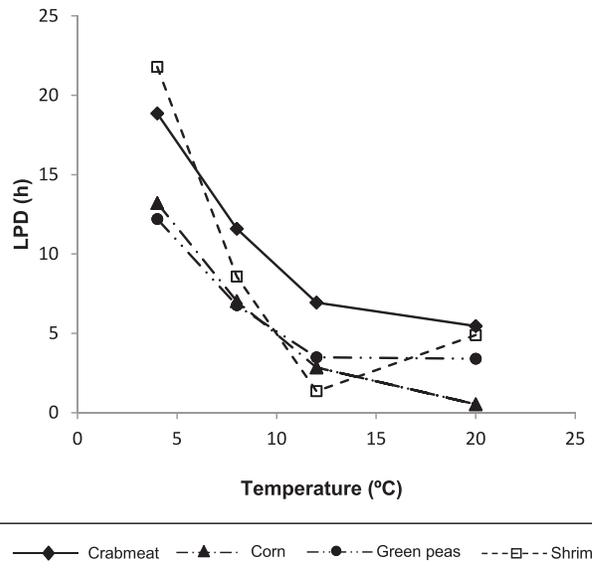
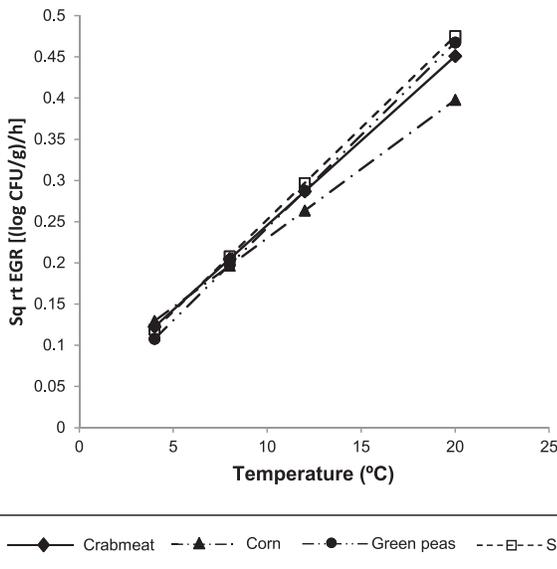


FIGURE 2. Square root model predictions of the exponential growth rate (EGR; [log CFU per gram]/hour) calculated from the two-phase linear (primary) model for *L. monocytogenes* in four types of thawed frozen foods (crabmeat, corn, green peas, and shrimp) over the temperature range of 4 to 20°C.

FIGURE 3. Quadratic model predictions of the lag-phase duration (LPD; hours) calculated from the two-phase linear (primary) model for *L. monocytogenes* in four types of thawed frozen foods (crabmeat, corn, green peas, and shrimp) over the temperature range of 4 to 20°C.

rapidly as the storage temperature increased for all foods. For example, *L. monocytogenes* reached stationary phase, when the growth curves appeared plateaued, after approximately 288 to 380 h in all four food types stored at 4°C, whereas the stationary phase was reached within 24 to 48 h, when samples were stored at 20°C. For all food types, the lag phase became shorter as the temperature increased. For instance, LPD was approximately 48 h for food samples stored at 4°C, whereas LPD was less than 12 h for food samples stored at 20°C. The final cell density was different in four types of foods. *L. monocytogenes* appeared to reach higher numbers in crabmeat and shrimp compared with corn and green peas overall, although statistical analysis was not conducted.

outcome from equation 1, to incorporate the effect of storage temperature. The results revealed the relationship with storage temperature on EGRs of *L. monocytogenes*, with the square root of the EGRs becoming greater, indicating faster growth, as the growth temperature was increased for all food types (Fig. 2). The fit of the secondary model was good ( $R^2 > 0.98$ ), as shown in Table 1.

**Calculation of LPD and EGR by using primary and secondary models.** The LPD and EGR for *L. monocytogenes* in each food type at each storage temperature were generated by using two-phase linear models (equation 1), based on the log growth data of each replicate. Then, an EGR value was further calculated by using linear regression analysis of the square root model (equation 2), based on the

For LPD, the quadratic model was used as the secondary model. Storage temperature had an impact on LPD, which generally decreased as the temperature increased in all food types (Fig. 3). However, the fit of the model was not ideal;  $R^2$  values ranged from 0.23 to 0.71 (Table 1), due to high variability among replicates, indicating the model does not describe the lag phenomenon in these food samples precisely. Still, the model may be able to describe average LPD. The shape of the curve for shrimp was concave, with increasing the predicted LPD at 20°C, and high variability among replicates at 20°C.

**Development of predictive models for *L. monocytogenes* in thawed frozen foods.** A linear regression equation derived from the regression analysis of equation 2 or 3 for

TABLE 1. Residual mean square ( $R^2$ ) values and formulas for each thawed frozen food sample (crabmeat, corn, green peas, and shrimp), based on linear regression analysis for the predicted LPDs and square root of EGRs from square root models and actual *L. monocytogenes* growth data

	LPD		Square root of EGR	
	$R^2$	Linear regression equation	$R^2$	Linear regression equation
Crabmeat	0.3748	LPD = 28.73 - 2.792temp + 0.0814temp <sup>2</sup>	0.9839	$\sqrt{\text{EGR}} = 0.0205\text{temp} + 0.0403$
Corn	0.7117	LPD = 21.41 - 2.300temp + 0.0628temp <sup>2</sup>	0.9816	$\sqrt{\text{EGR}} = 0.0168\text{temp} + 0.0623$
Green peas	0.3921	LPD = 19.77 - 2.164temp + 0.0673temp <sup>2</sup>	0.9812	$\sqrt{\text{EGR}} = 0.0225\text{temp} + 0.0178$
Shrimp	0.2369	LPD = 41.00 - 5.550temp + 0.1872temp <sup>2</sup>	0.9945	$\sqrt{\text{EGR}} = 0.0223\text{temp} + 0.0296$

TABLE 2. LPD and EGR predictions for *L. monocytogenes* in each thawed frozen food calculated from the predictive models as compared with USDA PMP predictions calculated by using parameters similar to food samples<sup>a</sup>

	Predicted LPD (h)				Predicted EGR ([log CFU/g]/h)			
	4°C	8°C	12°C	20°C	4°C	8°C	12°C	20°C
Crabmeat	18.86	11.60	6.94	5.45	0.015	0.042	0.082	0.203
Corn	13.21	7.03	2.85	0.53	0.017	0.039	0.070	0.159
Green peas	12.20	6.77	3.49	3.40	0.012	0.039	0.083	0.219
Shrimp	21.79	8.58	1.36	4.89	0.014	0.043	0.088	0.226
USDA PMP	62.03	32.00	17.56	6.35	0.027	0.056	0.107	0.303

<sup>a</sup> Aerobic, broth culture, pH (7.0), NaCl (0.5%), and NaNO<sub>2</sub> (0%).

each type of food is presented in Table 1. The aim of these equations is to predict EGRs or LPDs of *L. monocytogenes* in each type of the thawed frozen foods over the temperature range of 4 to 20°C. However, the LPD models were not reliable, which will be discussed subsequently.

**Predicted EGRs and LPDs and comparison with PMP predictions.** Predicted values of EGRs and LPDs for each food type from 4 to 20°C were calculated by using equations (established models: Table 1). A higher EGR value means a faster growth rate. Predicted EGR values demonstrated similar trends for all food types, with EGR increasing as storage temperature rose. The EGR values were slightly higher in crabmeat and shrimp than in green peas and corn. The predicted LPD values showed that a trend in which shorter LPDs were observed on the vegetables than the seafood, especially at lower temperatures (4 or 8°C). For example, thawed frozen vegetables had a predicted LPD of less than 13.2 h, and thawed frozen seafood had a predicted LPD of about 18 to 21 h at 4°C. These predicted LPDs and EGRs values were compared with the growth rates and lag phase derived from the USDA PMP (Table 2). At all four temperatures, the PMP predicted more rapid EGRs than were determined in the current study. However, the PMP predicted longer LPDs than those LPDs derived in this study.

#### Aerobic plate counts of uninoculated food samples.

Corn and green pea samples had higher initial aerobic plate counts (time zero), with 4.05 and 2.87 log CFU/g, respectively, while the crabmeat and shrimp began with 1.65 and 2.18 log CFU/g, respectively.

## DISCUSSION

Thawed frozen corn, green peas, crabmeat, and shrimp supported the growth of *L. monocytogenes* at each incubation temperature (4, 8, 12, or 20°C). The lag phase at 4°C was shorter than PMP predictions; however, the growth rates were consistent with PMP predictions and results in other publications. For example, Farber (13) showed 2- to 3-log growth of *L. monocytogenes* in 7 days in cooked shrimp and crabmeat incubated at 4°C; in the current study, a 2-log increase was seen in the same time frame. Hughey et al. (18) demonstrated 2 log of growth of *L. monocytogenes* in fresh corn and green beans in 9 days, which appears to be slightly less than the observation from

the current study (i.e., approximately 3 log in 9 days in corn or green pea samples). These studies and our own results indicate that *L. monocytogenes* grows more rapidly in seafood products than in vegetables overall. There have been various studies on developing predictive models for growth of *L. monocytogenes* in laboratory media or foods (7, 19, 22, 44), and predictive models for growth of the organism in smoked salmon have been investigated extensively, as explored in Giménez and Dalgaard (16). However, there is no study on a development of predictive models for the growth of this organism in thawed frozen foods. In the current study, growth parameters, LPDs and EGRs, of *L. monocytogenes* in thawed frozen foods were first calculated by using a two-phase linear model as a primary model based on experimental growth data. The two-phase model is a modified version of the three-phase linear model and allows the calculation of LPD and EGR without data from the stationary phase (4). Several studies have been published using the two-phase linear model (4, 10, 11, 25, 26). Secondary models were applied to incorporate the effect of storage temperature to EGRs and LPDs. In the current study, the square root model and quadratic model were used for prediction of EGR and LPD, respectively, based on the data obtained from a primary model. These models are simple and expandable to incorporate other factors and have been used in many published studies, as discussed in Ross and Dalgaard (31).

The goodness of fit for EGR predictions was high based on  $R^2$  values; hence, the equations derived from the regression analysis can be used to predict EGRs of *L. monocytogenes* between 4 to 20°C for those samples. On the contrary, the fit of model for LPDs was not ideal. Several models were used to fit data to predict LPDs, such as square root model and reciprocal model. None of the models provided an ideal fit. The quadratic model is one of empirical models, describing a set of data from experiments in a simple mathematical correlation (31). However, the equations derived for predicting LPDs in this study are not adequate and are not reliable to predict precise LPD. Therefore, they should not be used to predict LPD.

A possible reason for the undesirable fit and outcome could be that not enough data points were collected during the growth experiment, particularly during the lag phase. This resulted in “no lag time (0 h)” calculation at the primary model step for some samples and caused high variability among replicates. In comparison to the development of growth rate models, creating lag time models

that estimate accurate lag phases are more difficult because the lag phenomenon is still not clearly understood (1). There are many factors influencing lag behavior such as (i) adaptation mechanisms to a new environment, (ii) character and phenotype of the bacterium, (iii) physiological state of cells, (iv) physiological history of the cells, (v) inoculum size, or (vi) distribution condition in samples (36). Therefore, whichever model is used, it is important to consider that models can only describe the simplified form of real phenomena and the imprecision of lag-time predictions (1).

Despite being unable to adequately model the LPD, the growth curves showed that the lag phase was relatively short at each temperature, considering that the thawing process was included. Before conducting the experiment, it was hypothesized that freezing of the cultures may create an extended lag phase for this organism once the foods were thawed and held at refrigeration temperatures. However, this was not observed in the results. The short lag phases may indicate that there was no obvious effect of freezing and thawing to initiate growth of *L. monocytogenes* in thawed frozen foods incubated at 4 to 20°C. *L. monocytogenes* is known to be resistant to injury due to freezing in food and broth systems (12, 28). Beauchamp et al. (2) also found that various methods of thawing frozen hot dogs had little effect on survival and growth of *L. monocytogenes* during refrigerated storage. Furthermore, the short lag phase observed here may have been due to the use of inocula that were acclimated to refrigeration temperatures by growing to stationary phase at 4°C prior to freezing in the food. Usage of environment-acclimated organisms when conducting laboratory challenge studies is recommended because those organisms may better replicate a real-world scenario (34).

The predicted EGRs were compared with those from the USDA PMP. The values were in the same order of magnitude, but the PMP did produce slightly higher (i.e., rapid) EGR values. One reason why the PMP predictions were higher may be because the current study used actual food samples as growth media, which may be less supportive in nutrient composition for growth of this organism compared with laboratory broth media used to build the PMP predictions. Furthermore, the competing effect of background microflora is not incorporated in PMP predictions. Several researchers investigated inhibitory effect of spoilage organisms against *L. monocytogenes*. Buchanan and Bagi (3) demonstrated that growth of *L. monocytogenes* was inhibited due to coinoculation with *Pseudomonas fluorescens* in brain heart infusion broth with sodium chloride (5 and 25 g/L) at 4°C. In a study by Giménez and Dalgaard (16), growth of *L. monocytogenes* was inhibited due to a cocktail of spoilage organisms (lactic acid bacteria, *Enterobacteriaceae*, and *Photobacterium phosphoreum*) in vacuum-packaged cold-smoked salmon slices at 5, 10, 17.5, or 25°C. General prediction models established, based on laboratory conditions (i.e., broth culture), may display predictions different from predictive models derived from data in real food having a complex matrix with competing microflora (34).

The data generated in this study show that thawed frozen corn, green peas, crabmeat, and shrimp support the growth of *L. monocytogenes* in the temperature range of 4 to 20°C. Under the current experimental conditions, there was a relatively short lag phase, especially at the three higher temperatures (8, 12, and 20°C). Creating growth curves and subsequent predictive growth models of *L. monocytogenes* in these foods over a wide range of temperatures could aid in the development of specific handling and holding guidelines for the foods after thawing. Conducting additional research to obtain more data to develop predictive models for LPD would be highly desirable. Investigations of the prevalence and contamination level of *L. monocytogenes* in certain frozen foods could assist the industry to improve food safety and provide a better indication of the risk to public health.

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# Infectious Dose of *Listeria monocytogenes* in Outbreak Linked to Ice Cream, United States, 2015

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The relationship between the number of ingested *Listeria monocytogenes* cells in food and the likelihood of developing listeriosis is not well understood. Data from an outbreak of listeriosis linked to milkshakes made from ice cream produced in 1 factory showed that contaminated products were distributed widely to the public without any reported cases, except for 4 cases of severe illness in persons who were highly susceptible. The ingestion of high doses of *L. monocytogenes* by these patients infected through milkshakes was unlikely if possible additional contamination associated with the preparation of the milkshake is ruled out. This outbreak illustrated that the vast majority of the population did not become ill after ingesting a low level of *L. monocytogenes* but raises the question of listeriosis cases in highly susceptible persons after distribution of low-level contaminated products that did not support the growth of this pathogen.

Understanding the likelihood of developing invasive listeriosis after ingesting a given number of *Listeria monocytogenes* cells (dose-response relationship) is important in managing risks linked to this pathogen in food. Nevertheless, several challenges hamper characterization of this dose-response relationship, including the lack of an appropriate animal model, the relative rarity of outbreaks, long incubation periods that impede the collection of well-preserved implicated food samples, and heterogeneity of the initial contamination level (1).

In early 2015, an outbreak of invasive listeriosis linked to ice cream products was identified in the United States (2). A total of 10 case-patients with listeriosis related to this outbreak were reported from Arizona and Oklahoma (1 case each); Texas (3 cases); and Kansas (5 cases, all in inpatients of 1 hospital) (2). *L. monocytogenes*

isolates from 4 of the Kansas case-patients were indistinguishable by pulsed-field gel electrophoresis from isolates recovered from ice cream made in 1 plant of the implicated company (factory 1). The isolate from the fifth Kansas case-patient did not match any isolate recovered in this outbreak investigation. *L. monocytogenes* isolates from patients in other states were linked to ice cream products manufactured in another facility (factory 2) of the same company (2). The US Food and Drug Administration (FDA) collected a large volume of ice cream from factory 1 for microbiological testing.

This outbreak provided a unique opportunity to assess exposure levels to *L. monocytogenes* from implicated ice cream products among infected persons and the overall population. Because ice cream has a long shelf life and *L. monocytogenes* does not grow but survives for long periods in frozen products (3), the level of *L. monocytogenes* in implicated products manufactured during the outbreak, although collected after the outbreak, was likely to be representative of levels in products eaten by exposed persons. We assessed the outbreak data to gain insight into contamination levels among products from 1 factory implicated in the outbreak, the number of *L. monocytogenes* cells ingested by specific subpopulations during this outbreak, and the dose-response relationship for *L. monocytogenes*.

## Materials and Methods

### Framework for Dose-Response Derivation

In microbial dose-response frameworks, it is generally assumed that as few as 1 independently acting cell that survives host defense measures can initiate infection (1-hit theory [4,5]). This minimal infective dose of 1 cell is associated with a probability ( $r$ ) of infection. Assuming  $r$  is low and constant within a subpopulation (online Technical Appendix, <http://wwwnc.cdc.gov/EID/article/22/12/16-0165-Techapp1.pdf>),  $r$  can be estimated by the ratio of the number of invasive listeriosis cases in a

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subpopulation ( $X_p$ ), by the estimated number of *L. monocytogenes* cells ingested by the subpopulation  $D_p$ ; that is,  $r = X_p / D_p$ . In addition to using this classical derivation of  $r$ , we estimated in this study  $r$  values using the *L. monocytogenes* dose-response model of Pouillot et al. (6) (online Technical Appendix).

### Listeriosis Cases

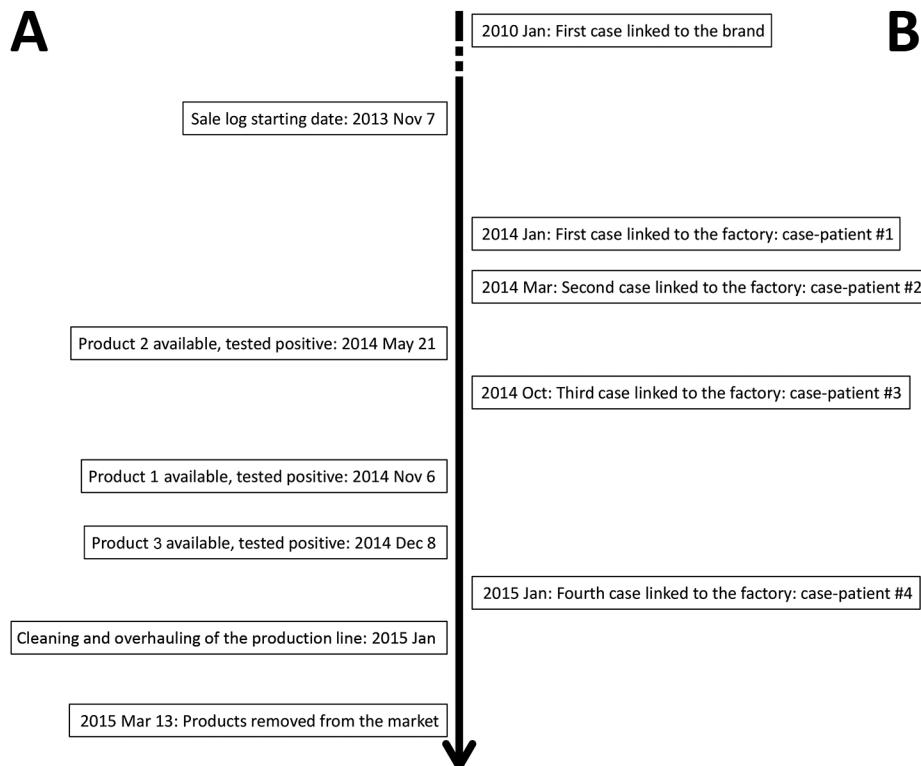
This study considers only the 4 hospitalized Kansas case-patients whose illnesses were confirmed to be linked to ingestion of products manufactured in factory 1. Illness onset dates ranged from January 2014 through January 2015 (Figure). All 4 were >67 years and <84 years of age. Medical records review indicated all 4 had underlying medical conditions that contributed to compromised immune function before exposure to *L. monocytogenes* in milkshakes. Food histories were available for 3 of the Kansas case-patients. All patients with food histories ate product 1 from factory 1 through milkshakes. One patient had 2 milkshakes (1 day at lunch and the following day at dinner); another had 2 milkshakes (1 day at dinner and 6 days later at dinner), and the remaining patient had 3 milkshakes (1 day at dinner and 4 and 9 days later at dinner and lunch, respectively). Two serving units of product 1, each weighing  $\approx 80$  g, were used to prepare each milkshake. Strains of *L. monocytogenes* isolated from the 4 patients were indistinguishable by pulsed-field gel electrophoresis to strains recovered from product 1.

### Number of *L. monocytogenes* Cells Ingested by the Population

The factory 1 production line linked to the Kansas cases made 8 different types of ice cream products (products 1–8) (7). (The website for this reference identifies 10 universal product codes corresponding to 8 different types of ice cream products; 2 products were sold individually and grouped in larger packages). FDA collected and counted *L. monocytogenes* cells in samples of products 1–3 (8; L.S. Burall, unpub. data). We characterized the variability of *L. monocytogenes* levels in products 1–3 (online Technical Appendix).

No samples of products 4–8 were collected. In a low-exposure scenario, products that were not tested were assumed to be uncontaminated. In a medium-exposure scenario and in a high-exposure scenario, contamination levels were predicted on the basis of the processes used to produce these products. Specifically, we specified in these scenarios that contamination levels were similar for products 1 and 4 and were similar for products 2 and 5–8 because the process used to produce product 4 was similar to that used for product 1, whereas production processes for products 5–8 were similar to that for product 2.

The number of *L. monocytogenes* cells ingested by the population was then estimated by multiplying the average number of *L. monocytogenes* organisms per serving by the number of servings distributed in the various subpopulations. The number of ice cream servings distributed in the



**Figure.** Timeline of listeriosis outbreak linked to ice cream, United States, 2015. A) Data for products produced in factory 1 (2); B) data for outbreak start and 4 case-patients at 1 hospital in Kansas.

various subpopulations was estimated from product distribution records for factory 1.

We do not know when contamination of the production line at factory 1 began. We isolated *L. monocytogenes* from a product manufactured on this line on May 21, 2014, but we had no samples manufactured before this date. Although the first known case associated with the brand of ice cream occurred in January 2010, the first case-patient specifically linked to factory 1 was hospitalized in Kansas on December 24, 2013, and listeriosis was diagnosed in January 2014 (patient 1, Figure). In the low-exposure scenario and medium-exposure scenario, we assumed the date at which contamination began at factory 1 was December 1, 2013, that is, a few weeks before hospitalization of the first case-patient whose illness was linked to ice cream produced at this facility. Contamination could have begun earlier than this date given that 1 listeriosis case-patient whose illness was linked to the same brand, but produced at factory 2, became ill in 2010. In the high-exposure scenario, we assumed contamination began 2.5 years before the outbreak was recognized, that is, midway between 2010 and the date the outbreak was recognized.

To estimate the proportion of servings that reached inpatients deemed to be highly susceptible to listeriosis, we multiplied the proportion of ice cream distributed to hospitals for patient consumption by the overall proportion of intensive care unit (ICU) beds in these hospitals (i.e., 10%) as a surrogate of the proportion of inpatients deemed to be highly susceptible to invasive listeriosis. To estimate the proportion of servings potentially eaten by pregnant women, ≥ 65 y. and ≥ 75 y. persons, we assumed that the implicated brand was eaten by different subpopulations similarly to other brands of ice cream (online Technical Appendix).

To understand why 4 cases of ice cream-associated listeriosis clustered at a single hospital, we created 2 indices

for the hospitals that received contaminated product(s) from factory 1 at least 1 time during November 7, 2013–March 16, 2015. The first index ascertained the severity of patient illness at each hospital (illness score) and was calculated by determining the percentage of total beds constituting ICU beds (scale: 0%–4.9%, 1 point; 5%–9.9%, 2 points; 10%–14.9%, 3 points; and ≥15%, 4 points). Hospitals were contacted by telephone and queried about the total number of beds licensed and the number dedicated to treatment of patients in ICU (medical, surgical, pediatric, neonatal, and burn). To quantify the availability of contaminated products at each hospital (supply score), we divided the total number of servings shipped to each facility during the recorded distribution period (16 months) by the total number of hospital beds (scale: <1 serving per bed, 1 point; 1–3.99, 2 points; 4–6.99, 3 points; and >7, 4 points). Using the 2 indices, we summed scores for all hospitals (maximum possible score 8) as an overall measure of patient illness and potential product exposure.

**Results**

**Number of *L. monocytogenes* Cells per Serving**

All tested samples of product 1 manufactured before the outbreak was recognized were positive for *L. monocytogenes* (8). Assuming the 5 lots of product 1 tested were representative of all lots of contaminated product 1, we estimated the mean number of *L. monocytogenes* cells in each 80-g unit of product 1 at 620 CFU (95% credible interval [CrI] 380–2,100 CFU). From the distribution of contamination level inferred from the model, we estimated that 0.1% of servings of product 1 had a dose >7,400 CFU (95% CrI 4,400–58,000 CFU) (see Table 1 for other statistics). *L. monocytogenes* was recovered from 80% of 294 units of product 2 (unit size 70 g) tested (mean 310 CFU/serving [95% CrI 55–11,000 CFU/serving]). Of the 95 units of product 3 tested, 45% yielded *L. monocytogenes* (mean 0.12 CFU/g).

**Table 1.** Estimated contamination level of *Listeria monocytogenes* per gram and per serving unit of 3 products in a multistate outbreak of ice cream-associated listeriosis, United States, 2015

Product/dose	Estimate (95% credible interval)		Quantile (95% credible interval)			
	Mean	SD	90%	99%	99.9%	99.99%
<b>Product 1</b>						
Per g	8	10	17	46	92	160
	(5–26)	(6–62)	(10–60)	(27–270)	(55–730)	(97–1,500)
Per 80-g serving	620	760	1,300	3,700	7,400	13,000
	(380–2,100)	(460–4,900)	(820–4,800)	(2,200–22,000)	(4,400–58,000)	(7,800–120,000)
<b>Product 2</b>						
Per g	5	200	2	48	520	3,600
	(1–160)	(17–35,000)	(1–10)	(11–620)	(91–12,000)	(470–140,000)
Per 70-g serving	310	14,000	140	3,400	37,000	250,000
	(55–11,000)	(1,200–2,500,000)	(43–710)	(800–43,000)	(6,400–840,000)	(33,000–9,800,000)
<b>Product 3</b>						
Per g	0.12 in 45% of products					
Per 160-g serving	8.64 in 45% of servings					

### Number of *L. monocytogenes* Cells Consumed by the Population

Sales data suggested widespread distribution of contaminated products to hospitals and the general population (e.g., schools, grocery stores, restaurants). We estimated that the general population ingested a total of  $1.5 \times 10^9$  (low-exposure scenario) to  $1.4 \times 10^{10}$  (high-exposure scenario) *L. monocytogenes* cells (Table 2). We estimated that, overall, the highly susceptible population ingested  $7.2 \times 10^6$  (low-exposure scenario) to  $3.3 \times 10^7$  (high-exposure scenario) *L. monocytogenes* cells.

Among hospitals that received  $\geq 1$  products from the production line of factory 1 known to produce contaminated ice cream, the median percentage of total beds constituting ICU beds (severity of illness score) was 8.7% (range 0%–70.7%; mean 10%). The median number of servings per bed (supply score) over the recorded distribution period (16 months) was 2 (range 0.1–93.7; mean 4.3). The Kansas hospital with the 4 cases of ice cream–associated listeriosis had 62.2 servings of the implicated products per bed (13.5% of beds in the hospital were ICU beds); the servings per bed value for the hospital was exceeded by only 1 other hospital (93.7 servings/bed; 6.5% ICU beds). After combining the severity of illness and supply scores for each hospital, we found the median value was 5 (range 2–7; mean 4.6); a combined score of 7 was achieved by 9%

of hospitals, of which 1 was the Kansas hospital with the 4 cases (the hospital with 93.7 servings/bed had a combined score of 6).

### Probability of Infection after Ingestion of 1 Cell

Under the low-exposure scenario, we estimated that the probability of infection,  $r$ , after ingestion of 1 bacterium in the overall population was

$$r = \frac{4}{1.5 \times 10^9} = 2.6 \times 10^{-9}$$

Using this same approach, we determined the value of  $r$  for the overall population was  $r = 6.5 \times 10^{-10}$  under the medium-exposure scenario and  $r = 2.9 \times 10^{-10}$  under the high-exposure scenario (Table 2). The integration of the model by Pouillot et al. (6), considering a normal distribution of the  $\log_{10}$  of the  $r$  parameter in the population rather than a constant one, led to a distribution with a mean  $-9.38$  and an SD of 0.88 for the overall population under the lower-exposure scenario, a mean of  $-10.0$  for the medium-exposure scenario, and a mean of  $-10.3$  for the high-exposure scenario (Table 2).

We also assessed persons at greatest risk for invasive listeriosis, including pregnant women, highly susceptible persons (e.g., those with compromised immune function), persons  $\geq 65$  years of age, and persons  $\geq 75$  years of age (Table 2). Because no ice cream–associated cases were reported among pregnant women, we used an estimate of 0.5

**Table 2.** Probability of invasive listeriosis after ingestion of ice cream products contaminated with *Listeria monocytogenes*, United States, 2015

Exposure scenario/model	Population, no. cases in population				
	All, n = 4	Highly susceptible, n = 4	Pregnant, n = 0*	Age $\geq 65$ y, n = 4	Age $\geq 75$ y, n = 2
<b>Lowert†</b>					
<i>r</i> constant					
No. <i>L. monocytogenes</i> cells consumed	$1.5 \times 10^9$	$7.2 \times 10^6$	$2.2 \times 10^7$	$2.3 \times 10^8$	$1.2 \times 10^8$
Estimated <i>r</i> parameter	$2.6 \times 10^{-9}$	$5.5 \times 10^{-7}$	$<2.3 \times 10^{-8}$	$1.7 \times 10^{-8}$	$1.7 \times 10^{-8}$
Corresponding to 1 case every... servings‡	37,867	181	>4,363	5,756	5,832
$\log_{10}(r)$ normally distributed					
Estimated $\mu$ parameter	-9.38	-6.19	<(-7.92)	-8.00	-8.02
Estimated $\sigma$ parameter	0.88	0.24	0.54	0.54	0.54
<b>Medium§</b>					
<i>r</i> constant					
No. <i>L. monocytogenes</i> cells consumed	$6.2 \times 10^9$	$1.5 \times 10^7$	$8.9 \times 10^7$	$9.4 \times 10^8$	$4.8 \times 10^8$
Estimated <i>r</i> parameter	$6.5 \times 10^{-10}$	$2.7 \times 10^{-7}$	$<5.6 \times 10^{-9}$	$4.3 \times 10^{-9}$	$4.2 \times 10^{-9}$
Corresponding to 1 case every... servings‡	154,612	375	>17,812	23,501	23,811
$\log_{10}(r)$ normally distributed					
Estimated $\mu$ parameter	-10.0	-6.40	<(-8.49)	-8.60	-8.62
Estimated $\sigma$ parameter	0.88	0.24	0.54	0.54	0.54
<b>High¶</b>					
<i>r</i> constant					
No. <i>L. monocytogenes</i> cells consumed	$1.4 \times 10^{10}$	$3.3 \times 10^7$	$2.0 \times 10^8$	$2.1 \times 10^9$	$1.0 \times 10^9$
Estimated <i>r</i> parameter	$2.9 \times 10^{-10}$	$1.2 \times 10^{-7}$	$<2.6 \times 10^{-9}$	$1.9 \times 10^{-9}$	$1.9 \times 10^{-9}$
Corresponding to 1 case every... servings‡	339,153	816	>39,071	51,552	52,230
$\log_{10}(r)$ normally distributed					
Estimated $\mu$ parameter	-10.3	-6.80	<(-8.83)	-8.97	-8.97
Estimated $\sigma$ parameter	0.88	0.24	0.54	0.54	0.54

\*0.5 used for computation.

†Products 1–3 contaminated beginning 2013 Dec 1; products 4–8 not contaminated.

‡Corresponding to 1 case every... servings, including 10,000 *L. monocytogenes* cells.

§Products 1–8 contaminated beginning 2013 Dec 1.

¶Products 1–8 contaminated beginning 2012 Jun 1.

cases and provided only an upper limit value for  $r$ . (This value was chosen arbitrarily. A Poisson process with mean 0.5 would have led to 0 cases in 90% of occurrence.)

## Discussion

This outbreak investigation provided unique data to characterize the dose-response relationship between *L. monocytogenes* in general and susceptible populations. Multiple factors compelled us to estimate as precisely as possible doses of *L. monocytogenes* ingested by consumers of contaminated products. First, the number of samples microbiologically tested was by far the largest ever reported from an outbreak setting (8). Second, because ice cream preserves the viability of *L. monocytogenes* but does not support its growth, levels of contamination were likely to have been accurately measured and have remained relatively constant over the extended shelf lives of the products. Finally, an exceptionally stable level of contamination within product types minimized variability in exposures. Hospital records indicated that patient 4 drank milkshakes made with product 1 on 3 different days during January 11–19, 2015, before sepsis caused by *L. monocytogenes* infection was diagnosed on January 23. This patient could have eaten ice cream from lots we enumerated. Only 4 (0.2%) of 2,320 samples of product 1 yielded a concentration >100 CFU/g, equivalent to a dose of  $\geq 16,000$  *L. monocytogenes* cells per milkshake (2 servings of 80 g  $\times$  100 CFU/g, assuming the 2 servings were >100 CFU/g). Inferences on the interlot, interbox, and intrabox variability helped us define precisely the distribution of contamination levels from serving to serving and confirmed that a very high concentration of *L. monocytogenes* cells in any given serving unit was not likely. The estimated mean dose per milkshake is 1,240 *L. monocytogenes* cells (95% CrI 760–4,200 *L. monocytogenes* cells). We estimate that 1 of 10,000 milkshakes would have a load >26,000 *L. monocytogenes* cells (95% CrI 15,600–240,000 *L. monocytogenes* cells). Assuming there was no initial contamination of the milkshake machines and no growth of the pathogen in the milkshakes, the mean contamination level of *L. monocytogenes* in the milkshakes (8 cells/g of ice cream) was relatively low compared with contamination levels in some other outbreaks (9–12). However, in the absence of leftovers from the actual implicated milkshakes, we cannot rule out the possibility that the 4 susceptible patients received some of the highest contaminated products from the factory line, triggering infection. Experimental trials of *L. monocytogenes* growth in milkshakes made from these naturally contaminated ice cream samples held at room temperature showed an absence of growth during 8 hours and an average population level increase after 14 hours limited to 1.14 log CFU/g (13). We cannot exclude the possibility that variations in procedures used to clean the milkshake machines might have enabled isolated mi-

crobial growth on  $\geq 1$  machines. We believe the extremely high prevalence of contamination of product 1 might have inoculated  $\geq 1$  machines with repeated preparations over the long period during which contaminated products were distributed; however, no *Listeria* was isolated from samples collected from these machines after the outbreak was recognized (Charles Hunt, Kansas Department of Health and Environment, pers. comm., 2016 Jun 27).

Although the 4 cases of ice cream-associated listeriosis in a single hospital raise the possibility of a systematic problem within the hospital, it is also possible that the combination of severely ill patients, including some with specific risk factors for listeriosis such as hematologic cancers (14), in a setting in which a large amount of contaminated ice cream was served contributed to this series of infections. Medical staff at the hospital also might have had a heightened suspicion of listeriosis after diagnosis of the initial case, which might have increased the likelihood of detecting cases. Overall, the Kansas hospital received 55% of all product 1 sold to hospitals. Thus, observing the 4 cases in this specific hospital was not improbable. (The probability to observe 4 successes out of 4 trials is 9% when the independent probability of success is 55%.)

Although precise quantification of exposure to *L. monocytogenes* ingestion through contaminated ice cream is difficult to infer for specific persons, an assessment of exposures among populations is more feasible. Despite the relatively low levels of contamination of ice cream products in this listeriosis outbreak, the exceptionally high prevalence of contaminated products, combined with the protracted duration of contamination of the production line (at least 1 year and possibly longer), contributed to exposure of many persons to *L. monocytogenes*. This finding suggests that widespread distribution of contaminated products with low-dose contamination by *L. monocytogenes* in a product that does not support growth of *L. monocytogenes* might lead to only a limited number of reported infections. We focused our study on 1 cluster of outbreak-related cases, the one for which FDA was able to collect samples of ice cream for microbiological testing. Five other cases of ice cream-associated invasive listeriosis were identified in states other than Kansas; these cases were linked to another production factory operated by the same company, expanding further the quantity of contaminated ice cream sold to the public.

The Food and Agriculture Organization of the World Health Organization (FAO/WHO) (15) estimated an  $r$  parameter of  $3.2 \times 10^{-7}$  in a well-documented listeriosis outbreak involving immunocompromised patients in Finland in 1998–1999 (16,17); in this outbreak, the median estimated dose ingested was  $8.2 \times 10^3$  *L. monocytogenes*. Our estimate of the  $r$  parameter for the susceptible population is in the same order of magnitude ( $1.2 \times 10^{-7}$  to 5.5

$\times 10^{-7}$ ). In the population of pregnant women, FAO/WHO (15) estimated a  $r$  parameter of  $2.6 \times 10^{-11}$  on the basis of an outbreak of cheese-associated listeriosis involving pregnant Hispanic women in Los Angeles County, California, USA, in 1985 in which the estimated dose was  $1.7 \times 10^7$  *L. monocytogenes* (10). More recently, Imanishi et al. (18) estimated an attack rate of 1 case/10,000 exposed pregnant women in Colorado, USA, during a 2011 multistate outbreak of listeriosis linked to contaminated cantaloupe (19); no enumeration data were available in this outbreak. Studies have shown that cut cantaloupe supports the growth of *L. monocytogenes* (20,21), suggesting that some exposures could have been high during this outbreak. In the ice cream-associated outbreak described here, no cases were reported among pregnant women despite presumably widespread exposures among this subgroup of susceptible persons. Specifically, a large number of contaminated ice cream products were presumably ingested by pregnant women during the long duration of contamination of the production line. From the expected number of *L. monocytogenes* cells ingested by this subpopulation, we estimate, under the various assumptions used in this study, a value of  $r < 2.6 \times 10^{-9}$  to  $r < 2.3 \times 10^{-8}$ . In summary, estimates for  $r$  derived in the present study are comparable in order of magnitude with estimates derived from previous outbreaks, a finding that is noteworthy in light of the low levels of contamination of ice cream products and the fact that these products did not support growth. Although other outbreaks were linked to higher level of contamination per serving than in the present study, the number of contaminated servings was much lower in those outbreaks than in the present one.

On the other hand, estimates for  $r$  obtained in the present study are higher than those estimated by using epidemiologic data (6,15,17). Using epidemiologic data, FAO/WHO (15) estimated that the probability of infection after consumption of 1 *L. monocytogenes* cell is in the order of  $r = 5 \times 10^{-12}$  for susceptible persons (immunocompromised persons, pregnant women, and elderly persons), and  $5 \times 10^{-14}$  for nonsusceptible persons (15). These values predict the occurrence of 1 listeriosis case for every 20 million exposures to 10,000 *L. monocytogenes* cells in the susceptible population (10,000, which was chosen arbitrarily, would correspond to the dose after ingestion of 100 g of a product contaminated at 100 CFU/g) and 1 case of listeriosis for every 2 billion exposures to 10,000 *L. monocytogenes* cells in the nonsusceptible population. The estimates obtained in our study were much higher than these values: 1 case expected for every 339,200 servings of 10,000 bacteria per serving, such as for the general population in the high-exposure scenario. Similarly, using the model of Pouillot et al. (6), we estimated that values from the ice cream outbreak data are  $\approx 2 \log_{10}$  higher than those based on epi-

miologic data. A possible explanation for these differences is that a particularly virulent strain of *L. monocytogenes* was present in ice cream. Differences in  $r$  estimates obtained from outbreak investigations versus epidemiologic data also could result from observation bias, wherein recognition of cases instigates a study, leading to high number of cases for equation input and thus higher estimates for  $r$ . In contrast, situations where contaminated products are distributed but no cases are recognized are underrepresented in such evaluations.

This outbreak of ice cream-associated listeriosis recognized in 2015 demonstrates that illnesses can occur when products with low-level contamination that do not support growth are distributed widely to the public, even though it is not possible to conclude with certainty whether the cases were linked directly to the products or indirectly after a growth step on a milkshake machine. The outbreak also illustrates that even when the distribution of products contaminated with *L. monocytogenes* is widespread, most consumers of the products will not become ill when contamination levels are low and no growth is facilitated. Finally, this outbreak adds yet further evidence of the risk for listeriosis faced by persons with weakened immune systems and calls for effective risk management to mitigate infections (22).

### Acknowledgments

We acknowledge the outbreak response partners whose contributions to the listeriosis investigation resulted in identification of the contaminated products, distribution records, and clinical case records vital to this study. We thank the state and local partners from the Alabama Department of Public Health, Kansas Department of Agriculture, Kansas Department of Health and Environment, Oklahoma Department of Agriculture, Food and Forestry, South Carolina Department of Health & Environmental Control, Texas Department of State Health Services, and Tulsa Health Department for their help in the outbreak investigation. We also thank the federal partners at the Centers for Disease Control and Prevention's Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases; FDA's Office of Regulatory Affairs, especially the Dallas, Kansas City, Atlanta, and New Orleans District Offices; FDA's Center for Food Safety and Applied Nutrition; and FDA's Coordinated Outbreak Response and Evaluation Network. We thank Libby Wei and Sara Kreshpanji, each supported by a University of Maryland/Joint Institute for Food Safety and Applied Nutrition student internship, for helping to gather and analyze data. This study used the high-performance computational capabilities of the Scientific Computing Laboratory at the FDA Center for Devices and Radiological Health. We thank Mike Mikailov, Brian Fitzgerald, Stuart Barkley, Luo Fu Jyh, Lohit Valleru, and Stephen Whitney for their invaluable contributions to supercomputing.

Dr. Pouillot is a visiting scientist in the Risk Analysis Branch within the Division of Risk and Decision Analysis, Center for Food Safety and Applied Nutrition, FDA. His research interest is using data analysis and models to understand and evaluate the risk for foodborne illnesses.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-020**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code to Require Detergent for Equipment Cleaning

**Issue you would like the Conference to consider:**

Under FSMA, hot water is not considered effective for removal of allergens. Currently the 2017 Food Code appears to allow the use of hot water without chemicals, for cleaning of equipment under 4-603.14 Wet Cleaning. This may allow allergens to persist on a food contact surface, resulting in cross cross-contact.

**Public Health Significance:**

Allergen proteins can difficult to remove from food contact surfaces as they can be sticky or even baked on/cooked onto a surface. Inadequate cleaning has been identified as a contributing factor for cross-contact; and cross-contact is one of the major causes of allergen recalls. Prevention measures for cross contact include the creation of a cleaning procedure proven effective for allergen removal. The use of hot water alone for cleaning of food contact surfaces, has not been proven effective for removal of allergens.

A reduction in cross contact would reduce the number of recalls within the food industry while also preventing adverse health outcomes in consumers.

Currently, the 2017 Food Code allows for the use of hot water only for cleaning equipment. This practice is prohibited under FSMA as hot water is considered ineffective for the removal of allergens. If adopted, the following language will allow for effective removal of allergens during cleaning.

The annex references chemical use through this section, but the specific language was not brought into the code itself.

**Recommended Solution: The Conference recommends...:**

A letter be sent to FDA to change Section 4-603.14 to address removal of allergens from equipment in the most current edition of the Food Code.

4-603.14 (A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be effectively washed to remove or completely loosen soils and major food allergens by using the manual or mechanical means necessary. ~~such as the application of detergents containing wetting agents and emulsifiers; acid; alkaline, or abrasive cleaners; hot water brushes; scouring pad; high pressure sprays; or ultrasonic devices.~~

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-021**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018 COUNCIL III 027; new or additional information has been included or attached.

**Title:**

Amend Food Code: Hand Cleanse-Sanitize Protocol Not Requiring Water

**Issue you would like the Conference to consider:**

The December 2019 Supplement to the 2017 Food Code removes the use of chemically treated towelettes as a hand washing protocol. This leaves operators without a convenient choice for water-compromised locations. Inconvenience limits hand washing and results in a public health risk.

Food service situations with compromised potable water supply are many and growing as operators respond to the public's demand to have safe food convenient to their daily trail. This results in food being prepared and served in venues without running water for hand washing. Gloves are not the full answer as when they are damaged or contaminated or a task change is required, there is no reasonable option to clean hands between glove changes.

Harvesting produce occurs in water-compromised fields. Workers contaminate ready-to-eat foods and inconvenient access to water results in infrequent soap-water hand washes.

A range of compromised water systems were approved by jurisdictions around the country based on the presence of water rather than its effectiveness. The flow rate in these options is normally far below the effective flow rate of 2.0 gallons per minute, specified in the Uniform Plumbing Code (UPC).

The most common interpretation of an alternative "approved method" for hand washing at venues without running water is a jug of water actuated by manually depressing a release button or lever, a cleaning agent, toweling and a waste receptacle to catch wastewater.

A cleanse-sanitize protocol was developed for the US Military in 2006 and picked up by special water-short venues in the Southern Nevada Health District, including use by Clark County Schools during water outages. Along with years of use, several independent research studies have been added, confirming the cleanse-sanitize antimicrobial effectiveness against bacteria and viruses.

Separate studies also identify three hand sanitizers effective on norovirus, the best of those three was selected by Clark County and other noro-concerned operators like the cruise ships and the world's largest 5 star resort - the Venetian and Palazzo properties. This protocol's superior convenience elevates compliance over the traditional alternative using a jug of water.

Under the 2013 FDA Food Code, Subparagraph 2-301.16 (A)(3) requires hand antiseptics "Be applied only to hands that are cleaned as specified under § 2-301.12. Pf" It has been demonstrated, documented and published in credible, peer-reviewed journal (Journal of Food Protection) that effective hand cleansing, "equivalent or superior" to hand washing with soap and water as specified in Section 5-203.11, can be achieved by applying an excess of alcohol based hand sanitizer as the cleaning agent, scrubbing for 15 seconds, wiping on a single-use towel, followed by an application of alcohol based hand sanitizer following normal label usage instructions.

The latest testing of this hand cleansing/degerming technique shows it to be effective in the presence of organic food soils. This adds an additional safety factor to support incorporation of the method into food safety practices.

This protocol is not a substitute for hand washing in stationary facilities where cleaning can be accomplished per Section 2-301.12.

#### **Public Health Significance:**

Potential contamination of ready-to-eat foods by inadequately washed or unwashed hands is increased in situations where access to running water is limited or unavailable. The new proposed option increases the odds of effective hand degerming in those situations.

#### **Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting the most current edition of the Food Code be amended as follows (new language underlined):

##### 5-203.11 Handwashing Sinks

(D) When food exposure is limited and handwashing sinks are not conveniently located, such as at outdoor events, mobile or temporary food service, and vending machine locations, employees may use a regimen using hand antiseptic as the cleansing agent wherein this step is treated as a handwash with full scrubbing action for 15 seconds and then, while wet, wiped off with a single-use paper towel, immediately followed by a second application which is allowed to dry per standard label instruction.

(1) Said hand antiseptic shall meet requirements as specified in Section 2-301.16.

(2) Said hand antiseptic shall have supporting test data indicating statistical equivalence to a standard handwash in hand degerming.

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**Supporting Attachments:**

- "JFP SaniTwice article"
- "Farm Hands Cleansing"
- "JFP Hand Hygiene Regimens"
- "JFP Hand Hygiene Interventions - part 1"
- "JFP Hand Hygiene Interventions - part 2"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

## Research Note

# SaniTwice: A Novel Approach to Hand Hygiene for Reducing Bacterial Contamination on Hands When Soap and Water Are Unavailable

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### ABSTRACT

The risk of inadequate hand hygiene in food handling settings is exacerbated when water is limited or unavailable, thereby making washing with soap and water difficult. The SaniTwice method involves application of excess alcohol-based hand sanitizer (ABHS), hand “washing” for 15 s, and thorough cleaning with paper towels while hands are still wet, followed by a standard application of ABHS. This study investigated the effectiveness of the SaniTwice methodology as an alternative to hand washing for cleaning and removal of microorganisms. On hands moderately soiled with beef broth containing *Escherichia coli* (ATCC 11229), washing with a nonantimicrobial hand washing product achieved a  $2.86 (\pm 0.64)$ -log reduction in microbial contamination compared with the baseline, whereas the SaniTwice method with 62% ethanol (EtOH) gel, 62% EtOH foam, and 70% EtOH advanced formula gel achieved reductions of  $2.64 \pm 0.89$ ,  $3.64 \pm 0.57$ , and  $4.61 \pm 0.33$  log units, respectively. When hands were heavily soiled from handling raw hamburger containing *E. coli*, washing with nonantimicrobial hand washing product and antimicrobial hand washing product achieved reductions of  $2.65 \pm 0.33$  and  $2.69 \pm 0.32$  log units, respectively, whereas SaniTwice with 62% EtOH foam, 70% EtOH gel, and 70% EtOH advanced formula gel achieved reductions of  $2.87 \pm 0.42$ ,  $2.99 \pm 0.51$ , and  $3.92 \pm 0.65$  log units, respectively. These results clearly demonstrate that the in vivo antibacterial efficacy of the SaniTwice regimen with various ABHS is equivalent to or exceeds that of the standard hand washing approach as specified in the U.S. Food and Drug Administration Food Code. Implementation of the SaniTwice regimen in food handling settings with limited water availability should significantly reduce the risk of foodborne infections resulting from inadequate hand hygiene.

Foodborne diseases are a serious public health concern (3, 4, 15), but despite preventive efforts there has been little recent progress in reducing infections caused by foodborne pathogens (6). Faulty food handling practices, particularly improper hand washing, contribute significantly to the risk for foodborne disease (11–13, 19, 25–27, 29). Proper hand hygiene reduces the risk of transmission of pathogens from hands to food (7, 20, 21) and is associated with a reduction in gastrointestinal illness (2, 8, 18). The U.S. Food and Drug Administration (FDA) Food Code for retail establishments requires hand washing as a preventive method and provides specific guidance on proper hand washing procedures (30). The five-step hand washing procedure outlined in the FDA Food Code consists of (i) rinsing under warm running water, (ii) applying the manufacturer-recommended amount of cleaning compound, (iii) rubbing the hands vigorously, (iv) rinsing thoroughly under warm running water, and (v) thoroughly drying the hands with individual paper towels, a continuous clean towel system, or a heated or pressurized hand air drying device. According to the Food Code,

alcohol-based hand sanitizers (ABHS) may be used in retail and food service only after proper hand washing.

ABHS are recommended as an alternative to traditional hand washing in the health care setting (5). Alcohols are highly effective against a range of bacterial pathogens, fungi, enveloped viruses, and certain nonenveloped viruses (2, 10). Although considered to be ineffective antimicrobial agents in the presence of visible dirt or proteinaceous material, alcohol-containing products were more effective than those containing triclosan (2, 14) or detergents (17) for removing microorganisms from hands contaminated with organic material. In health care facilities and other environments, easily accessible ABHS have resulted in greater hand hygiene compliance and reduction in infections (1, 9, 16, 31). Although ABHS are approved for use in the health care environment, the FDA does not regard these agents as adequate substitutes for soap and water in the food service setting (30).

A reliable hand hygiene method is needed for food service settings in which adequate hand washing facilities are limited or unavailable. These settings include portable bars, buffet lines, outdoor events, and catering functions at which the only available hand hygiene facility often is either “trickle hand washing” (i.e., hand washing done from a

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portable container of water over a bucket or other type of basin) or simply the use of a paper towel or damp cloth to rub the hands. These methods may be inadequate for proper hand cleansing.

SaniTwice (a registered trademark with James Mann, Handwashing for Life, Libertyville, IL) is a two-stage hand cleansing protocol that is performed using ABHS when water is not available. In this study, we evaluated the microbiological efficacy of the SaniTwice method on the hands of adult human participants. These studies were designed to assess (i) the antimicrobial efficacy of various ABHS used with the SaniTwice regimen as compared with that of a standard hand washing method with soap and water on soiled hands and (ii) the impact of the active ingredient and/or formulation of a hand sanitizer on antibacterial efficacy when used in a SaniTwice regimen.

## MATERIALS AND METHODS

**Test products.** All test products in this study were manufactured by GOJO Industries (Akron, OH). Two hand washing products were evaluated: a nonantimicrobial product (GOJO Luxury Foam Handwash) and an antimicrobial product (MICRELL Antibacterial Foam Handwash, 0.5% chloroxylenol active). Four ABHS also were evaluated: a 62% ethanol (EtOH) gel (PURELL Instant Hand Sanitizer Food Code Compliant), a 62% EtOH foam (PURELL Instant Hand Sanitizer Foam), a 70% EtOH gel (PURELL 70 Instant Hand Sanitizer), and a 70% EtOH Advanced Formula (AF) gel (PURELL Instant Hand Sanitizer Advanced Formula VF481).

**Overall study design.** Three studies were conducted by BioScience Laboratories (Bozeman, MT) to determine the in vivo antimicrobial efficacy of various test product configurations under conditions of moderate or heavy soil. The order of use of each product was determined randomly. A two-step testing sequence was used for all products. Each volunteer completed the baseline cycle, where hands were contaminated with moderate or heavy soil (as described below) containing *Escherichia coli* (ATCC 11229), and samples were collected for baseline bacterial counts. Following the baseline sampling, participants completed a 30-s nonmedicated soap wash followed by the product evaluation cycle, which consisted of a contamination procedure, application of the test product, and subsequent hand sampling. Between uses of different test products, participants decontaminated their hands with a 1-min 70% EtOH rinse, air drying, and a 30-s nonmedicated soap wash. A minimum of 20 min elapsed before the next testing sequence began. Baseline and postapplication samples were evaluated for the presence of *E. coli*. Testing was performed according to the FDA health care personnel hand washing product evaluation method (28) and modified as described previously (22).

The study was approved by the Gallatin Institutional Review, an independent review board unaffiliated with BioScience Laboratories, and was conducted in compliance with Good Clinical Practice and Good Laboratory Practice regulations. All participants provided written informed consent.

**Participants.** The study enrolled healthy adults with two hands. All participants were free of dermal allergies or skin disorders on the hands or forearms.

**Preparation of inoculum.** *E. coli* was used to test the efficacy of the test procedures. A 2-liter flask was filled with

1,000 ml of tryptic soy broth: 30.0 g of dehydrated tryptic soy broth medium (BD, Franklin Lakes, NJ) added to 1 liter of deionized water, heated, and sterilized for a final pH of  $7.3 \pm 0.20$ . The broth was inoculated with 1.0 ml of a 24-h culture of *E. coli* grown from a cryogenic stock culture. The flask was incubated for 24 h, and the suspension was used for challenge.

**Hand contamination procedures.** For the moderate soil study, a 24-h culture of *E. coli* was suspended in beef broth (Swanson low sodium beef broth, Campbell Soup Company, Camden, NJ) at  $1 \times 10^9$  CFU/ml. Three aliquots of 1.5 ml were transferred into each participant's cupped hands. Each aliquot was distributed over the entire front and back surfaces of the hands up to the wrists during a 20-s period and allowed to air dry for 30 s after the first and second aliquots and for 90 s after the third aliquot. After samples were collected for baseline bacterial counts and hands were decontaminated with a 30-s wash with non-medicated soap, a second cycle of contamination was initiated. After the 90-s final drying step, participants applied the randomly assigned test product.

For the heavy soil study, 5.0-ml aliquots of the challenge suspension of *E. coli* were transferred to 4-oz (113-g) portions of sterile 90% lean ground beef and distributed evenly with gloved hands to achieve contamination levels of approximately  $5.0 \times 10^8$  CFU per portion. Each participant then kneaded the inoculated raw hamburger for 2 min. Hands were air dried for 90 s and then sampled for baseline counts. After a 30-s decontamination with nonmedicated soap, the cycle was repeated, and the test product was applied.

**Test article or product application and SaniTwice procedure.** The hand washing procedure used for the nonantimicrobial and antimicrobial hand washing products was consistent with Food Code specifications. Table 1 shows the stepwise product application procedures for all test configurations.

**Bacterial recovery and microbial enumeration.** Within 1 min after contamination for baseline evaluation or after product application, powder-free sterile latex gloves were placed on each participant's hands and secured above the wrist, and 75 ml of sterile stripping fluid (0.4 g of  $\text{KH}_2\text{PO}_4$ , 10.1 g of  $\text{Na}_2\text{HPO}_4$ , and 1.0 g of isoocetylphenoxypolyethoxyethanol in 1 liter of distilled water, pH adjusted to 7.8) was transferred into each glove. Following a 60-s massage of the hands through the gloves, a 5.0-ml aliquot of the glove rinsate sample was removed and diluted in 5.0 ml of Butterfield's phosphate buffer solution with product neutralizers. Each aliquot was serially diluted in neutralizing solution, and appropriate dilutions were plated in duplicate onto MacConkey agar plates (BD; 50.0 g of dehydrated medium added to 1 liter of deionized water, heated, and sterilized; final pH,  $7.1 \pm 0.2$ ) and incubated for 24 to 48 h at 30°C. Colonies were counted and data were recorded using the computerized Q-COUNT plate-counting systems (Advanced Instruments, Inc., Norwood, MA).

**Data analysis and statistical considerations.** The estimated log transformed number of viable microorganisms recovered from each hand (the *R* value) was determined using the formula  $R = \log(75 \times C_i \times 10^D \times 2)$ , where 75 is the amount (in milliliters) of stripping solution instilled into each glove,  $C_i$  is the arithmetic average colony count of the two plate counts at a particular dilution, *D* is the dilution factor, and 2 is the neutralization dilution.

Descriptive statistics and confidence intervals were calculated using the 0.05 level of significance for type I (alpha) error. Statistical calculations of means and standard deviations were

TABLE 1. Test product application procedures<sup>a</sup>

Step	Food Code-compliant procedure for hand washing products	SaniTwice <sup>b</sup> procedure for ABHS	Procedure for 70% EtOH AF gel
1	Wet hands with water at 40°C	Dispense ~3 ml of product into cupped hands	Dispense ~1.5 ml of product into cupped hands
2	Apply ~1.5 ml of product	Rub vigorously over hands for 15 s to simulate washing	Rub hands together until dry
3	Lather for 15 s	Clean thoroughly with two paper towels	
4	Rinse with water for 10 s	Dispense additional ~1.5 ml of product	
5	Pat dry with two paper towels	Rub hands together until dry	

<sup>a</sup> All application procedures were initiated within 10 s of completing the 90-s drying step.

<sup>b</sup> SaniTwice is a registered trademark with James Mann (Handwashing for Life, Libertyville, IL).

generated for the log recovery data from baseline samples, postproduct application samples, and the log differences between baseline and postapplication samples. Product comparisons were made using a one-way analysis of variance with post hoc analysis (Bonferroni's multiple comparison test) using the 0.05 level of significance for alpha error.

## RESULTS

**Reduction in microbial contamination of moderately soiled hands.** Two studies were conducted to evaluate microbial count reductions on hands that had been contaminated by handling beef broth containing *E. coli*. Reductions from baseline produced by the five test product configurations in these two studies are shown in Figure 1.

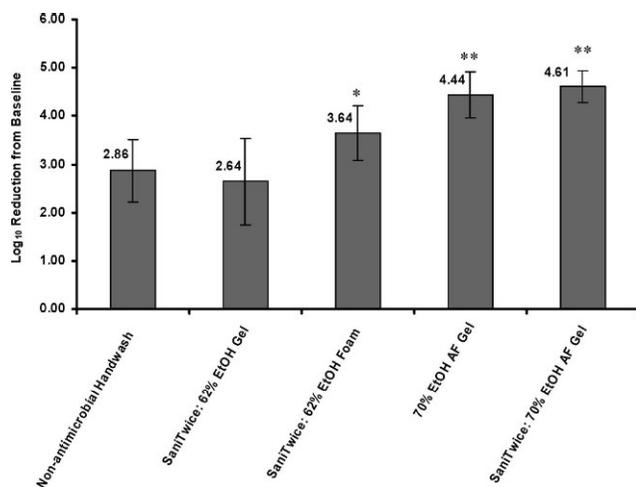


FIGURE 1. Log reduction from baseline for microbial contamination of hands moderately soiled with contaminated beef broth after application of test products. Error bars represent standard deviation. Data are from two separate studies. In study 1 ( $n = 11$ ), nonantimicrobial hand washing product and SaniTwice with 62% EtOH gel were compared. In study 2 ( $n = 12$ ), the conditions evaluated were nonantimicrobial hand washing product, SaniTwice with 62% EtOH foam, 70% EtOH AF gel without SaniTwice, and SaniTwice with 70% EtOH AF gel. Results for nonantimicrobial hand washing product represent pooled data from both studies. \*  $P < 0.05$  for SaniTwice with 62% EtOH foam versus nonantimicrobial hand washing product or SaniTwice with 62% EtOH gel. \*\*  $P < 0.05$  for 70% EtOH AF gel or for SaniTwice with 70% AF gel versus nonantimicrobial hand washing product, SaniTwice with 62% EtOH gel, or SaniTwice with 62% EtOH foam.

All SaniTwice regimens were equivalent to or better than the Food Code hand washing protocol. Reductions from baseline ranged from  $2.64 \pm 0.89$  log CFU/ml for SaniTwice with the 62% EtOH gel to  $4.61 \pm 0.33$  log CFU/ml for SaniTwice with the 70% EtOH AF gel.

SaniTwice using the 62% EtOH gel was equivalent to the nonantimicrobial Food Code hand washing protocol. However, SaniTwice using the 62% EtOH foam ( $3.64 \pm 0.57$ -log reduction) was more effective than SaniTwice with the 62% EtOH gel and the Food Code hand washing protocol ( $P < 0.05$ ).

The 70% EtOH AF gel was the most effective sanitizing product. When used independently, it was significantly more effective ( $4.44 \pm 0.47$ -log reduction) than SaniTwice with 62% EtOH foam or 62% EtOH gel or the nonantimicrobial hand washing product ( $P < 0.05$  for all comparisons). Although the log reduction data suggest that SaniTwice with 70% EtOH AF gel ( $4.61 \pm 0.33$ -log reduction) was equivalent to the 70% EtOH AF gel used independently, this lack of differentiation was most likely due to the limitations of the assay. The 4.61-log reduction was at the limit of detection for all participants using 70% EtOH AF gel with SaniTwice but for only half the participants using 70% EtOH AF gel alone. Therefore, the log reductions produced by the 70% EtOH AF gel after either a single sanitization or the SaniTwice regimen are likely underestimated, and the log reductions in both cases would likely be higher if the limits of detection were lower.

**Reduction in microbial contamination of heavily soiled hands.** Figure 2 shows microbial count reductions produced by test product configurations on hands that had been contaminated by handling ground beef containing *E. coli*. All SaniTwice regimens tested were equivalent to or better than the Food Code hand washing protocol, indicating that under conditions of heavy soil, the SaniTwice procedure is as effective as hand washing. The performance of the antimicrobial hand washing product was equivalent to that of the nonantimicrobial hand washing product in this heavy soil challenge, with log reductions of  $2.69 \pm 0.32$  and  $2.65 \pm 0.33$ , respectively. SaniTwice with the 70% EtOH AF gel outperformed all other sanitizer configurations tested and was superior to hand washing for reduction of organisms on heavily soiled hands ( $P < 0.05$  for comparisons of SaniTwice with 70% EtOH AF gel versus each of the other procedures).

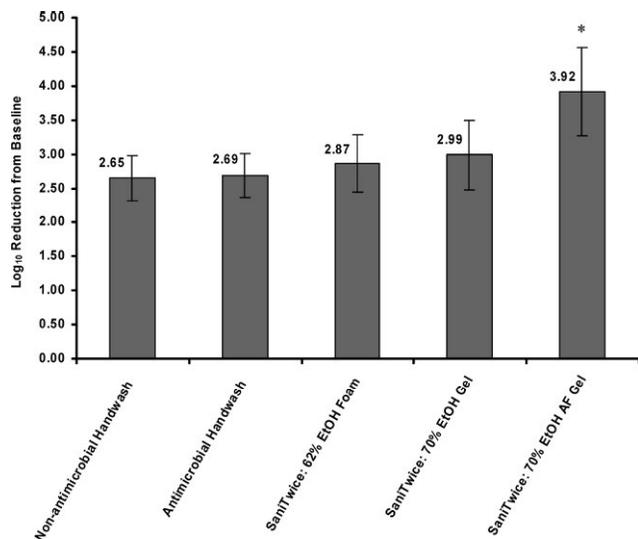


FIGURE 2. Log reduction from baseline for microbial contamination of hands heavily soiled with contaminated uncooked hamburger after application of test products and protocols. Error bars represent standard deviation. Data are from study 3 ( $n = 15$ ), in which five test configurations were evaluated. \*  $P < 0.05$  for SaniTwice with 70% AF gel versus nonantimicrobial hand washing product, antimicrobial hand washing product, SaniTwice with 62% EtOH foam, or SaniTwice with 70% EtOH gel.

Two ABHS used with SaniTwice under both moderate and heavy soil conditions produced greater log reductions in the moderate soil condition. Mean log reductions using SaniTwice (moderate versus heavy soil) were 3.64 versus 2.87 for 62% EtOH foam and 4.61 versus 3.92 for 70% EtOH AF gel.

## DISCUSSION

The SaniTwice method for hand disinfection was equivalent or superior to hand washing with soap and water for reducing viable bacteria on hands in the presence of representative food soils. Although the raw hamburger was a more difficult soil to penetrate, as demonstrated by approximately 1.0-log lower reductions compared with challenge by contaminated beef broth, the SaniTwice method with ABHS was equivalent to hand washing even under this worst-case simulation, underscoring the efficacy of this new method and indicating a potentially greater margin of safety.

The ABHS products used in this study exhibited a range of antimicrobial efficacy, suggesting that product formulation and the concentration of active ingredient may play a role in the observed efficacy. The impact of formulation was indicated by the significantly higher efficacy of the 62% EtOH foam compared with the 62% EtOH gel when challenged with moderate soil. This difference may be due to the additional foaming surfactants in the foam formulation, which may aid in lifting and removing bacteria and soil from the hands during the SaniTwice procedure. In addition, SaniTwice with the 70% EtOH AF gel was superior to SaniTwice with the 70% EtOH gel and 62% EtOH foam under heavy soil conditions. The 70% EtOH AF gel, whether tested as a single

application or with the SaniTwice method, was superior to hand washing and to the 62% EtOH gel or foam under moderate soil conditions. The 4.44-log reduction with a single use of the 70% EtOH AF gel demonstrates its high antimicrobial efficacy, which is further enhanced when used with the SaniTwice method. The 70% EtOH AF gel contains a patent-pending blend of ingredients that enhance the activity of the alcohol and likely contribute to the high efficacy observed in this study. The SaniTwice procedure gives the benefit of skin cleansing and soil removal, which is not obtained with single use of a product. The efficacy of ABHS used with SaniTwice against nonenveloped enteric viruses, which are more difficult to eradicate, remains to be determined.

In support of previous findings (23), the findings in this study indicate that the decontamination efficacy was similar for the antimicrobial and nonantimicrobial hand washing products under heavy soil conditions, suggesting that the cleansing properties of the surfactants in these soaps and the mechanical action of hand washing may be the primary contributors to efficacy rather than the antimicrobial activity of any constituent of the formulations. It is expected that with heavy hand soiling, the surfactant effect drives efficacy, and typical antibacterial constituents will have little additional effect.

In this study, SaniTwice was an effective hand hygiene regimen at least equivalent to hand washing with soap and water for reducing microbial contamination, even under worst case conditions of high bacterial load and heavy food soils. The current FDA Food Code allows use of ABHS only on hands that have been cleaned according to the recommended hand washing protocol (30). However, other than substitution of an ABHS for soap and water, the SaniTwice protocol mirrors the FDA-specified hand washing sequence. SaniTwice is at least as effective as hand washing when used with standard-efficacy ABHS; when used with a high-efficacy ABHS, the SaniTwice protocol is superior to washing with soap and water. The Food Code provides few specific recommendations for achieving good hand hygiene when water (or other hand washing supplies and equipment) is unavailable or limited. The Food Code (Section 2-301.16) severely restricts hand sanitizers by allowing use only after proper hand washing or in situations in which no direct contact with food occurs (30).

A potential solution to this gap in food safety practices is SaniTwice. The SaniTwice studies described here provide convincing scientific rationale for including the SaniTwice approach in the Food Code as an alternative method of hand hygiene when standard hand washing is impractical. The simplicity and ease of use of the SaniTwice method, which requires only a supply of ABHS and paper towels, should allow this protocol to be applied to various food service settings and other areas in which hand hygiene is needed but safe water is unavailable or in short supply.

The findings in the present study support and extend those from previous studies; ABHS used alone or in combination with hand washing can be effective for decontaminating hands in the presence of organic soils (17, 23, 24). A well-formulated ABHS in conjunction with

the SaniTwice regimen can have high efficacy, even in the presence of high organic load. Therefore, a reevaluation of the longstanding paradigm defining the use of ABHS in the presence of organic soils in both food handling and health care environments is warranted.

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## Hand Hygiene Regimens for the Reduction of Risk in Food Service Environments

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### ABSTRACT

Pathogenic strains of *Escherichia coli* and human norovirus are the main etiologic agents of foodborne illness resulting from inadequate hand hygiene practices by food service workers. This study was conducted to evaluate the antibacterial and antiviral efficacy of various hand hygiene product regimens under different soil conditions representative of those in food service settings and assess the impact of product formulation on this efficacy. On hands contaminated with chicken broth containing *E. coli*, representing a moderate soil load, a regimen combining an antimicrobial hand washing product with a 70% ethanol advanced formula (EtOH AF) gel achieved a 5.22-log reduction, whereas a nonantimicrobial hand washing product alone achieved a 3.10-log reduction. When hands were heavily soiled from handling ground beef containing *E. coli*, a wash-sanitize regimen with a 0.5% chloroxylenol antimicrobial hand washing product and the 70% EtOH AF gel achieved a 4.60-log reduction, whereas a wash-sanitize regimen with a 62% EtOH foam achieved a 4.11-log reduction. Sanitizing with the 70% EtOH AF gel alone was more effective than hand washing with a nonantimicrobial product for reducing murine norovirus (MNV), a surrogate for human norovirus, with 2.60- and 1.79-log reductions, respectively. When combined with hand washing, the 70% EtOH AF gel produced a 3.19-log reduction against MNV. A regimen using the SaniTwice protocol with the 70% EtOH AF gel produced a 4.04-log reduction against MNV. These data suggest that although the process of hand washing helped to remove pathogens from the hands, use of a wash-sanitize regimen was even more effective for reducing organisms. Use of a high-efficacy sanitizer as part of a wash-sanitize regimen further increased the efficacy of the regimen. The use of a well-formulated alcohol-based hand rub as part of a wash-sanitize regimen should be considered as a means to reduce risk of infection transmission in food service facilities.

Foodborne diseases are a serious and growing public health concern both in the United States (8, 19) and worldwide (46). The Centers for Disease Control and Prevention attributed 9.4 million illnesses, nearly 56,000 hospitalizations, and more than 1,300 deaths to foodborne pathogens annually in the United States (33). Many researchers believe that foodborne diseases are underreported (27, 39, 43).

The ever-changing nature of pathogens, including the emergence of new ones, is contributing to an increase in foodborne diseases (5). Enterotoxigenic *Escherichia coli* has been implicated in one of the largest foodborne outbreaks reported in the United States to date (3). According to the Foodborne Disease Outbreak Surveillance System (1998 to 2002), 31% of foodborne disease outbreaks and 41% of cases of infection with known etiology can be attributed to human norovirus (HNV) (27), and HNV is now recognized as the most significant cause of infectious gastrointestinal illnesses, with a growing number of virulent strains circulating (4, 9, 16, 44).

Poor personal hygiene of food service workers, in particular improper hand washing, contributes significantly to the risk of foodborne diseases (15, 17, 26, 38, 41). The

majority of HNV infection outbreaks are attributed to contamination of food via unwashed or improperly washed hands of food handlers (5, 9, 23). HNVs have a low infective dose (37, 44), persist in the environment, and are resistant to chlorination and freezing (23, 35, 44). These factors contribute to an increased risk of HNV illness transmission. Heavily soiled items are frequently encountered in food service settings when preparing food, and antimicrobial agents are considered to be less effective in the presence of such items (6). The U.S. Food and Drug Administration (FDA) Food Code requires that food service workers wash their hands with a cleaning compound and water before using alcohol-based hand rubs (ABHRs) (42). Although an improvement in compliance among food handlers with personal hygiene risk factors was observed between 1998 and 2008 in retail food facilities, hand washing practices were the most out-of-compliance risk factor for every type of facility evaluated (40). In 2008, hand washing practices were not being followed in 76% of restaurants and approximately 50% of delicatessens (40). In another study, compliance with Food Code recommendations for frequency of washing during production, service, and cleaning phases in restaurants was only 5% (36).

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TABLE 1. *Test products*

Test product	Description	Abbreviation
GOJO Luxury Foam Handwash	Nonantimicrobial hand washing product	Nonantimicrobial hand wash
MICRELL Antibacterial Foam Handwash	0.5% Chloroxylenol hand washing product	PCMX hand wash
GOJO Antibacterial Plum Foam Handwash	0.3% Triclosan hand washing product	Triclosan hand wash
PURELL Instant Hand Sanitizer Foam	62% Ethanol foam ABHR	62% EtOH foam
PURELL Instant Hand Sanitizer Advanced Formula VF481	70% Ethanol gel ABHR	70% EtOH gel

Various hand hygiene regimens reduce the risk of transmission of pathogens from the hands of food service workers to the food they handle and prepare (10, 29, 30). Proper hand hygiene has been associated with reductions of gastrointestinal illness ranging from 42 to 57% (5, 11, 25). However, some interventions are more effective for removing pathogens than are others. Hand washing with soap and water was more effective for reducing contamination on the hands than was rinsing with water or not washing at all (7, 10). Antimicrobial agents are more effective for removing bacteria on hands than is nonantimicrobial soap (13, 30). Even ABHRs used alone decontaminate hands at least as effectively as does washing with soap and water (12, 34). However, the combination of hand washing followed by the use of ABHRs produces even greater reduction of bacteria on hands (18, 29, 30, 32). When water is unavailable, a two-stage hand cleansing protocol using an ABHR known as the SaniTwice method (a registered trademark, James Mann, Handwashing for Life, Libertyville, IL) was at least as effective for removing bacteria from the hands as was only washing with soap and water (12).

A critical need remains for hand hygiene products with increased efficacy against hard-to-kill pathogens. Typical ABHR activity against nonenveloped enteric viruses varies depending on the type and concentration of alcohol (5, 6, 14, 21). Different strains of HNVs may be more resistant to antimicrobial agents than others (24). Several studies have been conducted on newly formulated ABHRs with significantly improved inactivation of nonenveloped viruses (24, 28). A 70% ethanol advanced formula (EtOH AF) gel reduced HNV by 3.74 log units in 15 s, a significantly greater HNV reduction than produced by six other commercially available hand hygiene products (24). This gel was the most effective product tested against two strains of HNV.

Quantitative data are scarce on the relative health impact of different hygiene interventions (5), in particular hand hygiene product performance against organisms commonly found in food service facilities, i.e., in food soils. This series of studies was designed to determine the antimicrobial effectiveness of various hand hygiene product regimens under moderate and heavy food soil conditions and against the murine norovirus (MNV), a surrogate for HNV. The impact of specific product formulation on antimicrobial efficacy also was evaluated.

## MATERIALS AND METHODS

**Test products.** The test products, which were manufactured by GOJO Industries (Akron, OH), are described in Table 1.

**Product application.** Table 2 shows the stepwise product application procedures for all test methods.

**Participants.** The study participants were healthy adults with two hands and were free of dermal allergies or any skin disorders on the hands or forearms. These studies were conducted in compliance with good clinical practice and good laboratory practice regulations and approved by local institutional review boards. All participants provided written informed consent.

**Overall design for antibacterial efficacy studies.** The purpose of the studies was to determine the antibacterial efficacy of various blinded test product configurations versus a relevant foodborne pathogen presented under conditions of moderate or heavy food soil. The order of use of each product configuration was determined randomly. All testing of antibacterial efficacy was performed using a modification of the ASTM International E1174-06 method (1). For both the moderate and heavy soil tests, a two-step testing sequence was used for all products. For the moderate and heavy soil tests 18 and 12 participants, respectively, tested each configuration. Each participant completed a baseline cycle, in which hands were contaminated with *E. coli* (ATCC 11229) in moderate soil (chicken broth) for the first study and in heavy soil (sterile ground beef (31)) in the second study. Samples were collected for baseline bacterial counts. After the baseline sampling, participants completed a 30-s nonmedicated soap wash followed by the product evaluation cycle, which consisted of a contamination procedure, application of the test product, and subsequent hand sampling. Baseline and postapplication samples were evaluated for the presence of *E. coli*. Each participant was used for only one test configuration and, on completion of testing, decontaminated their hands with a 1-min 70% EtOH rinse, air drying, and a 30-s nonmedicated soap wash.

**Preparation of inoculum.** A 2-liter flask was filled with 1,000 ml of tryptic soy broth, i.e., 30.0 g of dehydrated tryptic soy broth medium (BD, Franklin Lakes, NJ) added to 1 liter of deionized water, heated, and sterilized (final pH  $7.3 \pm 0.20$ ). The broth was inoculated with 1.0 ml of a 24-h culture of *E. coli* grown from a cryogenic stock culture. The flask was incubated for 24 h, and the suspension was used for the contamination challenge.

**Hand contamination procedures.** For the moderate soil study, a 24-h culture of *E. coli* was suspended in commercially available chicken broth (Swanson chicken broth, Campbell Soup Company, Camden, NJ) to a final concentration of  $1 \times 10^9$  CFU/ml. Three aliquots of 1.5, 1.5, and 2 ml were transferred into each participant's cupped hands. Taking care not to drip the suspension, each aliquot was distributed over the front and back surfaces of the hands up to the wrists for 20 s; hands were air dried for 30 s after the first and second aliquots and for 90 s after the third aliquot. After samples were collected from the hands for baseline bacterial counts, the hands were washed for 30 s with a

TABLE 2. Test product application procedures<sup>a</sup>

Step	Wash	Sanitize	Wash-sanitize regimen	SaniTwice regimen <sup>b</sup>
1	Wet hands with water at 40°C	Dispense 1.5 ml of product into cupped hands	Wet hands with water at 40°C	Dispense 3 ml of sanitizer into cupped hands
2	Apply 1.5 ml of product	Rub hands together until dry	Apply 1.5 ml of product	Rub vigorously over hands for 15 s to simulate washing
3	Lather for 30 s		Lather for 30 s	Clean thoroughly with two paper towels
4	Rinse with water for 30 s		Rinse with water for 30 s	Dispense additional 1.5 ml of product
5	Pat dry with two paper towels		Pat dry with two paper towels	Rub hands together until dry
6			Apply 1.5 ml of sanitizer to hands	
7			Rub until dry	

<sup>a</sup> All application procedures were initiated within 10 s of completing the 90-s drying step.

<sup>b</sup> SaniTwice is a registered trademark with James Mann (Handwashing for Life, Libertyville, IL).

nonmedicated soap, and a second cycle of contamination was performed. After the 90-s drying step, participants applied the randomly assigned test product.

For the heavy soil study, 5.0-ml aliquots of the challenge suspension of *E. coli* was transferred to 4-oz (113-g) portions of sterile 90% lean ground beef and distributed evenly with gloved hands to achieve contaminant levels of approximately  $5.0 \times 10^8$  CFU per portion. Each participant then kneaded the inoculated raw hamburger for 2 min. Hands were air dried for 90 s and then sampled for baseline counts. After a 30-s decontamination with nonmedicated soap, the cycle was repeated, and the test product was applied.

**Bacterial recovery and microbial enumeration.** Within 5 min after contamination for baseline evaluation and after product application, oversized powder-free sterile latex gloves were placed on each participant's hands, and 75 ml of sterile stripping fluid (0.4 g of  $\text{KH}_2\text{PO}_4$ , 10.1 g of  $\text{Na}_2\text{HPO}_4$ , and 1.0 g of isooctylphenoxypolyethoxyethanol in 1 liter of distilled water, pH adjusted to 7.8) was transferred into each glove. After a 60-s massage of the hands through the gloves, a 5.0-ml sample of the rinsate was removed from the glove and diluted in 5.0 ml of Butterfield's phosphate buffer solution with product neutralizers. Each aliquot was serially diluted in neutralizing solution, and appropriate dilutions were plated in duplicate onto MacConkey agar plates (50.0 g of dehydrated medium [BD] added to 1 liter of deionized water, heated, and sterilized; final pH  $7.1 \pm 0.2$ ) and incubated for 24 to 48 h at 30°C. Colonies were counted and recorded using the computerized Q-Count plate-counting systems (Advanced Instruments, Inc., Norwood, MA).

**Data analysis and statistical considerations.** The estimated log-transformed number of viable microorganisms recovered from each hand (the *R* value) was determined using the formula  $R = \log(75 \times C_i \times 10^D \times 2)$ , where 75 is the volume (in milliliters) of stripping solution instilled into each glove,  $C_i$  is the arithmetic average colony count of the two plate at a particular dilution, *D* is the dilution factor, and 2 is the neutralization dilution.

Descriptive statistics and confidence intervals were calculated using the 0.05 level of significance for type I (alpha) error. Statistical calculations of means and standard deviations were generated on the log recovery data from baseline samples, post-product application samples, and the log differences between baseline and post-product application samples. Product comparisons were made using a one-way analysis of variance with post hoc analysis (Bonferroni's multiple comparison test) at  $\alpha = 0.05$ .

**Overall design for HNV study.** The purpose of the HNV study was to determine the virucidal activity of various hand hygiene regimens against HNV. Because routine culture and infectivity assays of HNV are not possible, HNV surrogates are routinely used to evaluate the virucidal activity of disinfectants and antiseptics. MNV, which is a suitable surrogate for HNV (45), was used in this study. A modification of ASTM International E2011-09 method for evaluating hygienic hand wash formulations for virus-eliminating activity using the entire hand (2) was utilized in this study. The modification involved the use of the glove rinsate sampling method and a randomized cross-over design. A total of six participants completed testing on all of the products.

**Virus inoculum.** Strain MNV-G (Yale University, New Haven, CT) was confirmed by direct serial dilution and inoculation onto host cells. Virus stocks were stored in an ultracold freezer ( $\leq -60^\circ\text{C}$ ). Frozen viral stocks were thawed on the day of test. The

TABLE 3. *E. coli* recovery and reductions in the presence of moderate food soil load

Application procedure	Test products	Mean $\pm$ SD <i>E. coli</i> (log CFU/ml)			Statistical analysis <sup>a</sup>	
		Baseline recovery	Reduction			
Wash	Nonantimicrobial hand wash	8.58 $\pm$ 0.46	3.10 $\pm$ 0.61	A		
Wash	PCMX hand wash	8.62 $\pm$ 0.65	3.56 $\pm$ 0.74	A	B	
Wash-sanitize	Nonantimicrobial hand wash + 62% EtOH foam	8.32 $\pm$ 0.64	3.81 $\pm$ 0.89		B	C
Wash-sanitize	PCMX hand wash + 62% EtOH foam	8.25 $\pm$ 0.45	4.16 $\pm$ 0.91			C
Wash-sanitize	Nonantimicrobial hand wash + 70% EtOH AF gel	8.49 $\pm$ 0.42	5.13 $\pm$ 0.71			D
Wash-sanitize	PCMX hand wash + 70% EtOH AF gel	8.57 $\pm$ 0.53	5.22 $\pm$ 0.60			D

<sup>a</sup> Configurations with the same letter are statistically equivalent, and configurations with different letters are statistically different, with each letter increase (B through D) indicating that a configuration had a significantly higher log reduction.

titer of the stock virus was at least  $1 \times 10^7$  TCID<sub>50</sub> (median tissue culture infective dose) per ml. The organic soil concentration was adjusted to at least 5% fetal bovine serum of the volume of the viral suspension.

**Hand contamination procedures.** Before viral contamination, participants washed their hands with nonmedicated soap for 1 min, rinsed their hands, and dried their hands with sterile paper towels. Each participant's hands were then submerged to the wrists in a solution of 70% EtOH for 10 s. The solution was distributed over the entire front and back surfaces of the hands up to the wrists for 90 s and allowed to air dry until evaporation was complete. The alcohol submersion procedure was then repeated. The participants' hands were rinsed with approximately 200 ml of deionized water and dried with an air blower. After their hands were dry, participants waited at least 20 min until the next round of viral contamination and treatment. Each participant's hands were contaminated with 1.5 ml of MNV. The virus was rubbed over the entire surface of both hands for 90 s, not reaching above the wrists. The hands were dried for approximately 90 s. For the baseline control, samples for virus recovery were collected immediately after drying. A decontamination procedure was completed after the baseline sample collection, and a randomly assigned product regimen was applied. The decontamination procedure was repeated after all subsequent treatment rounds. Samples were collected from the participants' hands, and the required controls were evaluated for the amount of MNV capable of replicating in cell culture.

**Elution of virus.** Within 5 min after each treatment regimen, loose-fitting powder-free sterile latex gloves were placed on each participant's hands, and 40 ml of recovery medium was transferred into each glove. After a 60-s massage of the hands through the gloves, the rinsate was transferred from the glove to a sterile tube, vortexed, and serially diluted in cell culture medium. Appropriate dilutions were inoculated onto the host cell culture (RAW 264.7, ATCC TIB-71) and absorbed for 20 to 30 h at  $36 \pm 2^\circ\text{C}$  with  $5\% \pm 1\%$  CO<sub>2</sub>. The cultures were incubated for another 3 to 6 days at  $36 \pm 2^\circ\text{C}$  with  $5\% \pm 1\%$  CO<sub>2</sub> to allow for the development of viral infection.

**Calculation of virus titer and reduction.** The host cells were examined microscopically for the presence of infectious virions. The resulting virus-specific cytopathic effects (CPE) and test agent-specific cytotoxic effects were scored by examining both test samples and controls. The presence of residual infectious virions was scored based on virus-induced CPE. The TCID<sub>50</sub> per milliliter was determined using the Spearman-Kärber method (22).

When a sample contained no detectable virus, a statistical analysis was performed based on the Poisson distribution (20) to determine the theoretical maximum possible titer for that sample. The log viral reduction value was calculated by subtracting the log virus units of the treatment regimen samples from the log baseline units. Descriptive statistics and confidence intervals were calculated ( $\alpha = 0.05$ ). Statistical calculations of means and standard deviations were generated on the log recovery data from baseline samples, post-product application samples, and the log differences between baseline and post-product application samples. Test configuration comparisons were made using a one-way analysis of variance with post hoc analysis (Bonferroni's multiple comparison test) at  $\alpha = 0.05$ .

## RESULTS

**Reduction in microbial contamination of moderately soiled hands.** Reductions of *E. coli* on moderately soiled hands (chicken broth) ranged from 3.10 log CFU/ml for the nonantimicrobial hand wash to 5.22 log CFU/ml for the wash-sanitize regimen with the 0.5% chloroxylenol (PCMX) hand wash and the 70% EtOH AF gel (Table 3). Although the differences were not significant, the PCMX hand wash achieved higher log reductions than did the nonantimicrobial hand wash for all regimens tested. Regimens including the 70% EtOH AF gel were superior to all other configurations ( $P < 0.001$ ). The reductions for the majority of subjects were at the limit of detection (complete kill) for both regimens that included the 70% EtOH AF gel; therefore, these reductions may actually be underestimated. Overall, the wash-sanitize regimen was significantly superior to hand washing alone with one exception. The PCMX hand wash alone was equivalent in efficacy to the nonantimicrobial hand wash followed by the 62% EtOH foam.

**Reduction in microbial contamination of heavily soiled hands.** The four product configurations tested under conditions of heavy soil load produced *E. coli* log reductions ranging from 3.97 to 4.60 log CFU/ml (Table 4). The antimicrobial agent in the hand washing product did not impact efficacy of the regimen; the reductions produced by the same sanitizer used in combination with the 0.3% triclosan hand wash or the PCMX hand wash were equivalent. However, the choice of sanitizer did have a significant impact on efficacy. All configurations that included the 70% EtOH AF gel were superior in

TABLE 4. *E. coli* recovery and reductions in the presence of heavy food soil load

Application procedure	Test products	Mean $\pm$ SD <i>E. coli</i> (log CFU/ml)		
		Baseline recovery	Reduction	Statistical analysis <sup>a</sup>
Wash-sanitize	PCMX hand wash + 62% EtOH foam	7.50 $\pm$ 0.19	4.11 $\pm$ 0.48	A
Wash-sanitize	Triclosan hand wash + 62% EtOH foam	7.54 $\pm$ 0.18	3.97 $\pm$ 0.45	A
Wash-sanitize	PCMX hand wash + 70% EtOH AF gel	7.53 $\pm$ 0.19	4.60 $\pm$ 0.52	B
Wash-sanitize	Triclosan hand wash + 70% EtOH AF gel	7.46 $\pm$ 0.19	4.51 $\pm$ 0.43	B

<sup>a</sup> Configurations with the same letter are statistically equivalent, and configurations with different letters are statistically different, with a letter increase (b) indicating that a configuration had a significantly higher log reduction.

performance to configurations that included the 62% EtOH foam ( $P < 0.05$ ).

**Inactivation of MNV on soiled hands.** A third study was conducted to evaluate four hand hygiene configurations against MNV, a surrogate for HNV. Hand washing with the nonantimicrobial hand wash was minimally effective against MNV, producing a  $<2$ -log reduction (Table 5). Sanitizing with the 70% EtOH AF gel was significantly more effective than hand washing for reducing MNV ( $P < 0.01$ ). Using a wash-sanitize regimen was more effective than either hand washing or sanitizing alone ( $P < 0.05$ ). The SaniTwice method with the 70% EtOH AF gel was the most effective regimen, achieving a  $>4$ -log reduction of MNV ( $P < 0.01$ ).

## DISCUSSION

Previous findings suggest that hand hygiene regimens reduce the risk of transmission of pathogens from the contaminated hands of food service workers to food (10, 29, 30). The findings from our studies support and extend those from previous studies by demonstrating that hand hygiene regimens can be effective even in the presence of high organic loads and against nonenveloped viruses such as HNV.

These studies further demonstrate the improved effectiveness of wash-sanitize regimens over hand washing or sanitizing alone. In the presence of moderate food soil, the combination of the 70% EtOH AF gel with either a nonantimicrobial hand wash or an antimicrobial hand washing product each achieved  $>5$ -log reductions of *E. coli*. In contrast, hand washing achieved only a  $<3.6$ -log reduction. In the presence of heavy food soil, the use of 70% EtOH AF gel after the antimicrobial foam hand washing product in two different configurations achieved a

4.51-log reduction and a 4.60-log reduction, respectively. In the HNV study, hand washing alone produced a  $<2$ -log reduction. When used as part of a wash-sanitize regimen that included the 70% EtOH AF gel a 3.19-log reduction was achieved. These findings demonstrate that the addition of a high-efficacy sanitizer to a hand washing regimen results in a greater reduction of microorganisms. This finding is consistent with those of others, who reported that the primary factor influencing final microorganism levels on the hands is sanitizer use (30).

The current FDA Food Code (42) allows use of ABHRs only on hands that have been cleaned according to the recommended hand washing protocol. The Food Code (section 2-301.16) also severely restricts hand sanitizers by allowing their use only after a proper hand washing or where no direct contact with food occurs. The SaniTwice regimen has previously been shown to be an effective means for the reduction of bacteria on the hands when soap and water are unavailable. In the MNV study, use of the SaniTwice protocol with the 70% EtOH AF gel achieved a  $>4$ -log ( $>99.99\%$ ) reduction of MNV and was the most effective regimen tested. This combination is significantly more effective than hand washing or sanitizing alone and more effective than a wash-sanitize regimen. Therefore, these data indicate that the SaniTwice regimen is an effective method for significantly reducing bacteria and nonenveloped viruses.

In the studies presented here, the configurations that included the 70% EtOH AF gel consistently provided superior performance. These findings are consistent with previous findings that the in vivo activity of ABHRs is not solely dependent upon alcohol concentration (12, 24, 28). In a previous study, the 70% EtOH AF gel provided significantly greater HNV reduction than did other hand hygiene products that contained  $>85\%$  ethanol (24).

TABLE 5. MNV recovery and reductions

Application procedure	Test products	Mean $\pm$ SD MNV (log TCID <sub>50</sub> /ml)		
		Baseline recovery	Reduction	Statistical analysis <sup>a</sup>
Wash	Nonantimicrobial hand wash	6.98 $\pm$ 0.20	1.79 $\pm$ 0.29	A
Sanitize	70% EtOH AF gel		2.60 $\pm$ 0.41	B
Wash-sanitize	Nonantimicrobial hand wash + 70% EtOH AF gel		3.19 $\pm$ 0.31	C
SaniTwice	70% EtOH AF gel		4.04 $\pm$ 0.33	D

<sup>a</sup> Configurations with the same letter are statistically equivalent, and configurations with different letters are statistically different, with each letter increase (b through d) indicating that a configuration had a significantly higher log reduction.

Similarly, an earlier version of the 70% EtOH AF gel was more effective than hand hygiene products containing 95% ethanol and 75% isopropanol (28). Liu et al. (24) suggested that the additional ingredients in these novel ABHRs (a synergistic blend of polyquaternium polymer and organic acid) may work with the ethanol to denature the viral capsid protein. These comparisons demonstrate the importance of formulation in product efficacy.

As illustrated in the *E. coli* study with heavy food soil, the lower log reductions produced by the regimen including the PCMX hand wash with the 70% EtOH AF gel reflects the fact that the raw hamburger was a greater challenge than was the moderate soil (chicken broth). Despite this challenge, use of the 70% EtOH AF gel as part of the hand hygiene regimen probably would provide increased protection against the transmission of foodborne illness because it produced at least 0.5-log greater reductions than did washes paired with a typical hand sanitizer. A wash-sanitize regimen including a high-efficacy formulation should be used in high-risk environments in which uncooked meat is handled in the same vicinity as ready-to-eat foods.

A limitation of our study was that a surrogate virus, MNV, was utilized. Although MNV has been extensively studied and is considered an acceptable surrogate for HNV, the results obtained with this virus may not be an exact reflection of the actual efficacy of these products against various HNV strains. Future efforts should focus on developing routine and repeatable culture-based methods to quantify infectious HNV. Currently, clinical studies should focus on improving hand hygiene compliance by food handlers and on determining the effectiveness of hand hygiene regimens in food service settings.

This series of studies reveals that wash-sanitize regimens, particularly those including a well-formulated ABHR, can be highly efficacious, even in the presence of high organic loads and against HNV. Consequently, the inclusion of such formulations as part of a hand hygiene regimen could be a primary intervention for reducing the risk of infection transmission in food service facilities.

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# Ability of Hand Hygiene Interventions Using Alcohol-Based Hand Sanitizers and Soap To Reduce Microbial Load on Farmworker Hands Soiled during Harvest

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## ABSTRACT

Effective hand hygiene is essential to prevent the spread of pathogens on produce farms and reduce foodborne illness. The U.S. Food and Drug Administration Food Safety Modernization Act Proposed Rule for Produce Safety recommends the use of soap and running water for hand hygiene of produce handlers. The use of alcohol-based hand sanitizer (ABHS) may be an effective alternative hygiene intervention where access to water is limited. There are no published data on the efficacy of either soap or ABHS-based interventions to reduce microbial contamination in agricultural settings. The goal of this study was to assess the ability of two soap-based (traditional or pumice) and two ABHS-based (label-use or two-step) hygiene interventions to reduce microbes (coliforms, *Escherichia coli*, and *Enterococcus* spp.) and soil (absorbance of hand rinsate at 600 nm [ $A_{600}$ ]) on farmworker hands after harvesting produce, compared with the results for a no-hand-hygiene control. With no hand hygiene, farmworker hands were soiled (median  $A_{600}$ , 0.48) and had high concentrations of coliforms (geometric mean, 3.4 log CFU per hand) and *Enterococcus* spp. (geometric mean, 5.3 log CFU per hand) after 1 to 2 h of harvesting tomatoes. Differences in microbial loads in comparison to the loads in the control group varied by indicator organism and hygiene intervention (0 to 2.3 log CFU per hand). All interventions yielded lower concentrations of *Enterococcus* spp. and *E. coli* ( $P < 0.05$ ), but not of coliforms, than were found in the control group. The two-step ABHS intervention led to significantly lower concentrations of coliforms and *Enterococcus* spp. than the pumice soap and label-use ABHS interventions ( $P < 0.05$ ) and was the only intervention to yield significantly fewer samples with *E. coli* than were found in the control group ( $P < 0.05$ ). All interventions removed soil from hands ( $P < 0.05$ ), soap-based interventions more so than ABHS-based interventions ( $P < 0.05$ ). ABHS-based interventions were equally as effective as hand washing with soap at reducing indicator organisms on farmworker hands. Based on these results, ABHS is an efficacious hand hygiene solution for produce handlers, even on soiled hands.

Increases in produce-associated outbreaks highlight the need for effective microbial risk management on produce farms and in packing sheds. In the United States, from 1999 to 2008, contaminated produce was responsible for at least 23% of all reported foodborne illnesses (33). Produce contamination may occur at various points in the farm-to-fork continuum (19, 31). Some produce-associated outbreaks have been thought to be caused by infected farmworker and, possibly, inadequate hand hygiene (14, 16, 42).

Farmworker hands may be vehicles for microbial contamination of produce (23, 29). Harvest and packing, often done by hand, have been associated with increases in microbial contamination (2, 18, 22). A 2010 study found that of seven major fruit and vegetable crops, all were either exclusively or partially harvested by hand (7). Because

“workers often touch produce with their bare hands” the U.S. Food and Drug Administration Food Safety Modernization Act (FSMA) Proposed Rule for Produce Safety states that hand washing is a “key control measure in preventing contamination” of produce (39).

Effective hand hygiene reduces microbial risks and disease in health care and community settings (1, 6, 43), but there are few data on its efficacy in food handling settings (4), and it has just begun to be studied in the agricultural environment. The FSMA Proposed Rule for Produce Safety defines hand hygiene as “washing hands thoroughly, including scrubbing with soap and running water ... and drying hands thoroughly using single-service towels, clean cloth towels, sanitary towel service or other adequate hand drying devices” (39). However, soil on farmworker hands may limit the ability of hand washing to remove or inactivate microbes. Thus, it is important to assess the hypothesis that hand washing with soap is the most efficacious hygiene intervention for the agricultural envi-

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ronment. In addition, hand washing with soap may be difficult to achieve on every occasion specified in the rule due to barriers such as limited access to potable water near all work areas. Alcohol-based hand sanitizers (ABHS) are a logical alternative because they do not require potable water, and a large body of evidence exists to show that their antimicrobial efficacy results in reduced spread of infection in health care environments (6, 43). The FSMA Proposed Rule for Produce Safety prohibits the sole use of ABHS because “the effectiveness of hand sanitizers has been shown to be highly dependent upon the removal of organic material from the hands prior to their use” (39). However, a large body of research suggests that the efficacy of ABHS is not impacted when hands are soiled (10, 12, 25, 26, 28, 30, 35). One limitation of ABHS is that hands may still appear dirty, even if microbes have been inactivated. One method that may address this limitation is SaniTwice, a two-step technique where an excess of ABHS is applied to hands and removed with paper towels, followed by a second ABHS application (11). This technique has been shown to reduce *Escherichia coli* on hands soiled with beef broth and raw hamburgers (11) and to reduce bacteria and soil on agricultural workers’ hands (13).

The goal of this study was to assess the ability of two soap-based and two ABHS-based hygiene interventions to reduce microbes and soil on farmworker hands after harvesting produce, compared with a no-hygiene control. Traditional (nonantibacterial and nonabrasive) soap was included as the current “gold standard” (38). Pumice soap was chosen because it may be able to remove particles and organic compounds from hands that traditional soaps do not. ABHS interventions were included as waterless hygiene options as alternatives to traditional soap. The two-step ABHS intervention was included because of its previously demonstrated efficacy on soiled hands (10).

## MATERIALS AND METHODS

**Setting and population.** This study took place over a 4-week period in August and September 2014 on a farm that produces tomatoes in the state of Nuevo León, Mexico. The farm exported its produce to the United States and sold it to Mexican retailers and had established food safety protocols in place, as well as a dedicated food safety specialist on site. Approval for research on human subjects was conferred after ethics review by Emory University (institutional review board no. 00035460).

The study population consisted of 181 farmworkers who were employed by this farm to harvest tomatoes. Participants routinely used gloves for tomato harvest but removed them when participating in our study in order that the interventions be tested on the most highly soiled and microbially contaminated hands possible. During each of the five nonconsecutive days of the study prior to study enrollment, the farm food safety specialist introduced the study staff, who described the study and solicited volunteers. Inclusion criteria included that the participant was an employee of the farm assigned to harvest tomatoes and provided oral informed consent to participate in the study according to the institutional review board–approved protocol. There were no exclusion criteria. Oral consent was documented by study staff for each participant.

**Farm activities and intervention groups.** After consent was received, the farmworkers were randomly assigned to one of five

groups (described below), and each was given a name tag to indicate his or her group and unique sample identifier. To standardize the microbial load on farmworker hands, all farmworkers were asked to wash their hands with traditional (non-antibacterial and nonabrasive) soap (~3.5 ml of Pearl Lotion Hand Soap; Noble Chemical, Inc., Lancaster, PA) and potable water at a nearby hand washing station stocked with paper towels for drying (Servitoalla double-ply, 28 by 22.8 cm; Pétalo, Kimberly-Clark, Mexico City, Mexico). All potable water used in the study was provided by the Universidad Autónoma de Nuevo León (UANL) laboratory and assured to have no coliforms, *E. coli*, or *Enterococcus* spp. in a 100-ml aliquot (see “Absorbance and microbial analyses” for general description of microbial assays). The farmworkers were then asked to harvest tomatoes for 1 to 2 h (collecting approximately 30 bins per person), using their standard procedure but without gloves. After harvesting, each farmworker completed activities described below based on their assigned group, following the instructions and demonstration of study staff (Fig. 1). A convenience sample of at least 10 participants per study group also had their hands photographed before and after the activities described below.

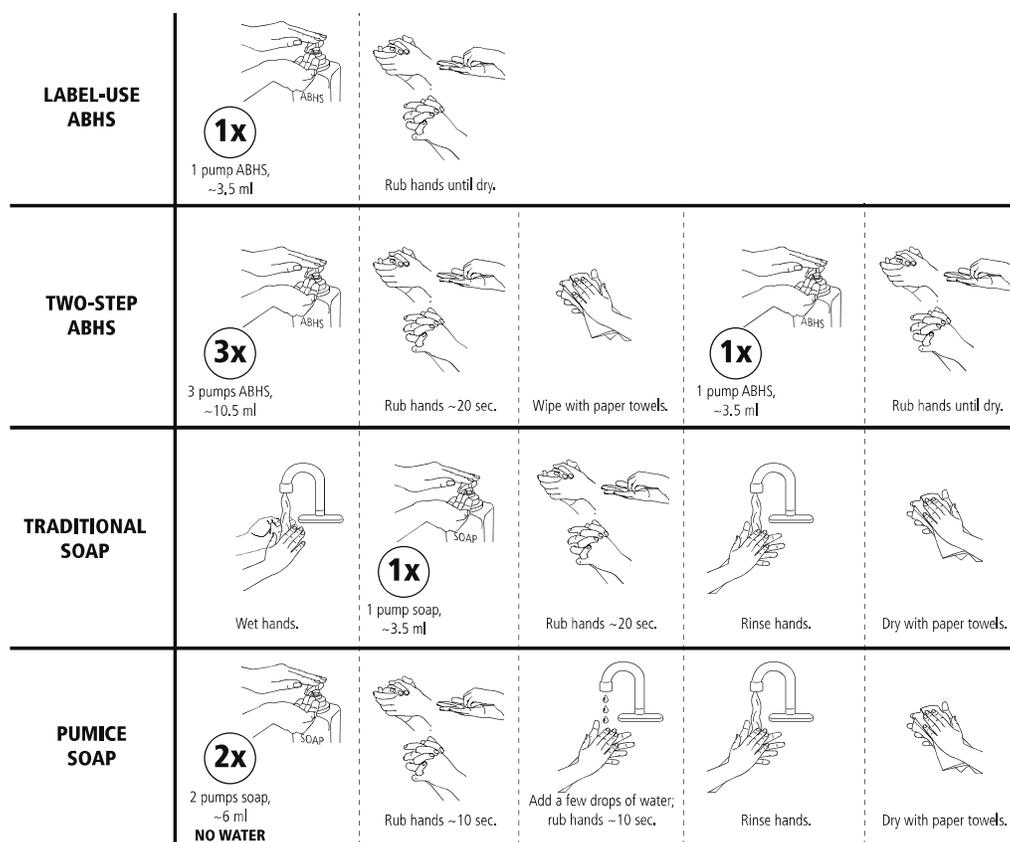
After harvesting, individuals in the control group did not perform any hand hygiene. Individuals in the label-use ABHS group used ABHS according to the product label instructions, with minor modifications. Individuals in this group received one pump of sanitizer gel (~3.5-ml of GOJO Purell Advanced Instant Hand Sanitizer, active ingredient 70% ethanol; GOJO Industries, Akron, OH) in the palm of one hand. They were then asked to rub their hands in the following manner used in all interventions: rub hands palm-to-palm, rub each palm on the dorsal surface of the opposite hand, and interlace fingers to distribute product over the fingers. They were asked to continue rubbing their hands until dry.

Individuals in the two-step ABHS group performed SaniTwice hand hygiene as described previously, with minor modifications (11). Briefly, they received three pumps of sanitizer gel (~10.5 ml, enough to keep hands wet for 20 s) in the palm of one hand. They were then asked to rub their hands as described above for about 20 s. After ~20 s of rubbing, they were given a paper towel to remove all remaining sanitizer on their hands. They then followed the steps described above for the label-use ABHS group.

Individuals in the traditional soap group received two pumps of potable water (approximately 220 ml) to wet their hands. They then received one pump (~3.5 ml) of the same traditional soap used by all participants prior to harvesting. They were asked to rub their hands as described above for about 20 s. After rubbing, they rinsed their hands with three pumps of the potable water provided (approximately 330 ml). A paper towel was provided, and they were asked to dry their hands as they normally would.

Individuals in the pumice soap group received two pumps of pumice soap (~6 ml of GOJO Natural Orange Pumice Hand Cleaner, a gel-based surfactant formula with pumice particles; GOJO Industries) in the palm of one hand. They were then asked to rub their hands as described above for about 20 s. During this rubbing, they also received a splash of potable water (approximately 2 ml). After rubbing, they rinsed their hands with three pumps of the potable water provided (approximately 330 ml). A paper towel was provided, and they were asked to dry their hands as they normally would.

Immediately after the activities described above were completed, the farmworkers were asked to provide a hand rinsate sample by inserting one hand in a Whirl-Pak bag (Nasco, Fort Atkinson, WI) containing 750 ml of sterile 0.1% peptone water (Thermo Fisher Scientific, Waltham, MA) while study staff massaged their fingers through the bag for 20 to 30 s. This process



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FIGURE 1. Visual description of the two ABHS-based and two soap-based hand hygiene interventions. Illustrations in this figure are courtesy of GOJO Industries, Inc.

was repeated for the second hand. The worker was provided a paper towel and small token of thanks for participation (e.g., bottled water, a cap, a bandana, or similar item). The labeled hand rinse sample was stored on ice packs in a cooler. For each study staff member collecting samples, at the end of the day, an additional unopened Whirl-Pak bag containing 750 ml of peptone water was retained as a negative collection control. All samples were transported to the Laboratory of Microbial Biochemistry and Genetics at UANL, where they were stored at 4°C until analysis. Analysis was performed within 48 h of field collection. If the microbial analysis results were outside the quantifiable range and a repeat analysis was necessary, the repeat analysis was conducted within 72 h of field collection.

**Absorbance and microbial analyses.** Absorbance readings of hand rinsate at 600 nm ( $A_{600}$ ) were taken to objectively measure the matter removed from hands during sampling, used as a proxy for “dirtiness of hands,” referred to as “soil” herein. Absorbance reading is an objective approach to assessing dirt on hands that is comparable to assessing the turbidity of hand rinse samples (27) and may be preferable to other, subjective methods, such as visual inspection of hands (25). Rinsate samples were inverted several times to resuspend any particulate matter, and then an aliquot was taken for measurement of absorbance at 600 nm ( $A_{600}$ ) using a spectrophotometer (Sequoia Turner, Mountain View, CA).

Samples were analyzed in random order (without regard to study group) to detect and enumerate coliforms, *E. coli*, and *Enterococcus* spp., three common, nonpathogenic types of bacteria used to indicate microbial load, hereinafter called indicator bacteria. Serial volumes of each hand rinse sample (100  $\mu$ l, 1 ml,

and 10 ml) were filtered through separate 0.45- $\mu$ m-pore-size cellulose filters (EMD Millipore Corporation, Billerica, MA) using a vacuum manifold filtration system (Pall Corporation, Port Washington, NY). When filtering volumes of less than 10 ml, the funnel (with the vacuum closed) was pre-filled with 10 ml of peptone water before the sample was added to allow even sample dispersion across the membrane prior to opening the vacuum. Following filtration through duplicate membranes for each serial volume of rinsate, each membrane was placed on a separate petri dish containing solidified agar for bacterial enumeration. To enumerate *E. coli* and coliform bacteria, membranes were placed on chromogenic Bio-Rad Rapid'*E. coli* 2 agar (Bio-Rad, Hercules, CA) and incubated at 44°C for 24 h for enumeration of typical colonies (pink to purple for *E. coli* and both blue to green and pink to purple for coliforms). To enumerate *Enterococcus* bacteria, membranes were placed on Kenner Fecal *Streptococcus* agar (BD, Franklin Lake, NJ) plates and incubated at 37°C for 48 h before enumeration of red-centered colonies. For all three organisms, the limit of detection was 37 CFU per hand and the upper limit of quantification was 8.3 log CFU per hand.

The remaining sample rinsate was stored at 4°C for no more than 72 h postcollection and reprocessed, as described above, for cases in which colony counts were inconsistent or larger than assay detection limits (e.g., more than 250 colonies per plate). For each day of sample collection, study staff processed a negative sample collection control (described above), a negative water control (sampled from the municipal water used for hand rinsing in the field), and a positive control (mixture of *Enterococcus faecalis* [ATCC 19433], *Salmonella enterica* serovar Typhimurium [ATCC 19428] as a surrogate for coliforms (15), and *E. coli* [ATCC

TABLE 1. Proportions of hand rinsate samples positive for indicator bacteria from the control group and four intervention groups of workers harvesting tomatoes on a farm in Mexico

Group <sup>a</sup>	No. of positive samples/total no. of samples (%) tested for <sup>b</sup> :		
	Coliforms	<i>Enterococcus</i> spp.	<i>E. coli</i>
Control	30/42 (71)	41/42 (98)	10/42 (24)
Label-use ABHS	28/34 (82)	31/34 (91)	2/34 (6)
Two-step ABHS	21/35 (60) <sup>c</sup>	28/35 (80)	0/35 (0) <sup>d</sup>
Traditional soap	28/35 (80)	31/35 (89)	2/35 (6)
Pumice soap	35/35 (100) <sup>d</sup>	35/35 (100)	1/35 (3)

<sup>a</sup> The control group samples were collected after farmworkers harvested tomatoes for 1 to 2 h. Hand rinsate samples were collected from the four intervention groups immediately after performing hand hygiene.

<sup>b</sup> Values are for hand rinsate samples tested for the given indicator bacteria within each study group.

<sup>c</sup> Result is significantly different from the result for the pumice soap group ( $\alpha = 0.05$ )

<sup>d</sup> Result is significantly different from the result for the control group ( $\alpha = 0.05$ )

25922]; American Type Culture Collection, Manassas, VA). The positive control was created by growing each strain overnight on tryptic soy broth (Difco, BD) and then seeding 1 ml of each strain into 11 ml of sterile 0.85% NaCl (Sigma Aldrich, St. Louis, MO), pH 7.0.

**Data entry and statistical analyses.** All data were entered independently by two trained individuals into separate Microsoft Excel databases (Microsoft, Redmond, WA), compared, and reconciled by review of the original laboratory forms. An additional check showed no discrepancies when 5% of the original laboratory forms were randomly selected and compared against the final database. Statistical analyses were performed using Stata 10 (STATA Corp., College Station, TX), JMP Pro 10, and SAS 9.3 (SAS Institute Inc., Cary, NC). The Shapiro-Wilk test (32) indicated that all data (e.g., absorbance values of hand rinsates and log-transformed indicator organism concentrations) were not normally distributed (data not shown). Therefore, all statistical tests used were nonparametric. When calculating the concentrations of indicator bacteria, any sample without detectable bacteria was assigned a value of 18.5 CFU per hand, half the limit of detection (37). Geometric means and standard deviations are used to describe bacterial concentrations as a convenience to the reader (40), and medians and standard deviations are used to describe absorbance data. To compare differences in percentages of samples positive for microbial indicators across study groups, a Pearson  $\chi^2$  test (9) and Bonferroni correction (17) were used. To compare  $A_{600}$  and microbial concentration values across study groups, the Kruskal-Wallis test (20) followed by the Steel-Dwass multiple comparison procedure (8) were used.

## RESULTS

In general, farmworkers' hands became contaminated with indicator bacteria (Table 1 and Fig. 2, control) and soiled while they harvested produce, prior to hand hygiene (Fig. 3, control). The percentages of samples positive for coliforms (71%) and *Enterococcus* bacteria (98%) in the control group were high (Table 1) relative to the percentage

of samples positive for *E. coli* (24%) (Table 1). The concentrations of bacteria on control group hands ranged widely: coliform concentrations in positive samples ranged from the lower limit of detection to the upper limit of quantification (37 CFU per hand to 8.3 log CFU per hand) (Fig. 2), *Enterococcus* concentrations in positive samples ranged from 93 CFU per hand to the upper limit of quantification (8.3 log CFU per hand) (Fig. 2), and *E. coli* concentrations in positive samples ranged from the lower limit of detection (37 CFU per hand) to 3.3 log CFU per hand. The geometric mean concentrations of coliforms (3.4 log CFU per hand) and *Enterococcus* bacteria (5.3 log CFU per hand) in control group samples were relatively high (Fig. 2) compared with the geometric mean concentration of *E. coli* bacteria (1.7 log or 50 CFU per hand) (Fig. 2). For microbial assays, all negative and positive controls consistently yielded the expected results. The median absorbance of control hand rinsate samples was 0.48, and the values varied greatly across the control group, ranging from  $A_{600}$  0.05 to 1.36. The visual appearance of hands postharvest and preintervention is shown in the "before intervention" photographs of hands in Figure 4. It appears that in just a few hours of harvesting produce, the farmworkers' hands accumulated high concentrations of some indicator bacteria and soil.

While hygiene interventions did not completely eliminate indicator bacteria from hands, in general, all hand hygiene interventions effectively reduced the concentrations of some bacteria. However, there were differences in the performance of the four interventions tested.

Compared with the results for the control group, none of the hand hygiene interventions yielded a significantly lower coliform concentration or percentage of samples positive for coliforms (Table 1 and Fig. 2). However, the two-step ABHS group had lower concentrations of coliforms than the label-use ABHS and pumice soap groups ( $P < 0.05$ ) (Fig. 2). Compared with the control group, all four intervention groups had lower concentrations of *Enterococcus* spp. ( $P < 0.05$ ) (Fig. 2), although similar to the result for coliforms, none of the hand hygiene interventions yielded significantly lower percentages of samples positive for *Enterococcus* than in the control group (Table 1). The two-step ABHS group had lower concentrations of *Enterococcus* than the label-use ABHS and pumice soap groups ( $P < 0.05$ ) (Fig. 2). For *E. coli*, all four hand hygiene interventions yielded significantly lower concentrations on hands than were found in the control group ( $P < 0.05$ , Fig. 2). However, two-step ABHS was the only intervention to have significantly fewer samples with detectable *E. coli* than the control group, and this group had no samples positive for *E. coli* ( $P < 0.05$ ) (Table 1). The other three interventions had only 1 or 2 samples positive for *E. coli* (3 to 6%), compared with 10 samples positive for *E. coli* (24%) in the control group (Table 1), but these differences did not reach statistical significance.

Using absorbance measurements of hand rinsate samples as a proxy for soil, all four interventions yielded significantly less soil on hands than in the control group (range,  $A_{600}$  0.05 to 1.36); soap-based interventions (range,  $A_{600}$  0.00 to 0.15) yielded significantly less soil remaining

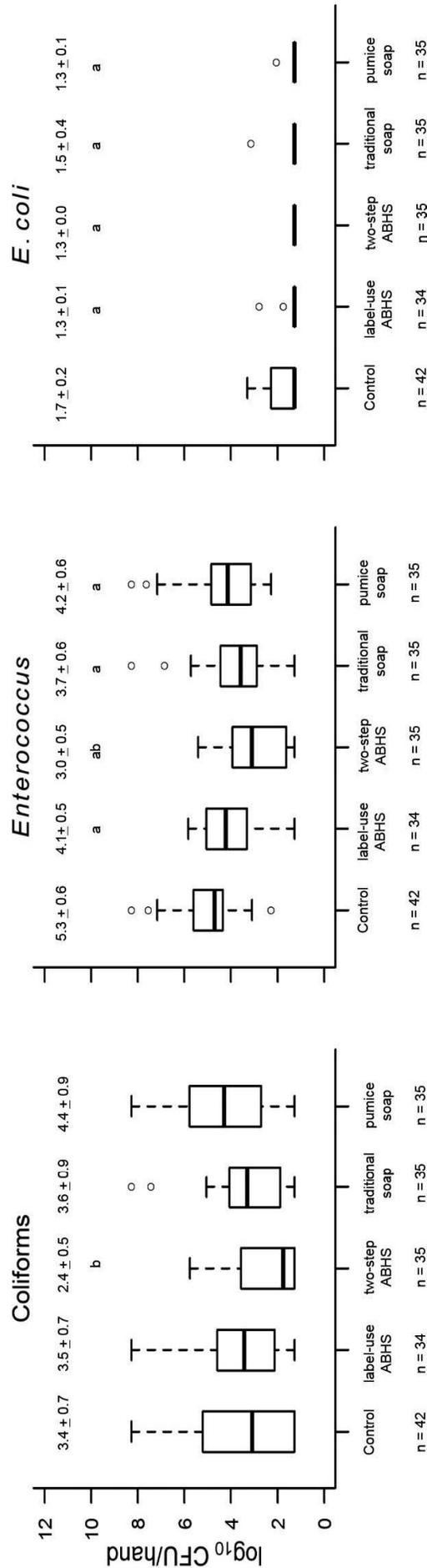


FIGURE 2. Concentrations of coliform, Enterococcus, and *E. coli* bacteria in hand rinse samples from the control group and four hand hygiene intervention groups of workers harvesting tomatoes. For each study group, the boxes display the quartiles (25th, 50th, and 75th) and whiskers extend to 1.5 times the interquartile range. Any data points outside the whiskers are displayed individually as dots. The values above each study group box plot indicate the geometric mean bacterial concentration and standard deviation (log CFU per hand). The control group samples were collected after farmworkers harvested tomatoes for 1 to 2 h. The four intervention groups had hand rinses collected immediately after performing hand hygiene. a, significantly different from the control group ( $\alpha = 0.05$ ); b, significantly different from the label-use ABHS and pumice soap groups ( $\alpha = 0.05$ )

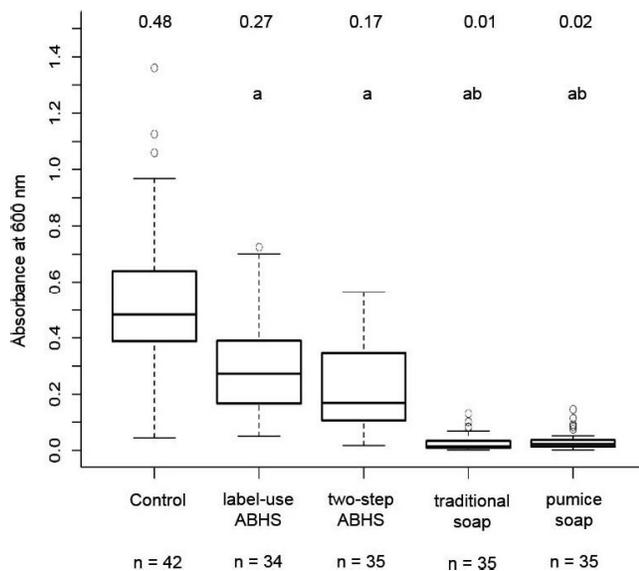


FIGURE 3. Absorbance (at 600 nm) in hand rinsate samples from the control group and four intervention groups of workers harvesting tomatoes. For each study group, the boxes display the quartiles (25th, 50th, and 75th) and whiskers extend to 1.5 times the interquartile range. Any data points outside the whiskers are displayed individually as dots. The value above each study group box plot indicates the median absorbance ( $A_{600}$ ). The control group samples were collected after farmworkers harvested tomatoes for 1 to 2 h. The four intervention groups had hand rinsates collected immediately after performing hand hygiene. a, significantly different from the control group ( $\alpha = 0.05$ ); b, significantly different from the label-use ABHS and two-step ABHS groups ( $\alpha = 0.05$ )

on hands than ABHS-based interventions (range,  $A_{600}$  0.02 to 0.73) ( $P < 0.05$ ) (Fig. 3). These absorbance results confirm the trends seen in the “after intervention” photographs taken of hands (Fig. 4).

## DISCUSSION

The goal of this study was to assess the ability of two soap-based (traditional or pumice) and two ABHS-based (label-use or two-step) hygiene interventions, compared with a no-hand-hygiene control, to reduce microbes (coliforms, *E. coli*, and *Enterococcus*) and soil ( $A_{600}$  of hand rinsate) on farmworker hands after harvesting produce. Without intervention, farmworkers’ hands were contaminated with high concentrations of indicator bacteria and were heavily soiled after 1 to 2 h of harvesting tomatoes. All four hygiene intervention groups had lower concentrations of *Enterococcus* and *E. coli* on their hands than the control group. Furthermore, all four interventions yielded significantly less soil remaining on hands, soap-based interventions more so than ABHS-based interventions. Based on these results, ABHS can be viewed as a promising hand hygiene solution for produce handlers, even on soiled hands. To build on these findings, future studies could investigate the efficacy of ABHS for pathogen inactivation on soiled hands in a controlled setting (e.g., an experimental greenhouse).

Farmworkers’ hands were heavily soiled and contaminated with high concentrations of indicator bacteria after 1

to 2 h of harvesting tomatoes. The control group results are supported by our previous field observational study of microbial contamination of produce, environmental samples, and farmworkers’ hands (23), where we found that 16 to 41% of farmworkers’ hands had detectable *E. coli*, 92 to 100% had detectable coliforms, and 70 to 99% had detectable *Enterococcus* bacteria, depending on the type of produce harvested. The lower percentage of samples positive for *E. coli* than of samples positive for coliforms and *Enterococcus* is expected, as *E. coli* is a gram-negative species of bacteria indicative of fecal contamination from a warm-blooded animal, whereas *Enterococcus* spp. (a genus of gram-positive bacteria) and coliforms (a general group of bacteria) are larger, more general categories of indicator bacteria. It is unlikely that the presence of these indicator bacteria is simply a result of poor sanitation and hygiene practices among the farmworkers given that they washed their hands with soap and water before beginning harvest and their sole activity was harvesting produce. It is more likely that farmworkers’ hands are accumulating organic matter and indicator bacteria present in the agricultural environment (e.g., on plants, soil, or produce bins). Both coliforms and *Enterococcus* are naturally present in the guts of animals (5, 36), but they are also present in the environment (36) and could be introduced into the agricultural environment through various pathways (e.g., irrigation water, soil amendments, or contaminated tools or equipment). Similarly, the *E. coli* seen on some farmworker hands after harvest may indicate recent fecal contamination from a warm-blooded animal (36) or may indicate past environmental contamination, as *E. coli* is known to be persistent in the environment (41).

Farmworkers in all four intervention groups had lower concentrations of *Enterococcus* and *E. coli* on their hands than those in the control group. These results indicated that all four interventions were efficacious at reducing the concentrations of viable microbes on hands. The soap-based interventions likely reduced bacterial concentrations because soap is, by definition, an emulsifier, meaning it suspends hydrophobic compounds and, with them, any particles and microbes. These particles and microbes are then removed when hands are rinsed. These traditional soap and pumice soap intervention results are consistent with the results from a pilot study of a hand hygiene intervention using foam soap on soiled farmworker hands (13). The ABHS-based interventions likely reduced bacterial concentrations because ethanol, the active ingredient in the ABHS, is an effective antimicrobial agent (3, 24). These results suggest that ABHS can be an efficacious hand hygiene method, even on soiled hands. Although the soap-based and ABHS-based interventions work by different mechanisms, they were both efficacious at reducing microbes on soiled hands.

No intervention resulted in lower concentrations of coliforms than in the control group. Given the high variability of coliform concentrations in the control and all intervention groups and the generally small reductions (0 to 2 log) in coliforms previously reported with hand washing with foam soap and ABHS in the field (13), a larger sample size would likely have been needed for these interventions to demonstrate a statistically significant difference in coliform

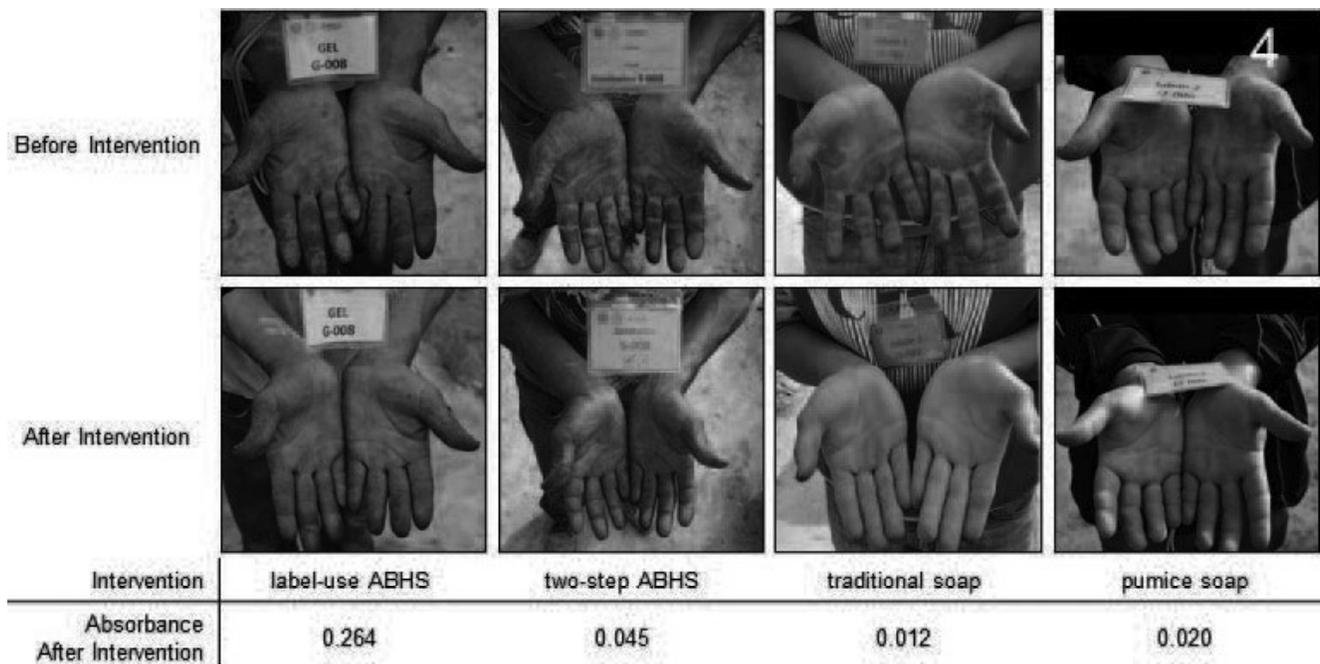


FIGURE 4. Photographs of hands and corresponding individual hand rinsate absorbance readings from samples collected after intervention from study participants—workers harvesting tomatoes on a farm in Mexico. Photographs were taken immediately before and after each worker performed hand hygiene.

concentration compared with the control group. In a previous study comparing two-step ABHS and foam soap to a control group, only two-step ABHS had significantly lower levels of coliforms ( $\sim 2$  log (13)) than the control group. These results suggest that coliforms may be more persistent on hands than *E. coli* and *Enterococcus* spp. after hand washing or ABHS use. Given that total coliforms are poor indicators of fecal contamination in an environmental setting (36), it is unclear whether this result has a practical application in hand hygiene techniques.

All four interventions significantly removed soil from hands, soap-based interventions more so than ABHS-based interventions. It was expected that soap-based interventions would be the most efficacious at soil removal, given soap's emulsion properties described above. The removal of soil from hands with label-use of ABHS was a somewhat unexpected result, as the intervention does not involve wiping or removing anything from the hands. This result contradicts previous research on alcohol-based gels (21, 34). However, study participants' hands were quite heavily soiled, and particles may have been solubilized in the ABHS and then dropped to the ground as the liquid portion evaporated. The two-step ABHS intervention uses paper towels to remove excess ABHS (11); it is likely that additional soil particles were also removed by the paper towel when wiping dry.

The label-use ABHS and pumice soap interventions were similar to the traditional soap intervention in their effectiveness at reducing the microbial load on farmworker hands. However, the two-step ABHS intervention was more efficacious than the label-use ABHS and pumice soap interventions and was at least as efficacious as traditional soap at reducing microbes on soiled farmworker hands. The two-step ABHS intervention resulted in significantly lower

percentages of positive samples and lower geometric mean concentrations of all indicators than did the label-use ABHS intervention (concentrations of coliforms and *Enterococcus* bacteria) (Fig. 2) and pumice soap intervention (prevalence and concentrations of coliforms and concentrations of *Enterococcus* bacteria) (Table 1 and Fig. 2). These results confirmed the results in a previous study of hand hygiene interventions with farmworkers harvesting jalapeños, where the same two-step ABHS intervention resulted in 1 to 2 log CFU fewer bacteria per hand than were found for the control group and performed better at eliminating indicator bacteria than hand washing with foam soap (13). The results suggest that the most efficacious hand hygiene intervention in the agricultural environment may be a dual-mechanism intervention, such as the two-step ABHS, that combines physical removal from hands (e.g., with paper towels) with inactivation of indicator bacteria (e.g., by ethanol, the active ingredient in the ABHS and an effective antimicrobial agent (3, 24)).

This study has several strengths and limitations. It addresses a gap in the hand hygiene literature by evaluating the efficacy of hygiene interventions in an agricultural environment under real-use conditions. The study also compares an array of hygiene interventions, both soap based and ABHS based. Although the study was conducted on only one farm with participants harvesting only one type of produce, the similarity of the results to those of a previous pilot study evaluating foam soap and two-step ABHS on a different farm with different produce (13) suggests that these results may be broadly applicable to the agricultural field environment during produce harvest.

The results of this field evaluation of hand hygiene techniques have several implications. Hands may be a source of produce contamination if a farmworker is ill, and

hands may also contribute to produce contamination by transferring indicator bacteria from the environment (e.g., soil, water, or produce bins) to the produce during harvest. These results show that the performance of hand hygiene interventions can vary with the hygiene product and technique, and hand hygiene recommendations may need to be tailored to meet the environment and availability of hygiene resources. Hand hygiene performed incorrectly or with an ineffective product may not improve the microbial quality of hands even if they appear cleaner after hygiene. Although they did not remove soil as well as soap-based interventions, the ABHS-based interventions reduced the concentrations of indicator bacteria similarly to the soap-based interventions and can be viewed as efficacious hand hygiene solutions even on soiled hands.

### ACKNOWLEDGMENTS

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-022**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend 2017 Food Code to improve the sanitary transport of wet wiping cloths

**Issue you would like the Conference to consider:**

The 2017 Food Code addresses only two states for wet wiping cloths.

- 1) Held in sanitary solution.
- 2) in use.

The Food Code does not account for a "third" state of sanitary towel use that is a reality in restaurants and bars.

- 3) The sanitary transportation of the cloth between 1 & 2 above.

**Public Health Significance:**

The ability to sanitize and use a vessel to carry wet wiping cloths would significantly reduce wet wiping cloths' exposure to and spreading of harmful microorganisms to tables, counters, utensils, equipment surfaces, and thus the public.

**Recommended Solution: The Conference recommends...:**

That section 3-304.14 (B)(2)(3) of the 2017 Food Code be amended to read;

3-304.14 Wiping Cloths, Use Limitation.

(A) Cloths in-use for wiping FOOD spills from TABLEWARE and carry out containers that occur as FOOD is being served shall be:

- (1) Maintained dry; and
- (2) Used for no other purpose.

(B) Cloths in-use for wiping counters and other EQUIPMENT surfaces shall be:

- (1) Held between uses in a chemical sanitizer solution at a concentration specified under § 4-501.114; and

(2) Transported in a manner that prevents cross contamination of tables, counters, utensils, and equipment surfaces and

~~(2)~~ (3) Laundered daily as specified under ¶ 4-802.11(D).

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**Supporting Attachments:**

- "OBSERVATIONS TO SUPPORT BIENNIAL MEETING ISSUE SUBMITTAL"
- "Yepiz-Gomez and Gerba Study Abstract"
- "Yepiz-Gomez and Gerba Study Excerpts with Data"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

## **ATTACHMENT 1**

### **OBSERVATIONS TO SUPPORT BIENNIAL MEETING ISSUE SUBMITTAL**

As a 40 year restaurant professional, one of the least hygienic practices I have consistently observed, is the treatment of wiping cloths. There have been studies conducted that provide detailed scientific information on the topic.

Despite clear intent of the Food Code that a cloth be either “in use”, or “stored in sanitary solution”, this is not the practice in the restaurant world. Restaurant workers must multi task to be efficient in their work. To that end, the wet wiping cloth so prevalent is commonly stashed in a pants pocket, dirty apron, an armpit, or my favorite, the back of one’s pants!!

As a solution in the past, I have offered staff various holsters and bags to carry their cloths – none of these were made of materials that could be sanitized, and in the end, may have been contributing to the cloths’ cross contamination.

A method and/or vessel should be required that can be sanitized along with the wiping cloth, light and flexible enough for them to easily put a wiping cloth in it, and be able to transport it to the location to be “in use”, all while maintaining the efficiency desired by the employer.

## ATTACHMENT 2

# 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

CATEGORIES: [FOOD SERVICE](#), [CLEANING MEASUREMENT](#), [IEQ MEASUREMENT](#), [HEALTH & HYGIENE](#)

TAGGED: [MEASUREMENT](#), [DISINFECTING](#), [SANITIZING SURFACES](#), [BACTERIA](#), [CLEANING MEASUREMENT](#), [FOOD SERVICE](#), [RESTAURANTS](#), [BARS](#), [E. COLI](#), [TABLETOPS](#), [DISHCLOTHS](#)

[1 comments](#)

### Abstract

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 heterotrophic plate count bacteria (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.

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Food Protection Trends – November 2006

Identity and Numbers of Bacteria Present on Tabletops and in Dishcloths Used  
to Wipe Down Tabletops in Public Restaurants and Bars: Created on April 9th,  
2010. Last Modified on April 9th, 2010

### **ATTACHMENT 3**

#### **Occurrence of Bacteria in Dishcloths Used in Restaurants and Survival of Respiratory Viruses on Produce**

Item Type text;	Electronic Dissertation
Authors	Yepiz, Maria Susana
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Greater numbers of bacteria were found on tabletops that had been cleaned with a dishcloth than before cleaning (Fig.1.5.3). Approximately  $3.56 \times 10^3$  cfu/156 cm<sup>2</sup> heterotrophic plate count bacteria were found before cleaning. This number increased to  $1.6 \times 10^5$  cfu/156 cm<sup>2</sup> (45-fold increase) after the tables were wiped down with a dishcloth. Likewise, the numbers increased for total coliforms (4.9 to 92.2 cfu/156 cm<sup>2</sup> ) and E. coli (< 1 to 2.3 cfu/156 cm<sup>2</sup> ) following cleaning.

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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 number 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 might be called for

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-023**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code – Clarification on allowable sanitizers in 4-501.114

**Issue you would like the Conference to consider:**

Section 4-501.114 of the FDA Food Code places constraints on certain variables that may impact efficacy of chemical sanitizers. Specifically, this section addresses water temperature, pH, concentration, and water hardness as it relates to efficacy of chemical sanitizers formulated with chlorine, iodine, and quaternary ammonium compounds. This section is often interpreted in such a manner as requiring all food contact sanitizers to be formulated with only one of these three active ingredients. This misinterpretation is a potential barrier to adoption of chemical sanitizers formulated with alternative active ingredients (i.e., actives other than chlorine, iodine, or quaternary ammonium compounds). Additional clarity is needed in this section in order to not inadvertently restrict innovative formulation in the area of chemical food contact sanitizers.

**Public Health Significance:**

Next generation chemical sanitizers are increasingly being formulated with active ingredients other than chlorine, iodine, or quaternary ammonium compounds. These innovative formulations have the potential to improve public health by offering broader spectrum kill claims and faster kill times for many organisms of public health significance in food settings. However, the benefits of these alternative active ingredients cannot be realized if unintended barriers to their adoption are in place. Adding clarification to section 4-501.114 will effectively lift restrictions on the innovation process in the field of chemical food contact surface sanitizers.

**Recommended Solution: The Conference recommends...:**

1. that a letter be sent to FDA requesting that Section 4-501.114 of the most current edition of the Food Code be amended as follows (added language underlined and italicized):

4-501.114 (E) If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be approved by the EPA for use as a food contact surface sanitizer, and it shall be applied in accordance with the EPA-registered label use instructions;<sup>p</sup>

1. that a letter be sent to FDA requesting that Section 4-501.114 of Annex 3 - Public Health Reasons/Administrative Guidelines be amended as follows (added language underlined and italicized):

With respect to chemical sanitization, section 4-501.114 addresses the proper use conditions for the sanitizing solution, i.e., chemical concentration range, pH, and temperature minimum levels and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these parameters are not as specified in the Code or on the EPA-registered label, then this provision is violated. *This section is not intended to limit formulation of food contact sanitizers to only chlorine, iodine, or quaternary ammonium compounds. Alternative active ingredients (e.g., ethanol, hydrogen peroxide, lactic acid, peroxyacetic acid, etc.) are permitted as long as they are listed in 40 CFR 180.940 and are approved by EPA as food contact sanitizers.*

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**Supporting Attachments:**

- "CFP Letter of Support"

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# CUYAHOGA COUNTY BOARD OF HEALTH

YOUR TRUSTED SOURCE FOR PUBLIC HEALTH INFORMATION

December 6, 2019

Chip Manuel PhD  
GOJO Industries  
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Dear Dr. Manuel,

Thank you for sharing your time and information regarding the Purell Food Service Surface Sanitizer. As we discussed, there are several inherent barriers to sanitarians in Ohio being able to properly understand and apply the Ohio Uniform Food Code relative to alternative and innovative food contact sanitizers, not the least of which is the language contained within the code.

When speaking with my colleagues around the state, we agree that based on our training and interpretation of the food code, first as new sanitarians and continuing through today, the trio of chlorine, iodine and quaternary ammonia sanitizers are the default choices for operators and inspectors due to their placement in the language. Over time, they have become the most commonly recognized and suggested products. With their specific concentrations being defined in the food code, it also makes it easier for sanitarians to understand and explain how to use these products.

However, the Ohio Uniform Food Code also states that any EPA-approved sanitizer that is food grade can be used on tables, utensils and all other food contact surfaces according to its label. Thus, when our agency's sanitarians see your PFSS product, we know it is approved for use. My concern is that without prior awareness and knowledge of such products and without a clearly-defined explanation of alternative active ingredients within the food code language, these products may be challenged and disapproved for use by many sanitarians, particularly those lacking extensive experience.

My suggestion for sustained clarity on this issue would be to make revisions to the FDA Model Food Code that would specifically state that chlorine, iodine and quaternary ammonia are not the only approved products. Given current conditions, it will certainly take time for new sanitarians and their trainers to understand and adopt innovative options.

Since your products are pre-mixed and ready for use, we would not require our food operators to use a kit to test their concentrations. We would suggest that sanitarians have a test kit when inspecting in case they are worried that an operator is improperly diluting the product.

Thank you for your efforts to bring increased awareness and efficiency to food service sanitization. Please don't hesitate to contact me for additional information.

Best regards,

Suzanne Hrusch MPH, RS  
Program Manager, Food Protection Unit  
Cuyahoga County Board of Health

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-024**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code by removing the flavor enhancers monosodium glutamate

**Issue you would like the Conference to consider:**

We would like the U.S. Food & Drug Administration (FDA) to amend the most current edition of the Food Code by removing the flavor enhancer monosodium glutamate (MSG) from the list on page 564 of 767 "*Annex 4, Table 2b- Added Chemical Hazard at Retail, Along with their Associated Foods and Control Measures.*"

By way of brief background, the *1999 Food Code* published examples of chemical hazards that included naturally occurring chemicals and added chemicals that was adopted from the textbook, "*HACCP Principles and Applications*" (Pierson and Corlett, Ed. 1992, Chapman & Hall, New York, NY). It is our understanding the *1999 Food Code* first mentioned monosodium glutamate as a chemical hazard. Subsequent Food Code publications have revised the table with a list of added chemical hazards and no longer references Pierson and Corlett, 1992; however, the Food Code retains monosodium glutamate as a chemical hazard even given the FDA's extensive review of MSG in the 1990s and its public position affirming the safety of MSG.

According to most current edition of the Food Code, it defines chemical hazards as, "... *naturally occurring or added to foods during processing. At high levels, toxic chemicals may cause acute cases of food borne illness while at low levels may cause chronic illnesses. Per 21 CFR Parts 109, chemical hazards may include poisonous or deleterious substances that are naturally occurring chemicals, and food allergens. In addition, food additives permitted for direct addition to food for human consumption (21 CFR Part 172) may have allowable limits for many of the chemicals added during processing.*"

It is important to note that MSG does not fit in the aforementioned definition of 'chemical hazards' categories. Per 21 CFR 182.1, MSG is a safe food ingredient regulated as a Generally Recognized as Safe (GRAS) substance, and the FDA has not set any limitation on its use other than Good Manufacturing Practices (GMPs). In fact, the FDA assigns MSG a GRAS status for its intended use alongside salt, pepper, vinegar, and baking powder.

It is also noteworthy that MSG is the sodium salt of glutamic acid, which is found in many foods that contain protein. In fact, the FDA's "*Questions and Answers on Monosodium Glutamate*" website states, "*MSG occurs naturally in ingredients such as hydrolyzed vegetable protein, autolyzed yeast, hydrolyzed yeast, yeast extract, soy extracts, and protein isolate, as well as in tomatoes and cheeses.*"<sup>2</sup> The human body utilizes and metabolizes MSG in the same way whether it comes from MSG or other dietary sources of protein. Furthermore, on average, an adult in the United States consumes approximately 0.55 grams per day added MSG, significantly lower quantity compared to 13 grams of glutamate consumed each day from protein in the diet.<sup>2</sup>

It is therefore inappropriate and contradictory to include MSG in the list of added chemical hazards in the Food Code because the FDA rightfully recognizes it to be a safe ingredient and has not been shown to elicit any reproducible adverse reactions in people<sup>2</sup>. The inclusion of MSG as a chemical hazard in the Food Code is misleading and could potentially weaken the integrity of the Food Code as a science-based document. In addition, it sends an erroneous message that there is a safety concern with MSG and distracts food service establishments from focusing on real concerns that pose legitimate known chemical hazards to the public. To our knowledge, the FDA has not listed MSG as a chemical hazard in other relevant guidance documents. For example, there is no mention of MSG as a chemical hazard on the FDA's *Fish and Fishery Products Hazards and Control Guidance*<sup>3</sup> or *A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems*.<sup>4</sup>

The FDA has investigated the safety of MSG on multiple occasions and concluded it to be a safe food ingredient. In the 1995 report by Life Sciences Research Office (LSRO) commissioned by the FDA, the review concluded, that MSG is safe for the general population<sup>5</sup>. The FDA website re-confirms the LSRO review that in studies with individuals who claim to be sensitive to MSG, when such individuals were given MSG or a placebo, scientists have not been able to consistently trigger adverse reactions. This conclusion is consistent to a double-blind, placebo-controlled with a crossover study design conducted at a multicenter, multiphase institutions at Harvard, Northwestern and the University of California Los Angeles where 130 individuals who claimed sensitivity to MSG following the administration of oral doses of up to 5 grams of MSG with and without food found "neither persistent nor serious effects from MSG ingestion are observed, and the responses were not consistent on retesting."<sup>6</sup>

There is no legitimate scientific evidence to include monosodium glutamate as a 'chemical hazard' in "*Table 2b- Added Chemical Hazard at Retail, Along with their Associated Foods and Control Measures*" in the most current edition of the *Food Code*. The overwhelming scientific evidence proves that monosodium glutamate is a safe food ingredient. We strongly urge the FDA to remove MSG as a chemical hazard from the Food Code because it is misleading and contradicts the agency's own internal documents and other global regulatory bodies' positions that affirm the safety of the ingredient.

### **Public Health Significance:**

Monosodium glutamate is a GRAS affirmed safe ingredient that has been thoroughly evaluated by the FDA, Joint FAO/WHO Expert Committee on Food Additives (JECFA), European Food Safety Authority (EFSA) and other major regulatory bodies. Furthermore,

MSG plays a useful role in reducing dietary sodium intake while at the same time enhancing the flavor of food. MSG contains approximately 12% sodium by weight, which is approximately one-third contained in regular table salt (39%).

Publications by authoritative bodies such as the Institute of Medicine's (IOM) *Strategies to Reduce Sodium Intake in the United States* mention MSG as flavoring techniques to reduce the need for added salt by imparting a savory taste ("umami") as well as a salt taste to food.<sup>7</sup> The *2019 Dietary Reference Intakes (DRI) for Sodium and Potassium* report, explores opportunities that can be applied to reduce sodium intake in the food supply using MSG. The report states that, "*a flavor enhancer to help reduce sodium is free glutamate, used mainly in the form of monosodium glutamate (MSG).*"<sup>8</sup> The statements from these authoritative bodies concurs with studies that have shown monosodium glutamate utility in flavor enhancement and sodium reduction.<sup>9</sup>

Listing MSG as a chemical hazard in the most current edition of the Food Code results in misinformation and confusion among the public at large and those employed in the food service industry, which can prevent them from addressing legitimate chemical hazards that can impact the health of their patrons. MSG is a well-studied, safe ingredient that can play a useful role in dietary sodium intake. Dietary sodium reduction is recommended for reducing hypertension, a major public health concern in the United States. Listing MSG as a chemical hazard in the Food Code threatens the use of this ingredient as a safe, effective way to reduce dietary sodium. Its listing also creates confusion by reinforcing an urban legend based on scientifically unconfirmed safety concerns about MSG when the FDA's publicly available information confirms the ingredient is safe.

Supportive References 1-9 on content document is provided as attachments: 1) References web link on MSG Safety and sodium reduction benefits 2) References on MSG sodium reduction benefits.

### **Recommended Solution: The Conference recommends...:**

The Conference recommends that a letter be send to the FDA requesting that the most recent edition of the Food Code be amended as follows:

*"Annex 4, Table 2b- Added Chemical Hazard at Retail, Along with their Associated Foods and Control Measures."* on page 564 of 767.

Added Chemical Hazard

Associated Foods

Control Measures

~~Flavor enhancers monosodium glutamate (MSG)~~

~~Asian or Latin American Food~~

~~Avoid using excessive amounts-~~

.

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**Content Documents:**

- "References web link on MSG safety and sodium reduction benefits"

**Supporting Attachments:**

- "Reference on MSG sodium reduction benefits"

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Attachment: References on monosodium glutamate safety and sodium reduction benefits.

1. 21 C.F.R. 182.1(a) *Substances that are generally recognized as safe.*  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=182.1>
2. FDA, *Questions and Answers on Monosodium glutamate (MSG)* (accessed on March 30, 2019 at <https://www.fda.gov/food/food-additives-petitions/questions-and-answers-monosodium-glutamate-msg>)
3. *Fish and Fishery Products Hazards and Controls Guidance (Fourth Edition – August 2019)* (accessed on August 30, 2019) at <https://www.fda.gov/media/80637/download>
4. *Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems (April 2006)* (accessed August 30, 2019 at <https://www.fda.gov/media/72067/download>)
5. Daniel J. Raiten John M. Talbot. *Executive Summary from the Report: Analysis of Adverse Reactions to Monosodium Glutamate (MSG).* *The Journal of Nutrition*, Volume 125, Issue 11, November 1995, Pages 2891S–2906S.  
<https://academic.oup.com/jn/article-abstract/125/11/2891S/4730581?redirectedFrom=fulltext>
6. Geha R., Beiser A., Ren C., Patterson R., Greenberger P., Grammer L., Ditto A., Harris K., Shaughnessy M., Yarnold P., Corren J., Saxon A., "Multicenter, double-blind, placebo-controlled, multiple-challenge evaluation of reported reactions to monosodium glutamate," *J Allergy Clin Immunol* 2000;106:973-80.  
<https://www.ncbi.nlm.nih.gov/pubmed/11080723>
7. *Institute of Medicine of the National Academies, National Academies Press Washington, DC. "Taste and Flavor Roles of Sodium in Foods: A Unique Challenge to Reducing Sodium Intake", pp.65-86, in Strategies to Reduce Sodium Intake in the United States, edited by Henney J.E. et al., 2010.* <https://www.nap.edu/catalog/12818/strategies-to-reduce-sodium-intake-in-the-united-states>
8. *National Academies of Sciences, Engineering, and Medicine. 2019. Dietary Reference Intakes for Sodium and Potassium.* Washington, DC: The National Academies Press. p. 410. <https://doi.org/10.17226/25353>
9. *International Glutamate Technical Committee. Glutamate contributes to the reduction of dietary sodium intake. Technical statement, 1, 2017. Attached.*

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## Glutamate Contributes to the Reduction of Dietary Sodium Intake

The World Health Organization (WHO) recommendation on sodium consumption for adults is 2 g sodium/day (equivalent to 5 g salt/day). However, most people consume much more with the current mean global sodium consumption estimated to be at 3.95 g sodium/day (Mozaffarian et al. 2014). Since high sodium intake is reported to be associated with various non-communicable diseases (NCDs) such as hypertension, cardiovascular disease and stroke, the reduction of sodium intake is a very important public health concern around the world (WHO, 2003).

While sodium reduction in the diet is an important objective, when salt (NaCl) levels are reduced in foods, its palatability is also generally decreased. Monosodium glutamate (MSG) is a flavour enhancer that contains about 12% sodium, which is less than half of that contained in regular table salt at about 39%. Therefore, by the addition of an appropriate amount of MSG, the palatability of low salt foods can be recovered with the overall sodium content of the food being substantially reduced.

Further reduction in dietary sodium can also be achieved through the use of other forms of glutamate, such as calcium di-glutamate (CDG) and monomagnesium di-glutamate (MDG), which do not contain sodium. These other forms of glutamate have been shown to provide similar taste enhancing properties that are only marginally lower than those obtained by the use of MSG, therefore maintaining food palatability without contributing to any dietary sodium intake.

A considerable number of studies have demonstrated that glutamates can help to reduce the use of salt in the diet by enhancing the palatability of different types of foods including soups, prepared dishes, processed meat and dairy products.

The use of glutamate to replace salt in foods

In Japan, Yamaguchi investigated the palatability of Japanese clear soup containing varying amounts of NaCl with or without MSG (as shown in the Fig. 1). When the use of NaCl alone was reduced from its optimal level of about 0.92%, the palatability score of the soup decreased dramatically. However, by combining 0.38% MSG with 0.41% NaCl, the palatability rating of the soup recovered to the same level of pleasantness as was achieved by 0.92% NaCl alone. The sodium content of the soup with 0.92% NaCl was 0.36%, compared with 0.21% in the soup with 0.38% MSG and 0.41% NaCl, representing a 40% overall sodium reduction (Yamaguchi & Takahashi, 1984).

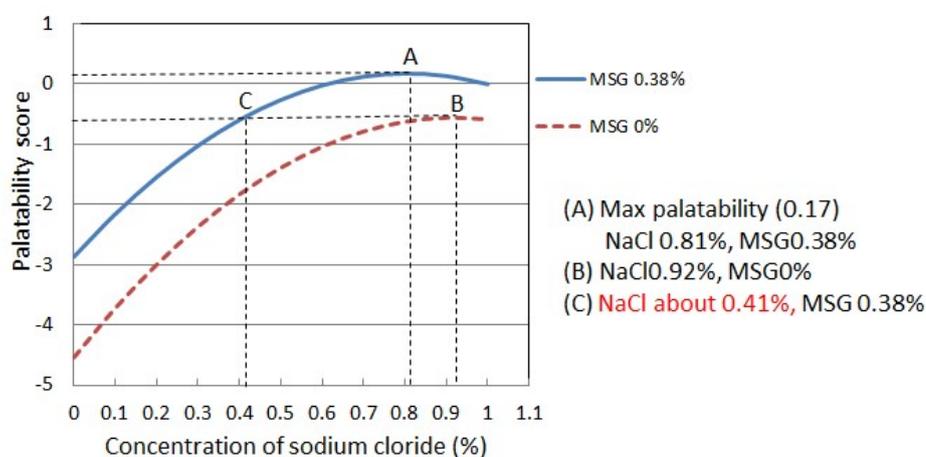


Fig 1. Palatability scores of clear soup at various concentrations of NaCl  
 (Created using the data by Yamaguchi and Takahashi, J. Food Sci. 49(1):82-85, 1984)

Research in the USA found that chicken broth containing 0.70% NaCl and 0.30% MSG had an equal palatability score when compared with a broth containing 0.84% NaCl and 0.19% MSG, representing a total sodium reduction of about 11% (Chi and Chen, 1992).

The effects of umami substances on the preferences on low-salt soups with 0.3% and 0.5% salt were assessed in Finland. The subjects consumed soup with or without MSG during six sessions in five weeks. Ratings were higher in soup containing MSG in both 0.3%- and 0.5%-salt groups. The authors concluded that the pleasantness ratings of reduced-salt foods could be increased by addition of umami substances such as MSG (Roininen *et al.*, 1996).

A group in Australia managed to reduce sodium content of a reference commercial pumpkin soup containing 150mM NaCl by substituting it with 50mM NaCl and 43mM MSG or CDG, while maintaining similarly acceptable taste characteristics. The level of sodium contained in a typical serving of the reference soup was estimated to contain 57 mmol of sodium. The soup prepared with the NaCl and CDG combination however contained only 33 mmol of sodium, representing a 40% reduction (Ball *et al.*, 2002).

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Another study in the USA by Carter et al. reported that CDG could partly replace NaCl at constant levels of liking and pleasantness (Carter *et al.*, 2011). They showed that pleasant and liking ratings of 0.85% NaCl chicken broths were not significantly different from that of 0.53% NaCl broths with 0.33% CDG. These data showed that sodium concentration of chicken broths could be reduced by 38% with CDG supplementation.

A Brazilian group evaluated the use of MSG together with KCl to replace 25% and 50% NaCl in varying proportions, which helped to maintain the sensory acceptability of a garlic seasoning salt formulation when applied to cooked rice (Rodrigues *et al.*, 2014).

In Malaysia, subjects were presented with local spicy soup dishes, such as curry chicken and chili chicken, containing varying amounts of NaCl and MSG. It was found that the optimal acceptance level of these dishes was 0.8% NaCl when used by itself. However, the partial replacement of NaCl with MSG in the ratio of 0.3% NaCl and 0.7% MSG achieved the same level of palatability. (Jinap *et al.*, 2016).

Similarly, the effects of sodium reduction and flavor enhancers such as MSG on the sensory profile of two types of hawker foods commonly consumed in Singapore, namely chicken rice and *mee soto* broth, were examined. Addition of 0.40% MSG into the 40% salt-reduced recipes resulted in a 22% sodium reduction, and the perception of saltiness of these recipes was maintained when compared with the control (Leong *et al.*, 2016).

Several groups also investigated the potential of glutamates to reduce salt in processed meat and dairy products. In France, Bellisle found that addition of MSG to meat *pâté* maintained its palatability even though NaCl content was reduced (Bellisle, 1998).

Elsewhere, CDG was used to improve palatability of salt-reduced sausage in a study conducted in Australia by using 0.12% NaCl and 0.10% CDG, which would be equivalent to a formulation with 0.69% NaCl (Woodward *et al.*, 2003).

In Brazil, the use of MSG in combination with other umami substances (disodium inosinate, disodium guanylate) and amino acids (lysine, taurine) helped to reduce the negative sensory properties, such as bitter, astringent and metallic tastes, of using KCl to replace 50% and 75% of NaCl in cooked sausages (dos Santos *et al.*, 2014). In a separate study, MSG in combination with KCl was used in reduced sodium formulations of Mozzarella cheese, which helped to maintain acceptable sensory properties for formulations with up to 54% sodium reduction (Rodriguez, 2014). Quadros et al. also examined the acceptability of fish burgers containing various concentrations of NaCl and MSG, with the formulation containing 0.75% NaCl and 0.3% MSG scoring equally if not better than the formulation containing 1.5% NaCl only, therefore providing a 50% reduction (Quadros et al., 2015).

Apart from sensory studies involving reduced-salt product formulations, a clinical study investigating the use of glutamate in the form of MDG as part of a low sodium diet and

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its effect on food intake and dietary sodium intake was undertaken by Kawano et al. Over several weeks, a group of psychiatric patients in Japan were alternately provided with standard meals containing 3.28g sodium/day and low sodium meals with MDG containing 2.43g sodium/day. Their food intake was measured and was found not to be significantly different when provided with standard meals or low sodium meals containing MDG, indicating that palatability was not adversely affected for the latter. As a result, average daily sodium intake was found to have decreased by 0.85g sodium/day when consuming the low sodium meal with MDG (Kawano *et al.*, 2015).

## Recognition of the role of glutamate in dietary salt reduction by authoritative public health bodies

In 2010, the Institute of Medicine (IOM) in the United States indicated that compounds imparting umami taste and flavour can be used to reduce the need for added salt. The IOM Report on Strategies to Reduce Sodium Intake in the United States stated that "It is possible to replace some of the salt in foods with other taste or flavor compounds. --- A prominent example of an added compound involves glutamic acid (an amino acid). Combining glutamic acid with sodium creates the well-known flavoring compound monosodium glutamate, or MSG. MSG imparts a savory taste (called "umami") as well as a salt taste to food. Some studies have shown that it is possible to maintain food palatability with a lowered overall sodium level in a food when MSG is substituted for some of the salt." (IOM, 2010)

In 2013, the Academy of Nutrition and Dietetics in the United States performed a systematic review to evaluate the effect of umami compounds (such as MSG) or foods rich in umami (such as soy sauce, fish sauce, etc.) on the sodium content in foods and/or sodium intake. Based on the evidence reviewed, it was concluded that "*the addition of umami compounds or foods rich in umami allows for reductions in sodium content of foods (reported as sodium chloride) without sacrificing taste, liking and pleasantness. However, the resulting reduction in sodium may vary depending on the type of food consumed as well as the amount and type of umami compounds present.*" (Academy of Nutrition and Dietetics, 2013)

## Conclusion

The reduction of sodium intake is a major health concern worldwide. However, it is very difficult to develop sodium-reduced diets with an acceptable palatability, since salt taste is an important basic taste that significantly contributes to the palatability of food. Based on the wide body of evidence from studies conducted in various geographical regions, the addition of glutamate to different types of foods belonging to different cultural traditions, can allow for substantial reductions in sodium consumption without a significant deterioration in palatability. The proper use of glutamate should therefore be considered in the discussion on how to reduce population sodium intake.

# INTERNATIONAL GLUTAMATE TECHNICAL COMMITTEE

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-025**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend definition of TCS to include caramel apples with an inserted stick

**Issue you would like the Conference to consider:**

Historically, uncooked fruits have been considered non-TCS food unless they were epidemiologically implicated in foodborne illness outbreaks and are capable of supporting the growth of pathogenic bacteria in the absence of temperature control. In light of a 2014 multi-state outbreak of listeriosis associated with consumption of caramel apples contaminated with *Listeria monocytogenes*, and subsequent scientific investigations into the factors that could have led to the outbreak, we recommend the Conference to consider modifying the definition of Time/Temperature Control for Safety Food to include "caramel apples with an inserted stick" in Chapter 1, Section 1-201.10.

**Public Health Significance:**

In 2014, there was a multi-state foodborne illness outbreak of listeriosis associated with consumption of caramel apples; these caramel apples had an inserted stick (FDA Report 2014; CDC Report 2015). At the end of its outbreak investigation, the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services had reported that a total of 35 people in 12 states were infected with the outbreak strain of *L. monocytogenes* (CDC Report). Of those 35 people:

- Thirty-four people were hospitalized;
- Listeriosis contributed to at least three of the seven deaths reported;
- Eleven illnesses were pregnancy-related (occurred in a pregnant woman or her newborn infant), with one illness resulting in a fetal loss;
- Three invasive illnesses (meningitis) were reported among otherwise healthy children aged 5-15 years; and
- Twenty-eight (90%) of the 31 ill people interviewed reported eating commercially produced, prepackaged caramel apples before becoming ill.

More information about FDA's investigation of this outbreak is available in the outbreak investigation report (FDA Report 2014). Three manufacturers of caramel apples issued voluntary recalls of caramel apples because they had the potential to be contaminated with *L. monocytogenes*. In addition, the apple supplier that provided apples to each of these manufacturers recalled apples implicated in the outbreak.

*L. monocytogenes* is a bacterium that can contaminate foods and cause a mild illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, illness (called invasive listeriosis (Codex, 2007). Invasive listeriosis has a relatively high mortality rate compared to most other foodborne illness (approximately 20 percent compared to less than 1 percent for *Salmonella* or *Escherichia coli* O157) (Scallan et al, 2011). Persons who have the greatest risk of experiencing listeriosis after consuming foods contaminated with *L. monocytogenes* are pregnant women and their fetuses, the elderly, and persons with weakened immune systems (Pouillot et al, 2015.). It is well established that foods that pose the greatest risk of foodborne listeriosis are those ready-to-eat (RTE) foods that have intrinsic characteristics (such as pH and water activity) that support the growth (i.e., multiplication to increase in number) of *L. monocytogenes*, whereas the RTE foods that pose the least risk of foodborne listeriosis are foods that have intrinsic characteristics that prevent the growth of *L. monocytogenes* (Codex, 2007). For example, *L. monocytogenes* does not multiply in a food that has a pH of 4.4 or below or in a food that has a water activity of the food that is less than or equal to 0.92 (Codex, 2007). Although *L. monocytogenes* can grow slowly during refrigerated storage and, thus, refrigeration is less effective as a control measure for *L. monocytogenes* than for other foodborne pathogens (such as *Salmonella*), *L. monocytogenes* grows more slowly under refrigeration than at room temperature.

Outbreaks of listeriosis from caramel apples were surprising because apples have a pH less than 4.0 and the caramel coating has a water activity less than 0.80, which are below the limits that allow growth of *L. monocytogenes* (Glass et al., 2015). However, research on the survival and growth of *L. monocytogenes* in caramel apples in which a stick was inserted at the stem end suggests that inserting the stick may release juices from the apple that leads to a microenvironment at the interface of the caramel and the apple in which significant growth of *L. monocytogenes* can occur at room temperature (Glass et al. 2015; Salazar et al., 2016). *L. monocytogenes* inoculation of the apple followed by stick insertion at the stem end and caramel coating resulted in significantly more growth in caramel-coated apples with sticks than in caramel-coated apples without sticks (Glass et al., 2015). *L. monocytogenes* did not grow on fresh apples (uncoated) stored at 25°C (77°F) for 49 days (Salazar et al., 2016) and showed limited growth on caramel-coated apples without sticks when stored at 25°C for 28 days (Glass et al., 2015). In contrast, *L. monocytogenes* increased by several logs in caramel apples with an inserted stick (Glass et al. 2015; Salazar et al., 2016). *L. monocytogenes* growth was significantly reduced when caramel apples on a stick were stored at refrigeration temperatures (5-7°C; 41-45°F) (Glass et al., 2015; Salazar et al., 2016). The interface between the stem end of the apple and the caramel layer may have a microenvironment with sufficiently high water activity and pH when the stick penetrates the apple. Thus, caramel-coated apples on a stick present a lower risk for illness when stored refrigerated storage compared to storage at room temperature.

**Recommended Solution: The Conference recommends...:**

The Conference recommends a letter be sent to FDA to request amending the definition of "Time/Temperature Control for Safety Food" by adding "caramel apples with an inserted stick" in part 2 of the definition of "Time/Temperature Control for Safety Food" in Chapter 1, Section 1-201.10.

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**Supporting Attachments:**

- "Outbreaks of Foodborne Illness"
- "Multistate Outbreak of Listeriosis Linked to Commercially Produced..."
- "Guidelines on the application of the General Principles of Food Hygiene"
- "Foodborne illness acquired in the US - major pathogens"
- "Listeria monocytogenes dose response revisited"
- "Fate of Listeria monocytogenes in Fresh Apples and Caramel Apples"
- "Growth of Listeria monocytogenes within a caramel-coated apple microenv..."

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# FDA Investigated Listeria monocytogenes Illnesses Linked to Caramel Apples

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## Update

August 21, 2015

After a U.S. Food and Drug Administration review, the agency considers the **January 9, 2015** recall of Gala and Granny Smith apples supplied by Bidart Bros. to be complete.

On this page:

- [What was the Problem and What was Done?](#)
- [What are the Symptoms of Listeriosis?](#)
- [Who is at Risk?](#)
- [What Specific Products were Recalled?](#)
- [What Do Consumers Need To Do?](#)
- [What Do Retailers and Restaurants Need To Do?](#)
- [Who Should be Contacted?](#)

*The U.S. Food and Drug Administration (FDA) along with the Centers for Disease Control and Prevention (CDC) and state and local authorities investigated a listeriosis outbreak linked to commercially-produced, prepackaged*

*whole caramel apples. Listeriosis is caused by the bacterium Listeria monocytogenes. According to the CDC, the outbreak appeared to be over as of February 12, 2015.*

## What was the Problem and What was Done?

The FDA, CDC and state and local officials investigated an outbreak of listeriosis linked to commercially-produced, prepackaged whole caramel apples.

[According to the CDC](#), 35 people from 12 states were infected with the outbreak strains of *Listeria monocytogenes*. The CDC reports that 34 ill people were hospitalized. Listeriosis contributed to at least three of the seven deaths that were reported. Eleven illnesses were pregnancy-related, with one illness resulting in a fetal loss. Illness onset dates ranged from October 17, 2014 to January 6, 2015.

The CDC reports that 28 of the 31 ill people interviewed reported eating commercially-produced, prepackaged whole caramel apples. To date, caramel apple brands named in interviews include Happy Apple, Carnival and Merb's Candies.

On December 18, 2014, the [Minnesota Department of Health](#) reported four illnesses. The Minnesota cases purchased caramel apples from Cub Foods, Kwik Trip, and Mike's Discount Foods, which carried Carnival brand and Kitchen Cravings brand caramel apples. These two brands are no longer available for purchase at retail locations.

The Public Health Agency of Canada (PHAC) has identified [two cases of listeriosis in Canada](#) with the same DNA fingerprints, or pulsed-field gel electrophoresis (PFGE) patterns, as seen in the US outbreak. PHAC is working with its provincial and territorial partners to determine the source of these illnesses. Since the investigation began, more detailed testing on the two Canadian cases has been completed, concluding that only a single case in Manitoba is genetically related to the U.S. outbreak of listeriosis.

Three companies have issued voluntary recalls of caramel apples because they have the potential to be contaminated with *Listeria monocytogenes*. These companies are:

- Happy Apple Company of Washington, Missouri
- California Snack Foods, of South El Monte, California
- Merb's Candies of St. Louis, Missouri

Each company reported receiving notice from Bidart Bros., an apple supplier headquartered in Bakersfield, California, that there may be a connection between the listeriosis outbreak and the apples supplied to them by Bidart Bros.

Investigating agencies worked to trace the origin of the caramel apples eaten by 11 ill

people involved in the outbreak. Although the manufacturers of the brands reported by these cases (including Happy Apple Company and Merb's Candies) received apples from other growers, the traceback investigation confirmed that Bidart Bros. is the only apple grower that supplied apples to each company.

On December 22, 2014, the FDA and the California Department of Public Health (CDPH) briefed Bidart Bros. on the status of the investigation.

On December 22, 2014, Bidart Bros. issued a recall of Granny Smith apples it sold in 2014 to those customers known to produce caramel apples. Then, on December 24, 2014, Bidart Bros. notified all customers receiving Granny Smith apples in 2014 to recall those apples if they had been used to make caramel apples.

On December 23, 2014, FDA and CDPH activated the California Food Emergency Response Team (CalFERT), a team comprised of CDPH and FDA specialists who rapidly respond to food emergencies in California. CalFERT conducted a joint investigation of the firm. The team took environmental samples, swabbing surfaces likely to come into contact with apples. Analyses of the samples revealed that several of these samples contained *Listeria monocytogenes*. CalFERT shared these laboratory results with Bidart Bros. on January 5, 2015.

On January 6, 2015, Bidart Bros. sent letters to its distributors, expanding its voluntary recall. Bidart Bros. is recalling all Granny Smith and Gala apples shipped from the company's Shafter, California packing facility in 2014.

On January 8, 2015, pulsed-field gel electrophoresis (PFGE) analysis of the *Listeria monocytogenes* isolated from environmental samples collected at Bidart Bros. confirmed that the PFGE patterns, or DNA fingerprints, of the pathogen matched the outbreak strains of *Listeria monocytogenes* isolated from people affected by the outbreak. *Listeria monocytogenes* matching the outbreak strains, by PFGE type, also was isolated from samples of Bidart Bros. whole apples collected along the distribution chain by FDA and state investigators in December 2014.

On January 9, 2015, Bidart Bros. issued a [news release announcing the recall](#) and reporting that December 2, 2014, was the last shipment date for the company's apples.

Other varieties of apples and apples from other growers are not affected by the recall.

On January 18, 2015, whole genome sequence (WGS) analysis of the *Listeria monocytogenes* isolated from environmental samples collected at Bidart Bros. confirmed that the genomes of the pathogens were highly related to the outbreak strains of *Listeria monocytogenes* isolated from people affected by the outbreak. Highly related *Listeria monocytogenes* strains were also isolated from samples of Bidart Bros. whole apples collected along the distribution chain by FDA and state investigators in December 2014.

According to the CDC, the outbreak appears to be over as of February 12, 2015.

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### **What are the Symptoms of Listeriosis?**

Listeriosis is a rare but serious illness caused by eating food contaminated with the bacterium called *Listeria monocytogenes*. Anyone who experiences fever and muscle aches, sometimes preceded by diarrhea or other gastrointestinal symptoms, or develops fever and chills after eating commercially-produced, prepackaged caramel apples should seek medical care and tell the health care provider about any history of eating those caramel apples. Symptoms can appear from a few days up to a few weeks after consumption of the contaminated food.

### **Who is at Risk?**

Listeriosis can be fatal, especially in certain high-risk groups. These groups include the elderly, and people with weakened immune systems and certain chronic medical conditions (such as cancer). In pregnant women, listeriosis can cause miscarriage, stillbirth, premature labor, and serious illness or death in newborn babies.

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### **What Specific Products were recalled?**

On December 24, 2014, the Happy Apple Company of Washington, Missouri, issued a [voluntary recall of Happy Apple Brand caramel apples](#) with a best use by date between August 25th and November 23rd 2014, because they have the potential to be contaminated with *Listeria monocytogenes*.

Happy Apple caramel apples are sold in single pack, three packs, four packs and eight packs and each package will have a best use by date on the front of the label. They were available for retail sale through grocery, discount and club stores, generally in the produce section and were distributed to retailers in the following states: Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Utah, Washington, Wisconsin.

Also, on December 24, 2014, the Canadian Food Inspection Agency (CFIA) announced the [recall in Canada of Happy Apple brand caramel apples](#) due to possible *Listeria monocytogenes* contamination.

On December 31, 2014, the [Happy Apple Company expanded this recall](#) to include Kroger Brand caramel apples produced by the Happy Apple Company with a best use by date between September 15th and November 18th 2014 because they have the

potential to be contaminated with *Listeria monocytogenes*.

Kroger brand caramel apples produced by Happy Apple are sold in single packs and three packs. Each package will have a best use by date on the front of the label. Some caramel apples sold under the Kroger brand are labeled as candy apples and some are labeled as caramel apples. The apples were distributed to retailers in the following states: Arizona, Alaska, Kansas, Idaho, Louisiana, Montana, Missouri, Nebraska, Nevada, Oregon, Texas, Utah, Washington and Wyoming.

On December 27, 2014, California Snack Foods, of El Monte, California, issued a [voluntary recall of California Snack Foods Karm'l Dapple brand caramel apples](#) with a best use by date between August 15th and November 28th, 2014, because they have the potential to be contaminated with *Listeria monocytogenes*.

California Snack Foods caramel apples are sold in single packs and three packs and each package will have a best use by date on the front of the label. They were available for retail sale through grocery, discount and club stores, generally in the produce section and were distributed to retailers in the following states: Arizona, California, Nevada, Texas and Utah.

On December 29, 2014, Merb's Candies of St. Louis, Missouri, issued a [voluntary recall of the Merb's Candies brand Bionic Apples and Double Dipped Apples](#) because they have the potential to be contaminated with *Listeria monocytogenes*.

Bionic Apples and Double Dipped Apples were available for retail sales at St. Louis area locations, through local supermarkets (located in the produce section) and through mail orders nationwide. The product is individually packaged in a clear, burgundy and gold cellophane bag and would have been available from September 8th through November 25th 2014 – no identifying lot codes were used.

The recalling companies report that the recalled caramel apples should no longer be available for purchase in stores.

On January 6, 2015, Bidart Bros. of Bakersfield, California issued a voluntary recall of all Gala and Granny Smith apples shipped from its Shafter, California packing facility in 2014.

On January 7, 2015, the [CFIA announced the recall](#) in Canada of Granny Smith apples and Gala apples from Bidart Bros due to possible *Listeria monocytogenes* contamination. According to CFIA, Bidart Apples are sold under the brand names "Big B" and "Granny's Best."

### **What Do Consumers Need To Do?**

After a U.S. Food and Drug Administration review the agency considers that the January 9, 2015 recall of Gala and Granny Smith apples supplied by Bidart Bros. to

be complete.

Recommendations for preventing listeriosis are available at the CDC *Listeria* website: <http://www.cdc.gov/listeria/prevention.html>.

*Listeria monocytogenes* can grow at refrigerator temperatures, as low as 40 degrees Fahrenheit (4 degrees Celsius). The longer ready-to-eat refrigerated foods are stored in the refrigerator, the more opportunity *Listeria* has to grow.

For refrigerators and other food preparation surfaces and food cutting utensils that may have come in contact with commercially-produced, prepackaged caramel apples, including those containing nuts, sprinkles, chocolate, or other toppings, it is very important that the consumers thoroughly clean the following areas:

- Wash the inside walls and shelves of the refrigerator, cutting boards and countertops; then sanitize them with a solution of one tablespoon of chlorine bleach to one gallon of hot water; dry with a clean cloth or paper towel that has not been previously used.

In addition, consumers can follow these simple steps for food safety:

- Wash hands with warm water and soap for at least 20 seconds before and after handling food.
- Wipe up spills in the refrigerator immediately and clean the refrigerator regularly.
- Always wash hands with warm water and soap following the cleaning and sanitization process.

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### **What Do Retailers and Restaurants Need To Do?**

Retailers and restaurants should work with their suppliers to ensure that they are not selling the Granny Smith and Gala apples being recalled by Bidart Bros., or caramel apples made using the recalled Bidart Bros. apples. This includes caramel apples containing nuts, sprinkles, chocolate, or other toppings.

Restaurants and retailers should also:

- Wash and sanitize display cases and refrigerators where potentially contaminated products were stored.
- Wash and sanitize cutting boards, surfaces, and utensils used to cut, serve, or store potentially contaminated products.
- Wash hands with warm water and soap following the cleaning and sanitation process.
- Retailers, restaurants, and other food service operators who have processed and

packaged any potentially contaminated products need to be concerned about cross contamination of cutting surfaces and utensils through contact with the potentially contaminated products.

- Regular frequent cleaning and sanitizing of cutting boards and utensils used in processing may help to minimize the likelihood of cross-contamination.

*Listeria* can grow at refrigeration temperatures. *Listeria* can also cross contaminate other food cut and served on the same cutting board or stored in the same area. Retailers, restaurants, and other food service operators may wish to consider whether other foods available for sale could have been cross-contaminated from the potentially contaminated products, and should be discarded.

### **Who Should be Contacted?**

Consumers with questions about the Bidart Bros. recall may contact the company at 661-399-0978.

Consumers with questions about the California Snack Foods recall may contact the company at 800-966-5501 Monday through Friday during normal business hours or via email at [info@californiasnackfoods.com](mailto:info@californiasnackfoods.com).

Consumers with questions about the Happy Apple recall may contact the company at 800-527-7532 Monday through Friday during normal business hours or via email at [customercare@happyapples.com](mailto:customercare@happyapples.com).

Consumers with questions about the Merb's Candies recall may contact the firm at [customercare.merbscandies@gmail.com](mailto:customercare.merbscandies@gmail.com) or during normal business hours Monday through Friday 9 a.m. to 5 p.m. CST at (314) 832-7206.

The FDA encourages consumers with questions about food safety to call 1-888-SAFEFOOD Monday through Friday between 10 a.m. and 4 p.m. Eastern time, or to consult <http://www.fda.gov>.

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*The information in this posting reflects the FDA's best efforts to communicate what it has learned from the manufacturer, the CDC, and the state and local public health and food regulatory agencies involved in the investigation. The agency will update this page as more information becomes available.*

For more information:

- [CDC Vital Signs Listeria](#)
- [FoodSafety.gov on Listeria](#)
- [CDC Web Page](#)

- [Minnesota Press Release](#)

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## Listeria (Listeriosis)

### Commercially Produced, Prepackaged Caramel Apples

Posted February 12, 2015 4:30 PM ET

This investigation is closed, and the shelf life of recalled products has passed. Read the [Advice to Consumers](#) to learn about products that were recalled.

- [Read the Advice to Consumers and Retailers>>](#)
- This outbreak appears to be over. However, recalled products may still be in people's homes. Consumers unaware of the recalls could continue to eat the products and get sick.
- On January 6, 2015, Bidart Bros. of Bakersfield, California [voluntarily recalled](#) Granny Smith and Gala apples because environmental testing revealed contamination with *Listeria monocytogenes* at the firm's apple-packing facility.
  - On January 18, 2015, FDA laboratory analyses using whole genome sequencing (WGS) showed that these *Listeria* isolates were highly related to the outbreak strains.



A total of 35 people infected with the outbreak strains of *Listeria monocytogenes* were reported from 12 states.

- Of these, 34 people were hospitalized. Listeriosis contributed to at least three of the seven deaths reported.
- Eleven illnesses were pregnancy-related (occurred in a pregnant woman or her newborn infant), with one illness resulting in a fetal loss.
- Three invasive illnesses (meningitis) were among otherwise healthy children aged 5–15 years.
- Twenty-eight (90%) of the 31 ill people interviewed reported eating commercially produced, prepackaged caramel apples before becoming ill.
- The Public Health Agency of Canada (PHAC) identified [one case of listeriosis](#) in Canada that is genetically related to the U.S. outbreak.

## Previous Updates

### Outbreak Summary

#### Introduction

CDC collaborated with public health officials in several states and with the [U.S. Food and Drug Administration \(FDA\)](#) to investigate an outbreak of *Listeria monocytogenes* infections (listeriosis). Joint investigation efforts indicated that commercially produced, prepackaged caramel apples made from Bidart Bros. apples were the likely source of this outbreak. *Listeria* can cause a serious, life-threatening illness. People at higher risk for listeriosis include adults 65 years or older, people with weakened immune systems, and pregnant

women.

Public health investigators used the [PulseNet](#) system to identify illnesses that were part of this outbreak.

PulseNet is the national subtyping network of public health and food regulatory agency laboratories coordinated by CDC. DNA “fingerprinting” is performed on *Listeria* bacteria isolated from ill people using techniques called [pulsed-field gel electrophoresis](#) (PFGE) and [whole genome sequencing](#) (WGS). WGS gives a more detailed DNA fingerprint than PFGE. PulseNet manages a national database of these DNA fingerprints to identify possible outbreaks of enteric illness. Two outbreak clusters were identified by the PFGE technique. When WGS was used, two *Listeria* isolates (one within each cluster) were found to be highly related but distinct between the two clusters. CDC investigated the two clusters together because one person was infected with both *Listeria* strains simultaneously and also because illnesses in the two clusters occurred during a similar time period and in similar regions of the country.

The 35 ill people included in this outbreak investigation were reported from 12 states: Arizona (5), California (3), Colorado (1), Minnesota (4), Missouri (5), Nevada (1), New Mexico (6), North Carolina (1), Texas (4), Utah (1), Washington (1), and Wisconsin (3). Illness onset dates ranged from October 17, 2014, to January 6, 2015. Eleven illnesses were associated with a pregnancy (occurred in a pregnant woman or her newborn infant). One fetal loss was reported. Among people whose illnesses were not associated with a pregnancy, ages ranged from 7 to 92 years, with a median age of 62 years, and 33% were female. Three invasive illnesses (meningitis) occurred among otherwise healthy children aged 5–15 years. Thirty-four people were hospitalized, and listeriosis contributed to at least three of the seven deaths reported.

The outbreak can be visually described with a chart showing the number of people who were diagnosed each day. This chart is called an [epidemic curve or epi curve](#).

The Public Health Agency of Canada (PHAC) identified [two cases of listeriosis](#) in Canada with the same PFGE patterns as those seen in the U.S. outbreak. More detailed testing using WGS showed that the isolate from only one of the two cases was genetically related to the U.S. outbreak. That person reported eating a caramel apple.

### Investigation of the Outbreak

In interviews, ill people answered questions about foods consumed and other exposures in the month before becoming ill. Twenty-eight (90%) of the 31 ill people interviewed reported eating commercially produced, prepackaged caramel apples before becoming ill.

Caramel apple brands named in interviews included Happy Apples, Carnival, and Merb's Candies. However, other brands may also have been consumed. The three ill people interviewed who did not report eating caramel apples did report eating whole or sliced green apples not covered in caramel. However, [most \(about 60%\) of the general US population report eating apples \[PDF – 29 pages\]](#) during a given week. The source of the reported whole or sliced green apples is unknown, and it is unknown whether these apples were linked to the patients' illnesses.

On January 6, 2015, Bidart Bros. of Bakersfield, California, [voluntarily recalled](#) Granny Smith and Gala apples because environmental testing revealed contamination with *Listeria monocytogenes* at the firm's apple-packing facility. The recall included all Granny Smith and Gala apples shipped from its Shafter, California, packing facility in 2014. On January 8, 2015, FDA laboratory analyses using PFGE showed that

environmental *Listeria* isolates from the Bidart Bros. facility were indistinguishable from the outbreak strains. On January 18, 2015, WGS found that these isolates were highly related to the outbreak strains. In addition, WGS showed that *Listeria* isolates from whole apples produced by Bidart Bros., collected along the distribution chain, also were highly related to the outbreak strains. CDC recommends that consumers not eat any of the recalled Granny Smith and Gala apples produced by Bidart Bros. and retailers not sell or serve them.

Three firms that produce caramel apples issued voluntary recalls after receiving notice from Bidart Bros. that there may be a connection between Bidart Bros. apples and this listeriosis outbreak. On December 24, 2014, Happy Apple Company of Washington, Missouri, [voluntarily recalled Happy Apples brand caramel apples](#) with a best use by date between August 25 and November 23, 2014. On December 31, 2014, Happy Apple Company [expanded the recall](#) to include Kroger brand caramel apples produced by Happy Apple Company with a best use by date between September 15 and November 18, 2014. On December 27, 2014, California Snack Foods [voluntarily recalled Karm'l Dapple brand caramel apples](#) with a best use by date between August 15 and November 28, 2014. On December 29, 2014, Merb's Candies of St. Louis, Missouri issued [a voluntary recall of Merb's Candies Bionic Apples and Double Dipped Apples](#) that would have been available from September 8 through November 25, 2014.

This outbreak appears to be over. However, recalled products may still be in people's homes. Consumers unaware of the recalls could continue to eat the products and get sick.

January 8, 2015

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December 31, 2014

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December 22, 2014

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Initial Announcement

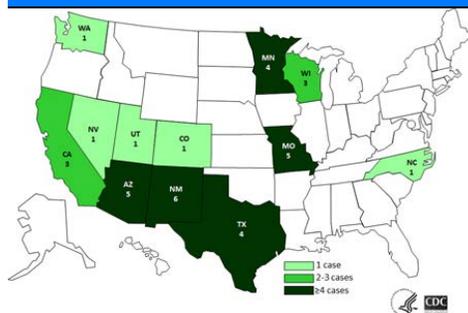
---

- Case Count: [35](#)
- States: [12](#)
- Deaths: 7
- Hospitalizations: 34
- Recall: [Yes](#)

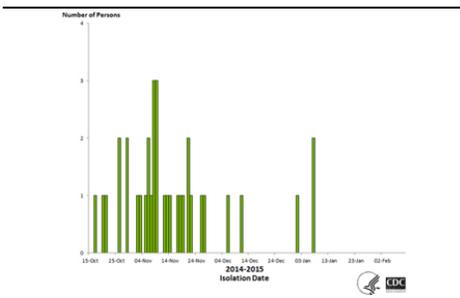
### More Information:

- [Recall & Advice to Consumers](#)
- [Signs & Symptoms](#)
- [Key Resources](#)

CLICK TO VIEW  
CASE COUNT MAP.



CLICK TO VIEW EPI  
CURVE GRAPHS.



## Caramel Apples



CDC recommends that U.S. consumers do not eat any commercially produced, prepackaged caramel apples that were made with Bidart Bros. apples produced in 2014.

Page last reviewed: February 12, 2015

### *Listeria* (Listeriosis)

Questions & Answers

Symptoms

Diagnosis & Treatment

Prevention

People at Risk



## Outbreaks

Reporting Timeline

Outbreak of *Listeria* Infections Linked to Hard-boiled Eggs

Outbreak of *Listeria* Infections

Outbreak of *Listeria* Infections Linked to Deli-Sliced Products

Outbreak of Listeria Infection Linked to Pork Products

Outbreak of Listeria Infections Linked to Deli Ham

Soft Raw Milk Cheese Made by Vulto Creamery

Listeriosis Linked to Frozen Vegetables

Listeriosis Linked to Raw Milk

Packaged Salads Produced at Dole Ohio Facility

Soft Cheeses Distributed by Karoun Dairies, Inc.

Blue Bell Creameries Ice Cream Products

### Commercially Produced, Prepackaged Caramel Apples

Recall & Advice to Consumers

Advice to Consumers en Español

Case Count Maps

Epi Curves

Signs & Symptoms

Key Resources

Oasis Brands, Inc. Cheese

Wholesome Soy Products, Inc. Sprouts



Roos Foods Dairy Products



Crave Brothers Farmstead Cheeses



Imported Frescolina Marte Brand Ricotta Salata Cheese



Jensen Farms Cantaloupes



For Health Professionals

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**GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO  
THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS**

CAC/GL 61 - 2007

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## INTRODUCTION

*Listeria (L.) monocytogenes* is a Gram-positive bacterium that occurs widely in both agricultural (soil, vegetation, silage, faecal material, sewage, water), aquacultural, and food processing environments. *L. monocytogenes* is a transitory resident of the intestinal tract in humans, with 2 to 10% of the general population being carriers of the microorganism without any apparent health consequences.<sup>1</sup> In comparison to other non-spore forming, foodborne pathogenic bacteria (e.g., *Salmonella* spp., enterohemorrhagic *Escherichia coli*), *L. monocytogenes* is resistant to various environmental conditions such as high salt or acidity. *L. monocytogenes* grows at low oxygen conditions and refrigeration temperatures, and survives for long periods in the environment, on foods, in the processing plant, and in the household refrigerator. Although frequently present in raw foods of both plant and animal origin, sporadic cases or outbreaks of listeriosis are generally associated with ready-to-eat, refrigerated foods, and often involves the post-processing recontamination of cooked foods.

*L. monocytogenes* has been isolated from foods such as raw vegetables, raw and pasteurised fluid milk, cheeses (particularly soft-ripened varieties), ice cream, butter, fermented raw-meat sausages, raw and cooked poultry, raw and processed meats (all types) and raw, preserved and smoked fish. Even when *L. monocytogenes* is initially present at a low level in a contaminated food, the microorganism may multiply during storage in foods that support growth, even at refrigeration temperatures.

*L. monocytogenes* causes invasive listeriosis wherein the microorganism penetrates the lining of the gastrointestinal tract and then establishes infections in normally sterile sites within the body. The likelihood that *L. monocytogenes* can establish a systemic infection is dependent on a number of factors, including the number of microorganisms consumed, host susceptibility, and virulence of the specific isolate ingested. Almost all strains of *L. monocytogenes* appear to be pathogenic though their virulence, as defined in animal studies, varies substantially. Listeriosis is an infection that most often affects individuals experiencing immunosuppression including individuals with chronic disease (e.g., cancer, diabetes, malnutrition, AIDS), foetuses or neonates (assumed to be infected *in utero*), the elderly and individuals being treated with immunosuppressive drugs (e.g., transplant patients). The bacterium most often affects the pregnant uterus, the central nervous system or the bloodstream. Manifestations of listeriosis include but are not limited to bacteremia, septicaemia, meningitis, encephalitis, miscarriage, neonatal disease, premature birth, and stillbirth. Incubation periods prior to individuals becoming symptomatic can be from a few days up to three months. *L. monocytogenes* can also cause mild febrile gastro-enteritis in otherwise healthy individuals. The public health significance of this type of listeriosis appears to be much lower than that of invasive listeriosis.

Available epidemiological data show invasive listeriosis occurs both as sporadic cases and outbreaks, with the former accounting for the majority of cases. Invasive listeriosis is a relatively rare, but often severe disease with incidences typically of 3 to 8 cases per 1,000,000 individuals and fatality rates of 20 to 30% among hospitalised patients.<sup>2</sup> During recent years, the incidence of listeriosis in most countries has remained constant, with a number of countries reporting declines in the incidence of disease. These reductions likely reflect the efforts in those countries by industry and governments (a) to implement Good Hygienic Practice (GHP) and apply HACCP to reduce the frequency and extent of *L. monocytogenes* in ready-to-eat foods, (b) to improve the integrity of the cold chain through processing, distribution, retail and the home to reduce the incidence of temperature abuse conditions that foster the growth of *L. monocytogenes*, and (c) to enhance risk communication, particularly for consumers at increased risk of listeriosis. However, further actions are needed to achieve continuous improvement of public health by lowering the incidence of human foodborne listeriosis worldwide. Periodically transitory increases in incidence have been noted in several countries. These have been associated typically with foodborne outbreaks attributable to specific foods, often from specific manufacturers. In such cases, the incidence of listeriosis returned to prior baseline values after the causative food was removed from the market, and consumers received effective public health information pertaining to appropriate food choices and handling practices.

<sup>1</sup> FAO (2000): Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods. FAO, Food and Nutrition Paper No. 71.

<sup>2</sup> FAO and WHO (2001): Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Risk characterisation of *Salmonella* spp. in eggs and broiler chickens and *L. monocytogenes* in ready-to-eat foods. FAO, Food and Nutrition Paper No.72.

Listeriosis has been recognised as a human disease since the 1930's, however, it was not until the 1980's, when there were several large outbreaks in North America and Europe, that the role that foods play in the transmission of the disease was fully recognised. Foods are now considered to be the major vehicle for *L. monocytogenes*. A variety of specific foods have been implicated in outbreaks and sporadic cases of listeriosis (e.g., processed meats, soft cheeses, smoked fish, butter, milk, coleslaw). The foods associated with listeriosis have been overwhelmingly ready-to-eat products that are typically held for extended periods at refrigeration or chill temperatures.

The large number of ready-to-eat foods in which *L. monocytogenes* is at least occasionally isolated has made it difficult to effectively focus food control programs on those specific foods that contribute the greatest risk to foodborne listeriosis. As a means of addressing this and a number of related questions, several formal quantitative risk assessments have been undertaken to address issues related to the relative risks among different ready-to-eat foods and the factors that contribute to those risks. Available governmental risk assessments currently include (1) a comparative risk assessment of 23 categories of ready-to-eat foods conducted by the U.S. Food and Drug Administration and the Food Safety and Inspection Service (FDA/FSIS, 2003)<sup>3</sup>, (2) a comparative risk assessment of four ready-to-eat foods conducted by FAO/WHO JEMRA at the request of the Codex Committee on Food Hygiene<sup>4</sup>, and (3) a product/process pathway analysis conducted by the U.S. Food Safety and Inspection Service for processed meats<sup>5</sup>, which examined the risk of product contamination from food contact surfaces.

Each of these assessments articulates concepts that countries can use to identify and categorise those ready-to-eat products that represent a significant risk of foodborne listeriosis. Five key factors were identified as contributing strongly to the risk of listeriosis associated with ready-to-eat foods:

- Amount and frequency of consumption of a food
- Frequency and extent of contamination of a food with *L. monocytogenes*
- Ability of the food to support the growth of *L. monocytogenes*
- Temperature of refrigerated/chilled food storage
- Duration of refrigerated/chilled storage

A combination of interventions is generally more effective in controlling the risk rather than any single intervention (FDA/FSIS, 2003)<sup>3</sup>.

In addition to the factors above, which influence the number of *L. monocytogenes* present in the food at the time of consumption, the susceptibility of an individual is important in determining the likelihood of listeriosis.

The risk assessments that have been conducted have consistently identified the impact that the ability of a food to support the growth of *L. monocytogenes* has on the risk of listeriosis. Those foods that are able to support growth during the normal shelf life of a product increase substantially the risk that the food will contribute to foodborne listeriosis. Control of growth can be achieved by several different approaches, including reformulation of the product such that one or more of the parameters influencing the growth of the bacterium (e.g., pH, water activity, presence of inhibitory compounds) is altered so the food no longer supports growth. Alternatively, strict control of temperature so that ready-to-eat foods never exceed 6°C (preferably 2°C- 4°C) and/or shortening the duration of the product refrigerated/chilled shelf life are other means for assuring that growth to any significant degree does not occur before the product is consumed.

<sup>3</sup> FDA/FSIS, 2003. Quantitative assessment of the relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods at [www.cfsan.fda.gov](http://www.cfsan.fda.gov)

<sup>4</sup> FAO/WHO, 2004. Risk assessment of *Listeria monocytogenes* in ready-to-eat foods. Technical Report. Microbiological Risk Assessment Series, No. 5.

<sup>5</sup> FSIS Rule Designed to Reduce *Listeria monocytogenes* in Ready-to-Eat Meat & Poultry at [http://www.fsis.usda.gov/factsheets/fsis\\_rule\\_designed\\_to\\_reduce\\_listeria/index.asp](http://www.fsis.usda.gov/factsheets/fsis_rule_designed_to_reduce_listeria/index.asp)

Many of the ready-to-eat products that are associated with foodborne listeriosis include a step in their production that is listericidal. Thus, the frequency and level of contamination of these products with *L. monocytogenes* is typically associated with the recontamination of the product prior to final packaging or from subsequent handling during marketing or home use. Thus, another strategy to control foodborne listeriosis is to reduce recontamination of the product and/or to introduce an additional mitigation treatment after final packaging. Control of the frequency and level of contamination is likely to be influenced strongly by factors such as attention to the design and maintenance of equipment and the integrity of the cold chain, the latter clearly being identified as a risk factor (i.e., the temperature of refrigerated/chilled storage).

Some ready-to-eat foods do not include a listericidal treatment. Product safety in those instances is dependent on steps taken during primary production, processing, and subsequent distribution and use to minimise or reduce contamination/recontamination and to limit growth through maintaining the cold chain and limiting the duration of refrigerated storage.

The FAO/WHO risk assessment also clearly indicated that in order for food control programmes to be effective, they must be capable of consistently achieving the degree of control required; the risk of listeriosis is largely associated with failures to meet current standards for *L. monocytogenes*, be they at 0.04 or 100 CFU/g. The analyses conducted within that risk assessment clearly indicate that the greatest risk associated with ready-to-eat products is the small portion of the products with high contamination levels of *L. monocytogenes*. Thus, a key component of a successful risk management program is assurance that control measures (e.g., preventing contamination and growth of the pathogen) can be achieved consistently.

## SECTION I - OBJECTIVES

These guidelines provide advice to governments on a framework for the control of *L. monocytogenes* in ready-to-eat foods, with a view towards protecting the health of consumers and ensuring fair practices in food trade. Their primary purpose of these guidelines is to minimise the likelihood of illness arising from the presence of *L. monocytogenes* in ready-to-eat foods. The guidelines also provide information that will be of interest to the food industry, consumers, and other interested parties.

## SECTION II - SCOPE

### 2.1 SCOPE

These guidelines are intended for ready-to-eat foods and are applicable throughout the food chain, from primary production through consumption. However, based on the results of the FAO/WHO risk assessment, other available risk assessments and epidemiological evaluations, these guidelines will focus on control measures that can be used, where appropriate, to minimize and/or prevent the contamination and/or the growth of *L. monocytogenes* in ready-to-eat foods. These guidelines highlight key control measures that affect key factors that influence the frequency and extent of contamination of ready-to-eat foods with *L. monocytogenes* and thus the risk of listeriosis. In many instances, these control measures are articulated in a general manner in the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) as part of the general strategy for control of foodborne pathogens in all foods. In providing these guidelines, it is assumed that these General Principles of Food Hygiene are being implemented. Those principles that are restated reflect the need for special attention for the control of *L. monocytogenes*.

Good Hygienic Practices (GHPs) as specified in the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and other applicable codes of hygienic practice should be suitable to control *L. monocytogenes* in non ready-to-eat foods. However, the additional measures described in the following guidelines should be consulted and implemented, as necessary to control *L. monocytogenes* in ready-to-eat foods.

### 2.2 DEFINITIONS

For the purpose of these Guidelines, the following definitions apply:

Definitions of the “Principles and Guidelines for the Conduct of Microbiological Risk Management” apply.

**Ready-to-eat food** – Any food which is normally eaten in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form which is normally eaten without further listericidal steps.

## SECTION III - PRIMARY PRODUCTION

Many ready-to-eat foods receive one or more treatments during processing or preparation that inactivate or inhibit the growth of *L. monocytogenes*. For these foods animal health and general application of good agricultural practices, including animal husbandry, should be sufficient to minimise the prevalence of *L. monocytogenes* at primary production.

In those ready-to-eat foods that are manufactured without a listericidal treatment, extra attention at primary production is needed to assure specific control of the pathogen (e.g., control of *L. monocytogenes* mastitis in dairy cattle and sheep where the milk will be used to make raw milk cheeses, frequency of *L. monocytogenes* in raw milk as related to the feeding of inadequately fermented silage, high levels of *L. monocytogenes* in pork for fermented sausages resulting from wet feeding systems, faecal contamination of fresh produce), including increased focus on personal hygiene and water management programs at the primary production sites.

Analysis of raw material for *L. monocytogenes* can be, where appropriate, an important tool for validating and verifying that the control measures at the primary production level are adequately limiting the frequency and level of contamination to that needed to achieve the required level of control during subsequent manufacturing.

### 3.1 ENVIRONMENTAL HYGIENE

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 3.3 HANDLING, STORAGE AND TRANSPORT

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 3.4. CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

## SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

Objectives:

Equipment and facilities should be designed, constructed and laid out to ensure cleanability and to minimise the potential for *L. monocytogenes* harbourage sites, cross-contamination and recontamination.

Rationale:

- The introduction of *L. monocytogenes* into the ready-to-eat processing environment has resulted from inadequate separation of raw and finished product areas and from poor control of employees or equipment traffic.
- Inability to properly clean and disinfect equipment and premises due to poor layout or design and areas inaccessible to cleaning has resulted in biofilms containing *L. monocytogenes* and harbourage sites that have been a source of product contamination
- The use of spray cleaning procedures that aerosolize the microorganism has been linked to the spread of the *L. monocytogenes* in the processing environment.
- Inability to properly control ventilation to minimise condensate formation on surfaces in food processing plants may result in the occurrence of *L. monocytogenes* in droplets and aerosols which can lead to product contamination.

## 4.1 LOCATION

### 4.1.1 Establishments

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 4.1.2 Equipment

Whenever possible, equipment should be designed and placed in a manner that facilitates access for efficient cleaning and disinfection, and thus avoid the formation of biofilms containing *L. monocytogenes* and harbourage sites.

## 4.2 PREMISES AND ROOMS

### 4.2.1 Design and Layout

Whenever feasible, premises and rooms should be designed to separate raw and finished ready-to-eat product areas. This can be accomplished in a number of ways, including linear product flow (raw to finished) with filtered airflow in the opposite direction (finished to raw) or physical partitions. Positive air pressure should be maintained on the finished side of the operation relative to the “raw” side (e.g., maintain lower air pressures in raw areas and higher pressures in finished areas).

Where feasible, the washing areas for food equipment involved in the manufacture of the finished product should be located in a separate room from the finished product processing area. This latter area should be separate from the raw ingredient handling area and the cleaning area for equipment used in the handling of raw ingredients in order to prevent recontamination of equipment and utensils used for finished products. Rooms where ready-to-eat products are exposed to the environment should be designed so that they can be maintained as dry as possible; wet operations often enhance the growth and spread of *L. monocytogenes*.

### 4.2.2 New construction/renovations

Due to the ability of *L. monocytogenes* to survive in the plant environment for long periods of time, disturbances caused by construction or modification of layouts can cause reintroduction of *L. monocytogenes* from harbourage sites to the environment. Where appropriate, care should be taken to isolate the construction area, to enhance hygienic operations and to increase environmental monitoring to detect *Listeria* spp. during construction/renovation (see Section 6.5).

### 4.2.3 Temporary/mobile premises and vending machines

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

## 4.3 EQUIPMENT

### 4.3.1 General

Due to the ability of *L. monocytogenes* to exist in biofilms and persist in harbourage sites for extended periods, processing equipment should be designed, constructed and maintained to avoid, for example, cracks, crevices, rough welds, hollow tubes and supports, close fitting metal-to-metal or metal-to-plastic surfaces, worn seals and gaskets or other areas that cannot be reached during normal cleaning and disinfection of food contact surfaces and adjacent areas.

Racks or other equipment used for transporting exposed product should have easily cleaned cover guards over the wheels to prevent contamination of the food from wheel spray.

Cold surfaces (e.g., refrigeration units) can be sources for psychrotrophic bacteria, especially *L. monocytogenes*. Condensate from refrigeration unit pans should be directed to a drain via a hose or drip pans should be emptied, cleaned and disinfected on a regular basis.

Insulation should be designed and installed in a manner that it does not become a harbourage site for *L. monocytogenes*.

#### 4.3.2 Food control and monitoring equipment

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

#### 4.3.3 Containers for waste and inedible substances

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 4.4 FACILITIES

#### 4.4.1 Water supply

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

#### 4.4.2 Drainage and waste disposal

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

#### 4.4.3 Cleaning

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

#### 4.4.4 Personnel hygiene facilities and toilets

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

#### 4.4.5 Temperature control

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

#### 4.4.6 Air quality and ventilation

Control of ventilation to minimise condensate formation is of particular importance in *L. monocytogenes* control, since the organism has been isolated from a wide variety of surfaces in food processing plants. Wherever feasible, facilities should be designed so that droplets and aerosols from condensates do not directly or indirectly contaminate food and food contact surfaces.

#### 4.4.7 Lighting

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

#### 4.4.8 Storage

Where feasible and appropriate for the food product, and where food ingredients and products support growth of *L. monocytogenes*, storage rooms should be designed so that a product temperature should not exceed 6°C, (preferably 2°C - 4°C). Raw materials should be stored separately from finished, processed products.

### SECTION V - CONTROL OF OPERATION

#### Objectives:

Processing operations should be controlled to reduce the frequency and level of contamination in the finished product, to minimise the growth of *L. monocytogenes* in the finished product and to reduce the likelihood that the product will be recontaminated and/or will support the growth of *L. monocytogenes* during subsequent distribution, marketing and home use.

**Rationale:**

For many ready-to-eat products listericidal processes<sup>6</sup> can ensure appropriate reduction in risk. However, not all ready-to-eat products receive such a treatment and other ready-to-eat products may be exposed to the environment and thus may be subject to potential recontamination. Prevention of cross-contamination, strict control of time and temperature for products in which *L. monocytogenes* can grow and formulation of products with hurdles to *L. monocytogenes* growth can minimise the risk of listeriosis.

**5.1 CONTROL OF THE FOOD HAZARD**

Control of *L. monocytogenes* for many ready-to-eat products will typically require a stringent application of Good Hygienic Practice and other supportive programs. These prerequisite programs, together with HACCP provide a successful framework for the control of *L. monocytogenes*.

The factors and attributes described below are components of Good Hygienic Practice programs that will typically require elevated attention to control *L. monocytogenes* and may be identified as critical control points in HACCP programs where *L. monocytogenes* is identified as a hazard.

**5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS****5.2.1 Time and temperature control**

The risk assessments done by the U.S. FDA/FSIS and FAO/WHO on *L. monocytogenes* in ready-to-eat foods demonstrated the tremendous influence of storage temperature on the risk of listeriosis associated with ready-to-eat foods that support *L. monocytogenes* growth. It is therefore necessary to control the time/temperature combination used for storage.

Monitoring and controlling refrigerated storage temperatures are key control measures. The product temperature should not exceed 6°C (preferably 2°C - 4°C). Temperature abuse that may occur supporting the growth of *L. monocytogenes* could result in a reduction of product shelf life.

The length of the shelf-life is another important factor contributing to the risk associated with foods that support *L. monocytogenes* growth. The shelf-life of such foods should be consistent with the need to control the growth of *L. monocytogenes*. Since *L. monocytogenes* is able to grow under refrigeration temperatures, the length of the shelf-life should be based on appropriate studies that assess the growth of *L. monocytogenes* in the food. Shelf-life studies and other information are important tools facilitating the selection of the length of shelf-life. If they are conducted, they should account for the fact that appropriate low temperatures may not be maintained throughout the entire food chain until the point of consumption. Temperature abuses may allow the growth of *L. monocytogenes*, if present, unless appropriate intrinsic factors are applied to prevent such growth. This should be taken into account when establishing shelf life.

**5.2.2 Specific process steps**

Listericidal processes should be validated to ensure that the treatments are effective and can be applied consistently (see Section V of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)).

In some products single parameters, such as a pH less than 4.4, a water activity less than 0.92 or freezing, may be relied upon to prevent *L. monocytogenes* growth. In other products a combination of parameters is used. Validation should be undertaken to ensure the effectiveness of these parameters in situations where combinations of parameters or bacteriostatic conditions are relied upon.

Products supporting the growth of *L. monocytogenes* that have undergone a listericidal treatment may be contaminated/recontaminated before final packaging. In these cases, additional control measures may be applied if necessary, (e.g., freezing the product, shortening the shelf life, reformulation of the product) to limit the extent of or prevent *L. monocytogenes* growth. Alternatively, a post-packaging listericidal treatment may be necessary (e.g. heating, high pressure treatment, irradiation, where accepted).

<sup>6</sup> Any appropriate treatment that kills listeria.

In raw, ready-to-eat food (e.g. lettuce), that support the growth of *L. monocytogenes*, that may be contaminated, specific control measures may be applied if necessary to limit the extent of or prevent the growth of *L. monocytogenes* (e.g. acid wash).

#### 5.2.3 Microbiological and other specifications

Refer to the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969) and *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1979).

#### 5.2.4 Microbiological cross-contamination

Microbiological cross-contamination is a major issue with respect to *L. monocytogenes*. It can occur through direct contact with raw materials, personnel, aerosols and contaminated utensils, equipment, etc.. Cross-contamination can occur at any step where the product is exposed to the environment, including processing, transportation, retail, catering, and in the home.

Traffic flow patterns for employees, food products, and equipment should be controlled between raw processing, storage area(s) and finished area(s) to minimise the transfer of *L. monocytogenes*. For example, a change of footwear or automated foam sprayers can be an effective alternative to footbaths where people, carts, forklifts and other portable equipment must enter an area where ready-to-eat foods are exposed. Another example is to use a colour coding system to identify personnel assigned to specific areas of the plant.

Utensils, pallets, carts, forklifts and mobile racks should be dedicated for use in either the raw area or the finished product area to minimise cross-contamination. Where this is not practical, they should be cleaned and disinfected before entry into the finished product area.

Reused brines and recycled process water used in direct contact with finished product should be discarded or decontaminated (e.g. chlorination for recycled water, heat treatment, or some other effective treatment) with sufficient frequency to ensure control of *L. monocytogenes*.

Ready-to eat foods that do not support the growth of *L. monocytogenes* but may have low levels of this pathogen should not be a source of contamination to other ready-to-eat foods that may support the growth of this pathogen. Consideration should be given to the fact that some ready-to-eat foods with special handling requirements (for example ice cream), that are handled after opening may present a lower risk for being a vector for cross contaminating other ready-to-eat foods, because such specially handled product is rapidly consumed. Other ready-to-eat products, however, with special formulation (for example dry fermented sausage), that are handled after opening may present a higher risk of being a vector for cross contaminating other ready-to-eat products if neither ready-to-eat product is rapidly consumed.

#### 5.2.5 Physical and chemical contamination

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

### 5.3 INCOMING MATERIAL REQUIREMENTS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

### 5.4 PACKAGING

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

### 5.5 WATER

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

### 5.5.1 In contact with food

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 5.5.2 As an ingredient

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 5.5.3 Ice and steam

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

## 5.6 MANAGEMENT AND SUPERVISION

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

## 5.7 DOCUMENTATION AND RECORDS

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

## 5.8 RECALL PROCEDURES

Based on the determined level of risk associated with the presence of *L. monocytogenes* in a given food product, a decision may be taken to recall the contaminated product from the market. In some instances, the need for public warnings should be considered.

## 5.9 MONITORING OF EFFECTIVENESS OF CONTROL MEASURES FOR *L. MONOCYTOGENES*

An effective environmental monitoring program is an essential component of a *Listeria* control program, particularly in establishments that produce ready-to-eat foods that support growth and may contain *L. monocytogenes*. Testing of food products can be another component of verification that control measures for *L. monocytogenes* are effective (see Section 5.2.3).

Recommendations for the design of an environmental monitoring program for *L. monocytogenes* in processing areas are given in Annex 1.

## SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

### Objectives:

To provide specific guidance on how preventive maintenance and sanitation procedures, along with an effective environmental monitoring program can reduce contamination of food with *L. monocytogenes*, particularly when the foods support growth of *L. monocytogenes*:

Well structured cleaning and disinfection procedures should be targeted against *L. monocytogenes* in food processing areas where ready-to-eat foods are exposed to reduce

- the likelihood that the product will be contaminated after processing,
- the level of contamination in the finished product.

### Rationale:

Basic cleaning and disinfection programs are critical to assuring control of *L. monocytogenes*. An environmental monitoring program for *Listeria* in processing areas where ready-to-eat foods are exposed is necessary to assess the effectiveness of control measures and, therefore, the likelihood of contamination of the food.

## 6.1 MAINTENANCE AND CLEANING

### 6.1.1 General

Establishments should implement an effective, scheduled preventive maintenance program to prevent equipment failures during operation and the development of harbourage sites. Equipment failures during production increase the risk of *L. monocytogenes* contamination as equipment is being repaired. The preventive maintenance program should be written and include a defined maintenance schedule.

The preventive maintenance program should include scheduled replacement or repair of equipment before it becomes a source of contamination. Equipment should be inspected periodically for parts that are cracked, worn or have developed spaces where food and moisture accumulate (i.e., harbourage sites). Preventive maintenance should include periodic examination and maintenance of conveyors, filters, gaskets, pumps, slicers, filling equipment, and packaging machines and support structures for equipment. Air filters for bringing outside air into the plant should be examined and changed based on manufacturer's specification or more frequently based on pressure differential or microbiological monitoring.

Wherever possible, tools used for maintenance of equipment to which ready-to-eat foods are exposed should be dedicated to the finished product area. Such tools should be washed and disinfected prior to use. Maintenance personnel in the finished product area should comply with the same hygiene requirements as the finished product production employees. Food contact surfaces on equipment should be cleaned and disinfected after maintenance work, prior to production use. Equipment that could have become contaminated during maintenance work on facility utilities, e.g. air system, water system, etc., or remodelling, should be cleaned and disinfected prior to use.

### 6.1.2 Cleaning procedures and methods

Experience indicates that over-reliance on the chemicals alone for cleaning can lead to increased levels of microbial contamination. The chemicals must be applied at the recommended use-concentration, for sufficient time, at the recommended temperature and with sufficient force (i.e., turbulence, scrubbing) to remove soil and biofilm. Instances of *L. monocytogenes* contamination have been linked, in particular, to insufficient manual scrubbing during the cleaning process.

Research and experience further indicates that *L. monocytogenes* does not possess an unusual ability to resist disinfectants or attach to surfaces. However, it is noted that *L. monocytogenes* has the ability to form biofilms on a variety of surfaces.

Solid forms of disinfectants (e.g., blocks of quarternary ammonium compounds (QAC)) can be placed in the drip pan of refrigeration units and solid rings containing disinfectants can be placed in drains to help control *L. monocytogenes* in drains. Granulated forms of disinfectants such as QAC, hydrogen peroxide and peroxyacetic acid can be applied to floors after routine cleaning and disinfecting. The development of antimicrobial resistance should be considered in the application and use of disinfectants.

The equipment used for cleaning, e.g. brushes, bottle brushes, mops, floor scrubbers, and vacuum cleaners should be maintained and cleaned so they do not become a source of contamination. The cleaning equipment should be dedicated either for raw areas or finished areas, and easily distinguishable (e.g., colour-coded cleaning tools).

To prevent aerosols from contacting ready-to-eat foods, food contact surfaces and food packaging materials, high-pressure water hoses should not be used during production or after equipment has been cleaned and disinfected.

It has been shown that *L. monocytogenes* can become established and persist in floor drains. Therefore, drains should be cleaned and disinfected in a manner that prevents contamination of other surfaces in the room. Utensils for cleaning drains should be easily distinguishable and be dedicated to that purpose to minimise the potential for contamination.

Floor drains should not be cleaned during production. High-pressure hoses should not be used to clear or clean a drain, as aerosols will be created that spread contamination throughout the room. If a drain backup occurs in finished product areas, production should stop until the water has been removed and the areas have been cleaned and disinfected. Employees who have been cleaning drains should not contact or clean food contact surfaces without changing clothes, and washing and disinfecting hands.

## 6.2 CLEANING PROGRAMS

The effectiveness of sanitation programs should be periodically verified and the programs modified as necessary to assure the consistent achievement of the level of control needed for a food operation to prevent *L. monocytogenes* contamination of ready-to-eat food and ready-to-eat food contact surfaces.

## 6.3 PEST CONTROL SYSTEMS

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 6.3.1 General

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 6.3.2 Preventing access

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 6.3.3 Harbourage and infestation

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 6.3.4 Monitoring and detection

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 6.3.5 Eradication

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

## 6.4 WASTE MANAGEMENT

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

## 6.5 MONITORING EFFECTIVENESS

Environmental monitoring (see 5.9) can also be used to verify the effectiveness of sanitation programs such that sources of contamination of *L. monocytogenes* are identified and corrected in a timely manner. Recommendations for the design of an environmental monitoring program in processing areas are given in Annex 1.

## SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

Objectives:

To prevent workers from transferring *L. monocytogenes* from contaminated surfaces to food or food contact surfaces.

Rationale:

Workers can serve as a vehicle for cross-contamination and should be aware of the steps that need to be taken to manage this risk.

### 7.1 HEALTH STATUS

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 7.2 ILLNESS AND INJURIES

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 7.3 PERSONAL CLEANLINESS

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 7.4 PERSONAL BEHAVIOUR

Employee hygienic practices play an important role in preventing contamination of exposed ready-to-eat foods with *L. monocytogenes*. For example, employees who handle trash, floor sweepings, drains, packaging waste or scrap product, should not touch the food, touch food contact surfaces or food packaging material, unless they change their smock or outer clothing, wash and disinfect hands, and wear clean new gloves for tasks requiring gloves. Adequate training and supervision should be provided to assure hygienic practices are accomplished.

### 7.5 VISITORS

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

## SECTION VIII – TRANSPORTATION

Objectives:

Measures should be taken where necessary to:

- protect food from potential sources of contamination including harbourage sites for *L. monocytogenes* in transportation equipment and to prevent the co-mingling of raw and ready-to-eat product;
- provide an adequately refrigerated environment (so that product temperature should not exceed 6°C, preferably 2°C - 4°C).

Rationale:

Food may become contaminated during transportation if not properly protected.

If refrigeration is inadequate, food may support the growth of *L. monocytogenes* to higher levels..

### 8.1 GENERAL

Transportation is an integral step in the food chain and should be controlled, particularly the product temperature which should not exceed 6°C (preferably 2°C - 4°C).

Transportation vehicles should be regularly inspected for structural integrity, cleanliness, and overall suitability when unloading ingredients and prior to loading finished products. In particular, the structural integrity of transportation vehicles (e.g., tanker trucks) should be monitored for stress cracks that act as harbourage sites for *L. monocytogenes*. Tankers should be dedicated to transport either ingredients or finished products.

### 8.2 REQUIREMENTS

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 8.3 USE AND MAINTENANCE

Food transportation units, accessories, and connections should be cleaned, disinfected (where appropriate) and maintained to avoid or at least reduce the risk of contamination. It should be noted that different commodities may require different cleaning procedures. Where necessary, disinfection should be followed by rinsing unless manufacturer's instruction indicates on a scientific basis that rinsing is not required.<sup>7</sup> A record should be available that indicates when cleaning occurred.

## SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

Objectives:

Consumers should have enough knowledge of *L. monocytogenes* and food hygiene such that they:

- understand the importance of shelf-life, sell-by or use-by dates written on food label;
- can make informed choices appropriate to the individual's health status and concomitant risk of acquiring foodborne listeriosis;
- prevent contamination and growth or survival of *L. monocytogenes* by adequately storing and preparing ready-to-eat foods.

Health care providers should have appropriate information on *L. monocytogenes* in foods and listeriosis to give advice to consumers and in particular susceptible populations

Rationale:

Consumers (in particular, the susceptible populations), health care providers, need to be informed about ready-to-eat foods supporting growth of *L. monocytogenes*, food handling, preparation practices and avoidance of certain foods by susceptible populations.

### 9.1 LOT IDENTIFICATION

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 9.2 PRODUCT INFORMATION

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 9.3 LABELLING

Countries should give consideration to labelling of certain ready-to-eat foods so that consumers can make an informed choice with regard to these products. Where appropriate, product labels should include information on safe handling practices and/or advice on the time frames in which the product should be eaten.

### 9.4 CONSUMER EDUCATION

Since each country has specific consumption habits, communication programs pertaining to *L. monocytogenes* are most effective when established by individual governments.

Programs for consumer information should be directed:

- at consumers with increased susceptibility to contracting listeriosis, such as pregnant women, the elderly and immunocompromised persons;  
to help consumers make informed choices about purchase, storage, shelf-life labelling and appropriate consumption of certain ready-to-eat foods that have been identified in relevant risk assessment and other studies, taking into consideration the specific regional conditions and consumption habits;

<sup>7</sup> Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food (CAC/RCP 47-2001).

- to consumers to educate them on household practices and behaviours that would specifically keep the numbers of *L. monocytogenes* that may be present in foods, to as low a level as possible by
  - setting refrigerator temperatures so that product temperatures should not exceed 6°C (preferably 2°C - 4°C) since the growth of *L. monocytogenes* is considerably reduced at temperatures below 6°C;
  - frequently washing and disinfecting the household refrigerator since *L. monocytogenes* can be present in many foods and grow at refrigerator temperatures, and thus contribute to cross-contamination;
  - respecting the shelf-life dates written on ready-to-eat foods;
  - using of thermometers inside home refrigerators.

Programs for health care providers should, in addition to information provided to consumers, be designed to provide them with guidance that

- facilitates rapid diagnosis of foodborne listeriosis;
- provides means to rapidly communicate information on preventing listeriosis to their patients, particularly those with increased susceptibility.

## SECTION X - TRAINING

Objective:

Those engaged in food operation who come directly or indirectly in contact with ready-to-eat foods should be trained and/or instructed in the control of *L. monocytogenes* to a level appropriate to the operations they are to perform..

Rationale:

Controls specific to *L. monocytogenes* are generally more stringent than routine Good Hygiene Practices.

### 10.1 AWARENESS AND RESPONSIBILITIES

Industry (primary producers, manufacturers, distributors, retailers and food service/institutional establishments) and trade associations have an important role in providing specific instruction and training for control of *L. monocytogenes*.

### 10.2 TRAINING PROGRAMS

Personnel involved with the production and handling of ready-to-eat food should have appropriate training in:

- the nature of *L. monocytogenes*, its harbourage sites, and its resistance to various environmental conditions to be able to conduct a suitable hazard analysis for their products;
- control measures for reducing the risk of *L. monocytogenes* associated with ready-to-eat foods during processing, distribution, marketing, use and storage;
- the means for verifying effectiveness of control programs, including sampling and analytical techniques;

### 10.3 INSTRUCTION AND SUPERVISION

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

### 10.4 REFRESHER TRAINING

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

## **ANNEX I: RECOMMENDATIONS FOR AN ENVIRONMENTAL MONITORING<sup>8</sup> PROGRAM FOR *LISTERIA MONOCYTOGENES* IN PROCESSING AREAS**

Manufacturers of ready-to-eat foods should consider the potential risk to consumers in the event their products contain *L. monocytogenes* when they are released for distribution. The necessity for an environmental monitoring program is highest for ready-to-eat foods that support *L. monocytogenes* growth and that are not given a post-packaging listericidal treatment. Recontamination has led to many of the recognised outbreaks of listeriosis. One effective element of managing this risk is to implement a monitoring program to assess control of the environment in which ready-to-eat foods are exposed prior to final packaging.

A number of factors (a – i) should be considered when developing the sampling program to ensure the program's effectiveness:

### **a) Type of product and process/operation**

The need<sup>9</sup> for and extent of the sampling program should be defined according to the characteristics of the ready-to-eat foods (supporting or not supporting growth), the type of processing (listericidal or not) and the likelihood of contamination or recontamination (exposed to the environment or not). In addition, consideration also needs to be given to elements such as the general hygiene status of the plant or the existing history of *L. monocytogenes* in the environment.

### **b) Type of samples**

Environmental samples consist of both food contact and non food contact surface samples. Food contact surfaces, in particular those after the listericidal step and prior to packaging, have a higher probability of directly contaminating the product, while for non food contact surfaces the likelihood will depend on the location and practices.

Raw materials may serve as a source of environmental contamination and may therefore be included in the monitoring program.

### **c) Target organisms**

While this document addresses *L. monocytogenes*, effective monitoring programs may also involve testing for *Listeria* spp; their presence is a good indicator of conditions supporting the potential presence of *Listeria monocytogenes*. Where appropriate and shown to be valid, other indicator organisms may be used<sup>10</sup>.

### **d) Sampling locations and number of samples**

The number of samples will vary with the complexity of the process and the food being produced.

Information on appropriate locations can be found in published literature, can be based on process experience or expertise or in plant surveys. Sampling locations should be reviewed on a regular basis. Additional locations may need to be sampled depending on special situations such as major maintenance or construction or when new or modified equipment has been installed.

### **e) Frequency of sampling**

The frequency of environmental sampling would be based primarily on the factors outlined under sub-heading "Type of product and process/operation". It should be defined according to existing data on the presence of *Listeria* spp. and/or *L. monocytogenes* in the environment of the operation under consideration.

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<sup>8</sup> Environmental monitoring is not to be confused with monitoring as defined in the HACCP.

<sup>9</sup> Products such as in pack pasteurised foods which are not further exposed to environment may not necessarily require a monitoring.

<sup>10</sup> Attributes contributing to the scientific support of the use of an indicator organism in view of a specific pathogen include: similar survival and growth characteristics; a shared common source for both organisms; direct relationship between the state or condition that contributes to the presence of the pathogen and the indicator organism; and practical, isolation, detection or enumeration methods for the potential indicator organism.

In the absence of such information sufficient suitable data should be generated to correctly define the appropriate frequency. These data should be collected over a sufficiently long period as to provide reliable information on the prevalence of *Listeria* spp. and/or *L. monocytogenes* and the variations over time.

The frequency of environmental sampling may need to be increased as a result of finding *Listeria* spp. and/or *L. monocytogenes* in environmental samples. This will depend on the significance of the findings (e.g. *L. monocytogenes* and a risk of direct contamination of the product).

#### **f) Sampling tools and techniques**

It is important to adapt the type of sampling tools and techniques to the type of surfaces and sampling locations. For example sponges may be used for large flat surfaces, swabs may be more appropriate for cracks and crevices or scrapers for hard residues.

#### **g) Analytical methods**

The analytical methods used to analyse environmental samples should be suitable for the detection of *L. monocytogenes* and of other defined target organisms. Considering the characteristics of environmental samples it is important to demonstrate that the methods are able to detect, with acceptable sensitivity, the target organisms. This should be documented appropriately.

Under certain circumstances it may be possible to composite (pool) certain samples without losing the required sensitivity. However, in the case of positive findings additional testing will be necessary to determine the location of the positive sample.

Fingerprinting isolates by one or more of the available genetic techniques (e.g., pulsed field gel electrophoresis, ribotyping) can provide very useful information about the source(s) of *L. monocytogenes* and pathway(s) that lead to contamination of the food.

#### **h) Data management**

The monitoring program should include a system to record the data and their evaluation, e.g. performing trend analyses. A long-term review of the data is important to revise and adjust monitoring programs. It can also reveal low level, intermittent contamination that may otherwise go unnoticed.

#### **i) Actions in case of positive results**

The purpose of the monitoring program is to find *L. monocytogenes* or other target organisms if present in the environment. Generally manufacturers should expect to find them occasionally in the processing environment. Therefore an appropriate action plan should be designed and established to adequately respond to positive findings. A review of hygiene procedures and controls should be considered.

The manufacturer should react to each positive result; the nature of the reaction will depend upon the likelihood of contaminating the product and the expected use of the products.

The plan should define the specific action to be taken and the rationale. This could range from no action (no risk of recontamination), to intensified cleaning, to source tracing (increased environmental testing), to review of hygienic practices up to holding and testing of product.

## **ANNEX II: MICROBIOLOGICAL CRITERIA FOR *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS**

### **1. INTRODUCTION**

The microbiological criteria presented in this Annex are intended as advice to governments within a framework for control of *L. monocytogenes* in ready-to-eat foods with a view towards protecting the health of consumers and ensuring fair practices in food trade. They also provide information that may be of interest to industry.

This Annex references and takes into account the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21 – 1997) and uses definitions, e.g. for microbiological criterion, as included in these principles. The provisions of this Annex should be used in conjunction with *Annex II: Guidance on Microbiological Risk Management Metrics of the Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

The risk assessments referenced in the introduction to the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Food* (CAC/GL 61-2007) have indicated that food can be categorized according to the likelihood of *Listeria monocytogenes* being present and its ability to grow in the food. Available risk assessments have been taken into account in the development of the microbiological criteria in this Annex. In addition, factors that might impact upon the ability of governments to implement these microbiological criteria such as methodological limitations, costs associated with different types of quantitative testing, and statistics-based sampling needs were taken into account.

### **2. SCOPE**

These microbiological criteria apply to specific categories of ready-to-eat foods, as described herein. The competent authority should consider the intended use and how specific ready-to-eat foods are likely to be handled during marketing, catering, or by consumers to determine the appropriateness of applying the microbiological criteria. Governments may apply these criteria, where appropriate, to assess the acceptability of ready-to-eat foods in international trade for imported products, at end of manufacture (finished product) for domestic products, and at point of sale for at least the expected shelf life<sup>11</sup> under reasonably foreseeable conditions of distribution, storage and use.

The microbiological criteria may be used as the basis for the development of additional criteria (e.g. process criteria, product criteria) within a food safety control system<sup>12</sup> to ensure compliance with these guidelines.

Different criteria or other limits may be applied when the competent authority determines that the use of such an approach provides an acceptable level of public health or when the competent authority determines a more stringent criterion is necessary to protect public health.

### **3. USE OF MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES* IN READY-TO-EAT FOODS**

There are various applications for microbiological criteria. As described, microbiological testing by lot can be used as a direct control measure, i.e., sorting of acceptable and unacceptable lots<sup>13</sup>. In this instance, microbiological criteria are implemented for those products and/or points of the food chain when other more

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<sup>11</sup> See definition in the Code of Hygienic Practice For Milk and Milk Products (CAC/RCP 57–2004).

<sup>12</sup> See: Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008).

<sup>13</sup> See: Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

effective tools are not available and where the microbiological criteria would be expected to improve the degree of protection offered to the consumer.

A microbiological criterion defines the acceptability of a product or food lot based on the absence or presence or number of microorganisms in the product. Testing for compliance with a microbiological criterion may be conducted on a lot by lot basis when there is little information about the conditions under which the product has been produced. Where there is information about the conditions of production, testing of lots for verification purposes may be conducted less frequently.

In addition, the application of the Hazard Analysis and Critical Control Point (HACCP) System describes how microbiological testing against a criterion can be used as a means of verifying the continuing effectiveness of a food safety control system<sup>14</sup>. Typically, such applications involve testing on less than a lot by lot basis and may be formalized into a system of process control verification testing (see Annex III).

Where possible and practicable, the risk-based approach to development of microbiological criteria as described in the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL-63-2007) can be used to assure or contribute to the assurance, that a food control system will achieve the required level of consumer protection.

The competent authority should use a risk-based approach to sampling for *L. monocytogenes* such as that found in the Codex General Guidelines on Sampling (CAC/GL 50 – 2004). It may consider modifying the frequency of testing for process control verification based on additional consideration of the likelihood of contamination, characteristics of the food, product history, conditions of production and other relevant information. For example, testing against microbiological criteria may have limited utility immediately following certain processing steps or if the level of *L. monocytogenes* in a ready-to-eat food is consistently well below the limit of detection taking into account practical limits for sample sizes.

In particular, testing against microbiological criteria for *L. monocytogenes* may not be useful for:

- (a) products that receive a listericidal treatment after being sealed in final packaging that ensures prevention of recontamination until opened by the consumer or otherwise compromised,
- (b) foods that are aseptically processed and packaged<sup>15</sup>, and
- (c) products that contain a listericidal component that ensures rapid inactivation of the pathogen if recontaminated (e.g., products that contain > 5 % ethanol)

Competent authorities may define other categories of products for which testing against microbiological criteria are not useful.

Different types of food present different risks from *L. monocytogenes*, hence different microbiological criteria could apply for the following categories of foods:

- (a) ready-to-eat foods in which growth of *L. monocytogenes* will not occur, and
- (b) ready-to-eat foods in which growth of *L. monocytogenes* can occur.

### **3.1 Ready-To-Eat foods in which growth of *L. monocytogenes* will not occur**

Ready-to-eat foods in which growth of *L. monocytogenes* will not occur would be determined based on scientific justification<sup>16</sup>, including the inherent variability of factors controlling *L. monocytogenes* in the

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<sup>14</sup> See: Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

<sup>15</sup> See: Code of Hygienic Practice For Aseptically Processed And Packaged Low-Acid Foods (CAC/RCP 40-1993).

product. Factors such as pH,  $a_w$ , are useful in preventing growth. For example, *L. monocytogenes* growth can be controlled in foods that have:

- a pH below 4.4,
- an  $a_w < 0.92$ ,
- a combination of factors (pH,  $a_w$ ), e.g. the combination of pH < 5.0 with  $a_w < 0.94$ .

Such growth can also be controlled by freezing (during that period when the product remains frozen).

In addition, inhibitors can control the growth of *L. monocytogenes* and synergy may be obtained with other extrinsic and intrinsic factors that would result in no growth.

Demonstration that *L. monocytogenes* will not grow in a ready-to-eat food can be based upon, for example, food characteristics, the study of naturally contaminated food, challenge tests, predictive modelling, information from the scientific literature and risk assessments, historic records or combinations of these. Such studies would generally be conducted by food business operators (or by the appropriate product board, sector organizations or contract laboratories) and must be appropriately designed to validate that *L. monocytogenes* will not grow in a food<sup>17</sup>.

The demonstration that *L. monocytogenes* will not grow in a ready-to-eat food should take into account the measurement error of the quantification method. Therefore, for example, for practical purposes, a food in which growth of *L. monocytogenes* will not occur will not have an observable increase in *L. monocytogenes* levels greater than (on average) 0.5 log CFU/g<sup>18</sup> for at least the expected shelf life as labelled by the manufacturer under reasonably foreseeable conditions of distribution, storage and use, including a safety margin.

For foods intended to be refrigerated, studies to assess whether or not growth of *L. monocytogenes* will occur should be conducted under reasonably foreseeable conditions of distribution, storage and use.

National governments should provide guidance on the specific protocols that should be employed to validate the studies demonstrating that growth of *L. monocytogenes* will not occur in a food during the expected shelf life.

If information is lacking to demonstrate that *L. monocytogenes* will not grow in a ready-to-eat food during its expected shelf life, the food should be treated as a ready-to-eat food in which growth of *L. monocytogenes* can occur.

### 3.2 Ready-to-eat foods in which growth of *L. monocytogenes* can occur

A ready-to-eat food in which there is greater than an average of 0.5 log CFU/g<sup>18</sup> increase in *L. monocytogenes* levels for at least the expected shelf life under reasonably foreseeable conditions of distribution, storage and use is considered a food in which growth of *L. monocytogenes* can occur.

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<sup>16</sup> References that have been addressed for identifying properties of ready-to-eat foods which will categorize them as foods in which growth of *L. monocytogenes* will not occur, or as foods in which growth of the pathogen can occur, include *Microorganisms in Foods 5 – Characteristics of Microbial Pathogens* (ICMSF, 1996) and *Microbiological Risk Assessment Series 4 and 5: Risk assessment of Listeria monocytogenes in ready to eat foods: Interpretative Summary and Technical Report* (FAO/WHO, 2004).

<sup>17</sup> See: Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008).

<sup>18</sup> 0.5 log is two times the estimated standard deviation (i.e. 0.25 log) associated with the experimental enumeration using viable counting/plate counts.

#### 4. MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES* IN READY-TO-EAT FOODS

Microbiological criteria for *L. monocytogenes* in ready-to-eat foods are described.

Another procedure for establishing microbiological criteria for *L. monocytogenes* other than the criteria at specified points in the food chain that are described below, would be through the application of risk-based metrics (e.g., Food Safety Objective (FSO), Performance Objective (PO)) according to the general principles established in the *Annex II: Guidance on Microbiological Risk Management Metrics of the Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

##### 4.1 Microbiological criteria for ready-to-eat foods in which growth of *L. monocytogenes* will not occur

The criterion in Table 1 is intended for foods in which *L. monocytogenes* growth will not occur under the conditions of storage and use that have been established for the product (see Section 3.1).

This criterion is based on the product being produced under application of the provisions of the general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods with appropriate evaluation of the production environment and process control and validation that the product meets the requirements of a food in which growth of *L. monocytogenes* will not occur (see Section 3.1).

If the factors that prevent growth cannot be demonstrated, the product should be evaluated based on criteria for ready-to-eat foods in which growth of *L. monocytogenes* can occur (see Section 4.2).

Another approach can also be used (see Section 4.3).

**Table 1:**

**Microbiological criterion for ready-to-eat foods in which growth of *L. monocytogenes* will not occur**

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	<i>Listeria monocytogenes</i>	5 <sup>a</sup>	0	100 cfu/g <sup>b</sup>	2 <sup>c</sup>

Where n = number of samples that must conform to the criterion; c = the maximum allowable number of defective sample units in a 2-class plan; m = a microbiological limit which, in a 2-class plan, separates acceptable lots from unacceptable lots.

<sup>a</sup> National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

<sup>b</sup> This criterion is based on the use of the ISO 11290-2 method.

Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140).

<sup>c</sup> Assuming a log normal distribution, this sampling plan would provide 95% confidence that a lot of food containing a geometric mean concentration of 93.3 cfu/g and an analytical standard deviation of 0.25 log cfu/g would be detected and rejected based on any of the five samples exceeding 100 cfu/g *L. monocytogenes*. Such a lot may consist of 55% of the samples being below 100 cfu/g and up to 45% of the samples being above 100 cfu/g, whereas 0.002% of all the samples from this lot could be above 1000 cfu/g. The typical actions to be taken where there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption, (2) recall the

product if it has been released for human consumption, and/or (3) determine and correct the root cause of the failure.

#### 4.2 Microbiological criteria for ready-to-eat foods in which growth of *L. monocytogenes* can occur

The criterion in Table 2 is intended for foods in which *L. monocytogenes* growth can occur under the conditions of storage and use that have been established for the product (see Section 3.2).

This criterion is based on the product being produced under application of general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods with appropriate evaluation of the production environment and process control (see Annex III).

The purpose of this criterion is to provide a specified degree of confidence that *L. monocytogenes* will not be present in foods at levels that represent a risk to consumers.

Another approach can also be used (see Section 4.3).

**Table 2:**

#### Microbiological criteria for ready-to-eat foods in which growth of *L. monocytogenes* can occur

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	<i>Listeria monocytogenes</i>	5 <sup>a</sup>	0	Absence in 25 g (< 0.04 cfu/g) <sup>b</sup>	2 <sup>c</sup>

<sup>a</sup> National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

<sup>b</sup> Absence in a 25-g analytical unit. This criterion is based on the use of ISO 11290-1 method. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140).

<sup>c</sup> Assuming a log normal distribution, this sampling plan would provide 95% confidence that a lot of food containing a geometric mean concentration of 0.023 cfu/g and an analytical standard deviation of 0.25 log cfu/g would be detected and rejected if any of the five samples are positive for *L. monocytogenes*. Such a lot may consist of 55% of the 25g samples being negative and up to 45% of the 25 g samples being positive. 0.5 % of this lot could harbour concentrations above 0.1 cfu/g.

The typical actions to be taken where there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption, (2) recall the product if it has been released for human consumption, and/or (3) determine and correct the root cause of the failure.

#### 4.3 Alternative approach

Further to the approaches described in sections 4.1 and 4.2 competent authorities may choose to establish and implement other validated limits for the *L. monocytogenes* concentration at the point of consumption or at other points that provide an acceptable level of consumer protection for foods in which *L. monocytogenes* will not grow as well as foods in which *L. monocytogenes* growth can occur.

Due to the large diversity among ready-to-eat food products in which growth of *L. monocytogenes* can occur, this approach would primarily be applied for specific categories or subcategories of ready-to-eat foods being

produced under application of the provisions of the general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods and that have a limited potential of growth over a specified shelf life.

In establishing such limits for *L. monocytogenes*, the competent authority needs to clearly articulate the types of information required of food business operators to ensure that the hazard is controlled and to verify that these limits are achieved in practice. Information needed by competent authorities should be obtained through validation studies or other sources, and may include

- specification for physicochemical characteristics of the products, such as pH,  $a_w$ , salt content, concentration of preservatives and the type of packaging system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf life<sup>19</sup> including a safety margin, and
- consultations of available scientific literature and research data regarding the growth and survival characteristics of *L. monocytogenes*.

When appropriate on the basis of the above mentioned studies, additional studies should be conducted, which may include:

- predictive mathematical modelling established for the food in question, using critical growth or survival factors for *L. monocytogenes* in the product,
- challenge tests and durability studies to evaluate the growth or survival of *L. monocytogenes* that may be present in the product during the shelf life under reasonably foreseeable conditions of distribution, storage and use including seasonal and regional variations.

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<sup>19</sup> See footnote 2 : Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57–2004).

## **ANNEX III: RECOMMENDATIONS FOR THE USE OF MICROBIOLOGICAL TESTING FOR ENVIRONMENTAL MONITORING AND PROCESS CONTROL VERIFICATION BY COMPETENT AUTHORITIES AS A MEANS OF VERIFYING THE EFFECTIVENESS OF HACCP AND PREREQUISITE PROGRAMS FOR CONTROL OF *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS**

### **Introduction**

These recommendations are for use by competent authorities if they intend to include environmental monitoring and/or process control testing as part of their regulatory activities. It is also anticipated that the annex will provide guidance that the competent authority can provide to industry. The recommendations provide an elaboration of the concepts in Sections 5 and 6 of the main text of this Code.

Guidance within Codex regarding microbiological testing is often restricted to the testing of end products using traditional lot-by-lot testing. However, the guidance provided in the main text of this Code emphasizes the criticality of enhanced control of sanitation, including the appropriate use of environmental monitoring. This is further elaborated in Annex I: *Recommendations for an Environmental Monitoring Program for Listeria monocytogenes in Processing Areas*, which provides recommendations to industry on implementation of environmental monitoring programs. The *Recommended International Code of Practice General Principles of Food Hygiene* (CAC/RCP 1-1969) emphasizes the need to apply control measures in a systematic manner using HACCP or other food safety control systems, including the testing of in-line or finished product samples for process control verification. This annex provides general recommendations on how competent authorities can use microbiological testing to verify the effectiveness of (a) general hygiene programs in the food operation environment and (b) control measures in facilities employing HACCP or other food safety control systems.

The two types of microbiological testing programs described below can be an important part of the ability of competent authorities to verify the effectiveness of *L. monocytogenes* control programs over time (see Section 5.9). In developing these recommendations, no attempt is made to establish specific decision criteria for the two types of microbiological testing or the specific actions that should be taken to re-establish control. Establishment of such specific criteria and actions is more appropriately the responsibility of competent authorities due to the diversity in products and manufacturing technologies.

#### **a) Environmental Monitoring**

In certain instances, competent authorities may incorporate the testing of the environment (food contact and/or non-food contact surfaces) for *L. monocytogenes* (or an appropriate surrogate microorganism (e.g., *Listeria* spp.)), as part of their regulatory requirements or activities. This can include sampling by a competent authority as part of its inspection activities or sampling performed by the individual food business operator that the competent authority can review as part of its verification of the business operator's controls (see Section 5.9). The aim of conducting and/or reviewing environmental testing programs by a competent authority is to verify, for example, that a manufacturer has successfully identified and controlled niches and harbourage sites for *L. monocytogenes* in the food plant and to verify that sanitation programs have been appropriately designed and implemented to control contamination by *L. monocytogenes*.

In developing environmental testing programs and the decision criteria for actions to be taken based on the results obtained, competent authorities should clearly distinguish between sampling of food contact surfaces and non-food contact surfaces. For example, sampling locations for competent authorities may be similar to those used by food business operators (See Annex I). In evaluating facilities that produce multiple products where at least one can support growth of *L. monocytogenes*, competent authorities should consider the importance of environmental sampling as a means of verifying that there is no cross contamination between the products (see Section 5.2.4). In the design of an environmental verification program, the competent authority should articulate the testing and sampling techniques that would be employed, including size, method and frequency of sampling, analytical method to be employed, locations where samples should be

taken, decision criteria, and actions to be taken if a decision criterion is exceeded (similar to recommendations in Annex I).

The competent authority should establish decision criteria that include specific conditions (e.g., specific number of positive samples) that will initiate follow-up actions (including additional testing) when an environmental sample is positive for *L. monocytogenes* or *Listeria* spp. The competent authority should also establish actions that the food business operator should anticipate if the criteria are exceeded. Detection of positive environmental samples by the competent authority exceeding the decision criteria should lead to an investigation by the food business operator and/or the competent authority to identify the source of contamination and action that should be taken by the food business operator to correct the problem. In reporting results of their analyses to food business operators, competent authorities should provide advice on the possible inferences the data provide in order to assist the food business operator in finding and correcting the source of contamination. For example, the competent authority could point out that the repetitive isolation of a specific subtype of *L. monocytogenes* is indicative of a harbourage site that current sanitation activities are insufficient to control.

Overall, sampling techniques and testing methods should be sufficiently sensitive for the decision criteria established and appropriate for the surface or equipment being evaluated. Methods used should be appropriately validated for the recovery of *L. monocytogenes* from environmental samples.

#### **b) Process Control Verification**

Business operators ensure the effectiveness of HACCP and other programs for the control of *L. monocytogenes* in their operating facilities. Further, business operators validate the food safety control systems they have in place. Competent authorities verify that the controls are validated and being implemented as designed, through activities such as monitoring of records and activities of production personnel.

For a well-designed food safety control system, a competent authority may consider establishing microbiological process control testing and decision criteria for products to identify trends that can be corrected before decision criteria are exceeded. When undesirable trends occur or decision criteria are exceeded, the food business operator will investigate the food safety control system to determine the cause and take corrective action(s). The competent authority verifies that appropriate actions are taken when criteria are exceeded. For example, the decision criteria for process control testing could be the frequency of contamination that would be indicative of a process no longer in control and likely to produce ready-to-eat foods that do not meet the microbiological criteria established in Annex II.

In addition to verifying that the process controls within the food safety control system are validated and operating as designed, process control testing of finished product (sometimes referred to as cross-lot or between-lot testing) has been used by business operators and/or competent authorities to detect changing patterns of contamination, which allows distinction between occasional 'in control' positive samples and an emerging loss of control. Process control testing of finished product contributes to the assessment of the continuing performance of a food safety control system and helps to ensure that corrective actions are implemented before microbiological criteria are exceeded. The competent authority verifies that the food safety control system remains 'in control' or ensures that the food business operator has taken corrective actions to prevent loss of control, which could include immediate corrections or changes to the food safety control system itself. The presence of *L. monocytogenes* in finished product can also indicate the lack of control of *L. monocytogenes* in the processing environment.

In certain instances, competent authorities may find it useful to establish an industry-wide process control-based criterion for *L. monocytogenes* for the purpose of ensuring that specific ready-to-eat foods undergo a consistent approach for verification of HACCP or other food safety control systems. This can include sampling by competent authorities as part of their inspection activities or sampling performed by the business operator that the competent authority can review as part of its verification of the food business operator's records.

As with other forms of verification via microbiological testing, the use of process control testing involves the establishment of decision criteria, specification of analytical methods, specification of a sampling plan, and actions to be taken in case of a loss of control. Details of process control testing principles and guidelines are beyond the scope of this annex, but are available through standard references.

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# Foodborne Illness Acquired in the United States—Major Pathogens

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Estimates of foodborne illness can be used to direct food safety policy and interventions. We used data from active and passive surveillance and other sources to estimate that each year 31 major pathogens acquired in the United States caused 9.4 million episodes of foodborne illness (90% credible interval [CrI] 6.6–12.7 million), 55,961 hospitalizations (90% CrI 39,534–75,741), and 1,351 deaths (90% CrI 712–2,268). Most (58%) illnesses were caused by norovirus, followed by nontyphoidal *Salmonella* spp. (11%), *Clostridium perfringens* (10%), and *Campylobacter* spp. (9%). Leading causes of hospitalization were nontyphoidal *Salmonella* spp. (35%), norovirus (26%), *Campylobacter* spp. (15%), and *Toxoplasma gondii* (8%). Leading causes of death were nontyphoidal *Salmonella* spp. (28%), *T. gondii* (24%), *Listeria monocytogenes* (19%), and norovirus (11%). These estimates cannot be compared with prior (1999) estimates to assess trends because different methods were used. Additional data and more refined methods can improve future estimates.

Estimates of the overall number of episodes of foodborne illness are helpful for allocating resources and prioritizing interventions. However, arriving at these estimates is challenging because food may become contaminated by many agents (e.g., a variety of bacteria, viruses, parasites, and chemicals), transmission can occur by nonfood mechanisms (e.g., contact with animals or consumption of contaminated water), the proportion of disease transmitted by food differs by pathogen and by host factors (e.g. age and immunity), and only a small proportion of illnesses are confirmed by laboratory testing and reported to public health agencies.

Laboratory-based surveillance provides crucial information for assessing foodborne disease trends. However,

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because only a small proportion of illnesses are diagnosed and reported, periodic assessments of total episodes of illness are also needed. (Hereafter, episodes of illness are referred to as illnesses.) Several countries have conducted prospective population-based or cross-sectional studies to supplement surveillance and estimate the overall number of foodborne illnesses (1). In 2007, the World Health Organization launched an initiative to estimate the global burden of foodborne diseases (2).

In 1999, the Centers for Disease Control and Prevention provided comprehensive estimates of foodborne illnesses, hospitalizations, and deaths in the United States caused by known and unknown agents (3). This effort identified many data gaps and methodologic limitations. Since then, new data and methods have become available. This article is 1 of 2 reporting new estimates of foodborne diseases acquired in the United States (hereafter referred to as domestically acquired). This article provides estimates of major known pathogens; the other provides estimates for agents of acute gastroenteritis not specified in this article (4).

## Methods

Adequate data for preparing national estimates were available for 31 pathogens. We estimated the number of foodborne illnesses, hospitalizations, and deaths caused by these 31 domestically acquired pathogens by using data shown in the online Appendix Table ([www.cdc.gov/EID/content/17/1/7-appT.htm](http://www.cdc.gov/EID/content/17/1/7-appT.htm)) and online Technical Appendix 1 ([www.cdc.gov/EID/content/17/1/7-Techapp1.pdf](http://www.cdc.gov/EID/content/17/1/7-Techapp1.pdf)).

Data were mostly from 2000–2008, and all estimates were based on the US population in 2006 (299 million persons). Estimates were derived from statistical models with many inputs, each with some measure of uncertainty (5). To reflect this uncertainty, we used probability distributions to describe a range of plausible values for all model

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inputs. We expressed model outputs as probability distributions summarized by a mean point estimate with 90% credible intervals (CrIs). We used 2 types of modeling approaches for different types of data: 1) models that began with counts of laboratory-confirmed illnesses and were adjusted for undercounts (because of underreporting and underdiagnosis) and thus scaled up to the estimated number of illnesses and 2) models that began with a US population and used incidence data to scale down to the estimated number of illnesses (Table 1). The modeling approaches used and parameters of these probability distributions are detailed in online Technical Appendixes 2 and 3 ([www.cdc.gov/EID/content/17/1/7-Techapp2.pdf](http://www.cdc.gov/EID/content/17/1/7-Techapp2.pdf) and [www.cdc.gov/EID/content/17/1/7-Techapp3.pdf](http://www.cdc.gov/EID/content/17/1/7-Techapp3.pdf), respectively); the proportions cited are modal values.

### Illnesses

Laboratory-based surveillance data were available for 25 pathogens (online Appendix Table). The following events must occur for an illness to be ascertained and included in laboratory-based surveillance: the ill person must seek medical care, a specimen must be submitted for laboratory testing, the laboratory must test for and identify the causative agent, and the illness must be reported to public health authorities. If a break occurs in any of the first 3 steps of this surveillance chain, the causative agent will not be laboratory confirmed (underdiagnosis). Furthermore, although all laboratory-confirmed illnesses are reported by active surveillance, some will not be reported by passive surveillance (underreporting). Therefore, to estimate the number of illnesses caused by pathogens under public health surveillance, we determined the number of laboratory-confirmed illnesses and adjusted for underdiagnosis and, if necessary, for underreporting by using a series of component multipliers.

Laboratory-confirmed illnesses for these 25 pathogens were reported through 5 surveillance programs: the Foodborne Diseases Active Surveillance Network (Food-

Net) for *Campylobacter* spp., *Cryptosporidium* spp., *Cyclospora cayetanensis*, Shiga toxin-producing *Escherichia coli* (STEC) O157, STEC non-O157, *Listeria monocytogenes*, nontyphoidal *Salmonella* spp., *Salmonella enterica* serotype Typhi, *Shigella* spp., and *Yersinia enterocolitica*; the National Notifiable Diseases Surveillance System (NNDSS) for *Brucella* spp., *Clostridium botulinum*, *Trichinella* spp., hepatitis A virus, and *Giardia intestinalis*; the Cholera and Other *Vibrio* Illness Surveillance (COVIS) system for toxigenic *Vibrio cholerae*, *V. vulnificus*, *V. parahaemolyticus*, and other *Vibrio* spp.; the National Tuberculosis Surveillance System (NTSS) for *Mycobacterium bovis*; and the Foodborne Disease Outbreak Surveillance System (FDOSS) for *Bacillus cereus*, *Clostridium perfringens*, enterotoxigenic *E. coli* (ETEC), *Staphylococcus aureus*, and *Streptococcus* spp. group A (online Appendix Table; online Technical Appendix 1). When data were available from >1 surveillance system, we used active surveillance data from FoodNet, except for *Vibrio* spp., for which we used COVIS because of geographic clustering of *Vibrio* spp. infections outside FoodNet sites. We used data on outbreak-associated illnesses from FDOSS only for pathogens for which no data were available from other systems.

Because FoodNet conducts surveillance at 10 sites (6), we estimated the number of laboratory-confirmed illnesses in the United States by applying incidence from FoodNet to the estimated US population for 2006 (7). We constructed a probability distribution based on extrapolation of rates by year (2005–2008) in each FoodNet site (online Technical Appendix 3). We used data from 2005–2008 because the FoodNet surveillance area was constant during that period and because FoodNet began collecting information on foreign travel in 2004. We used data from 2000–2007 for NNDSS, COVIS, and FDOSS and annual counts of reported illnesses for our probability distributions. Some evidence of trend was found for illness caused by hepatitis A virus, *S. aureus*, and *Vibrio* spp.; therefore, recent years were weighted more heavily (online Technical Appendixes

Table 1. Modeling approaches used to estimate the total number of illnesses for different types of data, United States\*

Pathogens for which laboratory-confirmed illnesses were scaled up			Pathogens for which US population was scaled down
Active surveillance data	Passive surveillance data	Outbreak surveillance data	
<i>Campylobacter</i> spp.	<i>Brucella</i> spp.	<i>Bacillus cereus</i>	Astrovirus
<i>Cryptosporidium</i> spp.	<i>Clostridium botulinum</i>	<i>Clostridium perfringens</i>	Norovirus
<i>Cyclospora cayetanensis</i>	<i>Giardia intestinalis</i>	ETEC†	Rotavirus
STEC O157	Hepatitis A virus	<i>Staphylococcus aureus</i>	Sapovirus
STEC non-O157	<i>Mycobacterium bovis</i>	<i>Streptococcus</i> spp. group A	<i>Toxoplasma gondii</i>
<i>Listeria monocytogenes</i>	<i>Trichinella</i> spp.		
<i>Salmonella</i> spp., nontyphoidal‡	<i>Vibrio cholera</i> , toxigenic		
<i>S. enterica</i> serotype Typhi	<i>Vibrio parahaemolyticus</i>		
<i>Shigella</i> spp.	<i>Vibrio vulnificus</i>		
<i>Yersinia enterocolitica</i>	<i>Vibrio</i> spp., other		

\*ETEC, enterotoxigenic *Escherichia coli*; STEC, Shiga toxin-producing *E. coli*.

†Numbers of *E. coli* other than STEC or ETEC assumed to be same as for ETEC.

‡Includes all serotypes other than Typhi.

2, 3). NTSS was used to determine the number of reported illnesses caused by *M. bovis* during 2004–2007.

We assumed that all laboratory-confirmed illnesses were reported to FoodNet active surveillance in the relevant catchment areas. Because COVIS and NNDSS conduct passive surveillance, we applied an underreporting multiplier (1.1 for bacteria and 1.3 for parasites) derived by comparing incidence of all nationally notifiable illnesses ascertained through FoodNet with that reported to NNDSS (online Technical Appendix 4, [www.cdc.gov/EID/content/17/1/7-Techapp4.pdf](http://www.cdc.gov/EID/content/17/1/7-Techapp4.pdf)). For the 5 bacteria for which only outbreak data were available, we estimated the number of laboratory-confirmed illnesses by creating an underreporting multiplier as follows. We determined the proportion of illnesses ascertained through FoodNet that were caused by *Campylobacter* spp., *Cryptosporidium* spp., *C. cayatanensis*, *L. monocytogenes*, *Salmonella* spp., *Shigella* spp., STEC, *Vibrio* spp., and *Y. enterocolitica* that were also reported to FDOSS as outbreak associated and applied the inverse of this proportion, 25.5, to those pathogens (online Technical Appendix 4). We assumed that all illnesses caused by *M. bovis* were reported to NTSS.

To adjust for underdiagnosis resulting from variations in medical care seeking, specimen submission, laboratory testing, and test sensitivity, we created pathogen-specific multipliers. To adjust for medical care seeking and specimen submission, we pooled data from FoodNet Population Surveys in 2000–2001, 2002–2003 (8), and 2006–2007 (Centers for Disease Control and Prevention, unpub. data) from which we estimated the proportion of persons who in the past month reported an acute diarrheal illness ( $\geq 3$  loose stools in 24 hours lasting  $>1$  day or resulting in restricted daily activities) and sought medical care and submitted a stool sample for that illness. Because persons with more severe illness are more likely to seek care (9), we estimated pathogen-specific proportions of persons with laboratory-confirmed infections who had severe illness (e.g., bloody diarrhea) and used medical care seeking and stool sample submission rates for bloody (35% and 36%, respectively) and nonbloody (18% and 19%, respectively) diarrhea as surrogates for severe and mild cases of most illnesses (online Technical Appendix 3). However, for infections with *L. monocytogenes*, *M. bovis*, and *V. vulnificus* and severe infections with hepatitis A virus, we assumed high rates of medical care seeking (i.e., we assumed that 100% of persons with *M. bovis* infection and 90% with *L. monocytogenes*, *V. vulnificus*, or severe hepatitis A virus infections sought care) and specimen submission (100% for hepatitis A virus and *M. bovis*, 80% for others). We accounted for percentage of laboratories that routinely tested for specific pathogens (25%–100%) and test sensitivity (28%–100%) by using data from FoodNet

(10,11) and other surveys of clinical diagnostic laboratory practices (online Technical Appendix 3). For the 5 pathogens for which data were from outbreaks only, we used the nontyphoidal *Salmonella* spp. underdiagnosis multiplier.

Alternative approaches were used for infections not routinely reported by any surveillance system (i.e., diarrheagenic *E. coli* other than STEC and ETEC, *T. gondii*, astrovirus, rotavirus, sapovirus, and norovirus) (online Technical Appendixes 1–3). We assumed diarrheagenic *E. coli* other than STEC and ETEC to be as common as ETEC. Illnesses caused by *T. gondii* were estimated by using nationally representative serologic data from the 1999–2004 National Health and Nutrition Examination Survey (12) and an estimate that clinical illness develops in 15% of persons who seroconvert (13). We assumed that 75% of children experience an episode of clinical rotavirus illness by 5 years of age, consistent with findings from other studies (14), and used this estimate for astrovirus and sapovirus. We estimated norovirus illnesses by applying mean proportion of all acute gastroenteritis caused by norovirus (11%) according to studies in other industrialized countries (15–18) to estimates of acute gastroenteritis from FoodNet Population Surveys (online Appendix Table; online Technical Appendixes 1–3) (4).

### Hospitalizations and Deaths

For most pathogens, numbers of hospitalizations and deaths were estimated by determining (from surveillance data) the proportion of persons who were hospitalized and the proportion who died and applying these proportions to the estimated number of laboratory-confirmed illnesses (online Appendix Table; online Technical Appendixes 1, 3). Rates of hospitalization and death caused by *G. intestinalis* and *T. gondii* were based on the 2000–2006 Nationwide Inpatient Sample. Because some persons with illnesses that were not laboratory confirmed would also have been hospitalized and died, we doubled the number of hospitalizations and deaths to adjust for underdiagnosis, similar to the method used by Mead et al. (3) but applied an uncertainty distribution (online Technical Appendix 3). For diarrheagenic *E. coli* other than STEC and ETEC, total numbers of hospitalizations and deaths were assumed to be the same as those for ETEC. For rotavirus, we used previous estimates (14). For astrovirus and sapovirus, we assumed that the number was 25% that of rotavirus (19,20). Numbers of norovirus hospitalizations and deaths were determined by multiplying the estimated number of hospitalizations and deaths caused by acute gastroenteritis, estimated by using national data on outpatient visits resulting in hospitalization, hospital discharge surveys, and death certificates (online Appendix Table; online Technical Appendixes 1–3)

(4), by the same norovirus proportion (11%) used to estimate illnesses (15–18).

### Domestically Acquired Foodborne Illnesses

Data from published studies and surveillance were used to determine, for each pathogen, the proportion of illnesses acquired while the person had been traveling outside the United States (online Technical Appendixes 1, 3). The remaining proportion was considered domestically acquired. We based our estimates of the proportion of domestically acquired foodborne illnesses caused by each pathogen on data from surveillance, risk factor studies, and a literature review (online Technical Appendixes 1, 3).

### Uncertainty Analysis

We used empirical data, when available, to define entire distributions or parameters of distributions (online Technical Appendix 3). When data were sparse, we made reasoned judgments based on context, plausibility, and previously published estimates. The parametric distribution used for almost all multipliers was a 4-parameter beta (modified PERT) distribution (21). The first 3 parameters are low, modal, and high. The fourth parameter is related to the variability of the distribution. We typically fixed this last parameter at 4, which yields the simple PERT distribution (21). However, when describing the outbreak reporting multiplier, we used a value of 20 (online Technical Appendix 4).

Uncertainty in the estimates is the cumulative effect of uncertainty of each of the model inputs. We iteratively generated sets of independent pathogen-specific adjustment factors and used these multipliers to estimate illnesses, hospitalizations, and deaths (Figure; online Technical Appendix 2). On the basis of 100,000 iterations, we obtained empirical distributions of counts corresponding to Bayesian posterior distributions and used these posterior distributions to generate a point estimate (posterior mean) and upper and lower 5% limits for 90% CrIs. Because incidence of illnesses differed by location and over time,

we included these variations in the models, which led to wider CrIs than if we had assumed that inputs represented independent random samples of a fixed US population. We used SAS version 9.2 (SAS Institute, Cary, NC, USA) for these analyses.

## Results

### Foodborne Illnesses

We estimate that each year in the United States, 31 pathogens caused 37.2 million (90% CrI 28.4–47.6 million) illnesses, of which 36.4 million (90% CrI 27.7–46.7 million) were domestically acquired; of these, 9.4 million (90% CrI 6.6–12.7 million) were foodborne (Table 2; expanded version available online, [www.cdc.gov/EID/content/17/1/7-T2.htm](http://www.cdc.gov/EID/content/17/1/7-T2.htm)). We estimate that 5.5 million (59%) foodborne illnesses were caused by viruses, 3.6 million (39%) by bacteria, and 0.2 million (2%) by parasites. The pathogens that caused the most illnesses were norovirus (5.5 million, 58%), nontyphoidal *Salmonella* spp. (1.0 million, 11%), *C. perfringens* (1.0 million, 10%), and *Campylobacter* spp. (0.8 million, 9%).

### Hospitalizations

We estimate that these 31 pathogens caused 228,744 (90% CrI 188,326–275,601) hospitalizations annually, of which 55,961 (90% CrI 39,534–75,741) were caused by contaminated food eaten in the United States (Table 3; expanded version available online, [www.cdc.gov/EID/content/17/1/7-T3.htm](http://www.cdc.gov/EID/content/17/1/7-T3.htm)). Of these, 64% were caused by bacteria, 27% by viruses, and 9% by parasites. The leading causes of hospitalization were nontyphoidal *Salmonella* spp. (35%), norovirus (26%), *Campylobacter* spp. (15%), and *T. gondii* (8%).

### Deaths

We estimate that these 31 pathogens caused 2,612 deaths (90% CrI 1,723–3,819), of which 1,351 (90% CrI

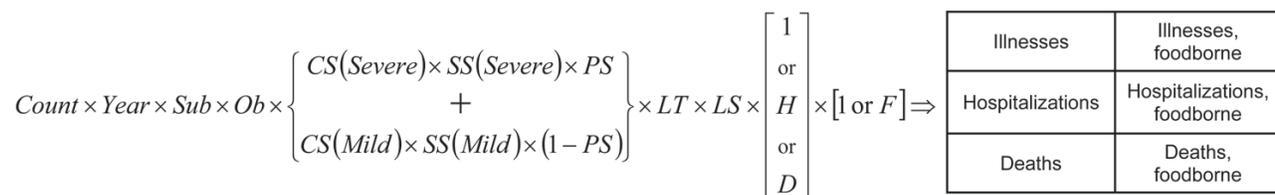


Figure. Example schematic diagram of the estimation and uncertainty model used to estimate episodes of illness, hospitalizations, and deaths in the United States. *Count*, data (empirical distribution); *Year*, factor to standardize non-2006 counts to 2006 (constant); *Sub*, expansive factor to scale area surveillance to the entire US population (constant); *Ob*, expansive factor to scale outbreak counts up to outbreak plus sporadic counts (beta distribution); *CS*, expansive factor to scale care seekers to all ill, with severe and mild illness versions (PERT distribution); *SS*, expansive factor to scale submitted samples to all visits, with severe and mild illness versions (PERT distribution); *PS*, estimated proportion of illnesses that are severe (PERT distribution); *LT*, expansive factor to scale tests performed up to samples submitted (PERT distribution); *LS*, expansive factor to scale positive test results up to true positive specimens (PERT distribution); *H*, contractive factor to scale illnesses down to hospitalized illnesses (PERT distribution); *D*, contractive factor to scale illnesses down to deaths (PERT distribution); *F*, contractive factor to scale illnesses down to foodborne illnesses (PERT distribution).

712–2,268) were caused by contaminated food eaten in the United States (Table 3). Of these, 64% were caused by bacteria, 25% by parasites, and 12% by viruses. The leading causes of death were nontyphoidal *Salmonella* spp. (28%), *T. gondii* (24%), *L. monocytogenes* (19%), and norovirus (11%).

Table 2. Estimated annual number of episodes of domestically acquired foodborne illnesses caused by 31 pathogens, United States\*

Pathogen	Laboratory confirmed	Multipliers		Travel related, %	Foodborne, %†	Domestically acquired foodborne, mean (90% credible interval)
		Under-reporting	Under-diagnosis			
<b>Bacteria</b>						
<i>Bacillus cereus</i> , foodborne	85‡	25.5	29.3	<1	100	63,400 (15,719–147,354)
<i>Brucella</i> spp.	120§	1.1	15.2	16	50	839 (533–1,262)
<i>Campylobacter</i> spp.	43,696¶	1.0	30.3	20	80	845,024 (337,031–1,611,083)
<i>Clostridium botulinum</i> , foodborne	25§	1.1	2.0	<1	100	55 (34–91)
<i>Clostridium perfringens</i> , foodborne	1,295‡	25.5	29.3	<1	100	965,958 (192,316–2,483,309)
STEC O157	3,704¶	1.0	26.1	4	68	63,153 (17,587–149,631)
STEC non-O157	1,579¶	1.0	106.8	18	82	112,752 (11,467–287,321)
ETEC, foodborne	53‡	25.5	29.3	55	100	17,894 (24–46,212)
Diarrheagenic <i>E. coli</i> other than STEC and ETEC	53	25.5	29.3	<1	30	11,982 (16–30,913)
<i>Listeria monocytogenes</i>	808¶	1.0	2.1	3	99	1,591 (557–3,161)
<i>Mycobacterium bovis</i>	195¶	1.0	1.1	70	95	60 (46–74)
<i>Salmonella</i> spp., nontyphoidal	41,930¶	1.0	29.3	11	94	1,027,561 (644,786–1,679,667)
<i>S. enterica</i> serotype Typhi	433¶	1.0	13.3	67	96	1,821 (87–5,522)
<i>Shigella</i> spp.	14,864¶	1.0	33.3	15	31	131,254 (24,511–374,789)
<i>Staphylococcus aureus</i> , foodborne	323‡	25.5	29.3	<1	100	241,148 (72,341–529,417)
<i>Streptococcus</i> spp. group A, foodborne	15‡	25.5	29.3	<1	100	11,217 (15–77,875)
<i>Vibrio cholerae</i> , toxigenic	8§	1.1	33.1	70	100	84 (19–213)
<i>V. vulnificus</i>	111§	1.1	1.7	2	47	96 (60–139)
<i>V. parahaemolyticus</i>	287§	1.1	142.4	10	86	34,664 (18,260–58,027)
<i>Vibrio</i> spp., other	220§	1.1	142.7	11	57	17,564 (10,848–26,475)
<i>Yersinia enterocolitica</i>	950¶	1.0	122.8	7	90	97,656 (30,388–172,734)
<b>Subtotal</b>						<b>3,645,773 (2,321,468–5,581,290)</b>
<b>Parasites</b>						
<i>Cryptosporidium</i> spp.	7,594¶	1.0	98.6	9	8	57,616 (12,060–166,771)
<i>Cyclospora cayetanensis</i>	239¶	1.0	83.1	42	99	11,407 (137–37,673)
<i>Giardia intestinalis</i>	20,305§	1.3	46.3	8	7	76,840 (51,148–109,739)
<i>Toxoplasma gondii</i>		1.0	0.0	<1	50	86,686 (64,861–111,912)
<i>Trichinella</i> spp.	13§	1.3	9.8	4	100	156 (42–341)
<b>Subtotal</b>						<b>232,705 (161,923–369,893)</b>
<b>Viruses</b>						
Astrovirus	NA	NA	NA	0	<1	15,433 (5,569–26,643)
Hepatitis A virus	3,576§	1.1	9.1	41	7	1,566 (702–3,024)
Norovirus	NA	NA	NA	<1	26	5,461,731 (3,227,078–8,309,480)
Rotavirus	NA	NA	NA	0	<1	15,433 (5,569–26,643)
Sapovirus	NA	NA	NA	0	<1	15,433 (5,569–26,643)
<b>Subtotal</b>						<b>5,509,597 (3,273,623–8,355,568)</b>
<b>Total</b>						<b>9,388,075 (6,641,440–12,745,709)</b>

\*All estimates based on US population in 2006. Modal or mean value shown unless otherwise stated; see online Technical Appendix 3 ([www.cdc.gov/EID/content/17/1/7-Techapp3.pdf](http://www.cdc.gov/EID/content/17/1/7-Techapp3.pdf)) for the parameters of these distributions. STEC, Shiga toxin-producing *Escherichia coli*; ETEC, enterotoxigenic *E. coli*; NA, not applicable. An expanded version of this table is available online ([www.cdc.gov/EID/content/17/1/7-T2.htm](http://www.cdc.gov/EID/content/17/1/7-T2.htm)).

†Percentage foodborne among domestically acquired illnesses.

‡Passive surveillance data on outbreak-associated illnesses from the Foodborne Disease Outbreak Surveillance System. Estimates based on the number of foodborne illnesses ascertained in surveillance and therefore assumed to reflect only foodborne transmission.

§Passive surveillance data from Cholera and Other *Vibrio* Illness Surveillance or the National Notifiable Disease Surveillance System.

¶Active surveillance data from Foodborne Diseases Active Surveillance Network, adjusted for geographic coverage; data from the National Tuberculosis Surveillance System for *M. bovis*.

## Discussion

We estimate that foods consumed in the United States that were contaminated with 31 known agents of foodborne disease caused 9.4 million illnesses, 55,961 hospitalizations, and 1,351 deaths each year. Norovirus caused the most illnesses; nontyphoidal *Salmonella* spp., norovirus, *Campylobacter* spp., and *T. gondii* caused the most hospitalizations; and nontyphoidal *Salmonella* spp., *T. gondii*, *L. monocytogenes*, and norovirus caused the most deaths. Scarce data precluded estimates for other known infectious

and noninfectious agents, such as chemicals. Foodborne diseases are also caused by agents not yet recognized as being transmitted in food and by unknown agents (22). The numbers of illnesses caused by these unspecified agents are estimated elsewhere (4).

Studies estimating the overall number of foodborne illnesses have been conducted in England and Wales and in Australia (23,24). Similar to our findings, in Australia norovirus was the leading cause of foodborne illness, accounting for 30% of illnesses caused by known pathogens.

Table 3. Estimated annual number of domestically acquired foodborne hospitalizations and deaths caused by 31 pathogens, United States\*

Pathogen	Hospitalization rate, %†	Hospitalizations, mean (90% credible interval)	Death rate, %†	Deaths, mean (90% credible interval)
<b>Bacteria</b>				
<i>Bacillus cereus</i> , foodborne‡	0.4	20 (0–85)	0	0
<i>Brucella</i> spp.	55.0	55 (33–84)	0.9	1 (0–2)
<i>Campylobacter</i> spp.	17.1	8,463 (4,300–15,227)	0.1	76 (0–332)
<i>Clostridium botulinum</i> , foodborne‡	82.6	42 (19–77)	17.3	9 (0–51)
<i>Clostridium perfringens</i> , foodborne‡	0.6	438 (44–2,008)	<0.1	26 (0–163)
STEC O157	46.2	2,138 (549–4,614)	0.5	20 (0–113)
STEC non-O157	12.8	271 (0–971)	0.3	0 (0–0)§
ETEC, foodborne	0.8	12 (0–53)	0	0
Diarrheagenic <i>E. coli</i> other than STEC and ETEC	0.8	8 (0–36)	0	0
<i>Listeria monocytogenes</i>	94.0	1,455 (521–3,018)	15.9	255 (0–733)
<i>Mycobacterium bovis</i>	55.0	31 (21–42)	4.7	3 (2–3)
<i>Salmonella</i> spp., nontyphoidal	27.2	19,336 (8,545–37,490)	0.5	378 (0–1,011)
<i>S. enterica</i> serotype Typhi	75.7	197 (0–583)	0	0
<i>Shigella</i> spp.	20.2	1,456 (287–3,695)	0.1	10 (0–67)
<i>Staphylococcus aureus</i> , foodborne‡	6.4	1,064 (173–2,997)	<0.1	6 (0–48)
<i>Streptococcus</i> spp. group A, foodborne‡	0.2	1 (0–6)	0	0
<i>Vibrio cholerae</i> , toxigenic	43.1	2 (0–5)	0	0
<i>V. vulnificus</i>	91.3	93 (53–145)	34.8	36 (19–57)
<i>V. parahaemolyticus</i>	22.5	100 (50–169)	0.9	4 (0–17)
<i>Vibrio</i> spp., other	37.1	83 (51–124)	3.7	8 (3–19)
<i>Yersinia enterocolitica</i>	34.4	533 (0–1,173)	2.0	29 (0–173)
<b>Subtotal</b>		<b>35,796 (21,519–53,414)</b>		<b>861 (260–1,761)</b>
<b>Parasites</b>				
<i>Cryptosporidium</i> spp.	25.0	210 (58–518)	0.3	4 (0–19)
<i>Cyclospora cayetanensis</i>	6.5	11 (0–109)	0.0	0
<i>Giardia intestinalis</i>	8.8	225 (141–325)	0.1	2 (1–3)
<i>Toxoplasma gondii</i>	2.6	4,428 (2,634–6,674)	0.2	327 (200–482)
<i>Trichinella</i> spp.	24.3	6 (0–17)	0.2	0 (0–0)
<b>Subtotal</b>		<b>4,881 (3,060–7,146)</b>		<b>333 (205–488)</b>
<b>Viruses</b>				
Astrovirus	0.4	87 (32–147)	<0.1	0
Hepatitis A virus	31.5	99 (42–193)	2.4	7 (3–15)
Norovirus	0.03	14,663 (8,097–23,323)	<0.1	149 (84–237)
Rotavirus	1.7	348 (128–586)	<0.1	0
Sapovirus	0.4	87 (32–147)	<0.1	0
<b>Subtotal</b>		<b>15,284 (8,719–23,962)</b>		<b>157 (91–245)</b>
<b>Total</b>		<b>55,961 (39,534–75,741)</b>		<b>1,351 (712–2,268)</b>

\*All estimates were based on US population in 2006. STEC, Shiga toxin-producing *Escherichia coli*; ETEC, enterotoxigenic *E. coli*. An expanded version of this table is available online ([www.cdc.gov/EID/content/17/1/7-T3.htm](http://www.cdc.gov/EID/content/17/1/7-T3.htm)).

†For laboratory-confirmed illnesses. Unadjusted hospitalization and death rates are presented here. These rates were doubled to adjust for underdiagnosis before being applied to the number of laboratory-confirmed cases to estimate the total number of hospitalizations and deaths. The hospitalization and death rates for astrovirus, norovirus, rotavirus, and sapovirus presented here are the percentage of total estimated illness and were not subject to further adjustment.

‡Estimates based on the number of foodborne illnesses ascertained in surveillance, therefore assumed to reflect only foodborne transmission.

§We report median values instead of means for the distributions of deaths caused by STEC non-O157 because of extremely skewed data.

In England and Wales, norovirus accounted for only 8% of known foodborne illnesses; however, stool sample reexamination using molecular techniques documented higher rates (18). Nontyphoidal *Salmonella* spp. and *Campylobacter* spp. were leading causes of foodborne illnesses in all 3 countries (England and Wales, Australia, and the United States), although nontyphoidal *Salmonella* spp. accounted for a greater proportion of illness in the United States. Recent serologic data from Europe suggest that *Salmonella* spp. infections are more common than estimated by our methods; however, many infections may be asymptomatic (25). Our estimates did not capture mild illnesses associated with some pathogens. For example, mild cases of botulism are often recognized as part of outbreaks, but affected persons seldom seek medical care and are not captured by surveillance except during outbreaks (26,27). Likewise, *L. monocytogenes* is rarely diagnosed as the cause of gastroenteritis and fever, partly because this organism is not detected by routine stool culture (28). Early spontaneous abortion or miscarriage associated with listeriosis may also be underdiagnosed.

Accurately estimating hospitalizations and deaths caused by foodborne pathogens is particularly challenging. National data on outpatient visits resulting in hospitalization, hospital discharges, and death certificates probably substantially underestimate pathogen-specific cases because for pathogen-specific diagnoses to be recorded, health care providers must order the appropriate diagnostic tests and coding must be accurate. Particularly in vulnerable populations, dehydration or electrolyte imbalance from a gastrointestinal illness may exacerbate a chronic illness, resulting in hospitalization or death well after resolution of the gastrointestinal illness; thus, the gastrointestinal illness may not be coded as a contributing factor. Moreover, if a pathogen is not detected, infections may be coded as non-infectious illnesses (29). For norovirus, we estimated the number of hospitalizations and deaths by applying the estimated proportion of acute gastroenteritis illnesses caused by norovirus to overall estimates of hospitalizations and deaths from acute gastroenteritis; this choice is supported by studies of hospitalizations for norovirus (30,31). For most other pathogens, we used data from surveillance to estimate pathogen-specific hospitalizations and deaths and doubled the numbers to adjust for underdiagnosis. More precise information about the degree of undercounting of hospitalizations and deaths for each pathogen would improve these estimates.

Our methods and data differed from those used for the 1999 estimates (3). Our estimate of medical care seeking among persons with a diarrheal illness, derived from the 3 most recent FoodNet Population Surveys conducted during 2000–2007, was higher than that estimated from the 1996–1997 FoodNet Population Survey used for the

1999 estimates (35% and 18% among persons reporting bloody and nonbloody diarrhea, respectively, compared with 15% and 12% in the earlier [1999] study) (8). These data resulted in lower underdiagnosis multipliers, which contributed to lower estimates of number of illnesses. The biggest change from the earlier estimate was the estimated number of norovirus illnesses, which decreased for 2 reasons. First, the number of acute gastrointestinal illnesses estimated from the FoodNet Population Survey and used in the current study was lower than the estimated number of acute gastrointestinal illnesses used in the 1999 assessment. The earlier study used data from 1996–1997; the sample size was one fifth as large as ours and incorporated data from US studies conducted before 1980 (32,33). Both estimates excluded persons reporting concurrent cough or sore throat, but the proportion of persons reporting these signs and symptoms was higher in the FoodNet Population Surveys we used than that in the older US studies (38% vs. 25%), contributing to a lower estimated prevalence of acute gastroenteritis (0.60 vs. 0.79 episodes/person/year) (4,32,33). Additionally, the current study excluded persons with vomiting who were ill for <1 day or whose illness did not result in restricted daily activities, whereas the earlier study included all vomiting episodes. These factors contributed to the new estimate of acute gastroenteritis being 24% lower than the earlier estimate, more likely the result of increased accuracy than a true decrease in illnesses (4). Second, the lower current estimate for norovirus illnesses resulted from a lower proportion of norovirus estimated to be foodborne (decreased from 40% to 26%); this lower proportion is similar to that estimated in recent studies from other countries (23,24). Because of these reasons and use of other data sources and methods, our estimate cannot be compared with the 1999 estimate for the purpose of assessing trends. FoodNet provides the best data on trends over time (34).

Data used in the current study came from a variety of sources and were of variable quality and representativeness. FoodNet sites, from which we used data for 10 pathogens, are not completely representative of the US population, but 1 study indicated that demographic data from FoodNet and from the 2005 US census did not differ much (6). For 5 pathogens, only data on foodborne outbreak-related cases were available. No routine surveillance data were available for most viruses, forcing us to use a different modeling approach for viruses than for most other pathogens. Given the large number of norovirus illnesses in these estimates, the paucity of supporting data is a major limitation. Moreover, combining different methods is not optimal because methods themselves may affect the estimates. We chose our modeling approach and used the PERT distribution for many inputs because data were sometimes limited and subjective decisions were required. Other investigators could

have chosen other distributions, for good reasons, and arrived at different estimates.

Our assumptions about the proportion of illnesses transmitted by food profoundly affect our estimates, but data on which to base these estimates were often lacking. We used data from surveillance, risk factor studies, and the current literature to estimate the proportion of pathogen-specific illnesses caused by consumption of contaminated food (35), but it is not known how representative these data are of total illnesses and whether the foodborne proportion is similar across age groups. For example, the proportion of some illnesses acquired from animals (e.g., STEC O157) may be higher among children than adults (36), and the proportions that spread person-to-person (e.g., norovirus) may be higher among institutionalized elderly persons (37). Because a higher proportion of cases are reportedly associated with hospitalization or death in these vulnerable groups, we may have overestimated the total contribution of foodborne transmission for these outcomes.

The methods used for this study could be adapted to estimate the proportion of illnesses attributable to other modes of transmission, such as waterborne and direct animal contact. The estimates from this study can be used to help direct policy and interventions; to conduct other analyses (e.g., evaluation of economic cost of these diseases and attribution to various food commodities); and as a platform for developing estimates of effects of disease caused by sequelae of foodborne infections.

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# ***Listeria monocytogenes* Dose Response Revisited—Incorporating Adjustments for Variability in Strain Virulence and Host Susceptibility**

**Régis Pouillot\*, Karin Hoelzer, Yuhuan Chen, and Sherri B. Dennis**

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Evaluations of *Listeria monocytogenes* dose-response relationships are crucially important for risk assessment and risk management, but are complicated by considerable variability across population subgroups and *L. monocytogenes* strains. Despite difficulties associated with the collection of adequate data from outbreak investigations or sporadic cases, the limitations of currently available animal models, and the inability to conduct human volunteer studies, some of the available data now allow refinements of the well-established exponential *L. monocytogenes* dose response to more adequately represent extremely susceptible population subgroups and highly virulent *L. monocytogenes* strains. Here, a model incorporating adjustments for variability in *L. monocytogenes* strain virulence and host susceptibility was derived for 11 population subgroups with similar underlying comorbidities using data from multiple sources, including human surveillance and food survey data. In light of the unique inherent properties of *L. monocytogenes* dose response, a lognormal-Poisson dose-response model was chosen, and proved able to reconcile dose-response relationships developed based on surveillance data with outbreak data. This model was compared to a classical beta-Poisson dose-response model, which was insufficiently flexible for modeling the specific case of *L. monocytogenes* dose-response relationships, especially in outbreak situations. Overall, the modeling results suggest that most listeriosis cases are linked to the ingestion of food contaminated with medium to high concentrations of *L. monocytogenes*. While additional data are needed to refine the derived model and to better characterize and quantify the variability in *L. monocytogenes* strain virulence and individual host susceptibility, the framework derived here represents a promising approach to more adequately characterize the risk of listeriosis in highly susceptible population subgroups.

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**KEY WORDS:** Dose response; *Listeria monocytogenes*; risk assessment

## **1. INTRODUCTION**

*Listeria monocytogenes* is one of the leading causes of hospitalization, fetal loss, and death due to foodborne illnesses in the United States.<sup>(1)</sup> Derivations of *L. monocytogenes* dose-response relationships, though crucially important for risk assessment and risk management, are impaired by the difficul-

ties of collecting adequate data from outbreak investigations or sporadic cases, by the lack of appropriate animal models, and by the inability to use volunteer studies due to ethical and practical concerns.<sup>(2,3)</sup>

Two well-accepted *L. monocytogenes* dose-response models have been developed by U.S. agencies<sup>(4)</sup> and an international expert panel,<sup>(5)</sup> both scaled to epidemiological data. In 2003, the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services and the Food Safety and Inspection Service (FSIS) of the U.S.

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Department of Agriculture published a joint risk assessment for *L. monocytogenes* in 23 selected categories of ready-to-eat (RTE) foods.<sup>(4)</sup> The risk assessment evaluated the risk of invasive listeriosis and death due to listeriosis for the total U.S. population as well as for three separate population subgroups: (i) neonates infected in utero through contaminated food consumed by their mothers; (ii) the intermediate-age population; and (iii) older adults. One dose-response relationship (i.e., modeling mortality in humans following the ingestion of *L. monocytogenes*) was initially developed and different multipliers were subsequently applied to generate models for invasive listeriosis for each of the population subgroups. To derive the dose-response relationship for mortality in humans, five dose-response models (i.e., probit, exponential, logistic, multihit, and Gompertz-log) were initially fitted to data obtained in mice challenged with a single *L. monocytogenes* strain. These models were weighted and used simultaneously to characterize uncertainty in the shape of the dose-response curve, with the best-fitting exponential model receiving the greatest weight. A distribution of median lethal dose values ( $LD_{50}$ ) observed in mice challenged with different *L. monocytogenes* strains was subsequently incorporated in the dose-response model to characterize *L. monocytogenes* strain variability in virulence and its uncertainty. Variability and uncertainty in host susceptibility within the three population subgroups were estimated based on observations in mice and epidemiological data, and incorporated in the dose-response model as well. Finally, because the derived model considerably overestimated the expected number of invasive listeriosis cases, surveillance data on the incidence of listeriosis in the United States were used to scale the dose-response relationship to reflect differences in susceptibility between humans and mice.<sup>(4)</sup>

In 2004, an international expert panel of the Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) developed another dose-response model based on a data subset extracted from the exposure estimates and the estimated annual number of cases used to derive the draft FDA/FSIS dose-response model published in 2001. The FAO/WHO dose-response model for invasive listeriosis is an exponential dose-response model.<sup>(6)</sup> The exponential dose-response model is a “single-hit” model.<sup>(6,7)</sup> It assumes that the probability of a given bacterial cell causing the adverse effect is independent of the number or char-

acteristics of other ingested pathogens, so that a single ingested microorganism is sufficient to cause the adverse effect with some probability greater than zero. The exponential dose-response model further assumes that the bacterial cells are randomly distributed in the food, hence the dose per portion follows a Poisson distribution, and that the average probability,  $r$ , that one pathogen, within a given exposure of a particular consumer to a specific population of pathogens, will survive the host-pathogen interaction to initiate infection and cause illness is constant.<sup>(8)</sup>

If the virulence of pathogens or the susceptibility of consumers varies from exposure to exposure, then  $r$  may vary and may be represented by a random variable with distribution  $f(r)$ .<sup>(8)</sup> Challenges remain regarding how best to quantify the distribution of  $r$  in relation to the host, the bacterial strain, and the exposure scenario. To account for differences in host susceptibility for *L. monocytogenes*, the FAO/WHO group of experts assumed the existence of two distinct values for  $r$ , applicable to the general population and population subgroups with increased susceptibility, respectively. The two  $r$  parameters (i.e., one value for each of the two population subgroups) were estimated from epidemiological<sup>(9)</sup> and food exposure<sup>(10)</sup> data obtained in the United States. The estimated  $r$  parameters were extremely low (i.e., approximately  $10^{-12}$ – $10^{-13}$  for the population with increased susceptibility and  $10^{-13}$ – $10^{-15}$  for the general population), translating into a very low probability of illness following the ingestion of a low dose of bacteria. This dose-response model or some adaptations of the model have been used in various risk assessments.<sup>(11-14)</sup>

Since 2004, new scientific data have become available, demonstrating the considerable variability in virulence among *L. monocytogenes* strains and molecular subtypes.<sup>(15-18)</sup> New data have, for example, shown that the entry of *L. monocytogenes* into certain human epithelial cells is primarily receptor mediated, depending on specific interactions between internalins on the bacterial surface and their respective host cell receptors.<sup>(19-22)</sup> Therefore, point mutations in the *inlA* gene can lead to virulence attenuation of *L. monocytogenes* strains.<sup>(16,23,24)</sup> New data are also available regarding the variability in susceptibility among individuals with different predisposing conditions such as pregnancy, old age, or other underlying conditions.<sup>(25-28)</sup> The relative risk of listeriosis for pregnant women, for example, has been estimated to be approximately 100 times higher than

that for nonpregnant women.<sup>(25–27)</sup> Relative risks higher than 1,000 have been reported for individuals with chronic lymphocytic leukemia when compared to a reference population of individuals <65-year old without any known underlying conditions.<sup>(26)</sup>

Because of the challenges in developing adequate dose-response models of listeriosis, an inter-agency expert workshop was held in the United States in 2011, with the goal of identifying new data, strategies, and insights for *L. monocytogenes* dose-response modeling. Short-term strategies identified during this workshop included updating the dose-response model developed by FDA/FSIS<sup>(4)</sup> by incorporating new data and insights about differences in strain virulence and *L. monocytogenes* pathophysiology. A key-events approach to dose-response modeling<sup>(29)</sup> was identified as a promising though extremely challenging, data-intensive, and potentially unachievable framework for future microbial dose-response models.<sup>(2)</sup>

Current dose-response models linked to epidemiological data tend to agree that a low dose of *L. monocytogenes* leads to an average low probability of invasive listeriosis in the general population as well as in broadly defined populations with heightened susceptibility.<sup>(4,5,30)</sup> However, a more nuanced evaluation of *L. monocytogenes* dose response for *L. monocytogenes* strains with different virulence and for different human population subgroups at heightened risk of listeriosis is needed to adequately characterize the listeriosis risk in different population subgroups, including those with highest susceptibility. Such nuanced models would allow for more in-depth inference about the listeriosis risk posed to highly susceptible population subgroups by highly virulent *L. monocytogenes* strains, and may become instrumental for evaluating key risk management issues such as the potential public health threat associated with the ingestion of a given dose of *L. monocytogenes*.

In this article, the existing exponential *L. monocytogenes* dose-response model<sup>(5)</sup> for invasive listeriosis is being revisited. A mathematical framework for considering variability in *L. monocytogenes* virulence and in host susceptibility is derived and applied to currently available epidemiological data, including data from one well-documented listeriosis outbreak.<sup>(4,5,31)</sup> Unlike other foodborne pathogens such as *Salmonella*,<sup>(32–34)</sup> *Campylobacter*,<sup>(35)</sup> or norovirus,<sup>(36,37)</sup> *L. monocytogenes* is characterized by an extremely low probability of illness at low exposure doses when averaging across the total popula-

tion or broadly defined population subgroups<sup>(4,5,30)</sup> and by extreme variability in the probability of infection among population subgroups with different predisposing risk factors.<sup>(5,26,27,38)</sup> Two dose-response models are evaluated and compared here in light of the unique challenges associated with modeling *L. monocytogenes* dose response.<sup>(2,4,5,29)</sup> The first evaluated model uses beta distributions to characterize variability in  $r$  from exposure to exposure, resulting in an “exact beta-Poisson” dose-response relation<sup>(6)</sup> (also known as “hypergeometric”<sup>(7)</sup> or “actual beta-Poisson”<sup>(8)</sup> dose-response relation), which may be simplified to an approximate “beta-Poisson” model if certain conditions are met.<sup>(7,39)</sup> The second model, a newly developed “lognormal-Poisson” model, characterizes variability in  $r$  due to variability in strain virulence and host susceptibility using lognormal distributions. As will be illustrated in this article, the lognormal distribution was found appropriate and useful for modeling the special case of *L. monocytogenes* dose response whereas the beta-Poisson model showed insufficient flexibility to adequately model one of the well-described *L. monocytogenes* outbreaks.

## 2. FRAMEWORK, MODEL, AND DATA

### 2.1. General Derivation of the Evaluated Dose-Response Models

A single-hit model is assumed.<sup>(6,7)</sup> The probability of acquiring the adverse effect under study (i.e., invasive listeriosis) if a dose of  $d$  bacterial cells is ingested in a certain serving is given by:

$$P(\text{ill}; d, r) = 1 - (1 - r)^d, \quad (1)$$

where “ill” stands for “illness” (here, invasive listeriosis) and  $r$  is the probability of developing invasive listeriosis from the ingestion of a bacterial cell in a given, specific serving. Note that  $r$  may be seen as constant for that serving,<sup>(6)</sup> or as an average probability that one cell of the specific population of pathogens present in the meal will survive and initiate the infection and illness of this specific consumer.<sup>(8)</sup> Assume that each serving is specific to a given context, determined by the individual  $i$  (characterized by the presence of a given set of predisposing risk factors at the time of consumption) consuming the food and by the *L. monocytogenes* strain  $s$  present in the ingested food (with a certain set of given virulence determinants at

the time of consumption). In this study,  $r$  is considered constant for this particular serving, but variable across servings, with its variability determined by the variation in susceptibility across individuals and the variation in virulence across strains.

Assume further that the *L. monocytogenes* dose in a given serving is Poisson distributed and the distribution of  $r$  across a given population of servings is described by a random variable with density function  $f(r; \theta)$ . Then the marginal probability of infection for an average dose  $d$  is described by:<sup>(6)</sup>

$$P(\text{ill}; d, \theta) = \int_0^1 (1 - \exp(-rd)) f(r; \theta) dr. \quad (2)$$

Any probability density function with practical domain  $[0; 1]$  can be chosen for  $f$ . A beta distribution is a convenient choice for modeling variability in  $r$  because its domain is restricted to  $[0,1]$ , it provides flexibility over the domain, and the simplified beta-Poisson model is easy to implement.<sup>(6)</sup> The exact and simplified beta-Poisson dose-response models have been repeatedly used for modeling illnesses from other foodborne pathogens such as norovirus,<sup>(37,40)</sup> *Salmonella*,<sup>(33,34)</sup> or *Campylobacter jejuni*.<sup>(8)</sup> The beta-Poisson model was also used to model *L. monocytogenes* dose-response from animal data.<sup>(41)</sup> If a lognormal (base 10) distribution is chosen for  $f$ , that is,  $\log_{10}(r) \sim \text{normal}(\mu, \sigma)$ , with negligible probability that  $r \geq 1$ , Equation (2) leads to:

$$P(\text{ill}; d, \mu, \sigma) = \frac{\log_{10}(e)}{\sigma \sqrt{2\pi}} \int_0^1 \left( \frac{1}{r} (1 - \exp(-rd)) \times \exp\left(-\frac{(\log_{10}(r) - \mu)^2}{2\sigma^2}\right) \right) dr. \quad (3)$$

Equation (3) has no closed form and requires numerical integration. However, it simplifies to an exponential dose-response model for any given value  $r$ .

$$P(\text{ill}; d, r) = 1 - \exp(-rd) \quad (4)$$

In this study, we investigated a beta distribution and a lognormal distribution to characterize the distribution of  $r$  from meal to meal, using data from multiple sources, including human surveillance and food survey data. The derivation using the beta-Poisson model can be found in the Appendix, which shows that this model is inappropriate for the special case of modeling *L. monocytogenes* dose response in humans, most notably because it could not adequately model extreme situations such as outbreaks. The log-

normal distribution was eventually chosen because its heavy-tail property was deemed useful for modeling the special case of *L. monocytogenes* dose response, and because its infinitively divisional property allowed for mathematically relatively simple separation of different sources of variability in dose response.

## 2.2. Dose-Response Model Within Populations Subgroups

The probability of developing listeriosis after ingesting a given dose of *L. monocytogenes* is highly variable from meal to meal, and considerably impacted by the *L. monocytogenes* strain and the presence and nature of underlying host conditions such as pregnancy, old age, or certain diseases and conditions.<sup>(25-27)</sup> The variability in  $r$  may be separated into three sources: variability in susceptibility across mutually exclusive population subgroups with a shared predisposing risk factor, variability in susceptibility across individuals within a given population subgroup, and variability in virulence among *L. monocytogenes* strains with different virulence determinants.

For a given population subgroup  $g$ , the marginal dose response can be rewritten as:

$$P(\text{ill}; d, \theta_g) = \int_0^1 (1 - \exp(-rd)) f(r; \theta_g) dr,$$

where  $\theta_g$  is characteristic of the subgroup  $g$ . The distribution  $f(r; \theta_g)$  represents the remaining individual (within group) susceptibility variability and strain virulence variability in  $r$ .

The resulting distribution of  $r$  across all population subgroups can be expressed as a mixture of distributions for individual population subgroups, weighted by the relative size of each population subgroup in the total population:

$$g(r) = \sum_g \pi_g f(r; \theta_g), \quad (5)$$

where  $\pi_g$ ,  $\sum_g \pi_g = 1$ , is the proportional size of the population subgroup  $g$  within the total population.

Substituting  $f(r)$  by  $g(r)$  in Equation (2) leads to the dose response for the total population. This dose-response relationship integrates, in addition to those factors accounted for by the subpopulation-specific dose-response model, the variability in mean susceptibility across population subgroups.

### 2.3. Specification of $\mu_g$ and $\sigma_g$ from Surveillance Data

Let  $c_g$  equal the number of invasive listeriosis cases in a given population subgroup  $g$  and  $M_{d,g}$  equal the number of servings with a given mean dose  $d$  ingested by the population subgroup  $g$ . Then, the expected value of  $c_g$  is given by:

$$E[c_g] = \int_0^\infty M_{d,g} P(\text{ill}; d, \theta_g) dd. \quad (6)$$

Estimating  $c_g$  from epidemiological data and  $M_{d,g}$  from food exposure data generates an infinite number of solutions for the ordered pair  $(\mu_g, \sigma_g)$ . However, if a measure of variability of  $r_g$  is known, the problem simplifies to a root-finding problem. As an example, if we are able to characterize  $Q_{90}$ , the  $\log_{10}$  of the ratio between the 5th and the 95th percentile of  $f(r; \theta_g)$ , we can estimate  $\theta_g$  for estimated  $E[c_g]$  and  $Q_{90}$  using some iterative solver routine.

### 2.4. Characterization of Variability

#### 2.4.1. Specification of $\sigma_g$

Under limited assumptions, the infinitively divisible property of lognormal distributions allows for a characterization and separation of interindividual and interstrain variability. The potential of a given *L. monocytogenes* strain to cause disease (i.e., strain virulence determined by a given set of transient and fixed virulence factors) may be considered independent of the susceptibility of a given host to listeriosis (i.e., host susceptibility due to a given set of comorbidities and other factors impacting individual susceptibility such as genetic predisposition).

In this study,  $r$  is defined as the probability of infection for a given individual following the ingestion of one given *L. monocytogenes* cell during a given serving. Note that  $r$  may be considered for our purpose as the product of two independent probabilities: the probability  $p_i$ , linked to events controlled by host factors that ultimately lead to a failure to stop infection, and  $p_s$ , which reflects bacterial factors that control virulence and pathogenicity:

$$r = p_i \times p_s. \quad (7)$$

We assume that  $p_s$  and  $p_i$  follow lognormal distributions. Because the product of two independent lognormally distributed random variables is itself a lognormal random variable,  $r$  is also lognormally distributed. Let  $p_i \sim \text{lognormal}(\mu_i, \sigma_i)$  for all  $i \in g$ , and let  $p_s \sim \text{lognormal}(\mu_s, \sigma_s)$  for strains  $s$ . Based on

Equation (7) we see that for a given population subgroup and strain,

$$r \sim \text{lognormal}\left(\mu_i + \mu_s, \sqrt{\sigma_i^2 + \sigma_s^2}\right), \quad (8)$$

and the marginal density across all strains can therefore be found by  $\mu_g = \mu_i + \mu_s$  and  $\sigma_g = \sqrt{\sigma_i^2 + \sigma_s^2}$ .

$Q_{90,i}$  is defined as the  $\log_{10}$  of the 90% individual within-group susceptibility variability range. Note that  $\sigma_i$  can be estimated as  $\sigma_i = (Q_{90,i}/2)/\Phi^{-1}(0.95)$  where  $\Phi^{-1}$  denotes the inverse of the standard normal cumulative density function. Here,  $\sigma_s$  can be estimated using the same rationale for the interstrain variability. If  $Q_{90,s}$  is the  $\log_{10}$  difference between the 5th and the 95th percentile,  $\sigma_s = (Q_{90,s}/2)/\Phi^{-1}(0.95)$ .

The subroutine must find  $(\mu_g, \sigma_g)$  solution of:

$$E[c_g] = \int_0^\infty M_{d,g} P(\text{ill}; \mu_g, \sigma_g) dd, \quad (9)$$

where

$$\sigma_g = \frac{\sqrt{Q_{90,i}^2 + Q_{90,s}^2}}{2\Phi^{-1}(0.95)}. \quad (10)$$

#### 2.4.2. Intragroup Variability $Q_{90,i}$

Due to a variety of factors, such as genetic predisposition, susceptibility to infection differs across individuals, even after accounting for underlying comorbidities, albeit with considerably decreased variability. To derive estimates for our model, we used the estimates of variability in susceptibility presented in FDA/FSIS.<sup>(4)</sup> In FDA/FSIS,<sup>(4)</sup> three distributions that encompass the range of susceptibility observed in animal studies were used to adjust the  $\log_{10}$  cfu of the effective dose for populations with low, medium, and high variability.<sup>(4)</sup> Assuming exponential dose response in animal studies, the range of variation in the  $\log_{10}$  LD<sub>50</sub> translates into the range of variation in the  $\log_{10}$   $r$  parameter.<sup>1</sup> Therefore, we represented the variability in the probability of illness from a single cell (in  $\log_{10}$   $r$ ) using the variability in the  $\log_{10}$  cfu that had been used to modify the effective dose in FDA/FSIS.<sup>(4)</sup> According to FDA/FSIS (Table IV-8 in Ref. 4), 90% of the individual variability within the population group with low, medium, and high

<sup>1</sup>We have, for an exponential dose response,  $r = \frac{-\ln(5)}{\text{LD}_{50}}$ . The LD<sub>50</sub> is inversely proportional to  $r$ . A variation of  $\pm x \log_{10}$  in  $\log_{10}$  LD<sub>50</sub> corresponds to a similar variation of  $\pm x \log_{10}$  in  $\log_{10}$   $r$ .

variability in susceptibility may be contained within a range of  $0.8 \log_{10}$ ,  $1.8 \log_{10}$ , and  $2.9 \log_{10}$ , respectively. FDA/FSIS<sup>(4)</sup> used the medium variability distribution for neonatal populations and high variability for intermediate-age and elderly subpopulations. In this study, we divided the population into 11 population subgroups with similar underlying conditions (Table I), essentially as described previously.<sup>(11,42)</sup> Assuming that our 11 subpopulations would be more precisely defined with regard to predisposing risk factors and therefore less variable in susceptibility than the broadly defined “elderly” and the “intermediate-age” population subgroups defined by FDA/FSIS,<sup>(4)</sup> we used FDA/FSIS<sup>(4)</sup> “medium variability” estimates for all of the 11 groups, that is,  $Q_{90,i} = 1.8 \log_{10}$ .

#### 2.4.3. Interstrain Virulence Variability $Q_{90,s}$

In the FDA/FSIS assessment, variations in host susceptibility and in strain virulence were represented by distributions that modified the effective dose for individual servings.<sup>(4)</sup> The distribution for strain virulence was estimated notably by the observed variation in  $LD_{50}$  (in  $\log_{10}$  cfu) among different *L. monocytogenes* strains in mouse experiments.<sup>(4)</sup> According to FDA/FSIS (Table IV-6 in Ref. 4), 90% of the strain variability ranges within a  $5 \log_{10}$ , leading to  $Q_{90,s} = 5 \log_{10}$ .

Substituting these values in Equation (10) generates  $\sigma_g = 1.62 \log_{10}$ .

### 2.5. Integration of the dose-response Models

#### 2.5.1. Exposure Data

The *L. monocytogenes* concentration distribution reported by Chen *et al.*<sup>(30)</sup> was used for exposure estimates. This distribution was obtained by fitting data from a survey of more than 31,000 RTE retail food samples, representing eight RTE categories sampled in the years 2000 and 2001 in two states of the United States.<sup>(43)</sup> *L. monocytogenes* was not detected in 98.2% of the samples. The  $\log_{10}$  concentration ( $\log_{10}$  cfu/g) in the remaining contaminated products followed a four-parameter beta distribution<sup>2</sup> with parameters  $\alpha = 0.29$ ,  $\beta = 2.68$ ,  $a = -1.69$ , and  $b = 6.1$ .<sup>(30)</sup> A 50 g serving size was assumed in this study. The number of servings of these eight RTE categories consumed by the U.S. popula-

tion was estimated at  $1.23 \times 10^{11}$  servings per year based on the FDA/FSIS risk assessment.<sup>(4)</sup> As considered in previous risk assessments,<sup>(4,5)</sup> we made the assumption of an identical distribution of *L. monocytogenes* doses and strains for all population subgroups.

#### 2.5.2. Epidemiological Data

To allow comparisons across population subgroups  $g$  with similar underlying conditions, we identified population subgroups with specific predisposing risk factors (e.g., different types of illness, old age, pregnancy), and evaluate variability in susceptibility within and across these subgroups.

Goulet *et al.*<sup>(26)</sup> published data on the relative risk of listeriosis in France for 36 mutually exclusive susceptible population subgroups, each consisting of individuals sharing a specific underlying condition. Because the data were too scarce to derive dose-response models separately for 36 mutually exclusive subgroups, the 36 subgroups identified by Goulet *et al.*<sup>(26)</sup> were combined (where appropriate) and regrouped into 11 subgroups based on underlying pathophysiology and expected degree of T-cell inhibition, essentially using a grouping scheme as previously described.<sup>(11,42)</sup>

We assumed that the relative risk of listeriosis for a given population subgroup and the relative size of each evaluated population subgroup would be comparable between France and the United States. The number of cases in each subgroup had to be normalized to the listeriosis burden estimates from the United States to allow extrapolation of the data (Table I). We evaluated two estimates of the total listeriosis cases in the United States, the first based on 1996–1997 data<sup>(9)</sup> and the second on 2005–2008 data<sup>(1)</sup> from FoodNet surveillance. We chose the latter, i.e., 1,591 cases per year, as input to derive the dose-response relationship because the 2000–2001 timeframe for the food survey<sup>(43)</sup> corresponded to the timeframes for the listeriosis estimates and, more importantly, the latter listeriosis estimate was based on new and improved methods for estimating overall foodborne illness in the United States.<sup>(1)</sup>

#### 2.5.3. Sensitivity Analysis

As will be discussed below, we identified two major assumptions needed to use the data described above. To evaluate the impact of these assumptions

<sup>2</sup> $x$  follows a four-parameter beta distribution with parameters  $(\alpha, \beta, a, b)$  if  $(x-a)/(b-a) \sim \text{Be}(\alpha, \beta)$

**Table I.** Number of Persons with Underlying Conditions and Number of Cases of Invasive Listeriosis Observed in France, 2001–2008;<sup>(26)</sup> Expected Number of Invasive Listeriosis Cases per Subgroups in the United States; See Text for Underlying Assumptions and Ref. 26 for a More In-Depth Description of the Population Subgroups

Population Subgroup	Number of Individuals in France (from and Adapted from Ref. 26)	Listeriosis Cases During an 8-Year Period in France (from and Adapted from Ref. 26)	Relative Risk (CI 95%) <sup>a</sup>	Expected Number of Listeriosis Cases in the United States (Based on 1,591 Cases from Ref. 1)
Less than 65 years old, no known underlying condition (i.e., “healthy adult”)	48,909,403	189	Reference group	153
More than 65 years old, no known underlying condition	7,038,068	377	13.9 (8.6, 23.1)	306
Pregnancy	774,000	347	116 (71, 194.4)	282
Nonhematological cancer	2,065,000	437	54.8 (34.2, 90.3)	355
Hematological cancer	160,000	231	373.6 (217.3, 648.9)	188
Renal or liver failure (dialysis, cirrhosis)	284,000	164	149.4 (82, 270.1)	133
Solid organ transplant	25,300	16	163.7 (26.3, 551.5)	13
Inflammatory diseases (rheumatoid arthritis, ulcerative colitis, giant cell arteritis, Crohn’s disease)	300,674	68	58.5 (25.2, 123.4)	55
HIV/AIDS	120,000	22	47.4 (10.5, 140.4)	18
Diabetes (type I or type II)	2,681,000	79	7.6 (3.5, 15.6)	64
Heart diseases	1,400,000	29	5.4 (1.5, 14.4)	24
Total population	63,757,445	1,959		1,591

<sup>a</sup>Estimated using a Poisson regression without adjustment. These 95% CIs should be considered only as indicative but suggest that all those groups have a risk of listeriosis significantly higher than the reference group.

on the generated risk estimates we conducted the following sensitivity analyses for these two assumptions. (i) Due to the lack of sufficient data, we assumed equal exposure to contaminated food for all population subgroups. This assumes that outreach targeted at minimizing foodborne exposures of high-risk population subgroups is ineffective. As a sensitivity analysis, the model was tested with the alternative assumption that the number of servings containing a given number of bacteria for all of the more susceptible subgroups are one-tenth of that for “healthy adults” (i.e., the <65 years of age without any known underlying conditions). (ii) The exposure data we used in deriving the dose-response model did not consider bacterial growth from retail to consumption, and considered a maximum level of contamination of  $6.1 \log_{10}$  cfu/g. Because growth in the consumer home has been identified as a potentially important risk factor in previous risk assessments, we conducted a sensitivity analysis to evaluate the impact of this assumption. The model was tested using the four-parameter beta distribution of  $\log_{10}$  concentration described in Section 2.5.1, with a maximum parameter increased from  $b = 6.1$  to  $b = 8.1 \log_{10}$  cfu/g. This distribution leads to an

average concentration in contaminated products of 20,545 cfu/g as compared to 390 cfu/g for the baseline scenario.

## 2.6. Dose-response Relationship Using Outbreak Data

It was assumed that a single food item and *L. monocytogenes* strain are involved in an outbreak affecting a specific population subgroup  $g$ , thus eliminating the impact of strain-to-strain variability in the dose-response evaluation. The virulence of the outbreak strain,  $p_{s(\text{outbreak})}$ , is then fixed but unknown. We used the lognormal-Poisson model (and the beta-Poisson model; see the Appendix) to analyze a well-documented listeriosis outbreak, the butter outbreak that occurred in Finland in 1998–1999,<sup>(31)</sup> as re-examined by FDA/FSIS<sup>(4)</sup> and FAO/WHO.<sup>(5)</sup> This outbreak was characterized by a relatively high attack rate among immunocompromised individuals (mostly hematological or organ transplant patients) for a relatively low dose of *L. monocytogenes*.<sup>(4,5)</sup> The FAO/WHO panel derived an  $r$  value of  $3.15 \times 10^{-7}$  from data collected during this outbreak.<sup>(5)</sup>

The lognormal dose-response properties help to evaluate the dose response during outbreaks. As can be inferred based on Equation (7),  $r$  is the product of a fixed value  $p_{s(outbreak)}$  and a lognormally distributed variable  $p_i$ . Thus:

$$r \sim \text{lognormal}(\mu_g + \log_{10}(p_{s(outbreak)}), \sigma_i). \quad (11)$$

Given that  $p_s \sim \text{lognormal}(\mu_s, \sigma_s)$ , the  $j$ th quantile of  $p_s$  is given by  $p_s(j) = 10^{(\mu_s + \Phi^{-1}(j) \times \sigma_s)}$ . Assuming that  $p_{s(outbreak)} = p_s(j)$ :

$$r \sim \text{lognormal}(\mu_i + \mu_s + \Phi^{-1}(j) \times \sigma_s, \sigma_i). \quad (12)$$

Substituting  $\mu_g$  for  $\mu_i + \mu_s$  gives for  $r$ :

$$r \sim \text{lognormal}(\mu_g + \Phi^{-1}(j) \times \sigma_s, \sigma_i). \quad (13)$$

Percentiles of interest can now easily be estimated using the parameters derived above.

All numerical integrations and optimizations of the models were performed using the R software.<sup>(44)</sup> The code is available from the corresponding author on request.

### 3. RESULTS

#### 3.1. Estimation of $r$ for Different Population Subgroups Using Food Exposure and Epidemiological Surveillance Data

Solutions for the ordered pair  $(\mu_g, \sigma_g)$  for all 11 population subgroups, based on numerical integration, are presented in Table II. Notably, estimates of  $\mu_g$  varied widely across population subgroups, ranging from  $\mu_g = -14.1$  for those less than 65 years of age without any known underlying conditions (i.e., “healthy adults”) to  $\mu_g = -11.0$  for individuals with hematological cancer. These estimates translate into mean values of  $r$  equaling  $7.9 \times 10^{-12}$  and  $9.6 \times 10^{-9}$ , respectively. The corresponding 99.9th percentiles equal  $7.7 \times 10^{-10}$  and  $9.3 \times 10^{-7}$  for healthy adults and individuals with hematological cancer, respectively, indicating that the risk of illness per ingested cell generally remains relatively low for most population subgroups and most types of exposure. The variation in dose response across population subgroups is illustrated in Fig. 1, highlighting in particular the comparison among the total population, pregnant women, and healthy adults. As expected, the marginal dose-response model for the total population more closely resembles that for healthy adults than those for the most susceptible population subgroups.

The probability of illness and the expected numbers of cases for a variety of population subgroups and ingested doses are presented in Table III. For healthy adults <65 years old, the mean probability of illness remains below 1:10,000 if doses below 7.5  $\log_{10}$  cfu/serving are ingested. However, for those with hematological cancer, ingestion of doses in the range of 5.5  $\log_{10}$  cfu/serving translates into a mean probability of illness around 1:1,000. Considering this dose-response relationship and the exposure to *L. monocytogenes* through food consumption, most of the 1,591 cases analyzed in this study are expected to be due to foods contaminated with doses between 3.5 and 7.5  $\log_{10}$  cfu/serving (Table III). Notably, 20% of the 188 expected cases among those with hematological cancer are expected to be due to contamination with doses  $\leq 5 \log_{10}$  cfu/serving. Doses of 4  $\log_{10}$  cfu/serving or lower are estimated to be responsible for 2% of cases among healthy adults, but an estimated 4% of cases among pregnant women and an estimated 5% of cases among individuals with hematological cancer are expected to be caused by such relatively low doses.

As shown above in Equation (4), for a fixed value of  $r$ , the dose-response model simplifies to an exponential dose-response model. Fig. 2 illustrates the dose-response relationships for the total population for the 0.01st, 0.1st, 1st, 50th, 99th, 99.9th, and 99.99th percentiles of the distribution (including group-to-group, individual within-group, and strain-to-strain variability) of  $r$ . This figure also overlays the marginal lognormal-Poisson model from this study with the exponential dose-response models reported previously by FAO/WHO<sup>(5)</sup> for the susceptible population as well as the one by Chen *et al.*<sup>(24)</sup> for *L. monocytogenes* strains with genes encoding a full-length *inlA* for the 25% higher-risk population. Notably, the dose response for the total population derived here results in a higher risk of infection for low doses than either of the two published dose-response models (Fig. 2). The dose-response model obtained in this study for the least virulent strains, however, leads to a considerably lower risk of illness at low doses than either of the published models.

#### 3.2. Sensitivity Analyses

When the model was tested with the alternative assumption that the number of servings including a given number of bacteria for all of the more susceptible subgroups equals one-tenth of that for

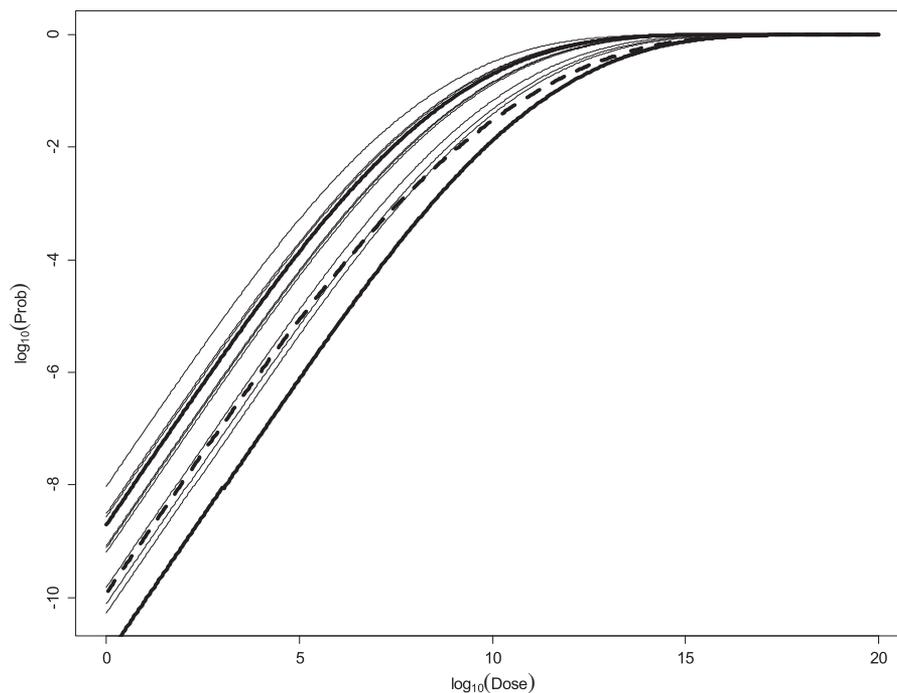
**Table II.** Parameters of the Lognormal-Poisson Dose-response Model for Invasive Listeriosis Following the Ingestion of *L. monocytogenes* in Different Population Subgroups and Resulting Statistics for  $r$ , the Probability of Illness Following the Ingestion of One Cell of *L. monocytogenes*; The Distribution of  $r$  Includes the Individual Within-Group and the Strain Variability

Population Subgroup	Estimates of a Log <sub>10</sub> Normal Distribution <sup>a</sup> of $r$		Estimates of $r$			
	$\mu$	$\sigma$	Mean	50th Percentile	99th Percentile	99.9th Percentile
Less than 65 years old, no known underlying condition (i.e., "healthy adult")	-14.11	1.62	$7.90 \times 10^{-12}$	$7.82 \times 10^{-15}$	$4.48 \times 10^{-11}$	$7.68 \times 10^{-10}$
More than 65 years old, no known underlying condition	-12.83	1.62	$1.49 \times 10^{-10}$	$1.47 \times 10^{-13}$	$8.44 \times 10^{-10}$	$1.45 \times 10^{-8}$
Pregnancy	-11.70	1.62	$2.01 \times 10^{-9}$	$1.99 \times 10^{-12}$	$1.14 \times 10^{-8}$	$1.95 \times 10^{-7}$
Nonhematological cancer	-12.11	1.62	$7.76 \times 10^{-10}$	$7.68 \times 10^{-13}$	$4.40 \times 10^{-9}$	$7.54 \times 10^{-8}$
Hematological cancer	-11.02	1.62	$9.60 \times 10^{-9}$	$9.51 \times 10^{-12}$	$5.44 \times 10^{-8}$	$9.33 \times 10^{-7}$
Renal or liver failure (dialysis, cirrhosis)	-11.56	1.62	$2.79 \times 10^{-9}$	$2.76 \times 10^{-12}$	$1.58 \times 10^{-8}$	$2.71 \times 10^{-7}$
Solid organ transplant	-11.51	1.62	$3.14 \times 10^{-9}$	$3.11 \times 10^{-12}$	$1.78 \times 10^{-8}$	$3.06 \times 10^{-7}$
Inflammatory diseases (rheumatoid arthritis, ulcerative colitis, giant cell arteritis, Crohn's disease)	-12.08	1.62	$8.43 \times 10^{-10}$	$8.35 \times 10^{-13}$	$4.78 \times 10^{-9}$	$8.19 \times 10^{-8}$
HIV/AIDS	-12.19	1.62	$6.50 \times 10^{-10}$	$6.44 \times 10^{-13}$	$3.69 \times 10^{-9}$	$6.32 \times 10^{-8}$
Diabetes (type I or type II)	-13.13	1.62	$7.47 \times 10^{-11}$	$7.39 \times 10^{-14}$	$4.23 \times 10^{-10}$	$7.26 \times 10^{-9}$
Heart diseases	-13.30	1.62	$5.01 \times 10^{-11}$	$4.96 \times 10^{-14}$	$2.84 \times 10^{-10}$	$4.86 \times 10^{-9}$
Whole population	N/A <sup>b</sup>	N/A	$1.19 \times 10^{-10}$	$1.56 \times 10^{-14}$	$2.47 \times 10^{-10}$	$6.87 \times 10^{-9}$

<sup>a</sup>The log<sub>10</sub> normal distribution is parameterized as  $x \sim \text{lognormal}(\mu, \sigma)$  if  $\log_{10}(x) \sim \text{normal}(\text{mean: } \mu, \text{ standard error: } \sigma)$ .

<sup>b</sup>Nonapplicable: the dose response for the whole population uses a mixture of log<sub>10</sub> normal distribution (see text for details).

<sup>c</sup>The distribution of  $r$  includes the individual and the strain variability.



**Fig. 1.** Marginal (over strains and individuals within subgroups) lognormal-Poisson dose-response models for the 11 population subgroups (thin lines), emphasizing (thick lines) the dose-response relationship for those <65 years of age without known underlying conditions (“healthy adult”; bottom thick line) and for pregnant women (top thick line). Marginal (over strains and individuals) lognormal-Poisson dose response for the total population (thick dashed line).

“healthy adults,” the dose response was shifted to the left for the susceptible groups. In this case, the overall expected number of cases for servings containing  $\leq 4 \log_{10}$  cfu equaled less than 6% of all cases as compared to 3% of all cases in the baseline scenario. The assumption of equal food consumption across population subgroups therefore only had a modest impact on our analysis. When the model was tested with a maximum *L. monocytogenes* level of  $8.1 \log_{10}$  cfu/g, a shift of the corresponding dose response to the right was logically obtained: with this maximum level, 0% of the cases would be predicted for a dose of  $4 \log_{10}$  cfu/g and 4% for a dose of  $6 \log_{10}$  cfu/g for the total population.

**3.3. Application of the Dose-response Framework to Listeriosis Outbreaks**

Fig. 3 compares the published exponential dose-response model<sup>(5)</sup> estimated from the Finnish butter outbreak data ( $r = 3.15 \times 10^{-7}$ )<sup>(5,31)</sup> to the dose-response model for transplant recipients derived in this study, showing both the prediction averaged across individual strains and for individual per-

centiles of the virulence distribution  $p_s$ . Fig. 3 suggests that the dose-response model from this study is able to predict the data observed in the Finnish outbreak, and that the strain was highly virulent, as the corresponding dose-response overlays that of a strain with a level of virulence close to the 99.9th percentile of  $r$ .

**4. DISCUSSION**

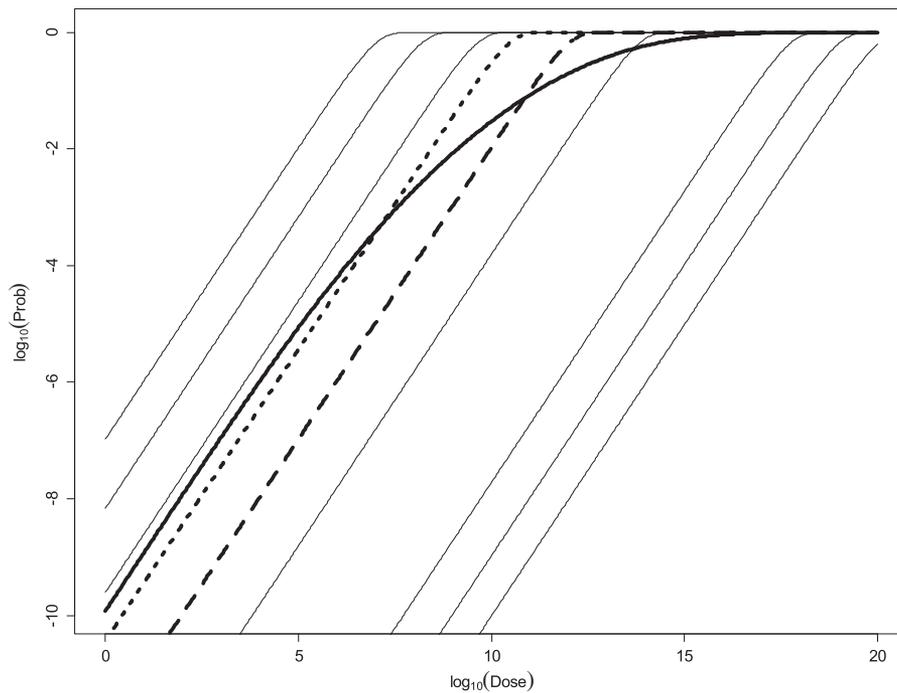
**4.1. The New Framework for *L. Monocytogenes* Dose-response, Adjusted for Variability in Host Susceptibility and Strain Virulence**

The FAO/WHO<sup>(5)</sup> dose-response model can be considered as a marginal dose-response model for a population exposed to a cross-section of *L. monocytogenes* strains. As such, this model averages across numerous individuals with differing levels of susceptibility and multiple *L. monocytogenes* strains with varying levels of virulence. While such evaluations can be highly informative for many purposes they may be inappropriate to evaluate certain rare but potentially highly relevant events, such as the

**Table III.** Marginal Probability of Illness and Expected Number of Cases in Selected Population Subgroups and in the General Population as a Function of the Dose, Considering Individual Susceptibility Within Groups, Strain Variability, and Dose Variability for a Given Mean Dose

Log <sub>10</sub> (Dose)	Marginal Probability of Illness for Individuals										Expected Number of Cases							
	<65-year old					>65-year old					>65-year old					Solid organ transplant		Whole population
	<65-year old	>65-year old	Pregnant women	Hematological cancer	Solid organ transplant	Whole population	<65-year old	>65-year old	Pregnant women	Hematological cancer	Solid organ transplant	Whole population	<65-year old	>65-year old	Pregnant women	Hematological cancer	Solid organ transplant	Whole population
0.0	8.8 × 10 <sup>-12</sup>	1.5 × 10 <sup>-10</sup>	2.0 × 10 <sup>-9</sup>	9.5 × 10 <sup>-9</sup>	3.1 × 10 <sup>-9</sup>	1.2 × 10 <sup>-10</sup>	0	0	0	0	0	0	0	0	0	0	0	0
0.5	2.8 × 10 <sup>-11</sup>	4.8 × 10 <sup>-10</sup>	6.2 × 10 <sup>-9</sup>	3.0 × 10 <sup>-8</sup>	9.8 × 10 <sup>-9</sup>	3.8 × 10 <sup>-10</sup>	0	0	0	0	0	0	0	0	0	0	0	0
1.0	8.8 × 10 <sup>-11</sup>	1.5 × 10 <sup>-9</sup>	2.0 × 10 <sup>-8</sup>	9.5 × 10 <sup>-8</sup>	3.1 × 10 <sup>-8</sup>	1.2 × 10 <sup>-9</sup>	0	0	0	0	0	0	0	0	0	0	0	1
1.5	2.8 × 10 <sup>-10</sup>	4.8 × 10 <sup>-9</sup>	6.3 × 10 <sup>-8</sup>	3.0 × 10 <sup>-7</sup>	9.9 × 10 <sup>-8</sup>	3.8 × 10 <sup>-9</sup>	0	0	0	0	0	0	0	0	0	0	0	1
2.0	8.8 × 10 <sup>-10</sup>	1.5 × 10 <sup>-8</sup>	2.0 × 10 <sup>-7</sup>	9.3 × 10 <sup>-7</sup>	3.1 × 10 <sup>-7</sup>	1.2 × 10 <sup>-8</sup>	0	0	0	0	0	0	0	0	0	0	0	1
2.5	2.8 × 10 <sup>-9</sup>	4.7 × 10 <sup>-8</sup>	6.2 × 10 <sup>-7</sup>	2.8 × 10 <sup>-6</sup>	9.6 × 10 <sup>-7</sup>	3.7 × 10 <sup>-8</sup>	0	0	1	1	0	0	0	1	1	0	0	3
3.0	8.8 × 10 <sup>-9</sup>	1.5 × 10 <sup>-7</sup>	1.9 × 10 <sup>-6</sup>	8.6 × 10 <sup>-6</sup>	2.9 × 10 <sup>-6</sup>	1.1 × 10 <sup>-7</sup>	0	0	1	1	0	0	0	1	1	0	0	6
3.5	2.5 × 10 <sup>-8</sup>	4.6 × 10 <sup>-7</sup>	5.8 × 10 <sup>-6</sup>	2.5 × 10 <sup>-5</sup>	8.9 × 10 <sup>-6</sup>	3.5 × 10 <sup>-7</sup>	1	2	3	3	0	0	0	3	3	0	0	14
4.0	7.8 × 10 <sup>-8</sup>	1.4 × 10 <sup>-6</sup>	1.7 × 10 <sup>-5</sup>	7.2 × 10 <sup>-5</sup>	2.6 × 10 <sup>-5</sup>	1.0 × 10 <sup>-6</sup>	2	4	6	5	0	0	0	6	5	0	0	29
4.5	2.5 × 10 <sup>-7</sup>	4.3 × 10 <sup>-6</sup>	5.0 × 10 <sup>-5</sup>	2.0 × 10 <sup>-4</sup>	7.5 × 10 <sup>-5</sup>	3.0 × 10 <sup>-6</sup>	4	9	12	10	1	1	1	12	10	1	1	60
5.0	7.6 × 10 <sup>-7</sup>	1.3 × 10 <sup>-5</sup>	1.4 × 10 <sup>-4</sup>	5.2 × 10 <sup>-4</sup>	2.0 × 10 <sup>-4</sup>	8.6 × 10 <sup>-6</sup>	8	19	22	17	1	1	1	22	17	1	1	115
5.5	2.4 × 10 <sup>-6</sup>	3.8 × 10 <sup>-5</sup>	3.7 × 10 <sup>-4</sup>	1.3 × 10 <sup>-3</sup>	5.4 × 10 <sup>-4</sup>	2.4 × 10 <sup>-5</sup>	15	35	38	28	2	2	2	38	28	2	2	200
6.0	7.1 × 10 <sup>-6</sup>	1.1 × 10 <sup>-4</sup>	9.5 × 10 <sup>-4</sup>	3.1 × 10 <sup>-3</sup>	1.3 × 10 <sup>-3</sup>	6.3 × 10 <sup>-5</sup>	27	58	56	38	3	3	3	56	38	3	3	308
6.5	2.1 × 10 <sup>-5</sup>	2.9 × 10 <sup>-4</sup>	2.3 × 10 <sup>-3</sup>	7.0 × 10 <sup>-3</sup>	3.2 × 10 <sup>-3</sup>	1.6 × 10 <sup>-4</sup>	39	77	68	42	3	3	3	68	42	3	3	389
7.0	6.1 × 10 <sup>-5</sup>	7.5 × 10 <sup>-4</sup>	5.2 × 10 <sup>-3</sup>	1.5 × 10 <sup>-2</sup>	7.1 × 10 <sup>-3</sup>	3.9 × 10 <sup>-4</sup>	41	73	56	33	3	3	3	56	33	3	3	344
7.5	1.7 × 10 <sup>-4</sup>	1.8 × 10 <sup>-3</sup>	1.1 × 10 <sup>-2</sup>	2.9 × 10 <sup>-2</sup>	1.5 × 10 <sup>-2</sup>	9.1 × 10 <sup>-4</sup>	17	27	19	10	1	1	1	19	10	1	1	121
8.0	4.5 × 10 <sup>-4</sup>	4.3 × 10 <sup>-3</sup>	2.3 × 10 <sup>-2</sup>	5.3 × 10 <sup>-2</sup>	2.9 × 10 <sup>-2</sup>	2.0 × 10 <sup>-3</sup>	0	0	0	0	0	0	0	0	0	0	0	0
8.5	1.1 × 10 <sup>-3</sup>	9.3 × 10 <sup>-3</sup>	4.3 × 10 <sup>-2</sup>	9.2 × 10 <sup>-2</sup>	5.4 × 10 <sup>-2</sup>	4.2 × 10 <sup>-3</sup>	0	0	0	0	0	0	0	0	0	0	0	0
9.0	2.7 × 10 <sup>-3</sup>	1.9 × 10 <sup>-2</sup>	7.6 × 10 <sup>-2</sup>	1.5 × 10 <sup>-1</sup>	9.4 × 10 <sup>-2</sup>	8.5 × 10 <sup>-3</sup>	0	0	0	0	0	0	0	0	0	0	0	0
9.5	6.1 × 10 <sup>-3</sup>	3.7 × 10 <sup>-2</sup>	1.3 × 10 <sup>-1</sup>	2.3 × 10 <sup>-1</sup>	1.5 × 10 <sup>-1</sup>	1.6 × 10 <sup>-2</sup>	0	0	0	0	0	0	0	0	0	0	0	0
10.0	1.3 × 10 <sup>-2</sup>	6.6 × 10 <sup>-2</sup>	2.0 × 10 <sup>-1</sup>	3.2 × 10 <sup>-1</sup>	2.3 × 10 <sup>-1</sup>	3.0 × 10 <sup>-2</sup>	0	0	0	0	0	0	0	0	0	0	0	0
10.5	2.6 × 10 <sup>-2</sup>	1.1 × 10 <sup>-1</sup>	2.9 × 10 <sup>-1</sup>	4.3 × 10 <sup>-1</sup>	3.3 × 10 <sup>-1</sup>	5.1 × 10 <sup>-2</sup>	0	0	0	0	0	0	0	0	0	0	0	0
11.0	4.8 × 10 <sup>-2</sup>	1.8 × 10 <sup>-1</sup>	3.9 × 10 <sup>-1</sup>	5.5 × 10 <sup>-1</sup>	4.4 × 10 <sup>-1</sup>	8.5 × 10 <sup>-2</sup>	0	0	0	0	0	0	0	0	0	0	0	0
Total							153	306	282	188	13	1591						

<sup>a</sup>No serving with >7.8 log<sub>10</sub> *L. monocytogenes* cells is expected from the set of exposure data, leading mathematically to no expected cases at or above 8.0 log<sub>10</sub>.

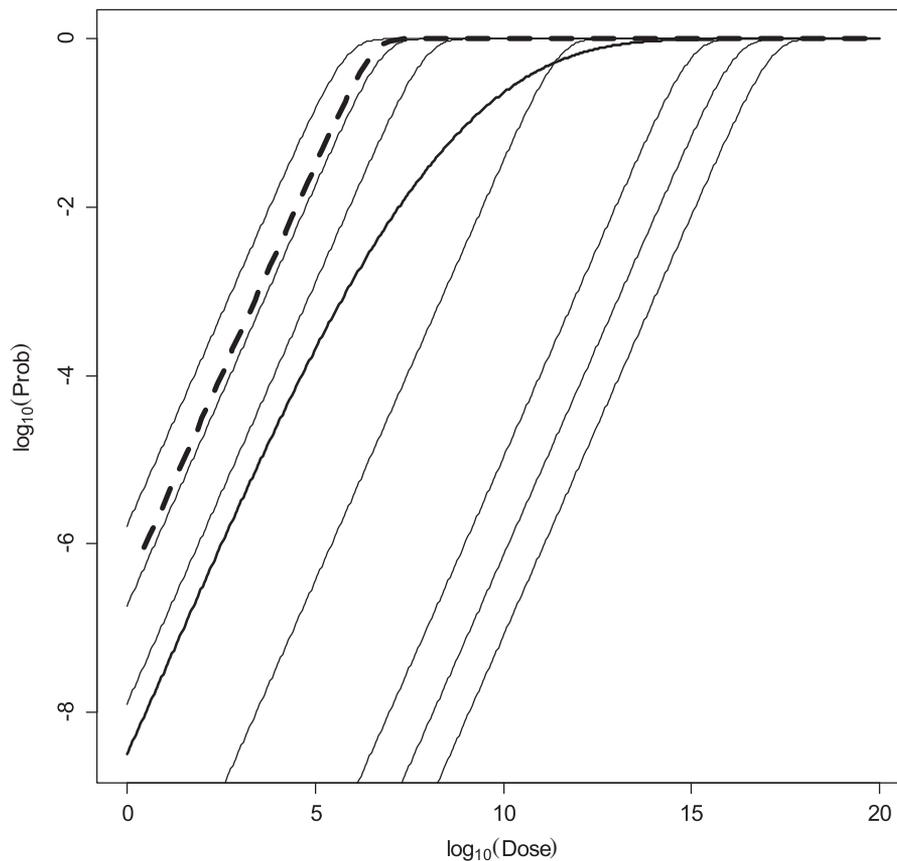


**Fig. 2.** Marginal lognormal-Poisson dose-response model for the total population (black solid line) and exponential dose-response model for  $r$  in the 0.01st, 0.1st, 1st, 50th, 99th, 99.9th, and 99.99th percentiles of the strain and individual distribution (thin black lines, from right to left). These estimates are compared to the dose-response relationships generated by FAO/WHO<sup>(5)</sup> for invasive listeriosis in the fraction of the population with increased susceptibility ( $r = 1.06 \times 10^{-12}$ ; see Ref. 5, p. 56) (dashed line) and by Chen *et al.*<sup>(24)</sup> for *L. monocytogenes* with genes encoding a full-length *inlA* for the 25% higher-risk population ( $\log_{10}(r) = -10.44$ ; dotted line).

ingestion of a highly virulent *L. monocytogenes* strain by a highly susceptible individual. Moreover, small population subgroups with extremely high susceptibility may not be adequately reflected in such dose-response relationships, potentially explaining at least in part why traditional exponential dose-response models of *L. monocytogenes* could so far not be reconciled with outbreak data.

The lognormal-Poisson dose-response models derived here extend and advance *L. monocytogenes* dose-response modeling to explicitly consider variability in strain virulence and in susceptibility across population subgroups. As such, the extended model more accurately captures the risk of listeriosis in those population subgroups at highest risk of listeriosis. Because the relative risk of listeriosis has been shown to vary by as much as 1,000-fold across population subgroups with clearly defined risk factors,<sup>(26)</sup> the ability to accurately characterize the listeriosis risk for different population subgroups is of paramount importance for risk management and for a comprehensive characterization of the listeriosis risk posed by different RTE food

items. Similarly, strains differ considerably in virulence. Chen *et al.*<sup>(24)</sup> found a 2–3  $\log_{10}$  difference in the marginal exponential dose-response parameters  $r$  for *L. monocytogenes* subtypes encoding a full length or truncated version of *inlA*, respectively. In a guinea pig model, Van Stelten *et al.*<sup>(23)</sup> found more than a 1  $\log_{10}$  increase in median infectious dose for a *L. monocytogenes* strain carrying a premature stop codon (PMSC) in *inlA* compared to that for an epidemic clone. Accounting for variability in strain virulence is therefore clearly of great importance. The variation in virulence used in this study (i.e., variability of 5  $\log_{10}$  based on inter 5th–95th percentiles) is higher than the differences in strain virulence that would be expected based on the data for strains with and without PMSCs in *inlA*. However, other virulence factors likely also contribute to virulence differences among *L. monocytogenes* strains.<sup>(21,45)</sup> Therefore, the true variability in strain virulence is likely larger than that estimated solely based on differences in *inlA* alleles. In addition, food matrix effects were implicitly accounted for in the variability in strain virulence, thus likely also increasing



**Fig. 3.** Lognormal dose-response relationships for invasive listeriosis following the ingestion of *L. monocytogenes*, comparing the marginal dose response for the transplant recipient population (solid thick line), the dose response for individual strains with virulence in the 0.01st, 0.1st, 1st, 50th, 99th, 99.9th, and 99.99th percentiles of the virulence distribution (thin lines, from right to left), and the exponential dose-response model for invasive listeriosis based on a butter outbreak in Finland, 1998–1999,<sup>(31)</sup> as reexamined by FAO/WHO ( $r = 3.15 \times 10^{-7}$ ,<sup>(5)</sup> p. 34; dashed line).

variability. Despite the progress that has been made in recent years, a better understanding of virulence differences among *L. monocytogenes* strains and, in particular, experimental data evaluating the potential impact of food matrix effects, is clearly needed to further refine *L. monocytogenes* dose-response models.

#### 4.2. Beta-Poisson vs. Lognormal-Poisson Dose Response

The beta distribution was introduced as a pragmatic choice to model the variability in  $r$ .<sup>(6,39)</sup> It offers a great amount of flexibility on the  $[0; 1]$  domain,<sup>(6)</sup> but a mechanistic basis for the choice of beta distributions is lacking. In the case of *L. monocytogenes*, the expected value of  $r$  is extremely low when averaging over the general population or

even over relatively broadly defined susceptible population subgroups, leading to extremely high values of parameter  $\beta$ . The shape of the beta distribution when used with such extreme parameters does not allow sufficient flexibility, making it impossible to fit the model to certain epidemiological listeriosis data, including the Finnish outbreak data, as illustrated in the Appendix. Therefore, even though the beta-Poisson represents a useful and often-used choice for modeling a number of foodborne pathogens, it appears suboptimal for the unique case of *L. monocytogenes* as evaluated here. Interestingly, if a gamma distribution with  $r \sim \text{gamma}(\alpha, 1/\beta)$ , with a negligible probability of  $r > 1$ , would be used to describe  $r$  variability, the associated probability of infection would also lead to the beta-Poisson dose-response model (Equation (12)).<sup>(8,46)</sup> Our result thus suggests that the use of a gamma distribution to model  $r$  would

similarly not be suitable for the unique case of *L. monocytogenes* dose response.

We used a lognormal distribution to model variability in host susceptibility and strain virulence, leading to a “lognormal-Poisson” dose-response relationship. Importantly, the resulting lognormal-Poisson dose-response equation does not simplify to a simple mathematical formula and requires numerical integration, thus making the use of this model mathematically more challenging. The domain of the lognormal distribution is defined as  $[0; \infty)$ . Yet, in this study we found that even for the most susceptible population subgroup (i.e., hematological cancer patients) the probability of  $r$  exceeding 1 is estimated at  $4.5 \times 10^{-12}$ , thus in the order of 1 in a trillion, and therefore *de facto* negligible. Because the probability of  $r$  exceeding 1 is *de facto* zero,  $r$  is theoretically  $[0; \infty)$  but practically distributed on the domain  $[0; 1]$  in the considered *L. monocytogenes* case. Importantly, this is most likely not true for pathogens other than *L. monocytogenes*. For other foodborne pathogens, the probability of illness after ingestion of a single cell is usually much higher than that for *L. monocytogenes* and the probability of  $r > 1$  would be nonnegligible, which would make it incorrect to use the lognormal-Poisson dose response. The lognormal distribution is a heavy-tail distribution. Using heavy-tail distributions is an appropriate modeling assumption if the objective is to describe extreme events such as the ingestion of a highly virulent *L. monocytogenes* strain by a highly susceptible individual. Importantly, the lognormal-Poisson dose-response model was able to predict a well-described outbreak of listeriosis where traditional models of *L. monocytogenes* dose response failed to do so, indicating the potential usefulness of this model.

#### 4.3. Limitations of the Currently Available Data

Whenever possible, health-protective assumptions that would lead to estimating a higher probability of infection for low doses were preferentially chosen in this study. However, the potential impact of some assumptions is more difficult to evaluate than for others. For instance, French data were used as the basis of extrapolations of the expected number of listeriosis cases per population subgroup in the United States. This extrapolation appears appropriate for several reasons. One key finding of the FAO/WHO<sup>(5)</sup> risk assessment of *L. monocytogenes* in RTE foods is a lack of evidence for differences in

the risk of listeriosis after consumption of a given *L. monocytogenes* dose by a member of given population subgroup across countries. Similarly, epidemiological studies have shown that the relative risk of listeriosis for pregnant women appears to be comparable between France and the United States.<sup>(26,27)</sup> Unfortunately, data on the relative risk of listeriosis is currently lacking for other population subgroups in the United States.<sup>(27)</sup> It was estimated that for each case of invasive listeriosis, 1.1 cases were not diagnosed in the United States.<sup>(1)</sup> This figure might be higher in neonatal and elderly cases as compared to other subpopulations.<sup>(47)</sup> Due to a lack of information, we have not addressed this uncertainty in the partitioning of the total number of cases in the United States among the different population subgroups.

In addition, the French relative size of population subgroups was directly extrapolated to the U.S. population. Even though certain indicators, such as the proportion of individuals with diabetes, are not the same in France and in the United States,<sup>(48)</sup> some major demographic parameters relevant in this study appear comparable between these countries, such as the proportion of people under 65 year of age, the proportion of people living with cancer, the fertility rates, and life expectancies.<sup>(49,50)</sup> Actually, the estimation of the relative size of population subgroups in the French study is based on a rigorous, specific, and complicated method designed to avoid duplicated counts.<sup>(26)</sup> Therefore, it appears preferable to use the French estimates directly rather than further adjusting the estimates to the relative size of U.S. populations with similar comorbidities.

For every risk assessment anchored to human surveillance data—such as our risk assessment presented here—the assumptions used to estimate exposure data highly influence the dose-response model and prediction. If it is estimated that only a small number of bacteria are consumed, any dose-response scaled to epidemiological data will mathematically be shifted to the left (i.e., toward a higher risk at low dose). We used data from Chen *et al.*,<sup>(30)</sup> which was the most extensive food survey in the United States on record. However, even this large of a study may not capture the true variability in the numbers of *L. monocytogenes* in RTE foods, particularly for the high end of the concentration distribution, and thus may be considered as underestimating exposure. Using these data leads to three implicit assumptions: (i) all bacterial cells consumed

in the population originate from only eight RTE food categories (i.e., fresh soft cheeses, bagged salad, blue veined cheeses, mold ripened cheeses, seafood salads, smoked seafood, luncheon meats, and deli salads) even though other products, such as low acid cut fruits<sup>(51,52)</sup> or vegetables,<sup>(53)</sup> could also be nonnegligible sources of *L. monocytogenes*; (ii) no growth is considered to occur between retail and consumption even though postretail growth has been shown to be one important factor increasing the risk for listeriosis<sup>(4,5)</sup>—these data have the advantage of being actual observed *L. monocytogenes* levels originating from a market basket survey<sup>(43)</sup> and not relying on predictive modeling that may overestimate the bacterial growth in products; and (iii) the maximal achievable concentration of *L. monocytogenes* in products equals  $6.1 \log_{10}$  cfu/g. This assumption is also underestimating exposure since others assume that *L. monocytogenes* can reach a maximal population density of  $8 \log_{10}$  in a food.<sup>(4,5)</sup> Altogether, these assumptions lead to an estimated lower exposure compared to other available data sets. In our study, it is estimated that only 120 servings include *L. monocytogenes* levels at or above  $10^8$  cells each year in the United States; by comparison, the FDA/FSIS<sup>(4)</sup> report, considering bacterial growth at the consumer step and 23 contaminated products, estimates 70,000,000+ servings at these levels. When tested with a maximum level of *L. monocytogenes* contamination of  $8.1 \log_{10}$  cfu/g, we confirmed the shift of the corresponding dose response to the right: with this maximum level, 0% of the cases would be predicted for a dose of  $4 \log_{10}$  cfu/g. Indeed, the maximum population density in a food has been shown to be an influential parameter for the predicted risk of invasive listeriosis.<sup>(54,55)</sup> Given the same dose response, the higher the maximum population density, the higher the predicted number of cases.<sup>(54,55)</sup> In addition, assumption on the maximum population density affects dose-response model parameters based on surveillance data.<sup>(5)</sup> The FAO/WHO risk assessment of *L. monocytogenes* in RTE foods<sup>(5)</sup> shows that a shift in the maximum population density by  $2 \log_{10}$  results in approximately one order of magnitude shift in the *r* value. The resulting dose-response presented here may be overestimating the probability of illness from a given dose.

As considered in previous risk assessments,<sup>(4,5)</sup> the assumption of equal exposure to contaminated food for all population subgroups does not consider the potential effectiveness of prevention cam-

paigns to change behavior of susceptible populations, notably for pregnant women, people with cancer, transplant recipients, for older adults, or for people with diabetes. Reported consumption estimates for certain food types suggests differences do exist in food consumption across population subgroups.<sup>(25,56)</sup> Nevertheless, the model appeared relatively insensitive to this assumption when tested with an alternative assumption of a lower exposure for the more susceptible subgroups than for “healthy adults.” Refinements accounting for differences in consumption habits across population subgroups would improve the current dose-response models. However, such data are currently not available for many of the 11 population subgroups analyzed here.

#### 4.4. Dose-response Evaluation in Highly Susceptible Groups and in Outbreak Situations

For the most susceptible population subgroup (i.e., hematological cancer patients), the marginal probability (i.e., averaged across all strains) of illness following the ingestion of 1 *L. monocytogenes* cell is estimated at  $9.5 \times 10^{-9}$ . It is  $9.3 \times 10^{-7}$  following the ingestion of 100 cells and  $7.2 \times 10^{-5}$  for the ingestion of 10,000 cells (e.g., 100 g of product contaminated with 100 cfu/g). These estimates are considerably higher than the ones estimated by FAO/WHO,<sup>(5)</sup> averaged over all possible risk factors. The corresponding estimates, using their *r* parameter of  $5.85 \times 10^{-12}$ , would be  $5.9 \times 10^{-12}$ ,  $5.9 \times 10^{-10}$ , and  $5.9 \times 10^{-8}$ , respectively, that is, 1,610, 1,576, and 1,220 times lower, respectively.

By characterizing specifically the most susceptible individuals and the most virulent strains in this study, the lognormal-Poisson dose-response analysis reconciles data observed in outbreaks with dose response derived from epidemiological studies, as illustrated Fig. 3. The high fat content of the food vehicle in the Finish butter outbreak (~80% fat) could potentially be partially responsible for this high probability of infection. High fat content in food may actually protect bacteria from gastric acid and, possibly, enhance uptake and survival in host cells *via* interaction with cell membrane lipids.<sup>(4,57)</sup>

#### 4.5. The Need for Better Data

Assumptions were made in the derivation of this model that lead to higher risk predictions at low dose

(higher predicted marginal probability of illness) compared to previously published dose-response models.<sup>(4,5)</sup> The estimates presented here should generally be viewed as overestimating the probability of illness. The characterization of the range of the individual susceptibility within groups and of the range of the strain virulence variability should be refined for a better characterization of these dose-response relationships. A mix of illness data from France<sup>(26)</sup> and the United States,<sup>(1)</sup> and exposure data obtained in two states from the United States,<sup>(30,43)</sup> were used, with the underlying assumptions that characteristics of listeriosis would be comparable in these areas. More current and detailed exposure data and data on the relative risk of listeriosis among different population subgroups in the United States are needed to refine this model. The primary purpose of this study was to derive a framework and to test with currently available data; to provide a definitive dose-response model is a secondary goal that would likely require refinements.

## 5. CONCLUSIONS

The exponential model has the oversimplifying assumption of a constant probability of infection following the ingestion of *L. monocytogenes* in a given population. This study incorporates variability in strain virulence and host susceptibility into the dose-response relationships. Additional data are needed to better understand and model the process from the ingestion of *L. monocytogenes* cells to the development of invasive listeriosis. However, several general conclusions can be made based on the available data. Overall, our model predicts the expected number of cases linked to the consumption of 10,000 cfu or less in 55 out of 1,591 cases, i.e., 3.5% of cases. Notably, these servings are expected to represent 99.96% of all RTE servings, indicating that most cases are expected to be caused by highly contaminated food items. Importantly, however, most of these cases attributable to low contamination doses are predicted to occur in the most highly susceptible population subgroups, including, for example, pregnant women. Using the model and assumptions discussed above led to the conclusion that, while most of the cases are linked to a medium to high exposure doses to *L. monocytogenes*, those at greatest risk of developing listeriosis are also at a measurable risk of illness when consuming food contaminated with relatively low doses of *L. monocytogenes*,

especially if highly virulent bacterial strains are involved.

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## APPENDIX: DERIVATIONS USING A BETA-POISSON MODEL

If a beta distribution  $Be(\alpha, \beta)$  is chosen for  $f$  in Equation (2), this integrate leads to the “exact beta-Poisson,”<sup>(6)</sup>

$$P(\text{ill}; d, \alpha, \beta) = 1 - {}_1F_1(\alpha, \alpha + \beta, -d), \quad (\text{A.1})$$

in which  ${}_1F_1$  is the Kummer confluent hypergeometric function. Equation (A.1) simplifies to the “beta-Poisson” dose-response model:

$$P(\text{ill}; d, \alpha, \beta) = 1 - \left(1 + \frac{d}{\beta}\right)^{-\alpha}, \quad (\text{A.2})$$

when  $\beta \gg \alpha$  and  $\beta \gg 1$ .<sup>(7,39)</sup> Note that these conditions are expected to be fulfilled for *L. monocytogenes*: the average probability of infection is very low,<sup>(30)</sup> thus  $E[r] = \frac{\alpha}{\alpha + \beta} \ll 1$ , leading to  $\beta \gg \alpha$  and  $\beta \gg 1$ .

Assume  $Be(\alpha_g, \beta_g)$  accounts for variability in  $r$  among *L. monocytogenes* strains and individuals within a given population subgroup  $g$ . Contrary to the lognormal distribution, the beta distribution does not easily allow for separation among interstrain and interindividual variability components of this distribution as in Equation (10). An overall (i.e., interindividual and interstrain) measure of the variability in  $r$  therefore needs to be estimated. Denote  $Q_{90}$ , the  $\log_{10}$  of the combined 90% individual susceptibility and strain virulence variability.  $Q_{90}$  equals the range between the 5th and the 95th percentile of  $Be(\alpha_g, \beta_g)$ . Using and combining FDA

FDA/FSIS<sup>(4)</sup> strain-to-strain virulence variability distributions (Table IV-5 in Ref. 4) and host susceptibility variability (Table IV-7 in Ref. 4) lead to an overall  $\log_{10}$  of the inter 5%–95% variability of  $Q_{90} = 5.4 \log_{10}$ .

Equivalently to Equation (9), the subroutine must find  $(\alpha_g, \beta_g)$  solutions of:

$$E[c_g] = \int_0^\infty M_{d,g} \left( 1 - \left( 1 + \frac{d}{\beta_g} \right)^{-\alpha_g} \right) dd, \quad (\text{A.3})$$

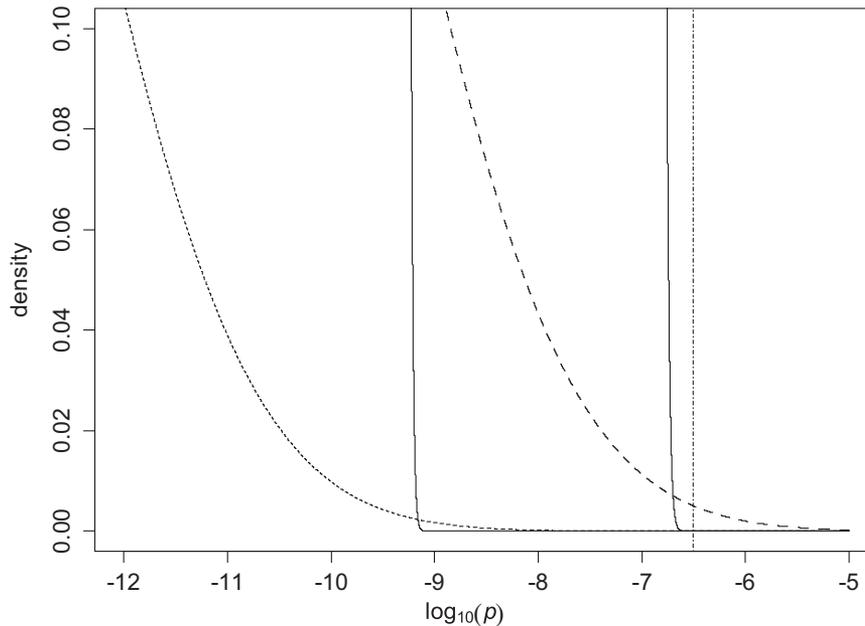
$$Q_{90} = \log_{10}(q_{0.95}) - \log_{10}(q_{0.05})$$

with  $q_x$  the  $x$ th quantile of the  $Be(\alpha_g, \beta_g)$  distribution.

The quantile function of beta distributions is not available in a closed form, and a numerical routine is required. Nevertheless, a solution exists for the parameters of a beta distribution given any combination of a lower and an upper quantile constraint.<sup>(58)</sup> The 11 pairs  $(\alpha_g, \beta_g)$  were evaluated numerically using R optimization subroutines. As expected, the  $\beta$ s were extremely high. Similar  $\alpha$ s were obtained for all populations. The parameters for the “healthy adult population” (i.e., the less susceptible subgroup) and the “hematological cancer population” (i.e., the more

susceptible subgroup) were  $(0.253, 3.86 \times 10^{10})$  and  $(0.253, 9.9 \times 10^7)$ , respectively.

A  $Be(0.253, 2.3 \times 10^8)$  was estimated for the “solid organ transplant” population subgroup. With this set of parameters, the probability to obtain a  $r$  parameter equal or higher than  $3.15 \times 10^{-7}$ , estimated from the Finnish butter outbreak data,<sup>(5,31)</sup> equals  $2.7 \times 10^{-34}$ . This extremely low probability proves that the Finnish outbreak cannot be predicted using the beta-Poisson dose-response model, as parameterized here. Fig. A.1 illustrates the density of the underlying beta distribution of the beta-Poisson dose-response model and the underlying lognormal distribution of the lognormal-Poisson dose-response models. The graph clearly illustrates the contrast between the very sharp decrease in the density for the beta distribution compared to the smoother decrease for the lognormal distribution. With such parameters ( $\beta \rightarrow \infty$ ), the beta distribution converge to a degenerate distribution with a single point mass at some  $x \in [0, 1]$ .<sup>(58)</sup> With parameters estimated from epidemiological data, the beta distribution is not flexible enough to predict  $r$  values high enough to explain the Finnish butter outbreak.



**Fig. A.1.** 1 Density of  $r$  according to the beta-Poisson dose response (plain) or the lognormal-Poisson dose response (dashed) for the healthy population (thin on the left) and the most susceptible population subgroup (hematological cancer population, thick on the right). The values estimated using the Finnish butter outbreak data by FAO/WHO<sup>(5)</sup> equals  $3.15 \times 10^{-7}$ , that is,  $10^{-6.5}$  (dot-dashed vertical line).

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## Fate of *Listeria monocytogenes* in Fresh Apples and Caramel Apples

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### ABSTRACT

An outbreak of listeriosis in late 2014 and early 2015 associated with caramel apples led to questions about how this product became a vector for *Listeria monocytogenes*. This investigation aimed to determine information about the survival and growth of *L. monocytogenes* in both fresh apples and caramel apples, specifically examining the effects of site and level of inoculation, inoculum drying conditions, and storage temperature. At a high inoculation level (7 log CFU per apple), *L. monocytogenes* inoculated at the stem end proliferated on Gala caramel apples at both 5 and 25°C and on Granny Smith caramel apples at 25°C by as much as 3 to 5 log CFU per apple. Fresh apples and caramel apples inoculated at the equatorial surface supported survival but not growth of the pathogen. Growth rates ( $\mu_{\max}$ ) for apples inoculated at the stem end, as determined using the Baranyi and Roberts growth model, were  $1.64 \pm 0.27$  and  $1.38 \pm 0.20$  log CFU per apple per day for Gala and Granny Smith caramel apples, respectively, stored at 25°C. At a low inoculation level (3 log CFU per apple), *L. monocytogenes* inoculated at the stem end and the equatorial surface survived but did not grow on fresh Gala and Granny Smith apples stored at 25°C for 49 days; however, on caramel apples inoculated at the stem end, *L. monocytogenes* had significant growth under the same conditions. Although certain conditions did not support growth, the pathogen was always detectable by enrichment culture. The inoculation procedure had a significant effect on results; when the inoculum was allowed to dry for 24 h at 5°C, growth was significantly slowed compared with inoculum allowed to dry for 2 h at 25°C. Variation in stick materials did affect *L. monocytogenes* survival, but these differences were diminished once sticks were placed into caramel apples.

Key words: Caramel apples; Fresh apples; Growth kinetics; *Listeria monocytogenes*; Survival

*Listeria monocytogenes* has caused outbreaks of listeriosis that have been associated with consumption of meats, dairy products, and fresh vegetables, but few documented cases of listeriosis have been linked to fresh fruits. In the United States, *L. monocytogenes* was first involved in an outbreak associated with fresh fruit, specifically cantaloupe, in 2011 (9). A total of 147 illnesses, 142 hospitalizations, and 33 deaths were attributed to this outbreak. Another unusual fruit-linked outbreak of listeriosis occurred in late 2014 and early 2015, and the vector was commercially produced prepackaged caramel apples. This outbreak resulted in a total of 35 illnesses in 12 states and included 34 hospitalizations and seven deaths; the Public Health Agency of Canada also reported one associated case (10). Of the illnesses, 11 were pregnancy related, 1 of which resulted in fetal loss. Of the 31 ill individuals interviewed, 28 reported eating commercially produced prepackaged caramel apples before becoming ill (10). The other three individuals who did not report eating caramel apples did

report consuming sliced or whole apples. Caramel apples from three manufacturers were implicated, and further investigation led to one apple grower-packer as the source of the apples. Fresh Gala and Granny Smith apples from the apple grower-packer were shipped either to retailers for direct consumption or to manufacturers to be processed into caramel apples. Only caramel apples, not fresh apples, were associated with the outbreak. The pathogen was isolated from environmental swab samples taken in the storage room and from food contact surfaces at the apple grower-packer facility. Commercial apple contamination by *L. monocytogenes* resulted in recalls of packaged fresh-cut apples in 2001 (18, 25) and of packaged apple slices in 2015 (8), although no illnesses were associated with either recall.

How the caramel apples became a vector for the listeriosis outbreak is not known. Apples are not an adequate medium for proliferation of this pathogen because of their low pH (<4.0) (5). *L. monocytogenes* cannot penetrate into the flesh through the peel unless scars or cuts are already present on the apple surface (4). Application of the hot molten caramel during the manufacture of caramel apples provides a thermal impediment to bacterial survival.

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TABLE 1. *L. monocytogenes* populations on inoculated fresh apples (without sticks) stored at 5 or 25°C<sup>a</sup>

Temp (°C)	Apple variety	Inoculation location	Mean ± SD log CFU/apple at <sup>b</sup> :					
			0 days	1 day	2 days	6 days	9 days	15 days
5	Gala	Stem end	5.7 ± 0.6	5.4 ± 0.8	6.1 ± 0.7	4.4 ± 0.8	5.9 ± 1.0	5.5 ± 0.6
		Surface	2.7 ± 0.3	2.7 ± 0.3	BE <sup>c</sup>	BE	4.7 ± 0.8	BE
25	Gala	Stem end	5.7 ± 0.6	5.4 ± 0.7	5.8 ± 0.7	3.8 ± 0.7	3.9 ± 0.7	3.9 ± 0.5
		Surface	2.7 ± 0.3	BE	BE	BE	5.7 ± 1.5	BE
25	Granny Smith	Stem end	6.7 ± 1.1	5.2 ± 0.9	BE	6.9 ± 1.7	6.0 ± 1.5	2.9 ± 0.5
		Surface	4.8 ± 0.8	BE	BE	BE	5.1 ± 0.8	3.3 ± 0.6

<sup>a</sup> Initial inoculation was 6.9 ± 0.6 log CFU per apple.

<sup>b</sup> Values are means for *n* = 6.

<sup>c</sup> BE, below sensitivity of place count assay (2.5 log CFU per apple). In all cases, *L. monocytogenes* was detectable by enrichment culture.

Current practices for caramel apple production may involve selection of apples based on the manufacturer's specifications, cleaning of apples using water washing, brushing, and sanitizing, dipping and coating the apples with molten caramel, drying, and packaging of the completed caramel apples. After packaging, the finished products may or may not enter the cold chain during transport to retailers, where they are stored at ambient temperature awaiting consumer purchase.

This study was conducted to determine potential factors in caramel apple production that may have influenced the survivability and growth of *L. monocytogenes*. Factors included contamination level, site of contamination, apple variety, storage temperature, presence or absence of caramel coating, and stick material.

## MATERIALS AND METHODS

***L. monocytogenes* strains and culture conditions.** Three clinical outbreak isolates of *L. monocytogenes* (573-035, 576-043, and 580-060) from patients with listeriosis associated with the 2014 caramel apple outbreak were kindly provided by the Wisconsin State Laboratory of Hygiene (Madison, WI). All strains were serotype 4b with GX6A16.0012 pulsed-field gel electrophoresis *AscI* patterns (24). All strains were grown separately in brain heart infusion (BD, Sparks, MD) broth at 37°C for 16 to 18 h with shaking at 200 rpm.

**Apple selection and experimental design.** Whole fresh waxed Gala apples and Granny Smith apples were purchased from local retail supermarkets. Apples with obvious bruising or cuts were discarded. Average weights of apples used for experiments were 178.9 ± 7.2 and 177.0 ± 10.1 g for Gala and Granny Smith apples, respectively. Experimental variables included temperature during storage (5 and 25°C), inoculation level (10<sup>7</sup> or 10<sup>3</sup> CFU per apple), inoculation site (equatorial surface and stem end), inoculum drying conditions (5°C for 24 h or 25°C for 2 h), and caramel coating with wood stick insertion. Apples were prepared in triplicate for each variable for each timepoint of 0, 1, 2, 6, 9, and 15 days for Gala apples stored at 5 and 25°C and Granny Smith apples stored at 25°C and for each timepoint of 0, 7, 14, 21, 28, 35, 42, and 49 days for Gala and Granny Smith apples stored at 25°C. For 5°C storage studies, variables were stem end inoculation, equatorial surface inoculation, stem end inoculation with caramel coating and stick, and equatorial surface inoculation with caramel coating and stick. For 25°C storage studies, an additional variable was stick material (plastic, paper, or wood). For each caramel apple

experiment, uninoculated control apples consisting of caramel coating and stick were assayed for pH and spoilage. All experiments were conducted in two independent trials.

***L. monocytogenes* inoculation of apples.** Overnight cultures of *L. monocytogenes* strains were normalized, washed with Butterfield's phosphate buffer (BPB; pH 7.4), and combined equally to make a cocktail of approximately 9 or 5 log CFU/ml. Apples were inoculated at the stem end or along the equatorial surface by pipetting 10 µl of the *L. monocytogenes* cocktail to yield final levels of 6.9 ± 0.6 or 3.1 ± 0.2 log CFU per apple, as determined by plate count assay of the cocktail on PALCAM (BD) agar. The inoculum was dried for 2 h at 25°C or for 24 h at 5°C. The *L. monocytogenes* population recovered from apples after drying and with or without caramel was approximately 2 log CFU lower than the initial inoculum (data not shown).

**Preparation of caramel apples.** A wood stick typically used for making caramel apples was inserted approximately 3 to 4 cm into the stem end of each apple prior to caramel coating. Where indicated for some experiments, paper or plastic sticks also were used. Caramel pieces (containing corn syrup, sugar, milk, fructose, hydrogenated coconut oil, butter, mono- and diglycerides, salt, soy lecithin, and vanillin; inherent water activity of 0.66) were purchased from local retailers and melted to 76°C in a 4211c Twin Caramel Apple Dip Warmer according to the manufacturer's instructions (Gold Medal Products Co., Bensenville, IL). Temperature was monitored with a candy thermometer inserted into the caramel. For apples on which inoculum had dried at 5°C for 24 h, apples were equilibrated to room temperature prior to dipping. Apples were dipped manually into the caramel so that approximately 3 cm of the stick was covered. Excess caramel was allowed to drip off, and the apples were placed onto wax paper to dry at ambient temperature for 2 h. After drying, all apples, with or without caramel, were placed into food-grade clamshell containers for storage at 5 or 25°C for various time periods. Fresh apple and caramel apple trials were conducted concurrently.

**Enumeration of *L. monocytogenes* from apples.** At the appropriate time intervals, apples were taken out of clamshells and placed into 3-liter stomacher bags. Visual and odor changes in apples were recorded. Apples were smashed five to seven times with a rubber mallet. 350 ml of buffered *Listeria* enrichment broth (BLEB, BD) was added, and the mixture was stomached for 1 min at 180 rpm in a stomacher (model 3500, Seward Laboratory Systems Inc., Davie, FL). BLEB was chosen because of its superior capacity to neutralize the acid from the apples and maintain the pH at approximately 7.0. A 10-ml sample of the

TABLE 2. *L. monocytogenes* populations and growth kinetics on inoculated caramel apples stored at 5 or 25°C<sup>a</sup>

Temp (°C)	Apple variety	Inoculation location	Mean ± SD log CFU/apple at:						Growth kinetics <sup>b</sup>		
			0 days	1 day	2 days	6 days	9 days	15 days	μ <sub>max</sub> ± SE	r <sup>2</sup>	Time to 1-log increase (h)
5	Gala	Stem end	5.4 ± 0.8	5.7 ± 0.8	7.0 ± 1.0	8.0 ± 1.3	8.4 ± 1.7	8.5 ± 2.2	0.95 ± 0.21 A	0.80	26.2 ± 0.2
		Stem end, dried <sup>c</sup>	3.3 ± 0.4	2.9 ± 0.3	BE <sup>d</sup>	3.5 ± 0.4	6.5 ± 1.3	6.4 ± 1.6	0.80 ± 0.31 A	0.81	172.8 ± 0.6
		Surface	4.7 ± 0.6	4.8 ± 0.6	4.5 ± 0.8	BE	4.4 ± 0.8	BE	ND <sup>e</sup>	ND	ND
25	Gala	Stem end	5.4 ± 0.8	5.6 ± 1.3	7.9 ± 2.0	9.5 ± 1.6	10.0 ± 2.5	9.6 ± 1.6	1.64 ± 0.27 B	0.89	14.9 ± 0.1
		Stem end, dried <sup>c</sup>	3.3 ± 0.4	BE	6.8 ± 2.4	7.8 ± 1.3	8.1 ± 1.4	8.6 ± 1.5	0.85 ± 0.19 B	0.85	29.3 ± 0.3
		Surface	4.7 ± 0.6	4.7 ± 0.6	4.4 ± 0.5	4.6 ± 0.5	4.4 ± 0.8	BE	0.38 ± 0.23 B	0.23	287.5 ± 2.3
25	Granny Smith	Stem end	5.5 ± 0.9	7.2 ± 1.2	8.1 ± 1.2	8.6 ± 1.4	8.7 ± 1.4	8.9 ± 1.5	1.38 ± 0.20 C	0.91	17.6 ± 0.2
		Stem end, dried <sup>c</sup>	4.4 ± 0.6	5.2 ± 0.9	6.8 ± 1.1	8.4 ± 1.4	8.5 ± 1.2	8.8 ± 1.5	1.19 ± 0.17 C	0.95	20.4 ± 0.2
		Surface	6.3 ± 1.1	4.6 ± 0.7	BE	BE	6.9 ± 1.2	6.4 ± 1.1	0.15 ± 0.09 C	0.11	219.2 ± 11.6

<sup>a</sup> Initial inoculation was 6.9 ± 0.6 log CFU per apple. Values are means for n = 6.

<sup>b</sup> μ<sub>max</sub> ± SE, mean maximum growth rate (log CFU per apple per day) ± standard error. Means with different letters are significantly different (P < 0.05) for comparisons of the same inoculation locations on different apple varieties at both temperatures; r<sup>2</sup>, coefficient of determination.

<sup>c</sup> Inoculum placed at the stem end was dried at 5°C for 24 h.

<sup>d</sup> BE, below sensitivity of plate count assay (2.5 log CFU per apple). In all cases, *L. monocytogenes* was detectable by enrichment culture.

<sup>e</sup> ND, not determined.

homogenate was placed into a 15-ml tube. Serial dilutions in BLEB were spread plated in duplicate onto PALCAM agar. For timepoints at which *Listeria* was expected to be below the sensitivity of the plate count assay of 3 log CFU/ml, duplicate 1-ml aliquots of homogenates were plated over three PALCAM agar plates to increase the assay sensitivity to 2.5 log CFU/ml. PALCAM plates were incubated at 37°C for 48 h. All apple homogenates in BLEB were also used for enrichment cultures. These cultures were incubated at 30°C for 4 h, supplements were added, and the cultures were incubated again at 30°C for 24 h. When no growth was present on enumeration plates, the BLEB enrichment cultures were streaked onto PALCAM plates and tested for the presence of *L. monocytogenes* using the *Listeria* Visual Immunoprecipitate Assay (BioControl Systems Inc., Bellevue, WA) according to the manufacturer's directions.

**Enumeration of native microbiota from apples.** Populations of native microbiota on apples were monitored at each timepoint using the control apples (no inoculation, with caramel coating and stick). Apples were stomached as previously described, and the homogenates were serially diluted and plated in duplicate onto Dichloran Rose Bengal (DRBA) and deMan Rogosa Sharpe (MRS) agars (BD) for enumeration of presumptive yeasts and molds and lactic acid bacteria, respectively. DRBA plates were incubated at 25°C for 48 h, and MRS plates were incubated anaerobically at 37°C for 72 h before enumeration.

**Apple pH.** Apple pH was monitored at each timepoint using the control apples (no inoculation, with caramel coating and stick). pH was measured using a PH/ORP waterproof pH spear (Oakton Instruments, Vernon Hills, IL) by inserting the tip of the spear into the stem end of the apple and allowing the pH reading to equilibrate for 2 min.

***L. monocytogenes* survival on various stick materials.** Overnight cultures of *L. monocytogenes* strains were normalized, washed with BPB, and combined equally to make a cocktail of approximately 9 log CFU/ml. Wood, paper, and plastic sticks (14 to 15 cm long) were each inoculated with five 2-μl spots, yielding a final inoculation of 7.0 ± 0.7 log CFU per stick. Sticks were stored in sterile containers at 5 or 25°C. At 0, 2, 5, 7, and 15 days, triplicate samples of each type of stick material were placed into sterile 1.2-liter stomacher bags with 100 ml of BLEB, massaged by hand for 1 min, and then stomached at 180 rpm for 1 min. A 10-ml sample of this homogenate was transferred to a 15-ml tube, and serial dilutions in BLEB were plated in duplicate onto PALCAM agar, which were incubated at 37°C for 48 h.

**Modeling.** The DMFit version 3.0 (Institute of Food Research, Norwich, UK) Excel (Microsoft, Redmond, WA) add-on from ComBase (www.combase.cc) was used to model the maximum growth rates (μ<sub>max</sub>) and lag phases of the *L. monocytogenes* cocktail based on the Baranyi and Roberts (3) model. The value at time 0 was the *L. monocytogenes* recovered from the fresh apples (after inoculum drying) or from the caramel apples (after 2 h of drying of caramel). Calculation of μ<sub>max</sub> was based on the *L. monocytogenes* recovered at different timepoints relative to time 0. Growth of *L. monocytogenes* on the apples was defined by the calculation of a positive growth rate using DMFit. Survival of the pathogen was defined by the detection of the pathogen after enrichment culture. Linear regression analysis with the μ<sub>max</sub> values was used to determine the time to achieve 1 log CFU of growth, assuming no lag phase, at each condition and temperature.

TABLE 3. *L. monocytogenes* populations on inoculated caramel apples stored long term at 25°C<sup>a</sup>

Apple variety	Inoculation location	Mean ± SD log CFU/apple at <sup>b</sup> :							
		0 days	7 days	14 days	21 days	28 days	35 days	42 days	49 days
Gala	Stem end	BE <sup>c</sup>	8.6 ± 1.4	8.8 ± 1.0	9.1 ± 1.8	9.3 ± 1.6	8.8 ± 1.8	8.0 ± 4.0	9.4 ± 3.1
	Stem end, dried <sup>d</sup>	BE	6.7 ± 1.4	8.2 ± 1.1	9.8 ± 1.7	8.3 ± 1.4	7.6 ± 1.3	6.6 ± 3.3	7.5 ± 2.4
	Surface	BE	BE	BE	BE	BE	BE	BE	BE
Granny Smith	Stem end	BE	8.9 ± 1.3	8.5 ± 1.4	9.1 ± 1.5	8.8 ± 1.4	7.5 ± 1.3	8.2 ± 1.0	8.4 ± 1.4
	Stem end, dried <sup>d</sup>	BE	7.9 ± 1.6	8.0 ± 1.0	9.1 ± 1.5	7.7 ± 1.3	7.4 ± 2.5	6.9 ± 3.3	7.7 ± 3.7
	Surface	BE	BE	2.9 ± 0.5	BE	BE	BE	BE	BE

<sup>a</sup> Initial inoculation was 3.1 ± 0.2 log CFU per apple.

<sup>b</sup> Values are means for  $n = 6$ .

<sup>c</sup> BE, below sensitivity of plate count assay (2.5 log CFU per apple). In all cases, *L. monocytogenes* was detectable by enrichment culture.

<sup>d</sup> Inoculum placed on the stem end was dried at 5°C for 24 h.

**Statistical analysis.** Data were statistically evaluated using Tukey's adjusted one-way analysis of variance using GraphPad InStat for Windows. A  $P$  value of less than 0.05 was considered significant.

## RESULTS

***L. monocytogenes* survival on fresh apples.** At an initial inoculation level of 7 log CFU per apple, *L. monocytogenes* inoculated both at the stem end and on the equatorial surface survived on Gala apples stored at both 5 and 25°C and on Granny Smith apples stored at 25°C; however, populations decreased by approximately 1 to 4 log CFU per apple (Table 1). Although *L. monocytogenes* levels were below the sensitivity of the plate count assay (2.5 log CFU per apple) at various timepoints during storage in these experiments, the pathogen was still present as determined by enrichment culture (data not shown).

At the initial inoculation level of 3 log CFU per apple, *L. monocytogenes* inoculated at the stem end and on the surface did not produce detectable growth on fresh Gala or Granny Smith apples stored at 25°C for 49 days. At most of the timepoints, the population of *L. monocytogenes* was below the sensitivity of the plate count assay. Nevertheless, the pathogen survived on the fresh apples, as determined by enrichment culture (data not shown).

***L. monocytogenes* survival and growth on caramel apples.** At an initial inoculation level of 7 log CFU per apple, *L. monocytogenes* inoculated both at the stem end and on the surface were capable of surviving and at times growing on Gala caramel apples stored at 5 and 25°C and on Granny Smith caramel apples stored at 25°C (Table 2). On Gala caramel apples inoculated at the stem end stored at 5°C, the population of *L. monocytogenes* increased by nearly 3 log CFU after 15 days of incubation. On the surface-inoculated Gala caramel apples stored at 5°C, *L. monocytogenes* remained nearly at initial inoculation levels or decreased to below the sensitivity of the plate count assay; however, the presence of the pathogen was detectable by enrichment culture. The highest  $\mu_{\max}$  value for Gala caramel apples stored at 5°C was found for *L. monocytogenes* inoculated at the stem end, 0.95 log CFU per apple per day, leading to a 1-log increase in only 26.18 h (Table 2).

During storage at 25°C, *L. monocytogenes* inoculated at the stem end at 7 log CFU per apple had 3- to 4-log increases in population on both Gala and Granny Smith caramel apples (Table 2). The  $\mu_{\max}$  value was 1.64 log CFU per apple per day on the stem end-inoculated Gala caramel apples, and 1.38 log CFU per apple per day on Granny Smith caramel apples, leading to a 1-log increase in just 17.58 h. Surface-inoculated caramel apples stored at 5 and 25°C had similar results; at the various timepoints, the populations appeared to be nearly at the initial inoculation levels or were below the assay sensitivity limit (Tables 2 and 3). At weeks 6 and 7 of storage at 25°C, the quality of both the fresh apples and the caramel apples was poor, with many of the apples exhibiting surface mold growth.

For *L. monocytogenes* inoculated at 3 log CFU per apple at the stem end and stored at 25°C, approximately 7- to 8-log increases were found on both Gala and Granny Smith caramel apples (Table 3). Because of insufficient data, an accurate growth rate could not be determined for these trials; nevertheless, the increase in population within week 1 of storage was substantial. Surface-inoculated *L. monocytogenes* levels were below the sensitivity of the assay except for one timepoint (Granny Smith, 14 days); however, in all cases the pathogen was detectable by enrichment culture.

**Effect of inoculum drying conditions on *L. monocytogenes* populations on caramel apples.** In all cases, drying of the inoculum at 5°C for 24 h resulted in lower  $\mu_{\max}$  values and longer times to achieve a 1-log increase in population compared with drying of the inoculum for 2 h at ambient temperature (25°C; compare "stem end, dried" and "stem end," respectively, in Table 2). On Gala apples inoculated with 7 log CFU per apple at the stem end and dried for 2 h at ambient temperature before the addition of a stick and dipping in caramel, *L. monocytogenes* had a  $\mu_{\max}$  value of 0.95 log CFU per apple per day during storage at 5°C; DMFit did not predict a lag phase. However, the apples for which inocula were dried for 24 h at 5°C and then stored at 5°C, DMFit did predict a lag phase (5.8 days) and a significantly lower  $\mu_{\max}$  value (0.80 log CFU per apple per day). Therefore, the *L. monocytogenes* population on the apples in which the inoculum was dried for 2 h at 25°C increased by 1 log CFU in only 26.2 h, compared with 172.8

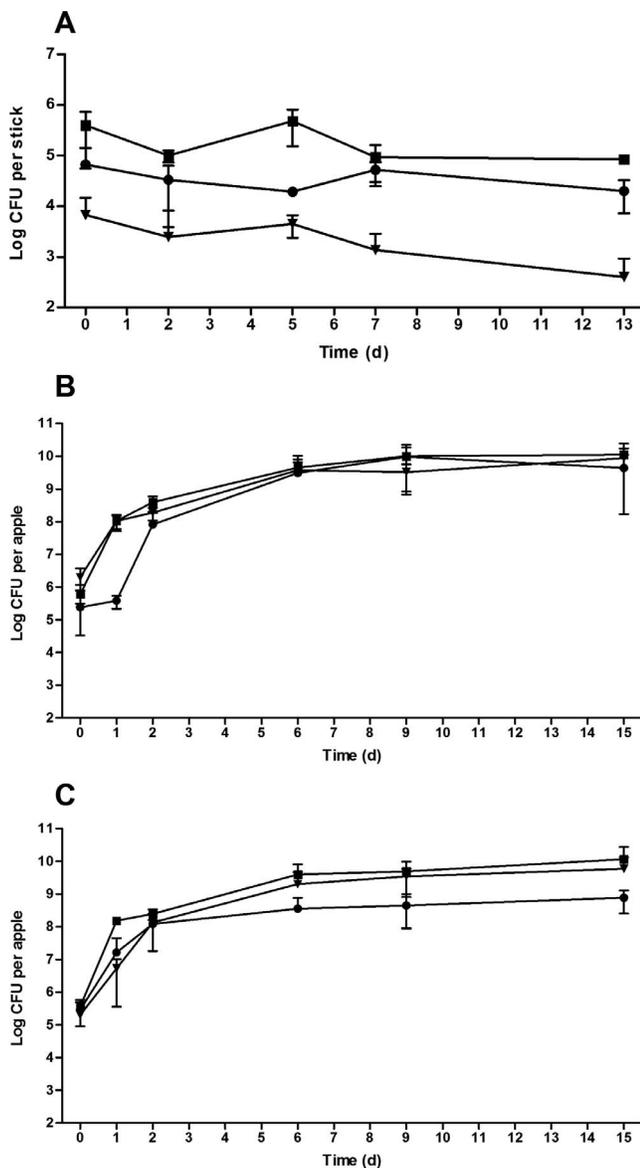


FIGURE 1. Survival of *L. monocytogenes* on stick materials (A) during storage at 5°C: paper (filled square), wood (filled circle), and plastic (filled triangle). Each data point represents the mean  $\pm$  SD log CFU per stick ( $n = 6$ ). *L. monocytogenes* survival and growth on Gala (B) and Granny Smith (C) caramel apples with different stick materials during storage at 25°C. Apples were inoculated at the stem end, and a wood stick (closed circle), paper stick (closed square), or plastic stick (closed triangle) was inserted. Each data point represents mean  $\pm$  SD log CFU per apple ( $n = 6$ ). The sensitivity of the assay was 2.5 log CFU per apple.

h on the apples that were dried for 24 h at 5°C. Although no other lag-phase values were determined by DMFit for apples inoculated at the stem end and dried for 24 h at 5°C, all the  $\mu_{\max}$  values were significantly lower than those for apples dried for 2 h at 25°C. However, the final population levels at the end of the storage periods were often similar for apples under both inoculum drying scenarios.

***L. monocytogenes* survival on stick materials.** In a comparison of *L. monocytogenes* survival on three caramel apple stick materials (paper, wood, and plastic), survival was

TABLE 4. *L. monocytogenes* growth kinetics on caramel apples with wood, paper, or plastic sticks during storage at 25°C for 15 days<sup>a</sup>

Stick material	Apple variety	$\mu_{\max} \pm SE^b$	$r^2$	Time to 1 log CFU growth (h)
Wood	Gala	1.64 $\pm$ 0.27 A a	0.89	14.9 $\pm$ 0.1
	Granny Smith	1.38 $\pm$ 0.20 B a	0.91	17.6 $\pm$ 0.2
Paper	Gala	1.40 $\pm$ 0.24 A b	0.77	17.4 $\pm$ 0.1
	Granny Smith	1.23 $\pm$ 0.28 B b	0.71	20.2 $\pm$ 0.2
Plastic	Gala	1.02 $\pm$ 0.14 A c	0.87	23.9 $\pm$ 0.1
	Granny Smith	1.25 $\pm$ 0.300 B b	0.73	20.0 $\pm$ 0.2

<sup>a</sup>  $\mu_{\max} \pm SE$ , mean maximum growth rate (log CFU per apple per day)  $\pm$  standard error;  $r^2$ , coefficient of determination.

<sup>b</sup> Means with different uppercase letters are significantly different ( $P < 0.05$ ) for comparisons of different apple varieties with the same stick material. Means with different lowercase letters are significantly different ( $P < 0.05$ ) for comparisons of the same apple variety with different stick materials.

significantly better on paper and wood than on plastic (Fig. 1A). After initial inoculation with 7 log CFU per stick, an approximately 1- to 2-log decrease occurred on both paper and wood sticks. A significantly greater decrease, i.e., approximately 3 log CFU, occurred on plastic sticks. After 13 days of incubation at 5°C, overall populations on paper and wood sticks did not decrease significantly, whereas the population on plastic sticks decreased by approximately 1 log CFU. Even though differences in *L. monocytogenes* survival on different stick materials were observed, these differences were diminished when the sticks were used in the preparation of caramel apples (Fig. 1B and 1C). Small but significant differences ( $P < 0.05$ ) in growth of the pathogen on Gala caramel apples stored at 25°C were found when wood, paper, and plastic sticks were used for caramel apple preparation (Table 4). A 3- to 4-log increase in populations of *L. monocytogenes* on Gala and Granny Smith apples was found after 15 days compared with initial levels.

**Native microbiota.** Populations of certain native microbiota (yeasts, molds, and lactic acid bacteria) that were monitored throughout the storage experiments increased during storage at 25°C for both apple varieties. At 5°C, only the yeast and mold populations increased (Fig. 2). A correlation could not be made between native microflora populations and pH changes in the apples during the storage periods.

## DISCUSSION

Although the listeriosis outbreak evaluated here is the first to be attributed to whole caramel apples, studies have shown that *L. monocytogenes* is capable of both surviving and growing on raw fruits such as whole and cut melons (13, 14, 20, 23, 27), melon pulp (26), cut pears (1, 11, 23), and whole and cut berries (1, 23). This pathogen also can proliferate on fresh-cut apple slices when contamination occurs after processing procedures, such as peeling and cutting (2, 4, 12). For example, the *L. monocytogenes* population on whole Red Delicious apples increased by 0.6 log CFU per apple slice after 7 days of storage at 10°C (18).

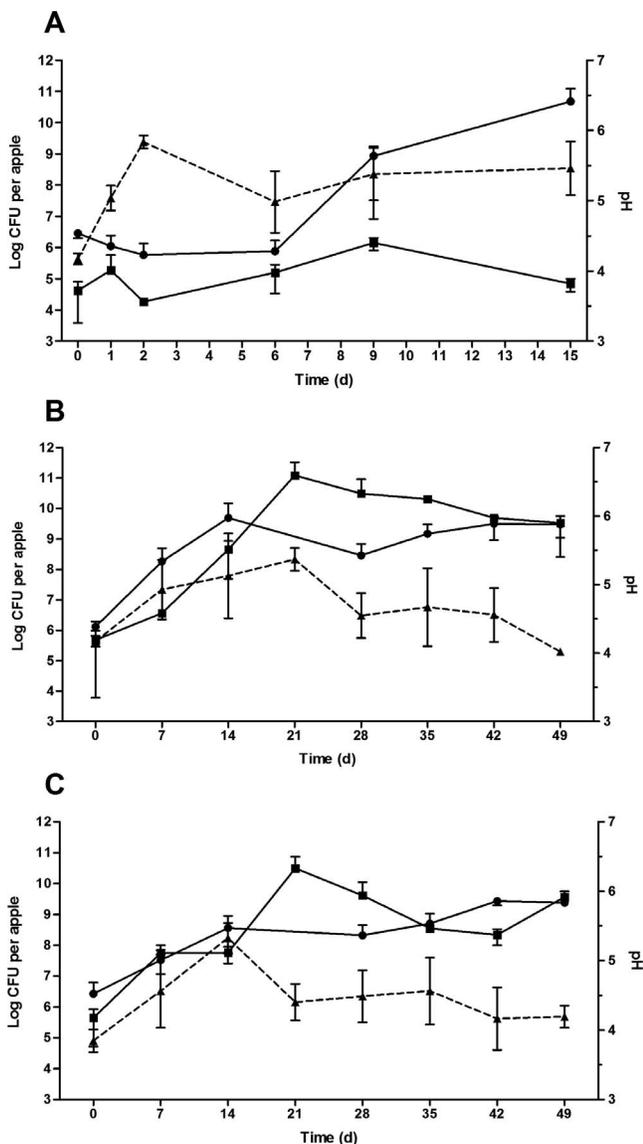


FIGURE 2. Comparison of pH (closed triangle, dotted line) and native microflora populations (yeasts and molds, closed circle; lactic acid bacteria, closed squares) on (A) control (no inoculation, with caramel coating and stick insertion) Gala apples stored at 5°C for 15 days; (B) control Gala apples stored at 25°C for 49 days, and (C) control Granny Smith apples stored at 25°C for 49 days. Each data point represents mean  $\pm$  SD log CFU per apple ( $n = 6$ ). Sensitivity of the assay was 2.5 log CFU per apple.

*Listeria innocua* (a nonpathogenic surrogate for *L. monocytogenes*) increased on Granny Smith and Golden Delicious apple plugs by 2 log CFU per plug after 2 days when stored at either 20 or 25°C; at 10°C, *L. innocua* increased by 2.4 log CFU per plug after 6 days (2). In addition to the increase in *L. monocytogenes* populations, the levels of general microbiota on apples can also increase during storage (17). The results of the present study revealed increases in populations of lactic acid bacteria and yeasts and molds. Yeasts may aid in growth of *L. monocytogenes* and other microorganisms on caramel apples because of their saccharolytic interactions with caramel and apple sugars (19).

In the present study, *L. monocytogenes* inoculation at the stem end of the apple followed by stem end stick insertion and caramel coating including 2 to 3 cm of stick resulted in an environment in which this pathogen was able to both survive and grow. The interface between the stem end of the apple and the caramel layer may produce a microenvironment with high water activity and high nutrient (apple and apple juices produced from the insertion of the stick) and sugar (caramel) concentrations (16). Specific microenvironments of multi-component foods can affect the survival and thermal behavior of pathogens such as *Salmonella enterica* (21). In the present study, the apples were submerged in the molten caramel just long enough for the apple and approximately 2 to 3 cm of the stick to be completely covered. *L. monocytogenes* residing in the microenvironment of the stem end of the apple would be exposed to molten caramel at 71 to 88°C in a caramel apple manufacturing plant during the dipping process. The length of time the pathogen is in contact with the caramel could determine, in part, pathogen survival (15). In the present study, some survival curves were highly variable, possibly because of inconsistencies in exposure of the pathogen to the molten caramel. For example, the most inconsistent recovery of *L. monocytogenes* was occurred with surface-inoculated caramel apples. Variable exposure of the pathogen to the thermal effects of the molten caramel could be attributed to location of the inoculum on the apple surface, the temperature of the caramel coating, and the amount of caramel applied, all of which may have produced different microenvironments for the pathogen. The most consistent trends observed in this study occurred with caramel apples inoculated at the stem end. In these apples, some inoculum cells may have been partially protected from thermal exposure by being pushed inside the apple during stick insertion. Nevertheless, the data indicate that manufacturers should not consider hot caramel dip a lethality step sufficient to reduce or eliminate the risk of *L. monocytogenes* contamination on caramel apples.

The mechanism of contamination may be a factor influencing pathogen survival. We studied the effects of two inoculation procedures to mimic two hypothetical contamination scenarios, i.e., contamination prior to cold storage (inoculum drying for 24 h at 5°C) and contamination as a short event at ambient temperature (inoculum drying for 2 h at 25°C). In this study, drying at 5°C slowed the growth of *L. monocytogenes* on caramel apples. In all cases, the inoculum dried for 24 h at 5°C always had a slower growth rate and took longer to achieve a 1-log increase (Table 2). Therefore, for conservative growth models and risk assessments, a 25°C inoculum drying time may be used for data generation. In all of the experiments the *L. monocytogenes* populations may be 2-log higher than indicated because of the efficiency of recovery (see “Materials and Methods”); thus, data depicting the final population levels may be estimated at approximately 2-log higher than the values actually recorded.

During washing of fresh apples, the stem and blossom ends are more difficult to clean than are the smooth surfaces, which is a significant problem (6, 7, 22). Postharvest processing procedures for fresh apples include washes with sanitizers such as chlorine to reduce the total microbial load and to eliminate pathogenic organisms such as *L. monocytogenes*. Once a wound is introduced at the stem end via the

insertion of a stick during caramel apple manufacture, microorganisms may invade the core or flesh and proliferate. This scenario may explain the growth of *L. monocytogenes* during the recent caramel apple outbreak. The Baranyi and Roberts (3) model used in this study determined values for growth rate, lag phase, and length of time for a 1-log increase in *L. monocytogenes* on the apples (Table 2). Apples were not washed prior to the experiments to ensure that native microflora remained and would interact with the pathogen in a realistic manner. The data provided a conservative model prediction of time to a 1-log increase in population and risk assessment for *L. monocytogenes* survival and growth on the apples. Apple variety and choice of stick material did not play significant biological roles in the growth of this pathogen on caramel apples. These results provide a starting point for the development of guidelines for caramel apple manufacturers on the safe handling practices of fresh apples and caramel apple products. Many questions remain with respect to potential preventive control options for caramel apple production, which may ultimately depend on the mechanisms by which contamination occurs.

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# Growth of *Listeria monocytogenes* within a Caramel-Coated Apple Microenvironment

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**ABSTRACT** A 2014 multistate listeriosis outbreak was linked to consumption of caramel-coated apples, an unexpected and previously unreported vehicle for *Listeria monocytogenes*. This outbreak was unanticipated because both the pH of apples (<4.0) and the water activity of the caramel coating (<0.80) are too low to support *Listeria* growth. In this study, Granny Smith apples were inoculated with approximately  $4 \log_{10}$  CFU of *L. monocytogenes* (a cocktail of serotype 4b strains associated with the outbreak) on each apple's skin, stem, and calyx. Half of the apples had sticks inserted into the core, while the remaining apples were left intact. Apples were dipped into hot caramel and stored at either 7°C or 25°C for up to 11 or 28 days, respectively. Data revealed that apples with inserted sticks supported significantly more *L. monocytogenes* growth than apples without sticks under both storage conditions. Within 3 days at 25°C, *L. monocytogenes* populations increased  $>3 \log_{10}$  in apples with sticks, whereas only a  $1 \log_{10}$  increase was observed even after 1 week for caramel-coated apples without sticks. When stored at 7°C, apples with sticks exhibited an approximately  $1.5 \log_{10}$  increase in *L. monocytogenes* levels at 28 days, whereas no growth was observed in apples without sticks. We infer that insertion of a stick into the apple accelerates the transfer of juice from the interior of the apple to its surface, creating a microenvironment at the apple-caramel interface where *L. monocytogenes* can rapidly grow to levels sufficient to cause disease when stored at room temperature.

**IMPORTANCE** Neither caramel nor apples are a food where the pathogenic bacterium *Listeria monocytogenes* should grow, as caramel does not contain enough free water and apples are too acidic. Caramel-coated apples, however, were recently linked to a deadly outbreak of listeriosis. We hypothesized that inserting a stick into the apple releases juice to the interface between the apple and caramel, providing a more hospitable environment than either component alone. To test this hypothesis, apples were inoculated with *L. monocytogenes* prior to caramel dipping. Some apples had sticks inserted into them before dipping, while others did not. No growth of *L. monocytogenes* occurred on refrigerated caramel apples without sticks, whereas slow growth was observed on refrigerated caramel apples with sticks. In contrast, significant pathogen growth was observed within 3 days at room temperature on caramel apples with sticks inserted. Food producers should consider interfaces between components within foods as potential niches for pathogen growth.

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This article is a direct contribution from a Fellow of the American Academy of Microbiology.

The 2014 caramel apple listeriosis outbreak infected 35 people across the United States and one additional person in Canada; seven deaths were reported, with listeriosis directly causing three of the deaths (1, 2). The outbreak took producers, public health officials, and food safety experts by surprise: caramel-coated apples are not a food on which *Listeria monocytogenes* should grow. First, the pH of apples is too low (usually <4.0) to support growth of *L. monocytogenes* (3). Second, the caramel coating used on apples both is hot (~95°C) and has low water activity, usually <0.80 (4), and most *L. monocytogenes* strains require water activity ( $a_w$ ) of at least 0.93 for growth (5). Although *Listeria* spp. are common in the produce fields (6), there are no surveys that suggest that *L. monocytogenes* is a pathogen routinely associated with apples (7). Additionally, intact apples have not been implicated previ-

ously in foodborne disease outbreaks (8), with one exception due to an unknown etiological agent (9).

The epidemiological association with caramel apples was strong, as 28 of the 31 persons interviewed reported eating them (2). Three additional patients sickened with the outbreak strains did not remember eating caramel apples but did recall eating whole or sliced green apples from an unknown source (1). At least three different caramel apple manufacturers were involved in the outbreak, although the apples were sourced from a single common apple producer. *Listeria monocytogenes* isolates from environmental samples collected from that apple producer's facility matched isolates from persons sickened in the outbreak, as determined by using whole-genome sequencing (2). These findings strongly suggested the *L. monocytogenes* originated on the apples

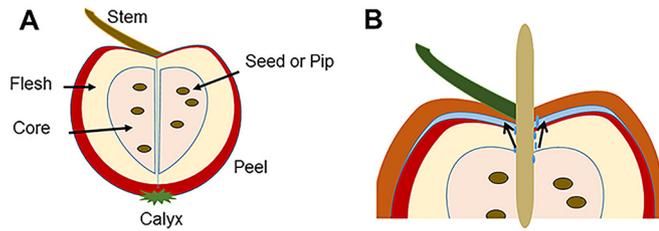


FIG 1 Key parts of the apple (A) and the caramel-apple interface microenvironment (B).

but left unanswered how the pathogen multiplied on caramel-coated apples.

*L. monocytogenes* is thought to have an infectious dose of about  $10^5$  to  $10^7$  CFU in high-risk individuals (10, 11). As noted above, the pathogen is common in the environment, including in soils, pastures, and decaying vegetation, and can colonize food processing plants as well. Strains that cause foodborne disease tend to be particularly adept at biofilm formation (12), making them especially difficult to eliminate in the environment once established. Importantly, *L. monocytogenes* has the ability to multiply at refrigeration temperatures.

We hypothesized that the caramel layer on the apple traps moisture next to the surface, creating a microenvironment on the surface of the apple that facilitates growth of *L. monocytogenes* cells that are already present on the apple surface (Fig. 1A). Insertion of the stick may expedite juice migrating to the surface of the apple, increasing the water activity in or just below the caramel layer. Although caramel-coated apples are typically distributed under refrigeration conditions, they may be unrefrigerated for 2 to 4 weeks by retailers or consumers. Storage at nonrefrigeration tem-

peratures can accelerate both moisture migration and microbial growth.

**Listerial growth on caramel-coated apples.** To test our hypothesis, three separate caramel apple growth trials were conducted, with three apples tested for each set of conditions and time point in each trial (a total of 144 apples assayed in the study). The results reported are the means and standard errors of enumeration data across all trials. We prepared a cocktail of four *L. monocytogenes* strains associated with the outbreak (all serotype 4b and described further in “*Listeria monocytogenes* inoculum preparation” below). Apples (as purchased, without any additional sanitation procedures or removal of wax) were inoculated on the skin, stem, and calyx regions (Fig. 1A) with an average of  $4.2 \pm 0.7$   $\log_{10}$  CFU per apple. A wooden stick was inserted through the stem of half of the apples. The other apples did not receive a stick. Dipping the apples into the hot caramel (95°C) resulted in an immediate reduction of  $\sim 0.8$  to  $1.2$   $\log_{10}$  *L. monocytogenes* per apple. Coated apples were allowed to cool and then stored at 25°C or 7°C. On caramel apples with sticks, the mean populations of *L. monocytogenes* increased an average 3.6  $\log_{10}$  CFU by day 3 when apples were stored at room temperature (25°C) and remained at least 3.4  $\log_{10}$  CFU above baseline for the duration of the study (Fig. 2). In contrast, listerial growth was delayed on caramel apples without sticks, with populations increasing an average 0.3, 1.5, and 2.1  $\log_{10}$  CFU above baseline by days 3, 7, and 11, respectively. Levels of *L. monocytogenes* growth on caramel-coated apples without sticks were statistically significantly different from those on apples without sticks ( $P < 0.05$ ).

Reducing the storage temperature to 7°C slowed *L. monocytogenes* growth on caramel apples, especially in the absence of sticks. No *L. monocytogenes* growth was observed on caramel apples

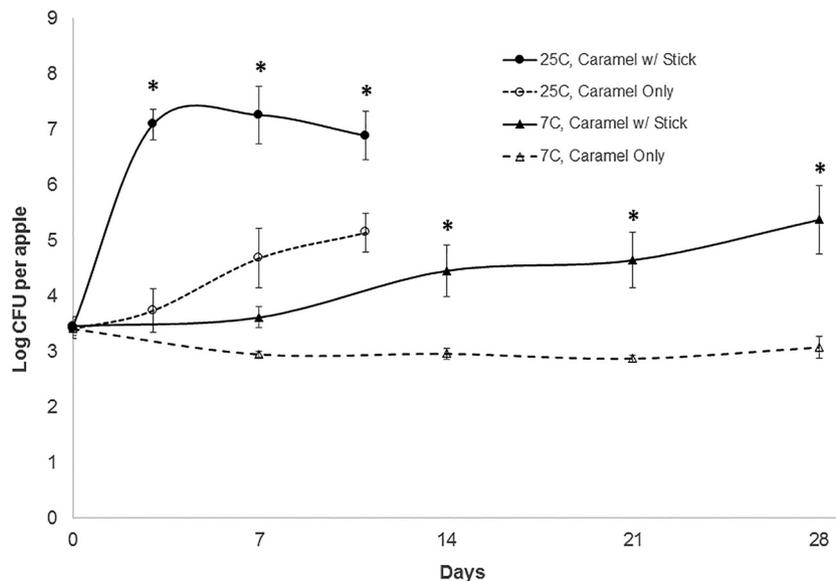


FIG 2 Changes in populations of *L. monocytogenes* in inoculated caramel-coated apples, with and without stick penetration, stored at 7 and 25°C for up to 28 days. Data are means and standard errors from three separate trials, with three apples per variable at each time interval ( $n = 9$ ); a total of 144 apples were assayed for the data presented. Asterisks indicate values that are statistically significantly different ( $P < 0.05$ ) from corresponding values for apples without sticks. After 3 days at 25°C, *L. monocytogenes* levels were statistically significantly different from baseline levels ( $P < 0.05$ ) in caramel apples with a stick. In contrast, for caramel apples without sticks, *L. monocytogenes* levels did not become statistically significantly different from baseline levels until 11 days at 25°C. At 7°C, *L. monocytogenes* levels in apples with sticks did not become statistically significantly different from baseline until 28 days. In caramel apples without sticks at 7°C, no change in *L. monocytogenes* levels was observed at any time point compared to baseline.

without sticks during 4 weeks of storage at 7°C (Fig. 2). When caramel apples were penetrated with sticks and stored at 7°C, no growth was detected at 1 week, but populations increased 1.0, 1.2, and 1.9 log<sub>10</sub> CFU per apple above baseline at 2, 3, and 4 weeks, respectively (Fig. 2). No *L. monocytogenes* growth (~0.4-log reduction) was observed on inoculated, uncoated apples stored at 7°C for 21 days (data not shown).

These data are consistent with the hypothesis that *L. monocytogenes* can grow in the microenvironment between the apple surface and caramel coating of contaminated caramel-coated apples that are stored at room temperature. We hypothesize that transpiration of moisture across the cuticle occurs during long-term storage of apples and that the moisture is trapped under the caramel coating, increasing the localized  $a_w$  even in the absence of a stick. *L. monocytogenes* growth was greater in apples into which a stick was inserted. Juice from the apple is expressed when the stick initially penetrates the apple core, and liquid may continue to migrate to the surface along the region where the stick was inserted (Fig. 1B) during storage. This increased amount of liquid could further raise the  $a_w$  under the caramel coating. The low pH of the juice is likely neutralized by the caramel during equilibration, resulting in conditions conducive to growth of *L. monocytogenes*.

Although we did not yet test whether *L. monocytogenes* grows on the surface of uncoated apples following stick insertion, the apple juice transported to the apple surface would evaporate quickly. This would restore a low  $a_w$  to the surface that would be unsuitable for bacterial growth. The use of wax coating on the apple reduces dehydration of the apple during storage. Wax (e.g., carnauba-shell wax) itself does not have antimicrobial activity against *L. monocytogenes* or *Escherichia coli* O157:H7 *in vitro* (13); however, lower populations of total bacteria, molds, and yeast were recovered from waxed apples than unwaxed apples throughout 5 months of storage at 1°C (13). Therefore, using unwaxed apples may not alter the growth rate of *L. monocytogenes* on the caramel-coated apples.

In addition, we hypothesize that some *L. monocytogenes* cells harbored in the stem area might be pushed into the core when the stick is inserted, where these bacterial cells would be protected from the heat of the caramel. Liquid could carry surviving *L. monocytogenes* cells to the surface, where they would be trapped under the caramel in a region where the local  $a_w$  might be sufficient for listerial growth. Both moisture transfer (which is trapped under the caramel layer) and microbial growth are accelerated at room temperature compared to refrigeration.

We chose regions of the apple surface (calyx, stem, and peel areas) for inoculation because intact apples rarely harbor bacteria within the flesh (7), and the stem and calyx regions are common harborage sites for microbes on apples (14, 15). We also focused on these regions for microbial collection from the caramel apples by immersing them in buffer and massaging the caramel off the apple. *L. monocytogenes* present in this wash buffer was then enumerated. It is unlikely that *L. monocytogenes* was also present within the flesh of the fruit because of the surface inoculation method used in our study. In addition, the pH of the apple flesh used in our experiments was measured to be 3.2, and growth of *L. monocytogenes* below pH 4.0 has not been reported (16). A previous study reported *L. monocytogenes* inactivation in pH 3.4 apple juice but growth in Red Delicious apples slices (pH 4.7) stored at 10 or 20°C (17). Both Granny Smith and Gala apples

were implicated in the 2014 listeriosis outbreak, but Granny Smith apples were chosen for these experiments because their exceptionally low pH represents a steeper hurdle for bacterial growth (3).

It is possible that other parts of the apple, such as the core or seeds, also hosted *L. monocytogenes* growth. These parts of the apple are not typically eaten completely, but may be bitten into by consumers. The pH of the core region of Granny Smith apples used in these experiments was not measured, but in other apple varieties, the core region pH may be 0.6 to 0.8 units higher than that in the apple flesh (18, 19). Future experiments are planned to investigate whether *L. monocytogenes* growth occurs in the core region.

It is unknown whether the strains of *L. monocytogenes* from this disease outbreak possess unusual resistance to low pH or exceptional virulence. Additional studies are in progress to determine the minimum pH for growth of the outbreak strains in laboratory media and apple juice and to determine if the addition of antimicrobials to the caramel dip can inhibit listerial growth. All outbreak strains tested were able to form biofilms, invade, and multiply within the human adenocarcinoma cell line Caco-2 and exhibit virulence in an established mouse model (N. G. Faith and C. Czuprynski, unpublished data), comparable to that of a different *L. monocytogenes* strain implicated in another significant food-borne disease outbreak (20).

The level of *L. monocytogenes* that was recovered from the surface of the apples following caramel dipping (3 to 3.4 log<sub>10</sub> CFU per apple) represents a level that could potentially be found on produce. A review of 165 prevalence studies found a 0.17% probability for *L. monocytogenes* to be present on a fresh or minimally processed vegetable at 3 log<sub>10</sub> CFU/g (21). Following 3 days of incubation at 25°C, some individual caramel apples with sticks had levels of *L. monocytogenes* as high as 7 log<sub>10</sub> CFU/apple, which is sufficient to cause disease if the product is consumed by a susceptible individual.

**Conclusions.** Our findings suggest that the 2014 listeriosis outbreak associated with caramel-coated apples can be explained by growth of *L. monocytogenes* occurring at the interface between two foods which, by themselves, are inhibitory to pathogen growth. If *L. monocytogenes* was present on or in the apple after coating with hot caramel, the typical extended storage at ambient temperature by the retailer, and perhaps the consumer, would be sufficient to allow the pathogen to grow to infectious levels. The insertion of the stick into the apples increased the growth rate of *L. monocytogenes* in caramel-coated apples, likely by enhancing the moisture migration to the caramel-apple interface and accelerating the development of optimal growth conditions. One might suggest eliminating the stick; however, this could hinder both production and consumption of the product and therefore may not be a useful strategy for the caramel apple industry. Practical intervention strategies might include validated disinfection of the apple, addition of growth inhibitors to the caramel coating or apple wax, or temperature-time controls to inhibit growth of *L. monocytogenes* on caramel apples.

***Listeria monocytogenes* inoculum preparation.** A four-strain mixture of *L. monocytogenes* clinical isolates was used in this study. The inoculum was composed of three strains from the 2014 caramel apple outbreak (573-035, 576-043, and 580-060; all serotype 4b) plus one additional strain (548-072, also a serotype 4b strain) that was not considered responsible for an outbreak case but matched the pulsed-field gel electrophoresis (PFGE) patterns of

the outbreak strains (provided by the Wisconsin State Laboratory of Hygiene, Madison, WI). Stocks of these strains were maintained in ceramic beads (CRYO/M; Copan Diagnostics Inc., Murrieta, CA) stored at  $-80^{\circ}\text{C}$ . For inoculum preparation, each individual strain bead was cultured in 10 ml of fresh Trypticase soy broth (TSB; Becton, Dickinson and Company, Sparks, MD, USA) at  $37^{\circ}\text{C}$  for 20 to 24 h. The freshly grown culture (0.1 ml) was further transferred into 10 ml of fresh TSB and incubated at  $37^{\circ}\text{C}$  for 18 to 22 h. Cells were harvested by centrifugation ( $4,000 \times g$ , 20 min) and suspended in 4.5 ml 0.1% buffered peptone water ( $\text{pH } 7.1 \pm 0.1$ ). Equivalent populations of each isolate were combined to provide a four-strain mixture of *L. monocytogenes*. Purity and populations of each strain were verified by plating on Trypticase soy agar (TSA) and modified Oxford agar (MOX; *Listeria* selective agar base; Difco, BD Biosciences, Sparks, MD).

**Inoculated apple preparation and testing.** Waxed Granny Smith apples (1.4-kg bags) and commercially prepared caramel apple dip (ingredients included high-fructose corn syrup, skim milk, corn syrup, palm oil, sugar, butter, modified corn starch, disodium phosphate, potassium sorbate, tert-butylhydroquinone, salt, mono- and diglycerides, and artificial flavors) were purchased from a local retailer. The pH of the apple flesh (skin removed) was 3.2, and the  $a_w$  was 0.98; the caramel apple dip had a measured  $a_w$  of 0.79 and a pH of 5.85. Apples with obvious damage/bruising were not used for these experiments. Granny Smith apples were chosen for tests because this variety was implicated in the listeriosis outbreak and because their high acidity represents a higher barrier for microbial growth.

In order to simulate/prepare *L. monocytogenes*-contaminated apples, 200  $\mu\text{l}$  of *L. monocytogenes* cocktail was pipetted into the bottom calyx of the apple ( $\sim 22^{\circ}\text{C}$ ). The inoculum was allowed to stand for 2 min; the residual volume was removed by pipette and applied to the stem region and allowed to sit for another 2 min; finally, the residual volume was applied over the surface of the apple using a sterile cotton swab. Apples were then divided into two groups; for one set of apples, wooden sticks (either flat sticks, 11.4 cm long by 0.95 cm wide by 0.2 cm high, or round sticks, 14 cm long by 0.6 cm in diameter; there was no difference in growth rates among apples with different stick dimensions) were inserted approximately 5 cm into the core region from the stem side, whereas no sticks were inserted into the second set of apples. The sticks were not sterilized or treated in any way before use, and the moisture content of the dry sticks was not measured in this study. All apples were air dried for a minimum 5 to 10 min at room temperature (visibly dry). *L. monocytogenes* populations were determined on triplicate inoculated apples after air drying as described below.

Caramel dip was placed in a 2.5-liter double-jacketed mixer (Universal Machine UMC-5; Stephan Machinery GmbH, Hameln, Germany) and heated with agitation to  $95^{\circ}\text{C}$  (commercial caramel apple makers typically use a temperature of 104 to  $116^{\circ}\text{C}$ , but temperatures can cool to  $<100^{\circ}\text{C}$  during production). The caramel was removed from the heat once it reached  $95^{\circ}\text{C}$ , and apples were then dipped into the caramel using either the stick or kitchen tongs. During the process, the caramel temperature decreased to  $85^{\circ}\text{C}$ . The dipping process resulted in a caramel coating approximately 3 mm thick.

Coated apples were placed on individual sanitized polystyrene weighing boats, transferred to household polyethylene storage containers, lidded, and then stored at 25 or  $7^{\circ}\text{C}$  (without addi-

tional humidity control); triplicate samples for each treatment were assayed before and after coating and on days 3, 7, 11, and 14 for  $25^{\circ}\text{C}$  and at weeks 1, 2, 3, and 4 at  $7^{\circ}\text{C}$ . The study was performed three times.

*L. monocytogenes* populations were enumerated from inoculated apples by transferring to sterile polypropylene sample bags and adding 100 ml of sterile 1% buffered peptone water to each package. The contents of the bag were massaged externally by hand for about 3 min to release the caramel and cells from the surface. Rinsates were serially diluted, and *L. monocytogenes* populations were enumerated by surface plating serial dilutions of rinse material on MOX. Typical colonies recovered on MOX were considered confirmatory.

**Statistical analysis.** Data were analyzed using a one-way analysis of variance (ANOVA) followed by Tukey's multiple comparison test. *P* values of 0.05 or less were considered statistically significant.

## ACKNOWLEDGMENTS

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-026**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend 3-302.11: When Raw Animal Products Do Not Need Separation from RTE

**Issue you would like the Conference to consider:**

Modify 3-302.11(A)(2) to indicate ready-to-eat foods may be combined as *ingredients* with raw animal foods.

**Public Health Significance:**

While 3-302.11(A)(1)(a) clearly states that raw animal products must be kept separate from "raw READY-TO-EAT FOOD such as fruits and vegetables", retailers often package meal kits combining fresh, raw animal products with ready-to-eat food. Whether it is raw turkey in an aluminum pan on top of prepared stuffing, raw chicken with sliced peppers, raw roast wrapped with a bag of peeled vegetables, or a package of ground beef wrapped with tortillas, shredded cabbage, and a lime, the meal kits often contain ready-to-eat products next to raw animal products sometimes with no additional separation.

While the consumer likely sees the need to safely handle and fully cook ready-to-eat foods when combined as ingredients in the same package with raw animal products, the presence of raw animal products next to ready-to-eat foods requiring separate handling or not needing a cook step, may increase the risk of cross contamination for the consumer.

The presence of the fresh meal kits and other combinations of raw animal products with ready-to-eat ingredients at national retailers indicates current practice across multiple jurisdictions. Modifying 3-302.11 to identify that ready-to-eat foods may be combined as an ingredient with raw animal products will alleviate confusion for retail production of raw, fresh animal product meal kits, will help increase nationwide consistency, and will help reduce risk of cross-contamination.

**Recommended Solution: The Conference recommends...:**

...that a letter be sent to FDA requesting that Section 3-302.11(A)(2) be modified as follows:

(A) FOOD shall be protected from cross contamination by:

...

(2) *Except when combined as ingredients*, separating types of raw animal FOODS ~~from each other~~ such as beef, FISH, lamb, pork, and POULTRY from READY-TO-EAT FOODS and each other during storage, preparation, holding, and display by:

(a) Using separate EQUIPMENT for each type, <sup>P</sup> or

(b) Arranging each type of FOOD in EQUIPMENT so that cross contamination of one type with another is prevented, <sup>P</sup> and

(c) Preparing each type of FOOD at different times or in separate areas; <sup>P</sup>

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**Supporting Attachments:**

- "3-302.11 Raw Meat Meal Kits at Retail"

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-027**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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**Issue History:**

This issue was submitted for consideration at a previous biennial meeting, see issue: 2010 III-015; new or additional information has been included or attached.

**Title:**

Temperature of Water for Handwashing Sinks

**Issue you would like the Conference to consider:**

Remove from the current published version of the 2017 Food Code Section 5-202.12(A) the requirement that a hand sink must deliver running water at a specific measured temperature and replacing the temperature to require warm water be provided.

**Public Health Significance:**

Safe food production is dependent on food production workers frequently washing their hands by following the hand cleaning procedure outlined in Section 2-301.12.

Harmonizing the language between 2-301.12 and 5-202.12(A) will help eliminate misinterpretation by many industry partners who try to comply with the food code by requiring employees to wash their hands using the minimum temperature specified in 5-202.12(A).

Additionally, a large percentage of hand sinks are installed in kitchens and restrooms with touch-free faucets. The water is pre-mixed to provide warm and comfortable water for hand washing. The use of touch-free faucets makes it difficult, without assistance of a plumber, for industry to periodically check the temperature of the hot water source at the hand sinks to monitor their compliance with 5-202.12(A).

An October 1, 2015 letter from the FDA titled "Handwashing water temperature" and published to the FDA Food Code Reference System clarifies that "...the FDA Food Code does not specify that hands are to be washed using water at a specific temperature..."

Public health is better protected by following the procedure outlined in 2-301.12 and hands are rinsed using warm, comfortable water as referenced in the attached October 1, 2015 FDA letter.

**Recommended Solution: The Conference recommends...:**

...that a letter be sent to the FDA recommending a change to the most current version of the 2017 Food Code section 5-202.12 Handwashing Sink, Installation (A) to read as follows: (new language is underlined; language to be removed is in strikethrough format):

(A) A HANDWASHING SINK shall be equipped to provide warm water ~~at a temperature of at least 38°C (100°F)~~ through a mixing valve or combination faucet. <sup>Pf</sup>

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**Content Documents:**

- "2017 FDA Food Code"

**Supporting Attachments:**

- "FCRS 2015 "Handwashing water temperature""

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Document 1

2017 FDA Food Code

Weblink: <https://www.fda.gov/media/110822/download>

Section: **5-202.12**

Page: 137



Reference Document: 2013 Food Code

Provision(s): 2-301.12; 5-202.12

Document Name: Handwashing water temperature

Date: October 1, 2015

Question: Does the FDA Food Code specify a specific water temperature at which hands are to be washed?

Response:

No, the FDA Food Code does not specify that hands are to be washed using water at a specific temperature.

Section 5-202.12 of the 2013 FDA Food Code establishes criteria for the installation of handwashing sinks used in a retail food establishment. Paragraph 5-202.12(A) states that a handwashing sink must be capable of delivering running water that is at least 38°C (100°F). Section 2-301.12 establishes criteria for how food employees are to clean their hands and exposed portions of their arms at a handwashing sink and specifically indicates that hands should be rinsed under warm running water. The word “warm” is not a defined term in the Food Code. Therefore, while the handwashing sink must be capable of delivering running water that is at least 38°C (100°F), flexibility is provided such that a food employee can adjust the temperature of the running water to suit his or her preference. In practice, this means that per the Food Code food employees may wash their hands under running water that is less than 38°C (100°F). Always check with applicable state and local codes, including plumbing codes, for specific jurisdictional requirements.

*The FDA Food Code is neither federal law nor federal regulation and is not preemptive. It represents FDA’s best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. The FDA Food Code provisions are designed to be consistent with federal food laws and regulations, and are written for ease of legal adoption at all levels of government.*

References:

1. 2013 Food Code, Section 2-301.12 Cleaning Procedure; Section 5-202.12 Handwashing Sink, Installation

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-028**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend 5-202.12 of Food Code to Change Hot Water Temperature

**Issue you would like the Conference to consider:**

A recommendation is being made to reconsider the requirement in the FDA Food Code that water for handwashing be available at 100°F based on more recent available science.

**Public Health Significance:**

Handwashing efficacy has been often studied to determine which factors are most important in reducing pathogen load on hands. Requirements of the FDA Food Code should be based on scientific data. Higher water temperatures require additional energy usage, and many public restrooms have lowered target water temperatures to combat scald concerns. There are documented risks of burns and scalds among elderly and children, and food service establishments often struggle juggling the requirement of hot water for handwashing with these risks. Numerous studies have been done to determine if the water temperature Research has been done to show that the temperature of water used in handwashing does not impact pathogens removed from hands during handwashing<sup>1</sup>. The temperature of the water serves as a comfort factor for the food employee who is participating in handwashing. Overall, since water temperature has been proven to have no impact on handwashing efficacy, the 100°F water temperature should be reduced to a lower temperature that considered employee comfort while allowing for reduced temperature for energy usage and scalding concerns<sup>2</sup>.

**References**

1. Michaels et al *Food Service Technology*, 2, pp. 139-149
2. Jensen et al *Journal of Food Protection*, 80, pp. 1022-1031

**Recommended Solution: The Conference recommends...:**

That a letter be sent to the FDA requesting that Section 5-202.12 of the most current edition of the Food Code be amended to change the minimum required water temperature for handwashing to 21°C (70°F).

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**Supporting Attachments:**

- "Water Temperature as a Factor in Handwashing Efficacy"
- "Quantifying Effects of Handwash Duration..."

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

# Water temperature as a factor in handwashing efficacy

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## Abstract

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### Keywords:

antibacterial soap, handwashing, personal hygiene, skin damage, skin flora, water temperature

For many years, sanitarians have specified that the hands of food service workers should be washed and rinsed in warm or hot water to reduce the risk of cross-contamination and disease transmission. In the food service environment, it has been suggested that handwashing with water at higher temperatures contributes to skin damage when frequent handwashing is necessitated, and that insistence on hot water usage is a deterrent to handwashing compliance. Separate handwashing studies involving different water temperatures and soap types (antibacterial versus non-antibacterial) were performed. The 'glove-juice' technique was employed for microbial recovery from hands in both studies. Initial work evaluated antimicrobial efficacy based on water temperature during normal handwashing with bland soap. Uninoculated, sterile menstrua (tryptic soy broth or hamburger meat) was used to study the effects of treatment temperatures (4.4°C, 12.8°C, 21.1°C, 35°C or 48.9°C) on the reduction of resident microflora, while *Serratia marcescens*-inoculated menstrua was used to evaluate treatment effects on the reduction of transient contamination. Results of this first study indicated that water temperature exhibits no effect on transient or resident bacterial reduction during normal handwashing with bland soap. The follow-up study examined the efficacy and skin irritation potential involving water temperatures with antimicrobial soaps. Hands of participants were contaminated with *Escherichia coli* inoculated ground beef, washed at one of two water temperatures (29°C or 43°C) using one of four highly active (USDA E2 equivalency) antibacterial soaps having different active ingredients (PCMX, Iodophor, Quat or Triclosan). Skin condition was recorded visually and with specialized instrumentation before and after repeated washing (12 times daily), measuring total moisture content, transepidermal water loss and erythema. Overall, the four soap products produced similar efficacy results. Although there were slight increases in Log<sub>10</sub> reductions, visual skin irritation, loss of skin moisture content and transepidermal water loss at higher temperatures, results were not statistically significant for any parameter.

## Introduction

A critical and thorough evaluation of simple handwashing procedures reveals numerous variables to be considered by food service managers in order to achieve maximum or appropriate de-germing of the hands and fingernail regions. Numerous studies have explored issues such as type of soap (i.e. antibacterial versus plain, liquid versus bar), amount of soap, nailbrush

use, drying technique (i.e. cloth versus paper towels, paper towels versus air-drying), and application of instant hand sanitizers (postwash liquids). Previous studies indicate that these variables are crucial in achieving effective removal of transient bacteria from the hands under controlled testing conditions. Rarely mentioned in the scientific literature is testing to determine specific guidelines for water temperatures and flow rates. Many of the currently employed hand-

washing practices are based on untested traditions that could possibly result in compromised skin health. It is expected that warm or hot water would be beneficial in reducing bacterial counts from hands during handwashing, as heat provides energy for the increased solubility and melting of fats, oils and other soils which may serve as vehicles for bacterial transfer from hands. Warm/hot water, combined with the detergents present in soap, should theoretically provide greater emulsification of contaminating soils on the skin, resulting in a more efficient lifting of these soils for rinsing away.

Some food safety experts strongly recommend the use of antimicrobial soaps for food service workers, while others are now focusing on handwashing frequency. With the rise of antibiotic resistance, increased concern has been expressed with respect to antimicrobial soap usage. The reasoning has been that when warm/hot water is combined with antimicrobial soap, the temperature of activation is approached, accelerating chemical reactions and improving kill rates. Soil emulsification should allow for greater exposure of microorganisms in the contaminating soil to the antimicrobial active agents. Thus, bacterial population numbers may be reduced two ways: through soil emulsification and lifting/rinsing away, and inactivation provided by the antimicrobial agent(s) with higher temperatures doing a significantly better job. The infected food worker is the focus of improved hygiene measures, and food safety managers and regulators would be remiss to not try to optimize effectiveness. Asymptomatic food handlers have been identified as being responsible for approximately one-third of outbreaks traced back to the infected worker. Poor personal hygiene has been cited as a contributory factor in an average of 30% of foodborne illness outbreaks occurring in the U.S. between the years of 1973 and 1997 (Bean & Griffin 1990; Bean *et al.* 1996; Olsen *et al.* 2000). The vast majority of foodborne illness outbreak cases attributed to the infected food handler occurs in the food service environment (Michaels *et al.* 2002).

The main initiative in hand hygiene is the reduction of potentially pathogenic microorganisms from contaminated skin surfaces. Optimization of all variables involved in this task must not only provide sufficient removal and/or kill of potential pathogens, but must also refrain from damaging the skin, as this can affect handwashing compliance (Boyce and Pittet 2001) and seriously compromise food service safety. Skin damage associated with work from routine and frequent handwashing has also been seen to result in colonization of workers hands with potential pathogens.

With so many variables involved in such a 'simple procedure', it would make sense to explore and maxi-

mize all possible aspects of the process while minimizing negative collateral. This is especially important due to the many observations of food service workers revealing what is considered to be poor habits in handwashing techniques. Studies indicate that handwashing compliance drops considerably without supervision and monitoring, or in situations where skin damage occurs. This further amplifies the need to strengthen knowledge of all variables that might improve or weaken daily handwashing practices throughout the food processing and service industry.

As described by Price, two types of flora exist on the hands, transient and resident species (Price 1938). The transient flora is generally removed fairly easily. They do not have adhesion characteristics that hold them to the skins' surface and are somewhat suppressed by secretions and competitive exclusion by the resident flora (Dunsmore 1972). Resident flora is removed more slowly. Because of coevolution, resident flora have adapted to conditions on the skins' surface that cause rapid die-off of most transients. Invaginations such as the nail fold, hair follicles and sebum-producing sebaceous glands support a rich resident flora. Transient flora may consist of pathogens, spoilage bacteria or harmless environmental species. Under certain conditions, transient flora can change status and become permanent residents. Resident flora, as a rule, are not pathogenic types. Although colonization with coagulase-positive staphylococcus is fairly common (Noble & Pitcher 1978). Frequent or prolonged exposure of the skin to microbial contamination in soils, skin damage or fissures provide portals of entry to deeper tissue, and may result in many pathogenic bacteria found among the resident species (Price 1938; Kaul & Jewett 1981). Food workers in a number of different food industry segments (including catering and bakery) have been found colonized by varying numbers of potential pathogens (Seligman & Rosenbluth 1975).

The effective water temperature used for washing and rinsing hands was a topic of intense discussion at the U.S. Year 2000 Conference for Food Protection. This biannual conference assembles federal and state regulators, food safety academicians, food service industry scientists and safety managers to establish and recommend guidelines to the United States Food and Drug Administration (FDA) for inclusion into the FDA Model Food Code. This code, as adopted by individual US states, forms the basis for food safety regulation and enforcement activities to the food service industry. Several submitters of issues, brought before science and technology council (Council III), expressed their concern regarding the use of higher water temperatures as recommended of the food service/processing industry (Table 1). The United States Food and Drug

**Table 1** Submitters and handwashing water temperature issues at the year 2000 Conference for Food Protection

Submitter	Issue	Reason
L. Wisniewski (Select Concepts – Consulting)	‘Warm Water’	1. Hand Discomfort Decreases Frequency
M. Scarborough (Georgia Department of Human Resources, Division of Public Health)	37.7°C (100°F)	1. No Science (43°C vs. 37.8°C) 2. Plumbing Code @ 100°F Max. (Safety Concerns)
J. Budd (Healthminder/Sloan Valve Company)	35°C (95°F)	1. No Scientific Basis 2. Max Soap Efficacy at 35°C 3. Hand Comfort 4. Hot Water Discourages Hand Washing
E. Rabotoski (Wisconsin Conference Food Protection)	‘Tempered’ 29.5°C (85°F) to 43°C (110°F)	1. Hand Discomfort 2. Possible Scalding
B. Adler (Minnesota Department of Health)	Impose Temp. Range 43°C 110°F To 54.4°C (130°F)	1. Need upper limit or subject to OSHA 2. Food workers Don’t Wash 25 Sec. So Cannot Scald.
Reimers (H.E.B. Grocery Company)	‘Tempered’ To Warm	1. No Science . 2. Max Soap Efficacy 3. 43°C Risks Injury 4. Waste Water as Wait for Temp. at 43°C

Administration (FDA) Food Code provides recommendations for the food service industry to follow regarding food handling practices, application of HACCP principles and personal hygiene implementation (US Public Health Service 1999; US Public Health Service 2001). The main goal of the FDA has been the creation of uniform practices throughout all of the United States. The 1999 FDA Food Code requires sinks used for handwashing to be equipped so as to be ‘capable of providing water of at least 43°C (110°F), accomplished through use of a mixing valve or a combination faucet’ [tap] (US Public Health Service 1999).

All but one of the submitters requested temperature decreases with the intent of improving hand comfort, as the discomfort associated with higher temperatures results in decreases in hand washing frequency or compliance. Several submitters note a lack of scientific information on the subject. There is concern that a minimum handwashing temperature of 43°C (110°F), in addition to causing discomfort, will result in injury or scalding and may even be in conflict with local plumbing codes. Two submitters point out that soaps currently available target maximum effectiveness at around 35°C (95°F). Two submitters requested that the minimum temperature of 110°F (43°C) be changed to warm water or that it be tempered to a range of 85°F (29.5°C) to 110°F (43°C). and finally, one submission sought to place an upper temperature limit of 130°F (54.4°C), for fear that these regulations would be subject to Occupational Safety and Health Administration (OSHA) scrutiny and criticism without a limit.

Interestingly, it was noted in this submission, through reference to the Consumer Product Safety Commission, that second or third-degree burns have been shown to occur in the elderly at temperatures not much over 43°C (110°F). Council I and the General assembly of voting delegates passed a recommendation to lower the regulatory water temperature minimum to 29.5°C (85°F). In recognition of concern expressed by a number of stakeholders with regards to the issue of handwashing water temperature, the initial results of the work described in this report and the will of state voting delegates, the 2001 Food Code lowered the required handwash water temperature to 37.8°C (100°F) (US Public Health Service 2001).

The universe of food handling situations requiring effective personal hygiene spans from temporary hand-wash stations set up in produce fields and county fairs to advanced state of the art clean room style kitchens used to produce extended shelf life ready-to-eat foods sold at retail. In quick service restaurants, workers frequently switch between food and money handling. Due to the potential for money to carry potential pathogens, as described by Michaels, hands may require washing from up to 40 times or more in an 8-h shift (Michaels 2002). In many of these situations, it is difficult to provide water meeting strict temperature ranges. With regard to international settings, it is doubtful that underdeveloped parts of the world will easily be able to tap into warm/hot water supplies, much less into clean water sources at all. Water temperature shortcomings have been a common point of criticism by

food safety experts when reviewing handwashing procedures in the developing world as part of HACCP activities. Further, no matter where the location, it is difficult to manage and monitor food handlers to insure that minimum temperature levels are maintained during all handwashing activities. When subject to regulatory inspections, in the U.S., violations are given to food industry entities based on Food Code specifications. In some cases, based on accumulation of violations with water temperature being one of them, mandatory 48 h closure can result. This appears to be both costly and unnecessary based on the results of the studies described here.

In an extensive literature review of the effect of water temperature on hygienic efficiency, only two existing experimental studies shed light on this issue. Both of these involved hand sampling studies, in which the objective was to remove, identify and enumerate as many bacteria on the hands as possible, either as normal or transient flora. In hand scrubbing experiments, Price found that at temperatures from 24°C (75.2°F) to 56°C (132.8°F) there was no difference in de-germing rate (Price 1938). Since he scrubbed hands with a brush for a specific period of time, each in turn in a series of sterile wash basins, he might have been capable of seeing differences upon counting the flora in each basin. After conducting over 80 experiments in a 9-year period, Price concluded that the largest variable in determining the rate of removal of bacteria from the hands was the vigorousness of scrubbing. Other factors such as soap used or water temperature were less important. In later hand sampling experiments by Larson and others (implementing the glove juice method for recovery of microorganisms), no differences in isolation rates were seen at either 6°C (42.8°F) or 23°C (73.4°F) (Larson *et al.* 1980). While this information is inconclusive and does not answer questions concerning bacterial loads suspended in a confounding soil, they tend to indicate that there may not be a noticeable difference in efficacy over a range of temperatures from 6°C (42.8°F) to 56°C (132.8°F).

Various menstria have been used for handwashing efficacy studies. For studies involving transient flora, the most often used soil is tryptic soy broth (TSB). Microorganisms exhibit good survivability, with even distribution of contaminating microorganisms into skin cracks, creases and invaginations being possible. Ground beef probably represents the most appropriate menstria because of concern for risks of *E. coli* O157:H7 infection, but is only occasionally used (Sheena & Stiles 1982; Stiles & Sheena 1985). Meade and others have shown numerous sporadic cases of foodborne illness have been tied to poor personal

hygiene after ground beef preparation (Meade *et al.* 1997). In addition, due to its viscosity, thixotropic properties and level of organic soil, it would appear to be a good surrogate for fecal material.

A review of pertinent literature was also undertaken to determine if, independent of efficacy, facts on skin damage support a lowering of the temperature. The Consumer Product Safety Commission (CPSC) has noted that residential water heater thermostat settings should be set at 49°C (120°F) to reduce the risk of the majority of tap water scald injuries. Although the majority of scalding attributed to the home occur in children under the age of five and the elderly, third-degree burns are known to result in a two second exposure to 66°C (150°F), six-seconds at 60°C (140°F) and 30 s at 54.4°C (130°F) (US Consumer Product Safety Commission 2000). As we age, our skin becomes thinner, losing suppleness. This fact is important as many seniors are now actively involved in the food service industry. Due particularly to the elder risk, some have recommended that water be delivered from the tap at even lower temperatures of less than 43°C (110°F) (Stone *et al.* 2000).

The activity of soaps, friction and rinsing become crucial since the temperatures recommended in handwashing water alone would not provide thermal destruction of pathogenic microorganisms. Relevant to the discomfort issue associated with hot water is a previously conducted study by Horn and Briedigkeit involving dishwashing soaps (Horn & Briedigkeit 1967). In that study, participants were only able to withstand water temperatures at 43°C, 45°C, and 49°C (110°F, 113°F and 120°F), with tolerance levels due to discomfort peaking at one-minute (Horn & Briedigkeit 1967). Even though considerably longer than the 10–25 second exposure period that would result from handwashing, it is indicative of the fact that temperatures from 43°C and upwards (110°F and upwards) are at or near the human discomfort threshold.

Friction has been described as a key element in removing microbial contaminants from hands (Price 1938; Kaul & Jewett 1981). Friction applied during hand drying is instrumental in finishing the process (Madeline & Tournade 1980; Knights *et al.* 1993; Michaels *et al.* 2002). Removal of transient flora appears to be even more friction dependent than removing resident flora. Surfactant and antimicrobial compounds in soap are responsible for lifting soil and killing microorganisms suspended in the soil. When using bland soap to wash hands, handwashing efficacy appears to be dependent on the effects of surfactant action of the soap along with friction applied during the washing and rinsing process. Rinsing also provides the necessary removal by dilution. To facilitate appro-

appropriate rinsing of the hands, some personal hygiene consultants have suggested the practice of using thicker, higher viscosity soaps in larger doses, which would require a longer, more vigorous rinsing routine.

Price, upon noticing that in his scrubbing experiments that water temperature had little effect at degreasing of the skin, commented that water applied to the skin at a given temperature quickly reaches equilibrium with normal skin surface temperature unless hands are totally immersed (Price 1938).

Skin oils derived from sebum are liquid in the sebaceous gland and solidify on the skin surface. Beef tallow has a melting point range between 35°C and 40°C (95°F and 104°F), while lard or butterfat are liquefied at around 30°C (86°F) (Lide 1990). If handwashing efficacy for both resident and transient floras embedded in both natural and artificially applied fats depended on thermal melting, then log<sub>10</sub> reduction figures should have been greatest at the highest temperature and least at temperatures causing fats and sebum to congeal.

Fats such as tallow or lard are distinguished from oils in that the latter are liquids at room temperature. Hand soap formulations are designed to lift soil through their foaming action, dispersing and solubilizing organic soils through action of detergent surfactants. Primary micelles are formed, having hydrophilic and hydrophobic groups attached to each end of the surfactant monomer. Soaps with multiple surfactants form mixed micelles, which increases efficiency with various soil mixtures. In water and organic soil mixtures, these form complex micelle structures around hydrocarbon moieties (encapsulation) resulting in microemulsions. Thus, the soap provides a 'bridge' between the oily droplet and water, permitting the soapy water to 'wash away' greasy material.

## Materials and methods

The quantity of soap used for handwashing has the ability to effect handwashing efficacy, as shown by Larson (Larson *et al.* 1987). Various investigators (Michaud *et al.* 1972, 1976; Ojajarvi 1980; Stiles & Sheena 1987; Mahl 1989; Larson *et al.* 1990; Rotter & Koller 1992; Miller & James-Davis 1994; Paulson 1994) have used soap amounts in the range of 2.5–5.0 mL in their handwashing efficacy protocols. The higher levels are considered excessive, except in the area of hospital infection control. Many food service operations set soap dispensers at 1 mL per pump, and employees often times use multiple pumps. For this study, 3 mL of soap was chosen to represent an amount found to be significantly effective in an earlier study described (Larson *et al.* 1987).

Determination of appropriate handwashing duration for these studies (15 s) was arrived at through review of various governmental regulatory standards, test method guidelines and food safety specialist recommendations along with previous handwashing study observations. Suggested lathering times by specific entities are: The 1999 FDA Food Code (US Public Health Service 1999) (20 s), The American Society for Testing and Materials (American Society for Testing and Material 1995) (15 s), The Association for Professionals in Infection Control and Epidemiology (APIC) (Jennings & Manian 1999) (minimum of 10 s), and The American Society for Microbiology (American Society For Microbiology 1996) (a 10–15 second vigorous scrub). Several studies support a washing duration of at least 10 s, with sufficient transient removal efficiency achieved by 30 s. A study by Stiles and Sheena involving workers in a meat processing facility determined that a wash of 8–10 s was too short for adequate soil removal from the hands (Stiles & Sheena 1987). A study by Ojajarvi compared a 15 second and 2 minute wash, with the latter providing only an additional 3% transient bacterial reduction (Ojajarvi 1980). One observational study in food service indicates average duration times of 20 s in a silver service restaurant kitchen (Ayers 1998).

In our first study, the effects of water temperature on the reduction of both resident (normal) and transient bacteria during handwashing was performed at each of the following temperatures: 4.4°C (40°F), 12.8°C (55°F), 21.1°C (70°F), 35°C (95°F), or 48.9°C (120°F). Two separate laboratories participated in this work. Silliker Laboratories (South Holland, IL, USA) was responsible for transient flora experiments while Bio-Science Laboratories (Bozeman, MI, USA) performed normal flora studies. For transient flora studies, the experimental subjects' hands were artificially contaminated with *Serratia marcescens* in Tryptic Soy Broth (TSB) or irradiated ground hamburger. Sterile, uninoculated TSB and irradiated ground hamburger were used as confounding soils in testing for the reduction of the resident flora. Following hand contamination, baseline microbial counts were acquired using the 'glove-juice' method on one hand. Hands were moistened and washed/lathered for 15 seconds with 3 mL bland (nonantibacterial) soap, rinsed for 10 seconds (water flow rate of 7 L/minute) at the assigned water temperature (also used for the prelather moistening), and the opposing hand was then sampled using the same glove-juice technique. No drying of hands was performed, which would have had the effect of diminishing differences between experimental groups. Baseline and postwash readings were then compared to obtain bacterial reduction values. For this study, no skin condition assessments were performed.

The first study was performed using a non-antibacterial soap and examined temperature effects on bacterial reductions based on the solubility of greasy soils. It did not address the increased temperature effect on antimicrobial activation or possible skin damage. Therefore, the second study was undertaken, which not only involved a comparison of the microbial reduction effects of four antibacterial soaps at two different temperatures, but also evaluated skin conditions on the hands of participants throughout the study. The potential of each soap to cause negative skin changes at each water temperature combination was assessed by measuring the skin moisture content, rate of water loss from the skin, skin scaliness by computerized analysis of a digitized skin image, and by visual assessment of the dryness and erythema. This study was performed at BioScience Laboratories, employing eight subjects and using four different antimicrobial soaps, each having a different antimicrobial active ingredient. The soaps had antimicrobial activity equivalent to USDA E2 ratings (50-p.p.m. chlorine equivalency). The active ingredients in these products were Quaternary Ammonium (3% dual Quat formulation), Triclosan (1%), Parachlorometaxyleneol (PCMX-3%), and Iodophor (7.5% PVP-I). Participants consisting of paid volunteers performed multiple handwashes during two five-day test periods (weeks one and two) seven days apart using *Escherichia coli* (ATCC #11229) contaminated gamma irradiated ground beef. On days one through five of weeks one and two, the skin condition was evaluated visually, for moisture content using the Corneometer<sup>®</sup> CM825, for total evaporative water loss using the TC350 Tewameter, and digitally using the Skin Visiometer<sup>®</sup> SV 500 with Visioscan<sup>®</sup> VC98. The visual skin dryness and erythema (redness) scoring was performed by a single blinded (unaware of subjects antimicrobial soap product/water temperature configuration) evaluator trained in assessment of skin damage or irritation using a 0–6 scoring system (see Table 2) as originally described by Griffith and others (Griffith *et al.* 1969). Log<sub>10</sub> reduction data was determined with the first wash of days one, three and five under each water temperature condition. After handling the contaminated ground beef in a way to uniformly contaminate hands, one hand was sampled immediately (again, using the ‘glove-juice’ technique) for a baseline reading. The subjects’ then washed both hands at the specific water temperature (85° ± 2°F for week one and 110° ± 2°F for week two) with their randomly assigned product with their opposing hand being sampled to establish microbial counts. Each subject then washed 11 consecutive times with their assigned test product each day drying hands between washes, then hands were evaluated visually and digitally 30 minutes fol-

**Table 2** Grading scale for evaluating the skin of the hands\*

Grade	Description
0	No visible damage, ‘perfect’ skin
1	Slight dryness, ashen appearance, usually involving dorsum only
2	Marked dryness, slight flaking involving dorsum only
3	Severe dryness dorsum, marked flaking, possibly fissures in webs
4	Severe flaking dorsum, surface fissures possibly with slight palmar dryness
5	Open fissures, slight erythema (>10% of dorsal and interdigital surface), with or without severe dryness, no bleeding
6	Bleeding cracks, deep open fissures, or generalized erythema (>25% of area)

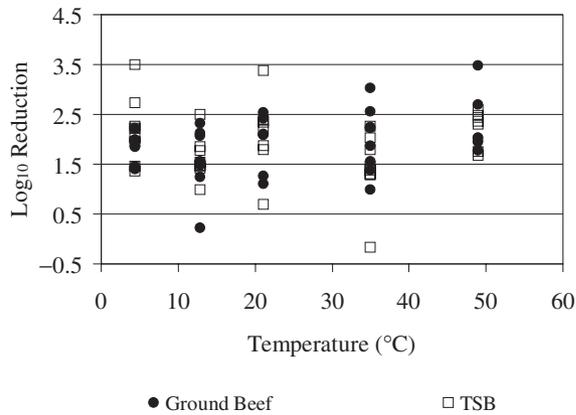
\*Griffith *et al.* 1969.

lowing the last wash. In all washing cases, lathering was performed for 15 seconds and rinsing for 10 seconds with three mL of the assigned test product.

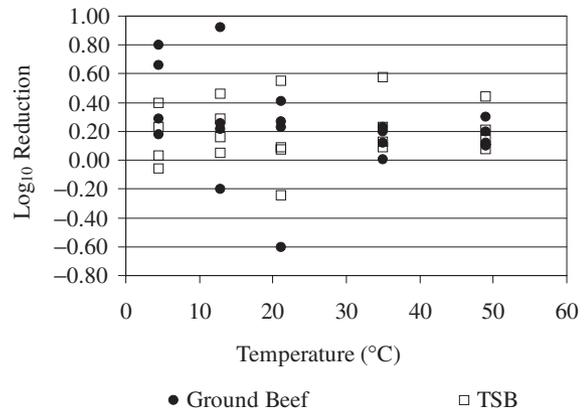
## Results and discussion

After extensive statistical analysis of the results from the first set of experiments, it was determined that there was no significant difference in bacterial log<sub>10</sub> reductions for either resident or transient bacteria at any of the test washing and rinsing temperatures. See Figs 1 and 2 for transient and resident flora data, respectively. Average log<sub>10</sub> reduction results for each soap are presented in Fig. 3.

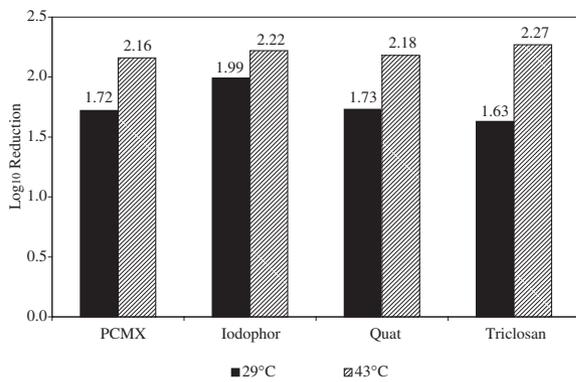
After extensive statistical analysis of the second experiment with antibacterial soaps involving the 2 sample *T*-test, Kruskal–Wallis test and Mann–Whitney test, no statistical difference in log<sub>10</sub> reductions was detected between the two wash temperatures for any of the products or as a group. Overall, the four products produced similar handwashing efficacy results. Although most of the washes at the higher temperature did produce a slight increase in bacterial reductions, it was not enough to be considered statistically significant. Figure 4 shows Tewameter<sup>®</sup> readings measuring *trans* epidermal water loss, while Figs 5 and 6 show visual dryness and baseline adjusted Corneometer<sup>®</sup> values, respectively. Skin scaliness values using a Visiometer<sup>®</sup> are shown in Fig. 7. Along with the slight additional reduction of bacteria at the higher temperature was increased skin visual dryness, increased transepidermal water loss and decreased scaliness, also determined to be statistically insignificant. Skin scaliness is highest on day one and two at the higher temperature but for days three, four and five, this reverses.



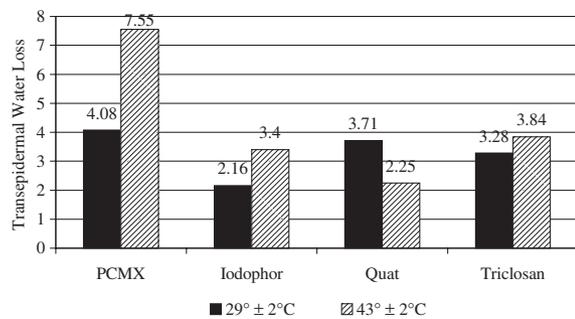
**Figure 1** Handwashing efficacy (Log<sub>10</sub> reduction) for transient flora (*S. marcescens*) in ground beef and TSB at selected water washing and rinsing temperatures.



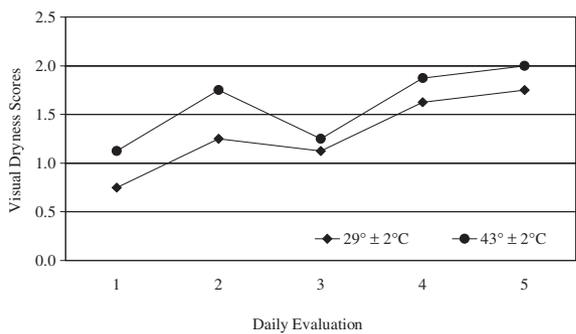
**Figure 2** Handwashing efficacy (Log<sub>10</sub> reduction) for resident flora in ground beef and TSB at selected water washing and rinsing temperatures.



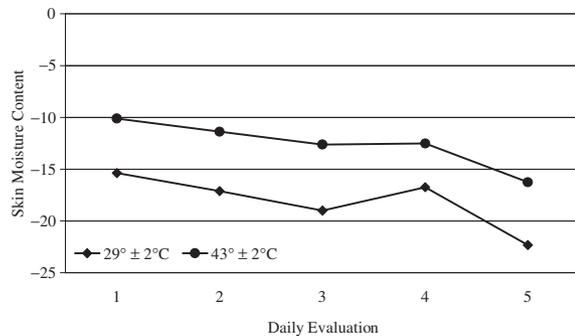
**Figure 3** Average Log<sub>10</sub> reduction of transient flora (*E. coli*) in ground beef using selected antimicrobial soaps.



**Figure 4** Average Tewameter® readings selected antimicrobial soaps at 2 different water temperatures.



**Figure 5** Average baseline-adjusted visual dryness scores (8 subjects) resulting from washing hands with 4 different E2 antimicrobial soaps for 5 days (12 x/day).

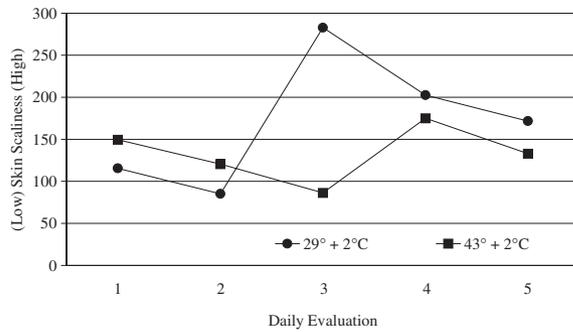


**Figure 6** Baseline-adjusted Corneometer® readings (8 subjects) resulting from washing hands with 4 different antimicrobial soaps for 5 days (12 x/day) at two different handwashing temperatures.

It is conceivable that the higher temperatures more rapidly removed loose layers of stratum corneum.

The results from both of these experiments are in agreement regarding the lack of hygienic benefits of

washing hands at higher water temperatures and particularly at temperatures at the upper end of human tolerance, sometimes described as ‘hot as you can stand’. From the first study, it is realized that higher water temperatures have no significant effect on the



**Figure 7** Average baseline-adjusted skin scaliness (8 subjects) resulting from washing hands with 4 different antimicrobial temperatures as measured using Visiometer®.

reduction of resident or transient bacteria in either easy to remove soil (TSB) or difficult to remove soil (ground beef) when using plain soap at a wide range of temperatures and using a standard hand wash. The second study provides additional support to the results of the first study by showing no statistically significant effect for the use of 110°F water (compared to 85°F water) to remove transient microorganisms embedded in ground beef from the hands when using any one of four different antibacterial based soaps or antibacterial soaps as a group. This experiment did show the trend toward higher kill as well as higher level of skin damage supporting propositions put forward by both camps.  $\text{Log}_{10}$  reductions do reflect slightly greater efficacy at higher temperatures but not at the level of significance expected, most probably due to the rapid equilibration to hand temperature described by Price (Price 1938).

Water has been identified as a skin irritant in its own rite, and part of this irritant potential can be exacerbated by temperature increase (Tsai & Maibach 1999). Repeated water exposure causes extraction or dilution of natural moisturizing factors in the stratum corneum. The water-holding property of the stratum corneum is provided in part by intercellular lipids and lipid rich sebaceous gland secretions (Noble & Pitcher 1978). The intercellular lipids, which when chromatographically fractionated, can be separated into cholesterol, cholesterol esters, phospholipids, free fatty acids, glycolipids and ceramide (Noble 1975; Imokawa *et al.* 1986). Loss of these lipid components results in a chapped and scaly skin appearance (Imokawa & Hattori 1985). Water induced irritation is known to exist in workers involved in continuous wet work, resulting in chapped and dry skin after wet work is completed (Halkier-Sorensen & Thestrup-Pedersen 1991).

Instances of primary irritant dermatitis to certain chemicals has been found to occur when hot water at 43°C (110°F) was used rather than lukewarm at 23°C–25°C (73°F–77°F) (Rothenborg *et al.* 1977). Detergent/surfactant formulations are known to cause changes to the stratum corneum such as disaggregation, swelling and morphological deterioration of corneocytes (Shukuwa *et al.* 1997). It has been found that heat plays a part in accelerating irritation of certain chemicals found in these detergent formulations. Berardesca and others found a significant difference between the temperatures of 20°C and 40°C (68°F and 104°F) in skin irritation to 5% sodium lauryl sulphate solution for a 4-day exposure period (Berardesca *et al.* 1995; Ohlenschlaeger *et al.* 1996). This irritation is documented using transepidermal water loss (TEWL) measurements, erythema (skin redness), skin reflectance, hydration (capacitance) and desquamation (stripping). Gross hand edema has been found to occur at temperatures between 35°C (95°F) and 45°C (113°F) when hands are completely immersed at those temperatures (King 1993). A significant increase in blood flow has also been shown in comparisons between 37°C and 43°C degrees (99°F and 110°F) (Nagasaka *et al.* 1987). Overall, these studies tend to show that food service workers derive no significant measurable benefit by using hot water (105°F+) to wash and rinse hands. Use of water at higher temperatures does seem to result in physiological changes collectively described as skin damage. There may be severe consequences of frequent use of hot water for handwashing at temperatures above 43°C (110°F), which can damage skin and heighten susceptibility to both allergens present in the food service environment and/or colonization (Larson *et al.* 1998). Rather, water temperature should be set at what is considered comfortable and generally conducive to handwashing.

The central components of effective handwashing thus consist of soap use in a way that promotes emulsification of soil (through vigorous friction/mechanical action) followed by thorough rinsing and drying, which again adds friction to the equation. Guidelines for handwashing in food service should probably not specify water temperature descriptors other than perhaps the word ‘comfortable’ when it comes to defining effective handwash standards. ‘Warm’ or ‘tempered’ would probably be acceptable, but more importantly as indicated by Jennings and Manian (1999), ‘running water’ should be to rinse away emulsified soils and associated transient contamination. Fingertips should be pointed down and hands rinsed and dried in a way to focus on parts of the hand that have shown to be missed during normal handwashing. This includes fingertips, thumbs and fingernail regions.

## Conclusions

A review of the literature on the subject of handwashing water temperature requirements showed considerable variation with respect to expert opinion on optimal temperature for removal of microbial contaminants from hands. There in fact was a virtual absence of data to back up the various positions on the subject. Sanitarians and food safety experts have specified water temperatures varying from room temperature (running water) up to 'as hot as you can stand', the latter of which is probably in the range of from 49°C (120°F) to 55°C (131°F). Regulations in the US and elsewhere tend to focus on temperatures between 43°C (110°F) and 49°C (120°F). Concern that these temperatures could be detrimental to skin health without documented efficacy led to the experiments described here. Hands were contaminated with soils similar to those encountered in the food service environment. These soils contained marker bacteria allowing handwashing efficacy to be determined at specified water temperatures against both transient flora and resident flora simultaneously.

The initial experiment involved testing with bland non-antimicrobial soap at 5 temperatures from 4.4°C (40°F) to 49°C (120°F). Independent of soil or bacterial type (resident or transient) there was no significant difference in efficacy attributed to water temperature. In the second experiment antimicrobial soaps (4) were used having different antimicrobial active ingredients, at each of two water temperatures, 29.5°C (85°F) and 43°C (110°F). Skin condition was monitored with frequent handwashes (12 ×/day) for the second set of water washing temperature experiments. In this experiment, even though slightly higher efficacy with was seen with antimicrobial soaps at higher temperatures, overall, there was no statistical difference in efficacy as measured in Log<sub>10</sub> reduction at the two water temperatures (regardless of soil or microflora types). Concomitant to the increase in efficacy at higher temperatures was a consistent trend for increases in measures of skin damage, such as skin moisture content, transepidermal water loss and erythema. This was also found not to be statistically significant.

Both the trend for higher efficacy of soaps with attendant skin damage at higher temperatures are grounded in theory. Under the conditions of these experiments neither was shown to be proven for practical application. Since efficacy is not markedly improved at higher temperatures but rather the real danger exists of skin damage, requirements for specific handwashing water temperature should be relaxed to improve acceptance of frequent handwashing by food workers at appropriate times to reduce foodborne illness potential.

Water temperature should be in a comfortable range, perhaps tempered.

As has been shown by many previous researchers, overall handwashing effectiveness is more dependent on the vigorousness of execution than details such as the type of soap, the length of handwash or in this case water temperature. The results obtained in these experiments confirm the observations made by Price (Price 1938) and Larson (Larson *et al.* 1980) indicating water temperature had little or no effect on the removal of bacteria from hands. While their original reports dealt with optimizing skin sampling efficacy, for the types of experiments performed and described in the current report.

Unfortunately, food service regulatory authorities, health inspectors and environmental health officers in the US and elsewhere have fixated on handwashing water temperature because it is measurable and in the somewhat mistaken belief that higher temperatures would result in cleaner hands. Up until recently, the existence of adequate hygiene facilities (functioning toilet, toilet paper, functioning sink, soap and paper towels) and water temperature measurement were to some extent the only measurable qualities whereby food safety inspectors could cite food service facilities for violation. Poor personal hygiene is often used after the fact to describe as a contributing factor aiding to an outbreak. With handwash monitoring devices employees' handwashing can be monitored, documented and verified within the HACCP framework (Michaels 2002). With this new technology and information from this report indicating that water temperature for handwashing is relatively unimportant, perhaps regulatory authorities will be able to focus on other more important factors having a bigger impact on food safety.

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## Research Paper

# Quantifying the Effects of Water Temperature, Soap Volume, Lather Time, and Antimicrobial Soap as Variables in the Removal of *Escherichia coli* ATCC 11229 from Hands

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## ABSTRACT

The literature on hand washing, while extensive, often contains conflicting data, and key variables are only superficially studied or not studied at all. Some hand washing recommendations are made without scientific support, and agreement between recommendations is limited. The influence of key variables such as soap volume, lather time, water temperature, and product formulation on hand washing efficacy was investigated in the present study. Baseline conditions were 1 mL of a bland (nonantimicrobial) soap, a 5-s lather time, and 38°C (100°F) water temperature. A nonpathogenic strain of *Escherichia coli* (ATCC 11229) was the challenge microorganism. Twenty volunteers (10 men and 10 women) participated in the study, and each test condition had 20 replicates. An antimicrobial soap formulation (1% chloroxylenol) was not significantly more effective than the bland soap for removing *E. coli* under a variety of test conditions. Overall, the mean reduction was 1.94 log CFU (range, 1.83 to 2.10 log CFU) with the antimicrobial soap and 2.22 log CFU (range, 1.91 to 2.54 log CFU) with the bland soap. Overall, lather time significantly influenced efficacy in one scenario, in which a 0.5-log greater reduction was observed after 20 s with bland soap compared with the baseline wash ( $P = 0.020$ ). Water temperature as high as 38°C (100°F) and as low as 15°C (60°F) did not have a significant effect on the reduction of bacteria during hand washing; however, the energy usage differed between these temperatures. No significant differences were observed in mean log reductions experienced by men and women (both 2.08 log CFU;  $P = 0.988$ ). A large part of the variability in the data was associated with the behaviors of the volunteers. Understanding what behaviors and human factors most influence hand washing may help researchers find techniques to optimize the effectiveness of hand washing.

Key words: Antimicrobial soap; Chloroxylenol; Hand hygiene; Hand washing; Soap volume; Water temperature

The U.S. Food and Drug Administration (FDA) Food Code (70) includes recommendations regarding hand washing frequency, duration, and technique; however, the scientific support for many of those recommendations is not always clear nor based on recent evidence. Section 2-301.12 of the Food Code requires the use of a “cleaning compound” (soap) during hand washing. The type of compound is not specified, and facilities may elect to use either bland (soap without an antimicrobial agent) or antimicrobial soap.

Recently, the FDA Center for Drug Evaluation and Research (71) issued a final rule establishing that over-the-counter consumer antiseptic washes (soaps) with specific active ingredients may not be marketed in the United States after 6 September 2017. The FDA indicated that the companies that produce these antimicrobial soaps have not provided sufficient evidence to prove that they are safe for daily use and are more effective than bland soap and water. This final rule covers 19 specific active ingredients,

including triclosan. However, the FDA has deferred the rule for three ingredients: benzalkonium chloride, benzethonium chloride, and chloroxylenol. This rule does not extend to hand sanitizers or antiseptic wipes and does not address antimicrobial soap sold for use in food service or food processing facilities.

The active ingredients used in antimicrobial soaps disrupt bacterial cell function by either destroying the cell (bactericidal) or inhibiting reproduction (bacteriostatic). These compounds are antiseptics and are not considered antibiotics (17, 60). The literature suggests that antimicrobial soaps provide a greater reduction in bacteria than do bland soaps (25, 28, 30, 53, 62, 65). However, in some studies minimal differences were found (15, 50, 67). A hand soap meta-analysis revealed that use of antimicrobial soaps, when accounting for all types of bacteria and formulations, tended to result in ~0.5-log greater reduction in microorganisms than did use of bland soap (53). Product formulation plays a key role in the effectiveness of antimicrobial agents and soaps, and many active antimicrobial compounds are available for use in soaps, and surfactants in addition to

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other ingredients in soaps or lotions can impede or enhance the activity of these compounds and the overall antimicrobial effect (14, 26, 69).

The combined literature on soap volume (i.e., the dose or amount used per hand washing event) indicates no significant interactions between soap volume and the effectiveness of the soap (28, 43, 53). These data can be confusing and often conflicting when many brands and formulations are compared. Fuls et al. (28) found that higher amounts of foaming 0.46% triclosan antimicrobial soap (1.5 to 3 g or two to four pumps of soap) increased the reduction of microorganisms by  $\sim 0.7$  log units ( $P < 0.001$ ) but did not observe a significant increase in microbial reduction when using a bland soap ( $P = 0.2$ ). Larson et al. (43) found that a control wash with bland soap was not significantly affected by the amount of soap used (1 versus 3 mL). However, these researchers also suggested that a higher volume of soap could contribute to skin damage and suggested that the minimal amount of soap required for a thorough wash should be used to reduce the likelihood of skin damage.

The temperature of the wash water required for effective hand washing has not been extensively evaluated and still generates interest. Wash water temperatures have an upper limit; very high temperatures that would rapidly destroy bacterial cells would also severely injure human skin (42, 68). The temperature of the water used during comfortable hand washing would not by itself inactivate resident microbes. Higher temperatures may still affect hand washing by increasing solvation or temperature dependent reaction rates. Boyce and Pittet (17) recommended avoiding use of hot water to wash hands because repeated exposure to hot water may increase the risk of dermatitis (damaged skin). Temperatures higher than 55°C can lead to scalding, and the recommended water temperature for human skin comfort is  $\leq 43^\circ\text{C}$  (42, 68). Results of a hand washing survey revealed that hand comfort and personal beliefs played key roles when persons choose the water temperature for hand washing (19). In two studies, Michaels et al. (49, 50) found no difference in microbial reductions after hand washing performed at various temperatures (4.4 to 48.9°C). However, the data in these two studies were obtained from only four volunteers, and only one study (50) included an antibacterial soap. Courtenay et al. (21) measured the differences in microbial reduction between a ServSafe recommended wash (which includes soap), a cool rinse, and a warm rinse. Only minor differences in microbial reduction were found between the cool rinse (26°C) and the warm rinse (40°C), but the interaction between temperature and soap could not be inferred from these data. In a study of various ways to sample bacteria from hands, no significant difference in bacteria recovered was found for sampling solutions at 6 or 23°C (45). Although in all of these studies the temperature of the wash water had no significant antimicrobial effect, the limited replicates (21, 49, 50), comparisons of a wash without soap (21), and lack of actual hand washing (45) indicate that more work on the effect of wash water temperature is needed.

The Food Code (section 2-301.12-B-3) (70) requires lathering for 10 to 15 s during hand washing. Although

specific studies of lather time as a variable have been published, the added friction (from a brush) has been evaluated (46, 59) with different results. Price (59) found greater microbial reduction with more scrubbing (constant and time dependent), but Loeb et al. (46) found no difference in microbial reduction between hand washing with or without a brush. A meta-analysis of the hand washing literature suggested that more studies are needed to understand the importance of wash duration (53). However, many researchers who have studied total wash time have suggested that longer wash times are correlated with greater microbial reductions (25, 28, 34, 47, 55). However, results of some studies surprisingly suggest that extended wash times, i.e.,  $>30$  s, may result in less effective reduction of transmissible microbes, which would diminish the intended purpose of hand washing (40, 50, 53). One research group hypothesized that extended washing ( $>30$  s) loosens but does not remove resident flora from hands, and these loosened microbes are now more easily transferred to other surfaces, resulting in a reduced overall benefit from removing microorganisms from hands (50). Extended washes and frequent washing can lead to damaged skin (4, 27, 29, 37–39, 57, 63, 66, 73, 74, 77), which promotes colonization by more dangerous microbes and reduces the ability of hand washing to remove bacteria from the (damaged) skin (40, 42, 44). Bidawid et al. (16) observed that when finger pads inoculated with hepatitis A virus were rinsed with 15 mL of water, no transfer of virus to lettuce pieces was detected, but when fingers were rinsed with only 1 mL of water, a 0.3% transfer was detected, suggesting that exposure to a greater volume of water may play a key role in hand washing. These conflicting results indicate that more research is needed to determine which hand washing step(s) can be lengthened to increase microbial reduction.

The literature on hand washing includes a tremendous amount of misinformation, and data on many issues are missing. Many hand washing recommendations are being made without scientific backing, and agreement among these recommendations is limited, as indicated by the major inconsistencies among hand washing signs (35). The goal of the present study was to close knowledge gaps in the hand washing literature pertaining to soap volume, water temperature, and lather time. The findings from this work will contribute to valid, evidence-based, helpful decisions concerning personal hygiene policies and practices.

## MATERIALS AND METHODS

**Volunteers.** Twenty-one volunteers were selected from Rutgers University (New Brunswick, NJ) and surrounding communities. Approval from the Rutgers Institutional Review Board was obtained via the standard process before volunteers were enrolled in this study. Volunteers were asked to refrain from using any type of antimicrobial hand soap and non-alcohol-based hand sanitizers for the duration of the study to avoid buildup of active antimicrobial ingredients on the skin, which could have interfered with the results (2, 12, 28, 54, 56, 64). Exclusion criteria included taking antibiotics or being ill during the 6 weeks before the start of the experiment, cuts or abrasions on the hands, self-identification as immunocompromised, or self-identification of discomfort with the experiment and a desire to be removed. One

volunteer asked to be removed and did not complete the study. The remaining volunteers (ages  $24.5 \pm 3.9$  years [mean  $\pm$  SD]) included 10 men (ages  $26 \pm 2.2$  years) and 10 women (ages  $23 \pm 4.7$  years).

**Questionnaire.** Volunteers were asked to fill out a questionnaire before participation in the experiments. The questionnaire included questions that may account for external variables that could affect skin quality and skin bacterial profiles. The answers were used to parse the volunteers into groups to evaluate whether log reduction data differed significantly between the groups. The demographic variables analyzed were age, sex, moisturizer use, facial cleanser use, medication use, hand washing frequency, recent illnesses, and lotion use.

**Experimental design.** Four variables (lather time, soap volume, water temperature, and product formulation) were evaluated using a fractional design. One set of conditions (5 s of lather time, 38°C water temperature, and 1 mL of product volume) served as the baseline, and the effect of each variable was studied while holding the other two variables constant. Each unique set of conditions was replicated 20 times such that the total number of experiments was  $20 \text{ baseline} + (3 \times 20 \text{ lather time}) + (2 \times 20 \text{ water temperature}) + (2 \times 20 \text{ product volume}) = 160$  hand washes. The entire design was repeated for bland soap and antimicrobial soap containing chloroxylenol, for a total of 320 hand washes. Each volunteer completed 16 hand washes. The target variables to be tested were randomly selected for each experiment. A volunteer performed only one wash per day until there were no more of the 16 sets for a volunteer to perform.

**Lather time.** Lather times of 5, 10, 20, and 40 s were evaluated. Lather time was defined as the length of time the volunteer lathered soap on their hands (by rubbing hands together) during a hand wash. Lather time did not include initial hand wetting ( $< 1$  s), soap application, hand rinsing (held constant at 10 s), or hand drying. Volunteers were instructed to lather their hands in a way that felt most comfortable.

**Water temperature.** Water temperatures of 38, 26, and 15°C (100, 80, and 60°F, respectively) were evaluated, and the water temperature was verified using a ThermoPen with  $\pm 0.4^\circ\text{C}$  accuracy (ThermoWorks, Lindon, UT). The temperature of the water was set prior to volunteer arrival and needed to be within  $\pm 2^\circ\text{F}$  at the target temperature for at least 60 s. The highest temperature used (38°C) was selected because the FDA Food Code (section 5-202.12) (70) indicates that a hand washing sink shall be equipped to provide water at a temperature of at least 38°C. The lowest temperature used (15°C) was deliverable by the existing plumbing and judged by the authors to be the lowest tolerable temperature for comfort.

**Estimation of energy consumption.** The energy consumption related to heating the water for hand washing was calculated with the following thermodynamic formula:

$$Q = M \cdot C_p \cdot dT / \eta$$

where  $Q$  is the amount of heat (kJ);  $M$  is mass (kg), representing the amount of water used for a hand wash where a flow of 1 gal (3.8 L) per minute is considered the average water flow with an aerator (1) and 10 s is assumed as the rinse time;  $C_p$  is the specific heat of water (kJ/kg K) at 4.19;  $dT$  is the temperature difference between the heated and ambient water, where an average

temperature of 10°C was assumed as the normal temperature for cold tap water and calculations were made for all three temperatures (38, 26, and 15°C); and  $\eta$  is the efficiency of the electric water heater, with an average efficiency of 0.92 based on guidance from the U.S. Office of Energy Efficiency and Renewable Energy (72).

**Soap volume.** Three volumes of soap were evaluated: 0.5, 1.0, and 2.0 mL. An automatic dispenser (GOJO Industries, Inc., Akron, OH) with a 0.5-mL output was used to dispense the soap. The dispenser was nondescript, had no timer, and did not reveal the formulation being used. This soap dispenser was validated before use each day by catching an aliquot of the foam solution from the dispenser and measuring this aliquot with a scale (Ohaus Scout Pro, Parsippany, NJ). This aliquot was compared with a 0.5-mL volume of the soap that was not converted to foam.

**Soap product formulation.** Two foaming soap formulations were used for all experiments, one bland soap (i.e., no antimicrobial active ingredients) and one antibacterial soap containing 1.0% chloroxylenol. Both soaps are commercially available (GOJO Industries) and used commonly in a variety of settings, including food service. The soaps were typical in formulation except for the antimicrobial agent and primarily contained a blend of amphoteric and anionic surfactants to remove soils, preservatives, and skin conditioners to soften the skin and balance the effects of the cleansing agents, which can be drying and irritating to the skin. Both soaps were slightly acidic; the pH was 5.2 for the bland soap and 5.5 for the antibacterial soap.

**Prewash procedure.** Volunteers performed a prewash before beginning the experiment. They were invited into the laboratory and shown the location of the sink but were not given any directions other than to simply wash their hands. No direction was given on how to wash hands or how long to wash. The researcher used a stop watch to discretely measure the amount of soap used, when the hands first touched the water, lather time, rinse time, and total wash time. Volunteers were given paper towels, one at a time, to dry their hands after washing and were given as many towels as requested.

**Challenge bacteria.** A nonpathogenic strain of *Escherichia coli* (ATCC 11229) served as the challenge bacterium for this experiment. Use of this strain is in accordance with current ASTM International hand washing protocols (8, 10). This strain is a well-established surrogate for transient bacteria transferred to hands during handling of raw foods. Cultures were made followed ASTM method E2946 (10). The *E. coli* was cultured in 10 mL of soybean-casein digest broth for  $24 \pm 4$  h at  $35 \pm 2^\circ\text{C}$ . This 24-h culture was harvested by centrifugation (Micro 12, Thermo Fisher Scientific, Waltham, MA) at  $7,000 \times g$  for 10 min and then washed in phosphate-buffered saline (PBS; 0.1 M, pH 7.2). The wash process was repeated three times, and cell pellets were resuspended in PBS to form a challenge suspension of  $\sim 8 \log$  CFU/mL.

**Hand contamination.** One milliliter of the *E. coli* challenge suspension was added to each volunteer's hands. Volunteers were instructed to rub their hands together (10 to 20 s) to cover all surfaces of their hands. Hands were held parallel to the floor to avoid unnecessary contamination of the forearms or elbows. The hands were allowed to dry until they did not appear visibly moist ( $\sim 40$  to 60 s). A sample was collected from the nondominant hand

TABLE 1. Mean, median, and range of log reductions of microorganisms after various hand washing treatments

Treatment <sup>a</sup>	Soap formulation	Microbial reduction (log CFU)					
		Mean	SD	Median	Maximum	Minimum	Range
All data	Antimicrobial	1.94	0.78	1.92	4.42	0.06	4.36
	Bland	2.22	0.74	2.22	4.40	-0.04	4.44
Baseline	Antimicrobial	1.92	0.68	1.87	3.13	0.69	2.44
	Bland	1.91	0.64	1.76	2.99	0.82	2.17
Lather time, 10 s	Antimicrobial	2.03	0.64	2.00	3.30	0.89	2.41
	Bland	2.16	0.74	2.22	3.60	1.03	2.58
Lather time, 20 s	Antimicrobial	1.95	1.00	1.82	4.39	0.35	4.03
	Bland	2.54	0.62	2.48	3.75	1.63	2.12
Lather time, 40 s	Antimicrobial	1.91	0.98	2.00	3.47	0.13	3.34
	Bland	2.43	0.71	2.25	4.09	1.57	2.52
Water temp, 15°C	Antimicrobial	1.88	0.62	1.91	3.34	0.76	2.57
	Bland	2.34	0.54	2.33	3.22	1.08	2.15
Water temp, 26°C	Antimicrobial	1.90	0.89	1.77	4.42	0.28	4.14
	Bland	1.98	0.71	1.99	3.07	0.80	2.27
Soap vol, 0.5 mL	Antimicrobial	2.10	0.77	2.18	3.24	0.06	3.18
	Bland	2.25	0.86	2.25	4.03	-0.04	4.07
Soap vol, 2.0 mL	Antimicrobial	1.83	0.65	1.81	3.34	0.64	2.69
	Bland	2.15	0.93	1.97	4.40	0.70	3.70

<sup>a</sup> Baseline treatment was 5-s lather time, 38°C water temperature, and 1-mL soap volume. Other treatments were identical to baseline except as noted. Sample size was 160 for the “all data” category, i.e.,  $n = 20$  per treatment.

before the hand wash, and that sample was used to calculate the prewash bacterial level.

**Bacteria recovery procedure.** A modification of the glove juice procedure (9, 11) was used to recover bacteria from volunteers' hands. A nitrile glove (powder-free nitrile examination gloves, Thermo Fisher Scientific) filled with 20 mL of PBS was placed over each hand, and the gloved hand was massaged for 60 s to dislodge the bacteria. The glove was then carefully removed, and the rinsate was poured into a collection tube (Falcon 50 mL Conical Centrifuge Tubes, Corning, Inc., Corning, NY). Tween 80 (10%) was used as a neutralizer in the sampling buffers for the antimicrobial soap experiments (7). Neutralization of the antimicrobial agent was confirmed using ASTM method E1054-08, section 9 (neutralization assay with recovery in liquid medium) (6).

**Sample dilution and plating.** PBS (pH 7.2 ± 0.1) was used for serial dilutions and contained the neutralizer when necessary. Samples were plated onto MacConkey agar (BBL, BD, Sparks, MD), and the CFUs were enumerated after incubating for 24 h at 35°C. The medium contained 4-methylumbelliferyl-β-D-glucuronide (Sigma-Aldrich, St. Louis, MO) to allow identification of *E. coli* without affecting colony morphology or viability (52).

**Hand washing.** Volunteer hand washing experiments were focused on the four variables: lather time, water temperature, soap volume, and soap formulation. Volunteers were given additional instructions as to how much soap to use (number of pumps), when to wet their hands, when to stop lathering, and when to stop rinsing. Volunteers were not told what formulation they were using or the water temperature. Volunteers did not dry their hands to avoid removal of bacteria with the paper towel (20, 32–34, 75).

**Postwash sampling.** Samples were collected from volunteers' hands immediately after the wash (<5 s). Both hands were sampled using the modified glove juice method (9, 11), and these samples were used to calculate the postwash bacterial levels.

**Postexperiment decontamination protocol.** Before leaving the testing area, volunteers washed their hands under running water for 20 s using bland soap and dried their hands with paper towels. One pump of alcohol-based hand sanitizer (Purell, GOJO Industries) was then applied to the volunteers' hands, and volunteers were asked to rub their hands together until the sanitizer was completely dry. The volunteers were then asked to leave the testing area.

**Data analysis.** Microbial reduction data gathered from the experiment were log transformed to achieve a normal distribution (61). The log reduction was determined by taking the logarithm of the prewash bacterial level on the nondominant hand (multiplied by 2 to estimate the level on both hands) and subtracting from that the logarithm of the sum of the postwash level on both hands.

A repeated-measures analysis of variance (ANOVA) and Tukey's range test and honest significant difference (HSD) test (Prism, GraphPad Software, La Jolla, CA) were used to determine whether multiple means were significantly different and whether any significant interactions existed between the variables. Differences were considered significant at  $P < 0.05$ . For scenarios in which only two variables were being compared, including when comparing groups from the questionnaires, a two-tailed  $t$  test was used to calculate  $P$  values (Excel, Microsoft, Redmond, WA) to determine whether significant differences existed between samples.

## RESULTS

Table 1 shows the overall log reductions for all treatment conditions tested and the mean log reductions overall for the antimicrobial soap containing chloroxylenol and the bland soap. Overall, the antimicrobial soap produced a mean (SD) 1.94 (0.78)-log CFU reduction in microbial levels (range, 1.83 to 2.10 log CFU). The bland soap produced a mean (SD) 2.22 (0.74)-log CFU reduction

TABLE 2. ANOVA of scenarios and volunteers

Variable	Soap formulation	SD	Degrees of freedom	Mean square
Between volunteers	Antimicrobial	0.9985	7	0.1426
	Bland	6.465	7	0.9235
Between scenarios	Antimicrobial	27.37	19	1.441
	Bland	26.2	19	1.379
Residual	Antimicrobial	68.08	133	0.5119
	Bland	54.5	133	0.4098
Total	Antimicrobial	96.45	159	
	Bland	87.17	159	

(range, 1.91 to 2.54 log CFU). The analysis revealed a significant effect for soap formulation ( $P = 0.00025$ ).

An ANOVA was performed to observe differences within the data sets and between volunteers (Table 2). The analysis revealed a significant difference between volunteers ( $P < 0.0001$ ) (person-to-person variability factors). The post hoc Tukey HSD test on the individual volunteer's mean log reduction data revealed significant differences ( $P < 0.05$ , data not shown). Multiple mean log reduction differences  $\geq 0.5$  log CFU were found between the volunteers, which suggests that a large part of the variability in the data sets were due to variability between the volunteers. A subsequent Tukey HSD test was performed to determine differences

between the individual scenarios (Table 3) to make sure that differences between scenarios were not overlooked when the two groups were combined. The analysis included lather time, water temperature, and soap volume as independent variables; the data were separated by soap formulation. For the bland soap, significant differences were found for lather time ( $P = 0.01$ ). A post hoc HSD test revealed that the bacterial reductions with the 20-s lather time were significantly different from those achieved with the baseline lather time of 5 s ( $P = 0.01$ ) but were significantly different from reductions achieved with the 10- and 40-s lather times. For bland soap, no significant effects on bacterial reduction were found for soap volume ( $P = 0.23$ ) and water temperature ( $P = 0.08$ ). For the antimicrobial soap, no significant effects on bacterial reduction were found for lather time ( $P = 0.85$ ), water temperature ( $P = 0.97$ ), and soap volume ( $P = 0.22$ ). However, for the antimicrobial soap data, the  $P$  values were higher for lather time and water temperature (lather time,  $P = 0.85$ ; temperature,  $P = 0.97$ ) than for the bland soap data (lather time,  $P = 0.01$ ; temperature,  $P = 0.08$ ).

Higher water temperature entails greater energy consumption (see Fig. 1). The energy consumption associated with heating water for 1,000 hand washes is 22.35 kWh for a water temperature of 38°C but only 12.77 kWh for a water temperature of 26°C, which is a reduction of 42%. The

TABLE 3. Tukey multiple comparison test results for antimicrobial and bland soap

Comparison	Antimicrobial			Bland <sup>a</sup>		
	Mean difference	$q$	95% CI	Mean difference	$q$	95% CI
Baseline vs lather 10 s	-0.110	0.687	-0.8079 to 0.5880	-0.244	1.708	-0.8689 to 0.3800
Baseline vs lather 20 s	-0.030	0.188	-0.7280 to 0.6679	-0.628*	4.384*	-1.252 to -0.003004*
Baseline vs lather 40 s	0.010	0.064	-0.6877 to 0.7082	-0.521	3.641	-1.146 to 0.1034
Baseline vs temp 15°C	0.033	0.207	-0.6648 to 0.7311	-0.427	2.982	-1.051 to 0.1977
Baseline vs temp 26°C	0.011	0.072	-0.6865 to 0.7094	-0.071	0.497	-0.6956 to 0.5533
Baseline vs vol 0.5 mL	-0.182	1.134	-0.8794 to 0.5165	-0.339	2.369	-0.9635 to 0.2854
Baseline vs vol 2 mL	0.083	0.518	-0.6151 to 0.7808	-0.233	1.625	-0.8571 to 0.3918
Lather 10 s vs lather 20 s	0.080	0.500	-0.6180 to 0.7779	-0.383	2.676	-1.008 to 0.2414
Lather 10 s vs lather 40 s	0.120	0.752	-0.5777 to 0.8182	-0.277	1.933	-0.9012 to 0.3478
Lather 10 s vs temp 15°C	0.143	0.895	-0.5548 to 0.8411	-0.182	1.274	-0.8068 to 0.4421
Lather 10 s vs temp 26°C	0.122	0.759	-0.5765 to 0.8194	0.173	1.211	-0.4512 to 0.7977
Lather 10 s vs vol 0.5 mL	-0.072	0.447	-0.7695 to 0.6265	-0.095	0.661	-0.7191 to 0.5299
Lather 10 s vs vol 2 mL	0.193	1.205	-0.5051 to 0.8908	0.012	0.082	-0.6127 to 0.6363
Lather 20 s vs lather 40 s	0.040	0.252	-0.6576 to 0.7383	0.106	0.743	-0.5181 to 0.7308
Lather 20 s vs temp 15°C	0.063	0.395	-0.6347 to 0.7612	0.201	1.402	-0.4238 to 0.8252
Lather 20 s vs temp 26°C	0.042	0.260	-0.6564 to 0.7395	0.556	3.887	-0.06816 to 1.181
Lather 20 s vs vol 0.5 mL	-0.151	0.947	-0.8494 to 0.5465	0.288	2.015	-0.3360 to 0.9129
Lather 20 s vs vol 2 mL	0.113	0.706	-0.5850 to 0.8109	0.395	2.758	-0.2296 to 1.019
Lather 40 s vs temp 15°C	0.023	0.143	-0.6751 to 0.7209	0.094	0.659	-0.5301 to 0.7188
Lather 40 s vs temp 26°C	0.001	0.008	-0.6967 to 0.6992	0.450	3.143	-0.1745 to 1.074
Lather 40 s vs vol 0.5 mL	-0.192	1.199	-0.8897 to 0.5062	0.182	1.272	-0.4424 to 0.8065
Lather 40 s vs vol 2 mL	0.073	0.454	-0.6253 to 0.7706	0.289	2.015	-0.3360 to 0.9129
Temp 15°C vs temp 26°C	-0.022	0.136	-0.7196 to 0.6763	0.356	2.484	-0.2688 to 0.9801
Temp 15°C vs vol 0.5 mL	-0.215	1.342	-0.9126 to 0.4833	0.088	0.613	-0.5367 to 0.7122
Temp 15°C vs vol 2 mL	0.050	0.311	-0.6482 to 0.7477	0.194	1.356	-0.4303 to 0.8186
Temp 26°C vs vol 0.5 mL	-0.193	1.206	-0.8909 to 0.5050	-0.268	1.872	-0.8924 to 0.3566
Temp 26°C vs vol 2 mL	0.071	0.446	-0.6266 to 0.7694	-0.162	1.128	-0.7860 to 0.4630
Vol 0.5 mL vs vol 2 mL	0.264	1.652	-0.4336 to 0.9623	0.106	0.743	-0.5181 to 0.7309

<sup>a</sup> \*  $P < 0.05$ .

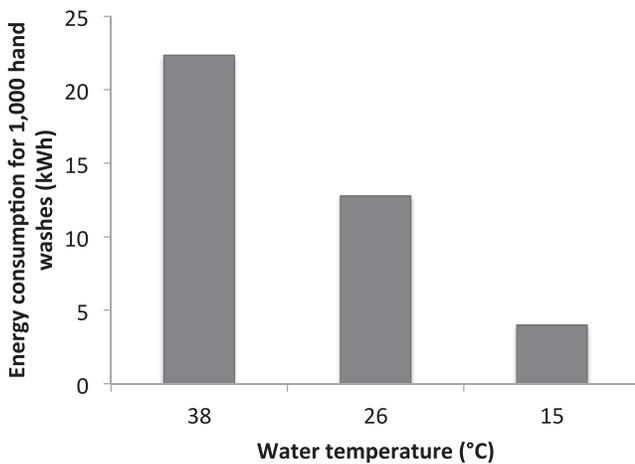


FIGURE 1. Energy consumption related to water heating for hand washing.

energy consumption associated with heating water for 1,000 hand washes is only 3.99 kWh for a water temperature of 15°C, which is a reduction of 68% compared with the baseline of 38°C.

**Questionnaire results.** No significant differences in bacterial reductions were found for volunteers who did versus did not use acne medication ( $P = 0.14$ ) or facial cleanser ( $P = 0.62$ ). Volunteer age also did not have an effect on mean log reductions ( $r^2 = 0.009$ ,  $P = 0.09$ ).

**Lotion use.** The questionnaire results indicate a significant difference in mean log microbial reduction ( $P = 0.02$ ) for volunteers based on high use of lotion (2.15 log CFU) versus low use of lotion (1.95 log CFU). The difference between volunteers who used lotion and those who did not use lotion was  $\sim 0.2$  log CFU.

**Hand washing frequency.** Sixteen volunteers indicated that they typically washed their hands more than four times per day, and four volunteers indicated that they washed their hands fewer than four times per day. The prewash mean total wash time differed significantly between these two groups ( $P = 0.012$ ); the high frequency hand washers washed for an average of 18.2 s, and the low frequency hand washers washed for an average of 15 s. Further analysis revealed that the difference in wash times was due to lather time, not rinse time. No significant difference was found for mean rinse times ( $P = 0.714$ ), but a highly significant difference in mean lather time was found ( $P = 0.000022$ ); frequent hand washers lathered for 6.8 s, and less frequent hand washers lathered for 4.0 s. Washing was significantly more effective for the low frequency hand washers than for the high frequency hand washers ( $P = 0.0008$ ) with an mean log reduction of 2.37 log CFU for low frequency washers and 2.01 log CFU for high frequency washers. This difference was still significant when accounting for formulation (antimicrobial soap,  $P = 0.048$ ; bland soap,  $P = 0.0045$ ). The four low frequency hand washers also reported the

highest usage of lotion (more than twice per day), which improved hand washing efficacy.

**Men versus women.** No significant difference in mean log reductions was found for men (2.08 log CFU) and women (2.08 log CFU) ( $P = 0.988$ ). The  $P$  value did not change for the antimicrobial or bland soap. However, a significant improvement in mean log reduction (2.34 log CFU) was found for men who used lotion versus men who did not use lotion (1.90 log CFU) ( $P = 0.0003.9$ ). This same comparison for women was not possible because all of the women volunteers reported using lotion at least once per day (high lotion usage).

**Prewash data.** Breakdown of the prewash data is shown in Table 4. During the prewash phase, the mean recorded lather time was 6.3 s, the mean rinse time was 11.4 s, and the mean total wash time was 17.7 s. The temperature of the wash water did not change the observed lather ( $P = 0.76$ ), rinse ( $P = 0.31$ ), and overall wash ( $P = 0.70$ ) times. For both men and women, no effect of water temperature on the observed wash times was found, and the respective  $P$  values remained roughly the same. Men lathered and rinsed their hands for a longer time ( $\sim 2$  s) than did women (lather time: men = 7.4 s, women = 5.4 s,  $P = 0.006$ ; rinse time: men = 12.3 s, women = 10.5 s,  $P = 0.04$ ), which resulted in a longer overall hand washing times for men ( $P = 0.002$ ). Minimal correlation was found between length of lather time and rinse time ( $R^2 = 0.03$ ) for all volunteers. The mean (SD) volume of soap used was 0.6 (0.25) mL (Fig. 2; approximately one pump of soap) for both men and women. Although the difference between men and women for volume of soap used was not significant ( $P = 0.39$ ), further analysis revealed a significant difference in volume of soap used across all volunteers ( $P = 0.000000135$ ), suggesting that personal behavior dictated choice of soap volume; 71% of volunteers used one pump, 26% used two pumps, 1% used three pumps, and 2% used no pumps of soap. These percentage differences did not noticeably change with water temperature. A volunteer did not change the number of pumps of soap used for each prewash and would routinely use the same amount of soap. A weak correlation (low  $R^2$ ) was found between total wash time and pumps of soap used ( $P = 0.001$ ,  $R^2 = 0.07$ ), and 43.4% of volunteers used water before applying soap, whereas 56.6% applied soap before using water. For the men, 56.8% used water first and 43.2% used soap first; for the women, 31.1% used water first and 68.9% used soap first.

## DISCUSSION

**Lather time (length of wash).** The 30-s wash (20 s of lathering and 10 s of rinsing) with bland soap produced a significantly different mean log reduction in bacterial counts compared with the baseline 15-s wash. Results of several other studies have indicated that a longer wash time can provide a greater microbial reduction benefit (25, 28, 34, 47, 55). However, these studies involved an overall wash time of  $< 30$  s and did not break the wash event into separate parts (lather versus rinse). In a meta-analysis of hand

TABLE 4. Prewash data<sup>a</sup>

Group	Total no. of washes	Mean wash time (s)			% volunteers using:					
		Lather	Rinse	Total	No soap	One soap pump	Two soap pumps	Three soap pumps	Water first	Soap first
All	198	6.3	11.4	17.7	2.0	70.7	26.3	1.0	43.4	56.6
15°C	31	7.0	10.6	17.6	0.5	11.1	4.0	0.0	6.6	9.1
26°C	47	6.1	12.5	18.6	0.5	16.7	6.1	0.5	9.1	14.7
38°C	120	6.3	11.1	17.4	1.0	42.9	16.2	0.5	27.8	32.8
Men	95	7.4	12.3	19.7	3.0	62.0	29.0	1.0	56.8	43.2
15°C	19	7.6	11.4	19.0	1.0	12.0	6.0	0.0	11.6	8.4
26°C	20	6.2	13.3	19.5	1.0	14.0	5.0	0.0	11.6	9.5
38°C	56	7.8	12.2	19.9	1.0	36.0	18.0	1.0	33.7	25.3
Women	103	5.4	10.5	15.9	1.0	78.0	23.0	1.0	31.1	68.9
15°C	12	6.0	9.3	15.3	0.0	10.0	2.0	0.0	1.9	9.7
26°C	27	6.3	11.9	18.0	0.0	19.0	7.0	1.0	6.8	19.4
38°C	64	4.9	10.2	15.1	1.0	49.0	14.0	0.0	22.3	39.8

<sup>a</sup> Percentages are of 198 washes for the “all” group, 95 washes for the men, and 103 washes for the women. Some of the prewash data were compromised (equipment malfunction), resulting in a different number of prewashes for men and women. Each pump of soap provided 0.5 mL of foaming product.

washing, 120-s washes resulted in a lower log reduction than did 30-s washes (53), suggesting that wash times >30 s may not be more effective. These results are consistent with our findings and suggest that microbial reduction will not increase significantly beyond 10- to 20-s lather times. One hypothesis to explain this finding is that microbes that are easier to remove are lifted from the hands by the wash in <30 s; however, microbes that are embedded in deeper layers or pores or are biochemically attached to skin will not be removed regardless of longer hand washing time.

**Water temperature.** In our study, no significant difference in washing effectiveness was found at different temperatures (15 to 38°C). This finding agrees with those of Michaels et al. (49, 50), who tested a wider range of water temperatures (4.4 to 48.9°C) but found mean microbial reductions of ~2 to 2.5 log CFU, very similar to our mean reductions of 1.9 to 2.3 log CFU. Courtenay et al. (21) found a small but significant difference (94 versus 99%;  $P < 0.05$ )

in microbial reduction between a cool rinse (26°C) and a warm rinse (40°C), but because none of these experimental washes included the use of soap, the relevance to a hand washing following the recommendation of the FDA Food Code (70) is unclear. Because Courtenay et al. studied hands inoculated with a ground beef matrix, the saturated fats in the meat may have been more easily removed at warmer water temperatures. Warmer water does not enhance antimicrobial activity but have a negative environmental impact (i.e., energy consumption); therefore, policy requirements for warm water hand washing (e.g., the Food Code) should be reconsidered.

**Volume of soap.** No significant difference for volume of soap used was found for either kind of soap (bland soap,  $P = 0.48$ ; antimicrobial soap,  $P = 0.41$ ). Both Fuls et al. (28) and Larson et al. (43) found no significant increase in microbial reduction when using bland soap. However, in contrast to our findings, Fuls et al. and Larson et al. did find that increasing the volume of the antimicrobial soap increased the log reductions. Both sets of authors suggested increased exposure to more antimicrobial agent as the explanation for increased microbial reduction. The difference in mean log reductions for a higher volume of antimicrobial soap may be due to the types of active agents being tested because formulation effects efficacy (14, 69). We used a 1% chloroxylenol antimicrobial soap, Larson et al. used a 4% chlorhexidine gluconate antimicrobial soap, and Fuls et al. used a 0.46% triclosan antimicrobial soap. The minimum volume of soap needed should also consider the soil removal required by the users, which is also likely to be significantly affected by soap formulation (especially surfactant choices).

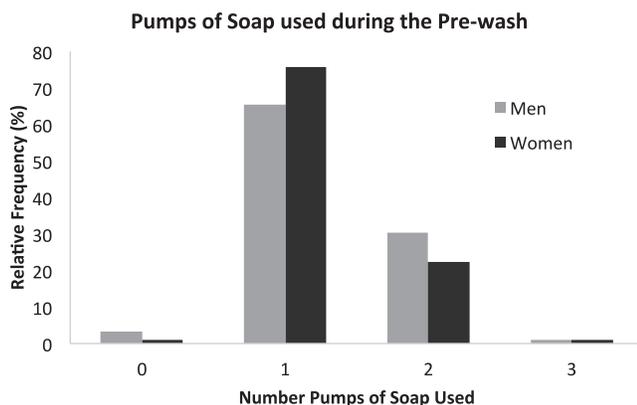


FIGURE 2. Number of pumps of soap used by women (solid) and men (shaded) during the prewash. Each pump delivered 0.5 mL of soap.

**Antibacterial and bland soaps.** A significant difference in microbial reduction was found between soap

formulations ( $P = 0.0003$ ). However, the difference in mean log reductions between the antimicrobial and bland soap (Table 1) was only  $\sim 0.3$  log CFU, which is within the range of error for microbiology data (i.e., a clinically insignificant difference). In several studies, greater microbial reductions were achieved with antimicrobial soaps than with bland soaps (25, 28, 30, 62, 65), and the effectiveness of antimicrobial soaps increased with repeated use by building up the antimicrobial agent on the skin (2, 12, 28, 54, 56). This effect can also be seen with hand sanitizers made with antimicrobial agents that remain on the skin (64), unlike those made with alcohol, which is not readily absorbed (13, 18). Given the FDA 1-year extension for soaps containing chloroxylenol (71), future work with the antimicrobial soap used in this study should take into consideration the need for buildup on the skin to improve efficacy and formulation style. In their meta-analysis of hand soaps, Montville and Schaffner (53) suggested that overall, accounting for all types of bacteria, antimicrobial soap should have a  $\sim 0.5$ -log greater reduction (mean, 2.4 log CFU) than bland soap (mean, 1.9 log CFU). We did not see a greater difference, but the bland soap data and the antimicrobial soap data both fell within the meta-analysis's range of mean log reductions (53). Future studies should take into consideration the surfactant profile of an antimicrobial soap, which can have a significant effect on the results (14, 69). We used two formulations that were both commonly used by the public and designed to be mild to the skin and similar in use. Highly efficacious antimicrobial soaps are made by designing the ingredient matrix around the antimicrobial active ingredient to create a formulation that does not inhibit but ideally highly activates the antimicrobial agent (14, 69). Future work should take into consideration the variety of antimicrobial soaps available and the various methods for testing these soaps.

**Lotion use.** Although the mean differences were small ( $\sim 0.2$  log CFU) between lotion users and non-lotion users, lotion use could affect several analyses. Skin damage from frequent hand washing is a well-established phenomenon (4, 27, 29, 37–39, 57, 63, 66, 73, 74, 77), and lotion often is used to repair this damaged skin (5, 41, 48). Damaged skin is more difficult to wash (40, 42, 44), so a slight, yet higher log reduction for the volunteers who indicated regular lotion use is not surprising. Although all women indicated using lotion more than once per day, not all men used lotion regularly ( $\sim 0.5$  log CFU greater mean reduction for men who were lotion users). This study did not provide sufficient evidence to draw a strong conclusion about the effect of lotion use on hand washing. However, the available evidence is enough to warrant more precisely controlled and designed investigations to measure the effect of hand lotion use on hand washing. Use of lotion to improve skin quality (5, 41, 48) and reduce pathogen colonization of damaged skin (40, 42, 44) would be an advantage to both health care workers and food handlers.

**Person-to-person variability.** A large part of the variability in the data sets was due to variability between the volunteers (Table 2). This finding is not uncommon for in vivo hand washing research, and large variability in results can be found both within and between hand washing studies (53). Microbial reductions  $>4$  log CFU have been consistently reported in hand sanitizer research, with limited variability (3, 22–24, 31, 36, 51, 58, 76), suggesting that hand soap and hand sanitizer effectiveness may be more influenced by human behavior and/or physiological hand differences than by the effectiveness of the soap and/or sanitizer, which is not surprising considering the number of steps recommended for proper hand washing (35). No published work was discovered that links physiological differences, such as skin moisture levels, skin sensitivity, hair density, scar tissue, and hand size, to hand washing outcomes. How these physiological differences affect microbial loads, reductions, and health risks would be an interesting topic for future hand hygiene research.

**Other observations.** Similar to our work, Larson et al. (43) also recorded the mean amount of soap (mL) used by health care workers. They observed that health care workers used  $\sim 2.7$  mL of soap when attending to high-risk patients,  $\sim 2$  mL when attending to low-risk patients, and  $\sim 1$  mL when not attending to patients. Our volunteers, who were not health care workers, used a much smaller amount of soap than did the participants in the study by Larson et al. (mean, 0.6 mL for the prewash; Fig. 2); 65% of men used one pump of soap, and 75% of women used one pump of soap. Larson et al. did not use a foaming soap but rather a liquid soap in a syringe dispenser and asked the volunteers to use an amount of soap they would normally use for hand washing. In our study, soap was released in 0.5-mL increments from a dispenser. Similar to the Larson et al. study (43), we found that volunteers used different amounts of soap, and each volunteer routinely used the same amount of soap for each of hand wash, i.e., consistently following their individual habits.

The results of this study indicate that water temperature is not a critical factor for the removal of transient microorganisms from hands. Combining these results with those of other studies of water temperature as a variable (49, 50), water temperature does not have a strong effect on hand washing. Therefore, it may be time to remove water temperature recommendations for hand washing from regulations and promote recommendations aimed at skin comfort (42, 68). Overall, the length of lather time and volume of soap used did not make a large difference, but a minimum of 0.5 mL of soap and 10 s of lather time is recommended based on our findings. Lotion use by the volunteers had an effect on the results; microbial reduction was greater for volunteers that used lotion regularly. One of the key findings from this study is that variability exists between people in both microbial reduction after hand washing and hand washing behavior. Understanding which behaviors, human factors, and physiological differences influence hand washing the most may allow future studies to

focus on which techniques can optimize the effectiveness of hand washing and thereby reduce infection transmission risk and improve food safety.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-029**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

3-306.13 Consumer Self-Service Operations

**Issue you would like the Conference to consider:**

The 2017 FDA Food Code allows Raw, Frozen, shell-on shrimp or lobster in a consumer self-service but does not allow raw meat. Overwrapped raw animal foods, such as beef, lamb, pork, poultry, and fish are no riskier to the public health of shoppers than if they buy unpackaged product. These overwrapped products leak and have meat juice on the outside of them in the preparation of the packaging itself. Consider the removal of 3-306.13 (A) and changing 3-306.13 (B) to be changed to all food requiring suitable utensils, not just READY-TO-EAT FOODS.

**Public Health Significance:**

The risk of raw animal products has no higher of a risk than section (2) or (3) of this violation, which are exemptions and allowable:

*"(2) Ready-to-cook individual portions for immediate cooking and consumption on the PREMISES such as CONSUMER-cooked MEATS or CONSUMER-selected ingredients for Mongolian barbecue; or (3) Raw, frozen, shell-on shrimp, or lobster. "*

In fact, neither (2) or (3) state they must be provided with suitable utensils as (B) only mentions READY-TO-EAT FOODS therefore there is no protection again cross contamination.

**Recommended Solution: The Conference recommends...:**

A letter be sent to FDA requesting that Section 3-306.13 of the most current edition of the Food Code be amended as follows:

3-306.13 Consumer Self-Service Operations.

~~(A) Raw, unPACKAGED animal FOOD, such as beef, lamb, pork, POULTRY, and FISH may not be offered for CONSUMER self-service. P~~

This paragraph does not apply to:

~~(1) CONSUMER self-service of READY TO EAT FOODS at buffets or salad bars that serve FOODS such as sushi or raw shellfish;~~

~~(2) Ready to cook individual portions for immediate cooking and consumption on the PREMISES such as CONSUMER-cooked MEATS or CONSUMER-selected ingredients for Mongolian barbecue; or~~

~~(3) Raw, frozen, shell-on shrimp, or lobster.~~

(B) CONSUMER self-service operations for READY TO EAT FOODS shall be provided with suitable UTENSILS for effective dispensing methods that protect the FOOD from contamination. Pf

(C) CONSUMER self-service operations such as buffets and salad bars shall be monitored by FOOD EMPLOYEES trained in safe operating procedures. Pf

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-030**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Cleaning of Food Contact Surfaces- Time as a Public Health Control

**Issue you would like the Conference to consider:**

4-602.11 Equipment Food-Contact Surfaces and Utensils; Frequency does not take into consideration the cleaning of food contact surfaces that use time as a public health control for 6 hours under 3-501.19 (C) Time-Maximum up to 6 hours. Code language is not clear if foods are required to be removed from contact surfaces within the 4 hours as stated in 4-602.11.

**Public Health Significance:**

The code allows for TCS foods to be safely used with an approved Time as a Public Health Control plan under 3-501.19 (C) if foods begin at 41 F and do not exceed 70 F in the six hours. Therefore, the cleaning frequency should match the allowed time of six hours.

**Recommended Solution: The Conference recommends...:**

*The Conference recommends....*

That a letter be sent to the FDA requesting that 4-602.11 (D) (8) of the most current edition of the Food Code be added as follows:

4-602.11 (D) (8) In-use utensils being used for foods under an approved plan as specified in 3-501.19 (C) shall be cleaned every 6 hours.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-031**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Deletion of "Use Limitations" for Cast Iron Cookware

**Issue you would like the Conference to consider:**

Deletion of Food Code Section 4-101.12 (Cast Iron, Use Limitation) to allow cast iron to be used for utensils or food-contact surfaces of equipment whether or not the surface is heated or used for cooking.

**Public Health Significance:**

Food Code Section 4-101.12 states that "...the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean." Based on Content Document "Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel", the data concludes that microorganisms can be removed from cast iron cookware with similar effectiveness of food grade stainless steel.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting that Section 4-101.12 Cast Iron, Use Limitation of the most current food code be deleted, as demonstrated below.

~~4-101.12 Cast Iron, Use Limitation. (A) Except as specified in §§ (B) and (C) of this section, cast iron may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT.~~

~~(B) Cast iron may be used as a surface for cooking.~~

~~(C) Cast iron may be used in UTENSILS for serving FOOD if the UTENSILS are used only as part of an uninterrupted process from cooking through service.~~

~~4-101.12 Cast Iron, Use Limitation. Equipment and utensils constructed of cast iron meet the requirement of durability as intended in section 4-101.11. However, the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean. On the other hand, when cast iron use is limited to cooking surfaces the residues~~

~~in the porous surface are not of significant concern as heat destroys potential pathogens that may be present.~~

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**Content Documents:**

- "Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

**Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel**

**Final Report**

December 18, 2019

Version 1

**Project Identification Number**

QL # 19269-2B

**Test Articles**

Cast Iron Cookware and Food Grade Stainless Steel Carriers

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## Test Summary

**Title:** Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

**Study Design:** This study was designed to demonstrate that microorganisms can be removed from cast iron cookware with similar effectiveness as from stainless steel surfaces. The equivalence of recovery was demonstrated by inoculating both materials with equivalent numbers of each microorganism. For this study the following microorganisms were used: *Staphylococcus aureus*, *Escherichia coli*, *Salmonella* Enteritidis, *Listeria monocytogenes*, and *Clostridium perfringens*. Following inoculation, surfaces were sampled.

**Test Articles:**

The test articles evaluated were provided to the testing facility by the study sponsor, complete with appropriate documentation. Test articles were sterilized via autoclave upon receipt and stored at ambient temperature (20 - 25 °C) in autoclaved aluminum foil.

1. Cast Iron Cookware
  - 1.1 14 Ounce Round Cast Iron Mini Server (SKU: HMSRD)
  - 1.2 12 Ounce Cast Iron Mini Serving Bowl (SKU: HMSB)
  - 1.3 16 Ounce Oval Cast Iron Mini Server (SKU: HM16OS)
  - 1.4 9 Ounce Oval Cast Iron Mini Server (SKU: HMSOV)
  - 1.5 14 Ounce Rectangular Cast Iron Mini Server (SKU: HMS14RC)
  - 1.6 10 Ounce Square Cast Iron Mini Server (SKU: HMSS)
2. Food Grade Stainless Steel Carriers (18 GA 300 series, brush finish)

**Sponsor:** Lodge Manufacturing  
204 East 5th Street  
South Pittsburgh, TN 37380

## Testing Conditions

### Challenge Microorganisms:

1. *Staphylococcus aureus* American Type Culture Collection (ATCC) 6538
2. *Escherichia coli* ATCC 8739
3. *Salmonella* Enteritidis ATCC 13076
4. *Listeria monocytogenes* ATCC 7644
5. *Clostridium perfringens* ATCC 12915

*Note:* Appropriate laboratory safety conditions was employed while working with enriched culture suspensions. These conditions included, but were not limited to, the use of appropriate PPE (including disposable gloves, beard nets, hair nets, and lab coats), Biological Safety Cabinets, and protective eyewear.

### Testing Conditions:

The evaluation was conducted at ambient temperature (20 - 25 °C).

### Media/Reagents:

1. Tryptic Soy Agar with 5% Sheep Blood (SBA) (Fisher Scientific, PN 221261) or equivalent
2. Microbial Content Test (MCT) agar MP107
3. Tryptic Soy Broth (TSB) MP058
4. Phosphate Buffered Saline (PBS) MP416
5. Columbia Blood Agar (CBA) with 5% Sheep Blood MP086
6. Reinforced Clostridial Medium (RCM) MP158

### Equipment/Supplies:

1. Incubator, temperature range  $35 \pm 1$  °C
2. Incubator thermometer, NIST traceable
3. Sterile containers
4. Steam autoclave
5. Vortex mixer
6. Calibrated, traceable minute/second timer
7. Refrigerator, temperature range 2 - 8 °C
8. Refrigerator thermometer, NIST traceable
9. Traceable thermometer/clock/humidity monitor
10. Adjustable pipettor, 1 µL - 200 µL capacity
11. Adjustable pipettor, 100 µL - 1000 µL capacity
12. Sterile serological pipettes
13. Sterile 100 µL and 1000 µL micropipette tips
14. Reichert Quebec<sup>®</sup> Colony Counter, or equivalent
15. Hand tally

16. Test tubes, sterilized
17. Sterile disposable Petri dishes, 100 x 15 mm
18. Sterile polyurethane tip swabs
19. Sterile disposable loops
20. Rotator/shaker
21. Anaerobic Sachets, BBL GasPaks or equivalent

### **Study Dates and Facility**

The analysis phase of this test was conducted at Q Laboratories in the Microbiology Research and Development Laboratory, 1930 Radcliff Drive, Cincinnati, Ohio 45204, from 10-28-19 to 11-11-19. The study sponsor and study director signed the protocol on 10-31-19. The final report was released 12-16-19.

### **Records to be Maintained**

All testing data, protocol, protocol modifications, test material records, the final report, and correspondence between Q Laboratories and the sponsor will be stored in the archives at Q Laboratories, 1930 Radcliff Drive, Cincinnati, Ohio 45204 for a period of at least seven (7) years.

### **Test Procedure**

#### **Test Microorganism Preparation:**

*Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Salmonella* Enteritidis ATCC 13076, and *Listeria monocytogenes* ATCC 7644 were propagated on Tryptic Soy Agar with 5% Sheep Blood (SBA) from a Q Laboratories frozen stock culture stored at -70 °C. SBA plates were incubated aerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony was picked to Tryptic Soy Broth (TSB) and incubated at 35 ± 1 °C for 24 ± 2 hours. Test articles were inoculated with the 24 hour TSB culture.

*Clostridium perfringens* ATCC 12915 was propagated on SBA from a Q Laboratories frozen stock culture stored at -70 °C. The SBA plate was incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony was transferred to pre-reduced Reinforced Clostridial Medium (RCM) and incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. Test articles were inoculated with the 24 hour RCM culture.

#### **Pre-Inoculation Preparation:**

The study sponsor reported that the test articles were pre-cleaned using one cycle in an industrial dishwasher prior to shipping.

Test articles and stainless-steel control carriers were placed in a sterile container and autoclaved after receipt by the testing facility. This step was done to ensure there is no residual bioburden prior to inoculation.

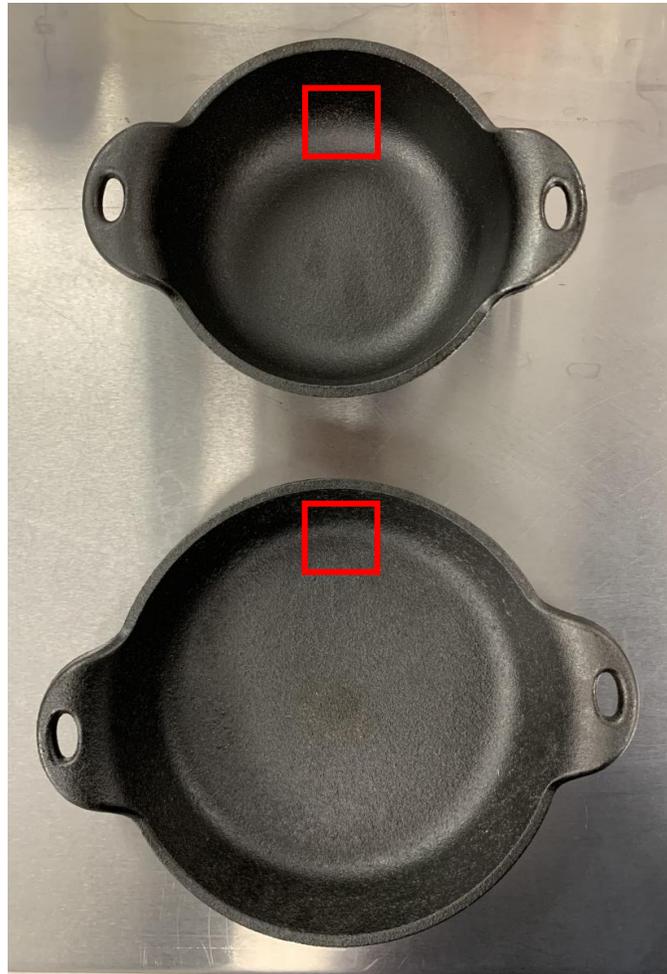
Using sterile gloves, the test article was placed on a disinfected flat surface. One (1) 1” x 1” location on each test article was marked for evaluation, depicted as red squares in Figures 1 - 4.

Inoculation of Test Articles:

A 100 µL aliquot of each test culture was applied to the 1” x 1” marked areas. The culture was uniformly spread over the sample area using 100 - 1000 µL micropipette tip to prevent areas of pooling.

After inoculation, the test articles were allowed to dry for 18 - 24 hours at ambient temperature (20 - 25 °C). After 18-24 hours, the test article was visually inspected to ensure the test culture suspension was uniformly dried and testing was initiated.

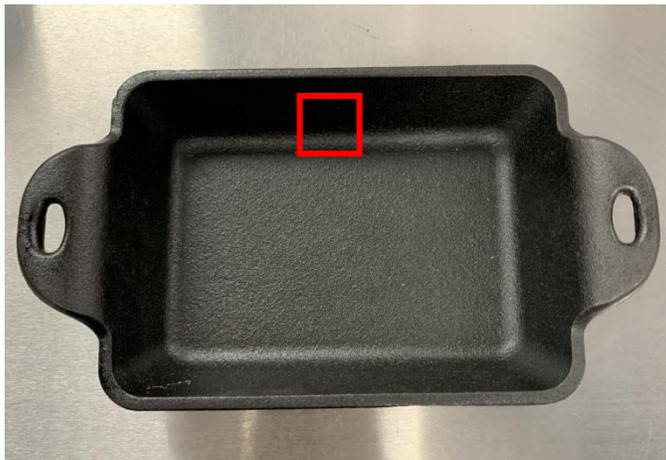
The inoculation steps above were repeated for the stainless-steel control carriers.



**Figure 1. 12 Ounce Cast Iron Mini Serving Bowl and 14 Ounce Round Cast Iron Mini Server Sample Areas.**



**Figure 2. 9 Ounce Oval Cast Iron Mini Server and 16 Ounce Oval Cast Iron Mini Server Sample Areas.**



**Figure 3. 14 Ounce Rectangular Cast Iron Mini Server Sample Area.**



**Figure 4. 10 Ounce Square Cast Iron Mini Server Sample Area.**

Three (3) replicates of the test articles and three (3) replicates using food grade stainless steel carries were evaluated for each microorganism. A summary of the recovery study parameters is presented in Table 1.

**Table 1. Summary of Recovery Study Parameters**

<b>Test Organisms</b>	<b>Test Article</b>	<b>No. of Test Replicates</b>	<b>No. of Stainless-Steel Control Replicates</b>
<i>S. aureus</i> , <i>E. coli</i> , <i>S. Enteritidis</i> , <i>L. monocytogenes</i> , <i>C. perfringens</i>	14 Ounce Round Cast Iron Mini Server	3	3
	12 Ounce Cast Iron Mini Serving Bowl	3	3
	16 Ounce Oval Cast Iron Mini Server	3	3
	9 Ounce Oval Cast Iron Mini Server	3	3
	14 Ounce Rectangular Cast Iron Mini Server	3	3
	10 Ounce Square Cast Iron Mini Server	3	3

### **Recovery and Enumeration Procedure:**

A 1.0 mL aliquot of PBS was added to a sterile swab. The marked 1" x 1" sample area was thoroughly swabbed in an up and down vertical motion and a left and right horizontal motion. This process was designed to remove viable microorganisms from the surface of the test article for enumeration.

The swab was placed in a test tube containing 9.0 mL of PBS. The swab was expressed into the test tube and thoroughly vortexed for  $30 \pm 5$  seconds. Ten-fold serial dilutions of the sample were prepared by transferring 1.0 mL from the initial dilution into 9.0 mL of PBS.

For *S. aureus*, *E. coli*, *S. Enteritidis* and *L. monocytogenes*, each dilution was plated into duplicate sterile Petri dishes and 12 - 15 mL of tempered MCT was added. Plates were mixed thoroughly and allowed to solidify. Plates were inverted and incubated at  $35 \pm 1$  °C for  $48 \pm 2$  hours.

For *C. perfringens* each dilution was spread plated with sterile plating beads onto duplicate pre-poured plates of Columbia Blood Agar (CBA) with 5% Sheep Blood (CBA). Plates were inverted and incubated anaerobically at  $35 \pm 1$  °C for  $48 \pm 2$  hours.

After incubation, typical colonies were enumerated, and raw data was recorded as CFU/plate. Duplicate plates were averaged and multiplied by the dilution factor to arrive at CFU/test article. Raw values were recorded and used for the calculations in Tables 2-6.

### **Study Controls:**

Food Grade Stainless Steel Controls – Three (3) 4" x 4" food grade stainless steel test articles were inoculated according to the test procedure. The recovered microorganisms were determined following the procedures found in Recovery and Enumeration. In order for the testing to be considered acceptable, the recovery data from the cast iron test articles had to be comparable to the food grade stainless steel.

### Statistical Analysis

A logarithmic transformation measuring surviving microbial populations of the positive control article and test replicates for each microorganism were performed.

Equivalence of Recovery was calculated as follows:

$\Delta\text{Log}_{10}$  = Equivalence Recovery

TR1 = Test Article Replicate 1

TR2 = Test Article Replicate 2

TR3 = Test Article Replicate 3

SS1 = Stainless Steel 1

SS2 = Stainless Steel 2

SS3 = Stainless Steel 3

$$\left(\frac{TR1 + TR2 + TR3}{3}\right) - \left(\frac{SS1 + SS2 + SS3}{3}\right) = \Delta\text{Log}_{10}$$

### Media Quality Controls

The MCT plating media was inoculated with an aliquot of each *S. aureus*, *E. coli*, *S. Enteritidis*, and *L. monocytogenes* suspension and incubated at  $35 \pm 1$  °C for  $48 \pm 2$  hours. These plates served as positive growth controls for the media.

The CBA and RCM media were inoculated with an aliquot of the *C. perfringens* suspension and incubated anaerobically at  $35 \pm 1$  °C for  $48 \pm 2$  hours. These served as positive growth controls for the media.

The acceptance criterion for these bacterial media controls was “typical growth” of the organisms.

For negative sterility controls, two tubes each of TSB, PBS, and three plates of MCT were incubated at  $35 \pm 2$  °C for  $48 \pm 2$  hours.

The acceptance criterion for these uninoculated media controls was “negative for growth”.

### References

U. S. Food and Drug Administration *Bacteriological Analytical Manual*, Chapter 3 *Aerobic Plate Count* (January 2001). (Accessed October 2019)

<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063346.htm>

### Summary of Results

The results of the initial microorganism recovery comparison are presented in Tables 2-6. The results of the retested test articles are presented in Tables 7-10. The mean Log values were obtained from duplicate plates. The Equivalence of Recovery was calculated as follows:

$\Delta\text{Log}10$  = Equivalence Recovery

TR1 = Test Article Replicate 1

TR2 = Test Article Replicate 2

TR3 = Test Article Replicate 3

SS1 = Stainless Steel 1

SS2 = Stainless Steel 2

SS3 = Stainless Steel 3

$$\left(\frac{TR1 + TR2 + TR3}{3}\right) - \left(\frac{SS1 + SS2 + SS3}{3}\right) = \Delta\text{Log}10$$

**Results**

**Table 2: *Staphylococcus aureus* ATCC 6538 Recovery Comparison  
Reported in CFU/mL recovered.**

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery ( $\Delta\text{Log}_{10}$ )
14 Ounce Round Cast Iron Mini Server	CFU/mL	2.6E+05	3.2E+05	3.8E+05	1.1E+05	2.6E+05	1.1E+05	0.3340
	Log CFU/mL	5.4150	5.5051	5.5798	5.0414	5.4150	5.0414	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	3.3E+05	4.2E+05	2.8E+05	1.2E+05	1.2E+05	1.1E+05	0.4630
	Log CFU/mL	5.5185	5.6232	5.4472	5.0792	5.0792	5.0414	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	3.0E+05	2.4E+05	2.1E+05	1.7E+05	1.5E+05	1.4E+05	0.2090
	Log CFU/mL	5.4771	5.3802	5.3222	5.2304	5.1761	5.1461	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	4.2E+05	5.0E+05	1.2E+05	1.6E+05	1.1E+05	1.2E+05	0.3589
	Log CFU/mL	5.6232	5.6990	5.0792	5.2041	5.0414	5.0792	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	4.6E+05	5.0E+05	4.9E+05	1.5E+05	8.4E+04	1.5E+05	0.5918
	Log CFU/mL	5.6628	5.6990	5.6902	5.1761	4.9243	5.1761	
10 Ounce Square Cast Iron Mini Server	CFU/mL	2.7E+05	3.0E+05	2.8E+05	7.4E+04	1.2E+05	1.3E+05	0.4311
	Log CFU/mL	5.4314	5.4771	5.4472	4.8692	5.0792	5.1139	

**Table 3: *Escherichia coli* ATCC 8739 Recovery Comparison  
Reported in CFU/mL recovered.**

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery ( $\Delta\text{Log}_{10}$ )
14 Ounce Round Cast Iron Mini Server	CFU/mL	1.2E+04	1.7E+04	6.0E+03	5.0E+03	1.6E+04	5.6E+03	0.1455
	Log CFU/mL	4.0792	4.2304	3.7782	3.6990	4.2041	3.7482	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	6.6E+03	3.0E+03	9.2E+03	4.4E+03	6.6E+03	7.0E+03	-0.0159
	Log CFU/mL	3.8195	3.4771	3.9638	3.6435	3.8195	3.8451	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	5.4E+03	1.0E+04	5.8E+03	2.6E+04	2.6E+04	3.0E+04	-0.6038
	Log CFU/mL	3.7324	4.0000	3.7634	4.4150	4.4150	4.4771	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	6.4E+03	8.0E+03	8.4E+03	1.7E+04	2.7E+04	3.6E+04	-0.5282
	Log CFU/mL	3.8062	3.9031	3.9243	4.2304	4.4314	4.5563	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	4.7E+03	4.1E+03	4.2E+03	4.0E+03	5.6E+03	4.6E+03	-0.0350
	Log CFU/mL	3.6721	3.6128	3.6232	3.6021	3.7482	3.6628	
10 Ounce Square Cast Iron Mini Server	CFU/mL	5.4E+03	6.0E+03	1.0E+04	3.1E+03	9.2E+03	8.3E+03	0.0454
	Log CFU/mL	3.7324	3.7782	4.0000	3.4914	3.9638	3.9191	

**Table 4: *Salmonella* Enteritidis ATCC 13076 Recovery Comparison  
Reported in CFU/mL recovered.**

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery ( $\Delta\text{Log}_{10}$ )
14 Ounce Round Cast Iron Mini Server	CFU/mL	7.0E+04	7.2E+04	3.9E+04	1.4E+04	3.6E+04	3.8E+04	0.3371
	Log CFU/mL	4.8451	4.8573	4.5911	4.1461	4.5563	4.5798	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	2.6E+04	1.3E+04	1.4E+04	8.9E+03	5.2E+04	4.6E+04	-0.2177
	Log CFU/mL	4.4150	4.1139	4.1461	3.9494	4.7160	4.6628	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	9.9E+03	8.7E+03	2.8E+04	4.6E+03	1.3E+04	8.8E+03	0.2204
	Log CFU/mL	3.9956	3.9395	4.4472	3.6628	4.1139	3.9445	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	3.2E+04	4.2E+04	3.4E+04	2.8E+04	1.2E+04	1.4E+04	0.3291
	Log CFU/mL	4.5051	4.6232	4.5315	4.4472	4.0792	4.1461	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	4.3E+04	3.4E+04	3.8E+04	1.2E+04	1.4E+04	2.7E+04	0.3627
	Log CFU/mL	4.6335	4.5315	4.5798	4.0792	4.1461	4.4314	
10 Ounce Square Cast Iron Mini Server	CFU/mL	6.3E+04	4.9E+04	5.8E+04	1.1E+04	1.7E+04	2.0E+04	0.5600
	Log CFU/mL	4.7993	4.6902	4.7634	4.0414	4.2304	4.3010	

**Table 5: *Listeria monocytogenes* ATCC 7644 Recovery Comparison  
Reported in CFU/mL recovered.**

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery ( $\Delta\text{Log}_{10}$ )
14 Ounce Round Cast Iron Mini Server	CFU/mL	1.1E+04	5.6E+03	1.6E+04	4.6E+03	1.3E+04	6.8E+03	0.1282
	Log CFU/mL	4.0414	3.7482	4.2041	3.6628	4.1139	3.8325	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	1.5E+04	5.8E+03	1.0E+03	6.3E+03	1.0E+03	6.4E+03	0.1133
	Log CFU/mL	4.1761	3.7634	3.0000	3.7993	3.0000	3.8062	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	1.1E+04	8.2E+03	1.3E+04	7.0E+02	3.2E+03	2.6E+03	0.7680
	Log CFU/mL	4.0414	3.9138	4.1139	2.8451	3.5051	3.4150	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	2.6E+04	3.0E+04	2.6E+04	1.2E+03	2.1E+03	3.4E+03	1.1247
	Log CFU/mL	4.4150	4.4771	4.4150	3.0792	3.3222	3.5315	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	1.2E+04	5.4E+03	5.5E+03	3.8E+03	3.0E+03	2.8E+03	0.3493
	Log CFU/mL	4.0792	3.7324	3.7404	3.5798	3.4771	3.4472	
10 Ounce Square Cast Iron Mini Server	CFU/mL	2.4E+03	1.7E+03	4.3E+03	1.8E+03	9.6E+02	1.7E+03	0.2587
	Log CFU/mL	3.3802	3.2304	3.6335	3.2553	2.9823	3.2304	

**Table 6: *Clostridium perfringens* ATCC 12915 Recovery Comparison  
Reported in CFU/mL recovered.**

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery ( $\Delta\text{Log}_{10}$ )
14 Ounce Round Cast Iron Mini Server	CFU/mL	2.3E+05	2.7E+05	3.9E+05	1.0E+05	1.3E+05	1.6E+05	0.3554
	Log CFU/mL	5.3617	5.4314	5.5911	5.000	5.1139	5.2041	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	2.9E+05	4.5E+04	2.9E+05	9.0E+04	1.0E+05	1.2E+05	0.1815
	Log CFU/mL	5.4624	4.6532	5.4624	4.9542	5.0000	5.0792	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	2.5E+05	2.7E+05	1.5E+05	1.6E+05	1.9E+05	1.6E+05	0.1061
	Log CFU/mL	5.3979	5.4314	5.1761	5.2041	5.2788	5.2041	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	3.7E+05	4.7E+05	2.6E+05	1.1E+05	1.8E+05	1.7E+05	0.3761
	Log CFU/mL	5.5682	5.6721	5.4150	5.0414	5.2553	5.2304	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	5.2E+05	3.8E+05	3.9E+05	1.7E+05	1.0E+05	2.6E+05	0.4138
	Log CFU/mL	5.7160	5.5798	5.5911	5.2304	5.0000	5.4150	
10 Ounce Square Cast Iron Mini Server	CFU/mL	1.9E+05	3.2E+05	2.6E+05	1.1E+05	8.0E+04	1.9E+05	0.3252
	Log CFU/mL	5.2788	5.5051	5.4150	5.0414	4.9031	5.2788	

**Table 7: *Staphylococcus aureus* ATCC 6538 Recovery Comparison  
Reported in CFU/mL recovered – Retested.**

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery ( $\Delta\text{Log}_{10}$ )
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	2.1E+05	2.9E+05	4.5E+05	5.3E+05	4.1E+05	3.9E+05	-0.1635
	Log CFU/mL	5.3222	5.4624	5.6532	5.7243	5.6128	5.5911	

**Table 8: *Escherichia coli* ATCC 8739 Recovery Comparison  
Reported in CFU/mL recovered - Retested.**

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery ( $\Delta\text{Log}_{10}$ )
16 Ounce Oval Cast Iron Mini Server	CFU/mL	1.3E+04	1.8E+04	2.4E+04	1.2E+04	3.4E+04	2.6E+04	-0.0921
	Log CFU/mL	4.1139	4.2553	4.3802	4.0792	4.5315	4.4150	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	1.5E+04	2.3E+04	2.7E+04	3.3E+04	2.9E+04	2.4E+04	-0.1306
	Log CFU/mL	4.1761	4.3617	4.4314	4.5185	4.4624	4.3802	

**Table 9: *Salmonella* Enteritidis ATCC 13076 Recovery Comparison  
Reported in CFU/mL recovered - Retested.**

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery ( $\Delta\text{Log}_{10}$ )
10 Ounce Square Cast Iron Mini Server	CFU/mL	5.5E+04	3.2E+04	6.2E+04	2.2E+04	2.5E+04	3.4E+04	0.2554
	Log CFU/mL	4.7404	4.5051	4.7924	4.3424	4.3979	4.5315	

**Table 10: *Listeria monocytogenes* ATCC 7644 Recovery Comparison  
Reported in CFU/mL recovered - Retested.**

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery ( $\Delta\text{Log}_{10}$ )
16 Ounce Oval Cast Iron Mini Server	CFU/mL	1.8E+04	2.6E+04	1.1E+04	3.4E+04	2.3E+04	3.8E+04	-0.2538
	Log CFU/mL	4.2553	4.4150	4.0414	4.5315	4.3617	4.5798	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	2.8E+04	3.9E+04	1.7E+04	2.0E+04	1.4E+04	4.5E+05	-0.2772
	Log CFU/mL	4.4472	4.5911	4.2304	4.3010	4.1461	5.6532	

## Conclusion

Based on the results presented in this study report, the microorganism recovery equivalence from cast iron products and food grade stainless met the performance criteria for 2 of the 6 test articles. The performance criteria states that for equivalent recovery, the cast iron test articles must be within 0.5 Log of the stainless-steel carrier controls. Both 14 Ounce Round Cast Iron Mini Server and 12 Ounce Cast Iron Mini Serving Bowl met the performance criteria for each inoculum. The 9 Ounce Oval Cast Iron and 16 Ounce Oval Cast Iron did not meet the performance criteria for *Listeria monocytogenes*, and *Escherichia coli*. The 14 Ounce Rectangle Cast Iron Mini Server did not meet the performance criteria for *Staphylococcus aureus*. The 10 Ounce Square Cast Iron Mini server did not meet the performance criteria for *Salmonella* Enteritidis.

Since failure to meet the performance criteria could have been caused by variable inoculum levels due to homogenization of the test culture or by variable die off rate during the overnight drying, any test articles that did not meet the performance criteria were retested. Upon retesting all test articles met the performance criteria. The performance criteria states that for equivalent recovery, the cast iron test articles must be within 0.5 Log of the stainless-steel carrier controls.

**Appendix 1**

Signed Protocol



**Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel**

**Protocol # QL19269-2B**

**Version 2**

**Prepared for:**

Lodge Manufacturing (Study Sponsor)  
204 East 5th Street  
South Pittsburgh, TN 37380

**Prepared by:**

Q Laboratories (Testing Facility)  
1930 Radcliff Drive  
Cincinnati, OH 45204  
(513) 471-1300

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1.0 **Title:** Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

2.0 **Sponsor:** Lodge Manufacturing  
204 East 5th Street  
South Pittsburgh, TN 37380

3.0 **Testing Facility:** Q Laboratories  
1930 Radcliff Drive  
Cincinnati, OH 45204

4.0 **Study Director:** Benjamin J. Bastin

5.0 **Purpose:**

This study is designed to demonstrate that microorganisms can be removed from cast iron cookware with similar effectiveness as from stainless steel surfaces.

6.0 **Scope:**

The equivalence of recovery will be demonstrated by inoculating both materials with equivalent numbers of each microorganism. For this study the following microorganisms will be used: *Staphylococcus aureus*, *Escherichia coli*, *Salmonella* Enteritidis, *Listeria monocytogenes*, and *Clostridium perfringens*. Following inoculation, surfaces will be sampled.

7.0 **Test Articles:**

The test articles to be evaluated will be provided to the testing facility by the study sponsor, complete with appropriate documentation. Test articles will be sterilized via autoclave upon receipt.

7.1 Cast Iron Cookware

7.1.1 14 Ounce Round Cast Iron Mini Server (SKU: HMSRD)

7.1.2 12 Ounce Cast Iron Mini Serving Bowl (SKU: HMSB)

7.1.3 16 Ounce Oval Cast Iron Mini Server (SKU: HM16OS)

7.1.4 9 Ounce Oval Cast Iron Mini Server (SKU: HMSOV)

7.1.5 14 Ounce Rectangular Cast Iron Mini Server (SKU: HMS14RC)

7.1.6 10 Ounce Square Cast Iron Mini Server (SKU: HMSS)

7.2 Food Grade Stainless Steel Carriers (18 GA 300 series, brush finish)

8.0 **Testing Conditions:**

8.1 The evaluation will be conducted at ambient temperature (20 - 25 °C).

## 9.0 Test Microorganisms:

- 9.1 *Staphylococcus aureus* American Type Culture Collection (ATCC) 6538
- 9.2 *Escherichia coli* ATCC 8739
- 9.3 *Salmonella* Enteritidis ATCC 13076
- 9.4 *Listeria monocytogenes* ATCC 7644
- 9.5 *Clostridium perfringens* ATCC 12915

*Note:* Appropriate laboratory safety conditions will be employed while working with enriched culture suspensions. These conditions will include, but are not limited to, the use of appropriate PPE (including disposable gloves, beard nets, hair nets, and lab coats), Biological Safety Cabinets, and protective eyewear.

## 10.0 Media/Reagents:

- 10.1 Tryptic Soy Agar with 5% Sheep Blood (SBA) Commercially available from BD 221261 or equivalent
- 10.2 Microbial Content Test (MCT) agar MP107
- 10.3 Tryptic Soy Broth (TSB) MP058
- 10.4 Phosphate Buffered Saline (PBS) MP416
- 10.5 Columbia Blood Agar (CBA) with 5% Sheep Blood MP086
- 10.6 Reinforced Clostridial Medium (RCM) MP158

## 11.0 Equipment/Supplies:

- 11.1 Incubator, temperature range  $35 \pm 1$  °C
- 11.2 Incubator thermometers, NIST traceable
- 11.3 Sterile containers
- 11.4 Steam autoclave
- 11.5 Vortex mixer
- 11.6 Calibrated, traceable minute/second timer
- 11.7 Refrigerator, temperature range 2 - 8 °C
- 11.8 Refrigerator thermometer, NIST traceable
- 11.9 Traceable thermometer/clock/humidity monitor
- 11.10 Adjustable pipettor, 1 µL - 200 µL capacity
- 11.11 Adjustable pipettor, 100 µL - 1000 µL capacity
- 11.12 Sterile serological pipettes
- 11.13 Sterile 100 µL and 1000 µL micropipette tips
- 11.14 Reichert Quebec® Colony Counter, or equivalent
- 11.15 Hand tally
- 11.16 Test tubes, sterilized
- 11.17 Sterile disposable Petri dishes, 100 x 15 mm
- 11.18 Sterile polyurethane tip swabs
- 11.19 Sterile disposable loops
- 11.20 Rotator/shaker
- 11.21 Anaerobic Sachets, BBL GasPaks or equivalent

**12.0 Test Microorganism Preparation:**

- 12.1 *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Salmonella* Enteritidis ATCC 13076, and *Listeria monocytogenes* ATCC 7644 will be propagated on Tryptic Soy Agar with 5% Sheep Blood (SBA) from a Q Laboratories frozen stock culture stored at -70 °C. SBA plates will be incubated aerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony will be picked to Tryptic Soy Broth (TSB) and incubated at 35 ± 1 °C for 24 ± 2 hours.
- 12.2 *Clostridium perfringens* ATCC 12915 will be propagated on SBA from a Q Laboratories frozen stock culture stored at -70 °C. The SBA plate will be incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony will be transferred to pre-reduced Reinforced Clostridial Medium (RCM) and incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours.

**13.0 Microorganism Recovery Study Parameters:**

- 13.1 Three (3) total replicates of the test articles will be evaluated for each microorganism. A summary of the recovery study parameters is presented in Table 1.
- 13.2 Three (3) total replicates using food grade stainless steel carries will be evaluated for each microorganism as controls. A summary of the antimicrobial activity study parameters is presented in Table 1.

**Table 1. Summary of Recovery Study Parameters.**

Test Organisms	Test Article	No. of Test Replicates	No. of Stainless-Steel Control Replicates
<i>S. aureus</i> , <i>E. coli</i> , <i>S. Enteritidis</i> , <i>L. monocytogenes</i> , <i>C. perfringens</i>	14 Ounce Round Cast Iron Mini Server	3	3
	12 Ounce Cast Iron Mini Serving Bowl	3	3
	16 Ounce Oval Cast Iron Mini Server	3	3
	9 Ounce Oval Cast Iron Mini Server	3	3
	14 Ounce Rectangular Cast Iron Mini Server	3	3
	10 Ounce Square Cast Iron Mini Server	3	3

**14.0 Test Procedure:**

**Preconditioning:**

- 14.1 The study sponsor reported that the test articles were pre-cleaned using one cycle in an industrial dishwasher prior to shipping.
- 14.2 Test articles and stainless-steel control carriers will be placed in a sterile container and autoclaved after receipt by the testing facility. This step will be done to ensure there is no residual bioburden prior to inoculation.

**Inoculation:**

- 14.3 Using sterile gloves, place the test article on a disinfected flat surface. One (1) 1" x 1" location on the test article will be marked for evaluation as depicted in Figures 1 - 4.
- 14.4 Apply 100  $\mu$ L of each test culture to the 1" x 1" marked areas. The culture will be uniformly spread over the sample area using 100 - 1000  $\mu$ L micropipette tip to prevent areas of pooling.
- 14.5 After inoculation, the test articles will be allowed to dry for 18 - 24 hours at ambient temperature (20 - 25 °C). After 18-24 hours, the test article will be visually inspected to ensure the test culture suspension is uniformly dried and testing will be initiated.
- 14.6 Repeat inoculation steps 14.2 to 14.4 for the stainless-steel control carriers.



**Figure 1. 12 Ounce Cast Iron Mini Serving Bowl and 14 Ounce Round Cast Iron Mini Server Sample Areas.**



**Figure 2. 9 Ounce Oval Cast Iron Mini Server and 16 Ounce Oval Cast Iron Mini Server Sample Areas.**



**Figure 3. 14 Ounce Rectangular Cast Iron Mini Server Sample Area.**



**Figure 4. 10 Ounce Square Cast Iron Mini Server Sample Area.**

**15.0 Recovery and Enumeration Procedure:**

- 15.1 Add 1.0 mL of PBS to a sterile swab. Thoroughly swab the 1" x 1" sample area in a both an up and down vertical motion and in a left and right horizontal motion. This process is designed to remove viable microorganisms from the surface of the test article for enumeration.
- 15.2 Place the swab in a test tube containing 9.0 mL of PBS. Express the swab into the test tube and thoroughly vortex. Prepare ten-fold serial dilutions of the sample by transferring 1.0 mL from the initial dilution into 9.0 mL of PBS.
- 15.3 For *S. aureus*, *E. coli*, *S. Enteritidis* and *L. monocytogenes*, plate each dilution into duplicate sterile Petri dishes and add 12 - 15 mL of tempered MCT to the Petri dishes. Mix thoroughly and allow the plates to solidify. Invert plates and incubate at  $35 \pm 1$  °C for  $48 \pm 2$  hours.
- 15.4 For *C. perfringens* spread plate each dilution on duplicate pre-poured plates of CBA. Spread inoculum with a sterile L-shaped spreader or sterile plating beads. Invert plates and incubate anaerobically at  $35 \pm 1$  °C for  $48 \pm 2$  hours.
- 15.5 After incubation, typical colonies will be enumerated and raw data recorded as CFU/plate. Duplicate plates will be averaged and multiplied by the dilution factor to arrive at CFU/test article. Raw values will be recorded and used for the calculations in section 18.0.

**16.0 Study Controls:**

- 16.1 Food Grade Stainless Steel Controls – Three (3) 4" x 4" food grade stainless steel test articles will be inoculated according to the procedures outlined in Section 14.0. The recovered microorganisms will be determined following the procedures in Section 15.0. In order for the testing to be considered acceptable, recovery data comparable to the cast iron test articles must be achieved.

**17.0 Statistical Analysis:**

- 17.1 A logarithmic transformation measuring surviving microbial populations of the positive control article and test replicates for each microorganism will be performed.
- 17.2 Equivalence of Recovery will be calculated as follows:  
 $\Delta\text{Log}_{10}$  = Equivalence Recovery  
TR1 = Test Article Replicate 1  
TR2 = Test Article Replicate 2  
TR3 = Test Article Replicate 3  
SS1 = Stainless Steel 1  
SS2 = Stainless Steel 2  
SS3 = Stainless Steel 3

$$\left(\frac{TR1 + TR2 + TR3}{3}\right) - \left(\frac{SS1 + SS2 + SS3}{3}\right) = \Delta\text{Log}_{10}$$

#### 18.0 Media Quality Controls:

- 18.1 The MCT plating media will be inoculated with an aliquot of each *S. aureus*, *E. coli*, *S. Enteritidis*, and *L. monocytogenes* suspension. The MCT plates will be incubated at  $35 \pm 1$  °C for  $48 \pm 2$  hours. These plates will serve as positive growth controls for the media.
- 18.2 The CBA and RCM media will be inoculated with an aliquot of the *C. perfringens* suspension. The CBA and RCM will be incubated anaerobically at  $35 \pm 1$  °C for  $48 \pm 2$  hours. These will serve as positive growth controls for the media.
- 18.3 The acceptance criterion for these bacterial media controls is “typical growth” of the organisms.
- 18.4 For negative sterility controls, two tubes each of TSB, PBS, and three plates of MCT will be incubated at  $35 \pm 2$  °C for  $48 \pm 2$  hours.

The acceptance criterion for these uninoculated media controls is “negative for growth”.

#### 19.0 Performance Criteria:

- 19.1 In order to demonstrate equivalent recovery the cast iron test articles must be within 0.5 Log of the stainless-steel carrier controls.

#### 20.0 Acceptance Criteria:

- 20.1 The study controls below must perform according to the criteria detailed for the data to be considered acceptable.
  - 20.1.1 Comparable growth acceptance will be within 50 - 200 % between the media. Sterility acceptance is no growth.
  - 20.1.2 The acceptance criteria are growth from inoculated streaks and no growth from the sterility controls.

#### 21.0 References:

- 21.1 U. S. Food and Drug Administration *Bacteriological Analytical Manual*, Chapter 3 *Aerobic Plate Count* (January 2001). (Accessed October 2019)  
<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063346.htm>

#### 22.0 Final Report:

A final validation report will be prepared upon completion of the study, including a tabularized summary of data and a description of results of the study.

#### 23.0 Documentation and Record-Keeping:

All documentation and records will be compiled, analyzed, and retained by Q Laboratories at its facility in Cincinnati, Ohio. All raw data for this study, as well as the final report, will be sent to the study sponsor and retained in safe storage by the testing facility for a period of at least seven (7) years (20 –ADMN-ISO-008D, Control of Records).

#### **24.0 Quality Compliance:**

Q Laboratories has developed and implemented a quality management system that enhances our ability to provide testing services that consistently meet client expectations and regulatory requirements. Q Laboratories quality documentation requirements are defined by ISO 17025, FDA Quality System Regulations (QSR), FDA Current Good Manufacturing Practices (cGMPs), FDA Good Laboratory Practices (GLP), and EPA Good Laboratory Practices standards (GLPs).

Q Laboratories applies the following standards as applicable:

- ISO 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories
- FDA 21 CFR Part 820 Quality System Regulation
- FDA 21 CFR Part 58 Good Laboratory Practice for Non Clinical Laboratory Studies
- FDA 21 CFR Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals
- FDA 21 CFR Part 210 Current Good Manufacturing Practice in Manufacturing Processing, Packing or Holding of Drugs; General
- EPA 40 CFR Part 160 FIFRA Good Laboratory Practice Standards

#### **25.0 Protocol Modifications:**

During the testing phase, changes to the protocol may be required. The study sponsor will be notified immediately of any modifications to the protocol. Approval of the modifications is required before any additional analysis is conducted. The modifications will be added to the protocol as an amendment and approved by both the study director and study sponsor.

#### **26.0 Test Article Disposition:**

All unused test material will be offered for return to the Study Sponsor at expense of Study Sponsor. If not desired by Study Sponsor, all unused test material to be disposed of within 90 days following the study completion.

27.0 Acceptance of Study Protocol:

**Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel**

**Q Laboratories** (Testing Facility)  
1930 Radcliff Drive  
Cincinnati, OH 45204

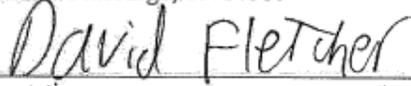
Laboratory  
Supervisor:

  
\_\_\_\_\_

Benjamin J. Bastin  
Microbiology R&D Laboratory Supervisor

10/31/19  
Date

**Lodge Manufacturing** (Study Sponsor)  
204 East 5th Street  
South Pittsburgh, TN 37380

  
\_\_\_\_\_

Representative

QA Supervisor  
\_\_\_\_\_

Title

10/31/19  
Date

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-032**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Manufacturer cooking instructions and disclosures

**Issue you would like the Conference to consider:**

The incidence rate for listeriosis, as reported by FoodNet (0.3 per 100,000 population in 2018 (CDC 2019); 0.25 in 2012 (CDC, 2013)), has changed little over the years, despite industry efforts to control *Listeria monocytogenes* in ready-to-eat foods (RTE foods). Foods that are not ready-to-eat (NRTE foods) are rarely associated with foodborne listeriosis, even if contaminated with *L. monocytogenes*, because cooking is an effective control measure to reduce the risk of foodborne listeriosis. Many manufacturers who intend for their food products to be consumed only after cooking provide cooking instructions on the product label. In addition, recent FDA regulations for the production of human food include a provision whereby food manufacturers and farms may sell their food products to a commercial entity for further commercial processing (such as cooking) to control pathogens rather than control the pathogens themselves, as long as the producers of these foods disclose that the pathogens have not been controlled.

At the retail level, there exists a gap. There is no requirement indicating that foods (other than raw animal foods) that are intended for consumption only after cooking be fully cooked prior to consumption. In an effort to ensure that retail food establishments recognize that they receive foods (other than raw animal foods) that may have hazards that need to be controlled by cooking, we would like the Conference to consider modifying the Food Code to specify that: (1) packaged food that bears a manufacturer's cooking instructions shall be cooked according to those instructions before use in foods that will not be cooked or offered to the consumer in unpackaged form for consumption (e.g., frozen vegetables used in refrigerated salads or served on salad bars), unless the manufacturer's instructions also specify that the food also can be consumed without cooking (e.g., dried soup mix with instructions to be cooked as a soup or used uncooked in preparing a dip); and (2) food that bears a disclosure that it has not been processed to control pathogens shall be cooked before use in ready-to-eat (RTE foods) or offered to the consumer for consumption.

**Public Health Significance:**

The incidence rate for listeriosis, as reported by FoodNet (0.3 per 100,000 population in 2018 (CDC 2019); 0.25 in 2012 (CDC, 2013)), has changed little over the years, despite industry efforts to control *Listeria monocytogenes* in RTE foods. Foods that are not ready-to-eat (NRTE foods) are rarely associated with foodborne listeriosis, even if contaminated with *L. monocytogenes*, because cooking is an effective control measure to reduce the risk of foodborne listeriosis. Food manufacturers that provide cooking instructions on the label or in labeling for their food products, without also providing suggestions for how to use the food product without cooking, generally intend that their food products are NRTE foods that should be consumed only after cooking and that cooking may be necessary to prevent foodborne illness. Frozen vegetables are an example of a food that often bears cooking instructions and are often intended for use only as NRTE food. Frozen vegetables also are an example of an NRTE food that has been linked to foodborne listeriosis, possibly as a result of failure to cook the food. Frozen corn (and possibly other frozen vegetables) that a producer considered to be NRTE food was linked to an outbreak of listeriosis, reported by the European Food Safety Authority (EFSA) and European Centre for Disease Prevention and Control (ECDC), that spanned the years 2015-2018 in five European countries (EFSA and ECDC, 2018). The published report of this outbreak noted that the consumption of thawed corn and thawed vegetables without cooking them is not an unusual practice (e.g. in salads and smoothies). To reduce the risk of *L. monocytogenes* infection due to frozen vegetables, EFSA and ECDC advised consumers to thoroughly cook frozen vegetables that are not labelled as RTE (EFSA and ECDC, 2018). Like consumers, retail and food service operations sometimes use frozen vegetables in making RTE foods such as salads and smoothies, or retail and food service operations may provide frozen vegetables such as peas and corn on salad bars. If *L. monocytogenes* is present in a frozen vegetable, and the frozen vegetable is thawed and prepared for use as an RTE food without cooking and this food is held refrigerated, the *L. monocytogenes* could multiply during refrigerated storage and potentially cause illness.

Spices (such as pepper) have been found to contain *Salmonella* and large outbreaks of *Salmonella* illness associated with the consumption of microbiologically contaminated black, red, or white pepper have occurred in the United States (FDA, 2017). Most spices that are packaged for retail sale have been processed to control pathogens such as *Salmonella* (FDA, 2017), and the Food Code includes spices as an example of RTE food. However, a 2015 FDA regulation (Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; 21 CFR part 117) allows a food manufacturer that produces a food (such as a spice or a spice/seasoning blend) that has a known or reasonably foreseeable hazard (such as *Salmonella*) to provide that food to a commercial retail or foodservice operation without first processing the food to control that hazard, as long as the manufacturer discloses to the commercial retail or foodservice operation that the food has not been processed to control the hazard. (See 21 CFR 117.136.) Retail and foodservice operations need to be aware that food that bears such a disclosure must be processed (e.g., by cooking) to control the hazard before making the food available to consumers. For example, a manufacturer might provide to a retail or foodservice operation a taco seasoning blend or spaghetti sauce spice blend designed to be added to a food that is to be cooked (e.g., tacos or spaghetti sauce).

Another 2015 FDA regulation (Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; the produce safety regulation; 21 CFR part 112) governs the production of produce unless the produce (such as potatoes and winter

squash) is rarely consumed raw. Produce (such as apples) that is covered by the produce safety regulation can be exempt from most requirements of that regulation if it will be commercially processed to control pathogens. (See 21 CFR 112.2(b).) For example, a farm that grows apples and sells the apples to a juice processor is exempt from most of the requirements of the produce safety regulation, as long as the apple grower discloses to the juice processor that the apples have not been processed to control pathogens. That apple grower could also sell its apples to a retail or foodservice operation - e.g., for use in making apple pies - as long as the apple grower discloses to the retail or foodservice establishment that the apples were not processed to control pathogens. Retail and foodservice operations need to be aware that produce that bears such a disclosure must be processed (e.g., by cooking) to control pathogens before making the produce available to consumers.

**Recommended Solution: The Conference recommends...:**

A letter be sent to FDA requesting that the Food Code address the cooking of Foods That Bear a Manufacturer's Cooking Instructions or That Disclose That the Food Has Not Been Processed to Control Pathogens specifying that: (1) packaged food that bears a manufacturer's cooking instructions shall be cooked according to those instructions before use in foods that will not be cooked or offered to the consumer in unpackaged form for consumption (e.g., frozen vegetables used in refrigerated salads or served on salad bars) unless the manufacturer's instructions also specify that the food also can be consumed without cooking (e.g., dried soup mix with instructions to be cooked as a soup or used uncooked in preparing a dip); and (2) food that bears a disclosure that it has not been processed to control pathogens shall be cooked before use in ready-to-eat (RTE foods) or offered to the consumer for consumption.

Note: This revision is not intended to apply to raw animal foods

**Submitter Information:**

Name: Jenny Scott  
Organization: U. S. Food and Drug Administration  
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**Supporting Attachments:**

- "Incidence and Trends of Infection with Pathogens Transmitted Commonly..."
- "Preliminary Incidence and Trends of Infections with Pathogens Transmitted.."
- "Multi-country outbreak of *Listeria monocytogenes* sergroup IVb, multi-locus"
- "Risk Profile: Pathogens and Filth in Spices"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

## Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 1996–2012

Foodborne diseases are an important public health problem in the United States. The Foodborne Diseases Active Surveillance Network\* (FoodNet) conducts surveillance in 10 U.S. sites for all laboratory-confirmed infections caused by selected pathogens transmitted commonly through food to quantify them and monitor their incidence. This report summarizes 2012 preliminary surveillance data and describes trends since 1996. A total of 19,531 infections, 4,563 hospitalizations, and 68 deaths associated with foodborne diseases were reported in 2012. For most infections, incidence was highest among children aged <5 years; the percentage of persons hospitalized and the percentage who died were highest among persons aged ≥65 years. In 2012, compared with the 2006–2008 period, the overall incidence of infection† was unchanged, and the estimated incidence of infections caused by *Campylobacter* and *Vibrio* increased. These findings highlight the need for targeted action to address food safety gaps.

FoodNet conducts active, population-based surveillance for laboratory-confirmed infections caused by *Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC) O157 and non-O157, *Shigella*, *Vibrio*, and *Yersinia* in 10 sites covering 15% of the U.S. population (48 million persons in 2011).§ FoodNet is a collaboration among CDC, 10 state health departments, the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS), and the Food and Drug Administration (FDA). Hospitalizations occurring within 7 days of specimen collection date are recorded, as is the patient's vital status at hospital discharge, or at 7 days after the specimen collection date if the patient was not hospitalized. All hospitalizations and deaths that occurred within a 7-day window are attributed to the infection. Surveillance for physician-diagnosed postdiarrheal hemolytic uremic syndrome (HUS), a complication of STEC infection characterized by renal failure, is conducted through a network of nephrologists and infection preventionists and by hospital discharge data review. This report includes 2011 HUS data for persons aged <18 years.

\* Additional information available at <http://www.cdc.gov/foodnet>.

† The overall incidence of infection combines data for *Campylobacter*, *Listeria*, *Salmonella*, STEC O157, *Vibrio*, and *Yersinia*, six key bacterial pathogens for which >50% of illnesses are estimated to be transmitted by food.

§ FoodNet personnel regularly contact clinical laboratories to ascertain all laboratory-confirmed infections in residents of the surveillance areas.

Incidence was calculated by dividing the number of laboratory-confirmed infections in 2012 by U.S. Census estimates of the surveillance population area for 2011.¶ A negative binomial model with 95% confidence intervals (CIs) was used to estimate changes in incidence from 2006–2008 to 2012 and from 1996–1998 to 2012 (1). The overall incidence of infection with six key pathogens for which >50% of illnesses are estimated to be foodborne (*Campylobacter*, *Listeria*, *Salmonella*, STEC O157, *Vibrio*, and *Yersinia*) was calculated (2). Trends were not assessed for *Cyclospora* because data were sparse, or for STEC non-O157 because of changes in diagnostic practices. For HUS, changes in incidence from 2006–2008 to 2011 were estimated.

### Incidence and Trends

In 2012, FoodNet identified 19,531 laboratory-confirmed cases of infection (Table 1). The number of infections and incidence per 100,000 population, by pathogen, were as follows: *Salmonella* (7,800; 16.42), *Campylobacter* (6,793; 14.30), *Shigella* (2,138; 4.50), *Cryptosporidium* (1,234; 2.60), STEC non-O157 (551; 1.16), STEC O157 (531; 1.12), *Vibrio* (193; 0.41), *Yersinia* (155; 0.33), *Listeria* (121; 0.25), and *Cyclospora* (15; 0.03). As usual, the highest reported incidence was among children aged <5 years for *Cryptosporidium* and the bacterial pathogens other than *Listeria* and *Vibrio*, for which the highest incidence was among persons aged ≥65 years (Table 2).

Among 6,984 (90%) serotyped *Salmonella* isolates, the top three serotypes were Enteritidis, 1,238 (18%); Typhimurium, 914 (13%); and Newport, 901 (13%). Among 183 (95%) *Vibrio* isolates with species information, 112 were *V. parahaemolyticus* (61%), 25 were *V. vulnificus* (14%), and 20 were *V. alginolyticus* (11%). Among 496 (90%) serogrouped STEC non-O157 isolates, the most common serogroups were O26 (27%), O103 (23%), and O111 (15%). Among 2,318 (34%) *Campylobacter* isolates with species information, 2,082 (90%) were *C. jejuni*, and 180 (8%) were *C. coli*.

The estimated incidence of infection was higher in 2012 compared with 2006–2008 for *Campylobacter* (14% increase; confidence interval [CI]: 7%–21%) and *Vibrio* (43% increase; CI: 16%–76%) and unchanged for other pathogens (Figure 1). In comparison with 1996–1998, incidence of infection was

¶ Final incidence rates will be reported when population estimates for 2012 are available.

**TABLE 1. Number of cases of bacterial and parasitic infection, hospitalizations, and deaths, by pathogen — Foodborne Diseases Active Surveillance Network, United States, 2012\***

Pathogen	Cases			Hospitalizations		Deaths	
	No.	Incidence <sup>†</sup>	Objective <sup>§</sup>	No.	(%)	No.	(%)
<b>Bacteria</b>							
<i>Campylobacter</i>	6,793	14.30	8.5	1,044	(15)	6	(0.09)
<i>Listeria</i>	121	0.25	0.2	116	(96)	13	(10.74)
<i>Salmonella</i>	7,800	16.42	11.4	2,284	(29)	33	(0.42)
<i>Shigella</i>	2,138	4.50	N/A <sup>¶</sup>	491	(23)	2	(0.09)
STEC O157	531	1.12	0.6	187	(35)	1	(0.19)
STEC non-O157	551	1.16	N/A	88	(16)	1	(0.18)
<i>Vibrio</i>	193	0.41	0.2	55	(29)	6	(3.11)
<i>Yersinia</i>	155	0.33	0.3	59	(38)	0	(0.00)
<b>Parasites</b>							
<i>Cryptosporidium</i>	1,234	2.60	N/A	236	(19)	6	(0.49)
<i>Cyclospora</i>	15	0.03	N/A	3	(20)	0	(0.00)
<b>Total</b>	<b>19,531</b>			<b>4,563</b>		<b>68</b>	

**Abbreviations:** N/A = not available; STEC = Shiga toxin-producing *Escherichia coli*.

\* Data for 2012 are preliminary.

<sup>†</sup> Per 100,000 population.

<sup>§</sup> *Healthy People 2020* objective targets for incidence of *Campylobacter*, *Listeria*, *Salmonella*, STEC O157, *Vibrio*, and *Yersinia* infections per 100,000 population.

<sup>¶</sup> No national health objective exists for these pathogens.

significantly lower for *Campylobacter*, *Listeria*, *Shigella*, STEC O157, and *Yersinia*, whereas the incidence of *Vibrio* infection was higher (Figure 2). The overall incidence of infection with six key pathogens\*\* transmitted commonly through food was lower in 2012 (22% decrease; CI: 11%–32%) compared with 1996–1998 and unchanged compared with 2006–2008.

The incidence of infections with specific *Salmonella* serotypes in 2012, compared with 2006–2008, was lower for Typhimurium (19% decrease; CI: 10%–28%), higher for Newport (23% increase; CI: 1%–50%), and unchanged for Enteritidis. Compared with 1996–1998, the incidence of infection was significantly higher for Enteritidis and Newport, and lower for Typhimurium.

Among 63 cases of postdiarrheal HUS in children aged <18 years (0.57 cases per 100,000 children) in 2011, 33 (52%) occurred in children aged <5 years (1.09 cases per 100,000). Compared with 2006–2008, the incidence was significantly lower for children aged <5 years (44% decrease; CI: 18%–62%) and for children aged <18 years (29% decrease; CI: 4%–47%).

## Hospitalizations and Deaths

In 2012, FoodNet identified 4,563 hospitalizations and 68 deaths among cases of infection with pathogens transmitted commonly through food (Table 1). The percentage of patients hospitalized ranged from 15% for *Campylobacter* to 96% for *Listeria* infections. The percentage hospitalized was greatest among those aged ≥65 years for STEC O157 (67%), *Vibrio* (58%), *Salmonella* (55%), *Cyclospora* (50%), *Shigella* (41%), STEC non-O157 (34%), *Cryptosporidium* (33%), and

**TABLE 2. Incidence\* of laboratory-confirmed bacterial and parasitic infections in 2012,<sup>†</sup> by pathogen and age group — Foodborne Diseases Active Surveillance Network, United States**

Pathogen	Age group (yrs)				
	<5	5–9	10–19	20–64	≥65
<b>Bacteria</b>					
<i>Campylobacter</i>	24.08	10.54	9.42	14.54	15.26
<i>Listeria</i>	0.17	0.00	0.03	0.17	1.05
<i>Salmonella</i>	63.49	19.33	11.26	12.15	17.22
<i>Shigella</i>	16.92	14.77	2.96	3.10	1.42
STEC <sup>§</sup> O157	4.71	2.31	1.65	0.58	0.74
STEC non-O157	4.81	1.33	1.65	0.70	0.92
<i>Vibrio</i>	0.07	0.26	0.14	0.43	0.78
<i>Yersinia</i>	1.33	0.29	0.16	0.23	0.49
<b>Parasites</b>					
<i>Cryptosporidium</i>	3.68	3.09	1.70	2.54	3.01
<i>Cyclospora</i>	0.00	0.00	0.00	0.04	0.03

\* Per 100,000 population.

<sup>†</sup> Data for 2012 are preliminary.

<sup>§</sup> Shiga toxin-producing *Escherichia coli*.

*Campylobacter* (31%). At least 95% of patients with *Listeria* infection in each age group<sup>††</sup> with cases were hospitalized. The percentage of patients who died ranged from 0% for *Yersinia* and *Cyclospora* to 11% for *Listeria* infections. The percentage that died was highest among persons aged ≥65 years for *Vibrio* (6%), *Salmonella* (2%), STEC O157 (2%), *Cryptosporidium* (1%), *Shigella* (1%), and *Campylobacter* (0.2%).

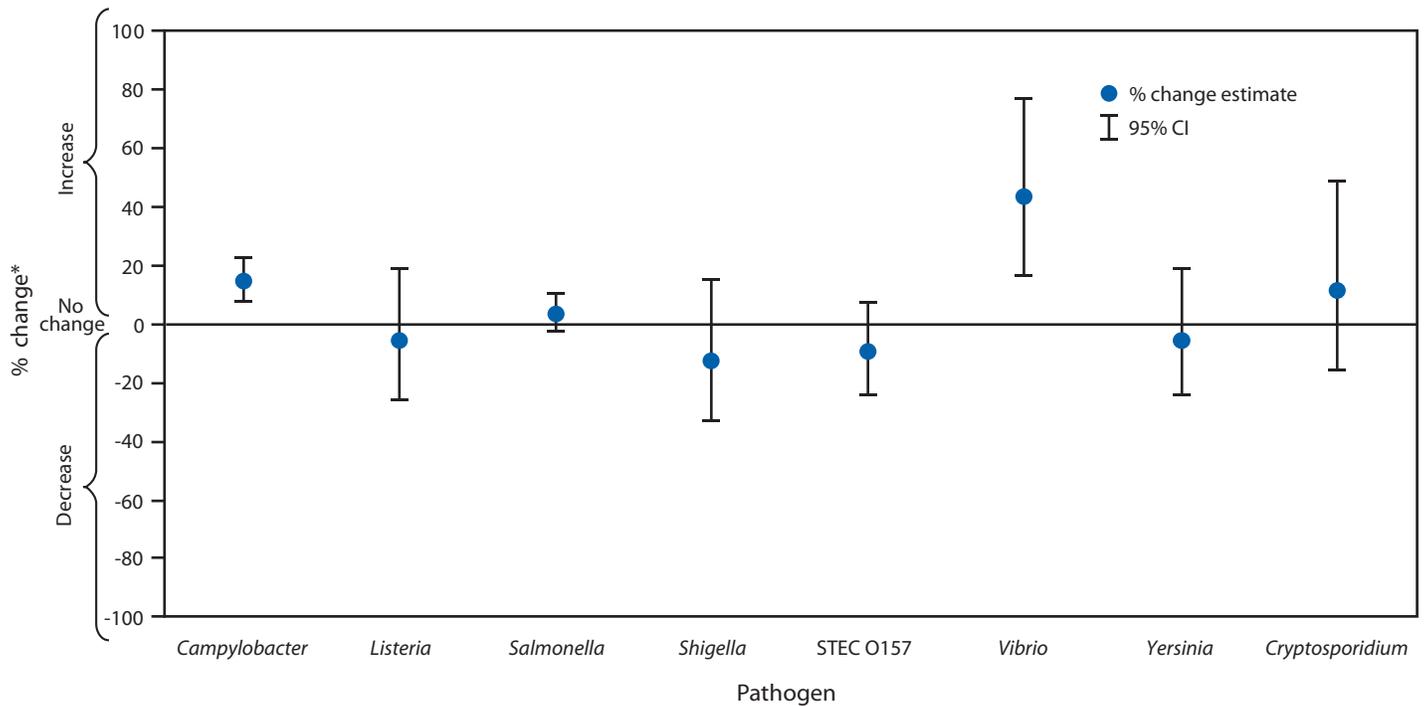
## Reported by

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\*\* *Campylobacter*, *Listeria*, *Salmonella*, STEC O157, *Vibrio*, and *Yersinia*.

<sup>††</sup> Age groups defined as <5 years, 5–9 years, 10–19 years, 20–64 years, and ≥65 years.

**FIGURE 1.** Estimated percentage change in incidence of laboratory-confirmed bacterial and parasitic infections in 2012 compared with average annual incidence during 2006–2008, by pathogen — Foodborne Diseases Active Surveillance Network, United States



**Abbreviations:** CI = confidence interval; STEC = Shiga toxin-producing *Escherichia coli*.

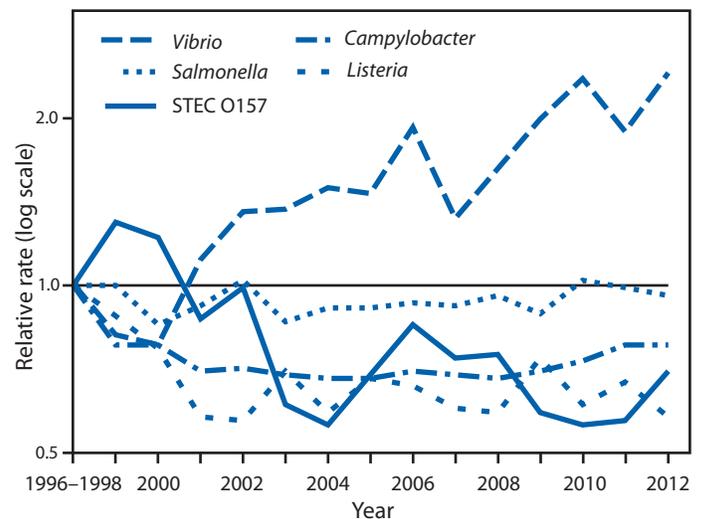
\* No significant change = 95% CI is both above and below the no change line; significant increase = estimate and entire CI are above the no change line; significant decrease = estimate and entire CI are below the no change line.

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**Editorial Note**

In 2012, the incidence of infections caused by *Campylobacter* and *Vibrio* increased from the 2006–2008 period, whereas the incidence of infections caused by *Cryptosporidium*, *Listeria*, *Salmonella*, *Shigella*, STEC O157, and *Yersinia* was unchanged. These findings highlight the need to continue to identify and address food safety gaps that can be targeted for action by the food industry and regulatory authorities.

**FIGURE 2.** Relative rates of laboratory-confirmed infections with *Campylobacter*, STEC\* O157, *Listeria*, *Salmonella*, and *Vibrio* compared with 1996–1998 rates, by year — Foodborne Diseases Active Surveillance Network, United States, 1996–2012<sup>†</sup>



\* Shiga toxin-producing *Escherichia coli*.

<sup>†</sup> The position of each line indicates the relative change in the incidence of that pathogen compared with 1996–1998. The actual incidences of these infections cannot be determined from this figure.

After substantial declines in the early years of FoodNet surveillance, the incidence of *Campylobacter* infection has increased to its highest level since 2000. *Campylobacter* infections are more common in the western U.S. states and among children aged <5 years (3). Although most infections are self-limited, sequelae include reactive arthritis and Guillain-Barré syndrome.<sup>§§</sup> Associated exposures include consumption of poultry, raw milk, produce, and untreated water, and animal contact (4,5).

Declines in U.S. campylobacteriosis during 1996–2001 might have been related to measures meat and poultry processors implemented to comply with the Pathogen Reduction and Hazard Analysis and Critical Control Points (HACCP) systems regulations issued by USDA-FSIS in the late 1990s.<sup>¶¶</sup> In 2011, USDA-FSIS issued new *Campylobacter* performance standards for U.S. chicken and turkey processors.<sup>\*\*\*</sup> Continued FoodNet surveillance can help to assess the public health impact of these standards and other changes. Detailed patient exposure information coupled with information on strain subtypes could help in assessing the relative contribution of various sources of infection and the effectiveness of control measures.

Although a significant increase was observed in reported *Vibrio* infections, the number of such infections remains low (6). *Vibrios* live naturally in marine and estuarine waters, and many infections are acquired by eating raw oysters (7). These infections are most common during warmer months, when waters contain more *Vibrio* organisms. Infections can be prevented by postharvest treatment of oysters with heat, freezing, or high pressure (8), or by thorough cooking. Persons who are immunocompromised or have impaired liver function should be informed that consuming raw seafood carries a risk for severe *Vibrio* infection. *Vibrios* also cause wound and soft-tissue infections among persons who have contact with water; for example, *Vibrio alginolyticus* typically causes ear infection (9).

The decrease in incidence of HUS in 2011 compared with 2006–2008 mirrors the decrease in the incidence of STEC O157 infection observed in 2011. The incidence of STEC O157 infection, which had declined since 2006, was no longer decreasing in 2012, and now exceeds the previously met *Healthy People 2010* target of one case per 100,000 persons. The continued increase in STEC non-O157 infections likely reflects increasing use by clinical laboratories of tests that detect these infections.

<sup>§§</sup> Additional information available at <http://www.who.int/mediacentre/factsheets/fs255/en/index.html>.

<sup>¶¶</sup> Additional information available at <http://www.fsis.usda.gov/oppde/rdad/frpubs/93-016f.pdf>.

<sup>\*\*\*</sup> Additional information is available at [http://www.fsis.usda.gov/science/haccp\\_verification\\_campylobacter\\_results\\_2011/index.asp](http://www.fsis.usda.gov/science/haccp_verification_campylobacter_results_2011/index.asp).

#### What is already known on this topic?

The incidence of infections transmitted commonly by food that are tracked by the Foodborne Diseases Active Surveillance Network (FoodNet) has changed little in recent years. Foodborne illness continues to be an important public health problem.

#### What is added by this report?

Preliminary surveillance data show that the incidence of infections caused by *Campylobacter* and *Vibrio* increased in 2012, whereas incidence of other foodborne infections tracked by FoodNet was unchanged (i.e., *Cryptosporidium*, *Listeria*, *Salmonella*, *Shigella*, Shiga toxin-producing *Escherichia coli* O157, and *Yersinia*).

#### What are the implications for public health practice?

Reducing the incidence of foodborne infections will require commitment and action to implement measures known to reduce contamination of food and to develop new measures. Farmers, the food industry, regulatory agencies, the food service industry, consumers, and public health authorities all have a role.

FoodNet surveillance relies on isolation of bacterial pathogens by culture of clinical specimens; therefore, the increasing use of culture-independent tests for *Campylobacter* and STEC might affect the reported incidence of infection (10). Data on persons with only culture-independent evidence of infection suggests that in 2012, the number of laboratory-identified *Campylobacter* cases could have been 9% greater and the number of STEC (O157 and non-O157) cases 7%–19% greater than that reported (CDC, unpublished data, 2013). The lack of recent decline in STEC O157 incidence is of concern; continued monitoring of trends in the incidence of HUS and use of culture-independent testing might aid in interpreting future data on STEC O157 incidence.

The findings in this report are subject to at least four limitations. First, health-care-seeking behaviors and other characteristics of the population in the surveillance area might affect the generalizability of the findings. Second, many infections transmitted commonly through food (e.g., norovirus infection) are not monitored by FoodNet because these pathogens are not identified routinely in clinical laboratories. Third, the proportion of illnesses transmitted by nonfood routes differs by pathogen, and the route cannot be determined for individual, nonoutbreak-associated illnesses and, therefore, the data provided in this report do not exclusively relate to infections from foodborne sources. Finally, in some cases counted as fatal, the infection with the enteric pathogen might not have been the primary cause of death.

Most foodborne illnesses can be prevented. Progress has been made in decreasing contamination of some foods and

reducing illness caused by some pathogens, as evidenced by decreases in earlier years. In 2010, FDA passed the Egg Safety Rule,<sup>†††</sup> designed to decrease contamination of shell eggs with *Salmonella* serotype Enteritidis. In 2011, USDA-FSIS tightened its performance standard for *Salmonella* contamination to a 7.5% positive rate for whole broiler chickens.<sup>§§§</sup> Finally, the Food Safety Modernization Act of 2011 gives FDA additional authority to improve food safety and requires CDC to strengthen surveillance and outbreak response.<sup>¶¶¶</sup> Collection of comprehensive surveillance information further supports reductions in foodborne infections by helping to determine where to target prevention efforts, supporting efforts to attribute infections to sources, guiding implementation of measures known to reduce food contamination, and informing development of new measures. Because consumers can bring an added measure of safety during food storage, handling, and preparation, they are advised to seek out food safety information, which is available online.<sup>\*\*\*\*</sup>

## Acknowledgments

Workgroup members, Foodborne Diseases Active Surveillance Network (FoodNet), Emerging Infections Program; communications team, Div of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Diseases, CDC.

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<sup>†††</sup> Additional information available at <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/eggs/ucm170615.htm>.

<sup>§§§</sup> Additional information available at <http://www.gpo.gov/fdsys/pkg/FR-2011-03-21/pdf/2011-6585.pdf>.

<sup>¶¶¶</sup> Additional information available at <http://www.fda.gov/food/guidanceregulation/fsma/ucm242500.htm>.

<sup>\*\*\*\*</sup> Additional food safety information is available at <http://www.cdc.gov/winnablebattles/foodsafety/index.html>, <http://www.foodsafety.gov> and <http://www.fightbac.org>.

# Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2015–2018

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Foodborne diseases represent a major health problem in the United States. The Foodborne Diseases Active Surveillance Network (FoodNet) of CDC's Emerging Infections Program monitors cases of laboratory-diagnosed infection caused by eight pathogens transmitted commonly through food in 10 U.S. sites.\* This report summarizes preliminary 2018 data and changes since 2015. During 2018, FoodNet identified 25,606 infections, 5,893 hospitalizations, and 120 deaths. The incidence of most infections is increasing, including those caused by *Campylobacter* and *Salmonella*, which might be partially attributable to the increased use of culture-independent diagnostic tests (CIDTs). The incidence of *Cyclospora* infections increased markedly compared with 2015–2017, in part related to large outbreaks associated with produce (*I*). More targeted prevention measures are needed on produce farms, food animal farms, and in meat and poultry processing establishments to make food safer and decrease human illness.

FoodNet conducts active, population-based surveillance for laboratory-diagnosed infections caused by *Campylobacter*, *Cyclospora*, *Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC), *Shigella*, *Vibrio*, and *Yersinia* in 10 sites covering 15% of the U.S. population (approximately 49 million persons in 2017). FoodNet is a collaboration among CDC, 10 state health departments, the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS), and the Food and Drug Administration (FDA). Bacterial infections are defined as isolation of the bacterium from a clinical specimen or detection of pathogen antigen, nucleic acid sequences, or, for STEC,<sup>†</sup> Shiga toxin or Shiga toxin genes. *Listeria* cases are defined as isolation of *L. monocytogenes* or detection of its nucleic acid sequences from a normally sterile site or from placental or fetal tissue in cases of miscarriage or stillbirth. *Cyclospora* infections are defined as detection of the parasite from a clinical specimen by direct fluorescent antibody, polymerase chain reaction, or light microscopy. Hospitalizations occurring within 7 days of specimen collection

are attributed to the infection, as is the patient's vital status at hospital discharge, or 7 days after specimen collection if the patient was not hospitalized.

Incidence per 100,000 population was calculated by dividing the number of infections in 2018 by U.S. Census estimates of the surveillance area population for 2017. A negative binomial model with 95% confidence intervals (CIs) was calculated using SAS (version 9.4; SAS Institute) to estimate changes in incidence.

Surveillance for physician-diagnosed postdiarrheal hemolytic uremic syndrome, a complication of STEC infection characterized by renal failure, thrombocytopenia, and microangiopathic anemia, is conducted through a network of nephrologists and infection preventionists and by hospital discharge data review. This report includes pediatric hemolytic uremic syndrome cases (those occurring in persons aged <18 years) identified during 2017, the most recent year for which data are available.

## Cases of Infection, Incidence, and Trends

During 2018, FoodNet identified 25,606 cases of infection, 5,893 hospitalizations, and 120 deaths. The incidence of infection (per 100,000 population) was highest for *Campylobacter* (19.5) and *Salmonella* (18.3), followed by STEC (5.9), *Shigella* (4.9), *Vibrio* (1.1), *Yersinia* (0.9), *Cyclospora* (0.7), and *Listeria* (0.3) (Table). Compared with 2015–2017, the incidence significantly increased for *Cyclospora* (399%), *Vibrio* (109%), *Yersinia* (58%), STEC (26%), *Campylobacter* (12%), and *Salmonella* (9%). The number of bacterial infections diagnosed by CIDT (with or without reflex culture<sup>§</sup>) increased 65% in 2018 compared with the average annual number diagnosed during 2015–2017; the increase ranged from 29% for STEC to 311% for *Vibrio* (Figure 1). In 2018, the percentage of infections diagnosed by DNA-based syndrome panels was highest for *Yersinia* (68%) and *Cyclospora* (67%), followed by STEC (55%), *Vibrio* (53%), *Shigella* (48%), *Campylobacter* (43%), *Salmonella* (33%), and was lowest for *Listeria* (2%). In 2018, a reflex culture was attempted on 75% of specimens with positive CIDT results, ranging from 64% for *Campylobacter* to 100% for *Listeria* (Figure 1). The percentage of specimens with a reflex culture in 2018 was 14% higher than that during

\* Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York (<https://www.cdc.gov/foodnet>).

<sup>†</sup> STEC cases are defined as identification of Shiga toxin or its genes by any laboratory; it is not possible to distinguish among serogroups using CIDTs.

<sup>§</sup> Culture of a specimen with a positive CIDT result.

**TABLE. Number of cases, hospitalizations, and deaths caused by bacterial and parasitic infections, incidence rate, and percentage change compared with 2015–2017 average annual incidence rate, by pathogen — CDC's Foodborne Diseases Active Surveillance Network,\* 2018†**

Pathogen	2018				2018 compared with 2015–2017
	No. of cases	No. (%) of hospitalizations	No. (%) of deaths	IR <sup>§</sup>	% (95% CI) Change in IR <sup>¶</sup>
<b>Bacteria</b>					
<i>Campylobacter</i>	9,723	1,811 (18)	30 (0.3)	19.6	12 (4 to 20)
<i>Salmonella</i>	9,084	2,416 (27)	36 (0.4)	18.3	9 (3 to 16)
Shiga toxin–producing <i>Escherichia coli</i> **	2,925	648 (22)	13 (0.4)	5.9	26 (7 to 48)
<i>Shigella</i>	2,414	632 (26)	1 (0.04)	4.9	–2 (–24 to 26)
<i>Vibrio</i>	537	151 (28)	9 (2)	1.1	109 (72 to 154)
<i>Yersinia</i>	465	95 (20)	4 (0.9)	0.9	58 (26 to 99)
<i>Listeria</i>	126	121 (96)	26 (21)	0.3	–4 (–23 to 21)
<b>Parasite</b>					
<i>Cyclospora</i>	332	19 (5)	1 (0.3)	0.7	399 (202 to 725)
<b>Total</b>	<b>25,606</b>	<b>5,893 (23)</b>	<b>120 (0.5)</b>	—	—

**Abbreviation:** CI = confidence interval; IR = incidence rate.

\* Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York.

† Data are preliminary.

§ Per 100,000 population.

¶ Increase or decrease.

\*\* All serogroups were combined because it is not possible to distinguish among them using culture-independent diagnostic tests.

2015–2017, ranging from a 7% decrease for STEC to a 55% increase for *Shigella* (Figure 2). Among specimens with reflex culture in 2018, the percentage that yielded the pathogen was highest for *Listeria* (100%) and *Salmonella* (86%), followed by STEC (64%), *Campylobacter* (59%), *Shigella* (56%), *Yersinia* (50%), and *Vibrio* (37%) (Figure 1) (Figure 2).

Among 7,013 (87%) serotyped *Salmonella* isolates, the three most common were Enteritidis (2.6 per 100,000 population), Newport (1.6), and Typhimurium (1.5), similar to those during 2015–2017. Among 1,570 STEC isolates tested, 440 (28%) were determined to be O157. Among 662 non-O157 STEC isolates serogrouped, the most common were O103 (31%), O26 (28%), and O111 (24%). The incidence compared with 2015–2017 remained unchanged for both O157 and non-O157 STEC.

FoodNet identified 54 cases of postdiarrheal hemolytic uremic syndrome in children (0.49 cases per 100,000) during 2017; 36 (67%) occurred among children aged <5 years (1.22 cases per 100,000). Incidence was not significantly different compared with that during 2014–2016.

## Discussion

*Campylobacter* has been the most commonly identified infection in FoodNet since 2013. It causes diarrhea, sometimes bloody, and 18% of persons are hospitalized. A rare outcome of *Campylobacter* infection is Guillain-Barré syndrome, a type of autoimmune-mediated paralysis. Poultry is a major source of *Campylobacter* (2). In August 2018, FSIS began using a new testing method; in a study of that method, *Campylobacter* was isolated from 18% of chicken carcasses and 16% of chicken parts sampled (3). FSIS currently makes aggregated test results

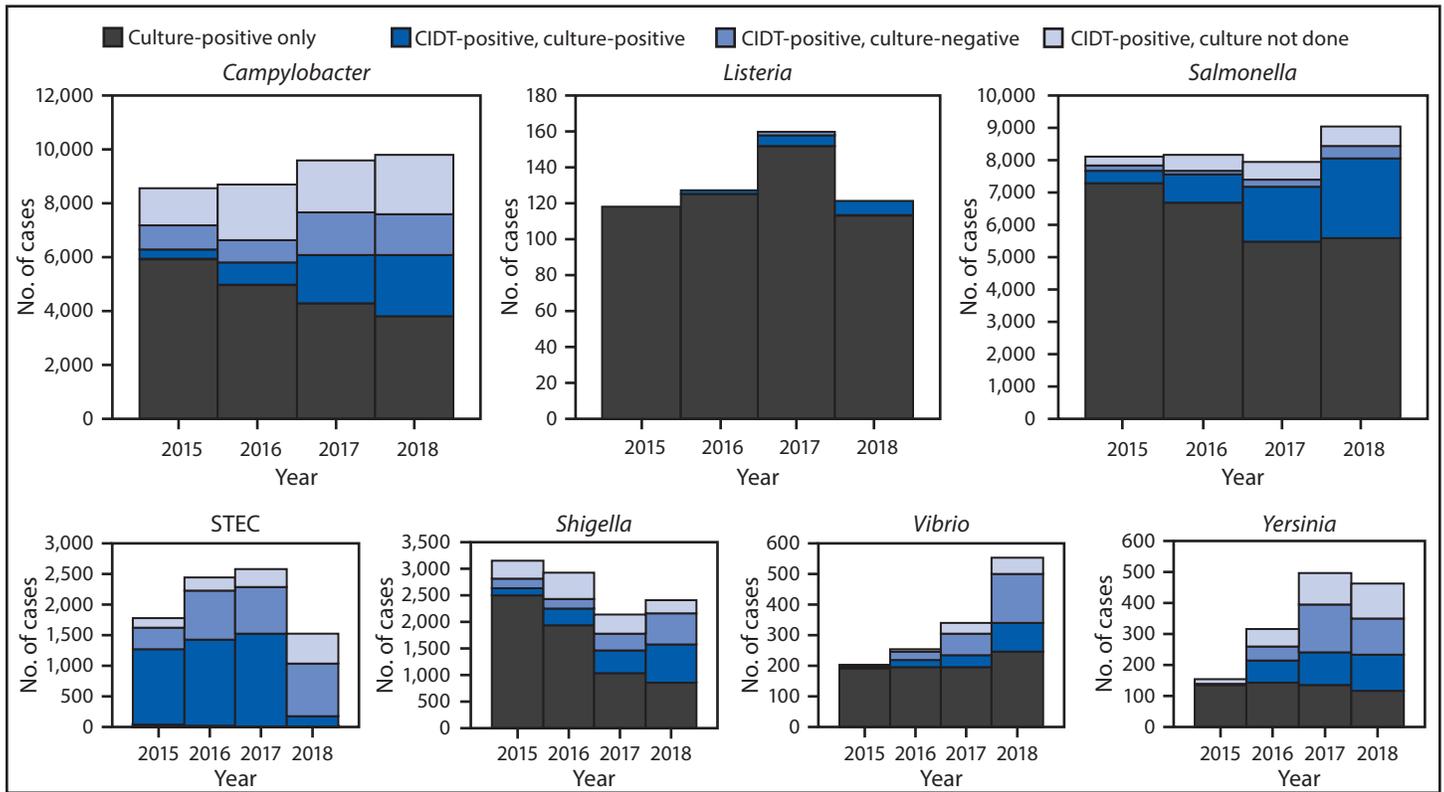
available and intends to update performance standards for *Campylobacter* contamination.

The incidence of infections with Enteritidis, the most common *Salmonella* serotype, has not declined in over 10 years. Enteritidis is adapted to live in poultry, and eggs are an important source of infection (4). By 2012, FDA had implemented the Egg Safety Rule,<sup>¶</sup> which requires preventive measures during the production of eggs in poultry houses and requires subsequent refrigeration during storage and transportation, for all farms with ≥3,000 hens. In 2018, a multistate outbreak of Enteritidis infections was traced to eggs from a farm that had not implemented the required egg safety measures after its size reached ≥3,000 hens (5). Chicken meat is also an important source of Enteritidis infections (4). In December 2018, FSIS reported that 22% of establishments that produce chicken parts failed to meet the *Salmonella* performance standard (USDA-FSIS *Salmonella* verification testing program\*\*). The percentage of samples of chicken meat and intestinal contents that yielded Enteritidis were similar in 2018 to those during 2015–2017 (USDA-FSIS, unpublished data). In contrast, a decline in serotype Typhimurium isolated from the same sources was observed during the same period. This trend coincides with declines in Typhimurium human illnesses. Changes in poultry production practices, including vaccination against Typhimurium, might have resulted in these declines (6). In the United Kingdom, vaccination of both broiler and layer chickens against Enteritidis, along with improved hygiene,

<sup>¶</sup> <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Eggs/ucm170615.htm>.

\*\* <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program>.

**FIGURE 1. Number of infections diagnosed by culture or culture-independent diagnostic tests (CIDTs), by pathogen, year, and culture status — CDC’s Foodborne Diseases Active Surveillance Network,\* 2015–2018†**

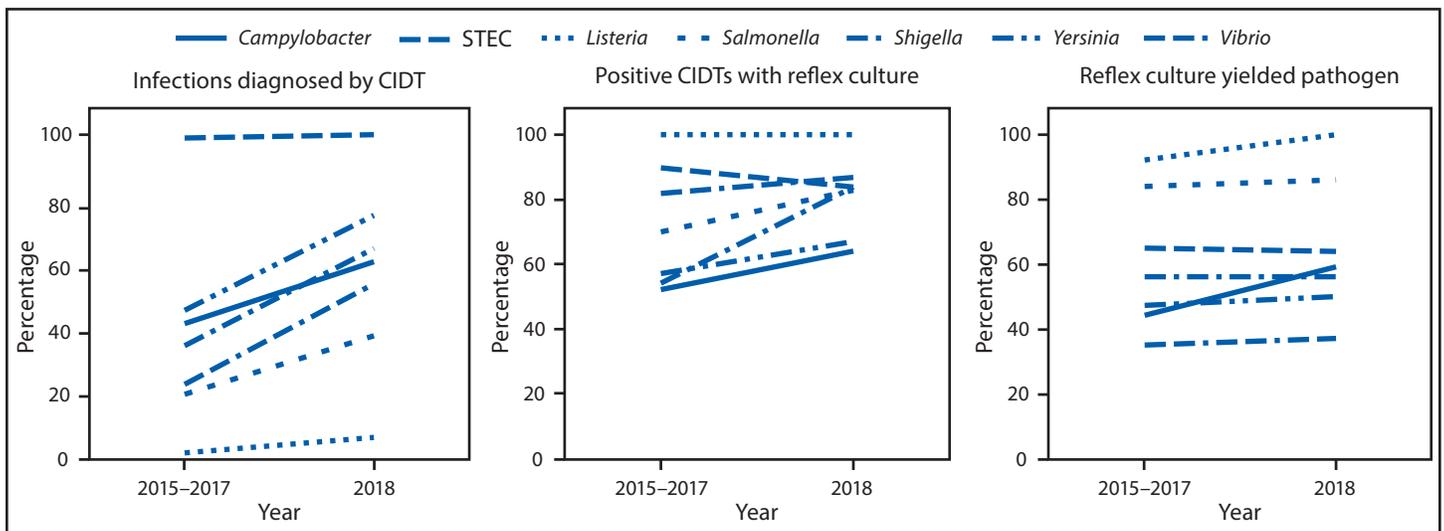


Abbreviation: STEC = Shiga toxin–producing *Escherichia coli*.

\* Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York.

† Data for 2018 are preliminary.

**FIGURE 2. Percentage of infections diagnosed by culture-independent diagnostic tests (CIDTs), positive CIDTs with a reflex culture,\* and reflex cultures that yielded the pathogen, by pathogen — CDC’s Foodborne Diseases Active Surveillance Network,† 2015–2017 and 2018§**



Abbreviation: STEC = Shiga toxin–producing *Escherichia coli*.

\* Culture of a specimen with a positive CIDT result.

† Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York.

§ Data for 2018 are preliminary.

**Summary****What is already known about this topic?**

The incidence of foodborne infections has remained largely unchanged. Clinical laboratories are increasingly using culture-independent diagnostic tests (CIDTs) to detect enteric infections. CIDTs benefit public health surveillance by identifying pathogens not routinely detected by previous methods but complicate data interpretation.

**What is added by this report?**

The incidence of most infections increased during 2018 compared with 2015–2017; this might be partially attributable to increased CIDT use. The incidence of *Cyclospora* infections increased markedly, in part related to large outbreaks associated with produce. The number of human infections caused by *Campylobacter* and *Salmonella*, especially serotype Enteritidis, remains high.

**What are the implications for public health practice?**

As use of CIDTs increases, it is important to obtain and subtype isolates and interview ill persons to monitor prevention efforts and develop more targeted prevention and control measures to make food safer and decrease human illness.

was followed by a marked decrease in human Enteritidis infections (7).

Produce is a major source of foodborne illnesses (2). During 2018, romaine lettuce was linked to two multistate outbreaks of STEC O157 infections (8). The marked increase in reported *Cyclospora* infections was likely attributable to several factors including produce outbreaks and continued adoption of DNA-based syndrome panel tests (1). Improved agricultural practices are needed to prevent produce-associated infections. FDA provides technical assistance to task forces created by the produce industry, to determine how to prevent contamination of romaine lettuce and facilitate outbreak investigations by improving product labeling and traceability. In 2018, FDA expanded surveillance sampling of foreign and domestically grown produce to assess its safety (9). FDA is implementing the Produce Safety Rule,<sup>††</sup> with routine inspections of large produce farms planned this spring. Because produce is a major component of a healthy diet and is often consumed raw, making it safer is important for improving human health (10).

The findings in this report are subject to at least three limitations. First, the changing diagnostic landscape makes interpretation of incidence and trends more complex. Increases in

reported incidence might be attributable entirely, or in part, to changes in clinician ordering practices, increased use of DNA-based syndrome panels that identify pathogens not routinely captured by traditional methods, and changes in laboratory practices in response to the availability of these panels. Second, some CIDT results might be false positives. Finally, year-to-year variations, attributable in part to large outbreaks, might not indicate sustained trends.

The need to obtain and subtype isolates from ill persons is becoming an increasing burden to state health departments but is critical for maintaining surveillance to detect and investigate outbreaks, evaluating prevention efforts, and developing targeted control measures. Measures that might decrease foodborne illnesses include enhanced efforts targeting *Campylobacter* contamination of chicken; strengthening prevention measures during egg production, especially within small flocks; vaccinating poultry against *Salmonella* serotype Enteritidis; decreasing *Salmonella* contamination of produce, poultry, and meat; and continued implementation of the Food Safety Modernization Act, specifically FDA's Produce Safety Rule. FoodNet continues to collect data and develop analytic tools to adjust for changes in diagnostic testing practices and test characteristics. These actions, along with FoodNet's robust surveillance, provide data to help evaluate the effectiveness of prevention efforts and determine when additional measures are needed.

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Work group members, Foodborne Diseases Active Surveillance Network (FoodNet), Emerging Infections Program, CDC; Brittany Behm, Robert Breazu, Staci Dixon, Elizabeth Greene, Logan Ray, Hazel Shah, Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, CDC.

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All authors have completed and submitted the ICMJE form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

<sup>††</sup> <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>.

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## **Multi-country outbreak of *Listeria monocytogenes* serogroup IVb, multi-locus sequence type 6, infections linked to frozen corn and possibly to other frozen vegetables – first update**

European Food Safety Authority  
European Centre for Disease Prevention and Control

### **Abstract**

An outbreak of invasive *Listeria monocytogenes* (*L. monocytogenes*) infections confirmed by whole-genome sequencing (WGS) and linked to frozen corn and possibly to other frozen vegetables has been ongoing in five EU Member States (Austria, Denmark, Finland, Sweden and the United Kingdom) since 2015. As of 15 June 2018, 47 cases have been reported and nine patients have died due to or with the infection (case fatality rate 19%). WGS analysis of 29 non-human *L. monocytogenes* isolates found them to be closely related to the multi-country human cluster of *L. monocytogenes* serogroup IVb, multi-locus sequence type 6 (ST6). The majority of the non-human isolates were obtained from 2017 season products: mainly frozen corn (13 samples), followed by frozen vegetable mixes including corn (8 samples), frozen spinach (1) and frozen green beans (1). Only one isolate was reported from a frozen vegetable mix produced in 2016, while three isolates were obtained from spinach products produced in 2018. In addition, two isolates were also obtained from two environmental samples collected at two different plants which were freezing and handling frozen vegetables in France and Hungary during the 2017 and the 2018 production seasons, respectively. The WGS analysis provides a strong microbiological link between the human and the non-human isolates and this is indicative of a common source related to frozen corn and other frozen vegetable mixes, including corn, persisting in the food chain. Traceability information for the contaminated products pointed to the source of contamination in a freezing plant in Hungary (company A). As *L. monocytogenes* IVb ST6 matching the outbreak strain has been isolated from frozen spinach and frozen green beans sampled at the Hungarian plant, it is possible that frozen vegetables other than corn which have been processed in this plant, could also be implicated as a vehicle of human infection. The finding of *L. monocytogenes* IVb, ST6 matching the outbreak strain in frozen corn and other frozen vegetables produced during the 2016, 2017 and 2018 production seasons at the plant of Hungarian company A suggests that this strain could be persisting in the environment of the processing plant after standard cleaning and disinfection procedures carried out during periods of no production activity and the rotation of the processed products. Moreover, the use of the contaminated production lines for several food products may represent an additional risk for potential cross-contamination of the various final products processed at the plant. The information available confirms contamination within the Hungarian processing plant, but does not yet enable identification of the exact point(s) and/or stage in production at which *L. monocytogenes* contamination has occurred. Further investigations, including thorough sampling and testing, are needed to identify the source of contamination at the Hungarian processing plant concerned. Consumption of frozen or non-frozen corn has been confirmed by eleven out of 26 patients interviewed from Denmark, Finland, Sweden and the United Kingdom. Of the other 15 cases, six consumed or possibly consumed frozen mixed vegetables, six did not know whether they had consumed corn or mixed vegetables and three cases reported not having consumed corn or mixed vegetables. Food business operators in Estonia, Finland, Poland and Sweden have withdrawn and recalled the implicated frozen corn products from the market. Since March 2018, the implicated Hungarian plant has been under increased official control and no frozen vegetable products from the 2018 production season have been distributed to the market yet. Following the positive findings from

food and environmental samples collected during the 2018 production, freezing activities at the affected Hungarian plant have been halted since June 2018. On 29 June 2018, the Hungarian Food Chain Safety Office banned the marketing of all frozen vegetable and frozen mixed vegetable products produced by the plant between August 2016 and June 2018, and ordered their immediate withdrawal and recall. This restrictive measure is likely to significantly reduce the risk of human infections and contain the outbreak. As the outbreak is still continuing or at least has been ongoing until very recently, there are indications that contaminated products may still be on the market or that contaminated products purchased before the recalls are still being consumed. Any potentially contaminated frozen vegetables (e.g. frozen corn, frozen vegetable mixes including corn, frozen spinach and frozen green beans) from the 2017 and 2016 production seasons could still represent a possible risk to consumers until completely withdrawn and recalled. This risk may exist even at a low level of contamination if the products are not properly cooked before consumption. In addition, new invasive listeriosis cases may be identified due to the long incubation period (1–70 days), the long shelf-lives of frozen corn products, and potential consumption of frozen vegetable products bought by consumers before the recalls and eaten without being properly cooked.

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**Key words:** *Listeria monocytogenes*, frozen corn, frozen vegetables, multi-country outbreak, multi-locus sequence type (MLST), Whole Genome Sequencing (WGS)

**Requestor:** European Commission

**Question number:** EFSA-Q-2018-00313

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**Amendment:** An editorial correction was carried out that does not materially affect the contents or outcome of this scientific output. On pages 1 and 18, the sentence (same sentence repeated on both pages): 'Of the other 15 cases, six consumed or possibly consumed frozen mixed vegetables, six did not know whether they had consumed corn or mixed vegetables and three cases reported not having consumed corn or mixed vegetables.' was replaced by the sentence: 'Of the 15 cases that did not report corn consumption, two replied that they had consumed non-frozen mixed vegetables, three cases reported no consumption of corn or mixed vegetables, six cases did not know if they consumed corn or mixed vegetables, four cases had possibly not consumed corn and one of these four had possibly consumed frozen mixed vegetables.'. On page 17, the sentence: 'Two cases from United Kingdom consumed the same brand of frozen corn from the same UK supermarket known to be supplied by Hungary' was replaced by the sentence: 'Two cases from United Kingdom consumed frozen corn from UK supermarket(s) known to be supplied by Hungary'. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

**Suggested citation:** EFSA (European Food Safety Authority) and ECDC (European Centre for Disease Prevention and Control), 2018. Multi-country outbreak of *Listeria monocytogenes* serogroup IVb, multi-locus sequence type 6, infections linked to frozen corn and possibly to other frozen vegetables – first update. EFSA supporting publication 2018:EN-1448. 19 pp. doi:10.2903/sp.efsa.2018.EN-1448

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## Multi-country outbreak of *Listeria monocytogenes* serogroup IVb, multi-locus sequence type 6, infections linked to frozen corn and possibly to other frozen vegetables – first update

3 July 2018

### Conclusions

An outbreak of invasive *Listeria monocytogenes* (*L. monocytogenes*) infections confirmed by whole-genome sequencing (WGS) and linked to frozen corn and possibly to other frozen vegetables has been ongoing in five EU Member States (Austria, Denmark, Finland, Sweden and the United Kingdom) since 2015. As of 15 June 2018, 47 cases have been reported and nine patients have died due to or with the infection (case fatality rate 19%).

WGS analysis of 29 non-human *L. monocytogenes* isolates found them to be closely related to the multi-country human cluster of *L. monocytogenes* serogroup IVb, multi-locus sequence type 6 (ST6). The majority of the non-human isolates were obtained from 2017 season products: mainly frozen corn (13 samples), followed by frozen vegetable mixes including corn (8 samples), frozen spinach (1) and frozen green beans (1). Only one isolate was reported from a frozen vegetable mix produced in 2016, while three isolates were obtained from spinach products produced in 2018. In addition, two isolates were also obtained from two environmental samples collected at two different plants which were freezing and handling frozen vegetables in France and Hungary during the 2017 and the 2018 production seasons, respectively.

The WGS analysis provides a strong microbiological link between the human and the non-human isolates and this is indicative of a common source related to frozen corn and other frozen vegetable mixes, including corn, persisting in the food chain. Traceability information for the contaminated products pointed to the source of contamination in a freezing plant in Hungary (company A). As *L. monocytogenes* IVb ST6 matching the outbreak strain has been isolated from frozen spinach and frozen green beans sampled at the Hungarian plant, it is possible that frozen vegetables other than corn which have been processed in this plant, could also be implicated as a vehicle of human infection.

The finding of *L. monocytogenes* IVb, ST6 matching the outbreak strain in frozen corn and other frozen vegetables produced during the 2016, 2017 and 2018 production seasons at the plant of Hungarian company A suggests that this strain could be persisting in the environment of the processing plant after standard cleaning and disinfection procedures carried out during periods of no production activity and the rotation of the processed products. Moreover, the use of the contaminated production lines for several food products may represent an additional risk for potential cross-contamination of the various final products processed at the plant. The information available

#### Errata

On 9 July 2018, the following corrections were made: p. 1 (last paragraph, last sentence), p. 18 (paragraph 5, third sentence) now read: 'Of the 15 cases that did not report corn consumption, two replied that they had consumed non-frozen mixed vegetables, three cases reported no consumption of corn or mixed vegetables, six cases did not know if they consumed corn or mixed vegetables, four cases had possibly not consumed corn and one of these four had possibly consumed frozen mixed vegetables'; p. 17 (paragraph 7, third sentence, now reads: 'Two cases from the United Kingdom consumed frozen corn from the UK supermarket(s) known to be supplied by Hungary'.

confirms contamination within the Hungarian processing plant, but does not yet enable identification of the exact point(s) and/or stage in production at which *L. monocytogenes* contamination has occurred. Further investigations, including thorough sampling and testing, are needed to identify the source of contamination at the Hungarian processing plant concerned. Consumption of frozen or non-frozen corn has been confirmed by eleven out of 26 patients interviewed from Denmark, Finland, Sweden and the United Kingdom. Of the 15 cases that did not report corn consumption, two replied that they had consumed non-frozen mixed vegetables, three cases reported no consumption of corn or mixed vegetables, six cases did not know if they consumed corn or mixed vegetables, four cases had possibly not consumed corn and one of these four had possibly consumed frozen mixed vegetables.

Food business operators in Estonia, Finland, Poland and Sweden have withdrawn and recalled the implicated frozen corn products from the market. Since March 2018, the implicated Hungarian plant has been under increased official control and no frozen vegetable products from the 2018 production season have been distributed to the market yet. Following the positive findings from food and environmental samples collected during the 2018 production, freezing activities at the affected Hungarian plant have been halted since June 2018. On 29 June 2018, the Hungarian Food Chain Safety Office banned the marketing of all frozen vegetable and frozen mixed vegetable products produced by the plant between August 2016 and June 2018, and ordered their immediate withdrawal and recall. This restrictive measure is likely to significantly reduce the risk of human infections and contain the outbreak.

As the outbreak is still continuing or at least has been ongoing until very recently, there are indications that contaminated products may still be on the market or that contaminated products purchased before the recalls are still being consumed. Any potentially contaminated frozen vegetables (e.g. frozen corn, frozen vegetable mixes including corn, frozen spinach and frozen green beans) from the 2017 and 2016 production seasons could still represent a possible risk to consumers until completely withdrawn and recalled. This risk may exist even at a low level of contamination if the products are not properly cooked before consumption. In addition, new invasive listeriosis cases may be identified due to the long incubation period (1–70 days), the long shelf-lives of frozen corn products, and potential consumption of frozen vegetable products bought by consumers before the recalls and eaten without being properly cooked.

## Options for response

In order to identify the exact point(s) and/or stage of production where the contamination with *L. monocytogenes* has occurred at the plant of Hungarian company A, it is strongly recommended that thorough sampling and testing are carried out at the critical sampling sites along the production lines. This should follow EFSA's recommendations for sampling and testing at frozen vegetable processing plants to detect *L. monocytogenes* [1a]. EFSA's guidelines, intended for both competent authorities and food business operators and requested by the European Commission, focus on sampling to identify the point of microbiological contamination at plants processing frozen vegetables, fruit and herbs, in particular during outbreak investigation.

It is strongly recommended that the processing plant concerned is completely cleaned and disinfected, which involves dismantling and thoroughly cleaning and disinfecting all the plant equipment, as well as any additional surfaces that may represent a point of *L. monocytogenes* contamination (e.g. refrigerator system).

In order to avoid *L. monocytogenes* being introduced into a plant through workers (e.g. uniforms, shoes, personnel) it is important that appropriate hygiene measures are adopted by food business operators.

The recommendations above also apply to other companies belonging to the same commercial group as the Hungarian company A if environmental contamination with *L. monocytogenes* is detected in their plants.

In order to reduce the risk of *L. monocytogenes* infection due to the consumption of contaminated non ready-to-eat frozen vegetables, consumers should thoroughly cook these products before consumption, as it is not unusual for them to be consumed without being cooked (e.g. in salads, smoothies). The affected countries are advised to consider targeted communication options (e.g. campaigns to inform consumers to properly cook frozen vegetables originating from potentially contaminated batches at the affected plants).

Competent authorities should report new human cases associated with this event and the findings of public health investigations to the Epidemic Intelligence Information System for Food- and Waterborne Diseases and Zoonoses (EPIS-FWD) and consider interviewing new and recent listeriosis cases about consumption of (frozen) corn, vegetable mixes, spinach, green beans and other (frozen) vegetables.

ECDC is supporting WGS analysis of human isolates from cases possibly related to this outbreak and reported in countries that do not routinely perform WGS. The European Reference Laboratory for *L. monocytogenes* (EURL for *Lm*) is providing support to those Member States who have no WGS capacity by performing WGS analysis of non-human isolates for strains possibly related to the outbreak.

ECDC and EFSA encourage the competent authorities of public health and food safety sectors in the affected EU countries and at European level to continue sharing information on epidemiological, microbiological and environmental investigations, including tracing information, and by issuing relevant notifications using the Early Warning and Response System (EWRS) and the Rapid Alert System for Food and Feed (RASFF).

EWRS is a rapid alert system for notifying alerts at EU level in relation to serious cross-border threats to health of biological, chemical, environmental or unknown origin. The EWRS enables the Commission and the competent authorities of the Member States to be in permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health. National competent authorities should notify an alert in EWRS where the development or emergence of a serious cross-border threat to health fulfils the criteria listed in Article 9 of Decision 1082/2013/EU on serious cross-border threats to health.

RASFF is the official EU system for sharing information on hazards found in food and feed, the trade of potentially contaminated batches between Member States and the tracing of such batches. RASFF notifications should be completed with information on exposure to food for related human cases, traceability information on the suspected food vehicles and analytical results to support traceability investigations.

## Source and date of request

On 11 April 2018, the European Commission sent a request to ECDC and EFSA to update the Rapid Outbreak Assessment published on 22 March 2018, and this request was accepted by EFSA and ECDC on 12 April 2018 [1].

## Public health issue

This document provides an updated assessment of the cross-border public health risk associated with consumption of frozen corn and possibly linked to other frozen vegetables contaminated with *L. monocytogenes*. ECDC published a rapid risk assessment concerning this event on 6 December 2017 [2] and a joint ECDC-EFSA Rapid Outbreak Assessment was published on 22 March 2018 [1b].

## Consulted experts

- ECDC experts (in alphabetical order): Margot Einöder-Moreno, Saara Kotila, Taina Niskanen, Ettore Severi, Johanna Takkinen, Therese Westrell.
- EFSA experts (in alphabetical order): Giusi Amore, Raquel Garcia Fierro, Ernesto Liebana Criado, Valentina Rizzi.
- European Reference Laboratory for *Listeria monocytogenes* (EURL for *Lm*): Benjamin Felix, Jean Charles Leblanc, Bertrand Lombard, Jean-François Mariet, Maroua Sayeb.
- External experts representing national authorities (in alphabetical order of countries):
  - Austria: Franz Allerberger, Steliana Huhulescu, Elisabeth Kanitz, Ariane Pietzka (Austrian Agency for Health and Food Safety - AGES);
  - Belgium: Marie Bienfait (Agence fédérale de la Sécurité de la Chaîne alimentaire);
  - Denmark: Sofie Gillesberg Raiser, Susanne Schjørring (Statens Serum Institut);
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  - United Kingdom: Lisa Byrne, Kathie Grant, Gauri Godbole, Sanch Kanagarajah (Public Health England – PHE), Alison Smith-Palmer (Health Protection Scotland – HPS).

## Disclaimer

ECDC issued this outbreak assessment document in accordance with Article 10 of Decision No 1082/13/EC and Article 7(1) of Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control (ECDC), and with the contribution of EFSA in accordance with Article 31 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety.

In the framework of ECDC's mandate, the specific purpose of an ECDC-EFSA outbreak assessment is to present different options on a certain matter, with their respective advantages and disadvantages. Responsibility regarding the choice of option and actions to take, including the adoption of mandatory rules or guidelines, lies exclusively with EU/EEA Member States. In its activities, ECDC strives to ensure its independence, high scientific quality, transparency and efficiency.

This report was written under the coordination of an internal response team at ECDC, with contributions from EFSA, at the behest of the European Commission based on a mandate requesting scientific assistance from EFSA in the investigation of multinational food-borne outbreaks (Ares (2013) 2576387, Mandate M-2013-0119, 7 July 2013).

All data published in this rapid outbreak assessment are correct to the best of our knowledge on 3 July 2018. Maps and figures published do not represent a statement on the part of ECDC, EFSA or its partners on the legal or border status of the countries and territories shown.

## Disease background information

### *Listeria monocytogenes* isolation in humans

Background information on listeriosis can be found in ECDC, US CDC and WHO disease fact sheets [3-5]. *L. monocytogenes* ST6 is a hypervirulent clone of *L. monocytogenes* associated with neurological forms of listeriosis [6,7]. Pregnant women, the elderly, and immunocompromised individuals are at increased risk of invasive listeriosis, which is associated with severe clinical course and potentially death.

In the years 2012–2016, between 1 754 and 2 555 *L. monocytogenes* cases were reported annually to The European Surveillance System (TESSy) by 30 EU/EEA countries [8]. PCR serogroup IVb [9] is the most commonly reported PCR serogroup (44% of cases with available information on PCR serogroup), with between 332 and 403 notifications annually from 13 EU/EEA countries. France, Germany and the United Kingdom, accounted for 45%, 23% and 17% respectively of the reported serogroup IVb cases in this period. Cases of PCR serogroup IVb were more common in males (52%) and among persons over 65 years (61% of cases) in both genders. The majority (99%) of the serogroup IVb cases were of domestic origin [10].

Of 2 969 *L. monocytogenes* isolates with 'Accepted' sequencing quality reported to TESSy isolate-based surveillance, 308 (10.4%) are ST6, spanning 2009–2017. Serotype is available for 263 of these isolates, with 247 (93.9%) serotype 4b, which belongs to serogroup IVb. Pulsed Field Gel Electrophoresis (PFGE) of 'Accepted' quality is available for 65 of these ST6 isolates based on multi-locus sequence type (MLST), including 26 unique PFGE profiles. Two isolates have indistinguishable combined PFGE profiles AscI.0003-ApaI.0070, with profiles of the *L. monocytogenes* serogroup IVb, ST6 Finnish representative outbreak strain (one isolate matching with 10 allelic differences (in cgMLST Moura scheme [11]) and the other one with 20 allelic differences).

### Growth of *Listeria monocytogenes* in frozen vegetables

A recent study has investigated the growth characteristics of *L. monocytogenes* inoculated onto frozen foods (including blanched, individually quick-frozen corn and individually quick-frozen green peas) and thawed by being stored at 4, 8, 12, and 20 °C [12]. The results of this study showed that thawed frozen corn and green peas supported the growth of *L. monocytogenes* at each of the storage temperatures, with the growth rate increasing with the temperature. This research demonstrated using real food samples that *L. monocytogenes* can initiate growth without a prolonged lag phase after being frozen, even at refrigeration temperature (4 °C).

The growth of *L. monocytogenes* in fresh corn and green peas was also observed in an older study [13].

## Event background information

On 3 November 2017, Finland launched an urgent inquiry in EPIS FWD relating to three *L. monocytogenes* clusters, confirmed by whole genome sequencing (WGS), with cases from different parts of Finland in 2017. The largest WGS cluster was associated with *L. monocytogenes* serogroup IVb, ST6, with 14 cases detected between January 2016 and January 2018. At the time the event was reported, two patients had died due to or with the infection.

## Multi-country investigations

### EU/EEA outbreak case definition

ECDC and the members of the outbreak investigation team in the affected countries agreed on an European outbreak case definition to harmonise the investigation of outbreak cases and take into account the different molecular typing systems (cgMLST, wgMLST, SNP-based analysis) for surveillance across Member States.

### Confirmed outbreak case

A laboratory-confirmed listeriosis patient with symptom onset on or after 1 January 2015 (date of sampling or date of receipt by the reference laboratory if date of onset is not available)

AND

- Fulfilling the additional laboratory criterion: with *L. monocytogenes* having  $\leq 7$  core-genome Multi-locus Sequence Typing (cgMLST) allelic differences from the outbreak isolate FI 122265 based on cgMLST analysis (assembly uploaded to EPIS UI-444 as IVb\_MLST6\_122265\_S3\_L001\_R\_q30w20.fasta). The cgMLST scheme is either that of Moura or Ruppitsch, or a respective scheme [11,14].

OR

- Fulfilling the additional laboratory criterion: with *L. monocytogenes* within a five SNP cluster from the outbreak isolate FI 122265 based on SNP analysis (assembly uploaded to EPIS UI-444 as IVb\_MLST6\_122265\_S3\_L001\_R\_q30w20.fasta).

### Probable outbreak case

A laboratory-confirmed listeriosis patient with symptom onset on or after 1 January 2015 (date of sampling or date of receipt by the reference laboratory if date of onset is not available)

AND

- Fulfilling the additional laboratory criteria: with an isolate of *L. monocytogenes* serogroup IVb and with PFGE indistinguishable from the profile AscI.0003-ApaI.0070 (TESSy) (uploaded to EPIS as UI-444: BioNumerics.PFGE.AscI.0003-ApaI.00070.zip).

A second PFGE profile was described from non-human isolates matching the outbreak genomic profile. The analysis of the profile is on-going to determine the reference type.

### Exclusion criteria

Cases with travel history outside of the EU/EEA in the 30 days before disease onset.

## Epidemiological and microbiological investigation of human cases

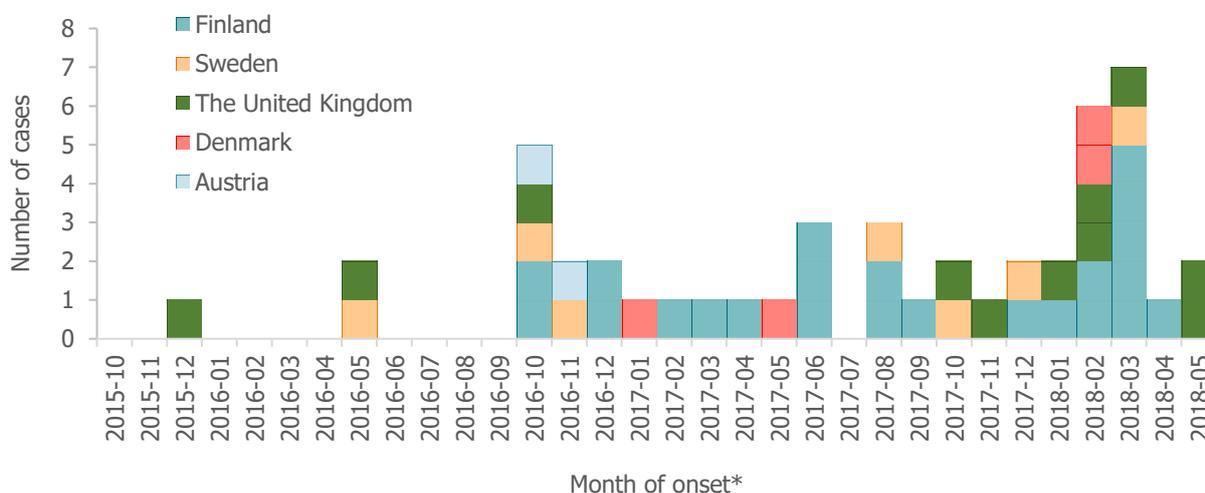
Following WGS, four Member States reported human cases with isolates closely matching the Finnish *L. monocytogenes* ST6 cluster (0 to 5 allelic differences based on cgMLST or 0 to 5 SNP difference from the representative outbreak isolate FI 122265).

Based on the European outbreak case definition, as of 15 June 2018, a multi-country foodborne outbreak has been verified in five countries, involving 47 confirmed cases and nine deaths due to or with the infection. Cases were detected in Finland (23 cases), United Kingdom (11 cases), Sweden (7 cases), Denmark (4 cases) and Austria (2 cases) (Table 1, Figure 1). The median age of cases was 72 years (interquartile range 56–85), 26 (55%) cases were females. Information on hospitalisation was available for 16 patients, who were all hospitalised.

**Table 1. *Listeria monocytogenes* IVb, ST6 confirmed outbreak cases by country and year, EU 2015–2018 (as of 15 June 2018)**

Country	Confirmed cases (No. of deaths)				Total number of cases	Total number of deaths
	2015	2016	2017	2018		
Austria	0	2 (1)	0	0	2	1
Denmark	0	0	2	2 (1)	4	1
Finland	0	4	10 (2)	9	23	2
Sweden	0	3 (1)	3 (1)	1 (1)	7	3
United Kingdom	1	2	2 (2)	6	11	2
<b>Total</b>	<b>1 (0)</b>	<b>11 (2)</b>	<b>17 (5)</b>	<b>18 (2)</b>	<b>47</b>	<b>9</b>

France, Germany, Ireland, Italy Luxembourg, the Netherlands, Norway and Portugal report no human isolates matching the European outbreak strain.

**Figure 1. *Listeria monocytogenes* PCR serogroup IVb, ST6 confirmed outbreak cases by month of symptom onset\*, European Union 2015–2018 (n=47)**

\* If month of onset missing: month of sampling or month of receipt at reference laboratory

## Food and environmental investigations

This section summarises country-specific information on food and environmental investigations associated with this outbreak reported as of 29 June 2018 through RASFF (news 17-849 and alert 2018.0216), EPIS FWD (UI- 444) and directly to EFSA by national competent authorities or provided by EURL for *Lm* since 22 March 2018 (publication date of the first Rapid Outbreak Assessment) [1]. A short summary of the information included in the published Rapid Outbreak Assessment is provided at the beginning of each country section.

Food and environmental investigations are ongoing in the Member States concerned. A teleconference with food crisis coordinators was organised by the Commission on 20 April 2018 to discuss the increase of cases, risk management action and the investigation required. The Commission is closely following this event with Member States' competent authorities through RASFF to ensure that the appropriate risk management action is taken and that the relevant countries are promptly informed about distribution in their countries.

### Finland

Overall, **seven food isolates matching the multi-country outbreak strain** (0-5 allelic differences) from the following batches of frozen corn (2017 production season) have been reported in Finland (RASFF alert 2018.0216, follow-up 35, issued on 12 April 2018; information provided by EURL for *Lm* on 19 June 2018):

- Batches A, B, D and E of frozen corn originating from Hungary
- Batch J (two isolates obtained from this batch) and K of frozen corn originating from Belgium.

## Summary from the previous Rapid Outbreak Assessment, published on 22 March 2018

As of 21 March 2018, Finland reported the presence of *L. monocytogenes* in two batches of frozen corn (batches A and B of the brand A) and in two additional batches of frozen corn (batch D and batch E) sampled at the premises of the Finnish trader/broker A. For the latter two batches, WGS analysis confirmed a match with the Finnish outbreak strain.

All these batches were delivered by the Polish company C who packed the product originating from Hungary. Batches A and B were then dispatched to the Finnish wholesaler A, who distributed the product on the Finnish market, as well as to a retailer B in Estonia.

The consumption of corn from brand A was confirmed for one Finnish patient but no information was provided on the batch number of the product consumed.

### New information

The two *L. monocytogenes* isolates detected from batches A and B of frozen corn were closely related by WGS to the Finnish human outbreak strain (0-1 allelic differences using cgMLST).

The EURL for *Lm* has performed WGS analyses on 15 additional *L. monocytogenes* isolates obtained in Finland from official food samples collected at border control points (upon entry to Finland). Eight of these 15 isolates were from frozen corn (two batches originating from Hungary, one batch from the Netherlands and five batches from Belgium), three isolates were from frozen peas-corn-bell pepper mix (originating from Hungary), two isolates from frozen vegetables (originating from Belgium) and two isolates from frozen bell peppers (originating from Hungary). Of these isolates, three obtained from two batches of frozen corn (batches J and K originating from Belgium) matched the outbreak strain (4-5 allele differences). According to information provided to EFSA by the Finnish Competent Authority on 27 June 2018, the contaminated batches J and K were produced at the Belgian company E. No further details are currently available on the origin of the frozen corn used to produce batch J and K.

## Sweden

Overall, **two food isolates matching the multi-country outbreak strain** (4-5 allelic differences) from the following batches of frozen corn (2017 production season) originating from Hungary have been reported in Sweden:

- Batches A and G of frozen corn.

## Summary from the previous Rapid Outbreak Assessment, published on 22 March 2018

As of 21 March 2018, Sweden reported the presence of *L. monocytogenes* in the batch A of frozen corn taken from an opened package stored in a consumer's fridge. WGS analysis confirmed a match of this isolate with the Finnish outbreak strain (4 allelic differences). The product was bought at the Swedish retailer A and was delivered by the Polish company C who packed the product originating from Hungary.

The consumption of corn was confirmed for the most recent Swedish patient but no information was provided on the brand or batch number of the product consumed.

### New information

*L. monocytogenes* was isolated in frozen corn (batch G) sampled during own checks carried out by the Swedish retailer A (RASFF alert 2018.0216 follow-up 33, issued on 12 April 2018). WGS analysis confirmed that this isolate found in frozen corn was clustered (5 allelic differences) to the *L. monocytogenes* ST6 representative outbreak strain (RASFF alert 2018.0216, follow-up 42, issued on 23 April 2018).

Batch G of frozen corn was delivered to the Swedish retailer A on 13 March 2018 by the Polish company C that packed the product originating from the Hungarian company A (RASFF alert 2018.0216, follow-up 41, issued on 23 April 2018).

Batch G of frozen corn has been withdrawn and recalled from the Swedish retailers. Another product containing corn, peas and red peppers was also withdrawn and recalled as a precautionary measure. The latter product was also packed at the Polish company C and processed at the Hungarian company A.

## Estonia

### Summary from the previous Rapid Outbreak Assessment, published on 22 March 2018

After the communication from the Finnish wholesaler A concerning the presence of *L. monocytogenes* in frozen corn from batches A and B, the Estonian retailer B recalled all batches of frozen corn of brand A from its clients.

### New information

No update from or in relation to Estonia.

## Poland

Overall, **two food isolates matching the multi-country outbreak strain** (3 allelic differences) from the following batches of frozen corn (2017 production season) originating from Hungary have been reported in Poland:

- Batches A and C of frozen corn.

### Summary from the previous ROA, published on 22 March 2018

As of 21 March, the Polish company C reported finding *L. monocytogenes* in the batches A, B, C and D of frozen corn. In total 14 batches of frozen corn (initial product) used to produce these batches were tested and 10 of them were contaminated with *L. monocytogenes*. All environmental samples taken at the premises of the Polish company C in November and December 2017 were *L. monocytogenes* negative.

The initial products were delivered to the Polish company C by the Polish company B, which provides only storage services, and originated from the Hungarian company A. The Polish company C dispatched batches A, B and D to the Finnish trader/broker A, and batches A and C to the Swedish retailer A. An additional batch E was also produced by the Polish Company C and delivered to Finnish trader/broker A where it was found positive for *L. monocytogenes*.

### New information

WGS analysis confirmed that the two *L. monocytogenes* IVb ST6 isolates found in batches A and C of frozen corn originating from Hungary were closely clustered (3 allelic differences) to the representative outbreak strain (information provided by the EURL for *Lm*).

In addition, *L. monocytogenes* <10 cfu/g was reported in three own-check samples from batch G of frozen corn sampled at the Polish company C. Batch G originated from the Hungarian company A, was packed in the Polish company C and then distributed to Sweden. Own-check samples from the two batches of frozen corn (initial materials) (batches X30 and X31) used for the production of batch G were also tested for enumeration and *L. monocytogenes* <10 cfu/g and 10 cfu/g was reported (RASFF news 17-849, follow-up 39, issued on 27 April 2018).

Between 24 April and 8 May 2018, one hundred official environmental samples collected at the plant of Polish company C were tested and two of them, taken from a mixer and a sealing silicone in the packaging hall, were found positive for *L. monocytogenes*. Following these analytical results, the Chief Sanitary Inspector requested the Polish plant to stop operating and conduct thorough cleaning and disinfection to eliminate *L. monocytogenes* from its environment (RASFF alert 2018.2016, fup-48; issued on 11 May 2018). According to serotyping performed by the Polish National Reference Laboratory, the two environmental isolates were type IIa and therefore not related to this outbreak. After thorough cleaning and disinfection at Polish Company C's plant, another 100 official swab environmental samples were collected and all were negative for *L. monocytogenes* (RASFF alert 2018.2016, fup-50, issued on 5 June 2018).

Between 19 and 29 May 2018, 45 samples taken from eight batches of frozen products (including vegetables and fruit) sampled at the plant of Polish company C were tested and *L. monocytogenes* was detected in five samples from frozen vegetables for frying and three samples from frozen corn. Serotyping is ongoing. The remaining samples collected from fruit (raspberry, forest fruit mix, forest fruit mix (pre-mixture), blackcurrant class A, raspberry >80% and strawberry) were negative for *L. monocytogenes* (RASFF alert 2018.2016, fup-50, issued on 5 June 2018).

## Hungary

Overall, **11 non-human isolates matched the multi-country outbreak strain** (3-6 allelic differences) from the following batches of frozen products and the environment at Hungarian company A:

- five isolates from batches H, I, L, M and N of frozen vegetable mixes (containing frozen corn and peas from Hungary and baby carrots from Belgium) sampled on 5 March 2018 (2017 production season)
- One isolate from batch T of frozen spinach sampled on 27 April 2018 (2017 production season)
- One isolate from batch U of frozen green beans sampled on 27 April 2018 (2017 production season)
- Two isolates from batch V of creamy spinach puree sampled before and after freezing on 17 May 2018 (2018 production season)
- One isolate from batch Y of frozen creamy spinach puree sampled on 17 May 2018 (2018 production season)
- One isolate from an environmental sample (floor drain at the packaging area) collected on 17 May 2018.

### Summary from the previous Rapid Outbreak Assessment, published on 22 March 2018

As of 21 March 2018, the Hungarian company A reported having tested several batches of frozen raw materials that were processed at the plant. Based on the enumeration method, all batches had results for *L. monocytogenes* < 10 cfu/g, with the exception of one batch (batch X28) where *L. monocytogenes* serogroup IIa (not related to the present outbreak) was found at levels of  $1.4 \times 10^3$  cfu/g. In total, 11 batches of frozen corn (initial product) (X1, X2, X12, X15, X16, X21, X23, X25, X26, X27 and X28) used in Poland for the production of batches A, B, C, D and E were produced in 2017 in the same growing area A of 31 hectares by the Hungarian supplier A and processed at Hungarian company A.

### New information

The main company supplying vegetables to the Hungarian company A was the Hungarian supplier A, which ceased operations at the end of 2017. At that time, company A had already concluded contracts for cultivation and supply of corn (supersweet, normal sweet) and beans with another Hungarian company (supplier B) of the same group as supplier A (RASFF ref 2018.0216, follow-up 40, issues on 23 April 2018).

The Hungarian company A is a freezing company that produces individually quick-frozen (IQF) vegetables such as peas, yellow- and green beans, spotted beans, corn (sweet, supersweet), root vegetables and leafy vegetables (spinach, sorrel, parsley leaf). Company A's plant freezes only vegetables. The production at Hungarian company A's plant is linked to the agricultural season. This company deals mainly with the production of quick-frozen vegetables during the respective seasons, and with the packaging of quick-frozen vegetables and fruits outside of the seasons. At this processing plant there are three production lines: production of IQF peas, corn, beans and root vegetables; production of peas and corn with Frigoscandia freezer and production of frozen leafy vegetables with contact freezer. The same production lines are used for several vegetables; cleaning and disinfection are carried out during the conversion of the production lines (RASFF alert 2018.0216, fup-49). No fruit is frozen and no prepared meals are processed in the factory. In addition to freezing, handling activities (e.g. storing and packing) are also undertaken at this plant. Packaging of frozen fruit (frozen by other companies) and vegetable mixes is carried out in a separate area of the plant. Some of the frozen vegetables included in the vegetable mixes are frozen by other companies (e.g. baby carrots from the Belgian company E) (RASFF alert 2018.0216, fup-57).

#### Information related to production season 2016

During August–September 2016, Hungarian company A's plant produced the batch F of frozen corn using four batches of frozen corn (initial products). This batch was delivered on 5 January 2017 to the French company G, which distributed it to French company F (RASFF news 17-849, fup-42 and fup-46; issued on 14 and 24 May 2018). The testing results of batch F are described in the country section 'France'.

#### Information related to production season 2017

On 5 March 2018, official samples were taken from several frozen products (from 2017 production season) at the plant of the Hungarian company A and *L. monocytogenes* IVb ST6 matching the outbreak strain (3-4 allelic differences) was detected in five batches of 'frozen classical vegetable mix' (RASFF news 17-849, follow-up 29, issued on 13 April 2018; WGS results provided by EURL for *Lm* on 19 June 2018):

- Batches H, I and L: contaminated with *L. monocytogenes* at level of 60 cfu/g.
- Batch M: contaminated with *L. monocytogenes* at level of 50 cfu/g.
- Batch N: contaminated with *L. monocytogenes* at level of 30 cfu/g.

These five batches (H, I, L, M, N) and two additional batches of "frozen classical vegetable mixes" (batches O and P) processed at the plant of Hungarian company A, were distributed to the Austrian retail chain C. The seven batches of 'frozen classical vegetable mixes' comprised three ingredients: peas (6-9 mm), baby carrots and corn. The peas and corn originated from Hungary, while the baby carrots were supplied by the Belgian company E to the Hungarian processing company A. (RASFF news 17-849; follow-up 46, issued on 24 May 2018).

There was a six-month seasonal period during which freezing activity was interrupted at the plant of Hungarian company A between November 2017 and May 2018.

In order to verify if *L. monocytogenes* IVb was still present after the period of seasonal inactivity and following cleaning and disinfection at the plant, the Hungarian competent authorities carried out two official samplings at Hungarian company A's plant on 27 April and 17 May 2018. In particular, on 27 April (during the non-production period) several frozen vegetables from the 2017 production season were sampled from the cold store (room temperature -18 °C) of the plant, and *L. monocytogenes* was found in spinach, green beans, cubed carrots, corn, peas and zucchini.

Two isolates of *L. monocytogenes* IVb ST6 matching the outbreak strain were isolated from:

- Batch T of natural frozen spinach (final product from consumer packaging). This final product had undergone the following processing stages before sampling: blanching, cutting and freezing (by plate freezing).
- Batch U of quick frozen green beans (semi-finished product for further packaging). This semi-finished product had undergone the following processing before sampling: blanching and IQF.

The isolates from the other positive samples were *L. monocytogenes* type IIa and therefore not related to the outbreak strain.

### **Information related to production season 2018**

The first vegetable processed at company A's plant in 2018 was spinach, followed by IQF green peas, while corn was planned to be processed from the end of summer onwards.

On 17 May 2018, several environmental and food samples were collected at the plant of Hungarian company A during different phases of the spinach production (2018 production season). Overall, the following environmental, water and food samples were taken:

- Four environmental samples were tested: three swab samples from bands (sorter band, blanching band and band leading to grinding machine) and one swab sample from floor drain at the packaging area, the latter being the only contaminated with *L. monocytogenes* IVb ST6 matching the outbreak strain with WGS. This positive environmental sample was taken from the floor drain near the filling machine, at the point where the creamy spinach puree was filled into consumer packaging, during the production.
- Two samples of water (pre-cooled water and incoming ice water) were also tested and found negative.
- In addition, five spinach samples from the same batch (batch V) were collected before and during the different processing stages, from fresh leafy spinach (initial product) to creamy spinach puree (final product): 1) fresh leafy spinach at reception (before processing); 2) spinach after washing; 3) spinach at grinder (after blanching and cooling); 4) creamy spinach puree after closing the package (after grinding and creaming, before freezing); 5) frozen creamy spinach puree (the creamy spinach puree is frozen after packaging, using contact freezer). *L. monocytogenes* serogroup IVb was detected only in the last three samples. WGS was performed only for two of the three isolates obtained in the positive samples from the batch V, both isolates matched the outbreak strain (Table 2). It is important to note that the grinding stage (where the first positive sample was taken) occurs after blanching (at 96°C for 110 seconds) and cooling (max 7 °C) of the spinach.
- Furthermore, another two different batches of creamy spinach puree (batches W and Y) were sampled and found positive for *L. monocytogenes*, and the isolate from batch Y matched the outbreak strain. Creamy spinach puree is not a ready-to-eat product. The following cooking instructions are supplied on the packaging: boil for one minute in a cooking pot or cook for 14 minutes in microwave oven at 600W.

WGS was performed for four non-human isolates (isolated from samples 04, 09, 10 and 12, see Table 2) and confirmed the match with the outbreak strain (3–6 allelic differences). Details on the type of products, the sampling location and the corresponding processing stages, as well as the testing results, are presented in Table 2.

**Table 2. *L. monocytogenes* testing results of non-human official samples collected during the different phases of the 2018 spinach production at Hungarian company A's plant (sampling date 17 May 2018)**

Sample ID	Sample type	Sampling location and/or processing stage	Batch code	Test results		
				Detection	Enumeration (cfu/g)	WGS*
<b>Environmental samples</b>						
01	swab	Sorter band during operation	NA	Negative	-	
02	swab	Blanching band during operation	NA	Negative	-	
03	swab	Band leading to grinding machine during operation	NA	Negative	-	
<b>04</b>	<b>Swab of floor drain</b>	<b>Packaging area during operation</b>	<b>NA</b>	<b>Positive</b>	-	<b>match</b>
05a	Pre-cooled water		NA	Negative	-	
05b	Incoming ice water		NA	Negative	-	
<b>Food samples</b>						
06	Fresh leafy spinach		V	Negative	-	
07	Sample of spinach	After washing	V	Negative	-	
<b>08</b>	<b>Sample of spinach</b>	<b>Grinder</b>	<b>V</b>	<b>Positive</b>	<b>&lt;10 cfu/g</b>	NA**
<b>09</b>	<b>Not frozen creamy spinach puree</b>	<b>After closing of the package</b>	<b>V</b>	<b>Positive</b>	<b>&lt;10 cfu/g</b>	<b>match</b>
<b>10</b>	<b>Frozen creamy spinach puree</b>	<b>After freezing</b>	<b>V</b>	<b>Positive</b>	<b>10 cfu/g</b>	<b>match</b>
<b>11</b>	<b>Frozen creamy spinach puree</b>	<b>Final product</b>	<b>W</b>	<b>Positive</b>	<b>Up to 30 cfu/g</b>	NA**
<b>12</b>	<b>Frozen creamy spinach puree</b>	<b>Final product</b>	<b>Y</b>	<b>Positive</b>	<b>&lt;10 cfu/g</b>	<b>match</b>

\* WGS match with the multi-country outbreak strain (cgMLST <7 allelic differences).

\*\* Please note that WGS was not performed for one of the three isolates obtained from the positive samples of batch V, or from the contaminated batch W. Thus, the WGS results for two positive samples (IDs 08 and 11) are not available (NA).

### Distribution and control measures

The frozen corn and frozen vegetable mixes produced at the plant of Hungarian company A have been distributed to other plants belonging to the same Company group A in other EU Member States (Belgium, United Kingdom, Germany, France and Poland). For further information on the branches of company group A in the different countries, see the section for Belgium). The final products have been also distributed to the following Member States: Romania, Italy, Slovenia, Slovakia, Germany, Finland, Czech Republic, Croatia and Austria. Frozen vegetable mixes were delivered only to the Austrian retailer C (RASFF 17-849, fup 42). No detailed documentation has been provided on the distributed products.

The following measures have been implemented by Hungary (RASFF news 2018.0216, follow-up 30, issued on 28 March 2018; RASFF ref 2018.0216, follow-up 36, issued on 12 April 2018; RASFF 17-849, follow-up 42, issued on 14 May 2018; most recent information provided to EFSA by email on 29 June 2018):

- At production level (Hungarian company A) (taken and ongoing):
  - complete revision of the HACCP system at the plant;
  - continuous cleaning and disinfection of the equipment;
  - product labelled with clear instructions on the need to heat treat;
  - review of the water supply system;
  - revision of the microbiological control plan (increase in the numbers of samples and sampling points);
  - new cleaning and disinfection plan developed;
  - measures taken to correct and eliminate the risk of contamination: built a 'double firewall' security measure for all products, implying that both semi-finished and end-user products can be released for marketing, used or delivered only after accredited laboratory test results;
  - the Hungarian plant is under increased official control since March 2018 and in accordance with the measures (ordered by the competent authority and implemented voluntarily by the food business operator), no product from the 2018 production season has been marketed yet;

- based on the laboratory results of the environmental and food samples collected at different phases of the spinach and green pea production in May 2018, the Hungarian competent authority recently decided to stop freezing activity at the affected plant.
- At distribution level:
  - On 29 June 2018, the Hungarian Food Chain Safety Office banned the marketing of all frozen vegetables and frozen mixed vegetable products produced by the Hungarian plant concerned between August 2016 and June 2018, and ordered their immediate withdrawal and recall.
- At retail level:
  - Clearly visible posters were placed next to/on the shelves of the products concerned with instructions concerning the safe use of the products.
- At consumer level (public warning):
  - Official press release
  - Communication through web and social media (Twitter, Facebook, official website, other media).

## Austria

Overall, **four food isolates matching the multi-country outbreak strain** (3-4 allelic differences) from the following batches of frozen vegetable mixes (all from 2017 production season, but one from 2016) have been reported by Austria:

- batch Q and S of 'frozen Mexican vegetable mixes'
- batches O and P of 'frozen classical vegetable mix'.

## Summary from the previous Rapid Outbreak Assessment, published on 22 March 2018

As of 21 March 2018, Austria reported two food isolates matching the multi-country cluster of *L. monocytogenes* ST6:

- One isolate was detected in 2016 from the product 'frozen classical vegetable mix' (batch O), produced and packed by company A in Hungary. Ingredients comprised: peas and corn (both originated from Hungary) and baby carrots (supplied by the Belgian company E (RASFF news 17-849; follow-ups 14, 15, 20 and 46; see also specific section for Hungary).
- The other isolate was detected in 2017 from a sample of 'frozen Mexican vegetable mix' (batch Q) brand B produced at the Belgian Company D. The frozen corn included in the vegetable mix originated from the Hungarian processing company A (RASFF news. 17-849; follow-ups 14, 15 and 20).

## New information

Two additional *L. monocytogenes* isolates matching the multi-country cluster of *L. monocytogenes* ST6 were reported in the framework of a study carried out in Austria from the following batches of frozen vegetable mixes (RASFF news 17-849, follow-ups 33):

- Batch P of 'frozen classical vegetable mix', comprising the same ingredients as batch O, originating from Hungarian company A.
- Batch S of 'frozen Mexican vegetable mix' originating from Belgian company E. *L. monocytogenes* IVb was detected at low levels (< 10 cfu/g). The ingredients used in this batch of 'frozen Mexican vegetable mixes' included: corn, red kidney beans, onion, red and yellow paprika, spices, etc. The frozen corn used in this vegetable mix originated from processing company A in Hungary, while the beans originated from Belgian company E (RASFF news 17-849; follow-up 44). The following two sets of preparation instructions are reported as appearing on the label of this 'frozen Mexican vegetable mix': Heat for 7–9 minutes in a skillet wok or 9 minutes at 600W in the microwave oven (RASFF news 17-849; follow-up 44, issued on....)

*L. monocytogenes* IVb was reported in an additional batch of 'frozen Mexican vegetable mix' (batch R) with the same ingredients, origin and label indications as batch S. However, according to the WGS results, the *L. monocytogenes* IVb isolate obtained from batch R was not genetically related to the outbreak strain.

In addition, *L. monocytogenes* serotype IIa, not related to this outbreak, was also detected in batches P and R.

## Belgium

Overall, information on **two food isolates matching the multi-country outbreak strain** (1-2 allelic differences) in frozen corn originating from the Hungarian company A (2017 production season) was provided by Belgium.

The Belgian company E is the legal owner of the companies belonging to the same group and located in different countries: Belgium (company D), Poland (company C), Hungary (company A) and France (company G). It is also the

legal owner of other companies belonging to the same group in different countries (for example, two branches in the United Kingdom). However, most of the branches in the different countries operate independently. Specifically, Belgian company D is dependent on company E, whereas the Polish and the French branches are run from their respective countries, and the Hungarian company A is operationally independent (RASFF news 17-849, fup 25).

Analyses were carried out by the Belgian company D on frozen corn (initial products). Two samples of frozen corn originating from the Hungarian company A were tested and found to be contaminated with *L. monocytogenes* IVb, ST6 and clustered closely (1-2 allelic differences) to the representative outbreak strain. In one of the two samples (taken from an already packaged product, batch Z1) the result for *L. monocytogenes* was <10 cfu/g, while the other sample (taken from a raw material that was repackaged, batch Z2) had a level of contamination of 80 cfu/g.

In parallel, the Belgian authorities took four official samples of the Hungarian corn used in batches Q, R and S of the 'frozen Mexican vegetable mixes'. These four samples were found to be contaminated with *L. monocytogenes* 1/2b at a level of <100 cfu/g (RASFF news 17-849, fup58).

At present, no action has been taken by the Belgian authorities.

## France

Overall, one environmental isolate matching the multi-country outbreak strain (4 allelic differences) has been reported by France.

### Summary from the previous Rapid Outbreak Assessment, published on 22 March 2018

As of 21 March 2018, France had reported one non-human isolate matching the multi-country cluster of *L. monocytogenes* serogroup IVb ST6 originating from an environmental sample collected at a food processing plant (company F) during own checks in August 2017 in an area where the following products could have been processed: frozen flat-leaved parsley, soft corn grains (frozen), potato cubes, green peas (frozen) (RASFF ref.17-849, follow-up 24, issued on 21 March 2018).

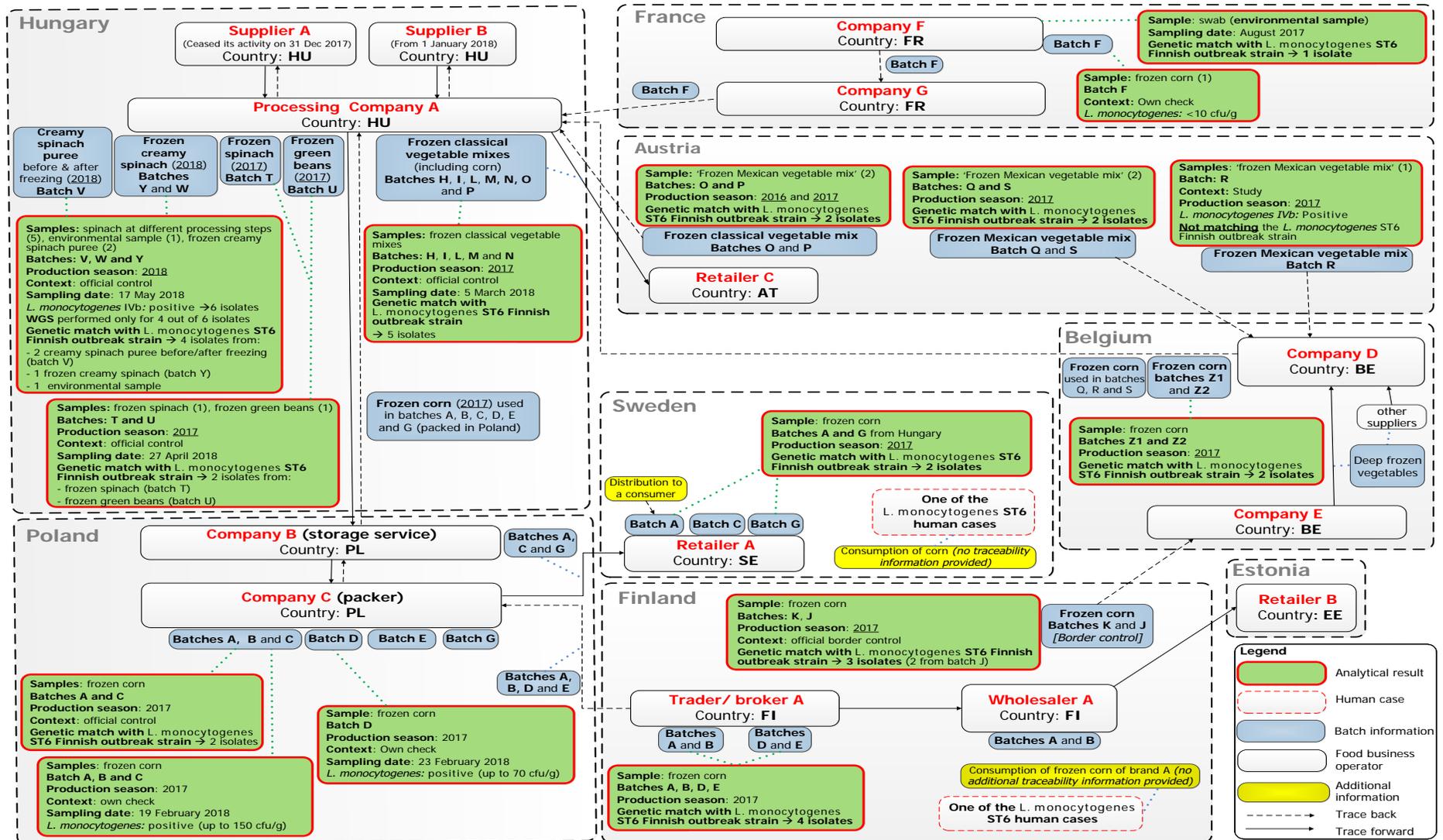
### New information

*L. monocytogenes* was also isolated from a batch of frozen corn (batch F) sampled at French company F and supplied by French company G, which received this batch from the Hungarian company A (RASFF news 17-849, follow-up 26). The isolate obtained from batch F was not kept and therefore it was not possible to compare it with the outbreak strain.

## United Kingdom

Food and environmental investigations are ongoing in the plants belonging to Company group A, which source corn from the Hungarian company A. No food or environmental isolates have yet been made available for further testing or comparison with the outbreak strain.

**Figure 3. Graphical representation of traceability and testing information available in RASFF or provided to EFSA by Member States, as of 29 June 2018**



Note: cfu/g: colony-forming unit per gram. AT: Austria, BE: Belgium, EE: Estonia, FI: Finland, FR: France; HU: Hungary, PL: Poland, SE: Sweden

## European whole genome sequencing analysis of human and non-human isolates

Raw sequence data from human *L. monocytogenes* isolates matching the European case definition were collected by ECDC. The EURL for *Lm* collected sequence data on non-human isolates from national reference centres and the NRL network of the EURL for *Lm*. WGS data analysis of human and non-human isolates was performed jointly by ECDC, the EURL for *Lm* and EFSA. The WGS results from the EURL *Lm* are presented below, and only major differences in the results obtained with other pipelines are indicated (see Table 3 footnote).

The reads were assembled with SPAdes v.3.7.1 in BioNumerics version 7.6.2 (Applied-Maths, Sint-Martens-Latem, Belgium) including post-assembly optimisation by mapping reads back onto the assembly and keeping the consensus. The cgMLST analysis was performed using assembly-based and assembly-free allele calling with the Moura scheme [11] in BioNumerics. Isolates were retained in the analysis if at least 1 661 (95%) of the 1 748 core loci were detected, no contamination with other *Listeria* species was detected and not more than one locus with more than one allele was called. Extracted fasta format allele sequences generated through mapping to reference alleles were used (replacing the assembly) to analyse data generated with IonTorrent platform not passing the QC. This was to mitigate the issues of indels that are inherent in the Ion Torrent assemblies generated from raw reads. Results from this analysis are described in Table 3 below and visualised in Figure 2.

Two strains from Sweden provided poor alignment results (i.e. Swedish non-human isolate only has 80% cg-allele coverage) and were analysed following an allele mapping extraction protocol provided by the SE NPHL. These results provided 99% cg allele coverage.

Four additional food isolates matching the outbreak strain from Finland (two isolates, 0-1 allele differences) and Belgium (two isolates, 1-2 allele differences) were not provided to EURL for *Lm* and were not included in this joint analysis (details on the origin of the isolates are described in the respective country sections on food and environmental investigations).

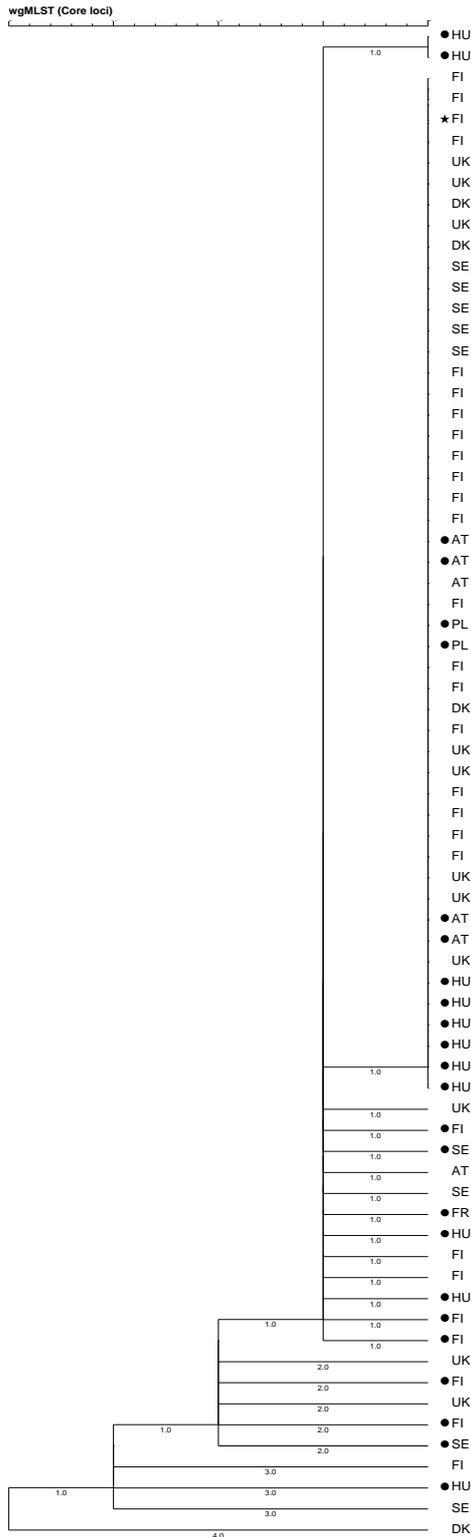
**Table 3. *Listeria monocytogenes* isolates within seven allelic differences from the *L. monocytogenes* ST6 Finnish representative outbreak strain by cgMLST, 2015–2018\***

Country	Number of human isolates (no. of differing cg alleles from the FI representative outbreak strain)	Number of non-human isolates (no. of differing cg alleles from the FI representative outbreak strain)
Austria	2 (3–4)	4 (3–4)
Denmark	4 (3–7)	–
Finland	23 (0–5)	5 (4–5)
France	–	1 (4)
Hungary	–	11 (3–6)
Poland	–	2 (3)
Sweden	7 (3–6)	2 (4–5)**
United Kingdom	11 (1–6)	–
<b>Total</b>	<b>47 (0–7)</b>	<b>25 (3–6)</b>

\* The non-human isolates were obtained from samples during the 2016, 2017 and 2018 production seasons.

\*\* One of the Swedish non-human isolates differed by nine allelic differences from the *L. monocytogenes* ST6 Finnish representative outbreak strain in the ECDC pipeline.

**Figure 2. CgMLST-based (Moura scheme) single-linkage tree including sequences from 47 human and 25 non-human *Listeria monocytogenes* isolates from six countries, 2015–2018 (software: BioNumerics version 7.6.2); data as of 20 June 2018**



*Note: The L. monocytogenes* ST6 Finnish representative outbreak strain 122265 is marked with a star and non-human isolates marked with a dot. Dates used for statistics (i.e. date of sampling or date of receipt if the former was not available) are included for human isolates. Isolates with  $\leq 7$  differing cg-alleles are considered as genetically closely related and form the basis of the confirmed case definition.

The single-linkage tree including all human (n=47) and non-human (n=25) isolates (Figure 2) shows that all of them are within six cg-allelic differences (and within 4-5 cg-allelic differences from the *L. monocytogenes* ST6 Finnish representative outbreak strain (122265)), indicating close genetic relatedness. The Finnish representative outbreak strain (122265) has 1 730 of the 1 748 core loci (98.97%), and 1583 of the 1 748 core loci (90.56%) were shared by all isolates – i.e. the unique loci were detected in each of the 72 isolates. The results of the WGS analysis were confirmed using the Ruppitsch cgMLST scheme [12] on Ridom SeqSphere+ 4.1.9 and the SPADES assembler on BioNumerics 7.6 (Applied-Maths, Sint-Martens-Latem, Belgium).

Information on the origin of the non-human isolates included in the joint WGS analysis is provided in the country specific sections on food and environmental investigations.

## Information on patient interviews

Information on patients' food exposure is captured at national level through interviews using national questionnaires. However, information on exposure to corn, the only common food item identified at the time which matched with non-human isolates, was not routinely requested in national questionnaires used in the affected countries.

Questions on consumption of corn and mixed vegetables were introduced into the national questionnaires after the identification of these as possible food vehicles. Recent and new cases were re-interviewed/interviewed with the updated questionnaires.

There were 26 patients interviewed from Denmark (2), Finland (11), Sweden (7) and the United Kingdom (6). Of the 26, 11 reported consumption of corn, nine patients reported no consumption (5)/possibly no consumption of corn (4) and six patients were unable to remember whether they had consumed corn.

Of the 11 patients reporting corn consumption, three reported consumption of frozen corn products, four reported having consumed both frozen and non-frozen corn and four only non-frozen corn. Of the four patients who had only consumed non-frozen corn, three had consumed vegetable mix and one reported only having consumed canned corn.

One of the Finnish patients confirmed having consumed frozen corn of one suspected brand, supporting an epidemiological link between the outbreak cases and frozen corn. However, no traceability and microbiological information was available for the corn consumed by the Finnish case. Two cases from the United Kingdom consumed frozen corn from the UK supermarket(s) known to be supplied by Hungary; both had frozen corn in their home freezers and the results of the microbiological tests performed are still pending.

Of the 15 cases that did not report corn consumption, two replied that they had consumed non-frozen mixed vegetables, three cases reported no consumption of corn or mixed vegetables, six cases did not know if they consumed corn or mixed vegetables, four cases had possibly not consumed corn and one of these four had possibly consumed frozen mixed vegetables.

## ECDC and EFSA threat assessment for the EU

An outbreak of *L. monocytogenes* serogroup IVb, ST6, is ongoing in Austria, Denmark, Finland, Sweden and the United Kingdom with 47 human cases reported since 2015. Nine patients have died. Eighteen outbreak cases have been reported in 2018 with the latest cases having disease onset in May 2018. Thus, the outbreak is continuing, or has been ongoing until very recently. It is also likely that the extent of this outbreak has been underestimated since the outbreak was identified through sequencing and only a subset of the EU/EEA countries routinely use this advanced technique to characterise *L. monocytogenes* isolates.

WGS analysis confirmed that all 47 human *L. monocytogenes* isolates have 0–7 allelic differences from the Finnish representative outbreak isolate FI 122265 based on cgMLST. In addition, 29 non-human isolates from Austria, Belgium, Finland, France, Poland, Hungary and Sweden were found to be closely related to the 47 human outbreak strains using cgMLST ( $\leq 6$  allelic differences). The majority of the non-human isolates were obtained in products from the 2017 production season: mainly frozen corn (13 samples), frozen vegetable mixes including corn (8 samples), frozen spinach (1) and frozen green beans (1). Only one isolate was reported from a frozen vegetable mix produced in 2016, while three isolates were obtained in spinach products produced in 2018. In addition, two isolates were also obtained from two environmental samples collected in two different plants freezing and handling frozen vegetables in France and Hungary during the 2017 and the 2018 production seasons, respectively.

The WGS analysis provides a strong microbiological link between the human and the non-human isolates and this is indicative of a common source related to frozen corn and other frozen vegetable mixes including corn persisting in the food chain. Traceability information of the contaminated products pointed to the source of contamination at a freezing plant in Hungary (company A). As *L. monocytogenes* IVb ST6 matching the outbreak strain has been isolated from frozen spinach and frozen green beans sampled at the Hungarian plant, it is possible that frozen

vegetables other than corn, which have been processed at this plant, could also be implicated as a vehicle of human infection.

The finding of *L. monocytogenes* IVb, ST6 matching the outbreak strain in frozen corn and other frozen vegetables produced in the 2016, 2017 and 2018 production seasons at the plant of the Hungarian company A suggests that the strain could be persisting in the processing environment after standard cleaning and disinfection procedures carried out in conjunction with periods of inactivity in the plant, as well as the rotation of the processed products. In particular, the finding of *L. monocytogenes* in three out of five spinach samples from one batch collected during the different phases of the 2018 spinach production further supports the hypothesis that contamination has occurred within the plant, during one and/or multiple processing stages. It is important to note that the grinding stage (where the first positive sample was taken) occurs after blanching (96°C for 110 seconds) and cooling of the spinach. WGS was only performed for two of the three isolates and both matched with the outbreak strain. The isolation of the *L. monocytogenes* IVb ST6 matching the outbreak strain in a sample from a floor drain at the packaging area confirms the environmental contamination of the Hungarian processing plant. It is also important to note that even though some environmental samples from different bands (i.e. sorter and blanching bands, band leading to the grinding machine) tested negative for *L. monocytogenes*, other sites in the processing line, less accessible and more difficult to clean (e.g. slicers, grinder, refrigerator systems, etc.) could be contaminated and could maintain *L. monocytogenes* contamination in the plant. Further investigations, including thorough sampling and testing [1a], are needed to identify the source of contamination at the Hungarian processing plant.

The use of the contaminated production lines for several frozen vegetables may represent an additional risk for potential cross-contamination of the final products processed at Hungarian company A's plant (e.g. frozen corn and frozen vegetable mixes). Cross-contamination of the frozen fruit appears to be less probable, as no freezing of fruit is carried out at the plant and fruit frozen by other factories are packed in a completely separate area of the plant. The plant of the Polish company C, which was initially [1] considered one of the possible points of contamination together with Hungarian company A's plant, was then excluded as a result of the intense environmental sampling and testing that made it possible to identify the points of contamination by *L. monocytogenes* IIa (not related to this outbreak) and carry out thorough cleaning and disinfection at the plant of Polish company C.

Food business operators in Estonia, Finland, Poland and Sweden have withdrawn and recalled the implicated frozen corn products from the market. Since March 2018, the implicated Hungarian plant has been under increased official control and no frozen vegetable products from the 2018 production season have been distributed to the market yet. Following the positive findings from food and environmental samples collected during the 2018 production, freezing activities were recently halted at the plant concerned. On 29 June 2018, the Hungarian Food Chain Safety Office banned the marketing of all frozen vegetable and frozen mixed vegetable products produced by the Hungarian plant between August 2016 and June 2018, and ordered their immediate withdrawal and recall. This restrictive measure is likely to significantly reduce the risk of human infections and contain this outbreak.

As the outbreak is still continuing or at least has been ongoing until very recently, there are indications that contaminated products may still be on the market or that contaminated products purchased before the recalls are still being consumed. Any potentially contaminated frozen vegetables (e.g. frozen corn, frozen vegetable mixes including corn, frozen spinach and frozen green beans) from the 2017 and 2016 production seasons could still represent a possible risk to consumers until completely withdrawn and recalled. This risk may exist, even at a low level of contamination, if the products are not properly cooked before consumption. It is worth noting that thawed and fresh corn and green peas have been shown to support the growth of *L. monocytogenes* at refrigeration temperature (4°C) [12,13]. In addition, new invasive listeriosis cases may be identified due to the long incubation period (1–70 days), the long shelf-lives of frozen corn products, and potential consumption of frozen vegetable products bought by consumers before the recalls and eaten without being cooked properly.

Information on corn consumption was not routinely requested during patient interviews in the affected countries. Questions on consumption of corn and vegetable mixes were introduced in the questionnaires once the match between human and non-human isolates was found. Consumption of frozen or non-frozen corn has been confirmed by 11 out of 26 patients interviewed from Denmark, Finland, Sweden and the United Kingdom. Of the 15 cases that did not report corn consumption, two replied that they had consumed non-frozen mixed vegetables, three cases reported no consumption of corn or mixed vegetables, six cases did not know if they consumed corn or mixed vegetables, four cases had possibly not consumed corn and one of these four had possibly consumed frozen mixed vegetables. The matching *L. monocytogenes* isolations in other types of frozen vegetables (spinach and green beans) give grounds to expand the collection of exposure data from patients with *L. monocytogenes* isolation matching the outbreak strain.

It is worth noticing that the frozen corn, frozen vegetable mixes and frozen creamy spinach were considered by the producer to be 'non ready-to-eat' food. However, consumers may have eaten these thawed products without having cooked them properly or at all. For example, foods cooked in the microwave may still have cold spots where the bacteria could survive. Moreover, the consumption of thawed corn and thawed vegetables without cooking them is not an unusual practice (e.g. in salads, smoothies, etc.)

Positive findings of other strains of *L. monocytogenes* which are different from the outbreak strain, have been reported in food (from frozen corn, frozen vegetable mixes, etc.) and environmental samples in the Hungarian company A (serogroup

IIa), the Polish company C (serogroup IIa), and the Belgian company D (serotype 1/2b). Although these strains are serologically different from the one related to the present outbreak, further sequencing of these *L. monocytogenes* isolates may provide information on additional potential links to human cases of relevance to public health.

Further studies on the risk of *L. monocytogenes* associated with the consumption of frozen vegetables could help clarify some important aspects, such as the growth kinetics of *L. monocytogenes* in frozen and thawed vegetables.

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Link to FDA's Risk Profile on Pathogens and Filth in Spices (2017):

<https://www.fda.gov/media/108126/download>

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-033**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Standardization for the Critical Limit and pH Monitoring of Acidified Rice

**Issue you would like the Conference to consider:**

A recommendation is being made to amend the 2017 FDA Food Code, Section 3-502 to include specific parameters for the target pH and pH testing method of white rice acidified to render it as a non-time/temperature control for safety food. The ability to hold acidified white rice at room temperature is of critical importance for the production of sushi as the texture of room temperature white rice is much more conducive to the rolling and forming of sushi rolls.

**Public Health Significance:**

The acidification of white rice is necessary to render it as a non-TCS food and control for the growth of *Bacillus cereus*, which can grow at a pH above 4.3 (Lee, 2014). The critical limits for the pH of acidified white rice and the techniques required to measure pH vary considerably between regulatory authorities. Standardizing requirements across regulatory authorities would provide consistency for providers operating in multiple jurisdictions and reduce confusion between regulatory authorities.

**Recommended Solution: The Conference recommends...:**

...that a letter be sent to the FDA recommending the most current edition of the Food Code be amended to include a standardized procedure for the requirements of a HACCP for acidified white rice. The clarifying language for written procedures as follows (new language is underlined):

*Bacillus cereus Controls*

3-502.13 Acidified White Rice pH Measurement and Critical Limit Criteria

A FOOD ESTABLISHMENT operating under a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 to acidify white rice as to

render it a non-TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall have a HACCP plan that includes:

(A) A description of the products produced;

(B) A recipe for the production of the acidified rice that specifies:

(1) The quantity of rice and water prior to cooking, and cooking instructions;

(2) The vinegar solution recipe including salts and sugars;

(3) The cooked rice to vinegar solution ratio that is to be thoroughly mixed to acidify the rice;

(4) The cooked and acidified rice shall have a targeted pH of 4.1, and a CRITICAL LIMIT of 4.3

(5) The vinegar solution shall be added to the rice within one hour of cooking.

(C) The method used to determine the pH of the cooked, acidified rice that includes the following:

(1) Conducting the pH test within one hour after acidification of the cooked rice and as often as necessary to assure a targeted pH of 4.1, and a CRITICAL LIMIT of 4.3.

(2) Making a rice slurry by gathering one-quarter cup of the cooked acidified rice consisting of five samples taken from the four corners and center of the batch and adding one-half cup of distilled water cup or other UTENSIL OR SINGLE-SERVICE ARTICLE.

(3) Blending the slurry with a UTENSIL for approximately twenty seconds to create a thorough mix.

(4) Inserting a pH probe or pH paper into the liquid portion of the slurry to ensure a pH of 4.3 or less is achieved.

(D) This acidified white rice shall have a shelf life of a maximum of 24 hours.

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**Supporting Attachments:**

- "Safety and pH Measurements of Sushi Rice in Japanese Restaurants in Burnaby"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

# Safety and pH Measurements of Sushi Rice in Japanese Restaurants in Burnaby BC, Canada

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## Abstract

**Background and Purpose:** The increasing popularity of sushi in Metro Vancouver raises public health concerns over the consumption of sushi rice being held out of temperature control. Although sushi rice is acidified to control growth of pathogenic microorganisms, there is no existing documented system to monitor the pH of sushi rice, and pH testing is rarely performed by Environmental Health Officers (EHOs)/Public Health Inspectors (PHIs) during routine inspections. The purpose of the study was to measure the pH of sushi rice samples collected from different sushi restaurants in Burnaby, BC and determine whether the pH meets the accepted standard of 4.6 or below.

**Methods:** 30 sushi rice samples were collected from 30 randomly selected sushi restaurants in Burnaby, British Columbia. The samples were kept at room temperature and then tested for pH using the Waterproof Palm pH Meter.

**Results:** The mean pH of the samples was 4.09; the median was 4.115; the standard deviation was 0.198; and the range was 0.82 with the minimum value of 3.71 and the maximum value of 4.53. 100% (30 out of 30 samples) had the pH less than 4.6. The statistical z-test resulted in a p-value of 0.00.

**Discussion:** All of the sushi rice samples had pH values less than 4.6. Therefore, the samples were adequately acidified to inhibit the growth of pathogens. The low pH values indicate that the samples are not considered potentially hazardous food, thus safe to be stored at room temperature for extended periods of time. However, due to the nature of *Bacillus cereus* that can grow at a pH 4.3 or higher, the target pH of sushi rice is 4.3 or lower.

**Conclusion:** Inadequately acidified sushi rice may pose a health risk if it is stored out of temperature control. The study shows that sushi rice being consumed by the public in Burnaby, BC is generally safe and has a low public health concern. Therefore, EHOs/PHIs can feel assured that sushi rice stored at room temperature is unlikely to cause potential foodborne illness.

Keywords: sushi, rice, pH, acidity, food safety, *Bacillus cereus*, *Staphylococcus aureus*, Burnaby, BC

## Introduction

Sushi, which literally means ‘seasoned rice’, is a type of Japanese cuisine consisting of acidified rice combined with various toppings and fillings, usually raw fish or other ingredients (Bergen, 2011). Since globalization has introduced sushi to many countries, it has gained a huge popularity across the world and has become a part of Canadian diets today. There are more than 400 sushi restaurants in Metro Vancouver, and the number of sushi restaurants is increasing every year.

As much as sushi is favored and consumed by many Canadians, it possesses potential health risks. Uncooked fish can be easily contaminated by various pathogens and may cause foodborne illness and other diseases. For example, Anisakiasis is caused by anisakis, a parasitic nematode found in raw seafood. 90% of all cases of anisakiasis described in the literature are caused by the consumption of sushi and sashimi (Bucci et al., 2013). Patients generally recover on their own, but surgery is often necessary for invasive anisakiasis that penetrates the intestine, liver and lungs (Sakanari & McKerrow, 1989).

Health concerns of eating sushi have been recognized since many people are aware of the risk of raw fish

consumption. However, public awareness of risks associated with sushi rice is low. Sushi rice is generally kept at room temperature or in warm holding unit in most sushi restaurants as sushi is supposed to be served warm (about 30°C) for the ideal taste. The control measure to keep the sushi rice safe at room temperature is the addition of a vinegar solution to reduce its pH to inhibit growth of harmful bacteria.

Environmental Health Officers (EHOs) or Public Health Inspectors (PHIs) have difficulty ensuring safety of sushi rice because each sushi chef uses his/her own recipe with differing amounts of the vinegar solution, and a pH test of sushi rice is rarely performed during inspections.

The focus of this study was to determine safety of sushi rice stored out of temperature control (4°C – 60°C) by creating a pH database of sushi rice collected from various sushi restaurants in the City of Burnaby, BC.

## Literature Review

### What is Sushi?

**History of Sushi:** The origin of sushi is believed to be fermented fish or meat for the purpose of preservation in the second century in Southeast Asia (Sushi Encyclopedia,

2007). Later on, rice was used to speed up the fermentation process. In the sixteenth century, vinegar was beginning to be added to further reduce the preparation time. This type of sushi was preferred over the original one and became a delicacy in Japan. From this point onward, fermentation was not favored anymore, and a new type of sushi using only vinegar and cooked rice began to evolve. Sashimi (slices of raw fish) was consumed for centuries in Japan, but it was in the early 1880's when raw fish and rice were first combined. This acidified rice with raw fish is the sushi widely known to the world today. During 1970s, sushi was first introduced in North America as Japanese businesses started expanding to the U.S. (Sushi Encyclopedia, 2007).

**Types of Sushi:** There are two main types of sushi sold in Burnaby: *nigiri* sushi and *maki* sushi (Figure 1). Literally translated, *nigiri* means “hand-pressed”. *Nigiri* sushi is small, oval shaped acidified rice with a firmly placed topping, such as slices of raw fish or other ingredients. *Maki* sushi is a cylindrical shaped roll consisting of acidified rice and fillings such as seafood, meat, and vegetables (Bargen, 2011).



Figure 1. *Nigiri* (left) and *Maki* (right)

### Factors Affecting the Growth and Survival of Microorganisms in Food

Cooked rice is a potentially hazardous food (PHF) (BCCDC, 2006). According to Food Premise Regulation, potentially hazardous food is food that is “capable of supporting the growth of disease-causing microorganisms or the production of toxins” (Food Premise Regulation BC, 1999). There are two types of factors that affect microbial growth on potentially hazardous food: intrinsic and extrinsic factors. Intrinsic factors include water activity ( $A_w$ ), oxygen availability, acidity (pH), available nutrients, and presence and identity of natural microbial flora. Extrinsic factors include temperature, relative humidity, atmosphere composition and packaging (Forsythe, 2010). The factors which can be controlled to limit microbial growth in sushi rice include acidity (pH), water activity ( $A_w$ ) and temperature.

**Water activity ( $A_w$ ):** Water activity ( $A_w$ ) is a measure of the available water content in a food sample. The  $A_w$  is calculated by the ratio of the water vapour pressure of the sample to that of pure water at the same temperature. Water activity ranges in value from 0.0 to 1.0. The  $A_w$  of pure water is 1.0 and the value decreases with the addition of solutes (Forsythe, 2010). Most microorganisms cannot survive in the environment where the  $A_w$  is lower than 0.86. Leung (2006) measured the  $A_w$  of sushi rice made by the recipe provided by SushiLink (2006). The  $A_w$  of the sushi

rice was 0.962 which is far above 0.86. This indicates that water activity does not play an important role in inhibiting growth of microorganisms in sushi rice.

**Temperature:** Temperature is one of the most important factors in safe food handling practices. Temperature values for microbial growth have a range with an optimum temperature for maximal growth. The temperature range between 4°C and 60°C (40°F and 140°F) is the Danger Zone where most bacteria grow (FoodSafe, 2006). If the temperature is greater than 60°C, most bacteria die. If the temperature is colder than 4°C, the bacteria stay alive but do not multiply rapidly. Storing sushi rice at room temperature for extended hours is clearly temperature abuse unless other factors such as pH are controlled to inhibit microbial growth.

**Acidity (pH):** pH is a measure of acid concentration in a food sample with a range of 0 to 14 (Forsythe, 2010). The pH range for a microorganism, like the temperature range, has a minimum and a maximum value with an optimum pH. Generally, the optimum pH of most bacteria is 6.8-7.2, and they cannot survive at pH 4.6 or lower. The pH range of plain white rice is 6.0-6.7 which falls into the range of the optimum pH of most bacteria (Forsythe, 2010).

### Pathogens Associated with Sushi Rice

Most microorganisms are killed during the rice cooking process. However, handling cooked rice is more important than the cooking process because cooked rice provides a good environment for pathogen growth. The primary pathogens of concern associated with cooked rice are *Bacillus cereus* and *Staphylococcus aureus*. In addition, sushi rice can be easily cross-contaminated by other pathogenic bacteria as well because sushi rice is always handled with sushi chef's bare hands that touch raw fish and other ingredients at the same time.

***Bacillus cereus*:** *B. cereus* is a spore-forming bacterium which may cause foodborne illness (Labbe and Garcia, 2001). Among various *Bacillus* species found in a wide variety of foods, *B. cereus* is most commonly associated with foodborne illness outbreaks. *B. cereus* produces toxins that cause illness. There are two recognized types of *B. cereus* foodborne illness: diarrheal (watery diarrhea, abdominal cramps and pain) and emetic (nausea and vomiting) (Forsythe, 2010). Diarrheal type of *B. cereus* is associated with meats, milk, vegetables, and fish. *B. cereus*-producing emetic toxin is found in rice and starchy food products (Forsythe, 2010). Rice can be easily contaminated by *B. cereus* during growth, harvesting, processing and handling (Haque and Russell, 2005). The spores of *B. cereus* survive during boiling and frying rice and germinate when the environment is favorable for growth (Gilbert et al, 1974). Between 1973 and 1985, *B. cereus* caused 17.8% of the total bacterial food poisoning in Finland, 0.8% in Scotland, 0.7% in Japan and 2.2% in Canada (Kotiranta et al, 2000). Growth requirements of *B. cereus* are as follows (Forsythe, 2010):

- Minimal water activity ( $A_w$ ) is 0.930

- Temperature range is 4°C – 52°C
- pH range is 4.3-9.3

The minimum water activity of *B. cereus* is lower than the average Aw of sushi rice, meaning that sushi rice provides enough moisture to support growth of *B. cereus*. The minimum pH that *B. cereus* can multiply is 4.3, which is slightly lower than general minimum pH for inhibition of pathogens. This indicates that *B. cereus* may grow on sushi rice if the pH is higher than 4.3.

**Staphylococcus aureus:** *S. aureus* is a toxin-producing bacterium commonly found on the skin and in the noses and throats up to 25% of healthy people (CDC, 2006). Most of *S. aureus* foodborne illness cases are caused by poor hygiene of food handlers and improper food handling practices. Symptoms usually develop within 1 to 6 hours after consumption of the contaminated food. Infected individuals experience nausea, vomiting, abdominal cramps, and often diarrhea (Forsythe, 2010). Poor personal hygiene and inappropriate food handling techniques increase the chance of *S. aureus* transferred to sushi rice.

Growth requirements of *S. aureus* are as follows (Forsythe, 2010):

- Minimal water activity is 0.83
- pH range is 4.0 – 10
- Temperature range is 7°C – 48°C

*S. aureus* can grow in the environment with low water activity (minimum 0.83) and low pH (minimum 4.0). This again indicates that storing sushi rice at room temperature will support the growth of *S. aureus* and toxin production if the pH is higher than 4.0.

**Other potential pathogenic microorganisms:** Although *B. cereus* and *S. aureus* are the primary pathogens of concern, sushi rice possesses a high potential for cross-contamination by other pathogens as well since it involves considerable bare hand contact. *Escherichia coli* is one of the common pathogens known to have caused outbreaks associated with sushi restaurants.

*Escherichia coli* is commonly found in the digestive tract of all animals including humans. The presence of *E. coli* is used as an indicator of fecal contamination (Labbe and Garcia, 2001). Sushi handlers who have poor personal hygiene may transfer *E. coli* to sushi rice while making sushi with bare hands. Inadequate pH and temperature abuse will support *E. coli* growth and cause foodborne illness. It was found that the *E. coli* outbreak in Nevada was caused by poor food-handling practices and infected foodhandlers in sushi restaurants, resulting in 130 reported illnesses (Jain *et al.*, 2008).

### Sushi Rice Preparation

**Acidification of rice:** Rice is acidified by adding a vinegar solution to reduce its pH enough to inhibit microbial growth, especially *B. cereus* and *S. aureus*. The acetic acid in vinegar lowers the pH of the rice and acts as a bacterial inhibitor (Wilson, 2001). Acidified sushi rice is known to be safe at

room temperature for up to 8 hours (University of Florida, 2004).

**White Sushi Rice vs. Brown Sushi Rice:** Sushi rice is commonly made of white rice. Brown rice is not typically acidified due to the harder surface coating on the rice which limits penetration of acid solutions. Due to this reason, the cooked brown sushi rice must be stored under refrigeration at 4°C or below to reduce the chance of foodborne illness (University of Florida, 2004).

### Legislation and Guidelines

BC Food Premise Regulation does not specify control measures for sushi rice. However, pursuant to section 14(2), “every operator of food premises must ensure that potentially hazardous food is stored or displayed at a temperature of not more than 4°C or not less than 60°C” (BC Food Premises Regulation, 1999). Acidified rice with pH 4.6 or less is not considered a potentially hazardous food as the pH will inhibit the growth of pathogens (University of Florida, 2004). This indicates that sushi rice should be refrigerated unless its pH is lower than 4.6.

BC Centre for Disease Control (BCCDC) released a sushi safety handout in 2010. It states that the pH of white sushi rice should be less than 4.6 to inhibit bacterial growth. Rice should be acidified as soon as it is cooked and discarded at the end of the day (BCCDC, 2010).

Health Authorities throughout North America have their own guidelines on sushi and sushi rice to ensure customer safety. For example, Alberta Health Services requires a written recipe for sushi rice with the amount of rice and acidification agent added to the rice (Alberta Health Services, 2011). In the County of San Bernardino, California, if sushi rice is to be held at between 4°C and 60°C, operators are required to submit a HACCP plan with a pH test result submitted from an accredited laboratory to the Health Authority. Operators also need to measure the pH of their sushi rice monthly using a pH test strip paper to ensure the pH is lower than 4.6 (Environmental Health Services, San Bernardino, 2008).

However, Health Authorities in Metro Vancouver – Vancouver Coastal Health and Fraser Health – do not currently have guidelines regarding sushi rice safety. EHOs/PHIs conduct inspections in sushi restaurants, but pH of sushi rice is rarely checked due to the semi-solid nature of rice that involves complicated on-site measurement or laboratory testing. This study will provide a good database for EHOs/PHIs to assess the general safety of sushi rice in Burnaby and will be a great tool to educate operators on the importance of pH control of sushi rice.

### Relevant Previous Research on Sushi Rice

The key factors in testing safety of sushi rice are pH value and microbial analysis. Mundo *et al.* (2005) investigated how sushi rice formulation affects pH and water activity (Aw) of rice and inhibits growth of *Bacillus cereus*. Twelve different commercial sushi rice recipes were used and the formulation

mainly consists of vinegar, sugar and salt. The study results indicate that *B. cereus* growth is most significantly inhibited by pH (Mundo *et al.*, 2005). Hence, pH should be accurately measured and monitored to prevent growth of *B. cereus* in sushi rice.

Sushi rice with pH 4.6 or lower is known to be safe at room temperature for extended hours since it is not considered a potentially hazardous food any more. Leung (2006), a former BCIT Environmental Health student, conducted an experiment to investigate a correlation between total aerobic bacterial growth and the number of hours that the sushi rice is left at room temperature. The results show that bacterial counts increased in the first 3 hours and declined in the next 3 hours (Leung, 2006). Although the hump shape pattern in the third hour needs further investigation to be explained, the study could not find any health risk of storing sushi rice out of safe temperature zone for extended hours (up to six hours) as long as the pH of the sushi rice is less than 4.6. While Leung's study focused on biological analysis of sushi rice made for the experiments, this study focuses on pH of actual sushi rice samples being consumed by the public.

Some studies were conducted to investigate the chemical and biological quality of sushi rice that is actually served to the consumers. Sushi rice samples collected from 19 restaurants in Seattle were tested for pH and microbiological analysis (Adams *et al.*, 1994). All of them had pH levels 4.6 or lower, and no fecal coliforms were detected. *Bacillus cereus* and *Staphylococcus aureus* were detected in the samples from 6 restaurants, but the levels were too low to be considered a public health concern (Adams *et al.*, 1994).

A similar study was done by New South Wales Food Authority (2008) which conducted a survey of food handling practices and microbiological quality of sushi in Australia. Sushi rice samples were also collected to measure pH, water activity, and microbiological quality. It was found that the pH of sushi rice was rarely confirmed after acidification process, resulting in 15% of the samples with a greater pH than 4.6. Although the microbiological quality of samples was generally acceptable, low levels of *B. cereus* and *S. aureus* were detected in some samples, indicating a potential health risk if proper acidification does not take place (NSW Food Authority, 2008).

This study was based on the principle of the studies conducted in Seattle and Australia. However, microbiological analysis was not included in the study due to limited technical resources.

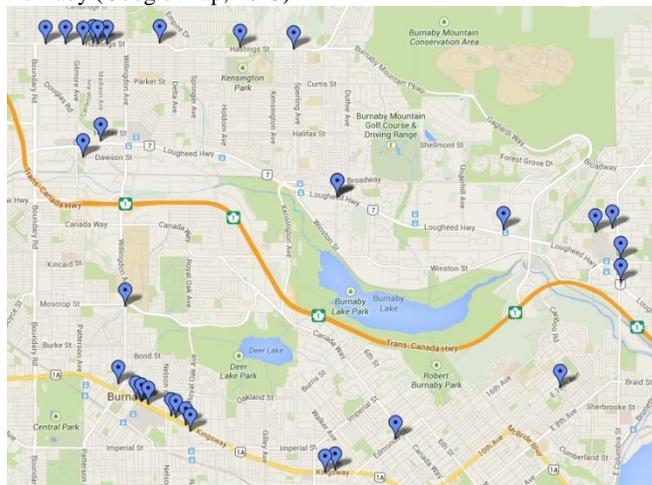
## Purpose of the Research Project

The purpose of this research project was to measure the pH of sushi rice samples collected from different sushi restaurants in Burnaby and determine whether the pH meets the satisfactory level – 4.6 or below – as suggested by BCCDC.

## Methods and Materials

The researcher visited 30 Japanese restaurants in the City of Burnaby and collected an acidified white sushi rice sample from each restaurant (Figure 2). The restaurants were randomly selected – every second sushi restaurant on Urbanspoon (2013). Collected samples were kept at room temperature, transported to the researcher's house and prepared for pH measurement. 15g of each sample was used. Due to the semi-solid nature of rice, each sample was ground using a mortar and pestle, and distilled water was added to obtain fluidity. Waterproof Palm pH Meter was calibrated with buffer solutions – 4.00 and 7.00. The pH of each sample was measured using the Waterproof Palm pH Meter (Model PH220A).

**Figure 2.** Map of Randomly Selected 30 Japanese Restaurants in Burnaby (Google Map, 2013)



## Reliability and Validity of Measures

**Accuracy of Equipment:** Waterproof Palm pH Meter was calibrated frequently to get the most accurate readings. The device itself provides accurate and reliable measurements if it is frequently calibrated and properly used. The manufacturer's instructions of Waterproof Palm pH Meter were strictly followed to increase accuracy of data collected. **Measurement Techniques:** In addition to the equipment, a good measurement technique is important to obtain accurate results. The same amount of the samples (15g) was used to measure the pH to minimize potential errors. Cross-contamination was prevented by thoroughly washing the electrode and other apparatus with distilled water after each use. The experiment was performed by only one researcher in a consistent fashion.

**External Environment:** Temperature as well as pH was recorded to ensure the sushi rice samples are held out of temperature control (4°C-60°C). The temperature was measured by the Waterproof Palm pH Meter.

## Inclusion and Exclusion Criteria

Any acidified white rice stored out of temperature control in Japanese restaurants in Burnaby, BC is eligible for this experiment. Other food items, such as non-acidified rice, acidified brown rice, acidified white rice with other ingredients added, and refrigerated acidified white rice, were excluded from this study.

## Pilot Study

A pilot study was conducted to examine feasibility of an approach and identify modifications needed in the design of the larger hypothesis testing study (Leon et al., 2011). 3 sushi rice samples were randomly collected from 3 different Japanese restaurants in Burnaby, and the pH of each sample was measured by the Waterproof Palm pH Meter. The results of the pilot study were evaluated to confirm that the materials, equipment and experimental procedure are capable of measuring pH of sushi rice samples.

## Results

The obtained pH data of 30 sushi rice samples underwent a statistical test to analyze statistical significance. The obtained data are numeric and continuous. Numeric continuous data is a measurement on a continuum, such as temperature and pH (Heacock & Sidhu, 2013a).

## Inferential Statistics

Z-test was performed to compare the pH of the samples to pH 4.6, the maximum pH of sushi rice suggested by BC Centre of Disease Control (BCCDC, 2010). Z-test compares the mean of the population to a specific value (Heacock & Sidhu, 2013b). The hypotheses of this study are as follows:

Null hypothesis (Ho):  $\mu > 4.6$

Alternative hypothesis (Ha):  $\mu \leq 4.6$

The null hypothesis predicts that the mean of the pH of sushi rice in Burnaby is greater than 4.6. The alternative hypothesis predicts that the mean of the pH data is equal or less than 4.6.

Probability,  $p = 0.05$  (or 5%), was used as a significance level to evaluate statistical significance. If  $p < 0.05$ , the researcher concludes that there is a significant difference between the mean of the data and the standard value, 4.6, and rejects the null hypothesis. If  $p \geq 0.05$ , the researcher concludes that the results are not statistically significant at the 5% level, thus does not reject the null hypothesis.

Microsoft Excel 2013 and NCSS 9 were used to conduct a statistical z-test. The obtained data was arranged in a table using MS Excel 2013 and then transferred to NCSS. Z-test is equivalent to 'One-Sample T-Test' in NCSS (Hintze, 2013). Instructions of running the z-test (or one-sample t-test) were provided in the NCSS manual (Hintze, 2013).

## Collected Data

Table 1 refers to the pH values of sushi rice samples collected from 30 different Japanese restaurants in Burnaby.

**Descriptive Statistics:** Descriptive statistics of the pH data were analyzed (Table 2). The results show that the mean of the samples is 4.09; the median is 4.115; the standard deviation is 0.198; and the range is 0.82 with the minimum value of 3.71 and the maximum value of 4.53. Among the 30 samples, no sample exceeded the pH 4.6.

**Statistical Results:** The results of the z-test (one-sample t-test) of the data were obtained. The p-value is 0.000 ( $p < 0.05$ ). The null hypothesis was rejected at  $\alpha = 0.05$ . The power for the null hypothesis is 1.000 at both  $\alpha = 0.05$  and  $\alpha = 0.01$ . The data is normally distributed according to Skewness, Kurtosis and Omnibus Normality tests.

**Interpretation:** The normally distributed data confirms that a parametric statistical test was appropriate. Since the p-value is 0.000, the null hypothesis was rejected at  $\alpha = 0.05$ , and the researcher concluded that there is a statistically significant difference between the mean pH of the sushi rice samples collected and the standard value, 4.6. The alternative hypothesis was therefore not rejected, indicating that the pH of the sushi rice samples is less than 4.6.

**Table 1.** pH values of the sushi rice samples collected from 30 different Japanese restaurants in Burnaby

Sample	Restaurants	pH	Temp (°C)
1	Kilala Sushi	3.83	19.5
2	Kokoro Sushi	3.82	21.2
3	Sushi S	3.8	21.8
4	Yo Sushi	3.71	21.1
5	Sushi Town	3.8	22.9
6	Osaka Sushi	3.91	23
7	Hong Sushi	3.92	21.9
8	Black Dragon	4.09	21
9	Nao Sushi	4.04	20.9
10	Fresh Box Sushi	4.16	21.8
11	Narita Sushi	3.86	20.7
12	Sushi Garden Metrotown	4.28	21.2
13	Tang Tang Sushi	4.24	21.4
14	Osaka Island	4.07	22.3
15	Kamamarui	4.48	22.6
16	Sushi Garden Brentwood	4.24	23
17	Asakusa Sushi	4.09	22.6
18	Yakko	4.19	22.8
19	Akira	4.36	21.9
20	Sushi &	4.05	22
21	Gaya Sushi	4.15	22.2
22	Kato Sushi	4.18	22.4
23	Sushi Gen	4.02	22.1
24	LA Sushi	4.23	21.9
25	Sushi California	4.53	22
26	Okoman Sushi	4.16	22.4
27	Kita Sushi	4.19	22.7
28	Sushi Oyama	4.14	22.8
29	Little Toko's Sushi	4.11	22.5
30	Sushi Kaku	4.12	22.6

**Table 2.** Descriptive Statistics of pH of the sushi rice samples

Mean	4.09
Median	4.115
Mode	3.8
Standard Deviation	0.198
Range	0.82
Minimum	3.71
Maximum	4.53
Count	30

Calculated by Microsoft Excel 2013 (MS Excel, 2013)

## Discussion

A common method carried out by EHOs/PHIs to ensure the safety of sushi rice is to educate operators to discard temperature-abused sushi rice after 2 hours since it has been made. Generally, potentially hazardous food is considered safe if it is consumed in 2 hours because it does not allow sufficient time for the pathogenic growth that causes foodborne illness. If sushi rice has pH 4.6 or below, then it is safe to be stored at room temperature for up to 8 hours (University of Florida, 2004).

As of December 2013, 56 Japanese restaurants are operating in Burnaby. The 30 collected samples represent about 57% of the total restaurants. The average pH value of the samples was 4.09, ranged from 3.71 to 4.53. The fact that all of the samples randomly collected for the experiment had the pH value less than 4.6 indicates that the samples were sufficiently acidified to inhibit the growth of pathogens, especially *Bacillus cereus* and *Staphylococcus aureus*, at the temperature above 4°C. In other words, the sushi rice samples were not considered potentially hazardous food, thus safe to be stored out of temperature control for extended hours. The pH values are slightly lower than the values from other previous research that identified some samples with the unacceptable pH values. The study conducted in Australia by NSW Food Authority showed that 15% of sushi rice samples had a pH value greater than 4.6, having an average pH of 5.3 and a maximum level of 6.8 (NSW Food Authority, 2008). A similar study conducted in Seattle had an average pH value of 4.3, ranged from 3.9 to 4.6 (Adams et al., 1994). In another study reported by a former BCIT student, Leung (2006) used a commercial sushi rice recipe to make sushi rice, and the pH was found to be 4.2, which is greater than the average pH value of the sushi rice samples collected in Burnaby. 23 out of 30 samples had a pH of less than 4.2. Therefore, the researcher is confident to conclude that sushi rice being consumed by the public in Burnaby is generally safe as all of the samples met the standard value of 4.6 or less as suggested by BCCDC.

However, the standard pH value of 4.6 to determine whether a food is a potentially hazardous food or not does not completely eliminate the possibility of all pathogenic growth. The pathogens of concern with sushi rice, such as *B. cereus* and *S. aureus*, can grow in a wide range of pH. The minimum pH that *B. cereus* can grow is 4.3 (Forsythe, 2010).

This means that *B. cereus* may slowly grow in high-acid environment even if the pH is less than 4.6. Improper cooling of cooked rice prior to acidification provides the environment for the growth of *B. cereus*. 3 samples of sushi rice in this study had the pH greater than 4.3. Although the pH of all of the three samples was less than 4.6, both *B. cereus* and *S. aureus* may still potentially grow. *S. aureus* may grow when the pH is 4.0 or higher (Forsythe, 2010). 22 samples out of 30 had pH of 4.0 or greater. This indicates that the majority of the samples may allow the growth of *S. aureus* at room temperature. Considerable bare hand contact when handling sushi rice and poor hygiene of food handlers increase the chance of introducing *S. aureus* to sushi rice. However, the risk can be reduced by frequent and proper hand washing and proper food handling techniques.

Food is preserved by various controlling techniques that limit microbial growth. Hurdle technology is a common method to preserve food by using multiple techniques simultaneously to increase the overall effectiveness (Leistner & Gorris, 1995). For example, a food product is acidified to lower the pH and then refrigerated to inhibit microbial growth. However, the only control measure for sushi rice is acidification. High water activity ( $A_w$ ) of sushi rice and temperature abuse provides an optimal environment for microbial growth. This emphasizes the importance of adequate acidification of sushi rice as there is no other hurdle. In this case, the pH value greater than 4.3 may not be sufficient to limit the growth of *B. cereus* even if it is less than the standard value of 4.6.

*B. cereus* is commonly associated with cooked rice. It produces spores that may not be destroyed by cooking. The spores will germinate when the conditions are met, and the germinated *B. cereus* will start to multiply (Labbe and Garcia, 2001). Considering the notable foodborne illness history of *B. cereus*, the safe limit of pH of sushi rice should be 4.3 or less. This means that the three samples with the pH greater than 4.3 need further acidification to lower the pH in order to ensure the safety of the sushi rice.

It is important to note that other ingredients of sushi affect the overall pH of the finished sushi. Even with a low pH of sushi rice, other ingredients may increase the total pH of the sushi products. For example, the ingredients of a California roll, such as avocado, cucumber and imitation crab meat, have a pH greater than acidified sushi rice (US FDA, 2008), increasing overall pH. This indicates that sushi products – *maki* and *nigiri* – are potentially hazardous food once made, and therefore should not be stored at room temperature.

## Limitations

The measured pH value of each sushi rice sample may not accurately represent the pH of the whole batch of sushi rice. Vinegar solution may have had not been distributed evenly to the cooked rice, resulting in inaccurate reading. In addition, only 15g of each sample was used once to measure the pH in this study. Taking multiple samples from each sample

collected will increase the accuracy of the pH values and decrease potential errors.

Furthermore, although the sample size is large and represents greater than 50% of the total Japanese restaurants in Burnaby, there is a possibility that one or more restaurants which were not part of this study may have inadequately acidified sushi rice. Any batch of inadequately acidified sushi rice provides the opportunity and conditions for pathogens to grow and may cause foodborne illness. Also, it is difficult to ensure the consistency of the amounts of vinegar added to acidify rice. Food handlers may not follow their recipe and add different amounts of vinegar solution when they prepare sushi rice. Lastly, the periods of time that the sushi rice samples were held out of temperature control vary because it was not possible to track the exact time when the fresh rice was cooked and when the rice was acidified.

## Recommendations

The existing guidelines of Fraser Health and Vancouver Coastal Health do not specify sushi rice safety. A mandatory pH testing from an accredited laboratory is recommended as part of a food safety plan to ensure the safety of sushi rice. Operators also need to monitor the pH of the sushi rice on a regular basis in order to reduce the health risk associated with inadequately acidified sushi rice. pH monitoring devices, such as pH test strips and a digital pH meter, should be available on-site. The pH of sushi rice should meet the standard value of 4.6 or less. However, target pH is 4.3 or less to completely inhibit potential growth of *B. cereus*. EHOs/PHIs should ensure that operators understand the public health significance of the pH of sushi rice and maintain proper handling techniques to prevent cross contamination. During routine inspections, it is recommended that EHOs/PHIs carry pH test strips or a pH meter to check the pH of sushi rice.

Acidified white rice with a pH less than 4.6 is not considered a potentially hazardous food, thus can be stored at room temperature for extended hours. Acidification should take place as soon as the rice is cooked (BCCDC, 2010). Rice should be made fresh daily and discarded at the end of the day. Acidified brown rice should be stored under refrigeration temperature below 4°C (BCCDC, 2010).

## Future Research

1. Microbiological analysis of sushi rice is recommended along with a pH test to monitor growth of some potential pathogens, such as *Bacillus cereus* and *Staphylococcus aureus*.
2. Conduct a similar study for other cities in Metro Vancouver to assess general safety of sushi rice being consumed by the public.
3. Measure the pH of sushi rice over time to monitor a potential association between pH value and time.

4. Develop simple pH testing equipment that enables EHOs/PHIs and operators to measure more accurate pH of sushi rice on-site.

## Conclusion

Sushi rice is commonly stored at room temperature or in a warm holding unit for the ideal warm taste. However, inadequately acidified sushi rice may pose a health risk if it is stored out of temperature control. The study results show that sushi rice being consumed by the public in Burnaby, BC is generally safe with the pH below 4.6 and therefore has a low public health concern. However, due to lack of other control measures and the nature of *B. cereus* which may grow in a low pH environment, it is recommended that pH of sushi rice is 4.3 or lower.

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## Competing Interest

The authors declare that they have no competing interests.

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**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-034**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Inclusion of the phrase "expelled air" in the definition of ROP

**Issue you would like the Conference to consider:**

The phrase "expelled air" in the definition of ROP Cook Chill Packing is confusing and is not defined. According to the current definition of Reduced Oxygen Packaging as outlined in 1-201.01 of the Food Code, a bag of hot product that is sealed does not meet the definition of ROP. However, the FDA suggests that the process of sealing a bag of hot product meets the definition even the air is not "expelled" in any form or fashion.

**Public Health Significance:**

There are many facilities who are using cook/chill methods. However, they are not expelling any air from the bags, they are simply sealing the bag without any vacuum method. Therefore, this process does not meet the definition of ROP because the air is not being 'expelled'. This causes significant enforcement issues because the process they are using does not meet the definition of ROP, but yet the FDA is providing guidance that says anytime a bag of warm food is sealed in any method, it constitutes ROP.

**Recommended Solution: The Conference recommends...:**

Remove the phrase "which have the air expelled" from the definition of Reduced Oxygen Packaging 2(b) Cook Chill PACKAGING as found in Section 1-201.10 of the 2017 Food Code.

*"(d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens;"*

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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*