Conference for Food Protection
2020 Issue Form

Issue: 2020 III-001

Council

Recommendation: Accepted as Submitted 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:
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 events1,2,3. One of the outbreaks in 20154 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\textsuperscript{5,6,7,8} 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\textsuperscript{8}. 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 joins, 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


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


**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"

*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: 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):

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.

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:**
   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
   b) 10/17/18: Conference call with Dr. James Dickson (Iowa State University) reviewing cooking handling, cooking, and common practices with preparing roaster pigs
   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
   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
   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
   f) 1/7/19: Conference call rescheduled for 1/28/19 due to federal work stoppage
   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
   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
   i) 3/11/19: Conference call to share rough draft of the guidance document and to create a subcommittee to initiate the review process.
   j) 4/23/19: Section 4 Subcommittee met to review the draft and provide preliminary comments before sending to the group.
   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.
   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.
   m) 9/23/19: Review complete document with the Committee and discuss edits and comments.
   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.
   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
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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
# Table of Contents

Introduction .................................................................................................................................................................................... 2

History of Associated Illnesses and Lessons Learned ................................................................................................................. 2

Improper Storage ............................................................................................................................................................................... 2

Inadequate Cooking ........................................................................................................................................................................... 3

Improper Cooling ............................................................................................................................................................................... 3

Cross-Contamination ....................................................................................................................................................................... 3

Preparing the Pig .................................................................................................................................................................................. 4

Purchasing and Receiving ................................................................................................................................................................. 4

Thawing and Storage ........................................................................................................................................................................... 5

Cooking Methods Overview ............................................................................................................................................................... 6

Pig Preparation ................................................................................................................................................................................... 8

Special Considerations If Stuffing a Pig ................................................................................................................................................. 9

Cooking ........................................................................................................................................................................................... 9

Serving and Leftovers ......................................................................................................................................................................... 10

Clean Up and Preventing Cross-Contamination ............................................................................................................................ 11

General Safety .................................................................................................................................................................................. 12

References ......................................................................................................................................................................................... 12

Roaster Pig Safety .............................................................................................................................................................................. 13
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 of 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 [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] 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.

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.

- **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.

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 be 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 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.
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.

References


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.
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
☒ Westlake, 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)
Salmonella Outbreak with Roaster Pigs

- Outbreak of Multidrug-Resistant Salmonella Infections Linked to Pork — Washington, 2015 - MMWR / April 15, 2016 / Vol. 65 / No. 14
- During June–July 2015, Public Health–Seattle & King County (PHSKC) and Washington State Department of Health (WADOC) investigated 22 clusters of Salmonella serotype I 4, [5], 12:i− infections. Serotype I 4, [5], 12:i− is the fifth most frequently reported Salmonella serotype in the United States, but is uncommon in Washington.

While this was a unique type of Salmonella for the state of Washington, the serotype is commonly identified in pigs in Iowa.

The peak in the epicurve is not uncommon due to the seasonality of roasting pigs at outdoor BBQ.

Information regarding the 2015 outbreak in Washington.

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.
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.

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.

There’s about a 1/3 of usable meat from a roaster pig. Again—this may drive people to stuff the carcass before cooking.

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.
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.

Testing was conducted at Iowa State University meat lab (by a coworker that had won awards in numerous national BBQ championships).

This pig is about 43 pounds and stuffed with boneless pork and tied back together.

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.]
Note the right shift of the temperature/time with the stuffed product indicated by the solid line (it took longer to get to temp).

(Note: We didn’t discuss cooling patterns—the products were planned to be rendered so proper cooling was not monitored.)

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.

Here’s what the pigs looked like when they are removed from the roaster. The data logger indicates the internal temperature exceeded 200°F.

Since this product is generally “pulled” most operators prefer to cook to 185°F or hotter for quality and yield.
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.

They identified very few materials available on whole roast pig cooking—he will provide the current material provided by some processors.

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

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/

Roll Call
☒ Baldwin, Tanja ☒ McGuire, Meg
☒ Beyer, Nancy ☒ Patel, Jaymin
☐ Bush, Lauren ☒ Rivas, April
☒ Cadet, Melissa ☒ Seaman, Chuck
☒ Hanson, Dana ☒ Sedlak, Mandy
☐ Hilton, DeBrena ☒ Sparks, Christopher
☒ Jackson, Jeff ☒ Vaccaro, Melissa
☒ Johnson, Thomas ☒ Villareal, Rolando
☒ Martin, Dave ☒ 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 ☐

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)

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
☐ Seldak, 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/

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.
Welcome and Roll Call

☐ Baldwin, Tanja ☐ McGuire, Meg
☒ Beyer, Nancy ☒ Patel, Jaymin
☐ Bush, Lauren ☐ Rivas, April
☒ Cadet, Melissa ☒ Seaman, Chuck
☒ Hanson, Dana ☒ Sedlak, Mandy
☐ Hilton, DeBrena (retired) ☐ Sparks, Christopher
☒ Jackson, Jeff ☒ Vaccaro, Melissa
☐ Johnson, Thomas ☒ Villareal, Rolando
☐ Martin, Dave ☒ 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 for 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 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 ☐

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 ☐

Welcome and Roll Call

☐ Baldwin, Tanja ☐ McGuire, Meg
☒ Beyer, Nancy ☐ Patel, Jaymin
☐ Bush, Lauren ☐ Rivas, April
☒ Cadet, Melissa ☐ Seaman, Chuck
☐ Hanson, Dana ☐ Sedlak, Mandy
☐ Hilton, DeBrena (retired) ☐ Sparks, Christopher
☒ Jackson, Jeff ☐ Vaccaro, Melissa
☐ Johnson, Thomas ☐ Villareal, Rolando
☒ Martin, Dave ☐ 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 ☐

Welcome and Roll Call

☑ Baldwin, Tanja ☐ McGuire, Meg
☒ Beyer, Nancy ☒ Patel, Jaymin
☐ Bush, Lauren ☐ Rivas, April
☐ Cadet, Melissa ☐ Seaman, Chuck
☐ Hanson, Dana ☐ Sedlak, Mandy
☐ Hilton, DeBrena (retired) ☐ Sparks, Christopher
☒ Jackson, Jeff ☐ Vaccaro, Melissa
☐ Johnson, Thomas ☐ Villareal, Rolando
☒ Martin, Dave ☐ 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.

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 ☐

Welcome and Roll Call

☐ Baldwin, Tanja  ☐ McGuire, Meg  ☐ Shelton, Susan
☒ Beyer, Nancy  ☒ Patel, Jaymin  ☐ Stapp-Kamotani, Erika
☐ Bush, Lauren  ☐ Rivas, April  ☐ Abley, Melanie
☒ Cadet, Melissa  ☐ Seaman, Chuck  ☐ Idjagboro, Charles
☐ Hanson, Dana  ☒ Sedlak, Mandy  ☐ Krzyzanowski, Becky
☐ Hilton, DeBrena (retired)  ☐ Sparks, Christopher  ☒ Moore, Veronica
☐ Jackson, Jeff  ☐ Vaccaro, Melissa  ☐ Johnson, Thomas
☐ Johnan, Thomas  ☐ Villareal, Rolando  ☐ Martin, Dave
☐ Martin, Dave  ☐ Westbrook, Tim  ☐ Westbroook, Tim

Co-Chairs

Non-Voting Members

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
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

Foodborne Illness Associated with a Pig Roast

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=Ovrrcr_NqFo&sig=ACfU3U3-8mcboxdc7ylfOE7_S8xG1Stt4Q&hl=en&sa=X&ved=2ahUKEwjBv7T50L_IAhWouVkJKHeQoCOU6AEwAnECAkQAQ#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

How to Roast a Pig on a Spit

How to Roast a Whole Pig: It's Easier Than You Think

How to Roast a Whole Pig: You'll Need Time, Average Cooking Skills – And a Mop

How to Roast a Whole Pig Over an Open Fire
https://gizmodo.com/how-to-roast-a-whole-pig-over-an-open-fire-1725473541

Investigation of Salmonellosis Among Attendees of a Pig Roast, Connecticut, 2016
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

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

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/vPLbSLwEPyoWHjha3jxlzBEh0fJOIhraklyQ7Thq5DgBu6ij
q19eUqkKCABXVPnhXmp3dWY1xgRe40HOvV9TKRIN1yloCToIvN4AxuC50OqCLHwaJwFMlqlfTwFpzxs6wOssnQwGQIjLglUv0bLmDBW3tGueVqbxRLuhbOeke3dauKimUnfAnq3kpgM7walSBIFdovadKcnRWiBlU4gqsbMOUTVNyRpxi6RSWhiDpN4LY390mUPPlq5EKYxc6e-
MyxLnsGcJ7yLQj9gKKSxh1hYMUSExIw9hinv4rPnD5cpfjCzo6A8y1yN0N8wjCN-zAzQijKvATqEXB2o6gLhP69Cb2_Ekl3DhxhmlzlzGHqQ3ntCvsoN1f8FbnZbou-
c_zB5B8WL_7N8m39UpNNNY2eCQDdv85r-p6mSSoyB--AK_E7Fol/?1dmy&current=true&url=e=wcm%3Apath%3A%2FFSIS-
Content%2Finternet%2Fmain%2Ftopics%2Frecalls-and-public-health-alerts%2Ffoodborne-illness-

Spit-Roasted Pig with Nona’s Rub and Basting Sauce

The Surprisingly Easy Way to Roast a Whole Pig

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://jfoodprotection.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
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
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.
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 arrange 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/restaurant owner, 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 Marvlus 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.

(To sign up for a free subscription to Food Safety News, click here.)
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.
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.

Want to Comment on this Blog? Visit our Facebook or Twitter pages to share your thoughts and start a conversation.

Posted in: Food Safety | Seasonal

Tagged: Pigs | Salmonella
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.

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](http://www.firepit-and-grilling-guru.com/where-to-buy-a-whole-hog) 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](http://www.firepit-and-grilling-guru.com/pork-tenderloin-barbecue). 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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*Done learning about the whole pig roast of a full size pig?*  
Go back to the Whole Pig Roast page.
Issue: 2020 III-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:
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.

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.
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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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.
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.

Submitter Information 1:
Name: Donald W Schaffner
Organization: Rutgers University
Address: 65 Dudley Road
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 NAME: Direct to Consumer Delivery Committee

DATE OF FINAL REPORT: November 6, 2019

COMMITTEE ASSIGNMENT: ☐ Council I ☐ Council II x 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 downloadable 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”. 
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Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery
based on an earlier draft from
Mail Order Foods Committee
2016-2018 Conference for Food Protection

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# Table of Contents

1. Preface .................................................................................................................. 5
2. Introduction and Scope .......................................................................................... 6
3. Definitions .............................................................................................................. 7
4. Foundational concepts ........................................................................................... 11
   A. Regulatory Requirements .................................................................................. 11
   B. Risk Management Overview ........................................................................... 11
5. Direct to Consumer guidance ................................................................................. 14
   A. Considerations Prior to Delivery .................................................................... 14
   B. Temperature Control During Transportation and Delivery ............................ 14
   C. Choosing Packaging ....................................................................................... 16
   D. Preventing Contamination ............................................................................. 18
   E. Other Delivery Considerations ........................................................................ 18
   F. Food Safety Training ....................................................................................... 19
   G. Consumer Communication .............................................................................. 20
   H. Best Practices for Managing a DTC Delivery Food Safety Program ............... 21
6. Third-Party Delivery guidance ............................................................................... 26
   A. Food Safety Responsibilities ........................................................................... 26
   B. Preventing Contamination ............................................................................. 26
   C. Food Safety Education and Training ................................................................. 28
   D. Management of Non-Compliance .................................................................... 30
   E. Other Food Safety Considerations ................................................................... 30
7. Appendices ............................................................................................................. 32
   A. Food regulation overview, labeling, and recalls .............................................. 32
   B. Other resources ................................................................................................ 37
   C. Trading standards and imported food issues ..................................................... 40
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/Food/GuidanceRegulation/FSMA/ucm383763.htm)

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.

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/Inquirypage 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.


**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.

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/FoodCod e/UCM595140.pdf
- FDA Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food
  https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformatio n/ucm517412.htm
- FDA Fish and Fishery Products Hazards and Controls Guidance
  https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformatio n/Seafood/ucm2018426.htm
- USDA Food Safety Information: Mail Order Food Safety
- Centers for Disease Control and Prevention: Tips for Meal Kit and Food Delivery Safety
- 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
- FDA Guidance for Industry: Control of Listeria monocytogenes in refrigerated or frozen ready-to-eat-food
  https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/uc m073110.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

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.

<table>
<thead>
<tr>
<th>Type of Hand Held Thermometer</th>
<th>Advantages</th>
<th>Disadvantages</th>
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</thead>
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<tr>
<td>Bi-Metal</td>
<td>Small – fits in pocket, Inexpensive, Can be calibrated</td>
<td>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</td>
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<tr>
<td>Digital</td>
<td>LCD display – easy to read, Wide temp range (-50 to +300°F), Sensor located at tip, Fast response time</td>
<td>Most require manufacturer calibration, Require batteries</td>
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<td>Thermocouple</td>
<td>Very wide temp range (-60 to +2000°F), Fast response time, Very accurate, Ideal for all food temp’s</td>
<td>Must be factory calibrated, Expensive</td>
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<tr>
<td>Infrared</td>
<td>Fast response time, Wide temp range (-25 to +900°F), Food contact not required, Non-destructive</td>
<td>Measures surface temperatures only, Used only as temperature indicator, Not suitable for regulatory purposes</td>
</tr>
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</table>

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
Issue: 2020 III-005

Council Recommendation: Accepted as Submitted

Delegate Action: Accepted

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:


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

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All information above the line is for conference use only.

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:

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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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.

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Content Documents:
• "Committee Final Report"
• "Committee Member Roster"
• ""Guide for Washing and Crisping Whole Raw Fruits and Vegetables at Food"

Supporting Attachments:
• "Meeting notes"

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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  x 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.

   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
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<th>First Name</th>
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<td>Starobin</td>
<td>Anna</td>
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Guide for Washing and Crisping Whole Raw Fruits and Vegetables at Food Establishments

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Disclaimer</td>
<td>2</td>
</tr>
<tr>
<td>II. Preamble</td>
<td>2</td>
</tr>
<tr>
<td>III. Introduction</td>
<td>2</td>
</tr>
<tr>
<td>IV. Definitions</td>
<td>3</td>
</tr>
<tr>
<td>V. Information to Assist the User</td>
<td>6</td>
</tr>
<tr>
<td>(A) Scope</td>
<td>6</td>
</tr>
<tr>
<td>(B) Understanding/Clarifying Sanitizers and Disinfectants</td>
<td>6</td>
</tr>
<tr>
<td>VI. Methods and Risk Controls for Washing Whole Raw Fruits and Vegetables ....</td>
<td>8</td>
</tr>
<tr>
<td>VII. Methods and Risk Controls for Crisping Whole Raw Fruits and Vegetables</td>
<td>12</td>
</tr>
<tr>
<td>VIII. Chemical Use and Regulations</td>
<td>16</td>
</tr>
<tr>
<td>IX. References</td>
<td>19</td>
</tr>
<tr>
<td>X. Acknowledgements</td>
<td>21</td>
</tr>
</tbody>
</table>

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).¹
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.”

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.

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.

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.
• **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. 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.

**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).

**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. Infiltration of microorganisms can occur through stem scars, cracks, cuts, or bruises in certain fruits and vegetables during washing. 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.

**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.

- 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)
**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).

**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. 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) For this Guide, RTE includes raw fruits and vegetables [RACs] that are washed as specified under FDA Food Code § 3-302.15.

**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)

**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. 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)....”

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.”

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. 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.

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. 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.”

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.

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 and in 21 CFR §184 as substances Generally Recognized As Safe.

Substances cleared for use in antimicrobial formulations as hard surface sanitizers are listed in 40 CFR 180.940.
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. 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)
• 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.
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<tr>
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<th>Risk Reductions</th>
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| (W1) Washing fruits and vegetables by rinsing or spraying under continuous running and draining water | • Rotating produce items so that all surfaces are washed/rinsed thoroughly  
• Providing sufficient water velocity to loosen soil and particles from the surface  
• Washing individual pieces or small batches of produce | • When produce is not submerged in water the risk of cross-contamination and microbial infiltration may be reduced.  
• This method could cross-contaminate if multiple pieces are rinsed at the same time.  
• Do not allow water to splash onto other product or food-contact surfaces.  
• This method may not be practical for large volumes of produce. |
| (W2) Washing fruits and vegetables by rinsing or spraying in a container under a continuous stream of running water with a continuous overflow | • Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration  
• Providing sufficient water velocity to loosen soil and particles from the surface and to float off loose particles in the overflow  
• Stirring the produce in the container to ensure equal exposure to the water flow  
• Washing small batches of produce | • The use of continuously flowing and draining water may reduce the potential risk of cross-contamination.  
• This method could cross-contaminate if multiple pieces are rinsed at the same time.  
• Do not allow water to splash onto other product or food-contact surfaces.  
• This method may not be practical for large volumes of produce. |
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| (W3) Washing fruits and vegetables by submerging or by spraying or rinsing under running water using an EPA registered antimicrobial treatment in the water | • Following all manufacturer’s instructions and the registered EPA label instructions for use  
• Using the concentration of the antimicrobial indicated by the manufacturer's use directions included in the EPA registered label  
• Agitating the produce to loosen soil and surface contaminants and to ensure all produce is exposed to the treated water | • Consult the EPA registered product label to determine if the product controls pathogens in the wash water, e.g., a 3-log reduction of Salmonella, Listeria monocytogenes, and E. coli O157:H7.  
• By reducing pathogens introduced into the water by contaminated produce, the risk of cross-contamination via the water and pathogen infiltration is reduced.  
• 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.  
• Decreasing produce soaking time has been shown to reduce water infiltration rate.  
• The treated water should be prepared, and the concentration verified, following manufacturer label instructions. |
| Note: The treatment may be provided in a concentrated form that has to be diluted for use as per label instructions. |  |  |
| (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 not registered as an antimicrobial by EPA | • Following the manufacturer’s instructions  
• Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration  
• Developing a policy for the frequency of changing the water  
• Agitating the produce to loosen soil and surface contaminants | • 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.  
• These wash products are not EPA registered, and do not make any pathogen kill or reduction claims.  
• Decreasing produce soaking time has been shown to reduce water infiltration rate.  
• The treated water should be prepared, and the concentration verified, following manufacturer label instructions. |

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<table>
<thead>
<tr>
<th>Method</th>
<th>Risk Reductions</th>
<th>Comments</th>
</tr>
</thead>
</table>
| (W5) Washing fruits and vegetables by submerging in water without adding anything to the water | • Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration  
• Developing a policy for the frequency of changing the water  
• Agitating the produce to loosen dirt and contaminants | • This method provides the fewest preventive controls.  
• 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.  
• Decreasing produce soaking time has been shown to reduce water infiltration rate. |
**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.” 18  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),” 5 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. 4, 5, 8  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.” 1  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 7-204.12.¹
- 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.
<table>
<thead>
<tr>
<th>Method</th>
<th>Risk Reductions</th>
<th>Comments</th>
</tr>
</thead>
</table>
| (C1) Produce is submerged in water containing an EPA registered antimicrobial | • Following all manufacturer’s instructions and the registered EPA label instructions for use  
• Using the concentration of the antimicrobial indicated by the manufacturer’s use directions included in the EPA registered label  
• Minimizing the time produce remains in the water  
• Holding the produce under refrigeration to complete the crisping process | • Consult the EPA registered product label to determine if the product controls pathogens in the wash water, e.g., a 3-log reduction of *Salmonella*, *Listeria monocytogenes*, and *E. coli O157:H7*.  
• By reducing pathogens introduced into the water by contaminated produce, the risk of cross-contamination via the water and pathogen infiltration is reduced.  
• 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.  
• The treated water should be prepared, and the concentration verified, following manufacturer label instructions. |
| (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 not registered by EPA as an antimicrobial | • Following the manufacturer’s instructions  
• Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration  
• Developing a policy for the frequency of changing the water  
• Minimizing the time produce remains in the water  
• Holding the produce under refrigeration to complete the crisping process | • These treatments are not EPA registered, and do not make any pathogen kill or reduction claims.  
• 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.  
• Decreasing produce soaking time has been shown to reduce water infiltration rate.  
• The treated water should be prepared, and the concentration verified, following manufacturer label instructions. |
<table>
<thead>
<tr>
<th>Method</th>
<th>Risk Reductions</th>
<th>Comments</th>
</tr>
</thead>
</table>
| (C3) Produce is submerged only in water, without adding anything to the water | • Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration  
• Developing a policy for the frequency of changing the water  
• Minimizing the time produce remains in the water  
• Holding the produce under refrigeration to complete the crisping process | • This method provides the fewest preventive controls.  
• Pathogens on the surface of produce may be introduced into the water which can then cross-contaminate other produce items in the same water.  
• It has been shown that submerging some produce in water that is colder than the produce can increase the risk of pathogen infiltration.  
• Decreasing produce soaking time has been shown to reduce water infiltration rate. |
| (C4) Produce is submerged in water in a container under a continuous stream of running water with a continuous overflow | • Maintaining water temperature warmer than the pulp temperature of the produce to reduce potential infiltration  
• Crisping small batches to minimize cross-contamination  
• Minimizing the time produce remains in the water  
• Holding the produce under refrigeration to complete the crisping process | • The use of continuously flowing and draining water may reduce the potential risk of cross-contamination.  
• This method may not be practical for large volumes of produce. |
**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

FOR EACH CHEMICAL SUBSTANCE IN THE PRODUCT:

- Approved food additive listed for this intended use in 21 CFR 173*
- Be generally recognized as safe (GRAS) for produce washing*
- Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification)*

PRODUCE WASH TREATMENTS

- No antimicrobial claims can be made
- Removes soil and other surface contaminants

PRODUCE WASH TREATMENTS with Antimicrobial Claims

- EPA Registered Product
  (Meet the requirements in 40 CFR 156 Labeling Requirements for Pesticide and Devices)*
- Controls public health microorganisms in the wash water
  (e.g. Listeria monocytogenes, Salmonella, E.coli 0157:H7)
- Controls spoilage organisms
- Removes soil and other surface contaminants*

*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.

<table>
<thead>
<tr>
<th>Treatment Types</th>
<th>Intended Use</th>
<th>Food Code Compliance</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimicrobial EPA registered chemicals</td>
<td>To control pathogens or spoilage organisms in wash water.</td>
<td>Could be used for Washing Fruits and Vegetable as specified in FDA Food Code 3-302.15</td>
<td>Consult the product label to determine if the chemical controls pathogens in the wash water (e.g., a 3-log reduction of <em>Salmonella</em>, <em>Listeria monocytogenes</em>, <em>E. coli O157:H7</em>) and/or reduces non-public health organisms (e.g. spoilage organisms).</td>
</tr>
<tr>
<td>Chemicals with no antimicrobial claims (not EPA registered)</td>
<td>To help loosen soil from the produce surfaces.</td>
<td>Could be used for Washing Fruits and Vegetable as specified in FDA Food Code 3-302.15</td>
<td>No antimicrobial efficacy claims are made. Cross-contamination via water is not addressed.</td>
</tr>
</tbody>
</table>

This table does not include chemicals designed for treatment of further processed produce.
IX. References


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 Reigter; 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.
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 overseeing 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 require 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) and Jaime Hernandez (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
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) and Jaime Hernandez (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) and Jaime Hernandez (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
This Antitrust Statement is to inform the Conference for Food Protection (CFP) Executive Board members and the general membership of CFP that whenever competitors within an industry gather together, appropriate care must be taken to ensure that violations of antitrust laws do not take place.

CFP functions, be they conferences, board or committee meetings, by their very nature, bring competitors together. To avoid antitrust allegations it is necessary to avoid discussions of sensitive topics. Agreements to engage in product boycotts, restrictive market allocations, refusal to deal with third parties and price-restraining activities are automatically illegal under antitrust laws.

An antitrust violation does not require proof of a formal agreement. There need not be written or verbal agreement to collude. Also, conversations regarding any of these sensitive areas may be construed as implicit violations. As a result, those attending CFP-sponsored functions should remember the importance of avoiding not only unlawful activities but even the appearance of unlawful activity.

The antitrust laws – the Sherman Act, Clayton Act, and the Federal Trade Commission Act – are intended to ensure free and open competition. Violations of these laws can have serious consequences for CFP and its members. Violations are felonies that can result in severe penalties and significant litigation expenses for CFP and its members. Even if a government or private suit is successfully defended, the cost and disruption of the litigation can be overwhelming. Taking antitrust precautions, therefore, is not only advisable but imperative.

For your protection, the Conference for Food Protection recommends that, should one of these subjects be brought up, it would be in your best interest to voice your objection and disassociate yourself from the discussion if it continues.
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:

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

Notes:

- All conference calls are recorded. To request a recording of the conference call, please email either Anna Starobin (Anna.Starobin@ecolab.com) or Jaime Hernandez (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
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) and Jaime Hernandez (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) and Jaime Hernandez (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) and Jaime Hernandez (Jaime.Hernandez@dc.gov) SOPs / instructions for produce washing and produce crisping used by your organization.
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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.

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Attendees:

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- 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

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https://drive.google.com/drive/folders/158-NUmDMyS3eZ_5WXicbslm8qLR3TbpP?usp=sharing

Notes:

- All conference calls are recorded. To request a recording of the conference call, please email either Anna (Anna.Starobin@ecolab.com) or Jaime (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) and Jaime (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) and Jaime (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) and Jaime (Jaime.Hernandez@dc.gov) with this information.
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) and Jaime (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) and Jaime (Jaime.Hernandez@dc.gov) on these emails.

Email both Anna (Anna.Starobin@ecolab.com) and Jaime (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).
This Antitrust Statement is to inform the Conference for Food Protection (CFP) Executive Board members and the general membership of CFP that whenever competitors within an industry gather together, appropriate care must be taken to ensure that violations of antitrust laws do not take place.

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PWCC 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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PWCC GoogleDrive link: (no need for Google Account or Google login)
https://drive.google.com/drive/folders/158-NUmDMY53eZ_5WXIcbslm8qLR3TbpP?usp=sharing

Notes:

- All conference calls are recorded. To request a recording of the conference call, please email either Anna (Anna.Starobin@ecolab.com) or Jaime (Jaime.Hernandez@dc.gov) and either will send you the recording.
- 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.
  

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
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

*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) and Jaime (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) and Jaime (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) and Jaime (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) and Jaime (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

This Antitrust Statement is to inform the Conference for Food Protection (CFP) Executive Board members and the general membership of CFP that whenever competitors within an industry gather together, appropriate care must be taken to ensure that violations of antitrust laws do not take place.

CFP functions, be they conferences, board or committee meetings, by their very nature, bring competitors together. To avoid antitrust allegations it is necessary to avoid discussions of sensitive topics. Agreements to engage in product boycotts, restrictive market allocations, refusal to deal with third parties and price-restraining activities are automatically illegal under antitrust laws.

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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.
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

Notes:

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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) or Jaime (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 though 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 serves 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.
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) and Jaime (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) and Jaime (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) and Jaime (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) and Jaime (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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PWCC 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:
   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.

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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) or Jaime (Jaime.Hernandez@dc.gov) and either will send you the recording.
- 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
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) and Jaime (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), Anna (Anna.Starobin@ecolab.com) and Jaime (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), Anna (Anna.Starobin@ecolab.com) and Jaime (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) and Jaime (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) and Jaime (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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PWPC 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:  
  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.

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https://drive.google.com/drive/folders/158-NUmDMyS3eZ_5WXIcbslm8qLR3TbpP?usp=sharing

Notes:  
- All conference calls are recorded. To request a recording of the conference call, please email either Anna (Anna.Starobin@ecolab.com) or Jaime (Jaime.Hernandez@dc.gov) and either will send you the recording.  
- 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
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:

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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), Anna (Anna.Starobin@ecolab.com) and Jaime (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) and Jaime (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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PWCC 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:
  Rick Barney, Janet Buffer, Betsy Craig, Chip Manuel, Kathleen O’Donnell, Matthew Reighter, Matthew Walker
- FDA Consultants:
  Kenya Moon, Laurie Williams

Committee Charges:

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Notes:

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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
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 the 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), Anna (Anna.Starobin@ecolab.com) and Jaime (Jaime.Hernandez@dc.gov).

- Review the chemicals document discussed during the call. Please provide edits/comments and email to Anna (Anna.Starobin@ecolab.com) and Jaime (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) and Jaime (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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Attendees:

- Voting Members:
  Al Baroudi, Carol Culbert, Jason Dickhaut, Amanda Garvin, Erich Hess, Jill Hollingsworth, Josh Jordan, Dianna Karlicek, Tom McMahan, Jennifer Nord, Todd Rossow, Chris Peasley, Kris Zetterlund, Anna Starobin
- At-Large Members:
  B.J. Mikeska, Matthew Reighter, Nela Romo, Matthew Walker
- 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_5WXIcbsIm8qLR3TbpP?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
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) and Jaime (Jaime.Hernandez@dc.gov).
- Review the draft guidance document. Please provide edits/comments by June 7th and email to Jill Hollingsworth (jillh@chemstarcorp.com), Anna (Anna.Starobin@ecolab.com) and Jaime (Jaime.Hernandez@dc.gov).
- The next conference call will occur Monday, June 24, 2019, from 3:00 PM – 4:00 PM EST.
Conference for Food Protection
Antitrust Statement

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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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2. Report findings and recommendations back to the 2020 Conference for Food Protection Biennial Meeting.

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Notes:

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- Roll Call: Josh Jordan (excused), Karl Matthews (excused), Todd Rosso (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.
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) and Jaime (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), Anna (Anna.Starobin@ecolab.com) and Jaime (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
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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:

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   a. Detail the handling, cleaning, and sanitation practices related to washing and crisping of produce.
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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 I being maintained throughout the document.
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) and Jaime (Jaime.Hernandez@dc.gov).
- Review the draft guidance document. Please provide edits/ comments and email to Jill Hollingsworth (jillh@chemstarcorp.com), Anna (Anna.Starobin@ecolab.com) and Jaime (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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Attendees:

- Voting Members:
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- At-Large Members:
  Carol McInnes, Nela Romo

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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 positon 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.
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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-
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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Title:

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.
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.

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.
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....
2. Thank committee members for their work;
3. Committee be disbanded.

Submitter Information 1:
Name: Veronica Bryant
Organization: Product Assessment Committee Chair
Address: 5605 Six Forks Rd
City/State/Zip: Raleigh, NC 27699
Submitter Information 2:
Name: Jon Freed, Vice-Chair
Organization: Product Assessment Committee
Address: 400 9th Ave N.
City/State/Zip: Seattle, WA 98109
Telephone: 213-718-0424
E-mail: jonfreed@amazon.com

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"

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 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.
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


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.
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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).
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 cases 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 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.

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.
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*
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).

#### Chart 11.1

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<tr>
<th>Pathogen</th>
<th>Pass</th>
<th>Fail</th>
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C. botulinum

| No toxin detected for the duration of the study. | Any toxin detected during the study. |

S. aureus, B. cereus or C. perfringens (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* -

2. *Evaluation and Definition of Potentially Hazardous Food* -

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
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

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does laboratory selection meet appropriate criteria from Section 1.0 of NACMCF document? (See Table 1 in the NACMCF document)</td>
<td></td>
</tr>
</tbody>
</table>

Section 3.0 – Factors related to tested product

<table>
<thead>
<tr>
<th>Critical Physical Property</th>
<th>Range for Product (indicate NA if not applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water activity ($a_w$)</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td></td>
</tr>
<tr>
<td>Salt content</td>
<td></td>
</tr>
<tr>
<td>Moisture</td>
<td></td>
</tr>
<tr>
<td>Other (including nitrites or inhibitors):</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intended Conditions for Storage</th>
<th>Range for Product (indicate NA if not applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage temperature</td>
<td></td>
</tr>
<tr>
<td>Storage shelf life</td>
<td></td>
</tr>
<tr>
<td>Shelf life duration during challenge study</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was product prepared and tested at intended conditions of use?</td>
<td></td>
</tr>
</tbody>
</table>

Section 4.0 – Organism Selection

Use Table 2 and Appendix C from NACMCF document to determine answers

<table>
<thead>
<tr>
<th>Pathogen (Expand rows as needed)</th>
<th>Growth in the $a_w$ of food being tested?</th>
<th>Growth in the pH of food being tested?</th>
<th>Concern in the food product category?</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>

Section 9.0 – Sample Considerations

<table>
<thead>
<tr>
<th>How many samples were analyzed initially and at required time intervals?</th>
<th>__________</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>
### Section 10.0 – Duration of Study and Sampling Intervals

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>Does growth inhibition study provide adequate safety margin for shelf life?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
<td>Were at least 5 to 7 sampling intervals done during challenge study?</td>
</tr>
</tbody>
</table>

Maximum shelf life allowed based on study and safety margin: ________________

### Section 11.0 – Interpreting Test Results

(note that a product does not support pathogen growth if growth does not exceed the initial inoculum level by the limits listed below throughout the intended shelf life of the product and across replicate trial)

- **Most foodborne pathogens**: 1-log increase above the initial inoculum level
- **S. aureus**: 3-log increase above the initial inoculum level
- **C. botulinum**: No toxin should be detected in the product

<table>
<thead>
<tr>
<th>Pathogen (Expand rows as needed)</th>
<th>Initial Inoculum level (CFU/g)</th>
<th>Highest Growth Level (CFU/g)</th>
<th>Total Growth (CFU/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| YES | NO | Do results of study meet PASS/FAIL criteria in Section 11 of NACMCF document? |

**COMMENTS ON AREAS OF STUDY THAT DO NOT MEET NACMCF CRITERIA** (expand rows as needed)

<p>| |</p>
<table>
<thead>
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</tbody>
</table>
DRAFT CFP Challenge Testing Worksheet to Determine Microbiological Stability of a Formulation

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.)</td>
<td></td>
</tr>
<tr>
<td>Appropriate Challenge Microorganisms Selected? See Tables 4-1/6-1 of the (IFT Report and Table 2 and Appendix C of the NACMCF Report</td>
<td></td>
</tr>
<tr>
<td>Proper Inoculum Level Used to Meet Objective? Typically, Between 2 and 3 log CFU/g</td>
<td></td>
</tr>
<tr>
<td>Does Study Describe Preparation of Inoculum Using Appropriate Media and Under Conditions to Optimize Growth?</td>
<td></td>
</tr>
<tr>
<td>Was Inoculation Method Used That Does Not Change the Critical Parameters of the Product Formulation Undergoing Challenge?</td>
<td></td>
</tr>
<tr>
<td>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%).</td>
<td></td>
</tr>
<tr>
<td>Was Each Key Factor Variable Tested that Controls a Product’s Microbiological Stability Under Worst-Case Conditions?</td>
<td></td>
</tr>
<tr>
<td>Did the Analysis Include the Supporting Data (Information Regarding the Product’s Formulation, Types of Ingredients, Processing, and Final Packaging)?</td>
<td></td>
</tr>
<tr>
<td>Did the Product Study Represent and Support the Conditions (Temperature, Packaging, Humidity, etc.) the Product Will Go Through at the Retail Level?</td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

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.

9/4/2019 Draft CFP Product Assessment Committee
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:

<table>
<thead>
<tr>
<th>Subcommittee</th>
<th>Preference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Template / checklist for reviewing challenge study</td>
<td></td>
</tr>
<tr>
<td>Organism selection tool</td>
<td></td>
</tr>
<tr>
<td>Interpreting Results Guidance tool</td>
<td></td>
</tr>
<tr>
<td>Computer modeling appropriateness</td>
<td></td>
</tr>
</tbody>
</table>
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. botulium, 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
    o Types of challenge studies
    o Determining when a challenge study is needed
    o Obtaining expert device and identifying a laboratory
    o Type of study
  - Lauren Bush and Rebecca Krzyzanowski
    o Factors related to the test product
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 repackeage 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/1HKyuoVvFNNJiiAja6Ztr4lajZ4buPF4KqNYXbAmdlG6g/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 cyclotrophic bacillus
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 real-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 us 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:  
Submitted  _____  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:
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:
Name: Veronica Bryant
Organization: Product Assessment Committee Chair
Address: 5605 Six Forks Rd
City/State/Zip: Raleigh, NC 27699
Telephone: 9192186943
E-mail: veronica.bryant@dhhs.nc.gov

Submitter Information 2:
Name: Jon Freed, Vice-Chair
Organization: Product Assessment Committee
Address: 400 9th Ave N.
City/State/Zip: Seattle, WA 98109
Telephone: 2137180424
E-mail: jonfreed@amazon.com

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-012

Council
Recommendation: Accepted as Submitted _____ 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:
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 downloadable 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 website 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

Submitter Information 1:
Name: Veronica Bryant
Organization: Product Assessment Committee Chair
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-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:
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....


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

Submitter Information 1:
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Conference for Food Protection
2020 Issue Form

Issue: 2020 III-014

Council
Recommendation: Submitted

Accepted as
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:

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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or a commercial proprietary process.
Skill Description: 2020 Issue Form

Issue: 2020 III-015

Council Recommendation: Accepted as Submitted _______ Amended _______ No Action _______

Delegate Action: Accepted _______ Rejected _______

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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."¹

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%² of retailers have no records associated with beef grinding in violation of 9 CFR 320.1(b)(4).³ 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.⁴ 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"¹ (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.⁵ 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)³). 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 2018,6 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.7,8 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)).9 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.8

Per FSIS routine ground beef sampling10, 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.6,8 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.10

The 2014 CFP guidance1 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)

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
7. 2017 Food Code Section 1-201.10(B) Terms Defined "Intact Meat" and "Meat". URL: https://www.fda.gov/media/110822/download.


**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:**
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Intended Use of Non-Intact Products

CFP April 16, 2018

Sherri Jenkins, JBS USA Food Company
WHAT DOES A PACKER DO?
JBS Beef Food Safety Intervention System

- Slaughter Dressing Audits – Carcass Contamination and HTP
  - Bacteriophage
  - Chlorine at Sinks skinning line
  - Steam Vacuums
  - Hock Vacuums
  - Lactic Shields Skinning Line

- Process Microbial Mapping – daily, 7 sample sites
  - Pre-ensis Wash with PAA
  - Final Wash Cabinet with PAA
  - Final Lactic Acid Cabinet
  - Hot Boxes with PAA

- Trim N60+ Testing – Single Combo Lots
  - Fab Organic Acid Carcass Spray
  - Subprimal PAA Spray
  - Trim PAA Spray
  - Ground Beef Trim PAA Spray

- Camera Auditing – RVA and Unbiased Plant Audits
  - Bacteriophage
  - Chlorine at Sinks skinning line
  - Steam Vacuums
  - Hock Vacuums
  - Lactic Shields Skinning Line
What do interventions look like?
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?

- 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?

- **Bacteria on surface**
- **Knife**
- **Subprimal**
- **Sterile interior**
- **Steak**
- **Trimmings**
- **Contamination throughout**
- **Ground Meat (Patty)**
- **Grinder**

*JBS* 
*Making Your World Stronger*
Non-intact or Intact Product
HACCP and Non-intact Products

- 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?

- 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.
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

- 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

- 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 _____ 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"

_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._
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?

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:


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

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**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 patty 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.” 1 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.” 2

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,” 3 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, 4 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 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).

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. 5 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 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). 6 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

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1 The NACMF-adopted minutes of the Subcommittee on Meat and Poultry are available for viewing in the FSIS docket room.
2 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.
3 The phrase “cubes for stew” generally refers to meat hand-cut into uniform squares.
4 The term “cubing” generally refers to the process of flattening and knitting together meat into cutlet size products by means of a machine.
5 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.
6 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).
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:**

**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. 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.

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

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7 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).

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.

FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef (including Veal) Processing Operations

2017 Compliance Guideline
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: 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](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](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

Table of Contents

What is the purpose of this Compliance Guideline? ........................................................................................................... ii
What changes have been made to the guideline from the last version................................................................. iii
How can I comment on this guideline? .............................................................................................................................. iii
Is this version of the guideline final? ................................................................................................................................. iii
What if I still have questions after I read this guideline? ............................................................................................... iii
Why was this guideline developed? ................................................................................................................................. 2
Where does STEC come from? ........................................................................................................................................ 3
What HACCP regulatory requirements apply to STEC? .......................................................................................... 3
Is STEC considered an adulterant in all beef? .................................................................................................................. 4

Are customary cooking practices or validating cooking instruction labels enough to address STEC in raw non-intact beef products? .................................................................................................................. 4
What controls are needed to address STEC for non-intact products? ........................................................................ 6
What is ongoing verification and how does it differ from initial validation? .......................................................... 8
Why does FSIS recommend testing as a verification activity? ............................................................................. 9
How often does ongoing verification need to be conducted? ................................................................................ 9
How do I design supportable “sampling” and “testing” protocols? ........................................................................ 11
How do establishments determine a production “lot”? ...................................................................................... 12
Do establishments and retailers that grind beef have to keep a “Grinding Log”? ..................................................... 13
How will the new “Grinding Log” rule be verified and enforced? ........................................................................ 15
What actions are required in the event of a STEC positive? .................................................................................. 15
Should grinding establishments address lymph nodes? ..................................................................................... 17
Scenarios ...................................................................................................................................................................... 18
Attachment 1 – STEC Decision-Making Flow Chart Guide .................................................................................. 21
Attachment 2 – Grinder’s Log .................................................................................................................................. 22
Resources and References ....................................................................................................................................... 23
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.

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 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.**

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.

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.

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
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.

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\textsuperscript{nd} month (6 times annually);
- <5,000 lb weekly - sample at least once every 3\textsuperscript{rd} 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.

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 in 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.

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”?**

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.
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.

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.

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

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 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 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.

### Source Material

- Does the establishment receive Letters of Guarantee (LOG) from each supplier? (outside supplier)
  - Yes
  - No
- Purchased Product – Cattle not slaughtered onsite
- Does the establishment implement other procedure to ensure STEC is below detectable levels?
  - Yes
  - No
- (self-supplier)
  - In-house materials derived from cattle slaughtered onsite
- Does the establishment maintain sanitary conditions during slaughter?
  - Yes
  - No

### Control Measure

- Does the establishment receive supporting documents to show STEC is below detectable levels in each lot received (e.g., COA)?
  - Yes
  - No
- Does the establishment conduct lot-by-lot testing of incoming product?
  - Yes
  - No
  - OR
- Does the establishment conduct lot-by-lot testing of finished product?
  - Yes
  - No
  - OR
- Does the establishment apply an antimicrobial or other lethality treatment?
  - Yes
  - No
  - OR
- Does the establishment treat or wash the product and trim the outer surface of the product?
  - Yes
  - No

### Ongoing Verification

- The establishment has support that STEC is below detectable levels in the non-intact products produced.
  - Yes
  - No
- Does the establishment conduct meaningful ongoing verification of the process controls to show the system is functioning as intended and to ensure STEC is below detectable levels? Typical measures may include:
  - Product Testing,
  - 3rd Party Audits, and/or
  - Communication with the Supplier
  - Meaningful ongoing verification should match the control measure(s) selected, and must be designed to show the system is functioning as intended to ensure STEC is below detectable levels.
  - Yes
  - No
- The establishment lacks support that STEC is below detectable levels in the non-intact products produced, and the HACCP system may be inadequate.
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

<table>
<thead>
<tr>
<th>Employee Name</th>
<th>Today’s Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date and Time of Grind</td>
<td>Manufacturer Name of Source Material Used for Product Produced</td>
</tr>
<tr>
<td></td>
<td>Supplier Lot #s, Product Code and/or Pack Date of Source Material Used</td>
</tr>
<tr>
<td></td>
<td>Est. Number(s) of Est. providing source material</td>
</tr>
<tr>
<td></td>
<td>Date and Time Grinder and Related FCSs Cleaned and Sanitized</td>
</tr>
<tr>
<td></td>
<td>Comments</td>
</tr>
</tbody>
</table>

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, establishment 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

Oxidizer antimicrobials

Hide-on carcass wash:

Steam vacuum systems:
Prot. 60: 107-113.


**Organic acid Rinses:**


**Hot water rinses:**


**Steam pasteurization:**

- AMI Lethality model, demonstrating lethality at 160°F at carcass surface.

**Electrolyzed oxidizing (EO) water**


**High Pressure Processing (HPP)**

- Bulut, S. 2014. The effects of high-pressure processing at low and subzero temperatures on inactivation of microorganisms in frozen and unfrozen beef mince inoculated with *Escherichia coli* strain ATCC 25922. *Food and Bioprocess Technology.* 1-12.

**Lymph Nodes**

Beef Processing Best Practices: Grinders Sanitation, Lotting, and Sampling

- Comprehensive guide meat ground at retail recordkeeping and sanitation (2013),
- Best practices for processing raw ground beef products (2009),
- Guidance Document for Sampling and Lotting of Beef Products and Sample Analysis for Pathogens,

[askFSIS](http://askfsis.custhelp.com/)

FSIS/USDA
www.fsis.usda.gov
2017
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

<table>
<thead>
<tr>
<th>Name of Source Product Ground (Trim, chub, cut, pull-back, bench trim, etc.)</th>
<th>Source Material Pack Date or Use by Date (From Supplier Label)</th>
<th>Establishment Number of Supplier</th>
<th>Lot Number of Product from Supplier</th>
<th>Retail Name (Name of Product on Retail Label or Menu)</th>
<th>Quantity Ground (in batch)</th>
<th>Time Equipment Cleaned &amp; Sanitized (Either Before or After Batch)</th>
<th>Associate Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEEF COARSE GROUND 73/27</td>
<td>7/18/2013</td>
<td>M354</td>
<td>771007180001</td>
<td>GROUND BEEF</td>
<td>30 LBS</td>
<td>7:13 AM</td>
<td>JTM</td>
</tr>
</tbody>
</table>

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***

<table>
<thead>
<tr>
<th>Store Location: Store #55</th>
<th>Production Date: 8/8/2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primal Product Name as Listed on the Box</strong></td>
<td><strong>Vendor/Supplier Name</strong></td>
</tr>
<tr>
<td>BEEF KNUCKLE</td>
<td>Swift</td>
</tr>
</tbody>
</table>

*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.
<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Position (Chair / Member)</th>
<th>Constituency</th>
<th>Employer</th>
<th>City</th>
<th>State</th>
<th>Telephone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baldwin</td>
<td>James</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Price Chopper</td>
<td>Schenectady</td>
<td>NY</td>
<td>(518) 379-1516</td>
<td><a href="mailto:JamesBaldwin@pricechopper.com">JamesBaldwin@pricechopper.com</a></td>
</tr>
<tr>
<td>Barney</td>
<td>Rick</td>
<td>(Chair)</td>
<td>Industry - Retail Food Stores</td>
<td>Delhaize America</td>
<td>Tampa</td>
<td>FL</td>
<td>(813) 620-1139</td>
<td><a href="mailto:rbarney@sweetbaysupermarket.com">rbarney@sweetbaysupermarket.com</a></td>
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<tr>
<td>Davis</td>
<td>Douglas</td>
<td>Member</td>
<td>Industry - Food Service</td>
<td>Marriott</td>
<td>Bethesda</td>
<td>MD</td>
<td>(301) 380-5736</td>
<td><a href="mailto:douglas.davis@mariott.com">douglas.davis@mariott.com</a></td>
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<tr>
<td>Deslauriers</td>
<td>Susan</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Big Y</td>
<td>Springfield</td>
<td>MA</td>
<td>(413) 504-4452</td>
<td><a href="mailto:deslaurs@bigy.com">deslaurs@bigy.com</a></td>
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<tr>
<td>Frappier</td>
<td>Robert D.</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Ahold USA</td>
<td>Quincy</td>
<td>MA</td>
<td>(617) 689-4090</td>
<td><a href="mailto:rfrappier@aholdusa.com">rfrappier@aholdusa.com</a></td>
</tr>
<tr>
<td>Girard</td>
<td>Loma</td>
<td>Member</td>
<td>Regulatory - State</td>
<td>State of Minnesota</td>
<td>St. Paul</td>
<td>MN</td>
<td>(651) 201-6591</td>
<td><a href="mailto:loma.girard@state.mn.us">loma.girard@state.mn.us</a></td>
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<tr>
<td>Goltry</td>
<td>Scott</td>
<td>Member</td>
<td>Other - Association</td>
<td>AMI</td>
<td>Washington</td>
<td>D.C.</td>
<td>(202) 587-4254</td>
<td><a href="mailto:sgoltry@meatami.com">sgoltry@meatami.com</a></td>
</tr>
<tr>
<td>Jennings</td>
<td>Allison</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Kroger</td>
<td>Cincinnati</td>
<td>OH</td>
<td>(513) 762-4281</td>
<td><a href="mailto:allison.jennings@kroger.com">allison.jennings@kroger.com</a></td>
</tr>
<tr>
<td>Kohl</td>
<td>Larry</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Delhaize America</td>
<td>Salisbury</td>
<td>NC</td>
<td>(704) 633-8250</td>
<td><a href="mailto:Larry.Kohl@delhaize.com">Larry.Kohl@delhaize.com</a></td>
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<tr>
<td>McMahan</td>
<td>Thomas</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Meijer</td>
<td>Grandville</td>
<td>MI</td>
<td>(616) 249-6035</td>
<td><a href="mailto:Thomas.Mcmahan@meijer.com">Thomas.Mcmahan@meijer.com</a></td>
</tr>
<tr>
<td>Mers</td>
<td>Donald Todd</td>
<td>(Chair)</td>
<td>Regulatory - State</td>
<td>Ohio Dept. of Agriculture</td>
<td>Reynoldsburg</td>
<td>OH</td>
<td>(614) 728-6250</td>
<td><a href="mailto:tmers@agri.ohio.gov">tmers@agri.ohio.gov</a></td>
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<tr>
<td>Nardone</td>
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<td>Member</td>
<td>Other - Software Services</td>
<td>N2N Global</td>
<td>Longwood</td>
<td>FL</td>
<td>(407) 331-5151</td>
<td><a href="mailto:anardone@us.n2nglobal.com">anardone@us.n2nglobal.com</a></td>
</tr>
<tr>
<td>O'Donnell</td>
<td>Kathleen</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Wegmans</td>
<td>Rochester</td>
<td>NY</td>
<td>(585) 429-3623</td>
<td><a href="mailto:kathleen.odonnell@wegmans.com">kathleen.odonnell@wegmans.com</a></td>
</tr>
<tr>
<td>Oswald</td>
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<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Wake Fern</td>
<td>Elizabeth</td>
<td>NJ</td>
<td>(908) 527-3624</td>
<td><a href="mailto:steve.oswald@wakefern.com">steve.oswald@wakefern.com</a></td>
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<td>Schnucks</td>
<td>St. Louis</td>
<td>MO</td>
<td>(314) 994-4346</td>
<td><a href="mailto:dpasley@schnucks.com">dpasley@schnucks.com</a></td>
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<tr>
<td>Pattee</td>
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<td>Member</td>
<td>Regulatory - State</td>
<td>Indiana Dept. of Health</td>
<td>Muncie</td>
<td>IN</td>
<td>(765) 747-7721</td>
<td><a href="mailto:spattee@isdh.in.gov">spattee@isdh.in.gov</a></td>
</tr>
<tr>
<td>Roberson</td>
<td>Michael</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Publix</td>
<td>Lakeland</td>
<td>FL</td>
<td>(863) 688-1188</td>
<td><a href="mailto:michael.roberson@publix.com">michael.roberson@publix.com</a></td>
</tr>
<tr>
<td>Scott</td>
<td>Bob</td>
<td>Member</td>
<td>Industry - Food Service</td>
<td>Darden</td>
<td>Orlando</td>
<td>FL</td>
<td>(407) 245-6764</td>
<td><a href="mailto:bscott@darden.com">bscott@darden.com</a></td>
</tr>
<tr>
<td>Seaman</td>
<td>Chuck</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Hy-Vee</td>
<td>West Des Moines</td>
<td>IA</td>
<td>(515) 559-5736</td>
<td><a href="mailto:cseaman@hy-vee.com">cseaman@hy-vee.com</a></td>
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<tr>
<td>Sharpe</td>
<td>Roxanne</td>
<td>Member</td>
<td>Regulatory - Local</td>
<td>Springfield Health Dept.</td>
<td>Springfield</td>
<td>MO</td>
<td>(417) 864-1424</td>
<td><a href="mailto:rsharp@springfieldmo.gov">rsharp@springfieldmo.gov</a></td>
</tr>
<tr>
<td>Siemens</td>
<td>Angie</td>
<td>Member</td>
<td>Industry - Manufacturer</td>
<td>Cargill</td>
<td>Wichita</td>
<td>KS</td>
<td>(316) 291-2146</td>
<td><a href="mailto:Angie_Siemens@cargill.com">Angie_Siemens@cargill.com</a></td>
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<tr>
<td>Stefanaki</td>
<td>Kristina</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>Stop and Shop</td>
<td>Quincy</td>
<td>MA</td>
<td>(617) 774-4438</td>
<td><a href="mailto:kstefans@stopandshop.com">kstefans@stopandshop.com</a></td>
</tr>
<tr>
<td>Swiechowski</td>
<td>Eric</td>
<td>Member</td>
<td>Industry - Retail Food Stores</td>
<td>BJ's</td>
<td>Westborough</td>
<td>MA</td>
<td>(321) 243-1028</td>
<td>eswiechowski@bj's.com</td>
</tr>
<tr>
<td>Last Name</td>
<td>First Name</td>
<td>Position (Chair / Member)</td>
<td>Constituency</td>
<td>Employer</td>
<td>City</td>
<td>State</td>
<td>Telephone</td>
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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  

Council Recommendation: Accepted as Submitted

Accepted as Amended

No Action

Delegate Action: Accepted Rejected

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-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\(^2,3,4\). Investigations in two of the outbreaks identified that inadequate cooking and cross contamination contributed to the outbreaks\(^1,5\) 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\(^1,5\). 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 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. 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.
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.

References (noted above with superscript numerals)


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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\(^1\). 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\(^2\). 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\(^2\). 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

**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

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

TABLE OF CONTENTS

I. INTRODUCTION

II. BACKGROUND

III. POLICY

A. Ready-to-Eat Food

B. Ready-to-Eat Foods that Support Growth of *L. monocytogenes*

C. Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes*

IV. REGULATORY ACTION GUIDANCE

A. Ready-to-Eat Foods that Support Growth of *L. monocytogenes*

B. Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes*

C. Foods that are Not RTE Foods

D. Other Considerations
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
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 \textit{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*.


B. Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes*


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]

Submit Comments

Submit comments on this guidance document electronically via docket ID: FDA-2013-S-0610 (https://www.regulations.gov/docket?D=FDA-2013-S-0610) - Specific Electronic Submissions Intended For FDA's Dockets Management Staff (i.e., Citizen Petitions, Draft Proposed Guidance Documents, Variances, and other administrative record submissions)

If unable to submit comments online, please mail written comments to:
Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

All comments should be identified with the title of the guidance.
Research Paper

Growth of *Listeria monocytogenes* in Thawed Frozen Foods

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MS 16-397: Received 23 September 2016/Accepted 8 November 2016/Published Online 16 February 2017

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 NaNO2 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. Listerosis mainly affects the elderly, the immunocompromised, pregnant women, and those consuming ready-to-eat foods without cooking or reheating. 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...
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), and 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) by using a spiral plater (model AP 4000, Spiral Biotech) and resuscitated 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) by using a spiral plater (model AP 4000, Spiral Biotech) and resuscitated 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 10⁸ 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 10⁸ 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 10⁸ 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 micoflora 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-µL aliquots of the culture cocktail that was distributed over the product surface by using a pipette. The initial inoculation level was approximately 10³ 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., Camberly, UK). If required, further decimal dilutions of samples were made with peptone water. The diluted samples were plated onto polymyxin–acriflavine–lithium chloride–ceftazidime–aesculin–mannitol agar (PALCAM; Difco, BD) by using a spiral plater (model AP 4000, Spiral Biotech, Northwood, 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:

\[
N = N_0 + IF[t < LPD,N_0, EGR \times (t - LPD)]
\]

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).
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.

\[
EGR = a(T/T_{\text{min}})^{2}
\]

where \( a \) is the constant, \( T \) is the temperature, and \( T_{\text{min}} \) 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.

\[
LPD = p_1 + p_2T + p_3T^2
\]

\( p_i = (i = 1, \ldots, 10) \) 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 NaNO₂ (0%). These parameters were selected based on sample characteristics. For NaCl (percentage) and NaNO₂ (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 \(-18^\circ\text{C}\) for 7 days. Then, the inoculated samples were incubated at 4, 8, 12, or \( 20^\circ\text{C} \), 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
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.

**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 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.

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

<table>
<thead>
<tr>
<th></th>
<th>LPD</th>
<th>Square root of EGR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$R^2$</td>
<td>Linear regression equation</td>
</tr>
<tr>
<td>Crabmeat</td>
<td>0.3748</td>
<td>LPD = 28.73 − 2.792temp + 0.0814temp$^2$</td>
</tr>
<tr>
<td>Corn</td>
<td>0.7117</td>
<td>LPD = 21.41 − 2.300temp + 0.0628temp$^2$</td>
</tr>
<tr>
<td>Green peas</td>
<td>0.3921</td>
<td>LPD = 19.77 − 2.164temp + 0.0673temp$^2$</td>
</tr>
<tr>
<td>Shrimp</td>
<td>0.2369</td>
<td>LPD = 41.00 − 5.550temp + 0.1872temp$^2$</td>
</tr>
</tbody>
</table>
TABLE 2. LPD and EGR predictions for L. monocytogenes in each thawed frozen food calculated by using parameters similar to food samples

<table>
<thead>
<tr>
<th></th>
<th>Predicted LPD (h)</th>
<th>Predicted EGR ([log CFU/g]/h)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4°C</td>
<td>8°C</td>
</tr>
<tr>
<td>Crabmeat</td>
<td>18.86</td>
<td>11.60</td>
</tr>
<tr>
<td>Corn</td>
<td>13.21</td>
<td>7.03</td>
</tr>
<tr>
<td>Green peas</td>
<td>12.20</td>
<td>6.77</td>
</tr>
<tr>
<td>Shrimp</td>
<td>21.79</td>
<td>8.58</td>
</tr>
<tr>
<td>USDA PMP</td>
<td>62.03</td>
<td>32.00</td>
</tr>
</tbody>
</table>

a Aerobic, broth culture, pH (7.0), NaCl (0.5%), and NaNO₂ (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 R² 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 (35). 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.

**ACKNOWLEDGMENTS**

The authors express gratitude to the American Frozen Food Institute, Seafood Industry Research Fund (formerly Fisheries Scholarship Fund), and Seafood Products Association for financial and technical support of this project. We also thank Dr. Jennifer McEntire (Grocery Manufacturers Association) for discussions and support in completing this study.

**REFERENCES**


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...
subpopulation \( (X) \), by the estimated number of \( L. \ monocyto-\) genes cells ingested by the subpopulation \( Dp \); that is, \( r = Xp / Dp \). In addition to using this classical derivation of \( r \), we estimated in this study \( r \) values using the \( L. \ monocyto-\) genes 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 \( L. \ monocyto-\) genes 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, respectively). Two serving units of product 1, each weighing \( \approx 80 \) g, were used to prepare each milkshake. Strains of \( L. \ monocyto-\) genes isolated from the 4 patients were indistinguishable by pulsed-field gel electrophoresis to strains recovered from product 1.

**Number of \( L. \ monocyto-\) genes 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 \( L. \ monocyto-\) genes cells in samples of products 1–3 (8; L.S. Burall, unpub. data). We characterized the variability of \( L. \ monocyto-\) genes 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 \( L. \ monocyto-\) genes cells ingested by the population was then estimated by multiplying the average number of \( L. \ monocyto-\) genes organisms per serving by the number of servings distributed in the various subpopulations. The number of ice cream servings distributed in the

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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 inpatients deemed to be highly susceptible to listeriosis, (i.e., 10%) as a surrogate of the proportion of inpatients hospitalized of intensive care unit (ICU) beds in these hospitals for patient consumption by the overall proportion of hospitalization of the first case-patient whose illness was specifically linked to factory 1 was hospitalization of the first case-patient whose illness was recognized.

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] 380–1,200 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>
<thead>
<tr>
<th>Table 1. Estimated contamination level of <em>Listeria monocytogenes</em> per gram and per serving unit of 3 products in a multistate outbreak of ice cream–associated listeriosis, United States, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product/dose</strong></td>
</tr>
<tr>
<td><strong>Product 1</strong></td>
</tr>
<tr>
<td>Per g</td>
</tr>
<tr>
<td>Per 80-g serving</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Product 2</strong></td>
</tr>
<tr>
<td>Per 70-g serving</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Product 3</strong></td>
</tr>
</tbody>
</table>

Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 22, No. 12, December 2016 2115
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 $1.5 \times 10^6$ (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 $3.3 \times 10^9$ (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

$$r = \frac{4}{1.5 \times 10^6} = 2.6 \times 10^{-9}$$

Using this same approach, we determined the value of $r$ for the overall population was $6.5 \times 10^{-10}$ under the medium-exposure scenario and $2.9 \times 10^{-10}$ 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 $\sim$9.38 and an SD of 0.88 for the overall population under the lower-exposure scenario, a mean $\sim$10.0 for the medium-exposure scenario, and a mean $\sim$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

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**Table 2.** Probability of invasive listeriosis after ingestion of ice cream products contaminated with *Listeria monocytogenes*, United States, 2015

<table>
<thead>
<tr>
<th>Exposure scenario/model</th>
<th>Population, no. cases in population</th>
<th>Highly susceptible, n = 4</th>
<th>Pregnant, n = 0*</th>
<th>Age $\geq 65$ y, n = 4</th>
<th>Age $\geq 75$ y, n = 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lower†</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$r$ constant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. <em>L. monocytogenes</em> cells consumed</td>
<td>$1.5 \times 10^6$</td>
<td>$7.2 \times 10^6$</td>
<td>$2.2 \times 10^6$</td>
<td>$2.3 \times 10^6$</td>
<td>$1.2 \times 10^8$</td>
</tr>
<tr>
<td>Estimated $r$ parameter</td>
<td>$2.6 \times 10^{-9}$</td>
<td>$5.5 \times 10^{-7}$</td>
<td>$&lt;2.3 \times 10^{-6}$</td>
<td>$1.7 \times 10^{-6}$</td>
<td>$1.7 \times 10^{-8}$</td>
</tr>
<tr>
<td>Corresponding to 1 case every... servings‡</td>
<td>37,867</td>
<td>181</td>
<td>$&gt;4,363$</td>
<td>5,756</td>
<td>5,832</td>
</tr>
<tr>
<td>log$_{10}(r)$ normally distributed</td>
<td>–9.38</td>
<td>–6.19</td>
<td>$&lt;-7.92$</td>
<td>–8.00</td>
<td>–8.02</td>
</tr>
<tr>
<td>Estimated $\mu$ parameter</td>
<td>0.88</td>
<td>0.24</td>
<td>0.54</td>
<td>0.54</td>
<td>0.54</td>
</tr>
<tr>
<td>Estimated $\sigma$ parameter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Medium§</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$r$ constant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. <em>L. monocytogenes</em> cells consumed</td>
<td>$6.2 \times 10^9$</td>
<td>$1.5 \times 10^7$</td>
<td>$8.9 \times 10^6$</td>
<td>$9.4 \times 10^8$</td>
<td>$4.8 \times 10^8$</td>
</tr>
<tr>
<td>Estimated $r$ parameter</td>
<td>$6.5 \times 10^{-10}$</td>
<td>$2.7 \times 10^{-7}$</td>
<td>$&lt;5.6 \times 10^{-6}$</td>
<td>$4.3 \times 10^{-9}$</td>
<td>$4.2 \times 10^{-9}$</td>
</tr>
<tr>
<td>Corresponding to 1 case every... servings‡</td>
<td>154,612</td>
<td>375</td>
<td>$&gt;17,812$</td>
<td>23,501</td>
<td>23,811</td>
</tr>
<tr>
<td>log$_{10}(r)$ normally distributed</td>
<td>–10.0</td>
<td>–6.40</td>
<td>$&lt;-8.49$</td>
<td>–8.60</td>
<td>–8.62</td>
</tr>
<tr>
<td>Estimated $\mu$ parameter</td>
<td>0.88</td>
<td>0.24</td>
<td>0.54</td>
<td>0.54</td>
<td>0.54</td>
</tr>
<tr>
<td>Estimated $\sigma$ parameter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>High¶</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$r$ constant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. <em>L. monocytogenes</em> cells consumed</td>
<td>$1.4 \times 10^{10}$</td>
<td>$3.3 \times 10^7$</td>
<td>$2.0 \times 10^8$</td>
<td>$2.1 \times 10^9$</td>
<td>$1.0 \times 10^9$</td>
</tr>
<tr>
<td>Estimated $r$ parameter</td>
<td>$2.9 \times 10^{-10}$</td>
<td>$1.2 \times 10^{-7}$</td>
<td>$&lt;2.6 \times 10^{-6}$</td>
<td>$1.9 \times 10^{-9}$</td>
<td>$1.9 \times 10^{-9}$</td>
</tr>
<tr>
<td>Corresponding to 1 case every... servings‡</td>
<td>339,153</td>
<td>816</td>
<td>$&gt;39,071$</td>
<td>51,552</td>
<td>52,230</td>
</tr>
<tr>
<td>log$_{10}(r)$ normally distributed</td>
<td>–10.3</td>
<td>–6.80</td>
<td>$&lt;-8.83$</td>
<td>–8.97</td>
<td>–8.97</td>
</tr>
<tr>
<td>Estimated $\mu$ parameter</td>
<td>0.88</td>
<td>0.24</td>
<td>0.54</td>
<td>0.54</td>
<td>0.54</td>
</tr>
<tr>
<td>Estimated $\sigma$ parameter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*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 \( >16,000 \) *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 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 microbial 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...
× 10^{-7}). In the population of pregnant women, FAO/WHO (15) estimated a $r$ parameter of 2.6 × 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 × 10^{5} 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 $5 \times 10^{-11}$ 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 epidemiologic 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/Johns Hopkins 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.

References


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Amend Food Code to Require Detergent for Equipment Cleaning

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 contact.

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

**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 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

(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.

**Submitter Information:**

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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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MS 10-220: Received 25 May 2010/Accepted 27 August 2010

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 ± 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 ± 0.89, 3.64 ± 0.57, and 4.61 ± 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 ± 0.33 and 2.69 ± 0.32 log units, respectively, whereas SaniTwice with 62% EtOH foam, 70% EtOH gel, and 70% BiOH advanced formula gel achieved reductions of 2.87 ± 0.42, 2.99 ± 0.51, and 3.92 ± 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 VP481).

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 ± 0.2. 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 × 10^8 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 nonmedicated 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 × 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 KH_2PO_4, 10.1 g of Na_2HPO_4, and 1.0 g of isooctylphenoxypolyethoxyethanol 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 rinse 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 ± 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 × C_l × 10^l × 2), where 75 is the amount (in milliliters) of stripping solution instilled into each glove, C_l 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

<table>
<thead>
<tr>
<th>Step</th>
<th>Food Code–compliant procedure for hand washing products</th>
<th>SaniTwice procedure for ABHS</th>
<th>Procedure for 70% EtOH AF gel</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Wet hands with water at 40°C</td>
<td>Dispense ~3 ml of product into cupped hands</td>
<td>Dispense ~1.5 ml of product into cupped hands</td>
</tr>
<tr>
<td>2</td>
<td>Apply ~1.5 ml of product</td>
<td>Rub vigorously over hands for 15 s to simulate washing</td>
<td>Rub hands together until dry</td>
</tr>
<tr>
<td>3</td>
<td>Lather for 15 s</td>
<td>Clean thoroughly with two paper towels</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Rinse with water for 10 s</td>
<td>Dispense additional ~1.5 ml of product</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Pat dry with two paper towels</td>
<td>Rub hands together until dry</td>
<td></td>
</tr>
</tbody>
</table>

a All application procedures were initiated within 10 s of completing the 90-s drying step.
b 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 ± 0.89 log CFU/ml for SaniTwice with the 62% EtOH gel to 4.61 ± 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 ± 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 ± 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 ± 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 ± 0.32 and 2.65 ± 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).
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-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 long-standing paradigm defining the use of ABHS in the presence of organic soils in both food handling and health care environments is warranted.

ACKNOWLEDGMENTS
Lakshmi Kamath and Meher Dustoor assisted in the preparation of this manuscript for publication.

REFERENCES
Farm Hand Cleansing

The no-water SaniTwice® solution

Developed originally for military use

1] Apply
Alcohol hand sanitizer generously.

2] Scrub
Vigorously for 15-20 seconds.

3] Wipe
Forcefully with paper towel while hands are wet.

4] Re-apply
Alcohol hand sanitizer per label instructions.

5] Air-dry
For ServeReady™ Hands

Always wash with soap when water is available

OVERCOMING UNDERWASHING

http://handwashingforlife.com

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Hand Hygiene Regimens for the Reduction of Risk in Food Service Environments

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MS 11-449; Received 3 October 2011/Accepted 17 January 2012

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 marine 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 SanTwice 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 gastroenteritis 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

<table>
<thead>
<tr>
<th>Test product</th>
<th>Description</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOJO Luxury Foam Handwash</td>
<td>Nonantimicrobial hand washing product</td>
<td>Nonantimicrobial hand wash</td>
</tr>
<tr>
<td>MICREL Antibacterial Foam Handwash</td>
<td>0.5% Chloroxylenol hand washing product</td>
<td>PCMX hand wash</td>
</tr>
<tr>
<td>GOJO Antibacterial Plum Foam Handwash</td>
<td>0.3% Triclosan hand washing product</td>
<td>Triclosan hand wash</td>
</tr>
<tr>
<td>PURLEL Instant Hand Sanitizer Foam</td>
<td>62% Ethanol foam ABHR</td>
<td>Ethanol foam 62%</td>
</tr>
<tr>
<td>PURLEL Instant Hand Sanitizer Advanced</td>
<td>70% Ethanol gel ABHR</td>
<td>70% EtOH gel</td>
</tr>
</tbody>
</table>

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 ABIR 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 AP) 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 ± 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 × 10⁶ 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
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 $5.0 \times 10^6$ CFU per portion. Each participant then neared 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 KH$_2$PO$_4$, 10.1 g of Na$_2$HPO$_4$, and 1.0 g of isooctylphenoxypolyethoxethanol 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 rinseate 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 ± 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 rinseate 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 ($\leq -60^\circ$C). Frozen viral stocks were thawed on the day of test. The
titer of the stock virus was at least $1 \times 10^7$ TCID$_{50}$ (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 rinseate 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 ± 2°C with 5% ± 1% CO$_2$. The cultures were incubated for another 3 to 6 days at 36 ± 2°C with 5% ± 1% CO$_2$ 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$_{50}$ per milliliter was determined using the Spearman-Karber 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

<table>
<thead>
<tr>
<th>Application procedure</th>
<th>Test products</th>
<th>Mean ± SD E. coli (log CFU/ml)</th>
<th>Baseline recovery</th>
<th>Reduction</th>
<th>Statistical analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wash-sanitize</td>
<td>PCMX hand wash + 62% EtOH foam</td>
<td>7.50 ± 0.19</td>
<td>4.11 ± 0.48</td>
<td>A</td>
<td></td>
</tr>
<tr>
<td>Wash-sanitize</td>
<td>Triclosan hand wash + 62% EtOH foam</td>
<td>7.54 ± 0.13</td>
<td>3.97 ± 0.45</td>
<td>A</td>
<td></td>
</tr>
<tr>
<td>Wash-sanitize</td>
<td>PCMX hand wash + 70% EtOH AF gel</td>
<td>7.53 ± 0.19</td>
<td>4.60 ± 0.52</td>
<td>B</td>
<td></td>
</tr>
<tr>
<td>Wash-sanitize</td>
<td>Triclosan hand wash + 70% EtOH AF gel</td>
<td>7.46 ± 0.19</td>
<td>4.51 ± 0.43</td>
<td>B</td>
<td></td>
</tr>
</tbody>
</table>

* 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.

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

<table>
<thead>
<tr>
<th>Application procedure</th>
<th>Test products</th>
<th>Mean ± SD MNV (log TCID50/ml)</th>
<th>Baseline recovery</th>
<th>Reduction</th>
<th>Statistical analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wash</td>
<td>Nonantimicrobial hand wash</td>
<td>6.98 ± 0.20</td>
<td>1.79 ± 0.29</td>
<td>A</td>
<td></td>
</tr>
<tr>
<td>Sanitize</td>
<td>70% EtOH AF gel</td>
<td>2.60 ± 0.41</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wash-sanitize</td>
<td>Nonantimicrobial hand wash + 70% EtOH AF gel</td>
<td>3.19 ± 0.31</td>
<td></td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>SaniTwice</td>
<td>70% EtOH AF gel</td>
<td>4.04 ± 0.33</td>
<td></td>
<td>D</td>
<td></td>
</tr>
</tbody>
</table>

* 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.

ACKNOWLEDGMENT

Ruth Carol assisted as a technical editor in the preparation of this manuscript.

REFERENCES


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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MS 15-102: Received 6 March 2015/Accepted 9 July 2015

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 (A600)) 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 A600, 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” (59). However, soil on farmworker hands may limit the ability of hand washing to remove or inactivate microbes. Thus, it is important to address the hypothesis that hand washing with soap is the most efficacious hygiene intervention for the agricultural envi-
enronment. 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-hygience 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 (nonantibacterial 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 (Servisota 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 then 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 rinseate 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
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 rinsate 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 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 (Sequioa 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, herein called indicator bacteria. Serial volumes of each hand rinse sample (100 µl, 1 ml, and 10 ml) were filtered through separate 0.45-µm-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 prefilled 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

<table>
<thead>
<tr>
<th>Groupa</th>
<th>Coliforms</th>
<th>Enterococcus spp.</th>
<th>E. coli</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>30/42 (71)</td>
<td>41/42 (98)</td>
<td>10/42 (24)</td>
</tr>
<tr>
<td>Label-use ABHS</td>
<td>28/34 (82)</td>
<td>31/34 (91)</td>
<td>2/34 (6)</td>
</tr>
<tr>
<td>Two-step ABHS</td>
<td>21/35 (60)c</td>
<td>28/35 (80)</td>
<td>0/35 (0)d</td>
</tr>
<tr>
<td>Traditional soap</td>
<td>28/35 (80)</td>
<td>31/35 (89)</td>
<td>2/35 (6)</td>
</tr>
<tr>
<td>Pumice soap</td>
<td>35/35 (100)d</td>
<td>35/35 (100)</td>
<td>1/35 (3)</td>
</tr>
</tbody>
</table>

a 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.
b Values are for hand rinsate samples tested for the given indicator bacteria within each study group.
c Result is significantly different from the result for the pumice soap group (p = 0.05).
d Result is significantly different from the result for the control group (p = 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 (72) 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 χ² test (9) and Bonferroni correction (17) were used. To compare A600 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) 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 95 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 A600 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, A600 0.05 to 1.36); soil-based interventions (range, A600 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 rinsates collected immediately after performing hand hygiene. a, significantly different from the control group (α = 0.05); b, significantly different from the label-use ABHS and pumice soap groups (α = 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.
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 (~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

We thank the farmers for their collaboration. We also thank Nereida Rivera, Roberto Blancaes, and Aldo Galván from Universidad Autónoma de Nuevo León for the collection and processing of samples and Sanemba Aya Fanny, Valerie Morrill, Carol Ochoa, Vidyasha Singh, and Amelia Van Pelt at Emory University for data entry. This project was financially supported by GOJO Industries, Inc., through an unrestricted research grant to cover partial salary for the effort of the study team, study supplies, and communication of results. Both Emory University and UANL covered the remainder of staff salary through internal funding and government fellowships and subsidies. UANL-affiliated authors provided significant input into the overall study design, data collection, and editing of the manuscript. Emory-affiliated authors provided significant input into the overall study design, data analysis, and writing of the manuscript. GOJO-affiliated authors provided significant input into the overall study design, choice of hygiene products evaluated, creation of Figure 1, and editing of the manuscript. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

REFERENCES

Conference for Food Protection  
2020 Issue Form

Issue: 2020 III-022

Council Recommendation:
Accepted as Submitted _____ Amended _____ No Action _____

Delegate Action:
Accepted _____ Rejected _____

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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"

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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.
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

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.
M. Susana Yepiz-Gomez, Kelly R. Bright, and Charles P. Gerba

The University of Arizona, Dept. of Soil, Water and Environmental Science, Tucson, AZ 85721, USA

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
Greater numbers of bacteria were found on tabletops that had been cleaned with a dishcloth than before cleaning (Fig.1.5.3). Approximately 3.56x10^3 cfu/156 cm^2 heterotrophic plate count bacteria were found before cleaning. This number increased to 1.6x10^5 cfu/156 cm^2 (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^2) and E. coli (<1 to 2.3 cfu/156 cm^2) following cleaning.

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.
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;

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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December 6, 2019

Chip Manuel PhD
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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 sanitation. 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
Issue: 2020 III-024

Council Recommendation: 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." 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.

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. 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 or A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems.

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. 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."

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. 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).” The statements from these authoritative bodies concurs with studies that have shown monosodium glutamate utility in flavor enhancement and sodium reduction.

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 benifits"

Supporting Attachments:
  • "Reference on MSG sodium reduction benifits"

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: 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/cfcfr/CFRSearch.cfm?fr=182.1


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).
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
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.
References

Academy of Dietetics and Nutrition. Without sacrificing taste, what is the effect of adding umami compounds (such as monosodium glutamate [MSG]) or foods rich in umami (such as soy sauce, fish sauce, etc.) on the sodium content in foods and/or sodium intake? Evidence Analysis Library, 2013.


Amend definition of TCS to include caramel apples with an inserted stick

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 \textit{L. monocytogenes}. In addition, the apple supplier that provided apples to each of these manufacturers recalled apples implicated in the outbreak.

\textit{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 \textit{Salmonella} or \textit{Escherichia coli} O157) (Scallan et al, 2011). Persons who have the greatest risk of experiencing listeriosis after consuming foods contaminated with \textit{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 \textit{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 \textit{L. monocytogenes} (Codex, 2007). For example, \textit{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 \textit{L. monocytogenes} can grow slowly during refrigerated storage and, thus, refrigeration is less effective as a control measure for \textit{L. monocytogenes} than for other foodborne pathogens (such as \textit{Salmonella}), \textit{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 \textit{L. monocytogenes} (Glass et al., 2015). However, research on the survival and growth of \textit{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 \textit{L. monocytogenes} can occur at room temperature (Glass et al. 2015; Salazar et al., 2016). \textit{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). \textit{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, \textit{L. monocytogenes} increased by several logs in caramel apples with an inserted stick (Glass et al. 2015; Salazar et al., 2016). \textit{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..."

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 Investigated Listeria monocytogenes Illnesses Linked to Caramel Apples

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.

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.

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...
Outbreaks > FDA Investigated Listeria monocytogenes Illnesses Linked to Caramel Apples

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

*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 sanitation process.

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.

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.

Consumers with questions about the Merb's Candies recall may contact the firm at 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](http://www.fda.gov).

**back to top**

*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](http://www.cdc.gov/vitalsigns/listeria)
- [FoodSafety.gov on Listeria](http://www.foodsafety.gov)
- [CDC Web Page](http://www.cdc.gov)
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)](https://www.fda.gov) 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
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 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

December 31, 2014

December 22, 2014

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.
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.
### Outbreaks

<table>
<thead>
<tr>
<th>Outbreak</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hard-boiled Eggs</td>
<td>Outbreak of <em>Listeria</em> Infections Linked to Hard-boiled Eggs</td>
</tr>
<tr>
<td>Deli-Sliced Products</td>
<td>Outbreak of <em>Listeria</em> Infections Linked to Deli-Sliced Products</td>
</tr>
<tr>
<td>Pork Products</td>
<td>Outbreak of Listeria Infection Linked to Pork Products</td>
</tr>
<tr>
<td>Deli Ham</td>
<td>Outbreak of Listeria Infections Linked to Deli Ham</td>
</tr>
<tr>
<td>Vulto Creamery</td>
<td>Soft Raw Milk Cheese Made by Vulto Creamery</td>
</tr>
<tr>
<td>Frozen Vegetables</td>
<td>Listeriosis Linked to Frozen Vegetables</td>
</tr>
<tr>
<td>Raw Milk</td>
<td>Listeriosis Linked to Raw Milk</td>
</tr>
<tr>
<td>Dole Ohio Facility</td>
<td>Packaged Salads Produced at Dole Ohio Facility</td>
</tr>
<tr>
<td>Karoun Dairies, Inc.</td>
<td>Soft Cheeses Distributed by Karoun Dairies, Inc.</td>
</tr>
<tr>
<td>Blue Bell Creameries</td>
<td>Ice Cream Products</td>
</tr>
</tbody>
</table>

### Commercially Produced, Prepackaged Caramel Apples

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall &amp; Advice to Consumers</td>
<td></td>
</tr>
<tr>
<td>Advice to Consumers en Español</td>
<td></td>
</tr>
<tr>
<td>Case Count Maps</td>
<td></td>
</tr>
<tr>
<td>Epi Curves</td>
<td></td>
</tr>
<tr>
<td>Signs &amp; Symptoms</td>
<td></td>
</tr>
<tr>
<td>Key Resources</td>
<td></td>
</tr>
<tr>
<td>Oasis Brands, Inc. Cheese</td>
<td></td>
</tr>
</tbody>
</table>
SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES .......................................................... 7

SECTION III - PRIMARY PRODUCTION ............................................................................................... 7

SECTION I - Objectives ................................................................................................................................. 6

SECTION II - SCOPE .................................................................................................................................... 6

INTRODUCTION ........................................................................................................................................... 4

2.1 Scope ..................................................................................................................................................... 6

2.2 Definitions ............................................................................................................................................. 6

3.1 Environmental hygiene .......................................................................................................................... 7

3.2 Hygienic production of food sources ..................................................................................................... 7

3.3 Handling, storage and transport .......................................................................................................... 7

3.4. Cleaning, maintenance and personnel hygiene at primary production .............................................. 7

4.1 Location ................................................................................................................................................. 8

4.1.1 Establishments ................................................................................................................................ 8

4.1.2 Equipment ....................................................................................................................................... 8

4.2 Premises and rooms ............................................................................................................................. 8

4.2.1 Design and layout .............................................................................................................................. 8

4.2.2 New construction/renovations ......................................................................................................... 8

4.2.3 Temporary/mobile premises and vending machines ....................................................................... 8

4.3 Equipment ........................................................................................................................................... 8

4.3.1 General ............................................................................................................................................ 8

4.3.2 Food control and monitoring equipment ......................................................................................... 9

4.3.3 Containers for waste and inedible substances ................................................................................. 9

4.4 Facilities ............................................................................................................................................. 9

4.4.1 Water supply ................................................................................................................................ 9

4.4.2 Drainage and waste disposal ........................................................................................................... 9

4.4.3 Cleaning .......................................................................................................................................... 9

4.4.4 Personnel hygiene facilities and toilets ........................................................................................... 9

4.4.5 Temperature control ......................................................................................................................... 9

4.4.6 Air quality and ventilation ............................................................................................................... 9

4.4.7 Lighting ....................................................................................................................................... 9

4.4.8 Storage ........................................................................................................................................ 9

5.1 Control of the food hazard .................................................................................................................... 10

5.2 Key aspects of hygiene control systems ............................................................................................. 10

5.2.1 Time and temperature control ........................................................................................................ 10

5.2.2 Specific process steps ....................................................................................................................... 10

5.2.3 Microbiological and other specifications ......................................................................................... 11

5.2.4 Microbiological cross-contamination ............................................................................................... 11

5.2.5 Physical and chemical contamination ................................................................. 11
5.3 INCOMING MATERIAL REQUIREMENTS .............................................................. 11
5.4 PACKAGING .......................................................................................................... 11
5.5 WATER ..................................................................................................................... 11
  5.5.1 In contact with food ......................................................................................... 12
  5.5.2 As an ingredient ............................................................................................... 12
  5.5.3 Ice and steam .................................................................................................. 12
5.6 MANAGEMENT AND SUPERVISION .................................................................. 12
5.7 DOCUMENTATION AND RECORDS ................................................................. 12
5.8 RECALL PROCEDURES ....................................................................................... 12
5.9 MONITORING OF EFFECTIVENESS OF CONTROL MEASURES FOR L. MONOCYTOGENES ... 12

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION ......................... 12
  6.1 MAINTENANCE AND CLEANING........................................................................ 13
    6.1.1 General .......................................................................................................... 13
    6.1.2 Cleaning procedures and methods ................................................................. 13
  6.2 CLEANING PROGRAMS ...................................................................................... 14
  6.3 PEST CONTROL SYSTEMS ................................................................................ 14
    6.3.1 General .......................................................................................................... 14
    6.3.2 Preventing access .......................................................................................... 14
    6.3.3 Harbourage and infestation ......................................................................... 14
    6.3.4 Monitoring and detection ............................................................................. 14
    6.3.5 Eradication .................................................................................................... 14
  6.4 WASTE MANAGEMENT ....................................................................................... 14
  6.5 MONITORING EFFECTIVENESS ...................................................................... 14

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE ..................................... 14
  7.1 HEALTH STATUS .................................................................................................. 15
  7.2 ILLNESS AND INJURIES .................................................................................... 15
  7.3 PERSONAL CLEANLINESS ................................................................................. 15
  7.4 PERSONAL BEHAVIOUR ................................................................................... 15
  7.5 VISITORS ............................................................................................................ 15

SECTION VIII – TRANSPORTATION ................................................................... 15
  8.1 GENERAL ............................................................................................................ 15
  8.2 REQUIREMENTS ................................................................................................ 15
  8.3 USE AND MAINTENANCE ................................................................................ 16

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS .................. 16
  9.1 LOT IDENTIFICATION .......................................................................................... 16
  9.2 PRODUCT INFORMATION ............................................................................... 16
  9.3 LABELLING ......................................................................................................... 16
  9.4 CONSUMER EDUCATION .................................................................................. 16

SECTION X - TRAINING ....................................................................................... 17
  10.1 AWARENESS AND RESPONSIBILITIES ......................................................... 17
  10.2 TRAINING PROGRAMS .................................................................................... 17
  10.3 INSTRUCTION AND SUPERVISION ............................................................... 17
  10.4 REFRESHER TRAINING .................................................................................... 17
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. 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. 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.

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)³, (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 Hygiene⁴, and (3) a product/process pathway analysis conducted by the U.S. Food Safety and Inspection Service for processed meats⁵, 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)³.

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.

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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\(^6\) 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 \(L.\) \textit{monocytogenes} can grow and formulation of products with hurdles to \(L.\) \textit{monocytogenes} growth can minimise the risk of listeriosis.

5.1 CONTROL OF THE FOOD HAZARD

Control of \(L.\) \textit{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 \(L.\) \textit{monocytogenes}.

The factors and attributes described below are components of Good Hygienic Practice programs that will typically require elevated attention to control \(L.\) \textit{monocytogenes} and may be identified as critical control points in HACCP programs where \(L.\) \textit{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 \(L.\) \textit{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 \(L.\) \textit{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 \(L.\) \textit{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 \(L.\) \textit{monocytogenes} growth. The shelf-life of such foods should be consistent with the need to control the growth of \(L.\) \textit{monocytogenes}. Since \(L.\) \textit{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 \(L.\) \textit{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 \(L.\) \textit{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 \(L.\) \textit{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 \(L.\) \textit{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 \(L.\) \textit{monocytogenes} growth. Alternatively, a post-packaging listericidal treatment may be necessary (e.g. heating, high pressure treatment, irradiation, where accepted).

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\(^6\) 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


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 \textit{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 \textit{L. MONOCYTOGENES}
An effective environmental monitoring program is an essential component of a \textit{Listeria} control program, particularly in establishments that produce ready-to-eat foods that support growth and may contain \textit{L. monocytogenes}. Testing of food products can be another component of verification that control measures for \textit{L. monocytogenes} are effective (see Section 5.2.3).

Recommendations for the design of an environmental monitoring program for \textit{L. monocytogenes} in processing areas are given in Annex 1.

**SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION**

<table>
<thead>
<tr>
<th>Objectives:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To provide specific guidance on how preventive maintenance and sanitation procedures, along with an effective environmental monitoring program can reduce contamination of food with \textit{L. monocytogenes}, particularly when the foods support growth of \textit{L. monocytogenes}:</td>
</tr>
<tr>
<td>Well structured cleaning and disinfection procedures should be targeted against \textit{L. monocytogenes} in food processing areas where ready-to-eat foods are exposed to reduce</td>
</tr>
<tr>
<td>• the likelihood that the product will be contaminated after processing,</td>
</tr>
<tr>
<td>• the level of contamination in the finished product.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Rationale:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic cleaning and disinfection programs are critical to assuring control of \textit{L. monocytogenes}. An environmental monitoring program for \textit{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.</td>
</tr>
</tbody>
</table>
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 \textit{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 \textit{L. monocytogenes} contamination have been linked, in particular, to insufficient manual scrubbing during the cleaning process.

Research and experience further indicates that \textit{L. monocytogenes} does not possess an unusual ability to resist disinfectants or attach to surfaces. However, it is noted that \textit{L. monocytogenes} has the ability to form biofilms on a variety of surfaces.

Solid forms of disinfectants (e.g., blocks of quaternary 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 \textit{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 \textit{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**

<table>
<thead>
<tr>
<th>Objectives:</th>
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<tbody>
<tr>
<td>Measures should be taken where necessary to:</td>
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<tr>
<td>- protect food from potential sources of contamination including harbourage sites for <em>L. monocytogenes</em> in transportation equipment and to prevent the co-mingling of raw and ready-to-eat product;</td>
</tr>
<tr>
<td>- provide an adequately refrigerated environment (so that product temperature should not exceed 6°C, preferably 2°C - 4°C).</td>
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</tbody>
</table>

**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. 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;

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7 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 \textit{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 \textit{L. monocytogenes} is considerably reduced at temperatures below 6°C;
  - frequently washing and disinfecting the household refrigerator since \textit{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.

\textbf{SECTION X - TRAINING}

\begin{tabular}{|p{1\textwidth}|}
\hline
\textbf{Objective:} \hfill \\
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 \textit{L. monocytogenes} to a level appropriate to the operations they are to perform.
\hline
\textbf{Rationale:} \hfill \\
Controls specific to \textit{L. monocytogenes} are generally more stringent than routine Good Hygiene Practices.
\hline
\end{tabular}

\textbf{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 \textit{L. monocytogenes}.

\textbf{10.2 TRAINING PROGRAMS}

Personnel involved with the production and handling of ready-to-eat food should have appropriate training in:

- the nature of \textit{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 \textit{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;

\textbf{10.3 INSTRUCTION AND SUPERVISION}

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

\textbf{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 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 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.

**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 subheading "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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8 Environmental monitoring is not to be confused with monitoring as defined in the HACCP.

9 Products such as in pack pasteurised foods which are not further exposed to environment may not necessarily require a monitoring.

10 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 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 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. In this instance, microbiological criteria are implemented for those products and/or points of the food chain when other more information is needed.
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\textsuperscript{14}. 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 \textit{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 \textit{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 \textit{L. monocytogenes} may not be useful for:

\begin{enumerate}
\item[(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,
\item[(b)] foods that are aseptically processed and packaged\textsuperscript{15}, and
\item[(c)] products that contain a listericidal component that ensures rapid inactivation of the pathogen if recontaminated (e.g., products that contain > 5 \% ethanol)
\end{enumerate}

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 \textit{L. monocytogenes}, hence different microbiological criteria could apply for the following categories of foods:

\begin{enumerate}
\item[(a)] ready-to-eat foods in which growth of \textit{L. monocytogenes} will not occur, and
\item[(b)] ready-to-eat foods in which growth of \textit{L. monocytogenes} can occur.
\end{enumerate}

### 3.1 Ready-To-Eat foods in which growth of \textit{L. monocytogenes} will not occur

Ready-to-eat foods in which growth of \textit{L. monocytogenes} will not occur would be determined based on scientific justification\textsuperscript{16}, including the inherent variability of factors controlling \textit{L. monocytogenes} in the

\textsuperscript{14} See: Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

\textsuperscript{15} 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\(^\text{17}\).

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\(^\text{18}\) 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\(^\text{18}\) 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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\(^{16}\) 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).

\(^{17}\) See: Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008).

\(^{18}\) 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

<table>
<thead>
<tr>
<th>Point of application</th>
<th>Microorganism</th>
<th>n</th>
<th>c</th>
<th>m</th>
<th>Class Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale</td>
<td>Listeria monocytogenes</td>
<td>5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0</td>
<td>100 cfu/g&lt;sup&gt;b&lt;/sup&gt;</td>
<td>2&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

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 10000 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:

<table>
<thead>
<tr>
<th>Point of application</th>
<th>Microorganism</th>
<th>n</th>
<th>c</th>
<th>m</th>
<th>Class Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale</td>
<td><em>Listeria monocytogenes</em></td>
<td>5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0</td>
<td>Absence in 25 g (&lt; 0.04 cfu/g)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>2&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<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\(^{19}\) 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.

\(^{19}\) 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.
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, 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) and online Technical Appendix 1 (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
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 and 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 (FoodNet) 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 system for toxigenic Vibrio cholerae, V. vulnificus, V. parahemolyticus, 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*

<table>
<thead>
<tr>
<th>Pathogens for which laboratory-confirmed illnesses were scaled up</th>
<th>Pathogens for which US population was scaled down</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active surveillance data</td>
<td>Passive surveillance data</td>
</tr>
<tr>
<td>Cryptosporidium spp.</td>
<td>Cyclospora cayetanensis</td>
</tr>
</tbody>
</table>

*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.
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). 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., 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 (≥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).
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 Appendix 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). 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). 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 1,123–1,651) were caused by contaminated food eaten in the United States (Table 4; expanded version available online, www.cdc.gov/EID/content/17/1/7-T4.htm). Of these, 91% were caused by bacteria, 8% by viruses, and 1% by parasites.

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 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*

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Laboratory confirmed</th>
<th>Under-reporting</th>
<th>Under-diagnosis</th>
<th>Travel related, %</th>
<th>Foodborne, %†</th>
<th>Domestically acquired foodborne, mean (90% credible interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacteria</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bacillus cereus</em>, foodborne</td>
<td>85‡</td>
<td>25.5</td>
<td>29.3</td>
<td>&lt;1</td>
<td>100</td>
<td>63,400 (15,719–147,354)</td>
</tr>
<tr>
<td><em>Brucella</em> spp.</td>
<td>120§</td>
<td>1.1</td>
<td>15.2</td>
<td>16</td>
<td>50</td>
<td>839 (533–1,262)</td>
</tr>
<tr>
<td><em>Campylobacter</em> spp.</td>
<td>43,696¶</td>
<td>1.0</td>
<td>30.3</td>
<td>20</td>
<td>80</td>
<td>845,024 (337,031–1,611,083)</td>
</tr>
<tr>
<td><em>Clostridium botulinum</em>, foodborne</td>
<td>25§</td>
<td>1.1</td>
<td>2.0</td>
<td>&lt;1</td>
<td>100</td>
<td>55 (34–91)</td>
</tr>
<tr>
<td><em>Clostridium perfringens</em>, foodborne</td>
<td>1,295‡</td>
<td>25.5</td>
<td>29.3</td>
<td>&lt;1</td>
<td>100</td>
<td>965,958 (192,316–2,483,309)</td>
</tr>
<tr>
<td><em>STEC O157</em></td>
<td>3,704¶</td>
<td>1.0</td>
<td>26.1</td>
<td>4</td>
<td>68</td>
<td>63,153 (17,587–149,631)</td>
</tr>
<tr>
<td><em>STEC non-O157</em></td>
<td>1,579¶</td>
<td>1.0</td>
<td>106.8</td>
<td>18</td>
<td>82</td>
<td>112,752 (11,467–287,321)</td>
</tr>
<tr>
<td><em>ETEC, foodborne</em></td>
<td>53§</td>
<td>25.5</td>
<td>29.3</td>
<td>55</td>
<td>100</td>
<td>17,894 (24–46,212)</td>
</tr>
<tr>
<td><em>Diarrheagenic E. coli</em> other than STEC and ETEC</td>
<td>53</td>
<td>25.5</td>
<td>29.3</td>
<td>&lt;1</td>
<td>30</td>
<td>11,982 (16–30,913)</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>808¶</td>
<td>1.0</td>
<td>2.1</td>
<td>3</td>
<td>99</td>
<td>1,591 (557–3,161)</td>
</tr>
<tr>
<td><em>Mycobacterium bovis</em></td>
<td>195§</td>
<td>1.0</td>
<td>1.1</td>
<td>70</td>
<td>95</td>
<td>60 (46–74)</td>
</tr>
<tr>
<td><em>Salmonella</em> spp., nontyphoidal</td>
<td>41,930¶</td>
<td>1.0</td>
<td>29.3</td>
<td>11</td>
<td>94</td>
<td>1,027,561 (644,786–1,679,667)</td>
</tr>
<tr>
<td><em>S. enterica</em> serotype Typhi</td>
<td>433¶</td>
<td>1.0</td>
<td>13.3</td>
<td>67</td>
<td>96</td>
<td>1,821 (87–5,522)</td>
</tr>
<tr>
<td><em>Shigella</em> spp.</td>
<td>14,864¶</td>
<td>1.0</td>
<td>33.3</td>
<td>15</td>
<td>31</td>
<td>131,254 (24,511–374,789)</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em>, foodborne</td>
<td>323§</td>
<td>25.5</td>
<td>29.3</td>
<td>&lt;1</td>
<td>100</td>
<td>241,148 (72,341–529,417)</td>
</tr>
<tr>
<td><em>Vibrio cholerae</em>, toxigenic</td>
<td>8§</td>
<td>1.1</td>
<td>33.1</td>
<td>70</td>
<td>100</td>
<td>84 (19–213)</td>
</tr>
<tr>
<td><em>V. vulnificus</em></td>
<td>111§</td>
<td>1.1</td>
<td>1.7</td>
<td>2</td>
<td>47</td>
<td>96 (60–139)</td>
</tr>
<tr>
<td><em>V. parahaemolyticus</em></td>
<td>287§</td>
<td>1.1</td>
<td>142.4</td>
<td>10</td>
<td>86</td>
<td>34,664 (18,280–58,027)</td>
</tr>
<tr>
<td><em>Vibrio</em>, other</td>
<td>220§</td>
<td>1.1</td>
<td>142.7</td>
<td>11</td>
<td>57</td>
<td>17,564 (10,848–26,475)</td>
</tr>
<tr>
<td><em>Yersinia enterocolitica</em></td>
<td>950¶</td>
<td>1.0</td>
<td>122.8</td>
<td>7</td>
<td>90</td>
<td>97,656 (30,388–172,734)</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3,645,773 (2,321,468–5,581,290)</td>
</tr>
<tr>
<td><strong>Parasites</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Cryptosporidium</em> spp.</td>
<td>7,594¶</td>
<td>1.0</td>
<td>98.6</td>
<td>9</td>
<td>8</td>
<td>57,616 (12,060–166,771)</td>
</tr>
<tr>
<td><em>Cyclospora cayetanensis</em></td>
<td>239¶</td>
<td>1.0</td>
<td>83.1</td>
<td>42</td>
<td>99</td>
<td>11,407 (137–37,673)</td>
</tr>
<tr>
<td><em>Giardia intestinalis</em></td>
<td>20,305§</td>
<td>1.3</td>
<td>46.3</td>
<td>8</td>
<td>7</td>
<td>76,840 (51,148–109,739)</td>
</tr>
<tr>
<td><em>Toxoplasma gondii</em></td>
<td>1.0</td>
<td>0.0</td>
<td>&lt;1</td>
<td>50</td>
<td></td>
<td>86,688 (64,861–111,912)</td>
</tr>
<tr>
<td><em>Trichinella</em> spp.</td>
<td>13§</td>
<td>1.3</td>
<td>9.8</td>
<td>4</td>
<td>100</td>
<td>156 (42–341)</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>232,705 (161,923–369,893)</td>
</tr>
<tr>
<td><strong>Viruses</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Astrovirus</em></td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>0</td>
<td>&lt;1</td>
<td>15,433 (5,569–26,643)</td>
</tr>
<tr>
<td><em>Hepatitis A virus</em></td>
<td>3,576§</td>
<td>1.1</td>
<td>9.1</td>
<td>41</td>
<td>7</td>
<td>1,566 (702–3,024)</td>
</tr>
<tr>
<td><em>Norovirus</em></td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>&lt;1</td>
<td>26</td>
<td>5,461,731 (3,227,078–8,309,480)</td>
</tr>
<tr>
<td><em>Rotavirus</em></td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>0</td>
<td>&lt;1</td>
<td>15,433 (5,569–26,643)</td>
</tr>
<tr>
<td><em>Sapovirus</em></td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>0</td>
<td>&lt;1</td>
<td>15,433 (5,569–26,643)</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5,509,597 (3,273,623–8,355,568)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9,388,075 (6,641,440–12,745,709)</td>
</tr>
</tbody>
</table>

*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) 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).
†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*.
**RESEARCH**

**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**

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Hospitalization rate, %†</th>
<th>Hospitalizations, mean (90% credible interval)</th>
<th>Death rate, %†</th>
<th>Deaths, mean (90% credible interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacteria</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bacillus cereus</em>, foodborne‡</td>
<td>0.4</td>
<td>20 (0–85)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><em>Brucella</em> spp.</td>
<td>55.0</td>
<td>55 (33–84)</td>
<td>0.9</td>
<td>1 (0–2)</td>
</tr>
<tr>
<td><em>Campylobacter</em> spp.</td>
<td>17.1</td>
<td>8,463 (4,300–15,227)</td>
<td>0.1</td>
<td>76 (0–332)</td>
</tr>
<tr>
<td><em>Clostridium botulinum</em>, foodborne‡</td>
<td>82.6</td>
<td>42 (19–77)</td>
<td>17.3</td>
<td>9 (0–51)</td>
</tr>
<tr>
<td><em>Clostridium perfringens</em>, foodborne‡</td>
<td>0.6</td>
<td>438 (44–2,008)</td>
<td>&lt;0.1</td>
<td>26 (0–163)</td>
</tr>
<tr>
<td>STEC O157</td>
<td>46.2</td>
<td>2,138 (549–4,614)</td>
<td>0.5</td>
<td>20 (0–113)</td>
</tr>
<tr>
<td>STEC non-O157</td>
<td>12.8</td>
<td>271 (0–971)</td>
<td>0.3</td>
<td>0 (0–0)§</td>
</tr>
<tr>
<td>ETEC, foodborne</td>
<td>0.8</td>
<td>12 (0–53)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Diarrheagenic <em>E. coli</em> other than STEC and ETEC</td>
<td>0.8</td>
<td>8 (0–36)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>94.0</td>
<td>1,455 (521–3,018)</td>
<td>15.9</td>
<td>255 (0–733)</td>
</tr>
<tr>
<td><em>Mycobacterium bovis</em></td>
<td>55.0</td>
<td>31 (21–42)</td>
<td>4.7</td>
<td>3 (2–3)</td>
</tr>
<tr>
<td><em>Salmonella</em> spp., nontyphoidal</td>
<td>27.2</td>
<td>19,336 (8,545–37,490)</td>
<td>0.5</td>
<td>378 (0–1,011)</td>
</tr>
<tr>
<td><em>S. enterica</em> serotype Typhi</td>
<td>75.7</td>
<td>197 (0–583)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><em>Shigella</em> spp.</td>
<td>20.2</td>
<td>1,456 (287–3,695)</td>
<td>0.1</td>
<td>10 (0–67)</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em>, foodborne‡</td>
<td>6.4</td>
<td>1,064 (173–2,997)</td>
<td>&lt;0.1</td>
<td>6 (0–48)</td>
</tr>
<tr>
<td><em>Streptococcus</em> spp. group A, foodborne‡</td>
<td>0.2</td>
<td>1 (0–6)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><em>Vibrio cholerae</em>, toxigenic</td>
<td>43.1</td>
<td>2 (0–5)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>V. vulnificus</td>
<td>91.3</td>
<td>93 (53–145)</td>
<td>34.8</td>
<td>36 (19–57)</td>
</tr>
<tr>
<td>V. parahaemolyticus</td>
<td>22.5</td>
<td>100 (50–169)</td>
<td>0.9</td>
<td>4 (0–17)</td>
</tr>
<tr>
<td><em>Vibrio</em> spp., other</td>
<td>37.1</td>
<td>83 (51–124)</td>
<td>3.7</td>
<td>8 (3–19)</td>
</tr>
<tr>
<td><em>Yersinia enterocolitica</em></td>
<td>34.4</td>
<td>533 (0–1,173)</td>
<td>2.0</td>
<td>29 (0–173)</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>35,796</td>
<td>(21,519–53,414)</td>
<td>861 (260–1,761)</td>
<td></td>
</tr>
<tr>
<td><strong>Parasites</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Cryptosporidium</em> spp.</td>
<td>25.0</td>
<td>210 (58–518)</td>
<td>0.3</td>
<td>4 (0–19)</td>
</tr>
<tr>
<td><em>Cyclospora</em> cayetanensis</td>
<td>6.5</td>
<td>11 (0–109)</td>
<td>0.0</td>
<td>0</td>
</tr>
<tr>
<td><em>Giardia intestinalis</em></td>
<td>8.8</td>
<td>225 (141–325)</td>
<td>0.1</td>
<td>2 (1–3)</td>
</tr>
<tr>
<td><em>Toxoplasma gondii</em></td>
<td>2.6</td>
<td>4,428 (2,634–6,674)</td>
<td>0.2</td>
<td>327 (200–482)</td>
</tr>
<tr>
<td><em>Trichinella</em> spp.</td>
<td>24.3</td>
<td>6 (0–17)</td>
<td>0.2</td>
<td>0 (0–0)</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>4,881</td>
<td>(3,060–7,146)</td>
<td>333 (205–488)</td>
<td></td>
</tr>
<tr>
<td><strong>Viruses</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Astrovirus</em></td>
<td>0.4</td>
<td>87 (32–147)</td>
<td>&lt;0.1</td>
<td>0</td>
</tr>
<tr>
<td>Hepatitis A virus</td>
<td>31.5</td>
<td>99 (42–193)</td>
<td>2.4</td>
<td>7 (3–15)</td>
</tr>
<tr>
<td>Norovirus</td>
<td>0.03</td>
<td>14,663 (8,097–23,323)</td>
<td>&lt;0.1</td>
<td>149 (84–237)</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>1.7</td>
<td>348 (128–586)</td>
<td>&lt;0.1</td>
<td>0</td>
</tr>
<tr>
<td>Sapovirus</td>
<td>0.4</td>
<td>87 (32–147)</td>
<td>&lt;0.1</td>
<td>0</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>15,284</td>
<td>(8,719–23,962)</td>
<td>157 (91–245)</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>55,961</td>
<td>(39,534–75,741)</td>
<td>1,351 (712–2,268)</td>
<td></td>
</tr>
</tbody>
</table>

*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/T3.htm).
†For laboratory-confirmed illnesses. Unadjusted hospitalization and death rates are presented here. These rates were doubled to adjust for undiagnosis 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.

Acknowledgments

We thank Tracy Ayers, Michael J. Beach, John Besser, Elizabeth Bosserman, Christopher R Braden, Anthony E. Fiore, Kelly A. Jackson, Rebecca Hall, Erin Hedican, Barbara L. Herwaldt, Scott D. Holmberg, Martha Iwamoto, Philip LoBue, Michael F. Lynch, Eric D. Mintz, John A. Painter, Ian T. Williams, Patricia A. Yu, and David L. Swerdlow for providing data and expert advice for these estimates. We also thank Barbara Mahon for reviewing the manuscript and the anonymous reviewers for helpful suggestions.

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References


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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

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.

**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. Derivations of *L. monocytogenes* dose-response relationships, though crucially important for risk assessment and risk management, are impaired by the difficulties 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.

Two well-accepted *L. monocytogenes* dose-response models have been developed by U.S. agencies and an international expert panel, 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.
Department of Agriculture published a joint risk assessment for \textit{L. monocytogenes} in 23 selected categories of ready-to-eat (RTE) foods.\textsuperscript{(4)} 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 \textit{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 \textit{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\textsubscript{50}) observed in mice challenged with different \textit{L. monocytogenes} strains was subsequently incorporated in the dose-response model to characterize \textit{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.\textsuperscript{(4)}

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.\textsuperscript{(6)} The exponential dose-response model is a “single-hit” model:\textsuperscript{(6,7)} it assumes that the probability of a given bacterial cell causing the adverse effect is independent of the number or characteristics 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.\textsuperscript{(8)}

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 \( f(r) \).\textsuperscript{(9)} 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 \textit{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\textsuperscript{(9)} and food exposure\textsuperscript{(10)} 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.\textsuperscript{(11-14)}

Since 2004, new scientific data have become available, demonstrating the considerable variability in virulence among \textit{L. monocytogenes} strains and molecular subtypes.\textsuperscript{(15-18)} New data have, for example, shown that the entry of \textit{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.\textsuperscript{(19-22)} Therefore, point mutations in the \textit{inlA} gene can lead to virulence attenuation of \textit{L. monocytogenes} strains.\textsuperscript{(16,21,24)} 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.\textsuperscript{(25-28)} The relative risk of listeriosis for pregnant women, for example, has been estimated to be approximately 100 times higher than
that for nonpregnant women. 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.

Because of the challenges in developing adequate dose-response models of listeriosis, an interagency 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 by incorporating new data and insights about differences in strain virulence and L. monocytogenes pathophysiology. A key-events approach to dose-response modeling was identified as a promising though extremely challenging, data-intensive, and potentially unachievable framework for future microbial dose-response models.

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. 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 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. Unlike other foodborne pathogens such as Salmonella, Campylobacter, or norovirus, L. monocytogenes is characterized by an extremely low probability of illness at low exposure doses when averaging across the total population or broadly defined population subgroups and by extreme variability in the probability of infection among population subgroups with different predisposing risk factors. Two dose-response models are evaluated and compared here in light of the unique challenges associated with modeling L. monocytogenes dose response. 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 (also known as “hypergeometric” or “actual beta-Poisson” dose-response relation), which may be simplified to an approximate “beta-Poisson” model if certain conditions are met. 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. 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:

\[ P(\text{ill}; d, r) = 1 - (1 - r)^d, \]

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, 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. 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
L. monocytogenes Dose-Response Variability

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:

$$P(\text{ill}; d, \theta) = \int_{0}^{1} (1 - \exp(-rd)) f(r; \theta) \, dr. \quad (2)$$

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.\(^{(6)}\)

The exact and simplified beta-Poisson dose-response models have been repeatedly used for modeling illnesses from other foodborne pathogens such as norovirus,\(^{(37,40)}\) Salmonella,\(^{(33,34)}\) or Campylobacter jejuni.\(^{(8)}\)

The beta-Poisson model was also used to model L. monocytogenes dose-response from animal data.\(^{(41)}\)

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 lognormal 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.\(^{(25–27)}\) 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:

$$E[c_g] = \int_0^{\infty} M_{d,g} P(\text{ill}; d, \theta_g) \, dd.$$  \hspace{1cm} (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:

$$r = p_i \times p_s.$$  \hspace{1cm} (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,

$$r \sim \text{lognormal}\left(\mu_i + \mu_s, \sqrt{\sigma_i^2 + \sigma_s^2}\right).$$  \hspace{1cm} (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, $\sigma_i$ 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:

$$E[c_g] = \int_0^{\infty} M_{d,g} P(\text{ill}; \mu_g, \sigma_g) \, dd,$$  \hspace{1cm} (9)

where

$$\sigma_g = \sqrt{\frac{Q_{90,i}^2 + Q_{90,s}^2}{2\Phi^{-1}(0.95)}}.$$  \hspace{1cm} (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.\(^{(4)}\) In FDA/FSIS,\(^{(4)}\) 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.\(^{(4)}\) Assuming exponential dose response in animal studies, the range of variation in the log$_{10}$ LD$_{50}$ translates into the range of variation in the log$_{10}$ $r$ parameter.\(^{1}\) 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.\(^{(4)}\) According to FDA/FSIS (Table IV-8 in Ref. 4), 90% of the individual variability within the population group with low, medium, and high

\(^{1}\)We have, for an exponential dose response, $r = \frac{-\ln(0.5)}{L_{D50}}$. The LD$_{50}$ is inversely proportional to $r$. A variation of $\pm x$ log$_{10}$ in log$_{10}$ LD$_{50}$ 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\(^{(4)}\) 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 1), essentially as described previously.\(^{(11,42)}\) 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,\(^{(4)}\) we used FDA/FSIS\(^{(4)}\) “medium variability” estimates for all of the 11 groups, that is, \(Q_{90,i} = 1.8 \log_{10}\).

2.4.3. Interstrain Virulence Variability \(Q_{90,i}^S\)

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.\(^{(4)}\) The distribution for strain virulence was estimated notably by the observed variation in \(L.\) \(d_{50}\) (in \(\log_{10}\) cfu) among different \(L.\) \(monocytogenes\) strains in mouse experiments.\(^{(4)}\) According to FDA/FSIS (Table IV-6 in Ref. 4), 90% of the strain variability ranges within a \(5 \log_{10}\), leading to \(Q_{90,i}^S = 5 \log_{10}\).

Substituting these values in Equation (10) generates \(\sigma_s = 1.62 \log_{10}\).

2.5. Integration of the dose-response Models

2.5.1. Exposure Data

The \(L.\) \(monocytogenes\) concentration distribution reported by Chen et al.\(^{(30)}\) 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.\(^{(43)}\) \(L.\) \(monocytogenes\) was not detected in 98.2% of the samples. The log10 concentration (\(\log_{10}\) cfu/g) in the remaining contaminated products followed a four-parameter beta distribution\(^2\) with parameters \(\alpha = 0.29, \beta = 2.68, a = -1.69,\) and \(b = 6.1\).\(^{(30)}\) A 50 g serving size was assumed in this study. The number of servings of these eight RTE categories consumed by the U.S. population was estimated at \(1.23 \times 10^{11}\) servings per year based on the FDA/FSIS risk assessment.\(^{(4)}\) As considered in previous risk assessments,\(^{(4,5)}\) 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.\(^{(26)}\) 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.\(^{(26)}\) 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.\(^{(11,42)}\)

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\(^{(9)}\) and the second on 2005–2008 data\(^{(1)}\) 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\(^{(43)}\) 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.\(^{(1)}\)

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
Table I. Number of Persons with Underlying Conditions and Number of Cases of Invasive Listeriosis Observed in France, 2001–2008; 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

<table>
<thead>
<tr>
<th>Population Subgroup</th>
<th>Number of Individuals in France (from and Adapted from Ref. 26)</th>
<th>Listeriosis Cases During an 8-Year Period in France (from and Adapted from Ref. 26)</th>
<th>Relative Risk (CI 95%)a</th>
<th>Expected Number of Listeriosis Cases in the United States (Based on 1,591 Cases from Ref. 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 65 years old, no known underlying condition (i.e., “healthy adult”)</td>
<td>48,909,403</td>
<td>189</td>
<td>Reference group</td>
<td>153</td>
</tr>
<tr>
<td>More than 65 years old, no known underlying condition</td>
<td>7,038,068</td>
<td>377</td>
<td>13.9 (8.6, 23.1)</td>
<td>306</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>774,000</td>
<td>347</td>
<td>116 (71, 194.4)</td>
<td>282</td>
</tr>
<tr>
<td>Nonhematological cancer</td>
<td>2,065,000</td>
<td>437</td>
<td>54.8 (34.2, 90.3)</td>
<td>355</td>
</tr>
<tr>
<td>Hematological cancer</td>
<td>160,000</td>
<td>231</td>
<td>373.6 (217.3, 648.9)</td>
<td>188</td>
</tr>
<tr>
<td>Renal or liver failure (dialysis, cirrhosis)</td>
<td>284,000</td>
<td>164</td>
<td>149.4 (82, 270.1)</td>
<td>133</td>
</tr>
<tr>
<td>Solid organ transplant</td>
<td>25,300</td>
<td>16</td>
<td>163.7 (26.3, 551.5)</td>
<td>13</td>
</tr>
<tr>
<td>Inflammatory diseases (rheumatoid arthritis, ulcerative colitis, giant cell arteritis, Crohn’s disease)</td>
<td>300,674</td>
<td>68</td>
<td>58.5 (25.2, 123.4)</td>
<td>55</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>120,000</td>
<td>22</td>
<td>47.4 (10.5, 140.4)</td>
<td>18</td>
</tr>
<tr>
<td>Diabetes (type I or type II)</td>
<td>2,681,000</td>
<td>79</td>
<td>7.6 (3.5, 15.6)</td>
<td>64</td>
</tr>
<tr>
<td>Heart diseases</td>
<td>1,400,000</td>
<td>29</td>
<td>5.4 (1.5, 14.4)</td>
<td>24</td>
</tr>
<tr>
<td>Total population</td>
<td>63,757,445</td>
<td>1,959</td>
<td></td>
<td>1,591</td>
</tr>
</tbody>
</table>

a 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 log10 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 log10 concentration described in Section 2.5.1, with a maximum parameter increased from $b = 6.1$ to $b = 8.1 \ log_{10} \text{cfu/g}$. 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, $P_{g(outbreak)}$, 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,(31) as re-examined by FDA/FSIS(4) and FAO/WHO.(5) 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.(4,5) The FAO/WHO panel derived an $r$ value of $3.15 \times 10^{-7}$ from data collected during this outbreak.(5)
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 \( p_S(\text{outbreak}) \) and a lognormally distributed variable \( p_t \). Thus:

\[
r \sim \text{lognormal} \left( \mu_g + \log_{10} \left( p_s(\text{outbreak}) \right), \sigma_r \right).
\]

Given that \( p_s \sim \text{lognormal} \left( \mu_S, \sigma_S \right) \), the \( j \)th quantile of \( p_s \) is given by \( p_i \left( j \right) = 10^{(\mu_S + \Phi^{-1}(j) \times \sigma_S)} \). Assuming that \( p_S(\text{outbreak}) = p_i \left( j \right) \):

\[
r \sim \text{lognormal} \left( \mu_i + \mu_s + \Phi^{-1}(j) \times \sigma_s, \sigma_r \right).
\]

Substituting \( \mu_g \) for \( \mu_i + \mu_s \) gives for \( r \):

\[
r \sim \text{lognormal} \left( \mu_g + \Phi^{-1}(j) \times \sigma_s, \sigma_r \right).
\]

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. 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 \( L.\ monocyto gene \)s 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 estimated 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 for the susceptible population as well as the one by Chen et al. for \( L.\ monocyto gene \) strains with genes encoding a full-length \( \text{inLA} \) 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

<table>
<thead>
<tr>
<th>Population Subgroup</th>
<th>( \log_{10} ) Normal Distribution(^ a ) of ( r )</th>
<th>Estimates of ( r )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( \mu )</td>
<td>( \sigma )</td>
</tr>
<tr>
<td>Less than 65 years old, no known underlying condition (i.e., &quot;healthy adult&quot;)</td>
<td>( -14.11 )</td>
<td>1.62</td>
</tr>
<tr>
<td>More than 65 years old, no known underlying condition</td>
<td>( -12.83 )</td>
<td>1.62</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>( -11.70 )</td>
<td>1.62</td>
</tr>
<tr>
<td>Nonhematological cancer</td>
<td>( -12.11 )</td>
<td>1.62</td>
</tr>
<tr>
<td>Hematological cancer</td>
<td>( -11.02 )</td>
<td>1.62</td>
</tr>
<tr>
<td>Renal or liver failure (dialysis, cirrhosis)</td>
<td>( -11.56 )</td>
<td>1.62</td>
</tr>
<tr>
<td>Solid organ transplant</td>
<td>( -11.51 )</td>
<td>1.62</td>
</tr>
<tr>
<td>Inflammatory diseases (rheumatoid arthritis, ulcerative colitis, giant cell arteritis, Crohn's disease)</td>
<td>( -12.08 )</td>
<td>1.62</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>( -12.19 )</td>
<td>1.62</td>
</tr>
<tr>
<td>Diabetes (type I or type II)</td>
<td>( -13.13 )</td>
<td>1.62</td>
</tr>
<tr>
<td>Heart diseases</td>
<td>( -13.30 )</td>
<td>1.62</td>
</tr>
<tr>
<td>Whole population</td>
<td>N/A(^ b )</td>
<td>N/A</td>
</tr>
</tbody>
</table>

\(^ a \)The \( \log_{10} \) normal distribution is parameterized as \( x \sim \lognormal(\mu, \sigma) \) if \( \log_{10}(x) \sim \normal(\text{mean}: \mu, \text{standard error}: \sigma) \).

\(^ b \)Nonapplicable: the dose response for the whole population uses a mixture of \( \log_{10} \) normal distribution (see text for details).

\(^ c \)The distribution of \( r \) includes the individual and the strain variability.
“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 \( \leq 4 \log_{10} \text{cfu} \) 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 \( L. \text{monocytogenes} \) level of \( 8.1 \log_{10} \text{cfu/g} \), 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 \( 4 \log_{10} \text{cfu/g} \) and 4% for a dose of \( 6 \log_{10} \text{cfu/g} \) for the total population.

3.3. Application of the Dose-response Framework to Listeriosis Outbreaks

Fig. 3 compares the published exponential dose-response model\(^{(5)} \) estimated from the Finnish butter outbreak data \( (r = 3.15 \times 10^{-7})\)\(^{(5,31)} \) to the dose-response model for transplant recipients derived in this study, showing both the prediction averaged across individual strains and for individual percentiles 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 \( L. \text{Monocytogenes} \) Dose-response, Adjusted for Variability in Host Susceptibility and Strain Virulence

The FAO/WHO\(^{(5)} \) dose-response model can be considered as a marginal dose-response model for a population exposed to a cross-section of \( L. \text{monocytogenes} \) strains. As such, this model averages across numerous individuals with differing levels of susceptibility and multiple \( L. \text{monocytogenes} \) 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>
<thead>
<tr>
<th>Log_{10}(Dose)</th>
<th>&lt;65-year old</th>
<th>&gt;65-year old</th>
<th>Pregnant</th>
<th>Hematological</th>
<th>Solid organ</th>
<th>Whole population</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0</td>
<td>8.8 x 10^{-12}</td>
<td>1.5 x 10^{-10}</td>
<td>2.0 x 10^{-9}</td>
<td>9.5 x 10^{-9}</td>
<td>3.1 x 10^{-9}</td>
<td>1.2 x 10^{-10}</td>
</tr>
<tr>
<td>0.5</td>
<td>2.8 x 10^{-11}</td>
<td>4.8 x 10^{-10}</td>
<td>6.2 x 10^{-9}</td>
<td>3.0 x 10^{-8}</td>
<td>9.8 x 10^{-9}</td>
<td>3.8 x 10^{-10}</td>
</tr>
<tr>
<td>1.0</td>
<td>8.8 x 10^{-11}</td>
<td>1.5 x 10^{-9}</td>
<td>2.0 x 10^{-8}</td>
<td>9.5 x 10^{-8}</td>
<td>3.1 x 10^{-8}</td>
<td>1.2 x 10^{-9}</td>
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<td>2.8 x 10^{-10}</td>
<td>4.8 x 10^{-9}</td>
<td>6.3 x 10^{-8}</td>
<td>3.0 x 10^{-7}</td>
<td>9.9 x 10^{-9}</td>
<td>3.8 x 10^{-9}</td>
</tr>
<tr>
<td>2.0</td>
<td>8.8 x 10^{-10}</td>
<td>1.5 x 10^{-8}</td>
<td>2.0 x 10^{-7}</td>
<td>9.3 x 10^{-7}</td>
<td>3.1 x 10^{-7}</td>
<td>1.2 x 10^{-8}</td>
</tr>
<tr>
<td>2.5</td>
<td>2.8 x 10^{-9}</td>
<td>4.7 x 10^{-8}</td>
<td>6.2 x 10^{-7}</td>
<td>2.8 x 10^{-6}</td>
<td>9.6 x 10^{-7}</td>
<td>3.7 x 10^{-8}</td>
</tr>
<tr>
<td>3.0</td>
<td>8.8 x 10^{-9}</td>
<td>1.5 x 10^{-7}</td>
<td>1.9 x 10^{-6}</td>
<td>8.6 x 10^{-6}</td>
<td>2.9 x 10^{-6}</td>
<td>1.1 x 10^{-7}</td>
</tr>
<tr>
<td>3.5</td>
<td>2.5 x 10^{-8}</td>
<td>4.6 x 10^{-7}</td>
<td>5.8 x 10^{-6}</td>
<td>2.5 x 10^{-5}</td>
<td>8.9 x 10^{-6}</td>
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<tr>
<td>4.0</td>
<td>7.8 x 10^{-8}</td>
<td>1.4 x 10^{-6}</td>
<td>1.7 x 10^{-5}</td>
<td>7.2 x 10^{-5}</td>
<td>2.6 x 10^{-5}</td>
<td>1.0 x 10^{-6}</td>
</tr>
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*No serving with >7.8 log_{10} L. monocytogenes cells is expected from the set of exposure data, leading mathematically to no expected cases at or above 8.0 log_{10}.*
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, 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.* 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.* found more than a 1 log_{10} increase in median infectious dose for *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. 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...
variability. Despite the progress that has been made in recent years, a better understanding of virulence differences among \textit{L. monocytogenes} strains and, in particular, experimental data evaluating the potential impact of food matrix effects, is clearly needed to further refine \textit{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 \( r \).\(^\text{(6,39)}\) It offers a great amount of flexibility on the \([0; 1]\) domain,\(^\text{(6)}\) but a mechanistic basis for the choice of beta distributions is lacking. In the case of \textit{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 \textit{L. monocytogenes} as evaluated here. Interestingly, if a gamma distribution with \( r \sim \gamma(\alpha, 1/\beta) \), 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)).\(^\text{(8,46)}\) 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(5) 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 a 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.(26,27) Unfortunately, data on the relative risk of listeriosis is currently lacking for other population subgroups in the United States.(27) It was estimated that for each case of invasive listeriosis, 1.1 cases were not diagnosed in the United States.(1) This figure might be higher in neonatal and elderly cases as compared to other subpopulations.(47) 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,(48) 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.(49,50) 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.(28) 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.*, 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 (51,52) or vegetables, (53) 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 (4,5)—these data have the advantage of being actual observed L. monocytogenes levels originating from a market basket survey (43) 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 log10 cfu/g. This assumption is also underestimating exposure since others assume that L. monocytogenes can reach a maximal population density of 8 log10 in a food. (4,5) 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 106 cells each year in the United States; by comparison, the FDA/FSIS (54) 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 log10 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 log10 cfu/g. Indeed, the maximal population density in a food has been shown to be an influential parameter for the predicted risk of invasive listeriosis. (54,55) Given the same dose response, the higher the maximum population density, the higher the predicted number of cases. (54,55) In addition, assumption on the maximum population density affects dose-response model parameters based on surveillance data. (5) The FAO/WHO risk assessment of L. monocytogenes in RTE foods (5) shows that a shift in the maximum population density by 2 log10 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, (4,5) the assumption of equal exposure to contaminated food for all population subgroups does not consider the potential effectiveness of prevention campaigns 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 suggest differences do exist in food consumption across population subgroups. (25,56) 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 × 10−9. It is 9.3 × 10−7 following the ingestion of 100 cells and 7.2 × 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, (5) averaged over all possible risk factors. The corresponding estimates, using their r parameter of 5.85 × 10−12, would be 5.9 × 10−12, 5.9 × 10−10, and 5.9 × 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. (4,57)

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...
5. CONCLUSIONS

The exponential model has the oversimplifying assumption of a constant probability of infection following the ingestion of \( L. \text{monocytogenes} \) 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 \( L. \text{monocytogenes} \) 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 \( L. \text{monocytogenes} \), those at greatest risk of developing listeriosis are also at a measurable risk of illness when consuming food contaminated with relatively low doses of \( L. \text{monocytogenes} \), especially if highly virulent bacterial strains are involved.

ACKNOWLEDGMENTS

This work was supported, in part, by an appointment to the Research Participation Program at the Center for Food Safety and Applied Nutrition administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S. Department of Energy and the U.S. Food and Drug Administration. We thank Eric Ebel (USDA-FSIS) and the anonymous reviewers for their constructive comments on the first draft of the article.

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”, \(^{(6)}\)

\[
P(\text{ill}; d, \alpha, \beta) = 1 - \frac{1}{\Gamma_1(\alpha + \beta, -d)}, \quad (A.1)
\]

in which \( \Gamma_1 \) is the Kummer confluent hypergeometric function. Equation (A.1) simplifies to the “beta-Poisson” dose-response model:

\[
P(\text{ill}; d, \alpha, \beta) = 1 - \left(1 + \frac{d}{\beta}\right)^{-\alpha}, \quad (A.2)
\]

when \( \beta \gg \alpha \) and \( \beta \gg 1 \).\(^{(7,39)}\) Note that these conditions are expected to be fulfilled for \( L. \text{monocytogenes} \): the average probability of infection is very low,\(^{(30)}\) 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 \( L. \text{monocytogenes} \) 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\(^{(4)}\) 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:

\[
E[r_g] = \int_0^\infty M_{d,g} \left(1 - \left(1 + \frac{d}{\beta_g}\right)^{-\alpha_g}\right) \, dd
\]

\[
Q_{90} = \log_{10}(q_{0.95}) - \log_{10}(q_{0.05}), \quad (A.3)
\]

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.\(^{(58)}\) 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,\(^{(5,31)}\) 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 \((\beta \to \infty)\), the beta distribution converge to a degenerate distribution with a single point mass at some \(x \in [0, 1]\).\(^{(58)}\) 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.

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**Fig. A.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\(^{(51)}\) equals \(3.15 \times 10^{-7}\), that is, \(10^{-6.5}\) (dot-dashed vertical line).
REFERENCES


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 (*μ*max) for apples inoculated at the stem end, as determined using the Baranyi and Roberts growth model, were 1.64 ± 0.27 and 1.38 ± 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 not 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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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 *Asc* I 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 (10^3 or 10^6 CFU per apple), inoculation site (equatorial surface and stem end), inoculum drying conditions (5°C for 2 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 and 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

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**Table 1. *L. monocytogenes* populations on inoculated fresh apples (without sticks) stored at 5 or 25°C**

<table>
<thead>
<tr>
<th>Temp (°C)</th>
<th>Apple variety</th>
<th>Inoculation location</th>
<th>0 days</th>
<th>1 day</th>
<th>2 days</th>
<th>6 days</th>
<th>9 days</th>
<th>15 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Gala</td>
<td>Stem end</td>
<td>5.7 ± 0.6</td>
<td>5.4 ± 0.8</td>
<td>6.1 ± 0.7</td>
<td>4.4 ± 0.8</td>
<td>5.9 ± 1.0</td>
<td>5.5 ± 0.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surface</td>
<td>2.7 ± 0.3</td>
<td>2.7 ± 0.3</td>
<td>BE</td>
<td>BE</td>
<td>4.7 ± 0.8</td>
<td>BE</td>
</tr>
<tr>
<td>25</td>
<td>Gala</td>
<td>Stem end</td>
<td>5.7 ± 0.6</td>
<td>5.4 ± 0.7</td>
<td>5.8 ± 0.7</td>
<td>3.8 ± 0.7</td>
<td>3.9 ± 0.7</td>
<td>3.9 ± 0.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surface</td>
<td>2.7 ± 0.3</td>
<td>BE</td>
<td>BE</td>
<td>BE</td>
<td>5.7 ± 1.5</td>
<td>BE</td>
</tr>
<tr>
<td>25</td>
<td>Granny Smith</td>
<td>Stem end</td>
<td>6.7 ± 1.1</td>
<td>5.2 ± 0.9</td>
<td>BE</td>
<td>6.9 ± 1.7</td>
<td>6.0 ± 1.5</td>
<td>2.9 ± 0.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surface</td>
<td>4.8 ± 0.8</td>
<td>BE</td>
<td>BE</td>
<td>BE</td>
<td>5.1 ± 0.8</td>
<td>3.3 ± 0.6</td>
</tr>
</tbody>
</table>

*a* Initial inoculation was 6.9 ± 0.6 log CFU per apple.

*b* Values are means for n = 6.

*c* BE, below sensitivity of plate count assay (2.5 log CFU per apple). In all cases, *L. monocytogenes* was detectable by enrichment culture.
TABLE 2. L. monocytogenes populations and growth kinetics on inoculated caramel apples stored at 5 or 25°C

<table>
<thead>
<tr>
<th>Temp (°C)</th>
<th>Apple variety</th>
<th>Inoculation location</th>
<th>0 days</th>
<th>1 day</th>
<th>2 days</th>
<th>6 days</th>
<th>9 days</th>
<th>15 days</th>
<th>Mean ± SD log CFU/apple</th>
<th>SE max</th>
<th>r²</th>
<th>Time to 1-log increase (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Gala</td>
<td>Stem end, dried</td>
<td>5.4 ± 0.8</td>
<td>5.7 ± 0.8</td>
<td>7.0 ± 1.0</td>
<td>8.0 ± 1.3</td>
<td>8.1 ± 1.7</td>
<td>8.5 ± 2.2</td>
<td>8.5 ± 1.7</td>
<td>6.4 ± 0.8</td>
<td>1.6 ± 0.5</td>
<td>1.04 ± 0.8</td>
</tr>
<tr>
<td>25</td>
<td>Gala</td>
<td>Stem end, dried</td>
<td>4.7 ± 0.4</td>
<td>5.0 ± 0.4</td>
<td>6.6 ± 0.5</td>
<td>7.9 ± 0.6</td>
<td>8.5 ± 1.2</td>
<td>9.5 ± 1.6</td>
<td>9.8 ± 1.6</td>
<td>7.2 ± 1.2</td>
<td>1.04 ± 0.8</td>
<td>1.01 ± 0.8</td>
</tr>
<tr>
<td>25</td>
<td>Granny Smith</td>
<td>Stem end, dried</td>
<td>5.4 ± 0.6</td>
<td>5.7 ± 0.6</td>
<td>6.6 ± 0.5</td>
<td>7.9 ± 0.6</td>
<td>8.5 ± 1.2</td>
<td>9.5 ± 1.6</td>
<td>9.8 ± 1.6</td>
<td>7.2 ± 1.2</td>
<td>1.04 ± 0.8</td>
<td>1.01 ± 0.8</td>
</tr>
</tbody>
</table>

a Initial inoculation was 6.9 ± 0.6 log CFU per apple. Values are means for n = 6. b SE, ± 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. c r², coefficient of determination. d Initial inoculation was 6.9 ± 0.6 log CFU per apple. Values are means for n = 6. e Inoculum placed at the stem end was dried at 5 °C for 24 h. f r², coefficient of determination.

**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 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.

**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 (μmax) 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 μmax 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 μmax values was used to determine the time to achieve 1 log CFU of growth, assuming no lag phase, at each condition and temperature.
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 μₘₐₓ 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 μₘₐₓ 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 μₘₐₓ 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 μₘₐₓ 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 μₘₐₓ 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
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 \( \mu_{\text{max}} \) 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 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).

TABLE 4. *L. monocytogenes* growth kinetics on caramel apples with wood, paper, or plastic sticks during storage at 25°C for 15 days

<table>
<thead>
<tr>
<th>Stick material</th>
<th>Apple variety</th>
<th>( \mu_{\text{max}} \pm \text{SE}^b )</th>
<th>( r^2 )</th>
<th>Time to 1 log CFU growth (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gala</td>
<td>1.64 ± 0.27 A a</td>
<td>0.89</td>
<td>14.9 ± 0.1</td>
</tr>
<tr>
<td>Wood</td>
<td>Granny Smith</td>
<td>1.38 ± 0.20 b a</td>
<td>0.91</td>
<td>17.6 ± 0.2</td>
</tr>
<tr>
<td>Paper</td>
<td>Gala</td>
<td>1.40 ± 0.24 A b</td>
<td>0.77</td>
<td>17.4 ± 0.1</td>
</tr>
<tr>
<td>Paper</td>
<td>Granny Smith</td>
<td>1.23 ± 0.28 b b</td>
<td>0.71</td>
<td>20.2 ± 0.2</td>
</tr>
<tr>
<td>Plastic</td>
<td>Gala</td>
<td>1.02 ± 0.14 A c</td>
<td>0.87</td>
<td>23.9 ± 0.1</td>
</tr>
<tr>
<td>Plastic</td>
<td>Granny Smith</td>
<td>1.25 ± 0.300 b b</td>
<td>0.73</td>
<td>20.0 ± 0.2</td>
</tr>
</tbody>
</table>

\( \mu_{\text{max}} \pm \text{SE}, \) mean maximum growth rate (log CFU per apple per day) \pm standard error; \( r^2, \) coefficient of determination.

\( ^b \) 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.

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.

700 SALAZAR ET AL. J. Food Prot., Vol. 79, No. 5
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

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**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 ± 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).
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.

ACKNOWLEDGMENTS

The authors sincerely thank Dr. Kathleen Glass for helpful discussions, Tim Monson (Wisconsin State Laboratory of Hygiene) for providing outbreak-associated *L. monocytogenes* strains, Karl Reinke and Travis Morrissey for help with acquiring apples for experiments, Dr. Yun Wang for laboratory support, and Dr. Don Zink for motivational guidance. The work was supported by grant U19FD005322 from the U.S. Food and Drug Administration to the Illinois Institute of Technology, J. K. Salazar and C. K. Carstens were supported by a Oak Ridge Institute for Science and Education Research Participation Program grant to the U.S. Food and Drug Administration. The sponsors had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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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<sub>10</sub> 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<sub>10</sub> in apples with sticks, whereas only a 1-log<sub>10</sub> 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<sub>10</sub> 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.

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 *L. monocytogenes* is a pathogen routinely associated with apples (3). Second, the caramel coating used on apples is hot (~95°C) and has low water activity, usually <0.80 (4), and most *L. monocytogenes* strains require water activity (a<sub>w</sub>) 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 previously 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.
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 temperatures 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 ~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 1](A) Key parts of the apple and the caramel-apple interface microenvironment (B).

![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$_{10}$ 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 result in 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-shellac 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 foodborne 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$_{10}$ 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$_{10}$ 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$_{10}$ 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°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°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°C for 18 to 22 h. Cells were harvested by centrifugation (4,000 × g, 20 min) and suspended in 4.5 ml 0.1% buffered peptone water (pH 7.1 ± 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. Waxied 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 aₙₐₙ was 0.98; the caramel apple dip had a measured aₙₐₙ 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 testing 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 μl of L. monocytogenes cocktail was pipetted into the bottom calyx of the apple (~22°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 of 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°C (commercial caramel apple makers typically use a temperature of 104 to 116°C, but temperatures can cool to <100°C during production). The caramel was removed from the heat once it reached 95°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°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°C (without additional humidity control); triplicate samples for each treatment were assayed before and after coating and on days 3, 7, 11, and 14 for 25°C and at weeks 1, 2, 3, and 4 for 7°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

This study was funded by the University of Wisconsin-Madison Food Research Institute (FRI).

We thank Amanda Skarlupka, Ming Mu, Subash Shrestha, Adam Bartling, Emily Merry, Katina Fisher, Anna Spenesly, Abby Dabson, and Katie Osterbauer for technical assistance during inoculation and testing. Ken Brandenburg for statistical analysis, and Nan Faith for virulence and biofilm testing. We are grateful to Tim Monson, Wisconsin State Laboratory of Hygiene, for the L. monocytogenes isolates and Rachel Klos, Wisconsin Division of Public Health, for helpful discussion.

REFERENCES


Issue: 2020 III-026

Council Recommendation: Accepted as Submitted ______ Amended ______ No Action ______

Delegate Action: 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, \(^a\) or

(b) Arranging each type of FOOD in EQUIPMENT so that cross contamination of one type with another is prevented, \(^b\) and

(c) Preparing each type of FOOD at different times or in separate areas; \(^c\)

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Supporting Attachments:

- "3-302.11 Raw Meat Meal Kits at Retail"

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.
3-301.11 & Raw Meat Meal Kits at Retail:
Current Examples of Raw Animal Foods Stored with RTE Foods

**Photo 1:** Chicken Fajita Mix: Raw chicken slices with raw vegetables (Note raw meat handling label)

**Photo 2:** Taco Meal Kit: Wrapped ground beef next to lime, wrapped cabbage, tortillas, seasonings, etc.

**Photo 3:** Turkey Dinner: Raw turkey on stuffing next to container of RTE potatoes, green beans, butter, and cranberry sauce.

**Photo 4:** Roast Meal Kit: Unwrapped beef wrapped with packaged sauce and bagged vegetables
### Conference for Food Protection
#### 2020 Issue Form

**Issue:** 2020 III-027

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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.

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Content Documents:
- "2017 FDA Food Code"

Supporting Attachments:
- "FCRS 2015 “Handwashing water temperature”"

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.

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
Council: Accepted as
Recommendation: Submitted ______ Amended ______ No Action ______
Delegate Action: Accepted ______ Rejected ______

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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 handwashing¹. 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 concerns².

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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Keywords:
antibacterial soap,
handwashing, personal hygiene, skin damage, skin flora, water temperature

Abstract

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 Log10 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 maximize 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 easy. They do not have adhesion characteristics that hold them to the skin’s 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 skin’s 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
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).

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 handwash 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

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### Table 1 Submitters and handwashing water temperature issues at the year 2000 Conference for Food Protection

<table>
<thead>
<tr>
<th>Submitter</th>
<th>Issue</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>M. Scarborough (Georgia Department of Human Resources, Division of Public Health)</td>
<td>37.7°C (100°F)</td>
<td>1. No Science (43°C vs. 37.8°C) 2. Plumbing Code @ 100°F Max. (Safety Concerns)</td>
</tr>
<tr>
<td>E. Rabotoski (Wisconsin ConferenceFood Protection)</td>
<td>‘Tempered’ 29.5°C (85°F) to 43°C (110°F)</td>
<td>1. Hand Discomfort 2. Possible Scalding</td>
</tr>
<tr>
<td>B. Adler (Minnesota Department of Health)</td>
<td>Impose Temp. Range 43°C 110°F To 54.4°C (130°F)</td>
<td>1. Need upper limit or subject to OSHA 2. Food workers Don’t Wash 2.5 Sec. So Cannot Scald.</td>
</tr>
</tbody>
</table>
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 48h 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 menstrua 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 menstrua 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 (Mead et al. 1997). In addition, due to it’s 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, loosing 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-
priate 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 deguming 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 log10 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-Sience 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, uninnoculated 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 tem-
peratures, but also evaluated skin conditions on the
hands of participants throughout the study. The poten-
tial of each soap to cause negative skin changes at each
water temperature combination was assessed by mea-
suring 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%),
Parachlorometaxylenol (PCMX-3%), and Iodophor
(7.5% PVP-I). Participants consisting of paid volun-
teeers 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® CM825, for total evaporative water loss
using the TC350 Tewameter, and digitally using the
Skin Visiometer® SV 500 with Visioscan® VC98. The
visual skin dryness and erythema (redness) scoring was
performed by a single blinded (unaware of subjects
antimicrobial soap product/water temperature configu-
ration) 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$_{10}$ reduction data was determined with
the first wash of days one, three and five under each
water temperature condition. After handling the cont-
aminated ground beef in a way to uniformly contami-
nate 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-
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.

### Table 2 Grading scale for evaluating the skin of the hands

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No visible damage, ‘perfect’ skin</td>
</tr>
<tr>
<td>1</td>
<td>Slight dryness, ashen appearance, usually involving dorsum only</td>
</tr>
<tr>
<td>2</td>
<td>Marked dryness, slight flaking involving dorsum only</td>
</tr>
<tr>
<td>3</td>
<td>Severe dryness dorsum, marked flaking, possibly fissures in webs</td>
</tr>
<tr>
<td>4</td>
<td>Severe flaking dorsum, surface fissures possibly with slight palmar dryness</td>
</tr>
<tr>
<td>5</td>
<td>Open fissures, slight erythema (&gt;10% of dorsal and interdigital surface), with or without severe dryness, no bleeding</td>
</tr>
<tr>
<td>6</td>
<td>Bleeding cracks, deep open fissures, or generalized erythema (&gt;25% of area)</td>
</tr>
</tbody>
</table>

*Griffith et al. 1969.*

### 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$_{10}$ reduc-
tions 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$_{10}$ reduction results for each soap are pre-
sented 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$_{10}$ reductions was
detected between the two wash temperatures for any
of the products or as a group. Overall, the four prod-
ucts 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 signifi-
cant. Figure 4 shows Tewameter® readings measuring
$trans$ epidermal water loss, while Figs 5 and 6 show
visual dryness and baseline adjusted Corneometer®
values, respectively. Skin scaliness values using a
Visiometer® are shown in Fig. 7. Along with the slight
additional reduction of bacteria at the higher tempera-
ture was increased skin visual dryness, increased transepidermal water loss and decreased scaliness, also
determined to be statistically insignificant. Skin scalin-
ess is highest on day one and two at the higher tem-
perature but for days three, four and five, this reverses.
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

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Figure 1 Handwashing efficacy (Log₁₀ reduction) for transient flora (S. marcescens) in ground beef and TSB at selected water washing and rinsing temperatures.

Figure 2 Handwashing efficacy (Log₁₀ reduction) for resident flora in ground beef and TSB at selected water washing and rinsing temperatures.

Figure 3 Average Log₁₀ 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.
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. Log10 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 & Thstrup-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 above 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 Log10 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 vigor 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.

References


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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MS 16-370: Received 9 September 2016/Accepted 27 January 2017/Published Online 15 May 2017

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
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 ~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 resident microbes. Higher temperatures may also 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 ≤43°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 researches 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 ± 3.9 years [mean ± SD]) included 10 men (ages 26 ± 2.2 years) and 10 women (ages 23 ± 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 baseline + (3 × 20 lather time) + (2 × 20 water temperature) + (2 × 20 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 Thermoan with ±0.4°C accuracy (ThermoWorks, Lindon, UT). The temperature of the water was set prior to volunteer arrival and needed to be within ±2°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 non-descript, 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 amphoter 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 ± 4 h at 35 ± 2°C. This 24-h culture was harvested by centrifugation (Micro 12, Thermo Fisher Scientific, Waltham, MA) at 7,000 × 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 ~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 (~40 to 60 s). A sample was collected from the nondominant hand
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 nitrite 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 or the water temperature. Volunteers did not dry their hands to

**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 levels 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>
<thead>
<tr>
<th>Treatment</th>
<th>Soap formulation</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Maximum</th>
<th>Minimum</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>All data</td>
<td>Antimicrobial</td>
<td>1.94</td>
<td>0.78</td>
<td>1.92</td>
<td>4.42</td>
<td>0.06</td>
<td>4.36</td>
</tr>
<tr>
<td>Baseline</td>
<td>Antimicrobial</td>
<td>2.22</td>
<td>0.74</td>
<td>2.22</td>
<td>4.40</td>
<td>−0.04</td>
<td>4.44</td>
</tr>
<tr>
<td>Lather time, 10 s</td>
<td>Antimicrobial</td>
<td>1.92</td>
<td>0.68</td>
<td>1.87</td>
<td>3.13</td>
<td>0.69</td>
<td>2.44</td>
</tr>
<tr>
<td>Lather time, 20 s</td>
<td>Antimicrobial</td>
<td>2.03</td>
<td>0.64</td>
<td>2.00</td>
<td>3.30</td>
<td>0.89</td>
<td>2.41</td>
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<tr>
<td>Lather time, 40 s</td>
<td>Antimicrobial</td>
<td>2.54</td>
<td>0.62</td>
<td>2.48</td>
<td>3.75</td>
<td>1.03</td>
<td>2.58</td>
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<tr>
<td>Water temp, 15°C</td>
<td>Antimicrobial</td>
<td>2.43</td>
<td>0.71</td>
<td>2.25</td>
<td>4.09</td>
<td>1.57</td>
<td>2.52</td>
</tr>
<tr>
<td>Water temp, 26°C</td>
<td>Antimicrobial</td>
<td>1.88</td>
<td>0.62</td>
<td>1.91</td>
<td>3.34</td>
<td>0.76</td>
<td>2.57</td>
</tr>
<tr>
<td>Soap vol, 0.5 mL</td>
<td>Antimicrobial</td>
<td>2.34</td>
<td>0.54</td>
<td>2.33</td>
<td>3.22</td>
<td>1.08</td>
<td>2.15</td>
</tr>
<tr>
<td>Soap vol, 2.0 mL</td>
<td>Antimicrobial</td>
<td>2.10</td>
<td>0.77</td>
<td>2.18</td>
<td>3.24</td>
<td>0.06</td>
<td>3.18</td>
</tr>
</tbody>
</table>

* a 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.
(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>
<thead>
<tr>
<th>Comparison</th>
<th>Mean difference</th>
<th>$q$</th>
<th>95% CI Mean difference</th>
<th>$q$</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline vs lather 10 s</td>
<td>-0.110</td>
<td>0.687</td>
<td>-0.8079 to 0.5880</td>
<td>-0.244</td>
<td>1.708</td>
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<tr>
<td>Baseline vs lather 20 s</td>
<td>-0.030</td>
<td>0.188</td>
<td>-0.7280 to 0.6679</td>
<td>-0.628*</td>
<td>4.384*</td>
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<tr>
<td>Baseline vs temp 15°C</td>
<td>0.010</td>
<td>0.064</td>
<td>-0.6877 to 0.7082</td>
<td>-0.521</td>
<td>3.561</td>
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<tr>
<td>Baseline vs temp 26°C</td>
<td>0.033</td>
<td>0.207</td>
<td>-0.6648 to 0.7311</td>
<td>-0.427</td>
<td>2.982</td>
</tr>
<tr>
<td>Baseline vs vol 0.5 mL</td>
<td>0.011</td>
<td>0.072</td>
<td>-0.6865 to 0.7094</td>
<td>-0.071</td>
<td>0.497</td>
</tr>
<tr>
<td>Baseline vs vol 2 mL</td>
<td>-0.182</td>
<td>1.134</td>
<td>-0.8794 to 0.5165</td>
<td>-0.339</td>
<td>2.369</td>
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<tr>
<td>Lather 10 s vs lather 20 s</td>
<td>0.083</td>
<td>0.518</td>
<td>-0.6151 to 0.7808</td>
<td>-0.233</td>
<td>1.625</td>
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<tr>
<td>Lather 10 s vs temp 15°C</td>
<td>0.080</td>
<td>0.500</td>
<td>-0.6180 to 0.7779</td>
<td>-0.383</td>
<td>2.676</td>
</tr>
<tr>
<td>Lather 10 s vs temp 26°C</td>
<td>0.120</td>
<td>0.752</td>
<td>-0.5777 to 0.8182</td>
<td>-0.277</td>
<td>1.933</td>
</tr>
<tr>
<td>Lather 10 s vs temp 26°C</td>
<td>0.143</td>
<td>0.895</td>
<td>-0.5548 to 0.8411</td>
<td>-0.182</td>
<td>1.274</td>
</tr>
<tr>
<td>Lather 10 s vs vol 0.5 mL</td>
<td>0.122</td>
<td>0.759</td>
<td>-0.5765 to 0.8194</td>
<td>0.173</td>
<td>1.211</td>
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<tr>
<td>Lather 10 s vs vol 2 mL</td>
<td>-0.072</td>
<td>0.447</td>
<td>-0.7695 to 0.6265</td>
<td>-0.095</td>
<td>0.661</td>
</tr>
<tr>
<td>Lather 20 s vs lather 40 s</td>
<td>0.193</td>
<td>1.205</td>
<td>-0.5051 to 0.8908</td>
<td>0.012</td>
<td>0.082</td>
</tr>
<tr>
<td>Lather 20 s vs temp 15°C</td>
<td>0.040</td>
<td>0.252</td>
<td>-0.6576 to 0.7383</td>
<td>0.106</td>
<td>0.743</td>
</tr>
<tr>
<td>Lather 20 s vs temp 26°C</td>
<td>0.063</td>
<td>0.395</td>
<td>-0.6347 to 0.7612</td>
<td>0.201</td>
<td>1.402</td>
</tr>
<tr>
<td>Lather 20 s vs vol 0.5 mL</td>
<td>0.042</td>
<td>0.260</td>
<td>-0.6564 to 0.7395</td>
<td>0.556</td>
<td>3.887</td>
</tr>
<tr>
<td>Lather 20 s vs vol 2 mL</td>
<td>-0.151</td>
<td>0.947</td>
<td>-0.8494 to 0.5465</td>
<td>0.288</td>
<td>2.015</td>
</tr>
<tr>
<td>Lather 40 s vs temp 15°C</td>
<td>0.113</td>
<td>0.706</td>
<td>-0.5850 to 0.8109</td>
<td>0.395</td>
<td>2.758</td>
</tr>
<tr>
<td>Lather 40 s vs temp 26°C</td>
<td>0.023</td>
<td>0.143</td>
<td>-0.6751 to 0.7209</td>
<td>0.094</td>
<td>0.659</td>
</tr>
<tr>
<td>Lather 40 s vs vol 0.5 mL</td>
<td>0.001</td>
<td>0.008</td>
<td>-0.6967 to 0.6992</td>
<td>0.450</td>
<td>3.143</td>
</tr>
<tr>
<td>Lather 40 s vs vol 2 mL</td>
<td>-0.192</td>
<td>1.199</td>
<td>-0.8897 to 0.5062</td>
<td>0.182</td>
<td>1.272</td>
</tr>
<tr>
<td>Temp 15°C vs temp 26°C</td>
<td>-0.022</td>
<td>0.136</td>
<td>-0.7196 to 0.6763</td>
<td>0.356</td>
<td>2.484</td>
</tr>
<tr>
<td>Temp 15°C vs vol 0.5 mL</td>
<td>-0.215</td>
<td>1.342</td>
<td>-0.9126 to 0.4833</td>
<td>0.088</td>
<td>0.613</td>
</tr>
<tr>
<td>Temp 15°C vs vol 2 mL</td>
<td>0.050</td>
<td>0.311</td>
<td>-0.6482 to 0.7477</td>
<td>0.194</td>
<td>1.356</td>
</tr>
<tr>
<td>Temp 26°C vs vol 0.5 mL</td>
<td>-0.193</td>
<td>1.206</td>
<td>-0.8909 to 0.5050</td>
<td>-0.268</td>
<td>1.872</td>
</tr>
<tr>
<td>Temp 26°C vs vol 2 mL</td>
<td>0.071</td>
<td>0.446</td>
<td>-0.6266 to 0.7694</td>
<td>-0.162</td>
<td>1.128</td>
</tr>
<tr>
<td>Vol 0.5 mL vs vol 2 mL</td>
<td>0.264</td>
<td>1.652</td>
<td>-0.4336 to 0.9623</td>
<td>0.106</td>
<td>0.743</td>
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</tbody>
</table>

* $P < 0.05$. 

TABLE 2. ANOVA of scenarios and volunteers

<table>
<thead>
<tr>
<th>Variable</th>
<th>Soap formulation</th>
<th>SD</th>
<th>Degrees of freedom</th>
<th>Mean square</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between volunteers</td>
<td>Antimicrobial</td>
<td>0.9985</td>
<td>7</td>
<td>0.1426</td>
</tr>
<tr>
<td></td>
<td>Bland</td>
<td>6.465</td>
<td>7</td>
<td>0.9235</td>
</tr>
<tr>
<td>Between scenarios</td>
<td>Antimicrobial</td>
<td>27.37</td>
<td>19</td>
<td>1.441</td>
</tr>
<tr>
<td></td>
<td>Bland</td>
<td>26.2</td>
<td>19</td>
<td>1.379</td>
</tr>
<tr>
<td>Residual</td>
<td>Antimicrobial</td>
<td>68.08</td>
<td>133</td>
<td>0.5119</td>
</tr>
<tr>
<td></td>
<td>Bland</td>
<td>54.5</td>
<td>133</td>
<td>0.4098</td>
</tr>
<tr>
<td>Total</td>
<td>Antimicrobial</td>
<td>96.45</td>
<td>159</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bland</td>
<td>87.17</td>
<td>159</td>
<td></td>
</tr>
</tbody>
</table>
The four low frequency hand washers also reported the effect on mean log reductions ($P = 0.02$) for volunteers based on high use of lotion (2.15 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).

**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 (~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 ($P = 0.00000135$), 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
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).

Antibacterial and bland soaps. A significant difference in microbial reduction was found between soap

<table>
<thead>
<tr>
<th>TABLE 4. Prewash data&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. of washes</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>All</td>
</tr>
<tr>
<td>15°C</td>
</tr>
<tr>
<td>26°C</td>
</tr>
<tr>
<td>38°C</td>
</tr>
<tr>
<td>Men</td>
</tr>
<tr>
<td>15°C</td>
</tr>
<tr>
<td>26°C</td>
</tr>
<tr>
<td>38°C</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>15°C</td>
</tr>
<tr>
<td>26°C</td>
</tr>
<tr>
<td>38°C</td>
</tr>
</tbody>
</table>

<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.

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.
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 $\sim 4 \log$ 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.

REFERENCES


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 against 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.
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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*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.*
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  
Accepted as 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: 
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

Study Director

Benjamin J. Bastin

Study Sponsor

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Performing Laboratory

Q Laboratories
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Cincinnati, OH 45204
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title Page</td>
<td>1</td>
</tr>
<tr>
<td>Table of Contents</td>
<td>2</td>
</tr>
<tr>
<td>Test Summary</td>
<td>3</td>
</tr>
<tr>
<td>Testing Conditions</td>
<td>4</td>
</tr>
<tr>
<td>Study Dates and Facility</td>
<td>5</td>
</tr>
<tr>
<td>Records to be Maintained</td>
<td>5</td>
</tr>
<tr>
<td>Test Procedure</td>
<td>5</td>
</tr>
<tr>
<td>Statistical Analysis</td>
<td>10</td>
</tr>
<tr>
<td>Media Quality Controls</td>
<td>10</td>
</tr>
<tr>
<td>References</td>
<td>10</td>
</tr>
<tr>
<td>Summary of Results</td>
<td>11</td>
</tr>
<tr>
<td>Results</td>
<td>12</td>
</tr>
<tr>
<td>Conclusion</td>
<td>19</td>
</tr>
<tr>
<td>Appendix 1</td>
<td>20</td>
</tr>
</tbody>
</table>
Test Summary

Title: Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

Study Design: This study was designed to demonstrate that microorganisms can be removed from cast iron cookware with similar effectiveness as from stainless steel surfaces. The equivalence of recovery was demonstrated by inoculating both materials with equivalent numbers of each microorganism. For this study the following microorganisms were used: *Staphylococcus aureus*, *Escherichia coli*, *Salmonella Enteritidis*, *Listeria monocytogenes*, and *Clostridium perfringens*. Following inoculation, surfaces were sampled.

Test Articles:

The test articles evaluated were provided to the testing facility by the study sponsor, complete with appropriate documentation. Test articles were sterilized via autoclave upon receipt and stored at ambient temperature (20 - 25 °C) in autoclaved aluminum foil.

1. Cast Iron Cookware
   1.1 14 Ounce Round Cast Iron Mini Server (SKU: HMSRD)
   1.2 12 Ounce Cast Iron Mini Serving Bowl (SKU: HMSB)
   1.3 16 Ounce Oval Cast Iron Mini Server (SKU: HM16OS)
   1.4 9 Ounce Oval Cast Iron Mini Server (SKU: HMSOV)
   1.5 14 Ounce Rectangular Cast Iron Mini Server (SKU: HMS14RC)
   1.6 10 Ounce Square Cast Iron Mini Server (SKU: HMSS)
2. Food Grade Stainless Steel Carriers (18 GA 300 series, brush finish)

Sponsor: Lodge Manufacturing
204 East 5th Street
South Pittsburgh, TN 37380
Testing Conditions

Challenge Microorganisms:

1. *Staphylococcus aureus* American Type Culture Collection (ATCC) 6538
2. *Escherichia coli* ATCC 8739
3. *Salmonella* Enteritidis ATCC 13076
4. *Listeria monocytogenes* ATCC 7644
5. *Clostridium perfringens* ATCC 12915

Note: Appropriate laboratory safety conditions was employed while working with enriched culture suspensions. These conditions included, but were not limited to, the use of appropriate PPE (including disposable gloves, beard nets, hair nets, and lab coats), Biological Safety Cabinets, and protective eyewear.

Testing Conditions:

The evaluation was conducted at ambient temperature (20 - 25 °C).

Media/Reagents:

1. Tryptic Soy Agar with 5% Sheep Blood (SBA) (Fisher Scientific, PN 221261) or equivalent
2. Microbial Content Test (MCT) agar MP107
3. Tryptic Soy Broth (TSB) MP058
4. Phosphate Buffered Saline (PBS) MP416
5. Columbia Blood Agar (CBA) with 5% Sheep Blood MP086
6. Reinforced Clostridial Medium (RCM) MP158

Equipment/Supplies:

1. Incubator, temperature range 35 ± 1 °C
2. Incubator thermometer, NIST traceable
3. Sterile containers
4. Steam autoclave
5. Vortex mixer
6. Calibrated, traceable minute/second timer
7. Refrigerator, temperature range 2 - 8 °C
8. Refrigerator thermometer, NIST traceable
9. Traceable thermometer/clock/humidity monitor
10. Adjustable pipettor, 1 µL - 200 µL capacity
11. Adjustable pipettor, 100 µL - 1000 µL capacity
12. Sterile serological pipettes
13. Sterile 100 µL and 1000 µL micropipette tips
14. Reichert Quebec® Colony Counter, or equivalent
15. Hand tally
16. Test tubes, sterilized
17. Sterile disposable Petri dishes, 100 x 15 mm
18. Sterile polyurethane tip swabs
19. Sterile disposable loops
20. Rotator/shaker
21. Anaerobic Sachets, BBL GasPaks or equivalent

Study Dates and Facility

The analysis phase of this test was conducted at Q Laboratories in the Microbiology Research and Development Laboratory, 1930 Radcliff Drive, Cincinnati, Ohio 45204, from 10-28-19 to 11-11-19. The study sponsor and study director signed the protocol on 10-31-19. The final report was released 12-16-19.

Records to be Maintained

All testing data, protocol, protocol modifications, test material records, the final report, and correspondence between Q Laboratories and the sponsor will be stored in the archives at Q Laboratories, 1930 Radcliff Drive, Cincinnati, Ohio 45204 for a period of at least seven (7) years.

Test Procedure

Test Microorganism Preparation:

*Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Salmonella* Enteritidis ATCC 13076, and *Listeria monocytogenes* ATCC 7644 were propagated on Tryptic Soy Agar with 5% Sheep Blood (SBA) from a Q Laboratories frozen stock culture stored at -70 °C. SBA plates were incubated aerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony was picked to Tryptic Soy Broth (TSB) and incubated at 35 ± 1 °C for 24 ± 2 hours. Test articles were inoculated with the 24 hour TSB culture.

*Clostridium perfringens* ATCC 12915 was propagated on SBA from a Q Laboratories frozen stock culture stored at -70 °C. The SBA plate was incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony was transferred to pre-reduced Reinforced Clostridial Medium (RCM) and incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. Test articles were inoculated with the 24 hour RCM culture.

Pre-Inoculation Preparation:

The study sponsor reported that the test articles were pre-cleaned using one cycle in an industrial dishwasher prior to shipping.

Test articles and stainless-steel control carriers were placed in a sterile container and autoclaved after receipt by the testing facility. This step was done to ensure there is no residual bioburden prior to inoculation.
Using sterile gloves, the test article was placed on a disinfected flat surface. One (1) 1” x 1” location on each test article was marked for evaluation, depicted as red squares in Figures 1 - 4.

*Inoculation of Test Articles:*

A 100 µL aliquot of each test culture was applied to the 1” x 1” marked areas. The culture was uniformly spread over the sample area using 100 - 1000 µL micropipette tip to prevent areas of pooling.

After inoculation, the test articles were allowed to dry for 18 - 24 hours at ambient temperature (20 - 25 °C). After 18-24 hours, the test article was visually inspected to ensure the test culture suspension was uniformly dried and testing was initiated.

The inoculation steps above were repeated for the stainless-steel control carriers.

![Figure 1. 12 Ounce Cast Iron Mini Serving Bowl and 14 Ounce Round Cast Iron Mini Server Sample Areas.](image)
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.
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**

<table>
<thead>
<tr>
<th>Test Organisms</th>
<th>Test Article</th>
<th>No. of Test Replicates</th>
<th>No. of Stainless-Steel Control Replicates</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>S. aureus</em>, <em>E. coli</em>, <em>S. Enteritidis</em>, <em>L. monocytogenes</em>, <em>C. perfringens</em></td>
<td>14 Ounce Round Cast Iron Mini Server</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>12 Ounce Cast Iron Mini Serving Bowl</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>16 Ounce Oval Cast Iron Mini Server</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>9 Ounce Oval Cast Iron Mini Server</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>14 Ounce Rectangular Cast Iron Mini Server</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>10 Ounce Square Cast Iron Mini Server</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>
Recovery and Enumeration Procedure:

A 1.0 mL aliquot of PBS was added to a sterile swab. The marked 1” x 1” sample area was thoroughly swabbed in an up and down vertical motion and a left and right horizontal motion. This process was designed to remove viable microorganisms from the surface of the test article for enumeration.

The swab was placed in a test tube containing 9.0 mL of PBS. The swab was expressed into the test tube and thoroughly vortexed for 30 ± 5 seconds. Ten-fold serial dilutions of the sample were prepared by transferring 1.0 mL from the initial dilution into 9.0 mL of PBS.

For *S. aureus*, *E. coli*, *S. Enteritidis* and *L. monocytogenes*, each dilution was plated into duplicate sterile Petri dishes and 12 - 15 mL of tempered MCT was added. Plates were mixed thoroughly and allowed to solidify. Plates were inverted and incubated at 35 ± 1 °C for 48 ± 2 hours.

For *C. perfringens* each dilution was spread plated with sterile plating beads onto duplicate pre-poured plates of Columbia Blood Agar (CBA) with 5% Sheep Blood (CBA). Plates were inverted and incubated anaerobically at 35 ± 1 °C for 48 ± 2 hours.

After incubation, typical colonies were enumerated, and raw data was recorded as CFU/plate. Duplicate plates were averaged and multiplied by the dilution factor to arrive at CFU/test article. Raw values were recorded and used for the calculations in Tables 2-6.

Study Controls:

Food Grade Stainless Steel Controls – Three (3) 4” x 4” food grade stainless steel test articles were inoculated according to the test procedure. The recovered microorganisms were determined following the procedures found in Recovery and Enumeration. In order for the testing to be considered acceptable, the recovery data from the cast iron test articles had to be comparable to the food grade stainless steel.
**Statistical Analysis**

A logarithmic transformation measuring surviving microbial populations of the positive control article and test replicates for each microorganism were performed.

Equivalence of Recovery was calculated as follows:

\[
\Delta \text{Log}_{10} = \text{Equivalence Recovery}
\]

\[
\begin{align*}
\text{TR}_1 &= \text{Test Article Replicate 1} \\
\text{TR}_2 &= \text{Test Article Replicate 2} \\
\text{TR}_3 &= \text{Test Article Replicate 3} \\
\text{SS}_1 &= \text{Stainless Steel 1} \\
\text{SS}_2 &= \text{Stainless Steel 2} \\
\text{SS}_3 &= \text{Stainless Steel 3}
\end{align*}
\]

\[
\left(\frac{\text{TR}_1 + \text{TR}_2 + \text{TR}_3}{3}\right) - \left(\frac{\text{SS}_1 + \text{SS}_2 + \text{SS}_3}{3}\right) = \Delta \text{Log}_{10}
\]

**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 ± 1 °C for 48 ± 2 hours. These plates served as positive growth controls for the media.

The CBA and RCM media were inoculated with an aliquot of the *C. perfringens* suspension and incubated anaerobically at 35 ± 1 °C for 48 ± 2 hours. These served as positive growth controls for the media.

The acceptance criterion for these bacterial media controls was “typical growth” of the organisms.

For negative sterility controls, two tubes each of TSB, PBS, and three plates of MCT were incubated at 35 ± 2 °C for 48 ± 2 hours.

The acceptance criterion for these uninoculated media controls was “negative for growth”.

**References**


[http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063346.htm](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:

\[
\Delta \text{Log}10 = \text{Equivalence Recovery}
\]

\[
\text{TR1} = \text{Test Article Replicate 1}
\]

\[
\text{TR2} = \text{Test Article Replicate 2}
\]

\[
\text{TR3} = \text{Test Article Replicate 3}
\]

\[
\text{SS1} = \text{Stainless Steel 1}
\]

\[
\text{SS2} = \text{Stainless Steel 2}
\]

\[
\text{SS3} = \text{Stainless Steel 3}
\]

\[
\left(\frac{\text{TR1} + \text{TR2} + \text{TR3}}{3}\right) - \left(\frac{\text{SS1} + \text{SS2} + \text{SS3}}{3}\right) = \Delta \text{Log}10
\]
Results

**Table 2: Staphylococcus aureus ATCC 6538 Recovery Comparison**

Reported in CFU/mL recovered.

<table>
<thead>
<tr>
<th>Test Article</th>
<th>Units</th>
<th>Cast Iron Replicate A</th>
<th>Cast Iron Replicate B</th>
<th>Cast Iron Replicate C</th>
<th>Stainless Steel Control A</th>
<th>Stainless Steel Control B</th>
<th>Stainless Steel Control C</th>
<th>Equivalence Recovery (ΔLog10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 Ounce Round Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>2.6E+05</td>
<td>3.2E+05</td>
<td>3.8E+05</td>
<td>1.1E+05</td>
<td>2.6E+05</td>
<td>1.1E+05</td>
<td>0.3340</td>
</tr>
<tr>
<td></td>
<td>Log CFU/mL</td>
<td>5.4150</td>
<td>5.5051</td>
<td>5.5798</td>
<td>5.0414</td>
<td>5.4150</td>
<td>5.0414</td>
<td></td>
</tr>
<tr>
<td>12 Ounce Cast Iron Mini Serving Bowl</td>
<td>CFU/mL</td>
<td>3.3E+05</td>
<td>4.2E+05</td>
<td>2.8E+05</td>
<td>1.2E+05</td>
<td>1.2E+05</td>
<td>1.1E+05</td>
<td>0.4630</td>
</tr>
<tr>
<td></td>
<td>Log CFU/mL</td>
<td>5.5185</td>
<td>5.6232</td>
<td>5.4472</td>
<td>5.0792</td>
<td>5.0792</td>
<td>5.0414</td>
<td></td>
</tr>
<tr>
<td>16 Ounce Oval Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>3.0E+05</td>
<td>2.4E+05</td>
<td>2.1E+05</td>
<td>1.7E+05</td>
<td>1.5E+05</td>
<td>1.4E+05</td>
<td>0.2090</td>
</tr>
<tr>
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<td>Log CFU/mL</td>
<td>5.4771</td>
<td>5.3802</td>
<td>5.3222</td>
<td>5.2304</td>
<td>5.1761</td>
<td>5.1461</td>
<td></td>
</tr>
<tr>
<td>9 Ounce Oval Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>4.2E+05</td>
<td>5.0E+05</td>
<td>1.2E+05</td>
<td>1.6E+05</td>
<td>1.1E+05</td>
<td>1.2E+05</td>
<td>0.3589</td>
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<td>Log CFU/mL</td>
<td>5.6232</td>
<td>5.6990</td>
<td>5.0792</td>
<td>5.2041</td>
<td>5.0414</td>
<td>5.0792</td>
<td></td>
</tr>
<tr>
<td>14 Ounce Rectangular Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>4.6E+05</td>
<td>5.0E+05</td>
<td>4.9E+05</td>
<td>1.5E+05</td>
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<td>Log CFU/mL</td>
<td>5.6628</td>
<td>5.6990</td>
<td>5.6902</td>
<td>5.1761</td>
<td>4.9243</td>
<td>5.1761</td>
<td></td>
</tr>
<tr>
<td>10 Ounce Square Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>2.7E+05</td>
<td>3.0E+05</td>
<td>2.8E+05</td>
<td>7.4E+04</td>
<td>1.2E+05</td>
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</tr>
<tr>
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<td>Log CFU/mL</td>
<td>5.4314</td>
<td>5.4771</td>
<td>5.4472</td>
<td>4.8692</td>
<td>5.0792</td>
<td>5.1139</td>
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</tr>
</tbody>
</table>
Table 3: *Escherichia coli* ATCC 8739 Recovery Comparison
Reported in CFU/mL recovered.

<table>
<thead>
<tr>
<th>Test Article</th>
<th>Units</th>
<th>Cast Iron Replicate A</th>
<th>Cast Iron Replicate B</th>
<th>Cast Iron Replicate C</th>
<th>Stainless Steel Control A</th>
<th>Stainless Steel Control B</th>
<th>Stainless Steel Control C</th>
<th>Equivalence Recovery (ΔLog10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 Ounce Round Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>1.2E+04</td>
<td>1.7E+04</td>
<td>6.0E+03</td>
<td>5.0E+03</td>
<td>1.6E+04</td>
<td>5.6E+03</td>
<td>0.1455</td>
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<tr>
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<td>Log CFU/mL</td>
<td>4.0792</td>
<td>4.2304</td>
<td>3.7782</td>
<td>3.6990</td>
<td>4.2041</td>
<td>3.7482</td>
<td></td>
</tr>
<tr>
<td>12 Ounce Cast Iron Mini Serving Bowl</td>
<td>CFU/mL</td>
<td>6.6E+03</td>
<td>3.0E+03</td>
<td>9.2E+03</td>
<td>4.4E+03</td>
<td>6.6E+03</td>
<td>7.0E+03</td>
<td>-0.0159</td>
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<td>Log CFU/mL</td>
<td>3.8195</td>
<td>3.4771</td>
<td>3.9638</td>
<td>3.6435</td>
<td>3.8195</td>
<td>3.8451</td>
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<tr>
<td>16 Ounce Oval Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>5.4E+03</td>
<td>1.0E+04</td>
<td>5.8E+03</td>
<td>2.6E+04</td>
<td>2.6E+04</td>
<td>3.0E+04</td>
<td>-0.6038</td>
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<td>Log CFU/mL</td>
<td>3.7324</td>
<td>4.0000</td>
<td>3.7634</td>
<td>4.4150</td>
<td>4.4150</td>
<td>4.4771</td>
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<tr>
<td>9 Ounce Oval Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>6.4E+03</td>
<td>8.0E+03</td>
<td>8.4E+03</td>
<td>1.7E+04</td>
<td>2.7E+04</td>
<td>3.6E+04</td>
<td>-0.5282</td>
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<td>Log CFU/mL</td>
<td>3.8062</td>
<td>3.9031</td>
<td>3.9243</td>
<td>4.2304</td>
<td>4.4314</td>
<td>4.5563</td>
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<tr>
<td>14 Ounce Rectangular Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>4.7E+03</td>
<td>4.1E+03</td>
<td>4.2E+03</td>
<td>4.0E+03</td>
<td>5.6E+03</td>
<td>4.6E+03</td>
<td>-0.0350</td>
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<td>Log CFU/mL</td>
<td>3.6721</td>
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<td>3.6021</td>
<td>3.7482</td>
<td>3.6628</td>
<td></td>
</tr>
<tr>
<td>10 Ounce Square Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>5.4E+03</td>
<td>6.0E+03</td>
<td>1.0E+04</td>
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</tbody>
</table>
Table 4: *Salmonella* Enteritidis ATCC 13076 Recovery Comparison Reported in CFU/mL recovered.

<table>
<thead>
<tr>
<th>Test Article</th>
<th>Units</th>
<th>Cast Iron Replicate A</th>
<th>Cast Iron Replicate B</th>
<th>Cast Iron Replicate C</th>
<th>Stainless Steel Control A</th>
<th>Stainless Steel Control B</th>
<th>Stainless Steel Control C</th>
<th>Equivalence Recovery (ΔLog10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 Ounce Round Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>7.0E+04</td>
<td>7.2E+04</td>
<td>3.9E+04</td>
<td>1.4E+04</td>
<td>3.6E+04</td>
<td>3.8E+04</td>
<td>0.3371</td>
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<td>Log CFU/mL</td>
<td>4.8451</td>
<td>4.8573</td>
<td>4.5911</td>
<td>4.1461</td>
<td>4.5563</td>
<td>4.5798</td>
<td></td>
</tr>
<tr>
<td>12 Ounce Cast Iron Mini Serving Bowl</td>
<td>CFU/mL</td>
<td>2.6E+04</td>
<td>1.3E+04</td>
<td>1.4E+04</td>
<td>8.9E+03</td>
<td>5.2E+04</td>
<td>4.6E+04</td>
<td>-0.2177</td>
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<tr>
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<td>Log CFU/mL</td>
<td>4.4150</td>
<td>4.1139</td>
<td>4.1461</td>
<td>3.9494</td>
<td>4.7160</td>
<td>4.6628</td>
<td></td>
</tr>
<tr>
<td>16 Ounce Oval Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>9.9E+03</td>
<td>8.7E+03</td>
<td>2.8E+04</td>
<td>4.6E+03</td>
<td>1.3E+04</td>
<td>8.8E+03</td>
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<td>Log CFU/mL</td>
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<td>4.1139</td>
<td>3.9445</td>
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</tr>
<tr>
<td>9 Ounce Oval Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>3.2E+04</td>
<td>4.2E+04</td>
<td>3.4E+04</td>
<td>2.8E+04</td>
<td>1.2E+04</td>
<td>1.4E+04</td>
<td>0.3291</td>
</tr>
<tr>
<td></td>
<td>Log CFU/mL</td>
<td>4.5051</td>
<td>4.6232</td>
<td>4.5315</td>
<td>4.4472</td>
<td>4.0792</td>
<td>4.1461</td>
<td></td>
</tr>
<tr>
<td>14 Ounce Rectangular Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>4.3E+04</td>
<td>3.4E+04</td>
<td>3.8E+04</td>
<td>1.2E+04</td>
<td>1.4E+04</td>
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</tr>
<tr>
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<td>Log CFU/mL</td>
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<td>4.5798</td>
<td>4.0792</td>
<td>4.1461</td>
<td>4.314</td>
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</tr>
<tr>
<td>10 Ounce Square Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>6.3E+04</td>
<td>4.9E+04</td>
<td>5.8E+04</td>
<td>1.1E+04</td>
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<tr>
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<td>Log CFU/mL</td>
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<td>CFU/mL</td>
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<td>Stainless Steel Control B</td>
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<td>5.000</td>
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<td>5.2041</td>
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<td>9 Ounce Oval Cast Iron Mini Server</td>
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</tr>
<tr>
<td>14 Ounce Rectangular Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>5.2E+05</td>
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<tr>
<td>10 Ounce Square Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>1.9E+05</td>
<td>3.2E+05</td>
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<td>5.0414</td>
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### Table 7: *Staphylococcus aureus* ATCC 6538 Recovery Comparison
Reported in CFU/mL recovered – Retested.

<table>
<thead>
<tr>
<th>Test Article</th>
<th>Units</th>
<th>Cast Iron Replicate A</th>
<th>Cast Iron Replicate B</th>
<th>Cast Iron Replicate C</th>
<th>Stainless Steel Control A</th>
<th>Stainless Steel Control B</th>
<th>Stainless Steel Control C</th>
<th>Equivalence Recovery (ΔLog10)</th>
</tr>
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<tbody>
<tr>
<td>14 Ounce Rectangular Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>2.1E+05</td>
<td>2.9E+05</td>
<td>4.5E+05</td>
<td>5.3E+05</td>
<td>4.1E+05</td>
<td>3.9E+05</td>
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<td>Log CFU/mL</td>
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<td>5.6128</td>
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### Table 8: *Escherichia coli* ATCC 8739 Recovery Comparison
Reported in CFU/mL recovered - Retested.

<table>
<thead>
<tr>
<th>Test Article</th>
<th>Units</th>
<th>Cast Iron Replicate A</th>
<th>Cast Iron Replicate B</th>
<th>Cast Iron Replicate C</th>
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<th>Stainless Steel Control C</th>
<th>Equivalence Recovery (ΔLog10)</th>
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</thead>
<tbody>
<tr>
<td>16 Ounce Oval Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>1.3E+04</td>
<td>1.8E+04</td>
<td>2.4E+04</td>
<td>1.2E+04</td>
<td>3.4E+04</td>
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<td>Log CFU/mL</td>
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<td>4.3802</td>
<td>4.0792</td>
<td>4.5315</td>
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<td>9 Ounce Oval Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>1.5E+04</td>
<td>2.3E+04</td>
<td>2.7E+04</td>
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<td>Log CFU/mL</td>
<td>4.1761</td>
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<td>4.5185</td>
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### Table 9: *Salmonella* Enteritidis ATCC 13076 Recovery Comparison
Reported in CFU/mL recovered - Retested.

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<th>Equivalence Recovery (ΔLog10)</th>
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<td>10 Ounce Square Cast Iron Mini Server</td>
<td>CFU/mL</td>
<td>5.5E+04</td>
<td>3.2E+04</td>
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<td>Log CFU/mL</td>
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### Table 10: *Listeria monocytogenes* ATCC 7644 Recovery Comparison
Reported in CFU/mL recovered - Retested.

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<th>Units</th>
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<th>Equivalence Recovery (ΔLog10)</th>
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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
# Table of Contents

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October 29, 2019
Protocol # QL19269-2B

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: HMB)
7.1.3 16 Ounce Oval Cast Iron Mini Server (SKU: HM16OS)
7.1.4 9 Ounce Oval Cast Iron Mini Server (SKU: HMSOV)
7.1.5 14 Ounce Rectangular Cast Iron Mini Server (SKU: HMS14RC)
7.1.6 10 Ounce Square Cast Iron Mini Server (SKU: HMSS)

7.2 Food Grade Stainless Steel Carriers (18 GA 300 series, brush finish)

8.0 Testing Conditions:

8.1 The evaluation will be conducted at ambient temperature (20 - 25°C).
9.0 **Test Microorganisms:**

9.1 *Staphylococcus aureus* American Type Culture Collection (ATCC) 6538
9.2 *Escherichia coli* ATCC 8739
9.3 *Salmonella Enteritidis* ATCC 13076
9.4 *Listeria monocytogenes* ATCC 7644
9.5 *Clostridium perfringens* ATCC 12915

*Note:* Appropriate laboratory safety conditions will be employed while working with enriched culture suspensions. These conditions will include, but are not limited to, the use of appropriate PPE (including disposable gloves, beard nets, hair nets, and lab coats), Biological Safety Cabinets, and protective eyewear.

10.0 **Media/Reagents:**

10.1 Tryptic Soy Agar with 5% Sheep Blood (SBA) Commercially available from BD 221261 or equivalent
10.2 Microbial Content Test (MCT) agar MP107
10.3 Tryptic Soy Broth (TSB) MP058
10.4 Phosphate Buffered Saline (PBS) MP416
10.5 Columbia Blood Agar (CBA) with 5% Sheep Blood MP086
10.6 Reinforced Clostridial Medium (RCM) MP158

11.0 **Equipment/Supplies:**

11.1 Incubator, temperature range 35 ± 1 °C
11.2 Incubator thermometers, NIST traceable
11.3 Sterile containers
11.4 Steam autoclave
11.5 Vortex mixer
11.6 Calibrated, traceable minute/second timer
11.7 Refrigerator, temperature range 2 - 8 °C
11.8 Refrigerator thermometer, NIST traceable
11.9 Traceable thermometer/clock/humidity monitor
11.10 Adjustable pipettor, 1 µL - 200 µL capacity
11.11 Adjustable pipettor, 100 µL - 1000 µL capacity
11.12 Sterile serological pipettes
11.13 Sterile 100 µL and 1000 µL micropipette tips
11.14 Reichert Quebec® Colony Counter, or equivalent
11.15 Hand tally
11.16 Test tubes, sterilized
11.17 Sterile disposable Petri dishes, 100 x 15 mm
11.18 Sterile polyurethane tip swabs
11.19 Sterile disposable loops
11.20 Rotator/shaker
11.21 Anaerobic Sachets, BBL GasPaks or equivalent
12.0 **Test Microorganism Preparation:**

12.1 *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Salmonella Enteritidis* ATCC 13076, and *Listeria monocytogenes* ATCC 7644 will be propagated on Tryptic Soy Agar with 5% Sheep Blood (SBA) from a Q Laboratories frozen stock culture stored at -70 °C. SBA plates will be incubated aerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony will be picked to Tryptic Soy Broth (TSB) and incubated at 35 ± 1 °C for 24 ± 2 hours.

12.2 *Clostridium perfringens* ATCC 12915 will be propagated on SBA from a Q Laboratories frozen stock culture stored at -70 °C. The SBA plate will be incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony will be transferred to pre-reduced Reinforced Clostridial Medium (RCM) and incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours.

13.0 **Microorganism Recovery Study Parameters:**

13.1 Three (3) total replicates of the test articles will be evaluated for each microorganism. A summary of the recovery study parameters is presented in Table 1.

13.2 Three (3) total replicates using food grade stainless steel carries will be evaluated for each microorganism as controls. A summary of the antimicrobial activity study parameters is presented in Table 1.

Table 1. Summary of Recovery Study Parameters.

<table>
<thead>
<tr>
<th>Test Organisms</th>
<th>Test Article</th>
<th>No. of Test Replicates</th>
<th>No. of Stainless-Steel Control Replicates</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>S. aureus</em>, <em>E. coli</em>, <em>S. Enteritidis</em>, <em>L. monocytogenes</em>, <em>C. perfringens</em></td>
<td>14 Ounce Round Cast Iron Mini Server</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>12 Ounce Cast Iron Mini Serving Bowl</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>16 Ounce Oval Cast Iron Mini Server</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>9 Ounce Oval Cast Iron Mini Server</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>14 Ounce Rectangular Cast Iron Mini Server</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>10 Ounce Square Cast Iron Mini Server</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>
14.0 Test Procedure:

Preconditioning:
14.1 The study sponsor reported that the test articles were pre-cleaned using one cycle in an industrial dishwasher prior to shipping.
14.2 Test articles and stainless-steel control carriers will be placed in a sterile container and autoclaved after receipt by the testing facility. This step will be done to ensure there is no residual bioburden prior to inoculation.

Inoculation:
14.3 Using sterile gloves, place the test article on a disinfected flat surface. One (1) 1" x 1" location on the test article will be marked for evaluation as depicted in Figures 1 - 4.
14.4 Apply 100 μL of each test culture to the 1" x 1" marked areas. The culture will be uniformly spread over the sample area using 100 - 1000 μL micropipette tip to prevent areas of pooling.
14.5 After inoculation, the test articles will be allowed to dry for 18 - 24 hours at ambient temperature (20 - 25 °C). After 18-24 hours, the test article will be visually inspected to ensure the test culture suspension is uniformly dried and testing will be initiated.
14.6 Repeat inoculation steps 14.2 to 14.4 for the stainless-steel control carriers.
Figure 1. 12 Ounce Cast Iron Mini Serving Bowl and 14 Ounce Round Cast Iron Mini Server Sample Areas.
Figure 2. 9 Ounce Oval Cast Iron Mini Server and 16 Ounce Oval Cast Iron Mini Server Sample Areas.
Figure 3. 14 Ounce Rectangular Cast Iron Mini Server Sample Area.

Figure 4. 10 Ounce Square Cast Iron Mini Server Sample Area.
15.0 **Recovery and Enumeration Procedure:**

15.1 Add 1.0 mL of PBS to a sterile swab. Thoroughly swab the 1" x 1" sample area in a both an up and down vertical motion and in a left and right horizontal motion. This process is designed to remove viable microorganisms from the surface of the test article for enumeration.

15.2 Place the swab in a test tube containing 9.0 mL of PBS. Express the swab into the test tube and thoroughly vortex. Prepare ten-fold serial dilutions of the sample by transferring 1.0 mL from the initial dilution into 9.0 mL of PBS.

15.3 For *S. aureus*, *E. coli*, *S. Enteritidis* and *L. monocytogenes*, plate each dilution into duplicate sterile Petri dishes and add 12 - 15 mL of tempered MCT to the Petri dishes. Mix thoroughly and allow the plates to solidify. Invert plates and incubate at 35 ± 1 °C for 48 ± 2 hours.

15.4 For *C. perfringens* spread plate each dilution on duplicate pre-poured plates of CBA. Spread inoculum with a sterile L-shaped spreader or sterile plating beads. Invert plates and incubate anaerobically at 35 ± 1 °C for 48 ± 2 hours.

15.5 After incubation, typical colonies will be enumerated and raw data recorded as CFU/plate. Duplicate plates will be averaged and multiplied by the dilution factor to arrive at CFU/test article. Raw values will be recorded and used for the calculations in section 18.0.

16.0 **Study Controls:**

16.1 Food Grade Stainless Steel Controls – Three (3) 4" x 4" food grade stainless steel test articles will be inoculated according to the procedures outlined in Section 14.0. The recovered microorganisms will be determined following the procedures in section 15.0. In order for the testing to be considered acceptable, recovery data comparable to the cast iron test articles much be achieved.

17.0 **Statistical Analysis:**

17.1 A logarithmic transformation measuring surviving microbial populations of the positive control article and test replicates for each microorganism will be performed.

17.2 Equivalence of Recovery will be calculated as follows:

\[
\Delta \log_{10} = \text{Equivalence of Recovery}
\]

\[
TR1 = \text{Test Article Replicate 1}
\]

\[
TR2 = \text{Test Article Replicate 2}
\]

\[
TR3 = \text{Test Article Replicate 3}
\]

\[
SS1 = \text{Stainless Steel 1}
\]

\[
SS2 = \text{Stainless Steel 2}
\]

\[
SS3 = \text{Stainless Steel 3}
\]

\[
\left(\frac{TR1 + TR2 + TR3}{3}\right) - \left(\frac{SS1 + SS2 + SS3}{3}\right) = \Delta \log_{10}
\]
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 ± 1 °C for 48 ± 2 hours. These plates will serve as positive growth controls for the media.

18.2 The CBA and RCM media will be inoculated with an aliquot of the *C. perfringens* suspension. The CBA and RCM will be incubated anaerobically at 35 ± 1 °C for 48 ± 2 hours. These will serve as positive growth controls for the media.

18.3 The acceptance criterion for these bacterial media controls is “typical growth” of the organisms.

18.4 For negative sterility controls, two tubes each of TSB, PBS, and three plates of MCT will be incubated at 35 ± 2 °C for 48 ± 2 hours.

The acceptance criterion for these uninoculated media controls is “negative for growth”.

19.0 **Performance Criteria:**

19.1 In order to demonstrate equivalent recovery the cast iron test articles must be within 0.5 Log of the stainless-steel carrier controls.

20.0 **Acceptance Criteria:**

20.1 The study controls below must perform according to the criteria detailed for the data to be considered acceptable.

20.1.1 Comparable growth acceptance will be within 50 - 200% between the media.

20.1.2 The acceptance criteria are growth from inoculated streaks and no growth from the sterility controls.

21.0 **References:**


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–ADMIN-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.
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. Baslin  
Microbiology R&D Laboratory Supervisor

Lodge Manufacturing (Study Sponsor)
204 East 5th Street
South Pittsburgh, TN 37380

Representative:  
David Fletcher  
QA Supervisor

Date

Q Laboratories
Issue: 2020 III-032

**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:
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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 in Foodborne Diseases

Incidence and Trends of Incidence 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 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.

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

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* 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.
¶ Final incidence rates will be reported when population estimates for 2012 are available.
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 1. Number of cases of bacterial and parasitic infection, hospitalizations, and deaths, by pathogen — Foodborne Diseases Active Surveillance Network, United States, 2012*

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Cases No.</th>
<th>Incidence†</th>
<th>Objective§</th>
<th>Hospitalizations No. (%)</th>
<th>Deaths No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacteria</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Campylobacter</em></td>
<td>6,793</td>
<td>14.30</td>
<td>8.5</td>
<td>1,044 (15)</td>
<td>6 (0.09)</td>
</tr>
<tr>
<td><em>Listeria</em></td>
<td>121</td>
<td>0.25</td>
<td>0.2</td>
<td>116 (96)</td>
<td>13 (10.74)</td>
</tr>
<tr>
<td><em>Salmonella</em></td>
<td>7,800</td>
<td>16.42</td>
<td>11.4</td>
<td>2,284 (29)</td>
<td>33 (0.42)</td>
</tr>
<tr>
<td><em>Shigella</em></td>
<td>2,138</td>
<td>4.50</td>
<td>N/A††</td>
<td>491 (23)</td>
<td>2 (0.09)</td>
</tr>
<tr>
<td>STEC O157</td>
<td>531</td>
<td>1.12</td>
<td>0.6</td>
<td>187 (35)</td>
<td>1 (0.19)</td>
</tr>
<tr>
<td>STEC non-O157</td>
<td>551</td>
<td>1.16</td>
<td>N/A</td>
<td>88 (16)</td>
<td>1 (0.18)</td>
</tr>
<tr>
<td><em>Vibrio</em></td>
<td>193</td>
<td>0.41</td>
<td>0.2</td>
<td>55 (29)</td>
<td>6 (3.11)</td>
</tr>
<tr>
<td><em>Yersinia</em></td>
<td>155</td>
<td>0.33</td>
<td>0.3</td>
<td>59 (38)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td><strong>Parasites</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Cryptosporidium</em></td>
<td>1,234</td>
<td>2.60</td>
<td>N/A</td>
<td>236 (19)</td>
<td>6 (0.49)</td>
</tr>
<tr>
<td><em>Cyclospora</em></td>
<td>15</td>
<td>0.03</td>
<td>N/A</td>
<td>3 (20)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>19,531</td>
<td></td>
<td></td>
<td>4,563</td>
<td>68</td>
</tr>
</tbody>
</table>

**Abbreviations:** N/A = not available; STEC = Shiga toxin–producing *Escherichia coli*.

* Data for 2012 are preliminary.
† Per 100,000 population.
§ Healthy People 2020 objective targets for incidence of *Campylobacter*, *Listeria*, *Salmonella*, STEC O157, *Vibrio*, and *Yersinia* infections per 100,000 population.
†† No national health objective exists for these pathogens.

### Table 2. Incidence* of laboratory-confirmed bacterial and parasitic infections in 2012,† by pathogen and age group — Foodborne Diseases Active Surveillance Network, United States

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Age group (yrs)</th>
<th>&lt;5</th>
<th>5–9</th>
<th>10–19</th>
<th>20–64</th>
<th>≥65</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacteria</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Campylobacter</em></td>
<td>24.08</td>
<td>10.54</td>
<td>9.42</td>
<td>14.54</td>
<td>15.26</td>
<td></td>
</tr>
<tr>
<td><em>Listeria</em></td>
<td>0.17</td>
<td>0.00</td>
<td>0.03</td>
<td>0.17</td>
<td>1.05</td>
<td></td>
</tr>
<tr>
<td><em>Salmonella</em></td>
<td>63.49</td>
<td>19.33</td>
<td>11.26</td>
<td>12.15</td>
<td>17.22</td>
<td></td>
</tr>
<tr>
<td><em>Shigella</em></td>
<td>16.92</td>
<td>14.77</td>
<td>2.96</td>
<td>3.10</td>
<td>1.42</td>
<td></td>
</tr>
<tr>
<td>STEC O157</td>
<td>4.71</td>
<td>2.31</td>
<td>1.65</td>
<td>0.58</td>
<td>0.74</td>
<td></td>
</tr>
<tr>
<td>STEC non-O157</td>
<td>4.81</td>
<td>1.33</td>
<td>1.65</td>
<td>0.70</td>
<td>0.92</td>
<td></td>
</tr>
<tr>
<td><em>Vibrio</em></td>
<td>0.07</td>
<td>0.26</td>
<td>0.14</td>
<td>0.43</td>
<td>0.78</td>
<td></td>
</tr>
<tr>
<td><em>Yersinia</em></td>
<td>1.33</td>
<td>0.29</td>
<td>0.16</td>
<td>0.23</td>
<td>0.49</td>
<td></td>
</tr>
<tr>
<td><strong>Parasites</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Cryptosporidium</em></td>
<td>3.68</td>
<td>3.09</td>
<td>1.70</td>
<td>2.54</td>
<td>3.01</td>
<td></td>
</tr>
<tr>
<td><em>Cyclospora</em></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.04</td>
<td>0.03</td>
<td></td>
</tr>
</tbody>
</table>

* Per 100,000 population.
† Data for 2012 are preliminary.
§ Shiga toxin–producing *Escherichia coli*.

*Campylobacter* (31%). At least 95% of patients with *Listeria* infection in each age group†† 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


†† Age groups defined as <5 years, 5–9 years, 10–19 years, 20–64 years, and ≥65 years.
Corresponding contributor: Stacy M. Crim, scrim@cdc.gov, 404-639-2257.

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.

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.

* Shiga toxin–producing Escherichia coli.
† 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. Pancreatitis associations are more common in the western U.S. states and among children aged <5 years (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. In 2011, USDA-FSIS issued new *Campylobacter* performance standards for U.S. chicken and turkey processors. 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.

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**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, 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. 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. 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.

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††† Additional information available at [http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/eggs/ucm170615.htm](http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/eggs/ucm170615.htm).


¶¶¶ Additional information available at [http://www.fda.gov/food/guidanceregulation/fsma/ucm242500.htm](http://www.fda.gov/food/guidanceregulation/fsma/ucm242500.htm).


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**Acknowledgments**

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**References**


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,§ 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§) 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

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* Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York (https://www.cdc.gov/foodnet).

§ 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†

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>2018 No. of cases</th>
<th>2018 No. (%) of hospitalizations</th>
<th>2018 No. (%) of deaths</th>
<th>IR$^6$</th>
<th>% (95% CI) Change in IR$^6$</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacteria</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Campylobacter</td>
<td>9,723</td>
<td>1,811 (18)</td>
<td>30 (0.3)</td>
<td>19.6</td>
<td>12 (4 to 20)</td>
</tr>
<tr>
<td>Salmonella</td>
<td>9,084</td>
<td>2,416 (27)</td>
<td>36 (0.4)</td>
<td>18.3</td>
<td>9 (3 to 16)</td>
</tr>
<tr>
<td>Shiga toxin–producing</td>
<td>2,925</td>
<td>648 (22)</td>
<td>13 (0.4)</td>
<td>5.9</td>
<td>26 (7 to 48)</td>
</tr>
<tr>
<td><em>Escherichia coli</em>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shigella</td>
<td>2,414</td>
<td>632 (26)</td>
<td>1 (0.04)</td>
<td>4.9</td>
<td>−2 (−24 to 26)</td>
</tr>
<tr>
<td>Vibrio</td>
<td>537</td>
<td>151 (28)</td>
<td>9 (2)</td>
<td>1.1</td>
<td>109 (72 to 154)</td>
</tr>
<tr>
<td>Yersinia</td>
<td>465</td>
<td>95 (20)</td>
<td>4 (0.9)</td>
<td>0.9</td>
<td>58 (26 to 99)</td>
</tr>
<tr>
<td>Listeria</td>
<td>126</td>
<td>121 (96)</td>
<td>26 (21)</td>
<td>0.3</td>
<td>−4 (−23 to 21)</td>
</tr>
<tr>
<td><em>Parasite</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cyclospora</td>
<td>332</td>
<td>19 (5)</td>
<td>1 (0.3)</td>
<td>0.7</td>
<td>399 (202 to 725)</td>
</tr>
<tr>
<td>Total</td>
<td>25,606</td>
<td>5,893 (23)</td>
<td>120 (0.5)</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

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 (26 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, 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,
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.

Produce is a major source of foodborne illnesses. During 2018, romaine lettuce was linked to two multistate outbreaks of STEC O157 infections. 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. 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. FDA is implementing the Produce Safety Rule, 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.

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.

Acknowledgments

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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.

References


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
Multi-country outbreak of *L. monocytogenes* linked to frozen corn and other frozen vegetables

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

**Correspondence:** zoonoses@efsa.europa.eu
Multi-country outbreak of L. monocytogenes linked to frozen corn and other frozen vegetables

Acknowledgements: EFSA wishes to thank the ECDC experts: Margot Einöder-Moreno, Saara Kotila, Taina Niskanen, Ettore Severi, Johanna Takkinen, Therese Westrell, EFSA experts: Giusi Amore, Raquel Garcia Fierro, Ernesto Liebana Criado, Valentina Rizzi, the European Reference Laboratory for Listeria monocytogenes (EURL for Lm): Benjamin Felix, Jean Charles Leblanc, Bertrand Lombard, Jean-François Mariet, Maroua Sayeb, and external experts representing national authorities (by alphabetical order of countries): Austria: Franz Allerberger, Steliania 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 Schjerring (Statens Serum Institut); Estonia: Jelena Sõgel and Elle Männisalu (Veterinary and Food Board); Finland: Ruska Rimhanen-Finne and Saara Salmenlinna (National Institute for Health and Welfare), Elna Leinonen, Maria Rönqvist (Finnish Food Safety Authority - Evira); France: Marc Lecuit, Alexandre Leclercq, Mylène Maury, Alexandra Moura (Institut Pasteur); Laurent Guiller, David Albert, Michel Yves Mistou, Nicolas Radomsky, Arnaud Felten (French Agency for Food, Environmental and Occupational Health & Safety), Marie-Pierre Donguy (Ministry of Agriculture, Agrifood, and Forestry); Hungary: Zsuzsanna Sréterné Lancz (Food Microbiological National Reference Laboratory, National Food Chain Safety Office, Orsolya Szalay (Food and Feed Safety Directorate, National Food Chain Safety Office), Edina Bors (Food and Feed Safety Directorate, National Food Chain Safety Office); Poland: Maciej Kałuża (Główny Inspektorat Sanitarny), Joanna Pietrzak (Wojewódzka Stacja Sanitarno-Epidemiologiczna w Bydgoszczy); Maćkwi Alżbieta (Polish National Reference Laboratory for L. monocytogenes); Sweden: Cecilia Jernberg, Lena Sundqvist (Public Health Sweden); Mats Lindblad (National Food Agency); the United Kingdom: Lisa Byrne, Kathie Grant, Gauri Godbole, Sanch Kanagarajah (Public Health England – PHE), Alison Smith-Palmer (Health Protection Scotland – HPS) for the support provided to this scientific output.

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

ISSN: 2397-8325

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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’.
RAPID OUTBREAK ASSESSMENT

Multi-country outbreak of *L. monocytogenes* linked to frozen corn and other frozen vegetables – 3 July 2018

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 \textit{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

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- European Reference Laboratory for \textit{Listeria monocytogenes} (EURL for \textit{Lm}): Benjamin Felix, Jean Charles Leblanc, Bertrand Lombard, Jean-François Mariet, Maroua Sayeb.
- External experts representing national authorities (in alphabetical order of countries):
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  - Belgium: Marie Bienfait (Agence fédérale de la Sécurité de la Chaîne alimentaire);
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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 ≤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)

<table>
<thead>
<tr>
<th>Country</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>Total number of cases</th>
<th>Total number of deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>0</td>
<td>2 (1)</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Denmark</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2 (1)</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Finland</td>
<td>0</td>
<td>4</td>
<td>10 (2)</td>
<td>9</td>
<td>23</td>
<td>2</td>
</tr>
<tr>
<td>Sweden</td>
<td>0</td>
<td>3 (1)</td>
<td>3 (1)</td>
<td>1 (1)</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1</td>
<td>2</td>
<td>2 (2)</td>
<td>6</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1 (0)</strong></td>
<td><strong>11 (2)</strong></td>
<td><strong>17 (5)</strong></td>
<td><strong>18 (2)</strong></td>
<td><strong>47</strong></td>
<td><strong>9</strong></td>
</tr>
</tbody>
</table>

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)

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 EU RL 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*10^2 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 1b and 6 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.
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;

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**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)**

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Sample type</th>
<th>Sampling location and/or processing stage</th>
<th>Batch code</th>
<th>WGS*</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Detection</td>
<td>Enumeration (cfu/g)</td>
<td></td>
</tr>
<tr>
<td>Environmental samples</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>01</td>
<td>swab</td>
<td>Sorter band during operation</td>
<td>NA</td>
<td>Negative</td>
<td>-</td>
</tr>
<tr>
<td>02</td>
<td>swab</td>
<td>Blanching band during operation</td>
<td>NA</td>
<td>Negative</td>
<td>-</td>
</tr>
<tr>
<td>03</td>
<td>swab</td>
<td>Band leading to grinding machine during operation</td>
<td>NA</td>
<td>Negative</td>
<td>-</td>
</tr>
<tr>
<td>04</td>
<td>Swab of floor drain</td>
<td>Packaging area during operation</td>
<td>NA</td>
<td>Positive</td>
<td>-</td>
</tr>
<tr>
<td>05a</td>
<td>Pre-cooled water</td>
<td></td>
<td>NA</td>
<td>Negative</td>
<td>-</td>
</tr>
<tr>
<td>05b</td>
<td>Incoming ice water</td>
<td></td>
<td>NA</td>
<td>Negative</td>
<td>-</td>
</tr>
<tr>
<td>Food samples</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>06</td>
<td>Fresh leafy spinach</td>
<td></td>
<td>V</td>
<td>Negative</td>
<td>-</td>
</tr>
<tr>
<td>07</td>
<td>Sample of spinach</td>
<td>After washing</td>
<td>V</td>
<td>Negative</td>
<td>-</td>
</tr>
<tr>
<td>08</td>
<td>Sample of spinach</td>
<td>Grinder</td>
<td>V</td>
<td>Positive</td>
<td>&lt;10 cfu/g</td>
</tr>
<tr>
<td>09</td>
<td>Not frozen creamy spinach puree</td>
<td>After closing of the package</td>
<td>V</td>
<td>Positive</td>
<td>&lt;10 cfu/g</td>
</tr>
<tr>
<td>10</td>
<td>Frozen creamy spinach puree</td>
<td>After freezing</td>
<td>V</td>
<td>Positive</td>
<td>10 cfu/g</td>
</tr>
<tr>
<td>11</td>
<td>Frozen creamy spinach puree</td>
<td>Final product</td>
<td>W</td>
<td>Positive</td>
<td>Up to 30 cfu/g</td>
</tr>
<tr>
<td>12</td>
<td>Frozen creamy spinach puree</td>
<td>Final product</td>
<td>Y</td>
<td>Positive</td>
<td>&lt;10 cfu/g</td>
</tr>
</tbody>
</table>

* 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

Hungary

Supplier A
Country: HU

Processing Company A
Country: HU

Supplier B
Country: HU

Creamy spinach puree before & after freezing (2018)

Samples:}
- 2 creamy spinach puree before/after freezing (batch V)
- 1 frozen creamy spinach (batch Y)

Production season: 2017
Batches: V, W and Y

Sampling date: 17 May 2018

L. monocytogenes WGS
Genetic match with Finnish outbreak strain
- 2 creamy spinach puree before/after freezing (batch V)
- 1 frozen creamy spinach (batch Y)

Poland

Company B (storage service)
Country: PL

Company C (packer)
Country: PL

Samples:}
- Frozen creamy spinach (2018) Batches Y and W
- Frozen green beans (2018) Batch Y

Production season: 2018

Batches: V, W and Y

Sampling date: 17 May 2018

L. monocytogenes positive (up to 70 cfu/g)
Genetic match with L. monocytogenes ST6 Finnish outbreak strain

Samples:}
- Frozen corn (2017) used in batches A, B, C, D, E and G (packed in Poland)
- Frozen corn

Production season: 2017
Context: official control
Sampling date: 27 April 2018

Genetic match with L. monocytogenes ST6 Finnish outbreak strain
- 2 isolates from frozen spinach (batch T)
- 1 frozen green beans (batch U)

Company F
Country: FR

Company G
Country: FR

Austria

Company D
Country: AT

Belgium

Company D
Country: BE

Samples: Frozen Mexican vegetable mix (2)
Batches: O and P
Production season: 2016 and 2017

Genetic match with L. monocytogenes ST6 Finnish outbreak strain
- 3 isolates

Samples: Frozen Mexican vegetable mix
Batch Q and S

Production season: 2017

Retailer C
Country: AT

Retailer B
Country: EE

Finland

Vendor/broker A
Country: FI

Wholesaler A
Country: FI

Samples:
- Frozen corn
Batches A and B
Production season: 2017
Context: own check
Sampling date: 23 February 2018

L. monocytogenes positive (up to 70 cfu/g)
Genetic match with L. monocytogenes ST6 Finnish outbreak strain
- 2 isolates

Estonia

Samples: Frozen corn
Batches A, B, D and E
Production season: 2017

Genetic match with L. monocytogenes ST6 Finnish outbreak strain
- 3 isolates

One of the L. monocytogenes ST6 human cases

Staple food (no additional traceability information provided)

Sweden

Sample: frozen corn
Batch A, B and C
Production season: 2017
Context: official control
Sampling date: 19 February 2018

L. monocytogenes positive (up to 70 cfu/g)
Genetic match with L. monocytogenes ST6 Finnish outbreak strain
- 2 isolates

Samples:}
- Frozen corn
Batches A, B, C and D
Production season: 2017
Context: own check
Sampling date: 23 February 2018

L. monocytogenes positive (up to 70 cfu/g)
Genetic match with L. monocytogenes ST6 Finnish outbreak strain
- 2 isolates

Samples: Frozen Mexican vegetable mix
Batches Q and S

Production season: 2017

Retailer C
Country: AT

Distribution to a consumer

Consumption of corn (no traceability information provided)

Deep frozen vegetables

Other suppliers

Food business operator

Additional information

Legend

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 1661 (95%) of the 1748 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***

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of human isolates (no. of differing cg alleles from the FI representative outbreak strain)</th>
<th>Number of non-human isolates (no. of differing cg alleles from the FI representative outbreak strain)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>2 (3–4)</td>
<td>4 (3–4)</td>
</tr>
<tr>
<td>Denmark</td>
<td>4 (3–7)</td>
<td>–</td>
</tr>
<tr>
<td>Finland</td>
<td>23 (0–5)</td>
<td>5 (4–5)</td>
</tr>
<tr>
<td>France</td>
<td>–</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Hungary</td>
<td>–</td>
<td>11 (3–6)</td>
</tr>
<tr>
<td>Poland</td>
<td>–</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Sweden</td>
<td>7 (3–6)</td>
<td>2 (4–5)**</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>11 (1–6)</td>
<td>–</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>47 (0–7)</strong></td>
<td><strong>25 (3–6)</strong></td>
</tr>
</tbody>
</table>

* 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 ≤7 differing cgalleles 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 1,583 of the 1,748 core loci (90.55%) 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 (≤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 properly cooked.

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.
References


1b. European Centre for Disease Prevention and Control (ECDC) and European Food Safety Authority (EFSA). Joint ECDC-EFSA Rapid Outbreak Assessment - Multi-country outbreak of *Listeria monocytogenes* serogroup IVb, multi-locus sequence type 6, infections probably linked to frozen corn. Stockholm: ECDC; 2017.


Link to FDA’s Risk Profile on Pathogens and Filth in Spices (2017):
https://www.fda.gov/media/108126/download
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*

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 (Bargen, 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,
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).

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 (Aw), 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 (Aw) and temperature.

Water activity (Aw): Water activity (Aw) is a measure of the available water content in a food sample. The Aw 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 Aw 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 Aw is lower than 0.86. Leung (2006) measured the Aw of sushi rice made by the recipe provided by SushiLink (2006). The Aw 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 (Aw) 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., 2010).

**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): μ > 4.6
Alternative hypothesis (Ha): μ ≤ 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 ≥ 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. pH values of the sushi rice samples collected from 30 different Japanese restaurants in Burnaby.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Restaurants</th>
<th>pH</th>
<th>Temp (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kilala Sushi</td>
<td>3.83</td>
<td>19.5</td>
</tr>
<tr>
<td>2</td>
<td>Kokoro Sushi</td>
<td>3.82</td>
<td>21.2</td>
</tr>
<tr>
<td>3</td>
<td>Sushi S</td>
<td>3.8</td>
<td>21.8</td>
</tr>
<tr>
<td>4</td>
<td>Yo Sushi</td>
<td>3.71</td>
<td>21.1</td>
</tr>
<tr>
<td>5</td>
<td>Sushi Town</td>
<td>3.8</td>
<td>22.9</td>
</tr>
<tr>
<td>6</td>
<td>Osaka Sushi</td>
<td>3.91</td>
<td>23</td>
</tr>
<tr>
<td>7</td>
<td>Hong Sushi</td>
<td>3.92</td>
<td>21.9</td>
</tr>
<tr>
<td>8</td>
<td>Black Dragon</td>
<td>4.09</td>
<td>21</td>
</tr>
<tr>
<td>9</td>
<td>Nao Sushi</td>
<td>4.04</td>
<td>20.9</td>
</tr>
<tr>
<td>10</td>
<td>Fresh Box Sushi</td>
<td>4.16</td>
<td>21.8</td>
</tr>
<tr>
<td>11</td>
<td>Narita Sushi</td>
<td>3.86</td>
<td>20.7</td>
</tr>
<tr>
<td>12</td>
<td>Sushi Garden Metrotown</td>
<td>4.28</td>
<td>21.2</td>
</tr>
<tr>
<td>13</td>
<td>Tang Tang Sushi</td>
<td>4.24</td>
<td>21.4</td>
</tr>
<tr>
<td>14</td>
<td>Osaka Island</td>
<td>4.07</td>
<td>22.3</td>
</tr>
<tr>
<td>15</td>
<td>Kamamarui</td>
<td>4.48</td>
<td>22.6</td>
</tr>
<tr>
<td>16</td>
<td>Sushi Garden Brentwood</td>
<td>4.24</td>
<td>23</td>
</tr>
<tr>
<td>17</td>
<td>Asakusa Sushi</td>
<td>4.09</td>
<td>22.6</td>
</tr>
<tr>
<td>18</td>
<td>Yakko</td>
<td>4.19</td>
<td>22.8</td>
</tr>
<tr>
<td>19</td>
<td>Akira</td>
<td>4.36</td>
<td>21.9</td>
</tr>
<tr>
<td>20</td>
<td>Sushi &amp;</td>
<td>4.05</td>
<td>22</td>
</tr>
<tr>
<td>21</td>
<td>Gaya Sushi</td>
<td>4.15</td>
<td>22.2</td>
</tr>
<tr>
<td>22</td>
<td>Kato Sushi</td>
<td>4.18</td>
<td>22.4</td>
</tr>
<tr>
<td>23</td>
<td>Sushi Gen</td>
<td>4.02</td>
<td>22.1</td>
</tr>
<tr>
<td>24</td>
<td>LA Sushi</td>
<td>4.23</td>
<td>21.9</td>
</tr>
<tr>
<td>25</td>
<td>Sushi California</td>
<td>4.53</td>
<td>22</td>
</tr>
<tr>
<td>26</td>
<td>Okoman Sushi</td>
<td>4.16</td>
<td>22.4</td>
</tr>
<tr>
<td>27</td>
<td>Kita Sushi</td>
<td>4.19</td>
<td>22.7</td>
</tr>
<tr>
<td>28</td>
<td>Sushi Oyama</td>
<td>4.14</td>
<td>22.8</td>
</tr>
<tr>
<td>29</td>
<td>Little Toko's Sushi</td>
<td>4.11</td>
<td>22.5</td>
</tr>
<tr>
<td>30</td>
<td>Sushi Kaku</td>
<td>4.12</td>
<td>22.6</td>
</tr>
</tbody>
</table>
Table 2. Descriptive Statistics of pH of the sushi rice samples

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>4.09</td>
</tr>
<tr>
<td>Median</td>
<td>4.115</td>
</tr>
<tr>
<td>Mode</td>
<td>3.8</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.198</td>
</tr>
<tr>
<td>Range</td>
<td>0.82</td>
</tr>
<tr>
<td>Minimum</td>
<td>3.71</td>
</tr>
<tr>
<td>Maximum</td>
<td>4.53</td>
</tr>
<tr>
<td>Count</td>
<td>30</td>
</tr>
</tbody>
</table>

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, ranging 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 (Aw) 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.

Acknowledgements
The authors thank the British Columbia Institute of Technology - Environmental Health for supporting this research.

Competing Interest
The authors declare that they have no competing interests.

References


http://www.cdc.gov/ncidod/dbmd/diseaseinfo/staphylococcus_food_g.htm


Conference for Food Protection  
2020 Issue Form

Issue: 2020 III-034

Council Recommendation: Accepted as Submitted  ______ 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:
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;"

Submitter Information:
Name: Garrett Guillozet, MPA, RS/REHS
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.