Conference for Food Protection
2016 Issue Form

Issue: 2016 III-001

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:

Report - Listeria Retail Guidelines (LRG) Committee

Issue you would like the Conference to consider:

At the 2014 Biennial Meeting of the Conference for Food Protection, the Listeria Retail Guidelines Committee was re-created and charged (Issue: 2014 III-008) to revise the "2006 Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* Within Food Establishments" to include:

1) sanitation guidance for equipment and food establishment environments,

2) good retail practices on how to prevent contamination and growth of Lm in retail establishments,

3) updated outdated links to other documents, and

4) information from and references to documents published by credible organizations on the topic of Lm prevention and control in food establishments.

(Note: the 2006 document titled "Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of Listeria monocytogenes Within Food Establishments" is currently available on the CFP website at http://www.foodprotect.org/media/guide/2006CFPLmInterventionvoluntaryguidelines.pdf)

The Conference also recommends that the committee report its recommendations back to the 2016 Biennial Meeting with Issues to address:

1) the above charges, and

2) recommendations that a letter be sent to FDA requesting that Annex 2 (References, Part 3-Supporting Documents) be amended by adding a reference to the revised voluntary guidelines.

The Listeria Retail Guidelines Committee requests acknowledgement of their final report and acknowledgement of the committee members for their hard work.

Public Health Significance:

Listeria contamination continues to be a significant public health issue. Although the 2006 CFP Listeria Guidelines provided useful general information about cleaning, sanitizing and good retail practices, the guidelines required updating to reflect new information and available resources. The process and the resulting updates were developed by a committee whose membership included a wide variety of viewpoints and expertise to help ensure that the guidelines provide the best possible information to help food establishments protect public health.

Recommended Solution: The Conference recommends...:

1. Acknowledgment of the 2014-2016 *Listeria* Retail Guidelines Committee report,
2. Thanking the members of the 2014-2106 *Listeria* Retail Guidelines Committee for their work on the "2016 Draft Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* within Food Establishments, Second Edition document", and
3. That the Committee be disbanded.

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Content Documents:

- "Reporrt-Listeria Retail (LRG) Committee"
- "Listeria Retail Guidelines (LRG) Committee Roster"
- "Listeria Retail Guidelines Document (2016)a"

Supporting Attachments:

- "2006 Listeria Guidelines"

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

Conference for Food Protection – Committee FINAL Report

Template approved: 08/14/2013

Committee Final Reports are considered DRAFT until deliberated and acknowledged by the assigned Council at the Biennial Meeting

COMMITTEE NAME: Listeria Retail Guidelines (LRG) Committee

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council III

DATE OF REPORT: November 20, 2015

SUBMITTED BY: Tom Ford and Don Schaffner (co-chairs)

COMMITTEE CHARGE(s):

Issue: 2014 III-008

The Conference recommends the re-creation of the *Listeria* Retail Guidelines Committee. The committee will be charged to revise the "2006 Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* Within Food Establishments" to include:

1) sanitation guidance for equipment and food establishment environments,
2) good retail practices on how to prevent contamination and growth of Lm in retail establishment,
3) updated outdated links to other documents, and
4) information from and references to documents published by credible organizations on the topic of Lm prevention and control in food establishments.

The Conference also recommends that the committee report its recommendations back to the 2016 Biennial Meeting with Issues to address:

1) the above charges, and
2) recommendations that a letter be sent to FDA requesting that Annex 2 (References, Part 3-Supporting Documents) be amended by adding a reference to the revised voluntary guidelines.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities: The committee met monthly beginning in October 2014 and reviewed, discussed and amended the draft 2014 Guidelines (a revision of the 2006 guidelines) that were never formally submitted to CFP by the 2012-2014 Committee. A quorum was present at almost every meeting, an open and frank dialogue was maintained at every meeting with input from all attendees. The final draft guidelines were accepted by a majority vote of the voting members. All charges were successfully achieved.

   The committee decided to use the never finalized draft document arising from the deliberations of the 2012-2014 committee, as it's starting point. Small changes were made

to almost every paragraph in the document. Entirely new paragraphs were added to many sections, often incorporating new information and/or references into the text.
For example:

a) The introduction to the revised document added significant text discussion the Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup risk assessment on *L. monocytogenes* in retail delicatessens that was published in 2013.
b) The Cleaning and Sanitizing section of the document now contains separate sections on cleaning, cleaning frequencies and sanitizers.
c) The Time and Temperature Control section of the document contains added information on consumer advice, as well as *Listeria* control via pH modification and preservative use.
d) A new section on the risks posed by remodeling was added to the Preventing Contamination section.
e) The section on verifying the effectiveness of sanitation programs was expanded significantly, adding sections on validation, monitoring and supplemental verification methods.
f) Entirely new sections on Supplier Specifications and Recalls were added to the document.
g) The formatting of the entire document was standardized using consistent MS Word styles for paragraphs and headers.

2. Recommendations for consideration by Council: The Committee recommends that the -2016 Draft "Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* (*Lm*) Within Food Establishments" be accepted as submitted and posted on the CFP website.

3. The committee recommends that since the charges have been met, the committee disband.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1) Report - Listeria Retail Guidelines (LRG) Committee
2) LRG 2 Voluntary Guidelines of Sanitation Practices…, Second Edition
to approve the "2016 Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* (*Lm*) Within Food Establishments, Second Edition"

Content Document Attachments:

- Listeria Retail Guidelines (LRG) Committee Roster
- Draft 2016 Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* (Lm) within Food Establishments, Second Edition

COMMITTEE MEMBER ROSTER (attached):

Listeria Retail Guidelines (LRG) Committee Roster

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Committee Name: 2014 - 2016 Listeria Retail Guidelines Committee - Council III

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Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* within Food Establishments

Second Edition

Originally Produced By: *Listeria monocytogenes* Intervention Committee of Council III 2004-2006 Conference for Food Protection

Current Edition By: *Listeria monocytogenes* Guidelines Committees of Council III 2012-2014 and 2014-2016 Conference for Food Protection

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Introduction

Listeria monocytogenes is a bacterium that can cause listeriosis, a serious disease that is primarily transmitted through foods and that can be introduced into foods at multiple points in the food chain. Despite the wide occurrence of *L. monocytogenes* in homes, in foods, in food manufacturing facilities and in food establishments, the incidence of listeriosis in the U.S. is low with an estimated 1,591 foodborne disease cases per year and 255 deaths (Scallan et al., 2011) and details on recent *L. monocytogenes* multistate outbreaks can be found on CDCs website. Extensive controls in the manufacturing of ready-to-eat foods have been responsible, in part, for reducing contamination of foods and a decreasing incidence of listeriosis.

Food establishments as defined by the FDA 2013 Food Code are very different from food processing plants. Food establishments are defined by the Food Code to be retail and foodservice establishments like grocery stores and restaurants. This guidance document is written to be relevant for all food establishments. They are open to the public, with customers, employees and others (e.g., contractors, delivery personnel) coming into the food establishment throughout the day. These situations increase the opportunity for *L. monocytogenes* to be introduced. Therefore, it is very important that food establishment operators utilize active managerial control (AMC) to implement appropriate procedures that minimize the potential for *L. monocytogenes* contamination of ready-to-eat foods within their food establishment.

Vigilant AMC is a key part in reducing the risk of listeriosis. AMC means the purposeful incorporation of specific actions or procedures by establishment management into the operation of their business to attain control over foodborne illness risk factors, as defined in the 2013 Food Code Annex 4, on pg. 549. It embodies a preventive rather than reactive approach to food safety through a continuous system of risk assessment, monitoring, and verification. Every food establishment needs to have AMC of risk factors associated with foodborne illness. This may be achieved through training programs, manager oversight and standard operating procedures. For example, some establishments incorporate control measures into individual recipes, production schedules, or employee job descriptions.

The FDA/Food Safety and Inspection Service (FSIS) 2003 *L. monocytogenes* Risk Assessment categorized the relative risk of ready-to-eat foods with respect to foodborne listeriosis. Ready-to-eat (RTE) foods were placed into categories ranging from very high to very low risk. The risk assessment identified very high and high risk foods to include: deli meats, unheated frankfurters, soft un-ripened cheeses, high fat and other dairy products, pasteurized fluid milk, pâté, meat spreads, unpasteurized fluid milk and smoked seafood. Food establishment operators could use these categories to identify specific foods and related areas and equipment within their establishments that should be the focus for *Listeria* control measures. It is important to note that the risk assessment did not address all ready-to-eat foods and any food that supports the growth of *L. monocytogenes* may have the potential to cause listeriosis.

The USDA FSIS/FDA Center for Food Safety and Applied Nutrition (CFSAN) Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup published a more recent risk assessment focused on *L. monocytogenes* in retail delicatessens in 2013. The purpose of the risk assessment was to provide a quantitative, scientific assessment of the risk of listeriosis posed by consumption of RTE foods prepared and sold in delicatessens inside of retail food stores and to mathematically model how that risk might be impacted by changes in practice.

There were five key findings from the 2013 risk assessment regarding the control of *Listeria:* (i) Practices that prevent bacterial growth dramatically reduced the predicted risk of listeriosis. (ii) Cross contamination by *L. monocytogenes* in the retail environment dramatically increased the predicted risk of listeriosis. (iii) Increasing *L. monocytogenes* concentration in incoming product increased the predicted risk of listeriosis, whether or not the contaminated RTE product itself supported growth. (iv) Sanitation practices that eliminate *L. monocytogenes* from food-contact surfaces resulted in a reduction in the predicted risk of illness. (v) Control of *L. monocytogenes* cross contamination at the slicer reduced the predicted risk of listeriosis.

Risk factors may be managed in a variety of ways; however, some food establishments may want to develop written records to ensure that monitoring is being performed using the correct method and at the proper frequency and that corrective actions are taken immediately. To minimize the risk of listeriosis, food establishment operators should know their suppliers and only buy foods from approved sources; keep refrigerated foods as cold as possible and limit their storage time; take steps to prevent contamination during in-store handling and storage; and target sanitation procedures to those areas most likely to harbor *L. monocytogenes*. Specific information on controlling *L. monocytogenes* in food establishments, with emphasis on these areas, is provided in this document.

Targeted Sanitation Procedures

L. monocytogenes can be found almost everywhere and may be present in food establishments. Sanitation is an important means of controlling *L. monocytogenes*.

When developing a sanitation program, specific areas and equipment should be targeted. Scientific studies have shown specific areas and equipment can provide niches and harbor *Listeria* or are more vulnerable to *Listeria* contamination. The items listed below are not exclusive and every operator should identify specific risk areas and priorities within their own operation.

Food Contact surfaces

- Slicers
- Cutting boards
- Knives, knife racks, tubs, bowls, platters and utensils
- Food containers and trays in display cases and refrigerators

- Food contact surfaces inside display cases

Non-Food Contact surfaces

- Floors, walls, coving and drains in preparation areas
- The interior of display cases and walk in coolers, specifically condensate, drip pans, drains, door tracks, light housings and bottom decks over fans and condensers
- Cleaning tools for food contact surfaces, such as brushes and cleaning cloths
- Cleaning tools such as mops, buckets and squeegees
- Three compartment sink
- Wet floors, standing water
- Prep sinks
- Floor wall juncture below and adjacent to sink drains
- Storage containers, including milk crates

Other items

Additionally, other items should be considered when developing a targeted sanitation program for *Listeria*. These may include:

- Door handles and handles of equipment
- Pallets, pallet jacks
- Push carts, especially the wheels
- Exterior of equipment or unused equipment
- Maintenance tools
- Non- disposable gloves, such as cleaning or safety gloves
- Ceilings
- Hollow table and/or equipment legs and supports
- Seams and seals around cooler, freezer and refrigerator doors
- Trash containers
- Air filters, blowers, vents and fans
- Motor housings on food processing equipment
- Unsealed joints in food preparation areas, such as riveted information tags or plates on equipment
- Scales
- Food wrapping machines
- Hand contact surfaces, such as on-off switches, knobs, handles, phones and intercoms
- Hoses and nozzles
- Ice machines and the drain areas under and behind ice machines
- Drain back-ups, toilet back-ups and roof leaks

The following should be properly installed, maintained and in good repair:

- Floors, coving and walls
- Gaskets and rubber seals in equipment and around doors

- Condensation units and drain lines
- Hoses
- Drains

Storing defective and unused equipment in food preparation areas and bringing in used equipment from another location to replace broken equipment, all raise potential *Listeria* concerns due to the potential for harborage and cross-contamination.

Cleaning and Sanitizing

Practices

The primary focus of cleaning and sanitizing should be on sources most likely to cause contamination in high-risk food preparation areas, as identified in the food contact and non-food contact sections above.

All equipment should be easily cleanable and free of defects. Equipment should comply with the specifications listed in the FDA and CFP Food Establishment Plan Review Guide.

Cleaning effectiveness depends upon the cleaning compound formulation and use conditions as well as and various other issues. Those issues are specific to the type of cleaning being attempted, the type of soil, water hardness, tools used, the training and execution of the procedure by the person doing the cleaning. A food establishment should implement written procedures for proper cleaning and sanitizing food contact and non-food contact surfaces. These procedures should include the frequency of cleaning, chemicals to use, instructions on how to perform the task and the steps to verify it is being done correctly. A visual examination should be done of all food contact surfaces before the start of operations to ensure appropriate compliance with cleaning procedures and to take corrective actions if necessary.

Cleaners

All cleaners used in a food establishment should have a product description, instructions on how to use the product, an effective concentration and safety information. Cleaners should be used according to a Sanitation Standard Operating Procedure (SSOP) specific to a location or piece of equipment being cleaned.

Cleaning Frequencies

A cleaning schedule should be developed for each establishment to include all food and non-food contact surfaces. Follow equipment manufacturer's instructions to assure complete disassembly and thorough cleaning of all equipment parts. Recommended cleaning and sanitizing frequencies are listed in the FDA Food Code.

Consider cleaning as you go and remove food spills quickly. Bacteria like cool damp areas; so limiting standing water helps control *L. monocytogenes* and most other bacteria. Bacteria from wet areas can easily be transferred to employee shoes, carts or

other equipment if not wiped up quickly.

Sanitizers

All sanitizers used in a food establishment should have a product description, instructions on how to use the product, an effective concentration and safety information. Sanitizing agents must be used in accordance with EPA-registered manufacturers label use instructions. Appropriate test kits should be available and in use. Effective sanitization can be achieved only when preceded by thorough cleaning and rinsing steps. The cleaning and sanitizing procedures should also include floor drains in food preparation areas (e.g., remove the drain cover and basket; remove all debris and discard into the trash container, use an appropriate procedure to remove organic material from the drain hole). Enzymatic cleaners may also be effective in removing organic material, prior to sanitation. Use an EPA registered product to sanitize the floor and drain area. Consider using bactericidal drain rings in drains located where ready-to-eat food is prepared and stored.

Additional Miscellaneous Cleaning Information

Minimize splash from hoses into floor drains. Plugged drains should be repaired immediately. Do not place equipment over floor drains, as this practice would make it difficult to clean the floor drain and could result in equipment contamination during cleaning or drain backups. Consider using 'best practices' when cleaning drains (e.g., controlling splash, use a drain brush with bristles smaller than the diameter of the drain line, clean/sanitize the drain brush itself).

Only a dry cleanup (i.e., clean up without the use of water) should be done during food production. Splash from a wet cleanup can easily contaminate a cleaned surface. Splash can aerosolize and spread contamination throughout the entire area. Avoid mid-shift wet cleanup because it can produce aerosols and add water in the food preparation area.

Use only low pressure or foaming hoses rather than high-pressure sprays. Do not use low-pressure hoses for cleaning during food preparation or when there is any exposed food, equipment, utensils or food packaging. Low-pressure foaming guns and sanitizer rinse guns may be used only after removal or protection of all foods, previously cleaned equipment and single service articles. Remove or protect all food from contamination before cleaning display cases or coolers. Keep the area where food-packaging and wrapping materials are stored clean.

Avoid pooling of water on low spots of the floor in food prep areas and coolers. Also, avoid collection of water beneath service and display cases from condensate or water trapped following cleaning.

Avoid water accumulation in condensate pans in service cases or coolers, which may potentially fall on open product.

Damaged, pitted, corroded or cracked equipment cannot be used and should be repaired or replaced. Do not repair equipment on site without protecting food and food contact surfaces. Avoid keeping unused equipment in food preparation areas.

Maintenance and other service providers can be a source of cross contamination so written procedures should define the areas within the food establishment where they are permitted during food preparation. Written procedures for food establishments should include the cleaning and sanitizing of maintenance tools. Maintenance tools and equipment (e.g., ladders) can become contaminated and can transfer *L. monocytogenes* from one area to another if not cleaned and sanitized appropriately. Store maintenance tools and equipment away from food, food contact equipment, utensils and food packaging materials. Repairs that are performed on food contact surfaces and equipment should be cleaned and sanitized after repair and before being reinstated/reinstalled for use.

Repair floor cracks and other floor surfaces in disrepair that can harbor bacteria.

Cleaning tools used in raw food production should never be used for cleaning in ready-to-eat food preparation areas. Consider color-coding these items to distinguish between raw and ready-to-eat and using separate color coded tools for cleaning of toilet rooms.

Take care to insure that hands or gloved hands do not contact clean surfaces and food products after touching unclean surfaces.

Prevent poor employee hygiene practices and inadequate cleaning by providing appropriate employee training. The training should include a direct observation of the employee's ability to follow the written procedure.

Time and Temperature Control

L. monocytogenes is unlike most other foodborne pathogens due to its ability to grow under refrigeration temperatures. *Listeria* can grow in temperatures ranging from 31°F to 113°F. The organism grows best between 70°F and 100°F and slows down considerably at lower temperatures such as those used in refrigeration. The Food Code requires that refrigerated foods be held at 41°F or below, but the colder the temperature of the food, the greater the impact on limiting growth of *Listeria*. It is important to get foods cold quickly and to keep them cold. If low levels of *L. monocytogenes* are accidentally present in a ready-to-eat food item that supports growth, over time the organism can multiply to higher numbers and increase the risk of illness. A system of controls should be in place to limit the cold storage time for foods that support growth of *Listeria*.

Temperature Control for Receiving

Temperature checks should be made of refrigerated deliveries. Frozen food should be

solidly frozen and refrigerated food should be 41°F or below, unless a higher temperature is permitted by law. Appropriate action should be taken in response to any high food temperature problems detected.

Calibrated temperature-monitoring devices should be used to ensure proper temperature control during shipment and storage.

Time/temperature control for safety (TCS) foods (formerly called potentially hazardous foods or PHF foods) should be placed into cold storage immediately. The goal is to ensure that food products remain at temperatures that minimize growth of pathogens such as *L. monocytogenes*.

Refrigeration and Freezer Units – Holding, Storage and Display

All refrigeration units used to store TCS foods should have adequate capacity and sufficient air circulation to maintain product temperatures of 41°F or below. Freezers should be capable of keeping foods frozen solid.

Cold holding units for storage and display should be equipped with at least one permanently affixed accurate thermometer that is located to allow for easy viewing by food employees. The temperature of the warmest part of the refrigeration unit should be monitored (see the FDA Food Code Section 4-204.112(A)). Food establishments might consider using temperature recording devices and refrigeration alarm systems to improve compliance. Cold holding units should not be loaded beyond the designated display load line, nor should vents be blocked to prevent proper airflow. Do not alter any shelving without verifying that proper airflow and temperatures are not adversely affected. Keep all refrigerated units and freezer doors closed whenever possible. Keeping the doors open may result in higher temperatures that could increase the potential for growth of *Listeria*.

Improper sanitation, maintenance, accent lighting, warm air currents within the store and loading a case with warm product may affect the ability to maintain proper product temperatures within refrigerated cases.

Time/Temperature Controls – Product Handling

During cooling or cold storage, refrigerated units should be set low enough to keep TCS foods at temperatures of 41°F or below. The 2003 FDA/FSIS Risk Assessment on *L. monocytogenes* in RTE foods demonstrated that this would have the biggest impact on preventing listeriosis.

Maintain a product rotation system based on the manufacturer‘s date code or recommended shelf life, using the product with the shortest remaining shelf life first.

The FDA Food Code recommends that ready-to-eat TCS foods prepared and held in a food establishment for more than 24 hours shall be clearly date marked. That date marking should indicate the date or day by which the food shall be consumed, sold, or

discarded when held at a temperature of 41°F or less for a maximum of 7 days (FDA Food Code Section 3-501.17). See the Food Code for which foods are exempt from date marking. Check with your state or local regulatory authority for specific requirements on date marking.

Minimize the time refrigerated foods are kept at room temperature. For temperature control during preparation, work with only small batches and limit the time that TCS foods are held at room temperature in order to minimize growth of pathogens such as *L. monocytogenes*.

FDA guidelines allow for a working supply of refrigerated TCS foods that are displayed or held for service for immediate consumption to be safely kept out of temperature control for a limited time; this is referred to as using "Time as a Public Health Control." The food must be marked with the time it was removed from temperature control and cooked, served, or discarded (FDA Food Code section 3-501.19). Check with your state or local regulatory authority for specific requirements for the use of Time as a Public Health Control.

Minimize adding to or topping off TCS ready-to-eat foods that are stored in bulk containers for display. When a topping off procedure is conducted, a system should be in place to ensure a complete break in the cycle of commingling ready-to-eat food products occurs. The timeframe should be 7 days or less from the time the first ready-to-eat food was prepared and placed on display. The temperature of the commingled ready-to-eat product should be kept at 41°F or below. For more details see the date marking provision of the Food Code (3-501.17 Ready-to-Eat Time/Temperature Control for Safe Food, Date Marking).

Every food establishment needs to have AMC of risk factors. Active managerial temperature control can be applied by incorporating a plan to monitor temperatures along every step in the process. Follow FDA Food Code guidelines for proper cold holding, thawing, cooking, hot holding and cooling recommendations. Control measures should include taking corrective actions immediately when food exceeds the required temperature.

Consumer labeling should be provided with the pack date (at the time of purchase) and information to store at temperatures below 41°F. Some retailers are providing information regarding the usable shelf life of products including 3 days for meats and 4 days for cheeses.

Retailers are in a position to proactively share food safety information with their customers because they are a credible resource and are frequently in communication with consumers. There are many resources on the topic of maintaining proper temperatures in home refrigerators and how to reduce the risk of *Listeria* contamination and these can be found in Appendix 1 of this document.

Controls Other Than Time and Temperature

Although time and temperature are the primary controls for minimizing or preventing the growth of *L. monocytogenes*, other factors such as pH and water activity can limit or prevent *Listeria* growth. It is well established that *L. monocytogenes* does not grow when the pH of the food is less than or equal to 4.4 or if the water activity of the food is less than or equal to 0.92. Foods may naturally have a pH or water activity that prevents growth of *L. monocytogenes* or may be intentionally processed to achieve these characteristics; for example, acidifying deli-type salads by the addition of vinegar or citric acid to bring the pH to less than or equal to 4.4. *Listeria* growth inhibitors can be added to food to prevent or limit *L. monocytogenes growth*; for example, some deli-meat manufacturers add inhibitors to their products. Likewise, antimicrobial substances such as sorbic acid are commonly used to prevent the growth of *L. monocytogenes* in foods such as cheeses.

Minimizing or preventing the growth of *L. monocytogenes* via pH, water activity, or the use of growth inhibitors requires knowledge of the various chemical and physical interactions that can take place in different types of food. FDA provides detailed information on how to determine if a food does not support pathogen growth based on pH and/or water activity, as indicated in reference that follows at the end of this paragraph. Some foods may fall into a category whereby a specific product assessment (PA) must be made to determine if the food can support growth. Refer to the FDA Food Code (1-2 Definitions, Time/Temperature Control for Safety Food and Annex 2, Time/Temperature Control for Safety Food) for details.

New technologies are constantly being tested and developed to further help in the effort to control *L. monocytogenes*. Among these are newly designed equipment such as cold holding cases, advanced packaging systems that incorporate antimicrobial agents and processing techniques and additives that inhibit the growth of *Listeria*.

Preventing Cross-Contamination

Since *Listeria* is present in many environments, it is extremely difficult to eliminate it completely in food establishments. Employees and incoming raw materials or products may easily reintroduce *Listeria* into the food establishment. Unclean equipment and poor sanitation can result in the transfer of *Listeria* onto ready-to-eat foods and food contact surfaces. The widespread nature of this organism means that a system-wide approach for control may be needed.

Preventing Cross Contamination of Ready-To-Eat Foods by Raw Foods

Ensuring complete separation of raw and ready-to-eat foods throughout all areas of receiving, storage, preparation, display and service is ideal for preventing contamination. Containers that held raw ingredients should not be re-used for storing other RTE ingredients without prior cleaning and sanitizing.

If space is limited where raw and ready-to-eat foods are kept in the same area, separation can be achieved by using physical space, physical dividers, different production times for raw and ready-to-eat food items with a complete cleaning and sanitizing in between, or storing raw foods below ready-to-eat foods.

Color-coding of cutting boards, handles on knives, tongs and utensils can be a useful visual reminder for keeping food contact surfaces that touch raw foods separate from those that touch ready-to-eat foods.

Preventing Contamination of Ready-To-Eat Foods From Other Sources

Food and packaging material should be protected from contamination during storage and display. Store food and food packaging material in a clean, dry location protected from overhead contamination. These items should be stored at least six inches above the floor on shelves, racks, pallets, or other means to reduce potential contamination, facilitate cleaning and aid in pest control.

Food or food packaging material should not be stored below dripping or leaking condensate.

Care should be taken when bringing items such as pallets, boxes, milk crates, shipping containers, shopping carts, etc. into ready-to-eat food preparation areas, since they may be a source of *Listeria* contamination. These items should be handled to minimize cross-contamination of food contact surfaces.

Foot traffic into food preparation areas should also be controlled, since shoes might be a source of *Listeria* contamination. Do not allow maintenance personnel, salespeople, customers, visitors, or other unauthorized individuals into areas where ready-to-eat food is being prepared unless they have followed proper preventative procedures. Maintenance personnel's clothing, tools and equipment such as ladders can also be a source of contamination. Their access into food preparation areas should be limited. Food and food packaging materials should be removed or otherwise protected during any necessary maintenance activities. Food processing equipment that may have been contaminated during any maintenance activities should be cleaned and sanitized prior to use. Whenever possible, defective equipment should not be repaired in a food preparation area.

Garnishes may also be a source of contamination. Fresh garnishes should be thoroughly washed if they contact ready-to-eat foods and replaced regularly. Plastic garnishes should be cleaned and sanitized between uses.

When it is necessary to temporarily retain product determined to be unsalable for any reason, it should be segregated in a designated area, labeled appropriately and separated from saleable food items. Unsalable products may include food items that are being returned to the distributor, food items that are out of date, or food items that are damaged or spoiled.

Remodeling

Food and food preparation areas should be protected against contamination from construction during remodels, extensive repairs and installing or removing equipment. Special attention should be made to prevent possible *Listeria* harborage sites that may get exposed or introduced during construction.

Make sure all food contact surfaces and equipment are covered and protected against contamination. Because *Listeria* may spread via the air, either perform repairs during off hours or protect food prep areas against contamination by installing a dust and vapor proof plastic barrier. Following construction and before starting any food preparation, clean and sanitize all food contact surfaces along with cleaning floors, walls, drains, sides of equipment and cabinets where harborage sites might have been exposed.

Employee Practices and Training

Employee Practices

A very important factor in limiting the risk of *L. monocytogenes* contamination is ensuring employees are trained and knowledgeable about the sources of contamination and practices that can minimize or prevent problems. Employees should be aware of the severity of listeriosis and the damaging impacts it could potentially have on the establishment and its customers.

A written employee health and personal hygiene policy should be established. Refer to the FDA Food Code (2-2 Employee Health, 2-3 Personal Cleanliness, 2-4 Hygienic Practices) for specific requirements. Employees should be trained on proper hand washing, glove usage and other practices to prevent risks related to *L. monocytogenes*.

Employees should avoid direct bare hand contact with any RTE foods. Single-service gloves or cleaned and sanitized utensils, such as tongs, spoons or ladles should be used whenever possible.

Gloves should be changed and discarded and hands washed every time the employee changes tasks or the gloves become damaged, soiled or contaminated. Gloves are never a substitute for proper hand washing.

Because employees clothing might become contaminated with *Listeria*, consideration should be given to having employees wear clean aprons or smocks (disposable is recommended) in ready-to-eat food areas. Prior to leaving food preparation areas, such as leaving for breaks, eating meals or visiting toilet facilities, employees should remove aprons and smocks. *Listeria* can enter the food establishment on employee's clothing, including shoes and then contaminate food or food contact surfaces through poor food safety practices.

Traffic flow of employees into and out of ready-to-eat food preparation areas should be limited where possible to prevent the introduction or spread of *Listeria*. When movement in and out of the ready-to-eat food area is necessary, appropriate precautions should be taken, e.g., change of outer clothing and immediate hand washing.

Employee Training

Knowledgeable food employees are vital to food safety. All food handlers need to understand risk factors associated with receiving, storing, preparing, holding, displaying and handling food as it relates to their assigned duties. Food safety training should be a part of every food establishments' AMC program. Training and supervision will provide employees with the knowledge and skills necessary to follow policies and procedures designed to control critical risk factors.

It is important for food establishment operators to design and implement a food safety training program appropriate for their operation. This *L. monocytogenes* guidance document can be used to assist in covering important intervention strategies.

Other training materials are also available and listed below. The list below is not exhaustive and does not imply endorsement by CFP.

- SafeMark
- ServSafe
- FDA's Managing Food Safety: A Guide For The Voluntary Use of HACCP Principles for Operators of Food Service and Retail Food Establishments
- FDA Oral Culture Learner Project – Educational Videos for Retail Food Employees
- Association of Food and Drug Officials Retail Meat and Poultry Processing Guidelines
- Penn State Universities Control of Listeria monocytogenes in Retail Establishments

Training should be a continual process to ensure compliance with company policies and the most current food safety practices. The training should cover basic information on *L. monocytogenes* interventions, including employee health and hygiene, proper cleaning and sanitizing, frequency of cleaning, protection against contamination and temperature control.

Verifying the Effectiveness of Sanitation Programs

Every food establishment should have a cleaning and sanitation program and should have a method for verifying its effectiveness. There are different ways to verify the effectiveness of sanitation programs and often a combination of approaches can be used.

It is important to understand the difference between validation and verification. In addition, monitoring is another step in assuring effective food safety programs. Each of these terms – validation, verification and monitoring – have different meanings.

Validation

Validation is the assurance or proof that the elements of the food safety plan, including standard operating procedures (SOPs), are effective and capable of controlling identified hazards. Validation steps may include, but are not limited to, the application of regulations, policies, guidance documents, scientifically proven processes, technical information, expert advice and recognized best practices. Retail food establishments will most likely use only those procedures, steps or practices that are already validated when developing SOPs or other food safety plans. That validation might occur at the corporate level in the case of a chain, or by chemical suppliers, universities or trade associations in the case of independently operated facilities. Therefore, it is unlikely a given retail food establishment will need to validate its food safety practices itself. However, if an operator decides to request a variance (FDA Food Code Section 8-103.10) and a HACCP Plan is required (FDA Food Code Section 8-201.14) the operator may be required to submit validation information.

Verification

Verification is the ongoing process of applying the observations, methods, procedures, tests and other evaluations to determine if monitoring tasks as described below have been performed correctly. Verification can be accomplished using onsite verification, record verification, or both.

- Onsite Verification – Examples include observations to ensure tasks are completed as described in a written program or checking the use of chemicals to verify proper concentrations and applications.
- Record Verification – When records are required or kept in accordance with a company's food safety plan, then a review of those records for completeness should be made to ensure records have been filled out correctly. Examples include internal audit reports, temperature recording devices, sanitation checklists or corrective action reports.

Different methods can be used to verify the effectiveness of sanitation programs. Sanitation programs should be verified using observation and monitoring. Visual inspections, observations, tracking chemical use, monitoring records and reviewing cleaning charts are simple, inexpensive and effective methods to verify compliance with cleaning procedures. Store management, internal food safety auditors, chemical suppliers, regulatory inspections or third party auditors can be used to conduct the verification.

Monitoring

Monitoring is an ongoing process of checking a specific limit or practice (temperature, cleaning, etc.) to ensure the standard is met and that results are properly recorded as

per the SOP or food safety plan. Monitoring is the act of:

- Conducting a planned sequence of observations or measurements
- Assessing if the step is under control and
- Recording the results of the check when required.

When monitoring a task, the steps outlined in the written program should be followed as written and all regulatory requirements must be met. Observing monitoring procedures and reviewing the findings are part of the verification process.

Supplemental verification methods

Additional verification methods are available to supplement observation and monitoring. These include: rapid sanitation tests and microbiological testing.

These two methods vary by cost and level of technical expertise needed to use them, and therefore may not be suitable depending upon the size and type of the facility. A customized approach based on the specific risks or technical expertise available in an operation is recommended. The following is a brief description of these two methods.

Rapid Sanitation Tests

To be of most benefit, these tests need to be done on a regular basis. A food establishment should be willing to make a commitment to using this method. The results of these tests can be used for tracking trends and establishing or monitoring the sanitation program.

Adenosine triphosphate (ATP) bioluminescence and glucose tests are examples of rapid test kits. These kits usually include a swab that is rubbed on a surface and a hand-held measuring device. These kits measure chemical components such as ATP or glucose that reflect the amount of organic matter, food debris, sugars, microorganisms, etc., on a surface and provide a general indication of cleanliness. They do not measure bacterial counts or provide information on types of organisms that may be present.

Microbiological Testing

Before undertaking microbial testing, a food establishment should evaluate several important factors. Most important is to have a clear understanding of regulatory requirements around testing. For example, would testing require a “test and hold” situation as would occur in a food manufacturing facility? Other important factors should be considered such as:

- What will be sampled?
- What organisms will be considered for sample evaluation?
- When and where will the samples be collected?
- Where will the samples be analyzed?

- What criteria suggest a potential problem?

A food establishment operator also needs to have a plan to specifically address what action will be taken to remedy the situation when results indicate a potential concern. There are many variables to be considered when designing a microbiological sampling program. If an establishment is interested in considering a microbial sampling program, it is recommended it seek specific guidance and expertise regarding microbiological sampling and its use to verify sanitation.

Additional resources to assist with this process can be found in Appendix 1 of this document.

Supplier Specifications

The following recommendations are meant to help food establishments identify and approve potential suppliers. It is understood that not all items listed will be found to be critical for all food establishments. It is also understood that some suppliers will treat specific information as proprietary and confidential. Nonetheless, the supplier should provide some evidence that the requested programs are in place.

1. Only buy from an approved source. All food suppliers, including producers, manufacturers and distributors, should provide proof that they have a proactive food safety and food security program in place. While the FDA Food Code does not define ‘approved source’, it does define ‘approved’ to mean acceptable to the regulatory authority based on a determination of conformity with principles, practices and generally recognized standards that protect public health.

2. Develop a relationship with all suppliers and understand their processes and cold chain distribution.

3. All suppliers should be audited at least annually by a federal, state or local regulatory authority or a third party. You may ask your supplier if they are certified against a Global Food Safety Initiative (GFSI) or other recognized scheme.

4. Does the supplier's food safety plan include internationally recognized HACCP and sanitation standards? How is the plan validated and verified? Is an environmental monitoring and product-monitoring program in place? Do these programs include test-and-hold provisions?

5. Food suppliers’ buildings, facilities, grounds and equipment should be constructed and maintained in a manner consistent with regulatory requirements to prevent the contamination of food or food packaging materials.

6. Letters of Guarantee should be obtained from every supplier for each product supplied to insure that all food safety requirements are being met. Ask your supplier about their sanitation practices, cold chain management, or performance against

international and regulatory practices.

7. Additional information should be obtained from the supplier regarding ingredients, preservatives and microbial growth inhibitors that impact listeriosis risk in select foods. It is important for the establishment operator to understand the benefits and limitations to the use of these compounds.

8. The suppliers' facility should have a documented inspection process that occurs after sanitation that monitors and tracks cleaning effectiveness.

9. The supplier should have written cleaning procedures for the equipment and infrastructure within the establishment with the defined frequency for routine and deep cleaning based on risk.

10. The supplier should map different areas in the facility using a risk-based approach.

11. The supplier should review the sanitary design of any incoming equipment. Special care should be taken when using second–hand or refurbished equipment.

12. The supplier should have a risk management plan in place to address contractor activity including any planned construction projects.

Recalls

As this document is focused on procedures and practices used to minimize contamination and growth of *L. monocytogenes* within food establishments, a detailed discussion of food recalls for *L. monocytogenes* is out of scope. Properly managed recalls are an important part of controlling the risk of listeriosis; however, a number of good resources are available for food establishments including guidance from FDA, USDA-FSIS and the AFDO Food Recall Manual developed by the University of Florida.

Appendix 1. Resources for expert guidance regarding *L. monocytogenes*. The list below is not exhaustive and does not imply endorsement by CFP.

Entity type	Examples
Federal agency	Centers for Disease Control and Prevention (CDC), cdc.gov Environmental Protection Agency (EPA), epa.gov Food and Drug Administration (FDA), fda.gov United States Department of Agriculture, Food Safety Inspection Service (USDA/FSIS), fsis.usda.gov
State and local governments	See dslo.afdo.org for a directory
Trade, professional and non-governmental organizations and associations	Association of Food and Drug Officials (AFDO), afdo.org American Society for Microbiology (ASM), asm.org Fight Bac!, fightbac.org Food Marketing Institute (FMI), fmi.org International Association for Food Protection (IAFP), foodprotection.org International Commission on the Microbiological Specifications of Foods (ICMSF), icmsf.org National Environmental Health Association (NEHA), neha.org National Restaurant Association (NRA), restaurant.org
	National Registry of Food Safety Professionals (NRFSP), www.nrfsp.com
Academic institutions	Many universities and local or county extension programs can provide *L. monocytogenes* food safety expertise

Commercial entities	A variety of commercial entities can also provide specific recommendations regarding *L. monocytogenes*. Commercial testing labs, cleaning and sanitation chemical and service providers and a variety of private consultants can all provide assistance.

Voluntary Guidelines of

Sanitation Practices

Standard Operating Procedures

and Good Retail Practices

To Minimize Contamination and

Growth of Listeria monocytogenes

Within Food Establishments

Developed by the 2004 - 2006

Conference for Food Protection

Listeria monocytogenes Intervention Committee

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Introduction

Listeria monocytogenes (*Lm*) is a bacterium that can cause listeriosis, a serious disease that is primarily transmitted through foods. It is a ubiquitous microorganism that can be introduced into foods at multiple points in the food chain. Despite the wide occurrence of *Lm* in homes (people, pets and the environment), in foods, in food manufacturing facilities, and in food establishments, the incidence of listeriosis in the U.S. is low (less than 1,000 cases per year), but the mortality rate is estimated to be 20 % or higher. Extensive controls in the manufacturing of ready-to-eat foods have been responsible, in part, for reducing contamination of foods and a decreasing incidence of listeriosis.

Food establishments are very different from processing plants. They are open to the public, with customers, salesmen, employees and deliveries coming into the food establishment throughout the day. These situations increase the opportunity for *Lm* to be introduced. Therefore, it is very important that food establishment operators utilize active managerial control to implement appropriate procedures that minimize the potential for *Lm* contamination of ready-to-eat foods within their facilities.

Vigilant active managerial control is a key part in reducing the risk of listeriosis. Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification. Every food establishment needs to have active managerial control of risk factors associated with foodborne illness. This may be achieved through training programs, manager oversight, and standard operating procedures. For example, some establishments incorporate control measures into individual recipes, production schedules, or employee job descriptions.

The FDA/FSIS *L. monocytogenes* Risk Assessment categorized the relative risk of ready-to-eat foods with respect to foodborne listeriosis. Ready-to-eat foods were placed into categories ranging from very high to very low risk. Food establishment operators can use these categories to identify specific foods, and related areas and equipment within their facilities that should be the focus for *Listeria* control measures.

The *L. monocytogenes* Risk Assessment identified very high and high risk foods to include: deli meats, unheated frankfurters, soft unripened cheeses, high fat and other dairy products, pasteurized fluid milk, pâté, meat spreads, unpasteurized fluid milk, and smoked seafood. It is important to note that the risk assessment did not address all ready-to-eat foods, and any food that supports the growth of *Lm* at refrigerated temperatures may also have the potential to cause listeriosis.

Risk factors may be managed without the use of formal record keeping; however, some food establishments may want to develop written records to ensure that monitoring is being performed using the correct method and at the proper frequency, and corrective actions are taken immediately. To minimize the risk of listeriosis, food establishment operators should keep refrigerated foods as cold as possible and limit their storage time; take steps to prevent contamination during in-store handling and storage, and target sanitation procedures to those areas most likely to be sources of *Lm*. Specific information on controlling *Lm* in food establishments, with emphasis on these areas, is provided in this document.

Targeted Sanitation Procedures

Listeria monocytogenes (*Lm*) is found almost everywhere and can be present in most environments, including the soil, plants, humans, equipment, animals, foods, drains, and supplies. The categories listed below identify areas that could likely harbor *Lm* within a retail food establishment. The items listed in the "areas of concern" category would generally have a higher probability of *Lm* contamination than the items listed in the "additional areas that could require special attention" category. The items listed below are not exclusive and every operator should do an evaluation to identify specific areas and priorities within their own operation.

<u>Areas of Concern</u>
Food Contact Areas:

- Slicers
- Cutting boards
- Knives, knife racks, tubs, bowls, platters and utensils
- Food containers and trays in display cases and refrigerators
- Food contact surfaces inside display cases

Non- Food Contact Surfaces:

- Floors, drains, in preparation areas
- The interior of display cases and walk in coolers, specifically condensate, drip pans, drains and door tracks
- Cleaning tools for food contact surfaces, such as brushes and cleaning cloths
- Cleaning tools such as mops and buckets
- Wet floors, standing water

<u>Additional Areas That Could Require Special Attention</u>

- Door handles and handles of equipment
- Pallets, pallet jacks
- Push carts, especially the wheels
- Exterior of equipment or unused equipment

- Maintenance tools
- Non- disposable gloves, such as cleaning or safety gloves
- Walls and ceiling
- Hollow table and/or equipment legs/supports
- Seams and seals around cooler, freezer and refrigerator doors
- Trash containers
- Air filters, blowers, vents and fans
- Motor housings on food processing equipment
- Unsealed joints in food preparation areas, such as riveted information tags or plates on equipment
- Scales
- Food wrapping machines
- Hand contact surfaces, such as on-off switches, knobs, handles, phones, and intercoms.
- Hoses and nozzles
- Ice machines and the drain areas under and behind ice machines

Maintenance Concerns

- Defective walls and ceilings, overhead pipes
- Worn or cracked rubber seals around doors
- Cracked hoses
- Defective and unused equipment
- Bringing in used equipment from another location to replace broken equipment

Cleaning and Sanitizing Practices

The primary focus should be on sources most likely to cause contamination in high-risk food preparation areas. Refer to the list above, identified in the food contact and non- food contact sections.

All equipment should be easily cleanable and free of defects. Equipment should comply with the specifications listed in the FDA *and* CFP Food Establishment Plan Review Guide (http://www.cfsan.fda.gov/~dms/prev-toc.html). Remove any defective or unused equipment from food preparation areas.

Sanitation programs to specifically address *Lm* consists of three actions:

1. Effective removal of soil
2. An effective rinse step
3. Proper application of a sanitizing agent, which includes contact time, concentration and temperature.

Cleaning effectiveness depends upon the formulation and how the product is used and various other issues specific to the cleaning being attempted, such as type of soil, water hardness, tools used, and even the training on the proper procedure and the execution of the procedure by the person doing the cleaning.

A food establishment should implement written procedures for proper cleaning and sanitizing food contact and non- food contact surfaces. These procedures should include the frequency of cleaning, chemicals to use, instruction on how to perform the task, and the steps to verify it is being done correctly. A visual examination should be done of all food contact surfaces before the start of operations to ensure appropriate compliance with cleaning procedures and to take corrective action if necessary.

Written procedures for food establishments should include the cleaning and sanitizing of maintenance tools. Maintenance tools and ladders can easily get contaminated and can transfer *Lm* from one area to another if not cleaned and sanitized appropriately. Store maintenance tools and ladders away from food, food contact equipment, utensils, and food packaging material.

The cleaning and sanitizing procedures should also include floor drains in food preparation areas. Remove the drain cover and basket; remove all debris and discard into the trash container. Use a drain brush to scrub and remove organic material from the drain hole. Use quaternary ammonium compounds to sanitize the floor and drain area. Consider using bactericidal drain rings where ready-to-eat food is prepared and stored. Enzymatic cleaners can also be effective in removing organic material, prior to sanitation.

Only a dry cleanup should be done during food production. Splash from a wet cleanup can easily contaminate a cleaned surface. Splash can aerosolize and spread contamination throughout the entire area. Avoid mid-shift wet cleanup because it can produce aerosols and add water in the food preparation area.

Use only low pressure or foaming hoses rather than high-pressure sprays. Do not use low-pressure hoses for cleaning during food preparation or when there is any exposed food, equipment, utensils or food packaging. Low-pressure foaming guns and sanitizer rinse guns may be used only after removal or protection of all foods, previously cleaned equipment, and single service articles. Remove or protect all food from contamination before cleaning display cases or coolers. Keep the area where food- packaging and wrapping material is stored clean.

Clean as you go; remove food spills quickly. Bacteria like cool damp areas, so limiting standing water helps control *Lm* and most other bacteria. Bacteria from wet areas can easily be transferred to employee shoes, carts or other equipment if not wiped up quickly.

<u>Sanitizers</u>

All cleaners and sanitizers used in a food establishment must have at least the following information: product description, instructions on how to use the product, properties, yield or effective concentration, and safety information.

Sanitizing agents shall be used in accordance with EPA-approved manufacturer's label use instructions. Effective sanitization can be achieved only when preceded by thorough cleaning and rinsing steps.

Cleaning Frequencies

A master-cleaning schedule should be developed for each facility to include all food and non-food contact surfaces. Follow equipment manufacturer's instructions to assure complete disassembly and thorough cleaning of all equipment parts. Cleaning and sanitizing frequencies are listed in the FDA Food Code.

Additional Important Information

Minimize splash from hoses into floor drains. Plugged drains must be repaired immediately. Do not place equipment over floor drains. This practice would make it difficult to clean the floor drain and could result in equipment contamination during cleaning or drain backups.

Avoid pooling of water on low spots of floor in food prep areas and walk-in coolers. Also, avoid collection of water beneath service and display cases from condensate or water trapped under cases following case or floor cleaning.

Avoid water accumulation in condensate pans in service cases or coolers, which may potentially fall on open product.

Never clean display cases or coolers until all food is removed or protected from contamination.

Damaged, pitted, corroded or cracked equipment cannot be used and must be repaired or replaced. Do not repair equipment on site without protecting food and food contact surfaces. Avoid keeping unused equipment in food preparation areas.

Avoid floor cracks and other floor surfaces in disrepair that can harbor bacteria.

Never use cleaning tools used in raw food production for cleaning in ready-to-eat food preparation areas. Consider color- coding these items.

Direct hand contact with previously cleaned surfaces and food products after touching unclean surfaces is prohibited.

Prevent poor employee practices and inadequate cleaning by providing appropriate employee training.

Time and Temperature Control

Lm is unlike most other foodborne pathogens due to its ability to grow under refrigeration temperatures. *Lm* can grow in temperatures ranging from 31° F to 113°F. The organism grows best between 70° F and 100° F and slows down considerably at lower temperature such as those used in refrigeration. Although the Food Code requires that refrigerated foods be held at 41°F or below, the colder the temperature of the food, the greater the impact on limiting growth of *Lm*. It is important to get foods cold quickly and to keep them cold. If low levels of *Lm* are accidentally present in a ready-to-eat food item that supports growth, over time the organism can multiply to higher numbers and pose a significant risk of illness. A system of controls should be in place to limit the cold storage time for foods that support growth of *Lm*.

Temperature Control for Receiving

Temperature checks should be made of refrigerated deliveries. Frozen food should be solidly frozen and refrigerated food should be 41° F or below, unless a higher temperature is permitted by law. Report any high temperature problems to management immediately.

Consider using temperature -monitoring devices or time-temperature indicators (TTI) to ensure proper temperature control during shipment and storage.

Minimize the time that delivered food remains un-refrigerated. Potentially hazardous foods (time/temperature control for safety food) should be placed into cold storage immediately. The goal is to ensure that food products remain at temperatures that minimize growth of pathogens such as *Lm.*

Refrigeration and Freezer Units

All refrigeration units should have adequate capacity and sufficient air circulation to maintain product temperatures of 41° F or below. Freezers should be capable of keeping foods frozen solid.

Cold holding units for storage and display must be equipped with at least one permanently affixed accurate thermometer that is located to allow for easy viewing by food employees. The temperature of the warmest part of the refrigeration unit should be monitored. (See the FDA Food Code Section 4-204.112) Larger food establishments might consider using temperature recording devices and refrigeration alarm systems.

Cold holding units should not be loaded beyond the designated display load line, nor should vents be blocked to prevent proper air- flow in the cold holding units. Do not alter any shelving without verifying that proper air- flow and temperatures are not adversely affected.

Keep all refrigerated units and freezer doors closed whenever possible. Keeping the doors open may result in higher temperatures that could increase the potential for growth of *Lm*.

Improper sanitation/maintenance, accent lighting, warm air currents within the store and loading the case with warm product may affect the ability to maintain proper product temperatures within refrigerated cases.

Time/Temperature Controls

During cold storage, refrigerated units must be set low enough to keep foods that require time temperature control for safety (TCS) at temperatures of 41° F or below. The FDA/FSIS Risk Assessment on *Lm* in RTE foods demonstrated that this would have the biggest impact on preventing listeriosis.

Maintain a product rotation system based on the manufacturer's date code or recommended shelf life, using the product with the shortest remaining shelf life first.

FDA guidelines recommend that certain ready to eat potentially hazardous foods (time/temperature control for safety), be date marked with a storage time of 7 days or less once opened or prepared in a food establishment and is stored at 41° F or below for more than 24 hours. (See the FDA Food Code Section 3-501.17) **Check with your state or local regulatory authority for specific requirements on Date Marking.**

Minimize the time refrigerated foods are kept at room temperature. For temperature control during preparation, work with only small batches, and limit the time that potentially hazardous foods (time/temperature control for safety) are held at room temperature in order to minimize growth of pathogens such as *Lm*.

FDA guidelines allow for a working supply of refrigerated potentially hazardous foods (time/temperature control for safety) that are displayed or held for service for immediate consumption to be safely kept out of temperature control for a limited time. The food must be marked with the time it was removed from temperature control and cooked and served, served, or discarded within six (6) hours. The food must have an initial temperature of 41° F or less when removed from temperature control and may not exceed 70° F. Written procedures must be maintained in the food establishment. (See the FDA Food Code Section 3-501.19) **Check with your state or local regulatory authority for specific requirements for the use of Time as a Public Health Control.**

Every food establishment needs to have active managerial control of risk factors. Active managerial temperature control can be applied by incorporating a plan to monitor temperatures along every step in the process. Follow FDA Food Code guidelines for proper cold holding, thawing, cooking, hot holding and cooling

requirements. Control measures must include taking corrective action immediately when food exceeds the required temperature.

Contamination

Since *Lm* is present in many environments, it is extremely difficult to eliminate it completely in food establishments. Employees and incoming raw materials or products may easily reintroduce *Lm* into the food establishment.
Unclean equipment and poor sanitation can result in the transfer of *Lm* onto ready-to-eat foods. The widespread nature of this organism mandates a systematic approach for control.

Preventing Cross Contamination of Ready-To-Eat Foods by Raw Foods
Ensuring complete separation of raw and ready-to-eat foods throughout all areas of receiving, storage, preparation, display, and service is ideal for preventing contamination.

If space is limited where raw and ready-to-eat foods are kept in the same area, separation can be achieved by using sufficient physical space, physical dividers, different production times for raw and ready-to-eat food items with a complete cleaning and sanitizing in between, or storing raw foods below ready-to-eat foods.

Color-coding of cutting boards, handles on knives, tongs and utensils can be a useful visual reminder for keeping food contact surfaces that touch raw foods separate from those that touch ready-to-eat foods.

Preventing Contamination of Ready-To-Eat Foods From Other Sources
Food and packaging material must be protected from contamination during storage and display. Store food and food packaging material in a clean, dry location protected from overhead contamination. These items must be stored at least six inches above the floor on shelves, racks, pallets, or other means to avoid moisture absorption and to facilitate cleaning and pest control.

Food or food packaging material should not be stored below dripping or leaking condensate.

Pallets, boxes, shipping containers or other items from outside the food establishment should not be brought directly into ready-to-eat food preparation areas, since they may be a source of *Lm* contamination.

Foot traffic into food preparation areas should also be controlled, since shoes might be a source of *Lm* contamination. Do not allow maintenance personnel, sales people, customers, visitors, or other unauthorized individuals into areas where ready-to-eat food is being prepared unless they have followed proper preventative procedures.

Maintenance personnel's clothing, tools and equipment such as ladders can also be a source of contamination. So their access into food preparation areas must be limited. Food and food packaging materials must be removed or otherwise protected during any necessary maintenance activities. Food processing equipment that may have been contaminated during any maintenance activities must be cleaned and sanitized prior to use. Whenever possible, defective equipment should not be repaired in a food preparation area.

Garnishes may also be a source of contamination. To reduce this risk, fresh garnishes should be thoroughly washed if they come in contact with ready-to-eat foods and replaced regularly. Plastic garnishes should be cleaned and sanitized between uses.

Minimize adding to or topping off ready-to-eat foods while on display. If this is not possible, a system should be in place to ensure a complete break in the cycle of commingling ready-to-eat food products. The timeframe should be seven (7) days or less from the time the first ready-to-eat food was prepared and placed on display. The temperature of the commingled ready-to-eat product must be kept at 41°F or below.

As noted previously, wet cleaning and sanitizing should only take place after all exposed food and packaging products have been removed from the area or covered to protect them from splash contamination.

When it is necessary to temporarily retain product determined to be unsaleable for any reason, it should be segregated in a designated area (morgue) separate from saleable food items. Unsaleable products may include food items that are being returned to the distributor, food items that are out of code, or food items that are damaged or spoiled.

Employee Practices to Prevent Lm Contamination

Lm can enter the food establishment on employee's clothing, including shoes, and contaminate food through poor food safety practices. A very important factor in limiting the risk of *Lm* contamination is ensuring employees are trained and knowledgeable about the sources of contamination and practices that can minimize or prevent problems. Employees should be aware of the severity of listeriosis and the damaging impacts it could potential have on the establishment and its customers.

A written employee health and personal hygiene policy should be established. Refer to the FDA Food Code (2-2 to 2-4) for specific requirements. Employees must be trained on proper hand washing, glove usage and other practices to prevent risks related to *Lm*.

An adequate number of hand washing sinks, including a supply of soap and paper towels, must be available and conveniently accessible to all employees in

food preparation areas and restrooms. If used, nailbrushes should be cleaned and sanitized regularly.

Employees should avoid direct bare hand contact with any RTE foods. Single-service gloves or cleaned and sanitized utensils, such as tongs, spoons or ladles should be used whenever possible.

Gloves should be changed and discarded and hands washed every time the employee changes tasks or the gloves become soiled or contaminated. Gloves are never a substitute for proper hand washing.

Because employees clothing might get contaminated with *Lm*, consideration should be given to having employees wear aprons or smocks in ready-to-eat areas. Prior to leaving food preparation areas, such as leaving for breaks, eating meals or visiting toilet facilities, employees should remove aprons and smocks.

Traffic flow of employees into and out of ready-to-eat food preparation areas should be limited where possible to prevent the introduction or spread of *Lm*. When movement in and out of the ready-to-eat food area is necessary, appropriate precautions must be taken, e.g., change of outer clothing and immediate hand washing.

Employee Training

Knowledgeable food employees are vital to a successful food operation. All food handlers need to understand risk factors associated with receiving, storing, preparing, holding, displaying and handling food in their food establishment. Food safety training should be a part of every food establishments' active managerial control program. Training and supervision will provide employees with the knowledge and skills necessary to follow policies and procedures designed to control critical risk factors.

It is important for food establishment operators to design and implement a food safety training program appropriate for their operation. This L*m* guidance document can be used to assist in covering important intervention strategies.

Other training materials are also available such as;
Super Safe Mark http://www.fmi.org/supersafemark/program.htm,
Serv Safe http://www.nraef.org/servsafe/,
Cornell University Control of Listeria in Ready to Eat Seafood
http://www.foodscience.cornell.edu/wiedmann/TrainingIndex.htm,
Managing Food Safety: A Guide For The Voluntary Use of HACCP Principles for Operators of Food Service and Retail Food Establishments
http://www.cfsan.fda.gov/~dms/hret2toc.html,
FDA 2005 Food Code http://www.cfsan.fda.gov/~dms/fc05-toc.html

Guidance for Processing Smoked Seafood at Retail (AFDO) http://www.afdo.org/afdo/upload/SmokedSeafood.pdf, Meat & Poultry Processing at Retail (AFDO) http://www.afdo.org/afdo/training/upload/Complete%20Meat%20and%20Poultry%20Manual.pdf , and Control of Listeria *monocytogenes* in Retail Establishments (Pennsylvania State University, video) http://www.foodsafety.psu.edu/retail_listeria.html

Training should be a continual process to ensure compliance with company policies and the most current food safety practices. The training should cover at least basic information on L*m* interventions, which include employee health and hygiene, proper cleaning and sanitizing, frequency of cleaning, protection against contamination, and temperature control.

Verifying the Effectiveness of Sanitation Programs

Cleaning and sanitizing are very effective means for controlling *Lm* in a food establishment. If surfaces or equipment become contaminated with *Lm*, they can transfer the organism to ready-to-eat food products. *Lm* can also be found throughout the environment in nooks and crannies, called niches, where it is more difficult to clean.

Every food establishment must have a cleaning and sanitation program and should have a method for verifying its effectiveness. There are different ways to verify the effectiveness of sanitation programs and often a combination of approaches can be used. When determining which method to use, consideration should be given to factors such as:

- How difficult the area is to clean
- Whether possible *Lm* harborage sites are present
- Whether there have been previous problems with sanitation

The person-in-charge should be responsible for ensuring that employees are properly trained for the tasks assigned to them and that they fully understand how to perform the sanitation procedures. This includes mixing and testing cleaning and sanitation solutions for proper strength, cleaning and sanitizing certain equipment according to a prescribed schedule, and checking to be sure equipment and surfaces are cleaned as needed throughout the day.

Different methods can be used to verify the effectiveness of sanitation programs, for example:

- Observation and monitoring
- Rapid sanitation tests
- Microbiological testing

These methods vary by cost and level of technical expertise needed to use them. The following is a brief description of these three methods.

Observation and Monitoring

Visual inspections, observations, tracking chemical use, monitoring records and reviewing cleaning charts are simple, inexpensive and effective methods to verify compliance with cleaning procedures. Store management, internal food safety auditors, chemical suppliers, or third party audits can be used to conduct the visual observations.

Rapid Sanitation Tests

Rapid tests will give food establishments immediate results. To be of most benefit, these tests need to be done on a regular basis over time, so a food establishment should be willing to make a commitment to using this method. The results of these tests can be used for tracking trends and monitoring compliance with the sanitation program.

ATP bioluminescence and glucose tests are examples of rapid test kits. These are usually simple kits, which include a swab that is rubbed on a surface and a hand-held measuring device. These kits measure chemical components such as ATP or glucose that reflect the amount of organic matter food debris, sugars, microorganisms, etc., on a surface and provide a general indication of cleanliness.

Microbiological Testing

Before undertaking microbial testing, a food establishment should evaluate several important factors such as:

- What will be sampled
- For what organisms will be the samples be examined
- When and where samples will be collected
- Where the samples will be analyzed and what criteria suggest a potential problem

A food establishment operator also needs to have a plan to address specifically what action will be taken to remedy the situation when results indicate a potential concern.

Total plate counts (TPC) and aerobic plate counts (APC) are more expensive than rapid testing and require using an internal or contract laboratory. TPC and APC can be used to assess the general level of bacteria on cleaned and sanitized surfaces. It is important to note that results from generic tests such as TPC or APC are not an indicator of the presence or absence of pathogens, including *Lm*. They can however provide useful information on the effectiveness of sanitation programs.

Testing the environment for *Listeria* species is more specific and can be useful if *Listeria* is suspected or known to be a problem. *Listeria* testing may be used as part of a foodborne illness investigation or as follow-up to a recall. It should be noted that *Listeria* species, and even *Lm,* can sometimes be found at retail

because *Listeria* is a common environmental contaminant. When detected, the goal is to remove the organism by rigorous cleaning and sanitation.

Sampling Protocol

Before microbiological sampling of the environment and food contact surfaces is undertaken, a food establishment should have a written protocol in place. One of the most important factors to consider in a microbial testing protocol for *Listeria* is how a food establishment will handle a positive result. The time delay between sample collection and receiving the test result may mean that the source of the pathogen, and any potentially contaminated product, are already gone.

Additional information regarding verification of sanitation can be obtained from local regulatory authorities, sanitation vendors, private laboratories, or consultants who specialize in food safety and sanitation.

Product Specifications and Recalls

Food establishments should develop product specifications with their suppliers that include, where appropriate, the following:

- Environmental testing
- Ingredient testing
- Finished product testing
- Use of ingredients known to inhibit *Lm* growth

Suppliers should have a system to hold products that are being tested. Guidance for holding tested products can be found at http://haccpalliance.org/alliance/HoldingTestedProdSept1905.pdf .

In addition, supplier auditing should be considered to verify that the controls that have been specified are being followed. The audits can be done using in-house personnel or third party auditing firms.

In the event that a product a food establishment makes or distributes was contaminated by *Lm,* the food establishment should have a recall plan in place. This plan needs to address both of the following scenarios:

- Product received from a supplier
- Product produced by the food establishment

The plan should:

- Describe how to identify the specific product(s) involved
- Identify how the distribution of the product is determined
- Specify how customers are to be notified
- Contain a draft letter/press release

The letter should contain language about *Lm* that is acceptable to the regulatory agencies. Sample letters are available at http://www.fda.gov/ora/compliance_ref/recalls/recallpg.html

When conducting a recall:

- Clearly identify the product(s). Include pictures of the packaging and coding if available.
- Segregate recalled product from previous or subsequent "safe" food. Refer to the FDA Food Code section 6-404.11 (http://www.cfsan.fda.gov/~dms/fc01-6.html#6-4)
- Give specific directions to customers on how to handle the recalled product: for example, destroy, return, or hold and segregate for pick-up.

For further information about recalls of FDA regulated foods see http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm.

Additionally, Subpart C of Part 7 of FDA regulations (21 CFR 7.40-59) provides general guidance for the voluntary recall of products, including those recalls initiated by a firm on its own and at FDA's request.

For USDA FSIS-regulated products refer to Directive 8080.1, revision 4. http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1_Rev4.pdf.

Another resource is the AFDO Food Recall Manual developed by the University of Florida. http://www.afdo.org/afdo/upload/FoodRecallManual11-09-2004.pdf.

Conference for Food Protection
2016 Issue Form

Issue: 2016 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:

LRG 2 - Approval of Listeria Retail Guidance Document

Issue you would like the Conference to consider:

At the 2014 Biennial Meeting of the Conference for Food Protection, the Listeria Retail Guidelines Committee was re-created and charged (Issue: 2014 III-008) to revise the "2006 Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* Within Food Establishments" to include:

1) sanitation guidance for equipment and food establishment environments,

2) good retail practices on how to prevent contamination and growth of Lm in retail establishments,

3) updated outdated links to other documents, and

4) information from and references to documents published by credible organizations on the topic of Lm prevention and control in food establishments.

The Conference also recommends that the committee report its recommendations back to the 2016 Biennial Meeting with Issues to address:

1) the above charges, and

2) recommendations that a letter be sent to FDA requesting that Annex 2 (References, Part 3-Supporting Documents) be amended by adding a reference to the revised voluntary guidelines.

Public Health Significance:

Listeria contamination continues to be a significant public health issue. Although the 2006 CFP Listeria Guidelines provided useful general information about cleaning, sanitizing and good retail practices, the guidelines required updating to reflect new information and available resources. The revision process and the resulting updates were developed by a committee whose membership included a wide variety of viewpoints and expertise to help

ensure that the guidelines provide the best possible information to help food establishments protect public health.

Recommended Solution: The Conference recommends...:

1. That the new "2016 Draft Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* within Food Establishments, Second Edition document", be approved, replacing the 2006 document by the Conference for posting in both PDF and editable formats on the CFP website *(document is attached to Issue titled: Report - Listeria Retail Guidelines Committee)*; and
2. That a letter be sent to the FDA encouraging them to amend the 2013 Food Code, Annex 2 (References, Part 3-Supporting Documents) by adding a reference to the 2016 revision of the Conference approved voluntary guidelines.

Submitter Information 1:

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-003

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Report - Hand Hygiene Committee (HHC)

Issue you would like the Conference to consider:

The 2014-2016 Hand Hygiene Committee was charged to work in collaboration with FDA, CDC, and FSIS to:

a. Ascertain if additional definitions are necessary to clarify the hand hygiene procedures listed in the Food Code.

b. Use current research including the documents created by the Committee's 2012- 2014 work (Hand Contamination Event Hazard Chart; Questions to Consider when Evaluating Studies of Alternative Handwashing Approaches; and Scientific, Regulatory and Behavioral Consideration of Hand Hygiene Regimes) to determine if alternatives to hand hygiene procedures equivalent to those described in the Food Code are available.

c. Identify situations where procedures exist to prevent hand soil and contamination.

d. Review available research on the efficacy and public health significance of antibacterial soaps, and their impact on hand hygiene procedures in the food industry.

And report back the Committee's findings, outcomes, and recommendations to the 2016 Biennial Meeting of the Conference for Food Protection.

Public Health Significance:

Proper handwashing, is a vital and necessary public health practice in retail and food service. Transmission of pathogenic bacteria, viruses, and parasites from raw food or from ill workers to food by way of improperly washed hands continues to be one of several major factors in the spread of foodborne illnesses.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the 2014-2016 Hand Hygiene Committee report.

2. Thanking the committee for the effort of the members put forth in working on the charges.
3. Disbanding the Hand Hygiene Committee.

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Content Documents:

- "2014-2016 Hand Hygiene Committee Final Report"
- "2014-2016 Hand Hygiene Committee Roster"
- "2014-2016 Comparison of Selected Hand Hygiene Efficacy Test Methods"

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Conference for Food Protection – Committee FINAL Report

Template approved: 08/2013

Committee Final Reports are considered DRAFT until deliberated and acknowledged by the assigned Council at the Biennial Meeting

COMMITTEE NAME: 2014–2016 Hand Hygiene Committee (HHC)

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council III

DATE OF REPORT: December 10, 2015

SUBMITTED BY: Lori LeMaster and Christina Bongo-Box, Co-Chairs

COMMITTEE CHARGE(s):

Issue: 2014 III-011
The committee is charged to:

1. Recreate the Hand Hygiene Committee, working in collaboration with FDA, CDC, and FSIS, to be charged with the following:

    a. Ascertain if additional definitions are necessary to clarify the hand hygiene procedures listed in the Food Code.

    b. Use current research including the documents created by the Committee's 2012- 2014 work (Hand Contamination Event HazardChart; Questions to Consider when Evaluating Studies of Alternative Handwashing Approaches; and Scientific, Regulatory and Behavioral Consideration of Hand Hygiene Regimes) to determine if alternatives to hand hygiene procedures equivalent to those described in the Food Code are available.

    c. Identify situations where procedures exist to prevent hand soil and contamination.

    d. Review available research on the efficacy and public health significance of antibacterial soaps, and their impact on hand hygiene procedures in the food industry.

2. Report back the Committee's findings, outcomes, and recommendations to the 2016 Biennial Meeting of the Conference for Food Protection.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

    a. During the first call of the HHC, the committee discussed the options for how to approach work on the assigned charges; specifically whether to work in subgroups or consider each charge together as the whole committee. The committee agreed that in order to obtain consensus on the charges, the work would be done by the entire HHC, rather than by sub-committees.

    The committee agreed on a biweekly call schedule and calls were held on 9/25/14, 10/9/14, 10/23/14, 12/4/14, 1/29/15, 2/5/15, 2/12/15, 2/26/15,3/26/15,4/9/15, 5/21/15, 6/18/15, 7/16/15,

7/30/15, 8/13/15, 8/27/15, 9/10/15, 10/8/15, and 10/22/15. Calls were recorded through Pragmatic and call recordings and call notes/minutes were shared with the group.

As a part of the March, 2015 HHC Progress Report, the HHC requested that the Executive Board provide clarification of the following sections of the charge:
Original Charge sections:

Section a - Ascertain if additional definitions are necessary to clarify the hand hygiene procedures listed in the Food Code.
. The HHC requested clarification whether the committee is also asked to provide recommendations for additional definitions if they are needed. The HHC provided the following recommended language: (Ascertain if additional definitions are necessary and proposed recommendations to clarify the hand hygiene procedures listed in the Food Code.

Section c - Identify situations where procedures exist to prevent hand soil and contamination. The HHC provided the following recommended language:
Identify methods and available research that describe where procedures exist to prevent hand soil and contamination.

Section d. Review available research on the efficacy and public health significance of antibacterial soaps, and their impact on hand hygiene procedures in the food industry. The committee voted unanimously to request that this charge be removed:

FDA published a proposed rule regarding the available data and FDA's criteria for establishing the safety and effectiveness of antiseptic washes for consumer use in December 2013. Although CDER has not yet defined antiseptic criteria for food handler use, we plan to address these products in the future.

The Executive Board denied the request to revise any of the charges and provided this guidance:

"The Committee can choose to explain how they fulfilled charges by the recommendations as stated in their report. However, charges cannot be changed or removed."

i. Regarding the first section of the Charge;1.a: Ascertain if additional definitions are necessary to clarify the hand hygiene procedures listed in the Food Code.

The committee considered this charge first and initially could not come to consensus that additional definitions were necessary to clarify the hand hygiene procedures in the Food Code. The group agreed to "table" this charge and work on the other charges and reconsider this item if gaps in definitions were identified through work on other charges.

After the HHC worked charge 1.b, the committee identified two potential definitions that would clarify the current hand hygiene procedures listed in the Food Code: HAND CLEANING COMPOUND and ANTISEPTIC HAND RUB The committee formed a small work group to research and recommend language to the whole committee. The entire HHC was able to achieve consensus to recommend the following be added as defined terms to the Food Code:

a) HAND CLEANING COMPOUND- A formulated hand hygiene product used to remove soils and transient microorganisms on hands, being submitted as Issue HHC-2

b) ANTISEPTIC HAND RUB- An antiseptic hand hygiene product applied to the hands and rubbed until dry, used to reduce the transient microorganisms, being submitted as Issue HHC-3

ii. Regarding the second section of the Charge; 1.b. Use current research including the documents created by the Committee's 2012-2014 work (Hand Contamination Event Hazard Chart; Questions to Consider when Evaluating Studies of Alternative Handwashing Approaches; and Scientific, Regulatory and Behavioral Consideration of Hand Hygiene Regimes) to determine if alternatives to hand hygiene procedures equivalent to those described in the Food Code are available.

The committee was charged with reviewing current research to determine if alternatives hand hygiene procedures exist that are equivalent to the hand hygiene procedures described in the Food Code.

The HHC began work on this charge on 12/4/14.

There was extensive discussion about how to approach this charge. The voting members voted unanimously on the following points:

a) There is no standard by which to determine "equivalent hand hygiene procedures"
b) To move forward by reviewing the submitted studies to look for trends in the literature.

The group divided into six small groups and each small work group was assigned a few of the studies listed below to review and report back to the whole group on the 1/29/15 call. The sub-committees met between 12/4/14 and 1/29/15.

The HHC reviewed the following studies:

- 2010-2012 Hand Hygiene Committee / Swanson Et. Al.,2012
- M. A. Davis, H. Sheng, J. Newman, D. D. Hancock and C. J. Hovde. "Comparison of waterless hand-hygiene preparation and soap-and-water hand washing to reduce coliforms on hands in animal exhibit settings". Epidemiol Infect 2006;134: 1024-1028..
- Sarah L. Edmonds,* James Mann, Robert R. Mccormack, David R. Macinga, Christopher M. Fricker, James W. Arbogast, And Michael J. Dolan. "SaniTwice: A Novel Approach to Hand Hygiene for Reducing Bacterial Contamination on Hands When Soap and Water are Unavailable". J Food Prot. 2010;73(12):2296-2300.
- Sarah L. Edmonds,* Robert R. Mccormack, Sifang Steve Zhou, David R. Macinga, and Christopher M. Fricker. "Hand Hygiene Regimens for Reduction of Risk on Food Service Environments" J Food Protect 2012;75(7):1303-1309.
- Sarah L. Edmonds, Ms; Carrie Zapka, Ms; Douglas Kasper, Md; Robert Gerber, Md;Robert Mccormack, Bs; David Macinga, Phd; Stuart Johnson, Md; Susan Sambol, Bs,Mt (Ascp); Christopher Fricker, Phd; James Arbogast, Phd; Dale N. Gerding, Md. "Effectiveness of Hand Hygiene for Removal of Clostridium difficile Spores from Hands". Infect Control Hosp Epidemiol 2013;34(3):302-305.
- Angela Fraser, James W. Arbogast, Lee-Ann Jaykus, Richard Linton, and Didier Pittet. "Rethinking Hand Hygiene in the Retail and Foodservice Industries: Are Recommended Procedures Based on the Best Science and Practical Under Real-world Conditions?" Food Protection Tends. December 2012.
- Akrum H. Tamimi • Sheri Carlino •Sarah Edmonds • Charles P. Gerba. "Impact of Alcohol-Based Hand Sanitizer Intervention on the Spread of Viruses in Homes". Food Environ. Virol 2014.
- Pengbo Liu • David R. Macinga • Marina L. Fernandez •Carrie Zapka • Hui-Mien Hsiao • Brynn Berger, "Comparison of the Activity of Alcohol-Based Handrubs Against Human

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Each of the small work groups reported to the full committee on the results of their review of their assigned studies during the 1/29/15 HHC call. Overall, the majority of the studies reviewed by the group were not applicable directly to food service, or they were limited in scope and application. The primary conclusion reiterated by every small group during their review of the literature is that a standard to determine an alternative method for hand hygiene procedures "equivalency" does not exist but is necessary. The HHC members agreed that there is a real need for food service-focused research to understand the different levels of risk associated with different food handling activities in food establishments.

Since the literature review could not establish alternatives that are equivalent to the handwashing procedures, the group formed a sub-group to review and report back to the entire HHC their findings regarding the following published standard handwashing methods:

- ASTM E2011-13 (" Standard Test Method for Evaluation of Hygienic Handwash and Handrub Formulations for Virus-Eliminating Activity Using the Entire Hand")
- ASTM E2946-13 ("Standard Test Method for Determining the Bacteria-Reducing Effectiveness of Food-Handler Handwash Formulations Using Hands of Adults")ASTM E2783 ("Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time-Kill Procedure")
- ASTM 1174 ("Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations")
- ASTM E2755 ("Standard Test Method for Determining the Bacteria-Eliminating Effectiveness of Healthcare Personnel Hand Rub Formulations Using Hands of Adults")
- EN 1276 ("Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)")

- EN 1499 (“Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2)”)
- EN 1500 (“Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)”)

The subcommittee developed a Comparison of Selected Hand Hygiene Efficacy Test Methods table (attached) to review and evaluate all of the standard methods listed above to assess their strengths, limitations, reproducibility, and relevance in food settings. The subcommittee recommended to the full committee that ASTM E2783 and ASTM 2946 could be included in the Food Code in a meaningful and logical way; by creating science based performance standards for hand hygiene products used in the food industry.

No recommendations of equivalent alternate procedures could be made by the full committee based on the subcommittee’s findings of no agreed-upon performance measure comparable to the Food Code procedures exist.
It was shared with the committee that FDA is working to develop performance standards that will allow for the evaluation of different methods for soil removal from hands of food service workers or food production situations. No clear timeframe for these performance standards was available at this time.

The HHC recommends that a letter be sent to the FDA encouraging the development of handwashing performance standards.

iii. Regarding the third section of the Charge 1.c. Identify situations where procedures exist to prevent hand soil and contamination. The committee identified the following procedures that potentially prevent hand soil and contamination:

1. Properly using utensils. For example, filling a glass with ice using a scoop.
2. Handling raw animal foods with tongs instead of bare hands.
3. Properly using gloves.
4. Using other barriers when handling food, such as deli paper.
5. Segregating job duties so that the food handlers assigned to work with raw animal foods are not required to also handle ready to eat foods or other clean utensils.
6. Double-gloving.

iv. Regarding the fourth section of the Charge1.d. Review available research on the efficacy and public health significance of antibacterial soaps, and their impact on hand hygiene procedures in the food industry.

FDA published a proposed rule regarding the available data and FDA’s criteria for establishing the safety and effectiveness of antiseptic washes for consumer use in December, 2013: https://www.federalregister.gov/articles/2013/12/17/2013-29814/safety-and-effectiveness-of-consumer-antiseptics-topical-antimicrobial-drug-products-for
The FDA Center for Drug Evaluation and Research (CDER) has not yet defined antiseptic criteria for food handler use.

The Hand Hygiene Committee membership agreed that it was unable to complete this charge because any recommendations resulting from the charge would include FDA policy matters that are outside the scope of the CFP. Resolution of the charges requires the active

engagement of FDA CDER, a regulatory body for drugs, with FDA Center for Food Safety and Applied Nutrition (CFSAN) and interagency engagement is beyond the scope of CFP.

The HHC Recommends that a letter be sent to the FDA encouraging the FDA to work in conjunction with CDER to define antiseptic criteria for food handler use.

2. Recommendations for consideration by Council:
Based on the committee's work, the Committee Co-Chairs are submitting 3 issues on behalf of the Committee. Recommendations of this Committee through these issues are:

a. Thank the Committee for its work, acknowledge the Committee's report, and disband the Committee.
b. Add the following definition to the Food Code:
Hand Cleaning Compound - A formulated hand hygiene product used to remove soils and transient microorganisms on hands.
c) Add the following definition to the Food Code:
Antiseptic Hand Rub - An antiseptic hand hygiene product applied to the hands and rubbed until dry, used to reduce the transient microorganisms.
d) Recommend that a letter be sent to the FDA encouraging the development of handwashing performance standards.
e) Recommend that a letter be sent to the FDA encouraging the FDA to work in conjunction with CDER to define antiseptic criteria for food handler use.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Issue 1- Report- 2014-2016 Hand Hygiene Committee (HHC)
2. Issue 2- HHC Recommended Food Code Definitions for "Hand Cleaning Compound" and
3. Issue 3 – HHC Recommended Food Code Definitions for - "Antiseptic Hand Rub"
4. Issue 4 – HHC recommended letters to FDA

1) Recommend that a letter be sent to the FDA encouraging the development of handwashing performance standards.
2) Recommend that a letter be sent to the FDA encouraging the FDA to work in conjunction with CDER to define antiseptic criteria for food handler use.

COMMITTEE MEMBER ROSTER (attached):

Committee Name: 2014 - 2016 Hand Hygiene Committee - Council III

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Table 1. Comparison of selected hand hygiene efficacy test methods by key step or variable

Key Step or Variable	ASTM E2783 (Time Kill)	EN 1276	Chlorine Equivalency former USDA E2/E3 rating)	ASTM E1174	ASTM E2755	ASTM E2946	ASTM E2011	EN 1499	EN 1500
Vitro/vivo	In Vitro	In Vitro	In Vitro	In Vivo	In Vivo	In Vivo	In Vivo	In Vivo	In Vivo
Purpose / Target Application in Design	"In vitro" hand hygiene product evaluation	"In vitro" antimicrobial activity of disinfectants and hand hygiene products	• "In vitro" designed to test efficacy of halogen based disinfectants and sanitizers	"In vivo" product evaluation ("healthcare personnel hand wash")	"In vivo" activity of hand hygiene personnel hand rubs	"In vivo" activity of food handler hand hygiene formulations	"In vivo" antiviral activity of hand hygiene formulations	"In vivo" hand washes – ensure a minimum performance standard	"In vivo" hand rubs – ensure a minimum performance standard
Test Organism(s)	*Any BSL 1 or 2 organisms; we could recommend a specific list that are highly food relevant (e.g. e. Coli, listeria, salmonella, etc.)*	*Ps. aeruginosa ATCC 15442, E. coli ATCC 10536,* *S. aureus ATCC 6538, Enterococcus hirae ATCC 10541*	*S. aureus ATCC 6538* *S. typhi ATCC 6539*	*Serratia marcescens and E. coli*	*Serratia marcescens ATCC 14756* *S. aureus ATCC 6538, or 33591*	*E. coli ATCC 11229*	*Human Rotavirus, Human Rhinovirus Type 37, Feline calicivirus, Human Adenovirus Type 5*	*E. coli K12 NCTC 10538*	*E. coli K12 NCTC 10538*

Key Step or Variable	ASTM E2783 (Time Kill)	EN 1276	Chlorine Equivalency former USDA E2/E3 rating)	ASTM E1174	ASTM E2755	ASTM E2946	ASTM E2011	EN 1499	EN 1500
Soil Type(s):	None	Flexible: Can be chosen based on the condition of use	Inoculated broth	4.5 mL of inoculums in nutrient broth	0.2 mL of inoculum in nutrient broth	Beef broth is "moderate" soil, Hamburger is "heavy" soil	Bovine serum	Inoculated broth	Inoculated broth
Soil Load (Quantity):	Volume of the inoculum in Nutrient broth used	0.3g/L clean conditions; 3 g/L dirty conditions	10 µl of inoculated broth for tube 1 and total 100 µl for tube 10	4.5 mL of inoculums in Nutrient broth	0.2 mL of inoculum in nutrient broth	4.5 mL of Beef broth for moderate soil Handling contaminated hamburger for 2 min	5% in the virus inoculum	Amount of inoculated broth which ends up on the hands during immersion of the hands	None specifically added. Just dried TSB from inoculating broth
Method of Contamination:	Inoculation of the product	Inoculation of the product	Inoculation of the product	3 -1.5 mL of an overnight broth culture of the test organism	200µl of a concentrated broth suspension of the test organism	4.5 mL of Beef broth for moderate soil Handling contaminated hamburger for 2 min	1.5 mL of the suspension, 90 sec spread, 90 sec dry Or 20µL of virus suspension on each finger tip	Immersion into seeded broth	Immersion into seeded broth
Baseline Recovery (Pre-Test Value):	Not specified	$1.5x10^8$-$5x10^8$	N/A	$5x10^8$-$1x10^9$ Liquid suspension used for contamination. Recovery is not specified	$\geq 10^8$ cfu/hand (Usually 8.5-9.0 log10 cfu/hand)	Suspension $1x10^8$	The virus "pull" shall contain $\geq 10^7$ infective unit/mL	Inoculum $2x10^8$-$2x10^9$ Log pre-values at least 5	Inoculum $2x10^8$-$2x10^9$ Log pre-values at least 5 per mL

Key Step or Variable	ASTM E2783 (Time Kill)	EN 1276	Chlorine Equivalency former USDA E2/E3 rating)	ASTM E1174	ASTM E2755	ASTM E2946	ASTM E2011	EN 1499	EN 1500
Test Article Application Details:	N/A	N/A	N/A	5 mL of the test product during handwashing using 40°C water for 1 min handwashing	1.5 ml of a test material (calculations for foaming materials provided)	5 mL of the test material Wash for 30±5 sec, rinse for 30±5 sec	Volume specified by manufacturer	3 ml applied and washed for 30 or 60 sec +15 sec rinse or following manufacturer instructions	3 ml applied and rubbed for 30 seconds, then sampled
Number of Subjects / Replicates (Minimum, Recommended)	N/A	N/A	N/A	Not specified FDA CDER asks for at least 12 subjects	At least 8 subjects Total depends on number of test materials, study purpose, and regulatory requirements governing the study.	At least 8 subjects	At least 6 subjects	At least 12 subjects	18-22 subjects
Internal Reference:	None	None	Referenced Chlorine solution	None	None	None	None	Soft soap (British Pharmacopoeia 1993) 200g/L	2x3ml of 60% isopropanol rubbed for 60 seconds total
Acceptance Criteria:	None	5 log reduction	Test article is at least equivalent to 50 ppm chlorine	None in the test method. Per 2015 FDA HC TFM: 2 Logs after the 1st application, 3 Logs after 10th application	None in the test method.	None in the test method.	None in the test method	Statistically non-inferior to the reference product	Statistically non-inferior to the reference product

Key Step or Variable	ASTM E2783 (Time Kill)	EN 1276	Chlorine Equivalency former USDA E2/E3 rating)	ASTM E1174	ASTM E2755	ASTM E2946	ASTM E2011	EN 1499	EN 1500
Can bland Handwash be a benchmark?	Yes, not in the test method	N/A	N/A	Yes, not in the test method	N/A	Yes, not in the test method	Yes, not in the test method	N/A	N/A
Product dilution	Undiluted	Undiluted	Undiluted	Undiluted	Undiluted	Undiluted	Undiluted	Undiluted	Undiluted
Contact time	Flexible; most typical is 15 sec, 30 sec and 60 sec.	5 min	1, 2.5 and 5 min	30 sec lather + 30 sec rinse	1.5 mL application volume, Rub until hands are dry. Or manufacturer's recommendations	30±5 sec	10-20 sec for handwash, 20-30 sec for hand rub, or other times representative use condition time	30 or 60 sec +15 sec rinse or following manufacturer instructions	30 sec

Table 2. Comparison of selected hand hygiene test methods by strengths and limitations and suitability for inclusion in Model Food Code

Method	Strengths	Limitations	Expected variability and reproducibility	Relevance and Fit for Food Code (H/M/L)	Recommended for CFP & Food Code
ASTM E2783 (Time Kill)	"In vitro" test, relatively inexpensive, can be run with many organisms and by many labs with good reproducibility. Large amount of data and experience using this method	"In vitro" test (i.e. results will not necessarily predict real world hand hygiene results or the *in-vivo* methods)	Results more variable when the product has high foam; results are highly dependent of the mixing technique	High: Good screening test, should be required as a means to ensure broad spectrum antimicrobial effectiveness before "in vivo" testing.	**Yes**
Chlorine Equivalency	"In vitro" test. Long history of use	Risks posed by working with *S. typhi* (typhoid fever) Data is not relevant for hand antiseptics in general, especially those that do not contain halogen based active ingredients	Products with border line efficacy have high variability in results	Low	No
EN 1276	"In vitro" test Includes options of soils to be added, based on the industry. Could be tested for clean and dirty conditions	Some of microorganisms are not relevant for food retail use The test method is not designed for chemistries affected by soil	No	Low	No
ASTM 1174	"In vivo" test	Designed for healthcare	Fair reproducibility	Medium	No

Method	Strengths	Limitations	Expected variability and reproducibility	Relevance and Fit for Food Code (H/M/L)	Recommended for CFP & Food Code
	A lot of data available for this test	applications No soil used besides the inoculum broth *E. coli* (not *Serratia*) should be required for food retail application	Cannot compare across tests		
ASTM E2755	"In vivo"	Price of the test (relatively expensive) Some of microorganisms are not relevant for food retail use	Fair reproducibility Cannot compare across tests	Medium	No
ASTM E2946	"In vivo" test Designed for food handler applications (bacteria) Two different food relevant soils (moderate and heavy)	Recently released, so limited experience with the method	Fair reproducibility Cannot compare across tests	High	**Yes**
ASTM E2011	"In vivo" test	No soil used besides the inoculum broth Viruses only Viruses are not included in FDA CDER Monograph for hand antiseptics.	Fair reproducibility Cannot compare across tests	Medium (viruses only)	No

Method	Strengths	Limitations	Expected variability and reproducibility	Relevance and Fit for Food Code (H/M/L)	Recommended for CFP & Food Code
EN 1499	"In vivo" test	Designed for healthcare applications Limited history of use in US	No	Low	No
EN 1500	"In vivo" test	Designed for healthcare applications Limited history of use in US	No	Low	No

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-004

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

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Issue History:

This is a brand new Issue.

Title:

HHC 2 - Definition for “Hand Cleaning Compound”

Issue you would like the Conference to consider:

The CFP Hand Hygiene Committee (HHC) was charged to ascertain if additional definitions are necessary to clarify the hand hygiene procedures listed in the Food Code.

The Hand Cleaning Procedures found in the 2013 FDA Food Code section 2-301.12(B)(2) requires food employees to "apply an amount of cleaning compound recommended by the cleaning compound manufacturer."

The HHC identified specific areas in the Food Code where amendments and definitions can provide further clarity to regulators and retail food stakeholders. Prevention of cross-contamination is essential in foodservice, and explicitness in the Food Code can help reduce potential risk. The HHC identified that defining "Hand Cleaning Compound" was necessary to eliminate ambiguity in what exactly could be used as a hand cleaning compound.

Public Health Significance:

The main purpose of washing hands is to cleanse the hands of soil, pathogens and chemicals that can potentially cause disease. Transmission of pathogenic bacteria, viruses and parasites to food from contaminated surfaces, raw food, or ill workers by way of improperly washed hands continues to be a major factor in the spread of foodborne illnesses.

Regulators and retail foodservice stakeholders reference the Food Code for guidance and clarity on appropriate approaches for removal or reduction of potential pathogens from hands. Therefore, the Food Code should be inclusive of clarifying language to assure the reader understands intent.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (using underlining for language additions):

1. Add a definition for "Hand Cleaning Compound"

"HAND CLEANING COMPOUND" - A formulated hand hygiene product used to remove soils and transient microorganisms on hands.

2. Replace the term "cleaning compound" with "HAND CLEANING COMPOUND" as appropriate throughout the Food Code and related guidance documents.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-005

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:

HHC 3 - Definition for “Antiseptic Hand Rub”

Issue you would like the Conference to consider:

The CFP Hand Hygiene Committee (HHC) was charged to ascertain if additional definitions are necessary to clarify the hand hygiene procedures listed in the Food Code.

The Hand Antiseptic section of the 2013 FDA Food Code; 2-301.16 (A) states "A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall..."

The HHC identified specific areas in the Food Code where amendments and definitions can provide further clarity to regulators and retail food stakeholders. The HHC identified that defining "Antiseptic Hand Rub" was necessary to eliminate ambiguity between an "antiseptic hand rub" and the other items listed in the section; hand antiseptic solutions used as hand dips and hand antiseptic soaps.

Prevention of cross-contamination is essential in foodservice, and explicitness in the Food Code can help reduce potential risk.

Public Health Significance:

The main purpose of washing hands is to cleanse the hands of soil, pathogens and chemicals that can potentially cause disease. Transmission of pathogenic bacteria, viruses and parasites to food from contaminated surfaces, raw food, or ill workers by way of improperly washed hands continues to be a major factor in the spread of foodborne illnesses.

Regulators and retail food service stakeholders reference the Food Code for guidance and clarity on appropriate approaches for removal or reduction of potential pathogens from hands. Therefore, the Food Code should be inclusive of clarifying language to assure the reader understands intent.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (using underlining for language additions):

1. Add a definition for "ANTISEPTIC HAND RUB."

"ANTISEPTIC HAND RUB" An antiseptic hand hygiene product applied to the hands and rubbed until dry, used to reduce the transient microorganisms on the hands.

2. Add reference to ANTISEPTIC HAND RUB to Section 2-301.16, Hand Antiseptics.

(A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, ANTISEPTIC HAND RUB, or a hand antiseptic soap shall:

(1) Comply with one of the following:

(a) Be an approved drug that is listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations as an approved drug based on safety and effectiveness; [Pf] or

(b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, [Pf] and

(2) Comply with one of the following:

(a) Have components that are exempted from the requirement of being listed in federal food additive regulations as specified in 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles;[Pf] or

(b) Comply with and be listed in:

(i) 21 CFR 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a food additive with conditions of safe use, [Pf] or

(ii) 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food, [Pf] and

(3) Be applied only to hands that are cleaned as specified under § 2-301.12. [Pf]

(B) If a hand antiseptic, ANTISEPTIC HAND RUB, or a hand antiseptic solution used as a hand dip does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be:

(1) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; [Pf] or

(2) Limited to situations that involve no direct contact with food by the bare hands. [Pf]

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-006

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

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Issue History:

This is a brand new Issue.

Title:

HHC 4 - Recommendations to FDA

Issue you would like the Conference to consider:

A letter be sent to the FDA:

1. Encouraging the development of handwashing performance standards that will allow evaluation of equivalent alternate procedures for soil removal from hands of food handlers.
2. Encouraging CFSAN (Center for Food Safety and Applied Nutrition) to work in conjunction with CDER (Center for Drug Evaluation and Research) to define antiseptic criteria for food handler use.

Public Health Significance:

Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to RTE food as well as other pathogens that can be transmitted from environmental sources.

In order to evaluate any alternate procedures that may be equivalent to the handwashing procedures that are prescribed in the Food Code, establishing performance standards by which to compare are necessary. Additionally, antiseptic criteria for food handler use is necessary.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA:

1. Encouraging the development of performance standards that will allow evaluation of equivalent alternate procedures for soil removal from hands of food handlers.
2. Encouraging CFSAN (Center for Food Safety and Applied Nutrition) to work in conjunction with CDER (Center for Drug Evaluation and Research) to define antiseptic criteria for food handler use.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-007

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

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Issue History:

This is a brand new Issue.

Title:

Re-create Hand Hygiene Committee to review "When to Wash" (2-301.14)

Issue you would like the Conference to consider:

Proper handwashing at appropriate times in FOOD ESTABLISHMENTS is critical to public health. To promote compliance at times when contamination may have occurred, it is important that code language be clear to not include times when contamination has not occurred. Section 2-301.14(G) of the 2013 FDA Food Code requires the washing of hands anytime a switch is made between working with raw and READY-TO-EAT FOOD. Circumstances likely exist in which contamination of the hands does not occur when working with raw FOOD, such as when appropriate utensils are used.

Public Health Significance:

Annex 3 of the 2013 Food Code states that "Many employees fail to wash their hands as often as necessary." By clarifying the times that are necessary for handwashing, and excluding times in which contamination has not occurred, industry will be better able to focus attention on quality handwashing at the necessary times. The CFP Hand Hygiene Committee can provide direction on this matter.

Recommended Solution: The Conference recommends...:

the re-created Hand Hygiene Committee be charged with the following:

1. Review the 2013 FDA Food Code and related sections and develop recommendations and direction on how to appropriately qualify Section 2-301.14 (When to Wash), part (G), to clarify handwashing requirements at times when risk may not actually exist, while still protecting public health.
2. Develop recommendations on revised language for the FDA Food Code and Annex 3.
3. Report back its findings and recommendations to the 2018 Biennial Meeting of the Conference for Food Protection.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-008

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

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Issue History:

This is a brand new Issue.

Title:

Allowing Specified Use of Hand Antiseptic in Place of Handwashing

Issue you would like the Conference to consider:

Section 2-301.14 requires handwashing before certain tasks after the hands may have been contaminated in various ways.

Compliance with handwashing requirements is often difficult to obtain.

The healthcare industry relies heavily on hand antiseptics in situations where low soil and grease conditions are expected.

One specific scenario in food establishments is analogous. Handling payments from customers, either cash, check, or credit/debit cards, should not present heavy soil or grease conditions that would limit the hand antiseptic's effectiveness. Coupled with an increased compliance rate, the public health should be protected at the same or greater level compared with traditional handwashing.

Public Health Significance:

Allowing appropriate hand antiseptic use in place of handwashing in certain, limited circumstances would increase compliance and reduce the chances of the spread of pathogens.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined):

2-301.14 When to Wash.

FOOD EMPLOYEES shall clean their hands and exposed portions of their arms as specified under § 2-301.12 immediately before engaging in FOOD preparation including working with exposed

FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLESERVICE and SINGLE-USE ARTICLES[P] and:

(I) *Except as specified in ¶ (J),* After engaging in other activities that contaminate the hands. [P]

(J) *A hand antiseptic specified in §2-301.16 may be used according to manufacturer's directions instead of handwashing as specified under §2-301.12 when contamination may occur during a payment transaction.* [P]

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2016 Issue Form

Issue: 2016 III-009

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

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Issue History:

This is a brand new Issue.

Title:

Updating the Handwashing Procedure to Reflect Liquid/Foam Soaps

Issue you would like the Conference to consider:

Section 2-301.12 of the 2013 FDA Food Code specifies the required handwashing procedure. The first step is to wet the hands.

However, this step does not seem necessary when a liquid or foam soap is used. Liquid and foam soaps allow the soap to be spread without first wetting the hands.

Some manufacturers' directions specify applying the soap to dry hands.

In addition, when the hands are wet before using the dispenser, with the exception of automatic dispensers, moisture is unnecessarily added to the dispenser, which could increase the spread of germs.

Public Health Significance:

Eliminating the requirement to first wet the hands when liquid or foam soaps are used will reduce an unnecessary regulatory burden and decrease unnecessary moisture in food establishments.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined):

Section 2-301.12

(B) FOOD EMPLOYEES shall use the following cleaning procedure in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:

(1) ~~R~~Unless using a liquid or foam cleaning compound, rinse under clean, running warm water; [P]

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-010

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

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Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014, III-017; new or additional information has been included or attached.

Title:

Hand Cleanse-Sanitize Protocol Not Requiring Running Water

Issue you would like the Conference to consider:

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 FDA requesting the 2013 Food Code be amended as follows (new language underlined):

5-203.11 Handwashing Sinks

(D) When food exposure is limited and handwashing sinks are not conveniently located, such as at outdoor events, mobile or temporary food service, and vending machine locations, employees may use a regimen using hand antiseptic as the cleansing agent wherein this step is treated as a handwash with full scrubbing action for 15 seconds and then, while wet, wiped off with a single-use paper towel, immediately followed by a second application which is allowed to dry per standard label instruction.

(1) Said hand antiseptic shall meet requirements as specified in Section 2-301.16.

(2) Said hand antiseptic shall have supporting test data indicating statistical equivalence to a standard handwash in hand degerming.

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Supporting Attachments:

- "SaniTwice: A Novel Approach to Hand Hygiene"

- "Hand Hygiene Regimens for the Reduction of Risk in Food Service Environment"
- "Ability of Hand Hygiene Interventions Using Alcohol-Based Hand Sanitizers"

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Research Note

SaniTwice: A Novel Approach to Hand Hygiene for Reducing Bacterial Contamination on Hands When Soap and Water Are Unavailable

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ABSTRACT

The risk of inadequate hand hygiene in food handling settings is exacerbated when water is limited or unavailable, thereby making washing with soap and water difficult. The SaniTwice method involves application of excess alcohol-based hand sanitizer (ABHS), hand ''washing'' for 15 s, and thorough cleaning with paper towels while hands are still wet, followed by a standard application of ABHS. This study investigated the effectiveness of the SaniTwice methodology as an alternative to hand washing for cleaning and removal of microorganisms. On hands moderately soiled with beef broth containing *Escherichia coli* (ATCC 11229), washing with a nonantimicrobial hand washing product achieved a 2.86 ($\pm$0.64)-log reduction in microbial contamination compared with the baseline, whereas the SaniTwice method with 62% ethanol (EtOH) gel, 62% EtOH foam, and 70% EtOH advanced formula gel achieved reductions of 2.64 $\pm$ 0.89, 3.64 $\pm$ 0.57, and 4.61 $\pm$ 0.33 log units, respectively. When hands were heavily soiled from handling raw hamburger containing *E. coli,* washing with nonantimicrobial hand washing product and antimicrobial hand washing product achieved reductions of 2.65 $\pm$ 0.33 and 2.69 $\pm$ 0.32 log units, respectively, whereas SaniTwice with 62% EtOH foam, 70% EtOH gel, and 70% EtOH advanced formula gel achieved reductions of 2.87 $\pm$ 0.42, 2.99 $\pm$ 0.51, and 3.92 $\pm$ 0.65 log units, respectively. These results clearly demonstrate that the in vivo antibacterial efficacy of the SaniTwice regimen with various ABHS is equivalent to or exceeds that of the standard hand washing approach as specified in the U.S. Food and Drug Administration Food Code. Implementation of the SaniTwice regimen in food handling settings with limited water availability should significantly reduce the risk of foodborne infections resulting from inadequate hand hygiene.

Foodborne diseases are a serious public health concern *(3, 4, 15),* but despite preventive efforts there has been little recent progress in reducing infections caused by foodborne pathogens *(6)*. Faulty food handling practices, particularly improper hand washing, contribute significantly to the risk for foodborne disease *(11–13, 19, 25–27, 29)*. Proper hand hygiene reduces the risk of transmission of pathogens from hands to food *(7, 20, 21)* and is associated with a reduction in gastrointestinal illness *(2, 8, 18)*. The U.S. Food and Drug Administration (FDA) Food Code for retail establishments requires hand washing as a preventive method and provides specific guidance on proper hand washing procedures *(30)*. The five-step hand washing procedure outlined in the FDA Food Code consists of (i) rinsing under warm running water, (ii) applying the manufacturer-recommended amount of cleaning compound, (iii) rubbing the hands vigorously, (iv) rinsing thoroughly under warm running water, and (v) thoroughly drying the hands with individual paper towels, a continuous clean towel system, or a heated or pressurized hand air drying device. According to the Food Code, alcohol-based hand sanitizers (ABHS) may be used in retail and food service only after proper hand washing.

ABHS are recommended as an alternative to traditional hand washing in the health care setting *(5)*. Alcohols are highly effective against a range of bacterial pathogens, fungi, enveloped viruses, and certain nonenveloped viruses *(2, 10)*. Although considered to be ineffective antimicrobial agents in the presence of visible dirt or proteinaceous material, alcohol-containing products were more effective than those containing triclosan *(2, 14)* or detergents *(17)* for removing microorganisms from hands contaminated with organic material. In health care facilities and other environments, easily accessible ABHS have resulted in greater hand hygiene compliance and reduction in infections *(1, 9, 16, 31)*. Although ABHS are approved for use in the health care environment, the FDA does not regard these agents as adequate substitutes for soap and water in the food service setting *(30)*.

A reliable hand hygiene method is needed for food service settings in which adequate hand washing facilities are limited or unavailable. These settings include portable bars, buffet lines, outdoor events, and catering functions at which the only available hand hygiene facility often is either ''trickle hand washing'' (i.e., hand washing done from a

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portable container of water over a bucket or other type of basin) or simply the use of a paper towel or damp cloth to rub the hands. These methods may be inadequate for proper hand cleansing.

SaniTwice (a registered trademark with James Mann, Handwashing for Life, Libertyville, IL) is a two-stage hand cleansing protocol that is performed using ABHS when water is not available. In this study, we evaluated the microbiological efficacy of the SaniTwice method on the hands of adult human participants. These studies were designed to assess (i) the antimicrobial efficacy of various ABHS used with the SaniTwice regimen as compared with that of a standard hand washing method with soap and water on soiled hands and (ii) the impact of the active ingredient and/or formulation of a hand sanitizer on antibacterial efficacy when used in a SaniTwice regimen.

MATERIALS AND METHODS

Test products. All test products in this study were manufactured by GOJO Industries (Akron, OH). Two hand washing products were evaluated: a nonantimicrobial product (GOJO Luxury Foam Handwash) and an antimicrobial product (MICRELL Antibacterial Foam Handwash, 0.5% chloroxylenol active). Four ABHS also were evaluated: a 62% ethanol (EtOH) gel (PURELL Instant Hand Sanitizer Food Code Compliant), a 62% EtOH foam (PURELL Instant Hand Sanitizer Foam), a 70% EtOH gel (PURELL 70 Instant Hand Sanitizer), and a 70% EtOH Advanced Formula (AF) gel (PURELL Instant Hand Sanitizer Advanced Formula VF481).

Overall study design. Three studies were conducted by BioScience Laboratories (Bozeman, MT) to determine the in vivo antimicrobial efficacy of various test product configurations under conditions of moderate or heavy soil. The order of use of each product was determined randomly. A two-step testing sequence was used for all products. Each volunteer completed the baseline cycle, where hands were contaminated with moderate or heavy soil (as described below) containing *Escherichia coli* (ATCC 11229), and samples were collected for baseline bacterial counts. Following the baseline sampling, participants completed a 30-s nonmedicated soap wash followed by the product evaluation cycle, which consisted of a contamination procedure, application of the test product, and subsequent hand sampling. Between uses of different test products, participants decontaminated their hands with a 1-min 70% EtOH rinse, air drying, and a 30-s nonmedicated soap wash. A minimum of 20 min elapsed before the next testing sequence began. Baseline and postapplication samples were evaluated for the presence of *E. coli*. Testing was performed according to the FDA health care personnel hand washing product evaluation method *(28)* and modified as described previously *(22)*.

The study was approved by the Gallatin Institutional Review, an independent review board unaffiliated with BioScience Laboratories, and was conducted in compliance with Good Clinical Practice and Good Laboratory Practice regulations. All participants provided written informed consent.

Participants. The study enrolled healthy adults with two hands. All participants were free of dermal allergies or skin disorders on the hands or forearms.

Preparation of inoculum. *E. coli* was used to test the efficacy of the test procedures. A 2-liter flask was filled with 1,000 ml of tryptic soy broth: 30.0 g of dehydrated tryptic soy broth medium (BD, Franklin Lakes, NJ) added to 1 liter of deionized water, heated, and sterilized for a final pH of 7.3 ± 0.20. The broth was inoculated with 1.0 ml of a 24-h culture of *E. coli* grown from a cryogenic stock culture. The flask was incubated for 24 h, and the suspension was used for challenge.

Hand contamination procedures. For the moderate soil study, a 24-h culture of *E. coli* was suspended in beef broth (Swanson low sodium beef broth, Campbell Soup Company, Camden, NJ) at 1×10^9 CFU/ml. Three aliquots of 1.5 ml were transferred into each participant's cupped hands. Each aliquot was distributed over the entire front and back surfaces of the hands up to the wrists during a 20-s period and allowed to air dry for 30 s after the first and second aliquots and for 90 s after the third aliquot. After samples were collected for baseline bacterial counts and hands were decontaminated with a 30-s wash with 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 rinsate sample was removed and diluted in 5.0 ml of Butterfield's phosphate buffer solution with product neutralizers. Each aliquot was serially diluted in neutralizing solution, and appropriate dilutions were plated in duplicate onto MacConkey agar plates (BD; 50.0 g of dehydrated medium added to 1 liter of deionized water, heated, and sterilized; final pH, 7.1 ± 0.2) and incubated for 24 to 48 h at 30°C. Colonies were counted and data were recorded using the computerized Q-COUNT plate-counting systems (Advanced Instruments, Inc., Norwood, MA).

Data analysis and statistical considerations. The estimated log transformed number of viable microorganisms recovered from each hand (the R value) was determined using the formula $R = \log(75 \times C_i \times 10^D \times 2)$, where 75 is the amount (in milliliters) of stripping solution instilled into each glove, C_i is the arithmetic average colony count of the two plate counts at a particular dilution, D is the dilution factor, and 2 is the neutralization dilution.

Descriptive statistics and confidence intervals were calculated using the 0.05 level of significance for type I (alpha) error. Statistical calculations of means and standard deviations were

TABLE 1. *Test product application procedures*[a]

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

[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.

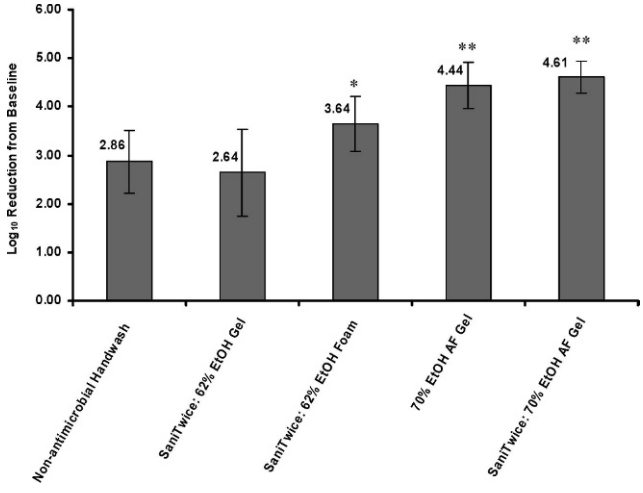

FIGURE 1. *Log reduction from baseline for microbial contamination of hands moderately soiled with contaminated beef broth after application of test products. Error bars represent standard deviation. Data are from two separate studies. In study 1 (*n = *11), nonantimicrobial hand washing product and 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).

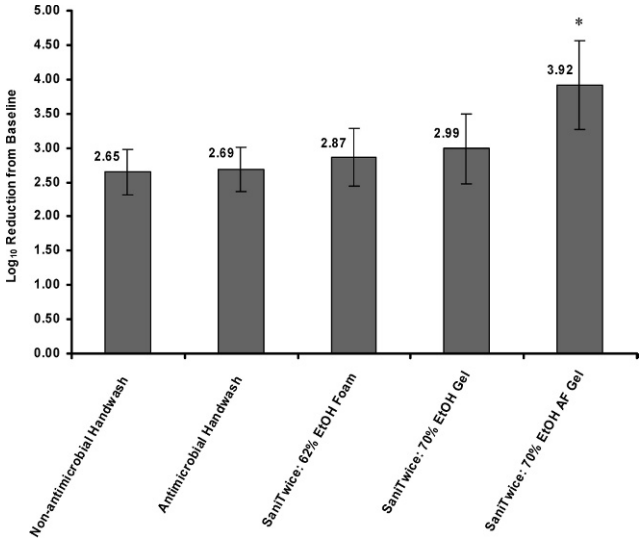

FIGURE 2. *Log reduction from baseline for microbial contamination of hands heavily soiled with contaminated uncooked hamburger after application of test products and protocols. Error bars represent standard deviation. Data are from study 3 (*n = *15), in which five test configurations were evaluated.* * P < *0.05 for SaniTwice with 70% AF gel versus nonantimicrobial hand washing product, antimicrobial hand washing product, SaniTwice with 62% EtOH foam, or SaniTwice with 70% EtOH gel.*

Two ABHS used with SaniTwice under both moderate and heavy soil conditions produced greater log reductions in the moderate soil condition. Mean log reductions using SaniTwice (moderate versus heavy soil) were 3.64 versus 2.87 for 62% EtOH foam and 4.61 versus 3.92 for 70% EtOH AF gel.

DISCUSSION

The SaniTwice method for hand disinfection was equivalent or superior to hand washing with soap and water for reducing viable bacteria on hands in the presence of representative food soils. Although the raw hamburger was a more difficult soil to penetrate, as demonstrated by approximately 1.0-log lower reductions compared with challenge by contaminated beef broth, the SaniTwice method with ABHS was equivalent to hand washing even under this worst-case simulation, underscoring the efficacy of this new method and indicating a potentially greater margin of safety.

The ABHS products used in this study exhibited a range of antimicrobial efficacy, suggesting that product formulation and the concentration of active ingredient may play a role in the observed efficacy. The impact of formulation was indicated by the significantly higher efficacy of the 62% EtOH foam compared with the 62% EtOH gel when challenged with moderate soil. This difference may be due to the additional foaming surfactants in the foam formulation, which may aid in lifting and removing bacteria and soil from the hands during the SaniTwice procedure. In addition, SaniTwice with the 70% EtOH AF gel was superior to SaniTwice with the 70% EtOH gel and 62% EtOH foam under heavy soil conditions. The 70% EtOH AF gel, whether tested as a single application or with the SaniTwice method, was superior to hand washing and to the 62% EtOH gel or foam under moderate soil conditions. The 4.44-log reduction with a single use of the 70% EtOH AF gel demonstrates its high antimicrobial efficacy, which is further enhanced when used with the SaniTwice method. The 70% EtOH AF gel contains a patent-pending blend of ingredients that enhance the activity of the alcohol and likely contribute to the high efficacy observed in this study. The SaniTwice procedure gives the benefit of skin cleansing and soil removal, which is not obtained with single use of a product. The efficacy of ABHS used with SaniTwice against nonenveloped enteric viruses, which are more difficult to eradicate, remains to be determined.

In support of previous findings *(23),* the findings in this study indicate that the decontamination efficacy was similar for the antimicrobial and nonantimicrobial hand washing products under heavy soil conditions, suggesting that the cleansing properties of the surfactants in these soaps and the mechanical action of hand washing may be the primary contributors to efficacy rather than the antimicrobial activity of any constituent of the formulations. It is expected that with heavy hand soiling, the surfactant effect drives efficacy, and typical antibacterial constituents will have little additional effect.

In this study, SaniTwice was an effective hand hygiene regimen at least equivalent to hand washing with soap and water for reducing microbial contamination, even under worst case conditions of high bacterial load and heavy food soils. The current FDA Food Code allows use of ABHS only on hands that have been cleaned according to the recommended hand washing protocol *(30)*. However, other than substitution of an ABHS for soap and water, the SaniTwice protocol mirrors the FDA-specified hand washing sequence. SaniTwice is at least as effective as hand washing when used with standard-efficacy ABHS; when used with a high-efficacy ABHS, the SaniTwice protocol is superior to washing with soap and water. The Food Code provides few specific recommendations for achieving good hand hygiene when water (or other hand washing supplies and equipment) is unavailable or limited. The Food Code (Section 2-301.16) severely restricts hand sanitizers by allowing use only after proper hand washing or in situations in which no direct contact with food occurs *(30)*.

A potential solution to this gap in food safety practices is SaniTwice. The SaniTwice studies described here provide convincing scientific rationale for including the SaniTwice approach in the Food Code as an alternative method of hand hygiene when standard hand washing is impractical. The simplicity and ease of use of the SaniTwice method, which requires only a supply of ABHS and paper towels, should allow this protocol to be applied to various food service settings and other areas in which hand hygiene is needed but safe water is unavailable or in short supply.

The findings in the present study support and extend those from previous studies; ABHS used alone or in combination with hand washing can be effective for decontaminating hands in the presence of organic soils *(17, 23, 24)*. A well-formulated ABHS in conjunction with

the SaniTwice regimen can have high efficacy, even in the presence of high organic load. Therefore, a reevaluation of the longstanding paradigm defining the use of ABHS in the presence of organic soils in both food handling and health care environments is warranted.

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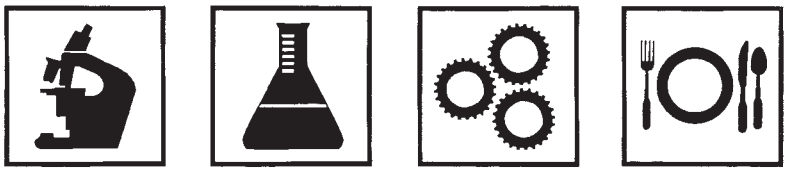

Hand Hygiene Regimens for the Reduction of Risk in Food Service Environments

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ABSTRACT

Pathogenic strains of *Escherichia coli* and human norovirus are the main etiologic agents of foodborne illness resulting from inadequate hand hygiene practices by food service workers. This study was conducted to evaluate the antibacterial and antiviral efficacy of various hand hygiene product regimens under different soil conditions representative of those in food service settings and assess the impact of product formulation on this efficacy. On hands contaminated with chicken broth containing *E. coli,* representing a moderate soil load, a regimen combining an antimicrobial hand washing product with a 70% ethanol advanced formula (EtOH AF) gel achieved a 5.22-log reduction, whereas a nonantimicrobial hand washing product alone achieved a 3.10-log reduction. When hands were heavily soiled from handling ground beef containing *E. coli,* a wash-sanitize regimen with a 0.5% chloroxylenol antimicrobial hand washing product and the 70% EtOH AF gel achieved a 4.60-log reduction, whereas a wash-sanitize regimen with a 62% EtOH foam achieved a 4.11-log reduction. Sanitizing with the 70% EtOH AF gel alone was more effective than hand washing with a nonantimicrobial product for reducing murine norovirus (MNV), a surrogate for human norovirus, with 2.60- and 1.79-log reductions, respectively. When combined with hand washing, the 70% EtOH AF gel produced a 3.19-log reduction against MNV. A regimen using the SaniTwice protocol with the 70% EtOH AF gel produced a 4.04-log reduction against MNV. These data suggest that although the process of hand washing helped to remove pathogens from the hands, use of a wash-sanitize regimen was even more effective for reducing organisms. Use of a high-efficacy sanitizer as part of a wash-sanitize regimen further increased the efficacy of the regimen. The use of a well-formulated alcohol-based hand rub as part of a wash-sanitize regimen should be considered as a means to reduce risk of infection transmission in food service facilities.

Foodborne diseases are a serious and growing public health concern both in the United States *(8, 19)* and worldwide *(46)*. The Centers for Disease Control and Prevention attributed 9.4 million illnesses, nearly 56,000 hospitalizations, and more than 1,300 deaths to foodborne pathogens annually in the United States *(33)*. Many researchers believe that foodborne diseases are underreported *(27, 39, 43)*.

The ever-changing nature of pathogens, including the emergence of new ones, is contributing to an increase in foodborne diseases *(5)*. Enterotoxigenic *Escherichia coli* has been implicated in one of the largest foodborne outbreaks reported in the United States to date *(3)*. According to the Foodborne Disease Outbreak Surveillance System (1998 to 2002), 31% of foodborne disease outbreaks and 41% of cases of infection with known etiology can be attributed to human norovirus (HNV) *(27),* and HNV is now recognized as the most significant cause of infectious gastrointestinal illnesses, with a growing number of virulent strains circulating *(4, 9, 16, 44)*.

Poor personal hygiene of food service workers, in particular improper hand washing, contributes significantly to the risk of foodborne diseases *(15, 17, 26, 38, 41)*. The majority of HNV infection outbreaks are attributed to contamination of food via unwashed or improperly washed hands of food handlers *(5, 9, 23)*. HNVs have a low infective dose *(37, 44),* persist in the environment, and are resistant to chlorination and freezing *(23, 35, 44)*. These factors contribute to an increased risk of HNV illness transmission. Heavily soiled items are frequently encountered in food service settings when preparing food, and antimicrobial agents are considered to be less effective in the presence of such items *(6)*. The U.S. Food and Drug Administration (FDA) Food Code requires that food service workers wash their hands with a cleaning compound and water before using alcohol-based hand rubs (ABHRs) *(42)*. Although an improvement in compliance among food handlers with personal hygiene risk factors was observed between 1998 and 2008 in retail food facilities, hand washing practices were the most out-of-compliance risk factor for every type of facility evaluated *(40)*. In 2008, hand washing practices were not being followed in 76% of restaurants and approximately 50% of delicatessens *(40)*. In another study, compliance with Food Code recommendations for frequency of washing during production, service, and cleaning phases in restaurants was only 5% *(36)*.

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TABLE 1. *Test products*

Test product	Description	Abbreviation
GOJO Luxury Foam Handwash	Nonantimicrobial hand washing product	Nonantimicrobial hand wash
MICRELL Antibacterial Foam Handwash	0.5% Chloroxylenol hand washing product	PCMX hand wash
GOJO Antibacterial Plum Foam Handwash	0.3% Triclosan hand washing product	Triclosan hand wash
PURELL Instant Hand Sanitizer Foam	62% Ethanol foam ABHR	62% EtOH foam
PURELL Instant Hand Sanitizer Advanced Formula VF481	70% Ethanol gel ABHR	70% EtOH gel

Various hand hygiene regimens reduce the risk of transmission of pathogens from the hands of food service workers to the food they handle and prepare *(10, 29, 30)*. Proper hand hygiene has been associated with reductions of gastrointestinal illness ranging from 42 to 57% *(5, 11, 25)*. However, some interventions are more effective for removing pathogens than are others. Hand washing with soap and water was more effective for reducing contamination on the hands than was rinsing with water or not washing at all *(7, 10)*. Antimicrobial agents are more effective for removing bacteria on hands than is nonantimicrobial soap *(13, 30)*. Even ABHRs used alone decontaminate hands at least as effectively as does washing with soap and water *(12, 34)*. However, the combination of hand washing followed by the use of ABHRs produces even greater reduction of bacteria on hands *(18, 29, 30, 32)*. When water is unavailable, a two-stage hand cleansing protocol using an ABHR known as the SaniTwice method (a registered trademark, James Mann, Handwashing for Life, Libertyville, IL) was at least as effective for removing bacteria from the hands as was only washing with soap and water *(12)*.

A critical need remains for hand hygiene products with increased efficacy against hard-to-kill pathogens. Typical ABHR activity against nonenveloped enteric viruses varies depending on the type and concentration of alcohol *(5, 6, 14, 21)*. Different strains of HNVs may be more resistant to antimicrobial agents than others *(24)*. Several studies have been conducted on newly formulated ABHRs with significantly improved inactivation of nonenveloped viruses *(24, 28)*. A 70% ethanol advanced formula (EtOH AF) gel reduced HNV by 3.74 log units in 15 s, a significantly greater HNV reduction than produced by six other commercially available hand hygiene products *(24)*. This gel was the most effective product tested against two strains of HNV.

Quantitative data are scarce on the relative health impact of different hygiene interventions *(5)*, in particular hand hygiene product performance against organisms commonly found in food service facilities, i.e., in food soils. This series of studies was designed to determine the antimicrobial effectiveness of various hand hygiene product regimens under moderate and heavy food soil conditions and against the murine norovirus (MNV), a surrogate for HNV. The impact of specific product formulation on antimicrobial efficacy also was evaluated.

MATERIALS AND METHODS

Test products. The test products, which were manufactured by GOJO Industries (Akron, OH), are described in Table 1.

Product application. Table 2 shows the stepwise product application procedures for all test methods.

Participants. The study participants were healthy adults with two hands and were free of dermal allergies or any skin disorders on the hands or forearms. These studies were conducted in compliance with good clinical practice and good laboratory practice regulations and approved by local institutional review boards. All participants provided written informed consent.

Overall design for antibacterial efficacy studies. The purpose of the studies was to determine the antibacterial efficacy of various blinded test product configurations versus a relevant foodborne pathogen presented under conditions of moderate or heavy food soil. The order of use of each product configuration was determined randomly. All testing of antibacterial efficacy was performed using a modification of the ASTM International E1174-06 method *(1)*. For both the moderate and heavy soil tests, a two-step testing sequence was used for all products. For the moderate and heavy soil tests 18 and 12 participants, respectively, tested each configuration. Each participant completed a baseline cycle, in which hands were contaminated with *E. coli* (ATCC 11229) in moderate soil (chicken broth) for the first study and in heavy soil (sterile ground beef *(31)*) in the second study. Samples were collected for baseline bacterial counts. After the baseline sampling, participants completed a 30-s nonmedicated soap wash followed by the product evaluation cycle, which consisted of a contamination procedure, application of the test product, and subsequent hand sampling. Baseline and postapplication samples were evaluated for the presence of *E. coli*. Each participant was used for only one test configuration and, on completion of testing, decontaminated their hands with a 1-min 70% EtOH rinse, air drying, and a 30-s nonmedicated soap wash.

Preparation of inoculum. A 2-liter flask was filled with 1,000 ml of tryptic soy broth, i.e., 30.0 g of dehydrated tryptic soy broth medium (BD, Franklin Lakes, NJ) added to 1 liter of deionized water, heated, and sterilized (final pH 7.3 $\pm$ 0.20). The broth was inoculated with 1.0 ml of a 24-h culture of *E. coli* grown from a cryogenic stock culture. The flask was incubated for 24 h, and the suspension was used for the contamination challenge.

Hand contamination procedures. For the moderate soil study, a 24-h culture of *E. coli* was suspended in commercially available chicken broth (Swanson chicken broth, Campbell Soup Company, Camden, NJ) to a final concentration of 1×10^9 CFU/ml. Three aliquots of 1.5, 1.5, and 2 ml were transferred into each participant's cupped hands. Taking care not to drip the suspension, each aliquot was distributed over the front and back surfaces of the hands up to the wrists for 20 s; hands were air dried for 30 s after the first and second aliquots and for 90 s after the third aliquot. After samples were collected from the hands for baseline bacterial counts, the hands were washed for 30 s with a

TABLE 2. *Test product application procedures*[a]

Step	Wash	Sanitize	Wash-sanitize regimen	SaniTwice regimen[b]
1	Wet hands with water at 40°C	Dispense 1.5 ml of product into cupped hands	Wet hands with water at 40°C	Dispense 3 ml of sanitizer into cupped hands
2	Apply 1.5 ml of product	Rub hands together until dry	Apply 1.5 ml of product	Rub vigorously over hands for 15 s to simulate washing
3	Lather for 30 s		Lather for 30 s	Clean thoroughly with two paper towels
4	Rinse with water for 30 s		Rinse with water for 30 s	Dispense additional 1.5 ml of product
5	Pat dry with two paper towels		Pat dry with two paper towels	Rub hands together until dry
6			Apply 1.5 ml of sanitizer to hands	
7			Rub until dry	

[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).

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 5.0×10^8 CFU per portion. Each participant then kneaded the inoculated raw hamburger for 2 min. Hands were air dried for 90 s and then sampled for baseline counts. After a 30-s decontamination with nonmedicated soap, the cycle was repeated, and the test product was applied.

Bacterial recovery and microbial enumeration. Within 5 min after contamination for baseline evaluation and after product application, oversized powder-free sterile latex gloves were placed on each participant's hands, and 75 ml of sterile stripping fluid (0.4 g of 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. After a 60-s massage of the hands through the gloves, a 5.0-ml sample of the rinsate was removed from the glove and diluted in 5.0 ml of Butterfield's phosphate buffer solution with product neutralizers. Each aliquot was serially diluted in neutralizing solution, and appropriate dilutions were plated in duplicate onto MacConkey agar plates (50.0 g of dehydrated medium [BD] added to 1 liter of deionized water, heated, and sterilized; final pH 7.1 $\pm$ 0.2) and incubated for 24 to 48 h at 30°C. Colonies were counted and recorded using the computerized Q-Count plate-counting systems (Advanced Instruments, Inc., Norwood, MA).

Data analysis and statistical considerations. The estimated log-transformed number of viable microorganisms recovered from each hand (the R value) was determined using the formula $R = \log(75 \times C_i \times 10^D \times 2)$, where 75 is the volume (in milliliters) of stripping solution instilled into each glove, C_i is the arithmetic average colony count of the two plate at a particular dilution, D is the dilution factor, and 2 is the neutralization dilution.

Descriptive statistics and confidence intervals were calculated using the 0.05 level of significance for type I (alpha) error. Statistical calculations of means and standard deviations were generated on the log recovery data from baseline samples, post–product application samples, and the log differences between baseline and post–product application samples. Product comparisons were made using a one-way analysis of variance with post hoc analysis (Bonferroni's multiple comparison test) at $\alpha = 0.05$.

Overall design for HNV study. The purpose of the HNV study was to determine the virucidal activity of various hand hygiene regimens against HNV. Because routine culture and infectivity assays of HNV are not possible, HNV surrogates are routinely used to evaluate the virucidal activity of disinfectants and antiseptics. MNV, which is a suitable surrogate for HNV *(45),* was used in this study. A modification of ASTM International E2011-09 method for evaluating hygienic hand wash formulations for virus-eliminating activity using the entire hand *(2)* was utilized in this study. The modification involved the use of the glove rinsate sampling method and a randomized cross-over design. A total of six participants completed testing on all of the products.

Virus inoculum. Strain MNV-G (Yale University, New Haven, CT) was confirmed by direct serial dilution and inoculation onto host cells. Virus stocks were stored in an ultracold freezer (≤ -60°C). Frozen viral stocks were thawed on the day of test. The

TABLE 3. E. coli *recovery and reductions in the presence of moderate food soil load*

Application procedure	Test products	Mean ± SD *E. coli* (log CFU/ml)		Statistical analysis[a]			
		Baseline recovery	Reduction				
Wash	Nonantimicrobial hand wash	8.58 ± 0.46	3.10 ± 0.61	A			
Wash	PCMX hand wash	8.62 ± 0.65	3.56 ± 0.74	A	B		
Wash-sanitize	Nonantimicrobial hand wash + 62% EtOH foam	8.32 ± 0.64	3.81 ± 0.89		B	C	
Wash-sanitize	PCMX hand wash + 62% EtOH foam	8.25 ± 0.45	4.16 ± 0.91			C	
Wash-sanitize	Nonantimicrobial hand wash + 70% EtOH AF gel	8.49 ± 0.42	5.13 ± 0.71				D
Wash-sanitize	PCMX hand wash + 70% EtOH AF gel	8.57 ± 0.53	5.22 ± 0.60				D

[a] Configurations with the same letter are statistically equivalent, and configurations with different letters are statistically different, with each letter increase (B through D) indicating that a configuration had a significantly higher log reduction.

titer of the stock virus was at least 1×10^7 $TCID_{50}$ (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 rinsate was transferred from the glove to a sterile tube, vortexed, and serially diluted in cell culture medium. Appropriate dilutions were inoculated onto the host cell culture (RAW 264.7, ATCC TIB-71) and absorbed for 20 to 30 h at 36 ± 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*

Application procedure	Test products	Mean ± SD *E. coli* (log CFU/ml)		Statistical analysis[a]
		Baseline recovery	Reduction	
Wash-sanitize	PCMX hand wash + 62% EtOH foam	7.50 ± 0.19	4.11 ± 0.48	A
Wash-sanitize	Triclosan hand wash + 62% EtOH foam	7.54 ± 0.18	3.97 ± 0.45	A
Wash-sanitize	PCMX hand wash + 70% EtOH AF gel	7.53 ± 0.19	4.60 ± 0.52	B
Wash-sanitize	Triclosan hand wash + 70% EtOH AF gel	7.46 ± 0.19	4.51 ± 0.43	B

[a] Configurations with the same letter are statistically equivalent, and configurations with different letters are statistically different, with a letter increase (B) indicating that a configuration had a significantly higher log reduction.

performance to configurations that included the 62% EtOH foam ($P < 0.05$).

Inactivation of MNV on soiled hands. A third study was conducted to evaluate four hand hygiene configurations against MNV, a surrogate for HNV. Hand washing with the nonantimicrobial hand wash was minimally effective against MNV, producing a <2-log reduction (Table 5). Sanitizing with the 70% EtOH AF gel was significantly more effective than hand washing for reducing MNV ($P < 0.01$). Using a wash-sanitize regimen was more effective than either hand washing or sanitizing alone ($P < 0.05$). The SaniTwice method with the 70% EtOH AF gel was the most effective regimen, achieving a >4-log reduction of MNV ($P < 0.01$).

DISCUSSION

Previous findings suggest that hand hygiene regimens reduce the risk of transmission of pathogens from the contaminated hands of food service workers to food *(10, 29, 30)*. The findings from our studies support and extend those from previous studies by demonstrating that hand hygiene regimens can be effective even in the presence of high organic loads and against nonenveloped viruses such as HNV.

These studies further demonstrate the improved effectiveness of wash-sanitize regimens over hand washing or sanitizing alone. In the presence of moderate food soil, the combination of the 70% EtOH AF gel with either a nonantimicrobial hand wash or an antimicrobial hand washing product each achieved >5-log reductions of *E. coli*. In contrast, hand washing achieved only a <3.6-log reduction. In the presence of heavy food soil, the use of 70% EtOH AF gel after the antimicrobial foam hand washing product in two different configurations achieved a 4.51-log reduction and a 4.60-log reduction, respectively. In the HNV study, hand washing alone produced a <2-log reduction. When used as part of a wash-sanitize regimen that included the 70% EtOH AF gel a 3.19-log reduction was achieved. These findings demonstrate that the addition of a high-efficacy sanitizer to a hand washing regimen results in a greater reduction of microorganisms. This finding is consistent with those of others, who reported that the primary factor influencing final microorganism levels on the hands is sanitizer use *(30)*.

The current FDA Food Code *(42)* allows use of ABHRs only on hands that have been cleaned according to the recommended hand washing protocol. The Food Code (section 2-301.16) also severely restricts hand sanitizers by allowing their use only after a proper hand washing or where no direct contact with food occurs. The SaniTwice regimen has previously been shown to be an effective means for the reduction of bacteria on the hands when soap and water are unavailable. In the MNV study, use of the SaniTwice protocol with the 70% EtOH AF gel achieved a >4-log (>99.99%) reduction of MNV and was the most effective regimen tested. This combination is significantly more effective than hand washing or sanitizing alone and more effective than a wash-sanitize regimen. Therefore, these data indicate that the SaniTwice regimen is an effective method for significantly reducing bacteria and nonenveloped viruses.

In the studies presented here, the configurations that included the 70% EtOH AF gel consistently provided superior performance. These findings are consistent with previous findings that the in vivo activity of ABHRs is not solely dependent upon alcohol concentration *(12, 24, 28)*. In a previous study, the 70% EtOH AF gel provided significantly greater HNV reduction than did other hand hygiene products that contained >85% ethanol *(24)*.

TABLE 5. *MNV recovery and reductions*

Application procedure	Test products	Mean ± SD MNV (log $TCID_{50}$/ml)		Statistical analysis[a]
		Baseline recovery	Reduction	
Wash	Nonantimicrobial hand wash	6.98 ± 0.20	1.79 ± 0.29	A
Sanitize	70% EtOH AF gel		2.60 ± 0.41	B
Wash-sanitize	Nonantimicrobial hand wash + 70% EtOH AF gel		3.19 ± 0.31	C
SaniTwice	70% EtOH AF gel		4.04 ± 0.33	D

[a] Configurations with the same letter are statistically equivalent, and configurations with different letters are statistically different, with each letter increase (B through D) indicating that a configuration had a significantly higher log reduction.

Similarly, an earlier version of the 70% EtOH AF gel was more effective than hand hygiene products containing 95% ethanol and 75% isopropanol *(28)*. Liu et al. *(24)* suggested that the additional ingredients in these novel ABHRs (a synergistic blend of polyquaternium polymer and organic acid) may work with the ethanol to denature the viral capsid protein. These comparisons demonstrate the importance of formulation in product efficacy.

As illustrated in the *E. coli* study with heavy food soil, the lower log reductions produced by the regimen including the PCMX hand wash with the 70% EtOH AF gel reflects the fact that the raw hamburger was a greater challenge than was the moderate soil (chicken broth). Despite this challenge, use of the 70% EtOH AF gel as part of the hand hygiene regimen probably would provide increased protection against the transmission of foodborne illness because it produced at least 0.5-log greater reductions than did washes paired with a typical hand sanitizer. A wash-sanitize regimen including a high-efficacy formulation should be used in high-risk environments in which uncooked meat is handled in the same vicinity as ready-to-eat foods.

A limitation of our study was that a surrogate virus, MNV, was utilized. Although MNV has been extensively studied and is considered an acceptable surrogate for HNV, the results obtained with this virus may not be an exact reflection of the actual efficacy of these products against various HNV strains. Future efforts should focus on developing routine and repeatable culture-based methods to quantify infectious HNV. Currently, clinical studies should focus on improving hand hygiene compliance by food handlers and on determining the effectiveness of hand hygiene regimens in food service settings.

This series of studies reveals that wash-sanitize regimens, particularly those including a well-formulated ABHR, can be highly efficacious, even in the presence of high organic loads and against HNV. Consequently, the inclusion of such formulations as part of a hand hygiene regimen could be a primary intervention for reducing the risk of infection transmission in food service facilities.

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Ability of Hand Hygiene Interventions Using Alcohol-Based Hand Sanitizers and Soap To Reduce Microbial Load on Farmworker Hands Soiled during Harvest

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ABSTRACT

Effective hand hygiene is essential to prevent the spread of pathogens on produce farms and reduce foodborne illness. The U.S. Food and Drug Administration Food Safety Modernization Act Proposed Rule for Produce Safety recommends the use of soap and running water for hand hygiene of produce handlers. The use of alcohol-based hand sanitizer (ABHS) may be an effective alternative hygiene intervention where access to water is limited. There are no published data on the efficacy of either soap or ABHS-based interventions to reduce microbial contamination in agricultural settings. The goal of this study was to assess the ability of two soap-based (traditional or pumice) and two ABHS-based (label-use or two-step) hygiene interventions to reduce microbes (coliforms, *Escherichia coli,* and *Enterococcus* spp.) and soil (absorbance of hand rinsate at 600 nm [A_{600}]) on farmworker hands after harvesting produce, compared with the results for a no-hand-hygiene control. With no hand hygiene, farmworker hands were soiled (median A_{600}, 0.48) and had high concentrations of coliforms (geometric mean, 3.4 log CFU per hand) and *Enterococcus* spp. (geometric mean, 5.3 log CFU per hand) after 1 to 2 h of harvesting tomatoes. Differences in microbial loads in comparison to the loads in the control group varied by indicator organism and hygiene intervention (0 to 2.3 log CFU per hand). All interventions yielded lower concentrations of *Enterococcus* spp. and *E. coli* ($P < 0.05$), but not of coliforms, than were found in the control group. The two-step ABHS intervention led to significantly lower concentrations of coliforms and *Enterococcus* spp. than the pumice soap and label-use ABHS interventions ($P < 0.05$) and was the only intervention to yield significantly fewer samples with *E. coli* than were found in the control group ($P < 0.05$). All interventions removed soil from hands ($P < 0.05$), soap-based interventions more so than ABHS-based interventions ($P < 0.05$). ABHS-based interventions were equally as effective as hand washing with soap at reducing indicator organisms on farmworker hands. Based on these results, ABHS is an efficacious hand hygiene solution for produce handlers, even on soiled hands.

Increases in produce-associated outbreaks highlight the need for effective microbial risk management on produce farms and in packing sheds. In the United States, from 1999 to 2008, contaminated produce was responsible for at least 23% of all reported foodborne illnesses *(33)*. Produce contamination may occur at various points in the farm-to-fork continuum *(19, 31)*. Some produce-associated outbreaks have been thought to be caused by infected farmworker and, possibly, inadequate hand hygiene *(14, 16, 42)*.

Farmworker hands may be vehicles for microbial contamination of produce *(23, 29)*. Harvest and packing, often done by hand, have been associated with increases in microbial contamination *(2, 18, 22)*. A 2010 study found that of seven major fruit and vegetable crops, all were either exclusively or partially harvested by hand *(7)*. Because "workers often touch produce with their bare hands" the U.S. Food and Drug Administration Food Safety Modernization Act (FSMA) Proposed Rule for Produce Safety states that hand washing is a "key control measure in preventing contamination" of produce *(39)*.

Effective hand hygiene reduces microbial risks and disease in health care and community settings *(1, 6, 43),* but there are few data on its efficacy in food handling settings *(4),* and it has just begun to be studied in the agricultural environment. The FSMA Proposed Rule for Produce Safety defines hand hygiene as "washing hands thoroughly, including scrubbing with soap and running water … and drying hands thoroughly using single-service towels, clean cloth towels, sanitary towel service or other adequate hand drying devices" *(39)*. However, soil on farmworker hands may limit the ability of hand washing to remove or inactivate microbes. Thus, it is important to assess the hypothesis that hand washing with soap is the most efficacious hygiene intervention for the agricultural envi-

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ronment. In addition, hand washing with soap may be difficult to achieve on every occasion specified in the rule due to barriers such as limited access to potable water near all work areas. Alcohol-based hand sanitizers (ABHS) are a logical alternative because they do not require potable water, and a large body of evidence exists to show that their antimicrobial efficacy results in reduced spread of infection in health care environments *(6, 43)*. The FSMA Proposed Rule for Produce Safety prohibits the sole use of ABHS because "the effectiveness of hand sanitizers has been shown to be highly dependent upon the removal of organic material from the hands prior to their use" *(39)*. However, a large body of research suggests that the efficacy of ABHS is not impacted when hands are soiled *(10, 12, 25, 26, 28, 30, 35)*. One limitation of ABHS is that hands may still appear dirty, even if microbes have been inactivated. One method that may address this limitation is SaniTwice, a two-step technique where an excess of ABHS is applied to hands and removed with paper towels, followed by a second ABHS application *(11)*. This technique has been shown to reduce *Escherichia coli* on hands soiled with beef broth and raw hamburgers *(11)* and to reduce bacteria and soil on agricultural workers' hands *(13)*.

The goal of this study was to assess the ability of two soap-based and two ABHS-based hygiene interventions to reduce microbes and soil on farmworker hands after harvesting produce, compared with a no-hygiene control. Traditional (nonantibacterial and nonabrasive) soap was included as the current "gold standard" *(38)*. Pumice soap was chosen because it may be able to remove particles and organic compounds from hands that traditional soaps do not. ABHS interventions were included as waterless hygiene options as alternatives to traditional soap. The two-step ABHS intervention was included because of its previously demonstrated efficacy on soiled hands *(10)*.

MATERIALS AND METHODS

Setting and population. This study took place over a 4-week period in August and September 2014 on a farm that produces tomatoes in the state of Nuevo León, Mexico. The farm exported its produce to the United States and sold it to Mexican retailers and had established food safety protocols in place, as well as a dedicated food safety specialist on site. Approval for research on human subjects was conferred after ethics review by Emory University (institutional review board no. 00035460).

The study population consisted of 181 farmworkers who were employed by this farm to harvest tomatoes. Participants routinely used gloves for tomato harvest but removed them when participating in our study in order that the interventions be tested on the most highly soiled and microbially contaminated hands possible. During each of the five nonconsecutive days of the study prior to study enrollment, the farm food safety specialist introduced the study staff, who described the study and solicited volunteers. Inclusion criteria included that the participant was an employee of the farm assigned to harvest tomatoes and provided oral informed consent to participate in the study according to the institutional review board–approved protocol. There were no exclusion criteria. Oral consent was documented by study staff for each participant.

Farm activities and intervention groups. After consent was received, the farmworkers were randomly assigned to one of five groups (described below), and each was given a name tag to indicate his or her group and unique sample identifier. To standardize the microbial load on farmworker hands, all farmworkers were asked to wash their hands with traditional (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 (Servitoalla double-ply, 28 by 22.8 cm; Pétalo, Kimberly-Clark, Mexico City, Mexico). All potable water used in the study was provided by the Universidad Autónoma de Nuevo León (UANL) laboratory and assured to have no coliforms, *E. coli,* or *Enterococcus* spp. in a 100-ml aliquot (see "Absorbance and microbial analyses" for general description of microbial assays). The farmworkers were then asked to harvest tomatoes for 1 to 2 h (collecting approximately 30 bins per person), using their standard procedure but without gloves. After harvesting, each farmworker completed activities described below based on their assigned group, following the instructions and demonstration of study staff (Fig. 1). A convenience sample of at least 10 participants per study group also had their hands photographed before and after the activities described below.

After harvesting, individuals in the control group did not perform any hand hygiene. Individuals in the label-use ABHS group used ABHS according to the product label instructions, with minor modifications. Individuals in this group received one pump of sanitizer gel (~3.5-ml of GOJO Purell Advanced Instant Hand Sanitizer, active ingredient 70% ethanol; GOJO Industries, Akron, OH) in the palm of one hand. They were then asked to rub their hands in the following manner used in all interventions: rub hands palm-to-palm, rub each palm on the dorsal surface of the opposite hand, and interlace fingers to distribute product over the fingers. They were asked to continue rubbing their hands until dry.

Individuals in the two-step ABHS group performed SaniTwice hand hygiene as described previously, with minor modifications *(11)*. Briefly, they received three pumps of sanitizer gel (~10.5 ml, enough to keep hands wet for 20 s) in the palm of one hand. They were then asked to rub their hands as described above for about 20 s. After ~20 s of rubbing, they were given a paper towel to remove all remaining sanitizer on their hands. They then followed the steps described above for the label-use ABHS group.

Individuals in the traditional soap group received two pumps of potable water (approximately 220 ml) to wet their hands. They then received one pump (~3.5 ml) of the same traditional soap used by all participants prior to harvesting. They were asked to rub their hands as described above for about 20 s. After rubbing, they rinsed their hands with three pumps of the potable water provided (approximately 330 ml). A paper towel was provided, and they were asked to dry their hands as they normally would.

Individuals in the pumice soap group received two pumps of pumice soap (~6 ml of GOJO Natural Orange Pumice Hand Cleaner, a gel-based surfactant formula with pumice particles; GOJO Industries) in the palm of one hand. They were then asked to rub their hands as described above for about 20 s. During this rubbing, they also received a splash of potable water (approximately 2 ml). After rubbing, they rinsed their hands with three pumps of the potable water provided (approximately 330 ml). A paper towel was provided, and they were asked to dry their hands as they normally would.

Immediately after the activities described above were completed, the farmworkers were asked to provide a hand rinsate sample by inserting one hand in a Whirl-Pak bag (Nasco, Fort Atkinson, WI) containing 750 ml of sterile 0.1% peptone water (Thermo Fisher Scientific, Waltham, MA) while study staff massaged their fingers through the bag for 20 to 30 s. This process

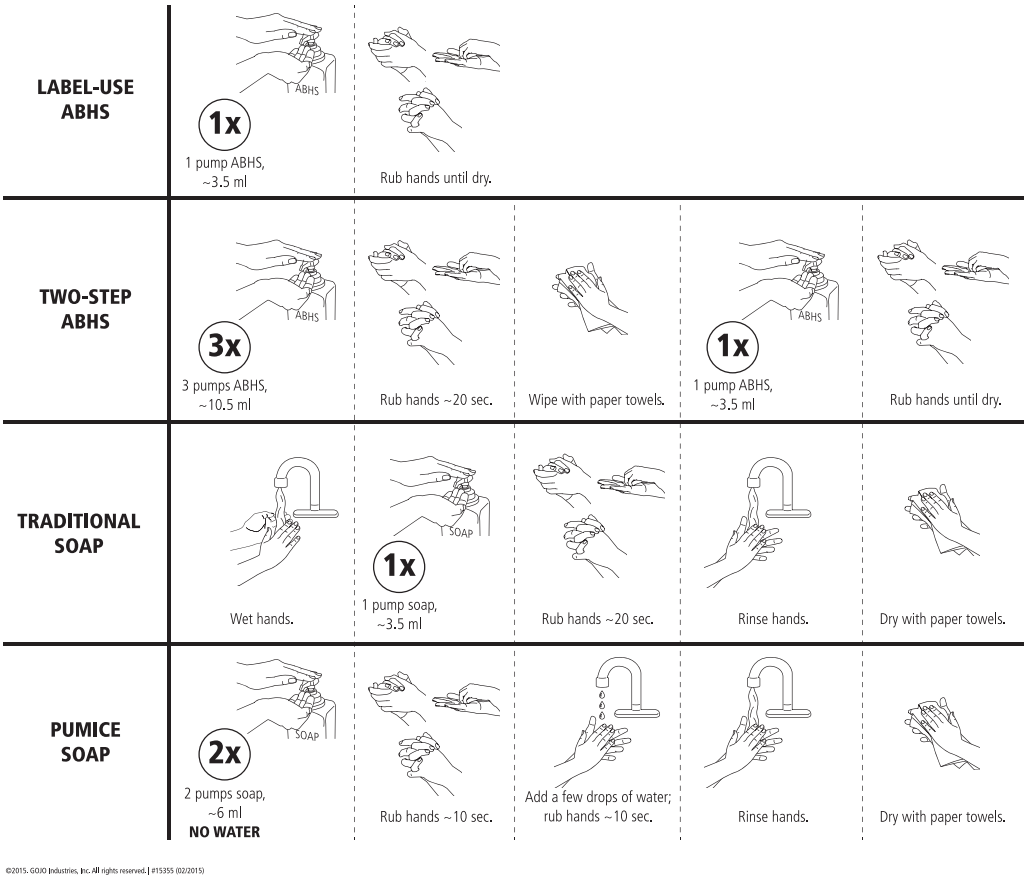

FIGURE 1. *Visual description of the two ABHS-based and two soap-based hand hygiene interventions. Illustrations in this figure are courtesy of GOJO Industries, Inc.*

was repeated for the second hand. The worker was provided a paper towel and small token of thanks for participation (e.g., bottled water, a cap, a bandana, or similar item). The labeled hand 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 *(27)* and may be preferable to other, subjective methods, such as visual inspection of hands *(25)*. Rinsate samples were inverted several times to resuspend any particulate matter, and then an aliquot was taken for measurement of absorbance at 600 nm (A_{600}) using a spectrophotometer (Sequoia Turner, Mountain View, CA).

Samples were analyzed in random order (without regard to study group) to detect and enumerate coliforms, *E. coli,* and *Enterococcus* spp., three common, nonpathogenic types of bacteria used to indicate microbial load, hereinafter called indicator bacteria. Serial volumes of each hand rinse sample (100 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*

Group[a]	No. of positive samples/total no. of samples (%) tested for[b]:		
	Coliforms	*Enterococcus* spp.	*E. coli*
Control	30/42 (71)	41/42 (98)	10/42 (24)
Label-use ABHS	28/34 (82)	31/34 (91)	2/34 (6)
Two-step ABHS	21/35 (60)[c]	28/35 (80)	0/35 (0)[d]
Traditional soap	28/35 (80)	31/35 (89)	2/35 (6)
Pumice soap	35/35 (100)[d]	35/35 (100)	1/35 (3)

[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 ($\alpha = 0.05$)

[d] Result is significantly different from the result for the control group ($\alpha = 0.05$)

25922]; American Type Culture Collection, Manassas, VA). The positive control was created by growing each strain overnight on tryptic soy broth (Difco, BD) and then seeding 1 ml of each strain into 11 ml of sterile 0.85% NaCl (Sigma Aldrich, St. Louis, MO), pH 7.0.

Data entry and statistical analyses. All data were entered independently by two trained individuals into separate Microsoft Excel databases (Microsoft, Redmond, WA), compared, and reconciled by review of the original laboratory forms. An additional check showed no discrepancies when 5% of the original laboratory forms were randomly selected and compared against the final database. Statistical analyses were performed using Stata 10 (STATA Corp., College Station, TX), JMP Pro 10, and SAS 9.3 (SAS Institute Inc., Cary, NC). The Shapiro-Wilk test *(32)* indicated that all data (e.g., absorbance values of hand rinsates and log-transformed indicator organism concentrations) were not normally distributed (data not shown). Therefore, all statistical tests used were nonparametric. When calculating the concentrations of indicator bacteria, any sample without detectable bacteria was assigned a value of 18.5 CFU per hand, half the limit of detection *(37)*. Geometric means and standard deviations are used to describe bacterial concentrations as a convenience to the reader *(40),* and medians and standard deviations are used to describe absorbance data. To compare differences in percentages of samples positive for microbial indicators across study groups, a Pearson χ^2 test *(9)* and Bonferroni correction *(17)* were used. To compare A_{600} and microbial concentration values across study groups, the Kruskal-Wallis test *(20)* followed by the Steel-Dwass multiple comparison procedure *(8)* were used.

RESULTS

In general, farmworkers' hands became contaminated with indicator bacteria (Table 1 and Fig. 2, control) and soiled while they harvested produce, prior to hand hygiene (Fig. 3, control). The percentages of samples positive for coliforms (71%) and *Enterococcus* bacteria (98%) in the control group were high (Table 1) relative to the percentage of samples positive for *E. coli* (24%) (Table 1). The concentrations of bacteria on control group hands ranged widely: coliform concentrations in positive samples ranged from the lower limit of detection to the upper limit of quantification (37 CFU per hand to 8.3 log CFU per hand) (Fig. 2), *Enterococcus* concentrations in positive samples ranged from 93 CFU per hand to the upper limit of quantification (8.3 log CFU per hand) (Fig. 2), and *E. coli* concentrations in positive samples ranged from the lower limit of detection (37 CFU per hand) to 3.3 log CFU per hand. The geometric mean concentrations of coliforms (3.4 log CFU per hand) and *Enterococcus* bacteria (5.3 log CFU per hand) in control group samples were relatively high (Fig. 2) compared with the geometric mean concentration of *E. coli* bacteria (1.7 log or 50 CFU per hand) (Fig. 2). For microbial assays, all negative and positive controls consistently yielded the expected results. The median absorbance of control hand rinsate samples was 0.48, and the values varied greatly across the control group, ranging from A_{600} 0.05 to 1.36. The visual appearance of hands postharvest and preintervention is shown in the "before intervention" photographs of hands in Figure 4. It appears that in just a few hours of harvesting produce, the farmworkers' hands accumulated high concentrations of some indicator bacteria and soil.

While hygiene interventions did not completely eliminate indicator bacteria from hands, in general, all hand hygiene interventions effectively reduced the concentrations of some bacteria. However, there were differences in the performance of the four interventions tested.

Compared with the results for the control group, none of the hand hygiene interventions yielded a significantly lower coliform concentration or percentage of samples positive for coliforms (Table 1 and Fig. 2). However, the two-step ABHS group had lower concentrations of coliforms than the label-use ABHS and pumice soap groups ($P < 0.05$) (Fig. 2). Compared with the control group, all four intervention groups had lower concentrations of *Enterococcus* spp. ($P < 0.05$) (Fig. 2), although similar to the result for coliforms, none of the hand hygiene interventions yielded significantly lower percentages of samples positive for *Enterococcus* than in the control group (Table 1). The two-step ABHS group had lower concentrations of *Enterococcus* than the label-use ABHS and pumice soap groups ($P < 0.05$) (Fig. 2). For *E. coli*, all four hand hygiene interventions yielded significantly lower concentrations on hands than were found in the control group ($P < 0.05$, Fig. 2). However, two-step ABHS was the only intervention to have significantly fewer samples with detectable *E. coli* than the control group, and this group had no samples positive for *E. coli* ($P < 0.05$) (Table 1). The other three interventions had only 1 or 2 samples positive for *E. coli* (3 to 6%), compared with 10 samples positive for *E. coli* (24%) in the control group (Table 1), but these differences did not reach statistical significance.

Using absorbance measurements of hand rinsate samples as a proxy for soil, all four interventions yielded significantly less soil on hands than in the control group (range, A_{600} 0.05 to 1.36); soap-based interventions (range, A_{600} 0.00 to 0.15) yielded significantly less soil remaining

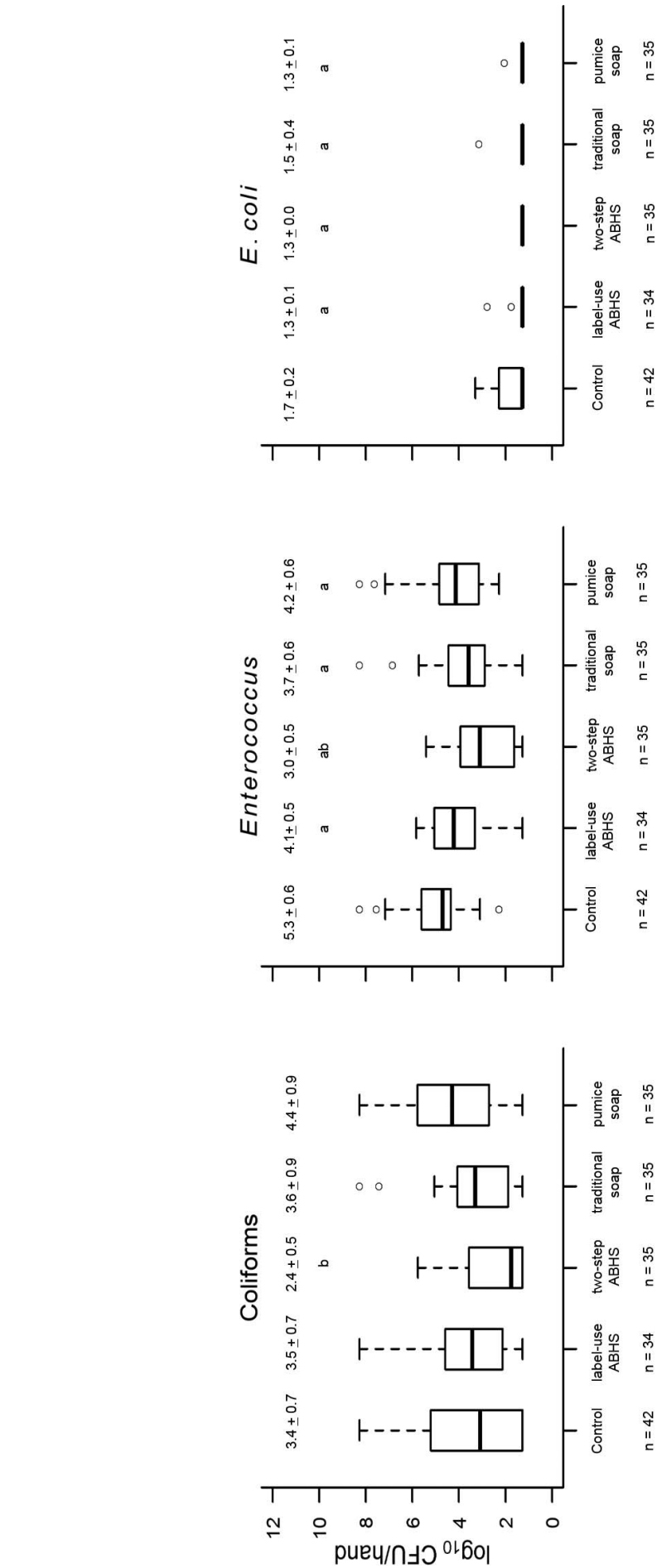

FIGURE 2. *Concentrations of coliform,* Enterococcus, *and* E. coli *bacteria in hand rinsate samples from the control group and four hand hygiene intervention groups of workers harvesting tomatoes. For each study group, the boxes display the quartiles (25th, 50th, and 75th) and whiskers extend to 1.5 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)*

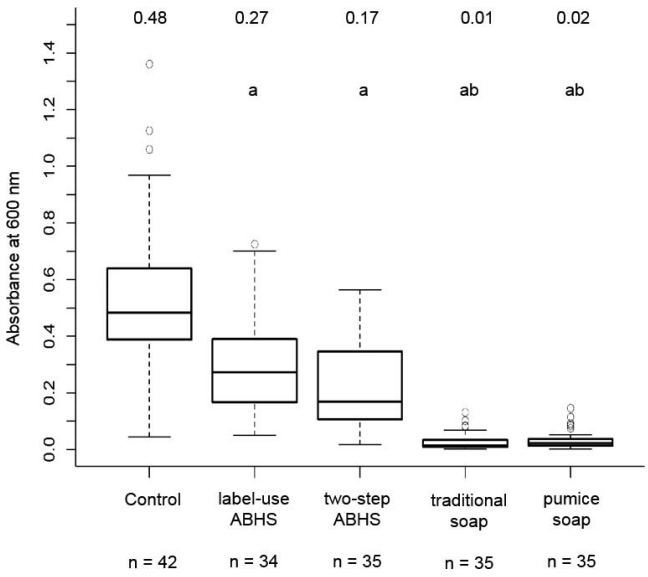

FIGURE 3. *Absorbance (at 600 nm) in hand rinsate samples from the control group and four intervention groups of workers harvesting tomatoes. For each study group, the boxes display the quartiles (25th, 50th, and 75th) and whiskers extend to 1.5 times the interquartile range. Any data points outside the whiskers are displayed individually as dots. The value above each study group box plot indicates the median absorbance (A_{600}). The control group samples were collected after farmworkers harvested tomatoes for 1 to 2 h. The four intervention groups had hand rinsates collected immediately after performing hand hygiene. a, significantly different from the control group ($\alpha = 0.05$); b, significantly different from the label-use ABHS and two-step ABHS groups ($\alpha = 0.05$)*

on hands than ABHS-based interventions (range, A_{600} 0.02 to 0.73) ($P < 0.05$) (Fig. 3). These absorbance results confirm the trends seen in the "after intervention" photographs taken of hands (Fig. 4).

DISCUSSION

The goal of this study was to assess the ability of two soap-based (traditional or pumice) and two ABHS-based (label-use or two-step) hygiene interventions, compared with a no-hand-hygiene control, to reduce microbes (coliforms, *E. coli,* and *Enterococcus*) and soil (A_{600} of hand rinsate) on farmworker hands after harvesting produce. Without intervention, farmworkers' hands were contaminated with high concentrations of indicator bacteria and were heavily soiled after 1 to 2 h of harvesting tomatoes. All four hygiene intervention groups had lower concentrations of *Enterococcus* and *E. coli* on their hands than the control group. Furthermore, all four interventions yielded significantly less soil remaining on hands, soap-based interventions more so than ABHS-based interventions. Based on these results, ABHS can be viewed as a promising hand hygiene solution for produce handlers, even on soiled hands. To build on these findings, future studies could investigate the efficacy of ABHS for pathogen inactivation on soiled hands in a controlled setting (e.g., an experimental greenhouse).

Farmworkers' hands were heavily soiled and contaminated with high concentrations of indicator bacteria after 1 to 2 h of harvesting tomatoes. The control group results are supported by our previous field observational study of microbial contamination of produce, environmental samples, and farmworkers' hands *(23),* where we found that 16 to 41% of farmworkers' hands had detectable *E. coli,* 92 to 100% had detectable coliforms, and 70 to 99% had detectable *Enterococcus* bacteria, depending on the type of produce harvested. The lower percentage of samples positive for *E. coli* than of samples positive for coliforms and *Enterococcus* is expected, as *E. coli* is a gram-negative species of bacteria indicative of fecal contamination from a warm-blooded animal, whereas *Enterococcus* spp. (a genus of gram-positive bacteria) and coliforms (a general group of bacteria) are larger, more general categories of indicator bacteria. It is unlikely that the presence of these indicator bacteria is simply a result of poor sanitation and hygiene practices among the farmworkers given that they washed their hands with soap and water before beginning harvest and their sole activity was harvesting produce. It is more likely that farmworkers' hands are accumulating organic matter and indicator bacteria present in the agricultural environment (e.g., on plants, soil, or produce bins). Both coliforms and *Enterococcus* are naturally present in the guts of animals *(5, 36),* but they are also present in the environment *(36)* and could be introduced into the agricultural environment through various pathways (e.g., irrigation water, soil amendments, or contaminated tools or equipment). Similarly, the *E. coli* seen on some farmworker hands after harvest may indicate recent fecal contamination from a warm-blooded animal *(36)* or may indicate past environmental contamination, as *E. coli* is known to be persistent in the environment *(41).*

Farmworkers in all four intervention groups had lower concentrations of *Enterococcus* and *E. coli* on their hands than those in the control group. These results indicated that all four interventions were efficacious at reducing the concentrations of viable microbes on hands. The soap-based interventions likely reduced bacterial concentrations because soap is, by definition, an emulsifier, meaning it suspends hydrophobic compounds and, with them, any particles and microbes. These particles and microbes are then removed when hands are rinsed. These traditional soap and pumice soap intervention results are consistent with the results from a pilot study of a hand hygiene intervention using foam soap on soiled farmworker hands *(13).* The ABHS-based interventions likely reduced bacterial concentrations because ethanol, the active ingredient in the ABHS, is an effective antimicrobial agent *(3, 24).* These results suggest that ABHS can be an efficacious hand hygiene method, even on soiled hands. Although the soap-based and ABHS-based interventions work by different mechanisms, they were both efficacious at reducing microbes on soiled hands.

No intervention resulted in lower concentrations of coliforms than in the control group. Given the high variability of coliform concentrations in the control and all intervention groups and the generally small reductions (0 to 2 log) in coliforms previously reported with hand washing with foam soap and ABHS in the field *(13),* a larger sample size would likely have been needed for these interventions to demonstrate a statistically significant difference in coliform

FIGURE 4. *Photographs of hands and corresponding individual hand rinsate absorbance readings from samples collected after intervention from study participants—workers harvesting tomatoes on a farm in Mexico. Photographs were taken immediately before and after each worker performed hand hygiene.*

concentration compared with the control group. In a previous study comparing two-step ABHS and foam soap to a control group, only two-step ABHS had significantly lower levels of coliforms (~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.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-011

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:

Reduce risk of cross-contamination by hands.

Issue you would like the Conference to consider:

Public health is best protected when code language is risk-based and easy to understand. When code language is not clear or when alternate interpretations lead to recommendations or to enforcement decisions that are not based on risk, compliance declines. This results in increased risk to public health. The handwashing section of the 2013 FDA Food Code (2-301.14) is a section that could benefit from further clarification.

2013 FDA Food Code §2-301.14(G) requires that hands be washed "When switching between working with raw FOOD and working with READY-TO-EAT FOOD." This language is based on the assumption that there was a contamination event (hands became contaminated) during the handling of the raw FOOD (e.g., through direct contact with the hand), but contamination of the hands does not always occur when handling raw FOOD and yet this section still requires hands to be washed.

In many operations, to help avoid cross contamination, UTENSILS (SINGLE-USE or multi-use) are used as a means to handle the raw FOOD. When contamination of hands and/or gloves is prevented through the use of UTENSILS, this route of hand based cross-contamination is eliminated.

The use of UTENSILS to prevent contamination is a far more reliable method for protecting public health than relying on proper handwashing to reduce contamination. Other sections of the Food Code (3-301.11(B)) recognize the value of UTENSILS in keeping hands and food separate.

The handwashing section of the Food Code, as written, needs further clarification to help ensure requirements to wash hands applies when contamination of the hands occurs.

Public Health Significance:

Annex 3 of the Food Code outlines that "Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to ready-to-eat (RTE) food as well as

other pathogens that can be transmitted from environmental sources. Many employees fail to wash their hands as often as necessary and even those who do may use flawed techniques."

By codifying allowance of another important method of "reducing fecal-oral pathogens that can be transmitted from hands to RTE food as well as other pathogens that can be transmitted from environmental sources," positive public health outcomes can be promoted.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that Section 2-301.14(G) of the 2013 Food Code be amended as follows (language to be added is underlined):

2-301.14 When to Wash.

FOOD EMPLOYEES shall clean their hands and exposed portions of their arms as specified under § 2-301.12 immediately before engaging in FOOD preparation including working with exposed FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLESERVICE and SINGLE-USE ARTICLES[P] and:

(G) Except when UTENSILS are used to prevent contact with raw FOOD, when switching between working with raw FOOD and working with READY-TO-EAT FOOD.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-012

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

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Issue History:

This is a brand new Issue.

Title:

Food Service Employees Not Meeting Hand Hygiene Timing Compliance Code

Issue you would like the Conference to consider:

Based on the multiple tests conducted by the Center for Disease Control (see attached Journal for Food Protection (JFP)- Factors Related to Food Worker Hand Hygiene Practices PDF) and sanitation departments around the nation, it is necessary for a person to wash their hands for a minimum of 15 - 20 seconds directly under water and with approved soaps to kill 99.9% of disease causing bacteria to reach a true clean (see attached Hand Washing Facts - Joe Hardy PDF). Based on a Michigan State University (see attached Michigan State University Hand Hygiene Compliance Study PDF) study of over 4,000 participants, only 5% of individuals are washing their hands correctly per the regulations where 15 to 20 seconds is required for a total germ free clean.

The average person only washes for 8 seconds. The average professional only washes for 12 seconds. As stated by the Center for Disease Control and local health departments nationwide, there is no direct and efficient substitute for hand sanitation than a simple correctly executed hand wash with soap and water. Poor hand hygiene accounts for up to 60%, which is the majority of food borne illness as outlined by the World Health Organization (see attached World Health Organization Hand Hygiene and Food Borne Illness PDF). This statistic is only of reported food borne illness cases where only a small fraction of all occurrences are actually reported to health authorities leaving this epidemic in reality to be exponentially higher. Poor hand washing also directly accounts for over 20,000 deaths annually in medical establishments in regards to contraction of Hospital Acquired Infections, the 4th leading cause of death in the United States today.

Public Health Significance:

The Center for Disease Control has researched, studied, and dictated the proper methodology of hand hygiene is washing your hands for a minimum of 20 seconds to avoid the spread of harmful bacteria from a person's hands. So many cases of food borne illnesses and hospital acquired infections are directly traced back to poor hand hygiene

practices being conducted by food service and medical professionals. *Staphylococcus aureus* is common on people's hair, nose, and skin and because shaking hands, fixing your hair, and wiping your nose are all ways of spreading this bacteria; washing your hands for 20 seconds is the most effective preventive measure to safeguard yourself and others from illnesses. It is the first sign of defense always outlined by health authorities to protect oneself from illness.

Food service employees that do not wash their hands for a minimum of 20 seconds are more prone to causing customer illness. As more and more people are going out to eat and the exponential growth of the hospitality industry, without proper hand washing timing tools, many food service employees can pass harmful bacteria onto others by simply having poor hand hygiene practices. *Clostridium difficile* is also becoming a huge epidemic in food service as well as medical facilities as it is extremely common among the general public and passed via touch and normal contact. Because it is a spore, it is resistant to hand sanitizers and thus the only way to properly kill and remove this bacteria is by washing one's hands correctly with soap and water to remove the spore bacterium. The requirement for a hand washing timer on every hand washing sink in a retail food service establishment will ensure that proper hand hygiene compliance will increase and food service employees can stop the spread of harmful bacteria in their establishments. This recommendation would ensure that users are meeting the 20 second cleaning procedure as stated in FDA 2013 Food Code 2-301.12 (Cleaning Procedure Section A). Such hand washing timers are readily available in today's market.

Recommended Solution: The Conference recommends...:

A letter be sent to the FDA requesting all retail food establishments be required to have a hand washing timer on all hand washing sinks in their establishment(s) and that language be amended to the 2013 FDA Food Code as follow:

1. adding a Paragraph E to Section 5-202.12 (Hand washing Sink, Installation) stating the requirement of a hand washing timer on all hand washing sinks in all retail food establishments
2. adding a Paragraph D to Section 5-205.11 (Using a Hand washing Sink) stating the requirement of a hand washing timer on all hand washing sinks in all retail food establishments.

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Supporting Attachments:

- "Michigan State University Hand Hygiene Compliance Study PDF"
- "Hand Washing Facts PDF"
- "World Health Organization Hand Hygiene and Food Borne Illness PDF"
- "JFP - Factors Related to Food Worker Hand Hygiene Practices"

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Hand Washing Practices in a College Town Environment

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Abstract **Many people do not wash their hands when the behavior in which they engage would warrant it. Most research of hand washing practices to date has taken place in high-traffic environments such as airports and public attraction venues. These studies have established a persistent shortcoming and a gender difference in hand washing compliance. Using field observations of 3,749 people in a college town environment, the research described in this article replicates and extends earlier work while identifying potential environmental and demographic predictors of hand washing compliance. Additionally, the authors' research suggests that proper hand washing practices, as recommended by the Centers for Disease Control and Prevention, are not being practiced. Finally, the authors' research raises a question as to the accuracy of earlier measurements of "proper" hand washing practices, suggesting that compliance rates are inflated. The results can help increase hand washing rates for the general public and thus decrease the risk of transmitting disease.**

Introduction

Many individuals take hand washing for granted and do not consider how essential hand washing is in the prevention of infections and disease. Thus they often fail to wash their hands when they engage in activity that would warrant or require hand washing. Research has established that people generally overstate the degree to which they wash their hands; that women are much more likely to wash their hands than men; and that while hand washing compliance appears to have increased in recent years much room for growth still exists. According to the Centers for Disease Control and Prevention (CDC) (Mead et al., 1999), failing to wash or insufficiently washing hands contributes to almost 50% of all foodborne illness outbreaks. Additionally, Curtis and Cairncross (2003) performed a meta-analysis that suggests that hand washing with soap can reduce diarrheal disease risks by more than 40% and that hand washing interventions could save one million lives annually. Yet we do not know why people fail to wash their hands at recommended rates and in the proper fashion. Our research attempted to establish predictors of hand washing that can be used to induce higher rates of hand washing compliance.

Current Hand Washing Practices

Recent surveys establish that U.S. adults claim to wash their hands after using public restrooms at very high rates. In 2009, 94% (N = 2,516) suggested that they consistently wash their hands (QSR Magazine, 2009), while in 2010, 96% (N = 1,006) stated that they always wash their hands after using a public restroom (Harris Interactive, 2010). Self-reports of hand washing behavior have been criticized as unreliable as hand washing is a socially desirable activity (Judah, Aunger, Schmidt, Granger, & Curtis, 2009) and observational research suggests these high self-report rates are inflated (Harris Interactive, 2010).

The potential discrepancy aside, it is important to note that hand washing rates have trended upwards in recent years. The American Society for Microbiology and the American Cleaning Institute have studied hand washing practices since 1996. Most recently they reported on hand washing in restrooms at public attractions in five cities across the U.S. The restroom locations included Turner Field in Atlanta, the Museum of Science and Industry and Shedd Aquarium in Chicago, Penn Station and Grand Central Terminal in New York, and the Ferry Terminal Farmers Market in San Francisco (Harris Interactive, 2010). All locations experience high volumes daily, and at the composite level, the 2010 data (N = 6,028) establishes that 85% of the observed adults wash their hands after using a public restroom. This is an increase from 77% in 2007 (N = 6,076), which was somewhat lower than the 2005 rate of 83% (N = 6,336). With the exception of the Shedd Aquarium, which has seen a 3% dip in hand washing rates since 2005, all the venues saw a slight upward trend in observed hand washing rates (Harris Interactive, 2010). In 2003, hand washing rates were also observed across six North American airports, averaging 74% compliance (N = 4,046). The highest hand washing rates were obtained in Toronto with 95% while Chicago had the lowest rate at 62% (American Society for Microbiology, 2003).

The research consistently finds a gender bias in hand washing practices. Women wash their hands more frequently than men. In the 2003 study (American Society for Microbiology) it was observed that 83% of women washed their hands after using the restroom,

whereas only 74% of the men did so. In a multi-year study across public attractions, women consistently wash more than men across all years and venues (Harris Interactive, 2010). The average observed hand washing rates for women were 93% in 2010, 88% in 2007, and 90% in 2005. The equivalent rates for men were 77%, 66%, and 75%, respectively.

A study of 120 secondary school students (Guinan, McGuckin-Guinan, & Sevareid, 1997) found that 58% of female students and 48% of male students washed their hands after using the restroom, although only 28% of the female students and 8% of the male students used soap. In a university campus public restroom study (Johnson, Sholoscky, Gabello, Ragni, & Ogonosky, 2003), 61% of women and 37% of men (N = 175) were observed washing their hands, while the hand washing rate climbed to 97% for women and fell to 35% of men when a sign was introduced to encourage hand washing. Similarly, in a British 32-day study of highway service station restrooms (N = 198,000) that observed entry and soap use with electronic sensors, it was found that 65% of women and 32% of men washed their hands, but that the hand washing rate increased to as much as 71% for women and 35% for men when messages designed to encourage hand washing were displayed using electronic dot matrix screens (Judah et al., 2009).

A study of the hand washing practices of university students living in a dormitory found that women wash their hands after urinating 69% of the time and after bowel movements 84% of the time, whereas the corresponding figures for males were 43% and 78% (Thumma, Aiello, & Foxman, 2008). In a study of restaurant food workers (Green et al., 2006), food handlers washed their hands only 32% of the time when their behaviors made such hand washing required.

A review of the literature on foodborne disease outbreaks from 1975 to 1998 identified 81 foodborne disease outbreaks involving 14,712 people within which 93% of the foodborne outbreaks involved infected food workers transmitting pathogens to the food with their unwashed hands (Guzewich & Ross, 1999). An observation of 80 women in a bar bathroom (Hayes, 2002) found that only 40% washed their hands; when the researcher engaged the subject and modeled hand washing, the hand washing rate increased to 56%, while it dropped to 27% when the researcher appeared to be simply talking on her cell phone. This research also noted that the female subjects were less likely to wash their hands later in the night than earlier in the evening (r = -.44, p < .01).

It is evident from the reviewed research that room for improvement exists in hand washing practices. Additional research is needed to further understand how and why hand washing rates differ and if such rates can be influenced by environmental factors within the restroom. Gender is associated with marked differences in hand washing rates. Are other demographic variables such as age also associated with hand washing rates? Furthermore, evidence exists that environmental variables such as signage and posters influence hand washing rates and other health-related behaviors (Etter & Laszlo, 2005; Judah et al., 2009). Do other environmental variables, such as sink conditions and type of faucet impact hand washing rates? Does the hand washing rate on campus differ from the rate off campus?

It is unclear from the reviewed literature whether the various reported rates of hand washing reflect hand washing with soap as recommended by the CDC or if the rates incorporate practices somewhat inconsistent with the established recommendations. As such, our study used three measures of hand washing, defined as 1) no washing—leaving the restroom without washing or rinsing hands, 2) attempted washing—wetting hands but not applying soap, and 3) washing hands with soap, in addition to measuring the duration of washing. This added distinction is important because Burton and co-authors (2011) reported that washing with soap and water is more effective at removing fecal bacteria from hands than washing with water alone.

Methods

Participants and Procedures

Direct observations of hand washing behaviors were conducted by 12 research assistants in restrooms located across a college town. Observers were instructed to be unobtrusive and disguise their observation of hand washing behaviors. To ensure this and ensure accurate measurement and coding consistency, each of the observers met researchers individually for training and attended training meetings as a group.

All observations were recorded according to a standard coding form. The coding form consisted of the subject ID, date, subject's age group, observation time, gender, hand washing behaviors, the type and availability of drying mechanisms (i.e., not available, hot air, paper towel, or both), location of restrooms (off campus versus on campus), type of faucet (standard faucet versus motion detection), the cleanliness of sink conditions, and availability of hand washing signage.

Washing behaviors were recorded into three categories: no washing (leaving the restroom without washing or rinsing their hands), attempted hand washing (wetting hands without using soap), and washing hands with soap. Observers also discreetly measured the total length of time in terms of the number of seconds subjects' hands were placed under running water during washing, lathering, and rinsing. The time of observation was collected and nominal time categories were formed for the purpose of analyses. Due to the unobtrusive nature of our observations, the subject's age group was estimated using the trained observers' subjective evaluations and the subject was placed into one of two groups: college age or younger and older than college age. The cleanliness of sink conditions had three categories including dirty, reasonable, and clean, which was also based on the subjective evaluation of observers. The presence of a hand washing sign was added to the coding form later based on observer feedback.

Statistical Analysis

Descriptive data were compiled and further analyzed using Chi-square analysis and ANOVA. Specifically, Chi-square analysis was used to identify statistically significant differences in subjects' demographic variables, environmental variables in the restrooms, and among hand washing behaviors. ANOVA was used to establish mean differences in the length of time hands were placed under running water across the above specified variables. Kappa and paired t-test statistics were calculated, using a subsample (n = 90) to evaluate inter-rater reliability.

Results

Inter-Rater Reliability

Evaluation of inter-rater agreement is an important step in ensuring reliability in observa-

tional studies, especially when studies involve multiple observers. We selected four different restrooms (n = 44, located in two off-campus restrooms; and n = 46, located in two on-campus restrooms) to determine the inter-rater reliability among observers. The observers agreed 100% on the environmental variables. For the two dependent variables, the time spent washing time and other washing behaviors, paired-samples t-tests (Fleiss, 1981), and Cohen's Kappa (Cohen, 1960) were used. A Kappa statistic of more than .8, more than .6, and more than .4 is considered to have "almost perfect," "substantial," and "moderate" agreement, respectively (Landis & Koch, 1971). Excellent inter-rater reliability was demonstrated as indicated by nonsignificant paired t-test result in estimating washing time (p > .01) and Kappa of .89 in evaluating washing behaviors.

Characteristics of Sample and Overall Findings

Table 1 presents characteristics of the sample and observation settings. Of the 3,749 subjects observed, approximately 54% of observations took place in restrooms located off campus. Sixty-two percent of observations took place in the afternoon, followed by evening/night (23.6%) and morning (14.4%). Of all subjects, 60.5% of the observed subjects were women. About 62% (61.6%) of the subjects were estimated as college age or younger, with the remainder estimated to be older than college. Nearly all restrooms had a mechanism for drying hands (98.7%). About 64% of the restrooms in the study contained signs encouraging hand washing. Seventy-seven percent of the restrooms were equipped with a standard faucet while 22.9% had motion detection faucets.

Overall, 66.9% of the subjects used soap when washing their hands. Of these, 1.2% did not dry their hands, but left the restrooms with wet hands. About 23% attempted to wash their hands, that is, they wet their hands but did not use soap. A total of 10.3% did not wash their hands *at all* after using the restroom. CDC (2012) recommends that people should rub their soaped hands for 15 to 20 seconds before rinsing thoroughly. Our measure of duration included the length of time placed under running water while subjects were washing, rubbing, and rinsing their hands. Nonetheless, as shown in Table 2, only 5% or so spent more than 15 seconds in combined washing, rubbing, and rinsing of their hands.

TABLE **1**

Characteristics of Sample and Restroom Settings (*N* = 3,749)

Variables	*n*	%
Observation time		
Morning	538	14.4
Afternoon	2,326	62.0
Evening/night	885	23.6
Gender		
Male	1,479	39.5
Female	2,270	60.5
Age		
College group and younger than college group	2,310	61.6
Older than college group	1,439	38.4
Drying		
Not available	47	1.3
Only paper	2,799	74.7
Only air dryer	331	8.8
Both paper and air dryer	572	15.3
Faucet		
Standard faucet	2,889	77.1
Motion detection	860	22.9
Sink condition		
Dirty	219	5.9
Reasonable	1,779	47.5
Clean	1,750	46.7
Location		
On campus	1,755	46.8
Off campus	1,994	53.2
Sign		
Sign	1,548	63.7
No sign	882	36.3

Results From Chi-Square Analysis

The Chi-square analysis revealed statistically significant differences in hand washing behaviors across time of observation, gender, age, sink condition, and hand washing signage (Table 3). For example, 12.4% observed during evenings did not wash their hands while the morning and afternoon rates of leaving the restroom without attempting to wash were 8.6% and 9.4%, respectively. Subjects washed their hands significantly more with soap during mornings (70.6%) than during afternoons (66.4%) and evenings (67%). The gender difference was confirmed with women using soap and engaging in proper hand washing behavior significantly more (77.9%) than men (50.3%). About 7% of the women and 14.6% of the men did not wash their hands at all, while 15.1% of the women and 35.1% of the men simply wet their hands with water. Those estimated to be older than college (70.3%) washed their hands with soap significantly more than the college age and younger group (64.8%).

When restrooms contained hand washing signs, subjects used soap more (68.5%) than subjects in restrooms that had no such signs (60.5%). Sink cleanliness influenced hand washing behaviors as well. When sinks were clean, 73.9% washed their hands using soap, while the rate for reasonably clean and dirty sinks was 61.2% and 59.4%, respectively. No

TABLE **2**

Overall Hand Washing Behavior and Length of Hand Washing Time (*N* = 3,749)

Variables	*n*	%
Washing behavior		
Not washing	384	10.3
Wetting hands without soap	856	22.8
Washing hands with soap	2,509	66.9
Length of hand washing time		
0 seconds	384	10.3
1–4 second(s)	824	22.0
5–8 seconds	1,432	38.2
9–14 seconds	911	24.2
15 seconds or longer	198	5.3

TABLE **3**

Chi-Square Test: Comparison of Hand Washing Behavior by Sample Demographics and Restroom Settings (*N* = 3,749)

Variables	Not Washing	Wetting Hands Without Soap	Washing With Soap	χ^2
	10.3% (*n* = 384)	22.8% (*n* = 856)	66.9% (*n* = 2,509)	
	%	%	%	
Observation time				13.2*
Morning	8.6	20.8	70.6	
Afternoon	9.4	24.2	66.4	
Evening/night	12.4	20.6	67.0	
Gender				311.3*
Male	14.6	35.1	50.3	
Female	7.1	15.1	77.9	
Age				12.9*
College group and younger than college group	10.6	24.6	64.8	
Older than college group	9.7	20.0	70.3	
Faucet				0.8
Standard faucet	9.8	22.9	67.3	
Motion detection	10.8	23.0	66.2	
Sink condition				91.2*
Dirty	19.6	21.0	59.4	
Reasonable	10.7	28.1	61.2	
Clean	8.1	17.9	73.9	
Location				4.8
On campus	10.3	24.3	65.4	
Off campus	9.7	21.6	68.6	
Sign				17.4*
Sign	9.7	21.7	68.5	
No sign	10.7	28.8	60.5	

*$p < .01$.

statistically significant differences in subjects' hand washing behavior were found across faucet type (standard faucet versus motion detection) or restroom location (on campus versus off campus).

Results From ANOVA

Multi-way ANOVA was conducted to evaluate the mean differences among identified factors in terms that may influence the length of washing time (Table 4). Statistically significant differences were found for gender, age group, type of faucet, sink condition, and hand washing signage. The average washing time for men and women, although short for both, was 6.27 seconds for men and 7.07 seconds for women. The gender effect persists. The age group older than college spent significantly more time washing their hands (mean = 6.93 seconds) than did college group and younger than college group (mean = 6.48 seconds). The presence of a sign also influenced washing time; the mean score in the presence of a sign was 7.08 seconds and 6.50 seconds without. Subjects spent significantly more time washing their hands when the sink condition was clean (mean = 7.20 seconds), compared to when the sink appeared reasonably clean (mean = 6.36 seconds) or dirty (mean = 6.16 seconds). No significant differences in hand washing time were found across time of observation or restroom locations.

Discussion

Hand washing is the most effective thing one can do to reduce the spread of infectious diseases according to CDC (CDC, 2012; Mead et al., 1999). Our study provided detailed information about how long and in what environments different groups engaged in various hand washing behaviors. While earlier research reported that not all wash their hands, prior studies have not identified factors associated with proper hand washing behaviors. Additionally, previous studies did not clearly distinguish between washing with and without soap. Our study recognizes the importance of environmental factors that promote proper hand washing behaviors. To our knowledge, our study was one of the first studies to focus on hand washing behaviors and the length of time spent washing while incorporating environmental factors and the time of observation.

The observed hand washing behaviors and the length of time washing hands relate differently to different factors. Our study supports earlier work in observing that men need more encouragement than women to engage in proper hand washing behaviors, although most men and women do wash their hands using soap. Nonetheless, the percentages who simply wet their hands was significantly higher for men (35.1%) than for women (15.1%).

While our study was not specifically designed to test for the intervention effect of a hand washing sign, the study did find that the presence of a sign influenced both hand washing behaviors and the length of washing time. This is an important finding as a high percentage of people fail to wash their hands properly, and signs that include messages highlighting correct hand washing or reminders to use soap may increase compliance. It appears that this kind of explicit reminder may be particularly useful in men's restrooms, given that more than one-third of men simply wet their hands without using soap.

In previous studies the automated and sequenced phases of the device/sink resulted in significant improvement in hand washing practices (Larson, Bryan, Adler, Lee & Blane, 1997; Larson, McGeer, & Quiaishi, 1991). Our study showed that the type of faucet itself (standard faucet versus motion detection) did not impact hand washing behaviors. Care must be taken in the interpretation of washing time, as it is possible to equate washing time with the motion-detected dispensing of water, much as our study did in terms of manual water flow.

More importantly, the findings of our study showed that it is important to maintain clean sink conditions, as clean sinks promoted proper hand washing procedures as well as increased length of time washing hands. When sinks are dirty, some may choose not to wash their hands, despite knowing they should. Studying the effect of time of day on hand washing behavior, a relatively new research focus, showed that hand washing generally decreased as the evening progressed.

The most important findings of our research relate to the distinctions among hand washing behaviors and the length of time hands were washed. Specifically, less than 6% of the sample approached the recommended hand washing duration. Furthermore, our study identified that a large proportion of subjects engaged in hand washing behavior that did not involve the use of soap. It is interesting to note that if the proportion of people who were observed using soap when washing their hands were combined with those who only used water, the hand washing rates reach the higher levels reported in other studies. This raises the question of whether hand washing compliance rates have been inflated by way of definition in earlier work.

TABLE **4**

Multi-Way ANOVA: Hand Washing Time by Demographics and Restroom Settings (*N* = 3,749)

Variables	Hand Washing Time Mean (Seconds)	*F*	η^2
Observation time		.92	.022
Morning	6.50		
Afternoon	6.81		
Evening/night	6.77		
Gender		25.21*	.082
Male	6.27		
Female	7.07		
Age		8.14*	.058
College group and younger than college group	6.48		
Older than college group	6.93		
Faucet		49.29*	.114
Standard faucet	6.45		
Motion detection	7.74		
Sink condition		15.76*	.091
Dirty	6.16		
Reasonable	6.36		
Clean	7.20		
Location		2.23	.024
On campus	6.63		
Off campus	6.86		
Sign		7.97*	.057
Sign	7.08		
No sign	6.50		

Note. Total mean = 6.75 (*SD* = 4.76), mean = 7.52 (*SD* = 4.41).
*$p < .01$.

Limitations and Future Research

While the data from our study are informative, it should be noted that observations only took place in one college town environment. Care should be therefore taken in generalizing the findings.

As an alternative to the self-reporting method, direct and unobtrusive observations of hand washing were used as a way to enhance reliability and validity. It should be recognized, however, that even an apparent unobtrusive observation may influence hand washing behaviors, as the simple presence of others in a restroom may lead to increased compliance (Bittner, Rich, Turner, & Arnold, 2002; Drankiewicz & Dundes, 2003; Edwards et al., 2002; Nalbone, Lee, Suroviak, & Lannon, 2005).

While our study attempted to investigate the role that a hand washing sign would have on hand washing behavior, the subjects were not asked whether they recalled seeing the sign or whether they could recall the messages. Future research should consider sign content, design, and placement.

In our study the act of drying was measured. Approximately 2% of subjects who

attempted to wash their hands (i.e., wetting hands without soap) or washed hands with soap did not dry their hands at all, but we do not know if those who attempted to dry their hands achieved dry hands. This would be good to include in future studies as studies have demonstrated that the transfer of microorganisms is more likely to occur from wet skin than from dry skin (Mackintosh, & Hoffman, 1984; Merry, Millder, Findon, Webster, & Neff, 2001; Patrick, Miller, & Findon, 1997).

Conclusion

Our study replicated and extended earlier work on hand washing practices. While past studies have focused on high-traffic venues such as transportation hubs and stadiums, our study focused on hand washing behaviors in a college town environment. Field observations by trained observers in a variety of restrooms provided a sample of 3,739 people who were unobtrusively watched to note their hand washing behaviors.

The findings were consistent with earlier research in that a significant gender bias was found. Women wash their hands significantly more often, use soap more often, and wash their hands somewhat longer than men. Both men and women fell far short, however, of CDC-recommended hand washing durations, averaging 6.27 and 7.07 seconds, respectively. Only 5.3% of the sample washed their hands for 15 seconds or more. Considering the definition of hand washing and the careful training of observers, this particular finding raises the specter of significant inflation in earlier reported hand washing compliance rates. Future studies need to measure hand washing compliance carefully.

Additionally, our study established that restroom environmental conditions and signage are important. Specifically, hand washing compliance was greater when restroom sinks were clean and when signs encouraging hand washing were posted.

Hand washing compliance and practices as reported in this and previous studies fall short of the ideal. The public needs to be continuously encouraged to engage in proper hand washing practices. In addition, careful attention to restroom environmental conditions and signage may help increase compliance. Given the established gender bias, consideration should be given to the content of the messages targeting men and women. Perhaps men and women would respond differently to gender-targeted messages.

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continued on page 24

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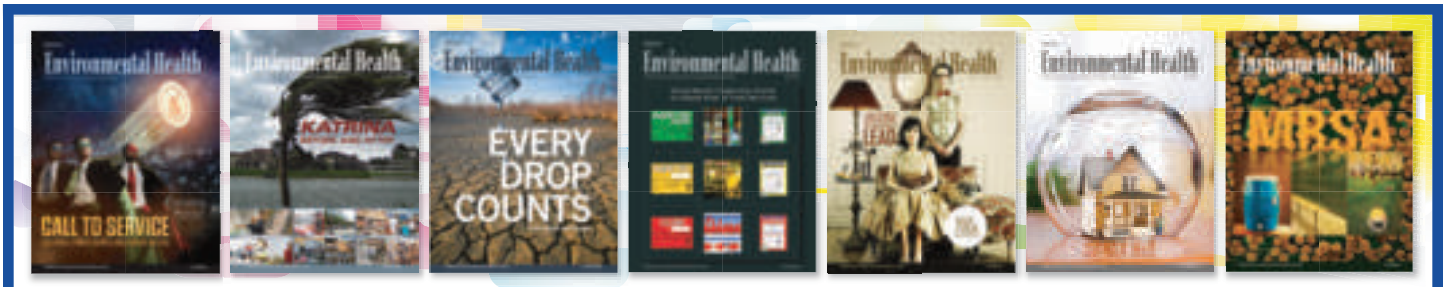

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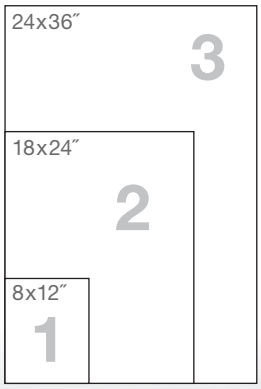

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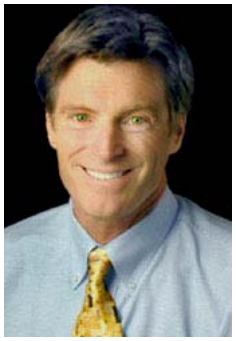
11 HAND WASHING FACTS

Could singing Yankee Doodle save your life?



By Jay Hardy, CLS, SM (ASCP)

Jay Hardy is the founder and president of Hardy Diagnostics.

After studying microbiology at California State Universities at Fullerton and Long Beach, he completed his Medical Technology internship at Santa Barbara Cottage Hospital.

The company began in 1980, shortly after Hardy served as a Medical Technologist and microbiologist at Goleta Valley Hospital in California.

1.

80% of all infectious diseases are transmitted by touch.

According to experts, without a vaccine, the single most important thing you can do to prevent getting the flu is to wash your hands.

2.

The Solution to Pollution is Dilution.

While soap may not kill all viruses, thorough hand washing will decrease the viral counts to a point below the infectious threshold.

3.

Caught in the act (or lack of).

95% of the population says that they wash their hands after using a public toilet. However when 8,000 people were monitored across five large cities in the US, they found the actual number to be more like 67%.

Chicago topped the list at 83%. New York was the worst at less than half.

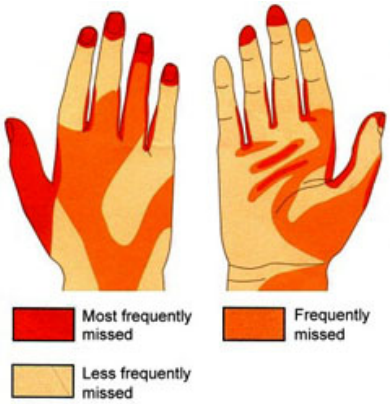
4.

Do as I say, not as I do…

A poll of pediatric ICU physicians showed that they ***claimed*** their rate of hand washing between patients was 73%, but when followed and observed, the hand washing rate was found to be less than 10%. Listen carefully and you can hear Dr. Semmelweis rolling over in his grave. The top excuses for not hand washing among doctors? Too busy and dry skin.

5.

Where's the dirt?



CDC studies show that the number of bacteria per square centimeter on the human body are as follows:

- Scalp – 1,000,000
- Forearm – 10,000
- Arm pit – 500,000
- Abdomen – 40,000
- Hands of medical personnel – 40,000 to 500,000

When it comes to hands, fingernails and the surrounding areas harbor the most microorganisms.

6.

Who has it?

A recent study showed that 21% of the health care workers in ICU had varying counts of *Staphylococcus aureus* on their hands.

7.

Too busy?

One study demonstrated that hand washing guidelines were followed 25% of the time during times when the floor was overcrowded and understaffed. Compliance rose to 70% when the floor was properly staffed and not overcrowded with patients.

8.

And the winner is…

Many studies have shown that alcohol rubs are more effective than plain or even antimicrobial soaps, unless the hands are heavily soiled. However we can't get overconfident with alcohol rubs. Despite its effectiveness against many organisms, alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain non-enveloped (nonlipophilic) viruses. In addition, alcohol has no residual effect as some antimicrobial soaps do.

9.

How long is enough?

The CDC recommends at least 15 seconds. However, studies show that the reduction of skin bacteria is nearly ten times greater by washing with soap for 30 seconds rather than 15. Even so, remember that alcohol gels are even more effective than soap.

The average wash time for health care workers? 9 seconds.

Children (and why not adults?) are taught to sing “Yankee Doodle Dandy” start to finish before rinsing. This takes about 15 seconds. If you don’t know the words to Yankee Doodle, the Happy Birthday song sung twice will suffice.

10.

Some like it hot.

But if they do, hot water can increase the chance of dermatitis. Hot or warm water has not been proven to increase the effectiveness of hand washing. Cold water, though not as comfortable, produces less skin damage from detergents especially with repeated washings.

11.

The two layers of bacteria.

The outer layer of bacteria found on your hands is termed “**Transient Flora**”. This layer is potentially the most dangerous for transmitting disease from one person to another. Fortunately, it is also the most easily eliminated by hand washing. The deeper layer is called “**Resident Flora**”. This bacterial population is more likely to be made up of innocuous bacteria such as *Staphylococcus epidermidis* and *Corynebacteria* spp. (diptheroids); and is more resistant to washing, since they occupy the deeper layers of skin cells.

Jay Hardy
HARDY DIAGNOSTICS

World Health Organization
REGIONAL OFFICE FOR Africa

Division of Prevention and Control of Non-Communicable Diseases
Food Safety and Nutrition

Fact Sheet 2º

Hand Washing and Food Safety

A bulk of the foodborne disease outbreaks are attributable to poor hygienic practices and improper handling of food. Undoubtedly, adequate personal hygiene practices are essential in reducing the risks of a foodborne illness. Hand washing is one of the most effective and cheapest measures against infections and foodborne diseases.

FAST FACTS

- Many foodborne diseases and pathogenic microorganisms are spread by contaminated hands.
- Foodborne pathogens, such as *salmonellosis, shigellosis, hepatitis A, giardiasis* and *campylobacteriosis* are transmitted via the faecal-oral route. These account for a substantial number of disease outbreaks in developing countries.
- Good quality drinking-water and good personal hygiene in food preparation and handling are therefore of utmost importance in preventing the spread of disease.[1]

Foodborne disease

Many foodborne diseases and pathogenic microorganisms are spread by contaminated hands. Many of these illnesses occur unnecessarily, since the faecal-oral routes of disease transmission are easily prevented.[1]

WHO reports that 90% of the annual deaths from diarrhoea are among children particularly in developing countries. A significant number of the deaths could be attributed to shigella, which causes dysentery or bloody diarrhoea. [2]

A study on the microbial quality of street foods in Accra, Ghana showed among others the significance of proper hand-washing practices, use of soap and environmental hygiene. Among the reported risk factors for street food contamination were cooking of food well in advance of consumption, exposure of food to flies, and working with food at ground level and by *hand*.[3]

Significance of proper hand washing to food safety

Judicious washing of hands can significantly reduce bacterial contamination and risk of foodborne illness.

Reports indicate that the simple act of washing hands with soap and water reduces incidents of diarrhoea from *shigella* and other causes by up to 35 percent. [2]

Proper hand washing

Hands should ideally be washed, with soap or ash, under running water. Rubbing hands vigorously 15-20 seconds until a soapy lather

[1] Healthy Villages – A guide for communities and community health workers. WHO. 2003.
[2] Water for Health: Taking Charge. WHO. 2001.
[3] Mensah *et al.* Street Foods in Accra, Ghana: How Safe Are They? Bulletin of the World Health Organization. 2002.

appears, and scrubbing between fingers and fingernails.

Where there is no system, running water can be organized by using a water butt with a tap. If there is a shortage of water, using soap with a small quantity of water in a bowl is adequate.[4]

Washing of hands should be particularly be done:

- Before food preparation;
- Before eating;
- Before serving food;
- During food preparation to avoid cross-contamination;
- Before and after handling raw meat, poultry and fish products;
- After changing diapers;
- After blowing nose/sneezing;
- After using the toilet, not just after defecation, since the pathogens can also be picked up from previous users of toilets via door handles, taps and drying towels.[5]
- After handling unsanitary objects such as waste/garbage containers;
- After contact with toxic substances or chemicals;
- After touching/handling livestock or pets

In all these activities hands may become contaminated with pathogens or toxic chemical residues that can be transferred to food.[5]

Health education in food safety

Experience has shown that well designed and implemented educational programmes, is a feasible and cost-effective means of improving health status.[6]

Adequate food safety and hygiene education/promotion particularly in schools with the provision of adequate sanitary and hand-washing facilities are essential.

WHO technical support and actions in food safety education

A special focus is being made at collaborating with education authorities to promote food safety education in primary and secondary level, among both students and parents. Work is also underway on the promotion of participatory community-based food safety education and awareness-raising strategies.

For More Information on Food Safety and Nutrition please contact Division of Prevention and Control of Non-communicable Diseases (DNC). B.P. 6 Congo Brazzaville.

[4] Food, Environment and Health: A Guide for Primary School Teachers. WHO. 1990

[5] Basic Food Safety for Health Workers. Adams M and Mortarjemi Y. WHO. Geneva. 1999

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Factors Related to Food Worker Hand Hygiene Practices†

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ABSTRACT

To identify factors related to food worker hand hygiene practices, we collected (i) observational data on food worker (n = 321) hand hygiene practices (hand washing and glove use) and (ii) observational and interview data on factors related to hygiene behavior, such as worker activity, restaurant characteristics, worker food safety training, and the physical and social environment. Results indicated that hand washing and glove use were more likely to occur in conjunction with food preparation than with other activities (e.g., handling dirty equipment) and when workers were not busy. Hand washing was more likely to occur in restaurants whose food workers received food safety training, with more than one hand sink, and with a hand sink in the observed worker's sight. Glove use was more likely to occur in chain restaurants and in restaurants with glove supplies in food preparation areas. Hand washing and glove use were also related to each other—hand washing was less likely to occur with activities in which gloves were worn. These findings indicate that a number of factors are related to hand hygiene practices and support suggestions that food worker hand hygiene improvement requires more than food safety education. Instead, improvement programs must be multidimensional and address factors such as those examined in this study.

Many reported foodborne illness outbreaks originate in food service establishments *(25),* and sporadic foodborne illnesses have been associated with having eaten outside the home *(11, 19).* Additionally, food workers' poor personal hygiene is an important contributor to foodborne illness outbreaks *(15, 25).* For example, Olsen et al. *(25)* found that annually from 1993 to 1997, poor personal hygiene of food workers was a contributing factor in 27 to 38% of foodborne illness outbreaks, and Guzewich and Ross *(15)* found that in 89% of outbreaks caused by food contaminated by food workers, pathogens were transferred to food by workers' hands.

The U.S. Food and Drug Administration's (FDA) Food Code for retail establishments includes guidelines on prevention of food contamination by workers' hands *(15, 29).* Hand washing is one of the FDA's recommended prevention methods, for it can significantly reduce transmission of pathogens from hands to food and other objects *(15, 22, 24).* The Food Code indicates that proper hand washing should take at least 20 s and include running warm water, soap, friction between the hands for 10 to 15 s, rinsing, and drying with clean towels or hot air. In addition, the Food Code specifies situations in which hands should be washed, such as before food preparation and after handling raw meat or poultry. The FDA also recommends that bare-hand contact should be prevented when working with ready-to-eat (RTE; i.e., safe to eat without further cooking) food and minimized when working with non-RTE food, because hand washing may not always be sufficient to prevent the transmission of pathogens from hands to other items, such as food *(3, 9, 22).* The Food Code suggests that barriers, such as deli tissue, tongs, and disposable gloves, be used for this purpose. Gloves are commonly used as barriers in food service establishments, and anecdotal evidence suggests that glove use for this purpose may be increasing. Proper glove use can decrease the transfer of pathogens from hands to food *(22, 23),* but some researchers and practitioners have argued that glove use may lead to less safe hand washing practices *(10, 15, 21).*

Research on the prevalence of hand washing and glove use in food-service establishments indicates that these hand hygiene practices do not occur as often as they should. For example, food workers have reported that they sometimes or often do not wash their hands and/or wear gloves when they should, do not always wash their hands after touching raw meat, and do not always change their gloves after touching raw meat *(6, 13).* Additionally, observational studies have found low rates of hand hygiene practices. For example, the FDA observed improper hand washing in 73% of restaurants and failure to prevent bare-hand contact with RTE foods in 57% of restaurants *(28).* Additionally, both Clayton and Griffith *(5)* and Green et al. *(14)* found that observed food workers washed their hands in only a third of the instances in which they should have washed them.

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† The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

TABLE 1. *Observed activities for which hand washing is recommended*

When hand washing should occur	Activity	Description
Before the activity	Food preparation	Engaging in food preparation, including working with exposed food, clean equipment and utensils, and unwrapped single-use articles
	Putting on gloves for food preparation	Putting on gloves in order to engage in food preparation (see above)
After the activity and before beginning another activity	Preparing raw animal product	Preparing raw animal product (animal products that have not been cooked or processed; uncooked eggs, meat, poultry, and fish)
	Eating, drinking, tobacco use	Eating, drinking, or using tobacco (unless from a closed beverage container handled to prevent hand contamination)
	Coughing, sneezing, tissue use	Coughing, sneezing, or using a handkerchief or disposable tissues
	Handling dirty equipment	Handling dirty equipment, utensils, or cloths
	Touching body	Touching human body parts other than clean hands and clean, unexposed arms

These findings, along with evidence that poor personal hygiene frequently contributes to foodborne-illness outbreaks, indicate that improvement of food workers' hygiene practices is needed. Researchers and practitioners contend that a range of personal, social, and environmental factors influence food worker practices and that these factors need to be addressed to successfully change food workers' behavior *(8, 26, 27).* Thus, the purpose of this study was to identify factors related to food worker hand hygiene practices.

This article is the second one based on a study we conducted on food worker hand hygiene practices. For this study, we observed food workers for an extended period and recorded specific information on their work activities and the hygiene practices associated with those activities. We also collected data on possible factors related to hygiene behavior through interviews with restaurant managers and observations of restaurant environments. In the first article on this study, we presented descriptive data on food worker hand washing and glove-use practices across different work activities *(14).* In this article, we present data on the relationships between hand washing and glove use and factors proposed to be related to hygiene behavior. These factors include worker activity (e.g., worker busyness), restaurant characteristics (e.g., ownership: chain versus independent), worker training, physical environment (e.g., number of sinks), and the social environment and management (e.g., management encouragement of hand hygiene). These factors were chosen because existing theories or data suggest that they may affect hygiene behavior (*1, 6–8, 12, 13, 16–18, 20, 26*).

MATERIALS AND METHODS

Restaurants. This study was conducted by environmental health specialists (specialists) affiliated with the Environmental Health Specialists Network (EHS-Net), a collaborative project of the Centers for Disease Control and Prevention (CDC), the FDA, the U.S. Department of Agriculture, and 9 states (California, Connecticut, New York, Georgia, Iowa, Minnesota, Oregon, Rhode Island, Tennessee; Colorado participated until 2005). EHS-Net is focused on the investigation of environmental antecedents of foodborne illness, including food preparation and hygiene practices.

The study comprised randomly selected restaurants located in designated geographical areas in six of the 2004 EHS-Net states (Colorado, Connecticut, Georgia, Minnesota, Oregon, Tennessee; see Green et al. *(14)* for more information on the sample). While there is variability in these states' adoption of the FDA Food Code, all had similar hand washing guidelines and none prohibited bare-hand food contact at the time of the study.

Data collection. The study was conducted over 3 months in the fall of 2004. Before the start of the study, the study protocol was reviewed and approved by CDC's Institutional Review Board (IRB) and the appropriate IRBs in the participating states. Additionally, all specialists participated in training designed to increase data collection consistency. (See Green et al. *(14)* for more information.)

In each restaurant, a specialist first interviewed the restaurant manager, owner, or other employee to collect data on restaurant characteristics, food preparation training and policies, manager certification, food preparation processes, and hand washing encouragement. The specialist then conducted a 10- to 15-min observation of the kitchen to collect information on the environment, such as the number of hand sinks with warm water, soap, and towels or hot-air drying methods. Then, using an observation method similar to the one designed by Clayton and Griffith *(5),* the specialist conducted a 45- to 50-min observation of one worker who was preparing food. Workers were chosen on the basis of the specialist's ability to observe them relatively unobtrusively (e.g., without interfering with their work). To limit the influence of the specialist's presence on worker behavior, the specialist observed the worker for 10 to 15 min before beginning the 45- to 50-min data collection period to allow the worker time to adjust to the specialist's presence. Additionally, workers were not made aware of precisely which aspects of their behavior were being recorded during the observations.

During this observation, the specialist recorded data on specific activities that required hand washing (according to the Food Code; see Table 1) and the hand hygiene behaviors associated with those activities. For the activities of food preparation and putting on disposable gloves for food preparation, hand washing should occur before each activity. For the remaining activities (preparing

TABLE 2. *Variables used in logistic regression models of appropriate hand washing and glove use*

Variable	Variable values	Hand washing model	Glove use model
Worker activity			
Actity type	Food preparation; putting on gloves for food preparation; preparing raw animal product; eating, drinking, using tobacco/coughing, sneezing, using tissue; handling dirty equipment; touching the body	✓	✓
Worker busyness	Yes (worker engaged in ≥8.6 [median] activities) vs no (worker engaged in <8.6 activities)	✓	✓
Hands washed appropriately with activity	Yes vs no		✓
Gloves worn during activity	Yes vs no	✓	
Restaurant characteristics			
Restaurant ownership—chain	Yes vs no	✓	✓
Complex food preparation processes	Yes vs no	✓	✓
Worker training			
Hand hygiene taught to workers	Yes vs no	✓	✓
Workers provided with food safety training	Yes vs no	✓	✓
Management certification required	Yes vs no	✓	✓
Physical environment			
Multiple hand sinks	Yes (>1 sink) vs no	✓	
Hand sink close to worker	Yes (<10 ft from sink) vs no (≥10 ft from sink)	✓	
Hand sink in worker's sight	Yes vs no	✓	
Hand washing supplies at hand sinks	Yes (all hand sinks had warm water, soap, and recommended drying methods) vs no	✓	
Glove supplies in food preparation areas	Yes vs no		✓
Social environment/management			
Worker visibility to manager	Yes (manager could see worker some/most of the observation) vs no	✓	✓
Worker visibility to customers	Yes (worker somewhat/fully visible) vs no	✓	✓
Management encouragement of hand washing	Yes (respondents said hand washing was encouraged) vs no	✓	

raw animal products; eating, drinking, or using tobacco; coughing, sneezing, or using tissues; handling dirty equipment or utensils; and touching human body parts other than clean hands and arms), hand washing should occur after each activity and before beginning another activity. Data were also collected on the activity of preparing raw produce. However, because of inconsistencies in the way specialists identified raw produce, these data were excluded from analysis.

The specialist also collected data on hand hygiene behaviors in which the worker engaged along with each of the observed activities. The specialist recorded whether the worker placed his or her hands under running water, whether the worker used soap, whether and how the worker dried his or her hands (e.g., paper towel, cloth towel, clothes), and whether the worker wore and removed his or her gloves. Data were also recorded on whether hand sanitizer was used, but those data are not discussed here. Finally, the specialist recorded data on the physical environment during the observation, such as proximity of the observed worker to the nearest sink.

Data analysis. We used multivariate logistic regression models to determine the combination of factors that best explained hand hygiene practices. Stepwise regression procedures were used to guide the determination of the explanatory variables included in the final models. A model was conducted for appropriate hand washing, which entailed (i) removing gloves, if worn; (ii) placing hands under running water; (iii) using soap; and (iv) drying hands with paper towels, cloth towels, or hot air. A model was also conducted for glove use, which entailed wearing gloves during work activities. For these models, the level of analysis was activity; thus, the outcome variables were dichotomous and indicated whether the hygiene practice (hand washing or glove use, depending on the model) occurred with each observed activity for which hand washing is recommended. Because the observed worker in each restaurant engaged in multiple activities during the observation, activity was treated as a repeated measure in all analyses. The state in which data collection took place was included as a control variable in both regression models. Preliminary forward stepwise regression analyses were conducted with the SAS software package (SAS, Cary, N.C.); all other regression analyses were conducted with the SUDAAN software package (RTI International, Research Triangle Park, N.C.) to account for the repeated measures aspect of these data.

Table 2 describes the explanatory variables included in the regression models. These fell into the categories of worker activity

(activity type, worker busyness, hands washed, gloves worn), restaurant characteristics (ownership: chain versus independent, complex food preparation processes [i.e., holding, cooling, reheating or freezing of foods]), worker training (hand hygiene taught to food workers, food safety training provided to food workers, management certification required), physical environment (multiple hand sinks, hand sink closeness to worker, hand sink in worker's sight, hand washing supplies at hand sinks, glove supplies in food preparation areas), and social environment and management (worker visibility to manager, worker visibility to customers, management encouragement of hand washing). All explanatory variables were included in the initial regression model of appropriate hand washing. All explanatory variables, except those expected to only be related to hand washing (multiple hand sinks, hand sink closeness to worker, hand sink in worker's sight, hand washing supplies at hand sinks, and management encouragement of hand washing) were included in the glove-use model. Additionally, whether gloves were worn in conjunction with the activity was included as an explanatory variable in the hand washing model and whether hands were washed appropriately in conjunction with the activity was included as an explanatory variable in the glove-use model. Odds ratios (ratios above 1 indicate that the hygiene behavior was more likely to occur with the activity; ratios below 1 indicate that the hygiene behavior was less likely to occur with the activity) and Wald *F* test probability values (values at 0.05 or lower are considered significant) are provided for each explanatory variable included in the final regression models.

RESULTS

Descriptive analyses. Of the 1,073 establishments we contacted, 808 were eligible to participate (i.e., met our definition of a restaurant, were open for business, and did not belong to a chain with an already participating restaurant). Of these, 333 agreed to participate, yielding a response rate of 41%. Because of missing information, data are reported on only 321 restaurants. Sixty-one percent (196) of the restaurants were independently owned, 38% (121) were chains or franchises, and 1% (4) had missing data concerning ownership.

The median duration of individual worker observations was 48 min (25% quartile = 45; 75% quartile = 48). Observed workers engaged in a total of 2,195 activities falling into one of the defined activity categories. The estimated median number of activities observed per hour per worker was 8.6 (25% quartile = 5; 75% quartile = 12.3). The most frequent activity, accounting for 36% of all activities (786 activities), was handling dirty equipment, followed by food preparation (23%; 514 activities); preparing raw animal product (17%; 384 activities); putting on gloves for food preparation (10%; 224 activities); touching the body (9%; 197 activities); eating, drinking, or using tobacco (3%; 77 activities); and coughing, sneezing, or using tissue (1%; 13 activities). Because of the low frequency of the last two groups of activities, they were combined into one category called ''eating/coughing'' for the remaining analyses.

Workers washed their hands appropriately (i.e., removed gloves, if worn; placed their hands under running water; used soap; and dried their hands with paper or cloth towels or hot air) in conjunction with 27% (588 of 2,195 activities) of all activities. They wore gloves during 28% (608 of 2,195 activities) of all work activities. More detailed descriptive data on these hand hygiene activities can be found in Green et al. *(14).*

TABLE 3. *Logistic regression model of appropriate hand washing (*n *= 2,149)*

Hand washing	Odds ratio[a]	Lower 95% CI[b]	Upper 95% CI
Worker activity			
Activity type			
Food preparation (reference)	—	—	—
Putting on gloves for food preparation	0.64	0.34	1.22
Preparing raw animal product	0.44*[c]	0.31	0.61
Eating/coughing	0.48*	0.31	0.74
Handling dirty equipment	0.13*	0.07	0.23
Touching body	0.39**	0.20	0.74
Worker was busy	0.45*	0.30	0.66
Worker wore gloves during the activity	0.41*	0.26	0.67
Worker training			
Workers provided with food safety training	1.81***	1.06	3.12
Physical environment			
Multiple hand sinks	1.63***	1.07	2.47
Hand sink in worker's sight	1.93**	1.15	3.23

[a] Odds ratios above 1 indicate that hand washing was more likely to occur with the activity; odds ratios below 1 indicate that hand washing was less likely to occur with the activity.
[b] CI, confidence interval.
[c] Wald *F* test probability values: * $P < 0.001$, ** $P < 0.01$, *** $P < 0.05$.

Appropriate hand washing. The final regression model for appropriate hand washing was comprised of the variables that best accounted for the variance in appropriate hand washing ($R^2 = 0.142$). Those included activity type, worker busyness, glove use, food safety training provided to food workers, multiple sinks, and hand sink in worker's sight (Table 3). Appropriate hand washing was more likely to occur with food preparation activities than with all other activities except putting on gloves. Appropriate hand washing was also more likely to occur in restaurants where food workers received food safety training, where there were multiple hand sinks, and where a hand sink was in the observed worker's sight. Appropriate hand washing was less likely to occur when workers were busy and when gloves were worn at the point at which hand washing should occur.

Glove use. The activities of food preparation and putting on gloves for food preparation were combined for these analyses. Specifically, all activities categorized as putting on gloves for food preparation were recategorized as food preparation activities in which gloves were worn. The final regression model for glove use was composed of the variables that best accounted for the variance in glove use ($R^2 = 0.235$). Those included activity type, worker busyness, hand washing, restaurant ownership, and glove supplies in food preparation areas (Table 4). Glove use was more likely

TABLE 4. *Logistic regression model of glove use (*n *= 2,160)*

Glove use	Odds ratio[a]	Lower 95% CI[b]	Upper 95% CI
Worker activity			
Activity type			
Food preparation (reference)[c]	—	—	—
Preparing raw animal product	0.69	0.41	1.18
Eating/coughing	0.17**[d]	0.05	0.62
Handling dirty equipment	0.42*	0.27	0.67
Touching body	0.52*	0.30	0.92
Worker was busy	0.51**	0.31	0.83
Worker washed hands along with activity	0.37*	0.23	0.58
Restaurant characteristics			
Restaurant ownership—chain	3.41*	1.91	6.09
Physical environment			
Glove supplies in food preparation areas	5.47*	2.88	10.38

[a] Odds ratios above 1 indicate that glove use was more likely to occur with the activity; odds ratios below 1 indicate that glove use was less liketly to occur with the activity.

[b] CI, confidence interval.

[c] The activities of food preparation and putting on gloves for food preparation were combined for this analysis.

[d] Wald F test probability values: * $P < 0.001$, ** $P < 0.01$, *** $P < 0.05$.

to occur during food preparation activities than during activities involving eating/coughing, handling dirty equipment, and touching the body. Glove use was also more likely to occur in chain restaurants and in restaurants with glove supplies in the food preparation areas. Glove use was less likely to occur when workers were busy and during activities with which workers washed their hands appropriately.

DISCUSSION

Both appropriate hand washing and glove use were related to activity type—workers were more likely to wash their hands appropriately and wear gloves with food preparation than with most other activities. This finding is encouraging, for it suggests that at least some workers understand the need to protect food from hand contamination. Appropriate hand washing and glove use were also related to worker busyness—these hand hygiene behaviors were less likely to occur when workers were busy (i.e., engaged in relatively larger numbers of activities needing hand washing). Because food workers have identified time pressure as a barrier to engaging in safe food preparation practices *(6, 12, 20),* these results are perhaps not surprising. However, given that time pressure is also inherent to the food service industry, these results are troubling. We have previously suggested that restaurant managers ensure adequate staffing for the workload and emphasize the importance of food safety over speed to combat the effects of time pressure on safe food preparation practices *(12).* Clayton and Griffith *(5)* have proposed that restaurants evaluate their food preparation activities in light of the frequency with which hand washing is needed. A reduction in the number of needed hand washings may lessen time pressure and thereby increase the likelihood that food workers will engage in the remaining needed hand washings and don gloves when appropriate.

Hand washing and glove use were related to each other—appropriate hand washing was less likely to occur with activities in which gloves were worn than with activities in which gloves were not worn. These results suggest that workers who wear gloves do not remove them and wash their hands as they should. Although some researchers and practitioners have contended that glove use can promote poor hand washing practices *(10, 15, 21),* little data exists on this issue. More research is needed to understand the relationship between glove use and hand washing.

Appropriate hand washing was positively related to two factors associated with restaurants' hand sinks: multiple hand sinks and a hand sink in the worker's sight. These factors contribute to sink accessibility, which likely promotes hand washing. Appropriate hand washing was also more likely to occur in restaurants in which the manager reported that food workers received food safety training. This finding is consistent with other findings of an association between knowledge and training and safe food preparation practices *(4).*

Glove use was related to restaurant ownership—workers were more likely to wear gloves in chain restaurants than in independent restaurants. This finding suggests that glove use may be determined, at least in part, by restaurant management. Some types of restaurants, such as chains, may be more likely to require and institutionalize glove use. Gloves were also worn more often when glove supplies were accessible in food preparation areas. As with sinks and hand washing, glove accessibility likely promotes glove use.

The findings of this study indicate that a number of factors are related to hand hygiene practices and support those who have suggested that food worker hand hygiene improvement requires more than the provision of food safety education. Instead, improvement programs must be multidimensional and address additional factors *(8, 26, 27).* These factors may include, but are certainly not limited to, those found to be significant in this study: activity type, worker busyness, number and location of hand sinks, availability of supplies (e.g., gloves, soap, towels), restaurant ownership, and the relationship between prevention methods (i.e., glove use and hand washing).

The FDA recommends that barriers such as gloves be used to prevent hand contact specifically with RTE food. Although we examined glove use during food preparation, we did not distinguish between RTE food and non-RTE food (other than raw meat or poultry). Explanatory variables for glove use with RTE food may differ from those identified in our study. Additionally, because of concerns about data collection complexity, we did not collect data on some hand hygiene behaviors that are considered important by the FDA *(29).* For example, we did not measure how long workers washed their hands or whether they cre-

ated friction between their hands. The inclusion of such factors may have affected our findings.

There are a number of factors that may impact hand hygiene behavior that we did not examine in this study. For example, we did not measure individual characteristics of the observed food workers, such as age, gender, and food safety knowledge, attitudes, and beliefs. Evidence suggests that such individual characteristics influence food safety behavior *(2, 13)*. This study also does not allow us to make causal inferences about the relationships among variables. For example, the relationship between hand washing and the presence of a hand sink in the observed worker's sight was significant and positive. However, we cannot determine if the presence of a sink in sight causes workers to wash their hands more frequently or if there is some other explanation for the relationship (e.g., workers choose to work close to a sink because they plan to wash their hands frequently). Thus, although our data indicate that there are significant relationships between a number of factors and hand hygiene behavior, more research is needed to determine the causal nature of those relationships.

ACKNOWLEDGMENTS

We thank Jim Mann with the Handwashing Leadership Forum for allowing portions of the "Handwashing for Life" videotape to be used in our data collection training. We also thank Curtis Blanton (CDC) and Michael Penne (RTI International) for their assistance with data analysis and E. Scott Brown (Lockheed Martin Information Technology) for developing the study database. Lastly, we thank the restaurant managers and owners who agreed to participate in the study.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-013

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Motion-Activated Handwashing Sinks

Issue you would like the Conference to consider:

The FDA made editorial changes to the Food Code in May 1, 2010, June 3, 2013, and March 6, 2014 and issued a response to the question of whether Section 5-202.12 (C) of the 2013 FDA Code addressed water-conserving motion sensor activated faucets if reactivation is by movement of the hands. FDA determined that even though § 5-202.12 (c) states that self-closing, slow-closing, or metering faucets at a handwashing sink shall provide a flow of water for at least 15 seconds without the need to reactive the faucet, it does not apply in the case of motion-activated handwashing faucets. If this determination has been made my FDA for almost 5 years and these motion-activated faucets are in use throughout the industry then it should be clearly stated in the Food Code that movement of hands is an acceptable means of reactivation if hands are not contaminated in the process.

Public Health Significance:

The attached letter for supporting documentation shows FDA justification that "there does not appear to be a conflict in achieving a proper handwashing per Section 2-301.12 with the use of water conserving motion-sensor activated handwashing faucets, as there would not be a restricted water flow or restricted use of the hands with the reactivation of the sensors".

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined)*:*

Section 5-202.12

(C) A self-closing, slow-closing, <u>motion-activated</u> or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

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Supporting Attachments:

- "Motion Sensor Activated Faucets v03"

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.

Reference Document: 2009 FDA Food Code

Provision(s): Paragraph 5-202.12 (C)

Document Name: Motion Sensor Activated Faucets v03

Date: May 1, 2010, Editorial Change June 3, 2013, Editorial Change March 6, 2014

Question: Does Food Code paragraph 5-202.12 (C) apply to water-conserving motion sensor activated faucets if re-activation is by movement of the hands under the faucet without physical contact with the fixture?

Response:
Paragraph 5-202.12 (C) of the Food Code states that self-closing, slow-closing, or metering faucets at a handwashing sink shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet. This paragraph (5-202.12 (C)) does not address the use of motion-activated handwashing faucets that can provide a flow of water for the required time period without restriction of handwashing during reactivation of the faucet. There does not, however, appear to be a conflict in achieving a proper handwashing per Section 2-301.12 with the use of water conserving motion-sensor activated handwashing faucets, as there would not be a restricted water flow or restricted use of the hands with the reactivation of the sensors.

References:
1. 2009 Food Code, 2-301.12 Cleaning Procedure, 2-301.14 When to Wash, 2-301.15 Where to Wash, 5-202.12 (C) Handwashing Sink, Installation, and Annex 3, Section 2-301.12.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-014

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:

Bandage, Finger Cot, and Stall contamination

Issue you would like the Conference to consider:

The addition of a requirement in the Food Code of the necessity to wear a glove over on any cuts on hands, fingers or wrists when working with exposed food.

Public Health Significance:

The possible physical contamination of a bandage, finger cot or stall in exposed food products from employees. Additionally, bandages, finger cots and stalls are not effectively cleaned with normal handwashing procedures.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined):

3-401 Bandages, Finger Cots, or Stall products on Wrists, Hands or Fingers

3-401.13 An impermeable cover such as a bandage, finger cot or stall located on the wrist, hand or finger of a food employee working with exposed food shall be covered with a Single-Use glove. [Pf]

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-015

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Issue History:

This is a brand new Issue.

Title:

Require disposable gloves at foodservice handwash sinks

Issue you would like the Conference to consider:

Amend the 2013 FDA Food Code to require each handwashing sink located in food preparation and service areas to be provided with a supply of disposable single-use gloves, if utilized.

Public Health Significance:

The proposed new language addresses a major risk factor and is designed to facilitate and achieve immediate corrective action while also supporting long term corrective action. Repeated on site correction changes behavior patterns which leads to long term compliance and lays a foundation that will improve hand hygiene habits.

The location and accessibility of disposable single-use gloves at foodservice handwashing sinks offers an intervention strategy and provides a solution to high priority Food Code violations in Section 2-301.14 (H). If gloves are utilized, they need to be located at the point where handwashing occurs. This will serve to remind and encourage proper handwashing prior to the use of gloves.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that a new Section be added to the 2013 Food Code as follows (language to be added is underlined):
6-301.15

Each handwashing sink located in food preparation and service areas shall be provided with a supply of disposable single-use gloves if utilized.[Pf]

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Conference for Food Protection
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Issue: 2016 III-016

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Issue History:

This is a brand new Issue.

Title:

Employee Health Interventions – Reducing Norovirus

Issue you would like the Conference to consider:

The employee health section of the 2013 FDA Food Code contains provisions for controlling the transmission of norovirus through exclusion and restriction of ill food employees. This Issue seeks to align the criteria for a food employee that is experiencing symptoms of vomiting and diarrhea with those for a food employee diagnosed with an infection from norovirus. This Issue also seeks to remove the distinction in criteria for exclusion and restriction between a highly susceptible population (HSP) and non-HSP.

Public Health Significance:

(note: specific references are noted numerically in parenthesis and can be found on the attached document titled: References-FDA Food Code Employee Health Interventions, Reducing Norovirus)

Norovirus is recognized as the most common cause of acute gastroenteritis (AGE), defined as vomiting or diarrhea, in all age groups worldwide and the leading cause of foodborne disease outbreaks in the United States (1-3). CDC estimates that each year in the U.S., norovirus causes 19-21 million illnesses and contributes to 56,000-71,000 hospitalizations and 570-800 deaths (4). Foodborne norovirus disease costs approximately two billion dollars each year in healthcare expenses and lost productivity alone (5). As highlighted by recent examples, the cost of norovirus outbreaks to the food service industry is also considerable. Consuming food that has been contaminated by infected food workers during preparation in restaurants and other retail settings has been identified as the most common scenario of foodborne norovirus outbreaks (3).

Vomiting and diarrhea are the most common symptoms of norovirus illness. However, food employees, like most people, do not routinely seek medical attention for these symptoms. If they do, they are likely not tested for norovirus by their health practitioner. As a result, the vast majority of norovirus illnesses are not diagnosed by a healthcare practitioner. Individuals infected with norovirus generally have symptoms for 1-3 days, but can shed

virus for an average of 4 weeks after infection and can shed between 10^5- 10^{11} viral copies per gram of feces, even if they are asymptomatic (6). Infected individuals can shed copious amounts of the virus long after symptoms have ended, and only 18-2,800 viral particles are required to infect a healthy individual (7,8).

Norovirus is highly transmissible and can readily cause outbreaks in a wide variety of settings (9). The virus can be transmitted not just through food, but through other modes, such as contact with contaminated environmental surfaces and direct person-to-person contact. Further, the virus can persist and remain infectious on environmental surfaces for days to weeks and can withstand both heating and freezing temperatures (10). As such, an infected individual that is restricted from food handling, but not excluded from a food establishment, can still readily cause an outbreak.

Currently, the 2013 Food Code recommends exclusion for a minimum of 24 hours after symptoms subside for food employees with vomiting or diarrhea symptoms. For symptomatic food employees diagnosed with norovirus infection, the Food Code recommends exclusion for a minimum of 48 hours after symptoms subside. For asymptomatic food employees with a norovirus diagnosis, the Food Code recommends exclusion for those working in an establishment serving a highly susceptible population (HSP), and restriction for those working in an establishment that does not serve a highly susceptible population.

Since employee health provisions for norovirus were originally placed in the 2005 Food Code, there has not been a recognized decline in the incidence of foodborne outbreaks caused by norovirus (4, 11). Several factors influence the likelihood of norovirus transmission from an infected food employee in the retail setting, such as:

- Norovirus is a fecal-oral route pathogen that is commonly spread when food is contaminated by infected food employees (9).
- Norovirus has a low infectious dose and can be shed by infected individuals even after symptoms cease (6-8).
- Norovirus persists on food contact and non-food contact surfaces (10).
- 20% of food workers report having worked while ill with vomiting or diarrhea during at least one shift per year, 61% of which reported working two or more shifts while ill (12), suggesting there may be at least 2.5 million shifts worked while ill with vomiting or diarrhea each year in the U.S. (13).
- Infected food employees that are restricted, but not excluded, may still work with food items, such as wrapped food and food service utensils.

The continued predominance of norovirus as the leading cause of foodborne disease outbreaks over the past decade suggests that the current recommendations in the Food Code may not be adequate. In an effort to address this public health concern, FDA and CDC would like to modify the employee health controls/interventions to aid in the reduction of foodborne norovirus outbreaks.

The longer we can keep infected people away from working with food, the greater we reduce the likelihood of occurrence of foodborne illness caused by norovirus. By amending the provisions of the Food Code to recommend a minimum exclusion of 48 hours after symptoms subside for food employees with vomiting and diarrhea in general (with a diagnosis of norovirus illness OR not) and eliminating the current distinction between HSP

and non-HSP settings within the employee health provisions specific to norovirus, we can further reduce the risk of transmitting norovirus at the retail level.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the 2013 Food Code, Part 2-2 Employee Health, Subpart 2-201 *Responsibilities of Permit Holder, Person in Charge, Food Employees, and Conditional Employees* be amended to reflect the following changes:

1. Extend the exclusion period for food employees symptomatic with vomiting or diarrhea and NO diagnosis of norovirus illness from a minimum of 24 hours after becoming asymptomatic to a minimum of 48 hours after becoming asymptomatic.
2. Remove the distinction in criteria for exclusion and restriction in highly susceptible populations (HSP) and non-HSP establishments, thereby requiring exclusion until a minimum of 48 hours after becoming asymptomatic in all settings.
3. Remove the allowance to restrict a food employee that has been diagnosed with an infection from norovirus (exclusion criteria only).
4. Extend the exclusion period for a food employee who is asymptomatic and diagnosed with norovirus illness from a minimum of 24 hours to a minimum of 48 hours.

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Supporting Attachments:

- "References- FDA Food Code Employee Health Interventions, Reducing norovirus"

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Attachment A - References (FDA Food Code Employee Health Interventions – Reducing Norovirus)

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-017

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Issue History:

This is a brand new Issue.

Title:

Amend Food Code – Clarify Clean-up of Vomiting and Diarrheal Events

Issue you would like the Conference to consider:

A recommendation is being made to change the 2013 FDA Food Code, Section 2-501.11 Clean-up of Vomiting and Diarrheal Events to include a clarification of specific written procedures for managing vomit events. FDA Food Code 2-501.11 discusses general information on addressing vomit and diarrheal events but current science has evolved sufficiently to provide more details on procedures to address risk factors.

Public Health Significance:

Human norovirus (NoV) causes a disease characterized by vomiting- its hallmark symptom, with nausea, diarrhea, abdominal pain, headache, and low-grade fever. By virtue of the sheer numbers of cases per year, even a low likelihood of severe disease (0.03%) or death (<0.1%) will still result in a large number of serious outcomes (Scallan et al., 2011). Current estimates are that human NoVs are responsible for 56,000 - 71,000 hospitalizations and 570 - 800 deaths annually (Hall et al., 2013).

Infected individuals shed high concentrations (up to 1011 genomic copies/g feces measured by RT-qPCR) of virus in their feces before, during and after illness (Atmar et al., 2008). In human challenge studies with Norwalk virus, virus shedding was first detected a median of 36 hours (ranging 18-110 hours) after exposure and lasted a median of 28 days (range of 13-56 days). Peak Norwalk virus concentration (median of 9.5 x 1010 genomic copies/g feces) occurred 4 days post-challenge and then decreased after 2 weeks.

Aside from the well-recognized impact that fecal material plays in NoV transmission, vomitus can also play a major role. In fact, aerosolization of NoV caused by vomiting has long been believed to be important to transmission (Sawyer LA et al., 1988; Gellert and Glass 1994; Caul EO 1994; Chadwick and MaCann 1994; Marks et al., 2000; Marks et al., 2003). Greenberg et al., 1979 estimated that 3 x 107 virus particles are released in 30 ml of vomitus based on electron microscopic analysis. At the time of this writing, these were the only quantitative data available. Further, human NoV have been detected in both oral

mouthwash and fecal samples collected from individuals who had experienced illness for over three weeks. Human NoV detection in mouthwash samples correlated with vomiting incidents (Kirby et al., 2010). There is also a substantial body of evidence supporting a role for vomiting in the transmission in human NoV, including outbreaks occurring in hotels, schools, aircraft, concert halls and cruise ships (Cheesbrough et al., 2000; Kimura et al., 2011; Marks et al., 2000; Thornley et al., 2011; Marks et al., 2003; Evans et al., 2002; Cheesbrough et al., 1997; Gallimore et al., 2006; Gallimore et al., 2008; Isakbaeva et al., 2005). It has been hypothesized that widespread environmental contamination due to virus aerosolization (Marks et al., 2000; Marks et al., 2003) has been and important contributing factor in such outbreaks.

Instances of vomiting have been implicated as the source of human NoV contamination of ready-to-eat foods. For instance, an ill baker vomited in a sink prior to preparing bread rolls for a large buffet lunch, causing 250 individuals to become ill (deWit et al., 2007). In another example, a kitchen assistant vomited in a sink, resulting in contamination of potato salad that caused half of over 100 guests at a wedding reception to become ill (Patterson et al., 1997). Vomiting into a waste bin at a restaurant was also implicated as the source of NoV contamination of an antipasti platter that resulted in workers and over 350 patrons getting sick (CDC 2007).

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending the 2013 Food Code be amended to include clarifying language for written procedures as follows (new language is underlined):

2-501.11 Clean-up of Vomiting and Diarrheal Events.

A FOOD ESTABLISHMENT shall have <u>written</u> procedures for EMPLOYEES to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the FOOD ESTABLISHMENT. The procedures shall address the specific actions EMPLOYEES must take to minimize the spread of contamination and the exposure of EMPLOYEES, consumers, FOOD, and surfaces to vomitus or fecal matter.

<u>In the case of a vomit event, these written procedures must include cordoning off an area of no less than 25 feet in diameter, initial cleaning of gross visible contamination with water to minimize spread and take into account the likelihood of aerosolization of virus particles. Procedures must also include subsequent disinfection with 1000 ppm chlorine (or other disinfectant registered as effective against norovirus by the Environmental Protection Agency (EPA). Procedures must also include steps for segregating cleaning and sanitation equipment from food preparation, storage and handling areas. Procedures also must include a training program for clean-up employees, include the use of personal protective equipment (PPE), and the monitoring of clean-up employees for symptoms for 72 hours post event</u>.

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Supporting Attachments:

- "Detection and quantification of airborne norovirus during outbreaks in heal"
- "Aerosolization of a Human Norovirus Surrogate, Bacteriophage MS2, during Si"

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Detection and quantification of airborne norovirus during outbreaks in healthcare facilities

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40-WORD SUMMARY

This study investigates the presence of norovirus bioaerosols during gastroenteritis outbreaks in healthcare facilities. It shows the presence and the resistance of bioaerosols to the stress of aerosolization, suggesting a potential mode of transmission for norovirus.

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ABSTRACT

Background. Noroviruses are responsible for at least 50% of all gastroenteritis outbreaks worldwide. Noroviruses GII can infect humans via multiple routes including direct contact with an infected person, contact with fecal matter or vomitus, and with contaminated surfaces. Though norovirus is an intestinal pathogen, aerosols could, if inhaled, settle in the pharynx and later be swallowed. The aims of this study were to investigate the presence of norovirus GII bioaerosols during gastroenteritis outbreaks in healthcare facilities as well as studying the *in vitro* effects of aerosolization and air sampling on the noroviruses using murine norovirus as a surrogate.

Methods. A total of 48 air samples were collected during norovirus outbreaks in 8 healthcare facilities. Samples were taken 1 m away from each patient, in front of the patient's room and at the nurses' station. The resistance to aerosolization stress of murine norovirus MNV-1 bioaerosols was also tested *in vitro* using an aerosol chamber.

Results. Norovirus genomes were detected in 6/8 healthcare centers. The concentrations ranged from $1.35x10^1$ to $2.35x10^3$ genomes per m^3 in 47% of air samples. Norovirus MNV-1 preserved its infectivity and integrity during *in vitro* aerosol studies.

Conclusion. Norovirus genomes are frequently detected in the air of healthcare facilities during outbreaks, even outside patients' rooms. In addition, *in vitro* models suggest this virus may withstand aerosolization.

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INTRODUCTION

Noroviruses are non-enveloped, single-stranded RNA viruses, belonging to the Caliciviridae family. They are the most common cause of epidemic gastroenteritis, responsible for at least 50% of all gastroenteritis outbreaks worldwide [1]. They are a major cause of foodborne illnesses and one of the major pathogens responsible for nosocomial infections [2-4]. Gastroenteritis outbreaks mostly occur in facilities where hygiene is compromised and contact between infected patients and personnel is intense, such as hospitals and nursing homes [7]. In the United-States, norovirus infections represent 2 millions of outpatient visits, 414 000 emergency room visits, 56 000 -71 000 hospitalizations and up to 800 deaths each year [8]. Children, elderly, immunocompromised persons and people living/working in healthcare facilities are at higher risk of contracting the disease [5].

Noroviruses are highly contagious, with an infectious dose ranging from 18 to 2 800 particles, making their spread difficult to prevent [10]. A descriptive study performed in 2011-2012 to estimate the incidence of norovirus outbreaks in hospitals and nursing homes in Catalonia demonstrated the occurrence of norovirus to be very high and associated with significant mortality [11] and that even small amount of contamination can lead to a potential risk to public health [10, 12]. Multiple routes of infection transmission have been documented including: direct contact with an infected person and/or fecal matter and vomitus droplets, and contact with contaminated surfaces [5, 9]. Indirect evidence suggests that norovirus could be transmitted through the airborne route and this route of transmission has already been suggested in literature [13-16]. Nenonen *et al.* showed high nucleotide similarity between norovirus GII.4 strains present in the dust of rooms of patients infected by norovirus [17]. However, norovirus has never

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been detected in the air of hospitals outside patients' rooms and the infectious potential of airborne noroviruses has never been studied since this virus was, until very recently, not culturable [18]. Assessing the norovirus' capacity to withstand the stress associated with aerosolization is essential to investigate its potential for airborne dissemination. Several models have been developed to assess the persistence of norovirus infectivity in the environment and surrogates for human noroviruses are used: feline calcivirus, bacteriophages MS2 and murine norovirus (MNV) [12]. Murine norovirus (MNV-1) shares similar genetic and structural features with the human norovirus therefore is a culturable surrogate [19] and used to study the resistance to environmental stress of human norovirus [12].

A virus is generally considered infective if its integrity is documented. In recent years, a new technique, propidium monoazide (PMA), has been developed to assess the structural integrity of microorganisms and differentiate intact and membrane compromised microorganisms. It is a DNA/RNA intercalating dye with a photo-inducible azide group, which allows covalently cross-links with RNA after an exposure to bright light. In virology studies, PMA only penetrates viruses with damaged capsid and can hence differentiate intact from compromised virions that will not be amplified by PCR. This method was previously used to determine the integrity of norovirus particles [20].

The general aim of this study was to investigate the potential for airborne transmission of human norovirus. To achieve this goal, two distinct and complementary objectives were designed: 1) quantify the presence of norovirus GII in air samples during gastroenteritis outbreaks in healthcare facilities and 2) study the virus' resistance to aerosolization by assessing its integrity when subjected to *in vitro* aerosolization stress using murine norovirus as surrogate. Integrity

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preservation was determined by culture and PMA. The use of PMA qPCR method as an indicator of murine norovirus integrity was also validated.

MATERIALS AND METHODS

Field study

Sampling human norovirus in health-care facilities

Air sampling was performed in 8 healthcare facilities of the Quebec City area (Canada) when viral gastroenteritis outbreaks occurred. Norovirus was established as the causal agent of the gastroenteritis outbreaks (PCR) by the public health laboratory of the Quebec Province (LSPQ). Air samples were taken in 3 distinct locations on patients wards: (1) inside the room of patients with gastroenteritis symptoms (<24h); (2) in the hallways or the common room outside of the rooms of patients with symptoms; and (3) at the nurses' station. A total of 48 air samples were collected: 26 from patient rooms, 16 from hallways/common areas and 6 from nurse's stations. Air samples were taken with the Coriolis µ® (Bertin Technologies, St-Berthely, France) set at 200 L/min for 10 minutes (sampler D50 <0,5µm) and 15 mL of phosphate buffered solution (PBS) was used for fluid collection (Lonza, Bâle, Switzerland). Samples were concentrated on Amicon Ultra-15 centrifugal filter unit (porosity of 50 kDa (Millipore, Billerica, MA)) to a final volume of 400 µl. Concentrated air samples were spiked with 1 µl of a MS2 bacteriophage suspension (10^6 ge/ml) as an internal control for RNA extraction and qPCR.

RNA isolation of human norovirus

Viral RNA was isolated using the MagMax® Viral RNA Isolation Kit (Life Technologies, Carlsbad, CA). Total RNA was eluted and immediately transcribed into complementary DNA or frozen at -80ºC until RT-PCR was performed.

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In vitro experiments

Murine norovirus and cells

MNV-1 and macrophages RAW 264.7 cells were cultivated as mentioned by Wobus *et al*., in presence of macrophages RAW 264.7 in DMEM (Cellgro, Mediatech, Herndon, Virginia, United States) [21]. An initial stock at 10^7 PFU/ml was prepared, divided into subsamples (70 ml of MNV-1 at 10^7 PFU/ml) for each experiment and then kept at -80ºC.

MNV-1 aerosolization

Aerosolization was performed in an aerosol chamber (GenaMini, SCL Medtech Inc., Montreal, Canada). Sixty-five mL of MNV-1 (10^7 PFU/ml) in DMEM were nebulized (Single-Jet Atomizer, model 9302, TSI Inc., Shoreview, MN) at a rate of 3 L/min using HEPA filtered air. The average liquid flow rate of the nebulizer was of 0.18 ± 0.2 mL per min. Aerosols were dried through a desiccator (EMD Chemicals Inc., Gibbstown, NJ,) allowing the formation of droplet nuclei before entering the chamber and were diluted with HEPA-filtered dry air at a rate of 23 L/min [22]. An Aerodynamic Particle Sizer (APS; model 3321, TSI Inc.) was used to monitor particle size distribution and concentration during aerosol sampling. Temperature and relative humidity were also measured.

Aerosols sampling

Air samples were collected using National Institute for Occupational Safety and Health (NIOSH) 2-stage cyclone aerosol sampler prototype (NIOSH-251, CDC/NIOSH, Morgantown, WV) [23, 24] for 25 min at 10 L/min then particles were eluted from the first stage and from the filter using 4 ml PBS and from the second stage with 1 ml PBS using an orbital shaker (WIS Biomed, San

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Mateo, CA) for 15 min at room temperature. All eluents were pooled together. Aerosolization experiments were performed five times. Viral culture, RNA extraction and cDNA synthesis were performed the same day as the aerosolization experiments took place.

Quantification by plaque assay

The plaque assays were performed as previously described by Gonzalez-Hernandez *et al.* [25] except that plaques were visualized by crystal violet staining after fixation with formaldehyde. Each plaque assay had one negative control well.

RNA isolation of murine norovirus

Total viral RNA was extracted using the QIAamp viral RNA Mini kit (Qiagen, Mississauga, Ontario, Canada). Total RNA was eluted in 80 µl of elution buffer, supplied with the kit.

Viral genome quantification

Viral genomes cDNA synthesis

RNA was converted to cDNA using the iScript ™ cDNA Synthesis Kit (BioRad, Hercules, CA), following manufacturer instructions.

Quantification of viruses by qPCR

Separate reactions were performed for the detection of MS2 (internal control), human norovirus GII from field air samples and MNV-1 from *in vitro* study air samples. MS2 genomes were detected using qPCR described by [22]. Every sample was positive for MS2, which shows that the RNA extraction and cDNA synthesis were efficient.

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Detection of norovirus GII cDNA and MNV-1 was done using qPCR as described by Kageyama *et al*. [26] and Girard *et al.* [27] respectively. Quantification was performed using a standard curve of a ten-fold dilution series of MNV-1 plasmid DNA preparation or norovirus GII plasmid DNA preparation [27]. Serial 10-fold dilutions from 10^1 to 10^7 molecules per reaction tube were used. The curve was prepared using the pGC™ Blue Cloning & amplification kits (Lucigen, Middleton, WI). The DNA plasmids were purified using the Qiagen plasmid mini kit and were quantified with a NanoDrop™ 2000 spectrophotometer (Thermo scientific, Waltham, MA).

PMA- qPCR

This method, previously used with norovirus by Parshionikar *et al.* [20] allows quantification of virus with an intact capsid. Propidium monoazide (PMA, Biotium Inc., Hayward, CA, USA) was dissolved in 20% dimethyl sulfoxide to create a 5 mM stock solution and stored at -20°C in the dark. 4.2 µl of PMA™ was added to 140 µl of air samples aliquots to a final concentration 150 µM in light-transparent 1.5 ml tubes (Fisher Scientific Co., Ottawa, ON). Following an incubation period of 5 min in the dark with occasional mixing, samples were exposed to light for 10 min using a PMA-Lite LED Photolysis Device (a long-lasting LED Lights with 465-475 nm emission for PMA™ activation; Biotium Inc.). Viral RNA extraction was performed as mentioned previously.

RESULTS

Field study

Norovirus GII genomes were detected in air samples from six of the eight healthcare facilities (75%) and in 23/48 air samples. Norovirus RNA was detected in fourteen symptomatic patient's

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rooms out of twenty-six (54%), six hallways out of sixteen (38%) and three nurse stations out of six (50%). Positive samples concentrations ranged from $1.35x10^1$ to $2.35x10^3$ genomes per m^3 (Table 1).

***In vitro* experiments**

For all experiments, the aerosols median mass aerodynamic diameter in the GenaMini chamber ranged from 0.89 to 1.08 µm, and the total particles concentration was from $2.42x10^4$ to $5.37x10^4$ particles per cm^3. The RH and temperature inside the chamber fluctuated between 5.9 ± 1.9% and 24.1 ± 0.9°C. The concentration of infectious viruses, total genomes and intact viruses into the nebulizer of the aerosol chamber did not vary significantly between the beginning and the end of the aerosolization process (Figure 1). The concentrations of norovirus MNV-1 in the nebulizer were $1x10^7$ infectious virus/ml (Figure 1A), $2\text{-}4x10^9$ intact viruses/ml (Figure 1C), and $6\text{-}8x10^{10}$ genomes/ml (Figure 1B) as determined by plaque assay, qPCR and PMA-qPCR, respectively.

Using PMA qPCR, it has been possible to determine the relative percentage of intact norovirus MNV-1 within the NIOSH-251. Figure 2 shows that the NIOSH-251 recovered more than 89% intact viruses. The cultivable-to-genome ratio in the nebuliser and the sampler was calculated and the result was converted into a percentage to determine the norovirus resistance to aerosolization and air sampling. The relative percentage of norovirus MNV-1 infectivity varied from 76% to 86%. The NIOSH-251 was efficient in preserving MNV-1 infectivity (Figure 2).

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DISCUSSION

This study provides original quantitative data regarding the airborne dissemination of norovirus in healthcare facilities and documents for the first time widespread dissemination of human norovirus GII in the air of healthcare facilities during gastroenteritis outbreaks. The lack of positive norovirus detection does not necessarily mean there was no human norovirus in the air but simply that the detection limit of the test was reached. The air from patient rooms may contain up to 2000 genomes/m^3, and considering that an average human breaths approximately 6 liters of air per minute, a healthcare worker could inhale up to 60 copies of human norovirus during a 5-minute stay in the room of a symptomatic patient. For some individuals, this quantity could be sufficient to cause the disease.

Many processes can lead to the creation of norovirus aerosols and several sources can be identified such as resuspension from fomites [28-32], flushing toilets [33, 34], vomit droplets [16] and healthcare workers (serving as vector for aerosolized particles) [3]. All of these sources need to be considered to avoid epidemics. Overall, the detection of significant concentrations of human norovirus genomes in the air of corridors and nursing stations suggests that they can remain suspended in the air for prolonged periods of time. This provides additional support to the hypothesis that human norovirus may be an airborne disease as suspected by Sawyer *et al*. [35]. Although norovirus is an intestinal pathogen, noroviruses could be transmitted through the airborne route and subsequently could, if inhaled, settle in the pharynx and later be swallowed.

Hence, *in vitro* studies were performed to evaluate the preservation of the aerosolized norovirus infectious potential using MNV-1 as a surrogate and a NIOSH-251 air sampler. Noroviruses

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could withstand aerosolization with no significant loss of infectivity. The difference between the concentration of infectious viruses and intact viruses might be explained by the presence of damaged receptors, making their attachment impossible, but also by the fact that aggregated viruses can only be detected as a single plaque-forming unit. Since culture methods for human norovirus were only recently published (after this study was completed), we suggest that NIOSH-251 sampler could be used in the field to evaluate culturability and infectivity of airborne human viruses. These results may explain in part the propensity of this virus to cause abrupt and widespread outbreaks in healthcare settings and confined environments such as aircrafts [36] and cruise ships [37]. A few years ago, Marks *et al.* also raised the possibility of an airborne spread of norovirus following infections by inhalation in hotels, restaurants and schools [14, 15].

The findings presented in this report could have an important impact on the infection control practices and recommendations for managing norovirus outbreaks in healthcare facilities. They suggest that air may be an important but yet underappreciated mode of transmission of norovirus and may explain in part the well-known difficulty of controlling norovirus outbreaks. Currently, the US Centers for Diseases Control recommends the implementation of contact precautions only when caring for patients with norovirus gastroenteritis [38]. This recommendation is based on the belief that norovirus are unlikely to remain viable on air currents that travel long distances. There is a need for identifying the optimal infection prevention measures required to ensure a safe hospital environment; for example, the use of full airborne precautions (including the use of respirators, the closing of patient rooms' doors and the use of negative pressure rooms) could help prevent transmission of this troublesome virus.

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CONCLUSION

This study detected high concentrations of infectious norovirus GII in the air of healthcare facilities during outbreaks. *In vitro* models suggest this virus may withstand aerosolization, supporting a probable mode of transmission for norovirus.

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NOTES

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TABLE 1: Detection and concentration of norovirus GII RNA recovered from the air in patient rooms, hallways and nursing stations during 8 confirmed norovirus outbreaks, Quebec, 2012. Air samples were taken with the Coriolis µ® set at 200 L/min for 10 minutes.

Healthcare centers Location	**Number of positive sample detected in the air**	**Range of Norovirus GII (Genome/m^3)**
Patient room	14/26	$1.46x10^1 – 2.35x10^3$
Nurse station	3/6	$1.35x10^1 – 1.22x10^2$
Hallway/Common area	6/16	$1.54x10^1 – 5.43x10^2$

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FIGURE LEGENDS

Figure 1: MNV-1 concentration in the nebulizer at the beginning (black bar) and at the end (grey bar) of the aerosolization. 2A: Infectious MNV-1 concentration, 2B: MNV-1 genome concentration, 2C: concentration of MNV-1 with intact viral capsid. There is no significant difference between virus concentration at the beginning and at the end of the aerosolization.

Figure 2: Relative percentage on MNV-1 with intact capsid after aerosolization and sampling with the NIOSH-251 (black round) as determined using PMA-qPCR assay. Relative MNV-1 infectious percentage after aerosolization and sampling with the NIOSH-251 (black triangle). Horizontal bars represent the mean of experiments with standard deviation.

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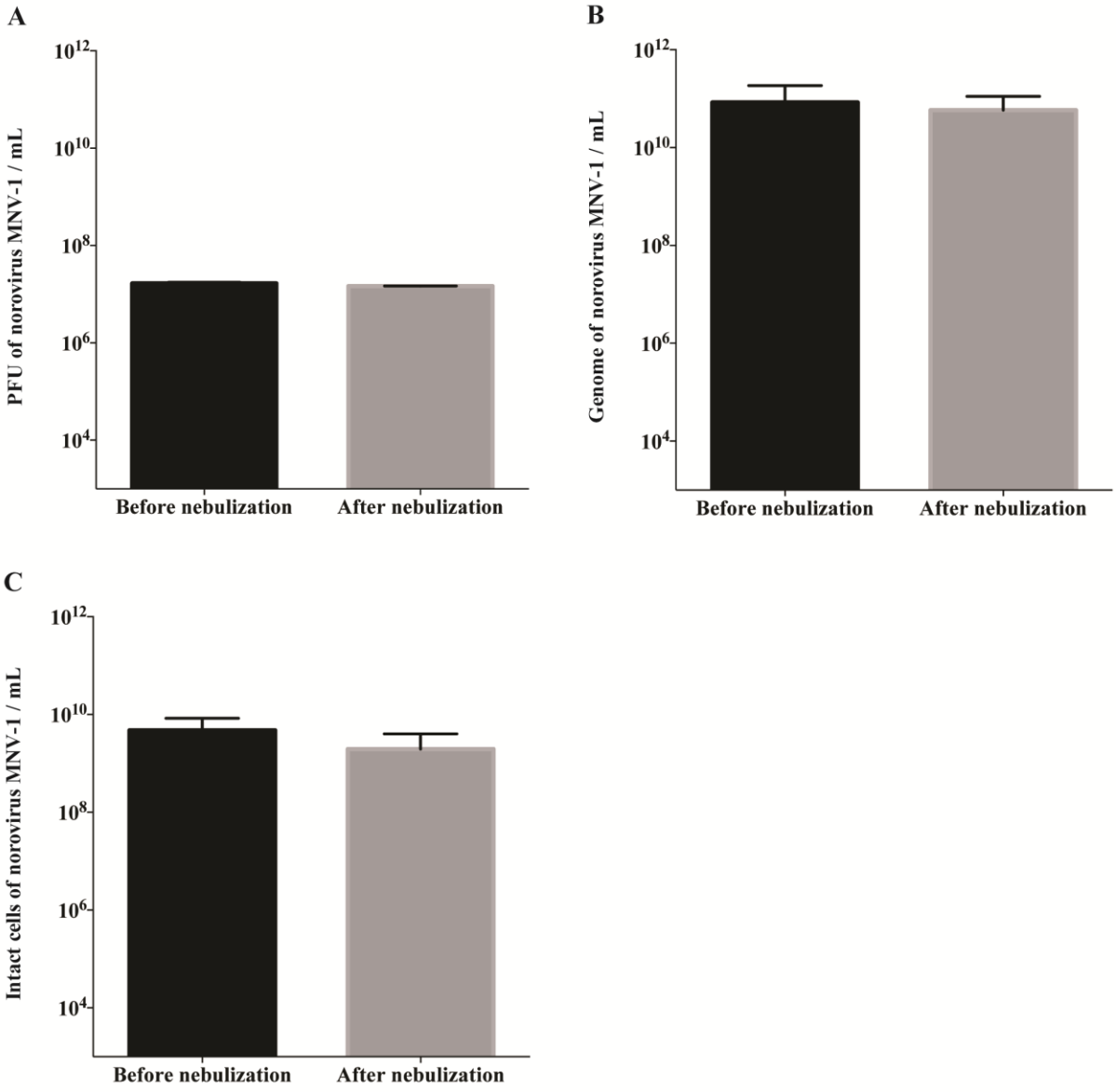

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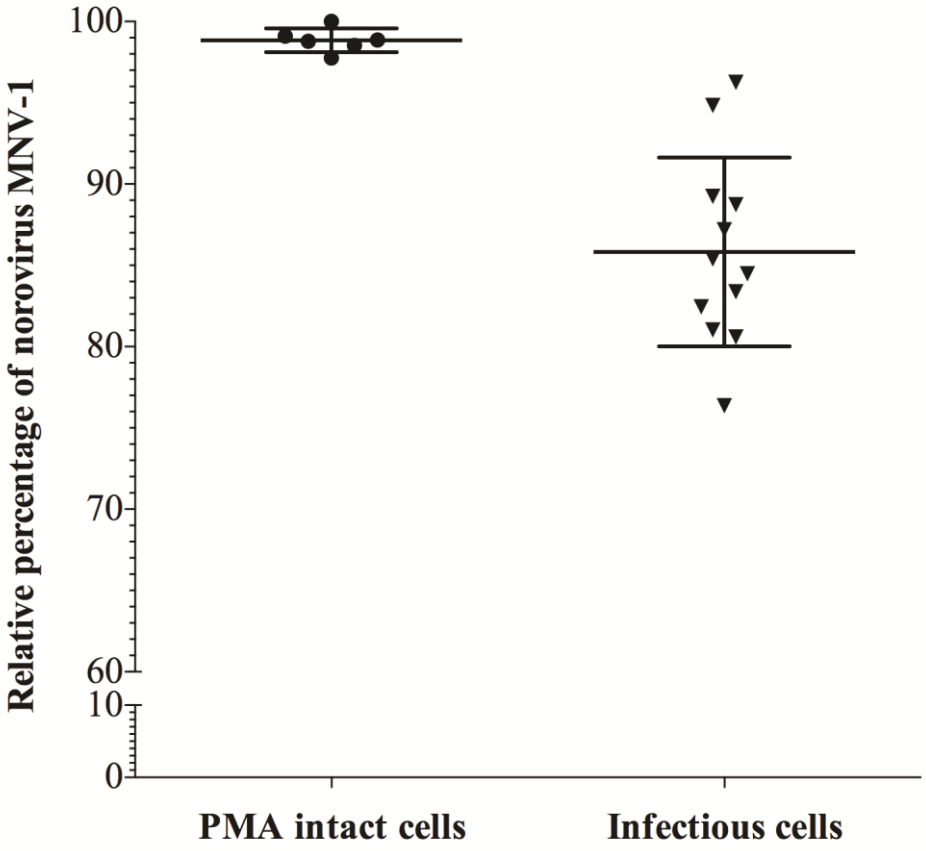

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PLOS ONE

RESEARCH ARTICLE

Aerosolization of a Human Norovirus Surrogate, Bacteriophage MS2, during Simulated Vomiting

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Abstract

Human noroviruses (NoV) are the leading cause of acute gastroenteritis worldwide. Epidemiological studies of outbreaks have suggested that vomiting facilitates transmission of human NoV, but there have been no laboratory-based studies characterizing the degree of NoV release during a vomiting event. The purpose of this work was to demonstrate that virus aerosolization occurs in a simulated vomiting event, and to estimate the amount of virus that is released in those aerosols. A simulated vomiting device was constructed at one-quarter scale of the human body following similitude principles. Simulated vomitus matrices at low (6.24 mPa*s) and high (177.5 mPa*s) viscosities were inoculated with low (10^8 PFU/mL) and high (10^{10} PFU/mL) concentrations of bacteriophage MS2 and placed in the artificial "stomach" of the device, which was then subjected to scaled physiologically relevant pressures associated with vomiting. Bio aerosols were captured using an SKC Biosampler. In low viscosity artificial vomitus, there were notable differences between recovered aerosolized MS2 as a function of pressure (i.e., greater aerosolization with increased pressure), although this was not always statistically significant. This relationship disappeared when using high viscosity simulated vomitus. The amount of MS2 aerosolized as a percent of total virus "vomited" ranged from 7.2×10^{-5} to 2.67×10^{-2} (which corresponded to a range of 36 to 13,350 PFU total). To our knowledge, this is the first study to document and measure aerosolization of a NoV surrogate in a similitude-based physical model. This has implications for better understanding the transmission dynamics of human NoV and for risk modeling purposes, both of which can help in designing effective infection control measures.

Competing Interests: The authors have declared that no competing interests exist.

Introduction

There are 21 million cases of human norovirus (NoV) infection in the U.S. each year, and this virus genus is now recognized as the leading cause of outbreaks of acute gastroenteritis. According to CDC National Outbreak Reporting Systems (NORS) data for 2009–2010, NoV are responsible for 68% of reported enteric disease outbreaks and 78% of illnesses. They have also been associated with 46% of hospitalizations and 86% of deaths associated with these enteric disease outbreaks. The majority of these outbreaks occur in healthcare facilities (64%), but about 15% occur in association with food service establishments (e.g., restaurants and banquet facilities) [1]. In fact, NoV have been associated for over 50% of all foodborne disease outbreaks [2].

Human NoV can be transmitted by a variety of means. The most widely recognized is the fecal-oral route, which is particularly relevant to contamination of food. However, the virus is also released during projectile vomiting, the hallmark symptom of NoV illness. It is estimated that as many as 30 million virus particles are released in a single episode of vomiting [3,4]. When combined with their low infectious dose (20–1300 particles) [5,6] it is likely that vomiting facilitates NoV transmission. In fact, there have been many outbreaks occurring in hotels, schools, aircraft, concert halls, and cruise ships for which vomiting has been implicated as having a role in transmission [7–11].

Epidemiological evidence from outbreaks suggests that projectile vomiting produces aerosols that contain human NoV [12,13]. Aerosolization of virus during vomiting could potentially extend the spread of virus, result in contamination of surfaces and other fomites, and increase the duration of exposure if viruses remain airborne. Air currents could further disperse aerosolized virus, making contamination even more widespread [4].

Aside from epidemiological studies, the relative importance of aerosol formation in the transmission of human NoV through vomiting is largely unknown. However, there have been studies on aerosolization of influenza virus, usually in association with the physical act of coughing or sneezing. The aerosolization of pathogens by sneezing, coughing, talking, or exhaling depends on many factors such as the flow rate of air suspending the pathogens, evaporation, and the velocity of coughing or sneezing [14,15]. The likelihood of transmission via aerosols is also influenced by the size of the particles, which depends on evaporation, virus aggregation, and properties of the suspending matrix [16].

There are many challenges that hinder work with human NoV, not the least of which is that they cannot be cultivated *in vitro*, nor is there an animal model for their propagation. Consequently, surrogate viruses that are morphologically similar, but cultivable, are often used in studies to mimic human NoV behavior. The male-specific bacteriophage MS2 is one such surrogate that resembles human NoV in that it has a positive sense single stranded RNA genome, icosahedral capsid symmetry, and is within the same size range [17,18]. Bacteriophage MS2 is easily cultivated in the laboratory to high titers (~10^{11} plaque forming units (PFU)/mL). As a bacteriophage, it is also non-pathogenic to humans or animals and is commonly used in aerosolization studies as a surrogate for pathogenic viruses [19].

The purpose of this study was to demonstrate that virus aerosolization occurs in a simulated vomiting event, and to estimate the amount of virus that is released in those aerosols. The work was performed in two parts: (i) creation of a laboratory physical model to simulate human vomiting; and (ii) using that model to characterize the degree of virus aerosolization under various conditions of volume and pressure. The human NoV surrogate MS2 was used in the simulated vomiting experiments.

Materials and Methods

Physiological parameters used in vomiting device

To better understand the physiology of vomiting and potential effects on aerosolization, and in the absence of data in the literature, an expert in gastroenterology (author KLK) provided advice to aid in estimating values for key design features. There were a number of parameters in which this advice was useful. The first was volume of vomitus, which varies depending on a person's height, weight, and diet consumed prior to a vomiting episode. Considering these variations, 800 mL of vomitus in a single vomiting episode was estimated to be a maximum volume. It was assumed to be unlikely that a person would expel less than 50 mL, as this volume might be considered a "dry heave." The 800 mL estimated vomitus volume was used exclusively in this study to allow the use of a manageable scaled down volume (see Simulated Vomiting Experiments).

The second variable for expert consideration was vomitus viscosity, which depends upon the mix of solid, semi-solid, and liquefied (triturated) foods present in the stomach prior to the vomiting episode. Vomitus with high solids contents would be thick with suspended food particles; pre-gelatinized starch was chosen as a model for high solids content vomitus. Vomitus with low solids contents would be very thin and watery; artificial saliva was used as a model for low solids content vomitus.

It was pointed out that air is present in the gastric fundus, the portion of the stomach immediately distal to the lower esophageal sphincter (LES). The fundic air volume likely contributes to the aerosolization of vomitus and was estimated to be in the range of 50–200 mL. Further, the LES is normally contracted to prevent reflux of gastric content into the esophagus. The normal sphincter pressure ranges from 13 mmHg to 43 mmHg. Increases in intragastric pressure and reverse peristalsis in the gastric antrum and corpus result in abrupt relaxation of the lower esophageal sphincter pressure during vomiting [20]. The upper esophageal sphincter also relaxes during vomiting. Greater intra-abdominal and intra-gastric pressures during vomiting result in more vigorous expulsion of gastric contents and result in the so-called "projectile" vomiting.

Finally, during vomiting the neck is flexed with the mouth pointed toward the ground, a posture that limits the potential for aspiration of vomitus. It was assumed that reproduction of the exact size and shape of the stomach was not necessary in model design as long as scaled lengths and diameters of the esophagus and mouth were used, as well as physiologically relevant pressures of the stomach and esophagus.

Model Construction

The simulated vomiting device was constructed based on the concept of similitude, which allows a scaled prototype to behave similarly to the full-scale phenomenon being simulated. In this case, the device was designed to function similarly to the full-scale human upper gastrointestinal tract but created at one-quarter scale. Achieving similitude in an engineered model is based on three types of similarity to the full-scale application: geometric, kinematic, and dynamic [21]. Having geometric similarity means that the model and prototype must have the same shape, and that all of the linear dimensions of the model must be related to corresponding dimensions in the prototype by the same scaling factor [21]. To achieve kinematic similarity, velocities at corresponding points in the model must have the same direction and differ by the same constant scale factor as the prototype [21]. Dynamic similarity means that the ratios of all the forces acting on the fluid particles are constant when comparing the model and the prototype. A list of all parameters, data upon which they are based [22–24], their assumptions, and

Table 1. Summary of Model Parameters, Assumptions, and Relevant Formulae used in Scaling the Simulated Vomiting Device.

	Human Dimension (cm)	Equation Used in Scaling	Machine Dimensions (cm)	Adjusted for Material Availability (cm)
Esophagus Length	25	1	6.35	-
Esophagus Diameter	2.5	1	0.63	-
Mouth Length	9.7	1	2.46	2.54
Mouth Diameter	5.72	1	1.45	1.27
Maximum Vomitus Volume Used	800	2	13.08	-
Minimum Vomitus Volume Used	200	2	3.27	-
Volume of Air in Stomach Used	200	2	3.27	-
Maximum Stomach Pressure	5.6	3	86.8	-
Average Stomach Pressure	1.6	3	24.8	-
Minimum Stomach Pressure	0.77	2	11.9	-
Equations:				
$(1)\ Machine\ Length = \frac{Human\ Length}{3.94}$ $(2)\ Machine\ Volume = \frac{Human\ Volume}{61.16}$ $(3)\ Machine\ Pressure = Human\ Pressure * 15.5$				

Assumptions:

(1) Flow through the human esophagus and machine esophagus was treated as flow through a smooth pipe.

(2) In some cases, the machine dimensions were rounded to the nearest available dimension offered by material manufacturers.

(3) The vomitus fluid inside the human body will be the same inside the vomiting machine; achieved by using surrogate vomitus with similar viscosities.

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relevant formulas are provided in Table 1. A detailed description of the calculations used for scale up is provided in the Supporting Information (S1 File).

Fig 1A shows a diagram of the device. A clear PVC tube (7.62 cm long) attached to two PVC caps, a solid PVC piston, and pressure gauge connected to a pump were designed to act as a surrogate stomach. A brass check valve in the center of one of the PVC caps prevented air from escaping when pressurizing the system. Connecting the stomach chamber to the surrogate esophagus is a ball valve representing the lower esophageal sphincter (LES); in the human body the LES abruptly relaxes in order for the vomitus to be ejected from the stomach. When the valve was opened, the PVC piston pushed the vomitus out of the stomach into the esophagus, represented as a 0.64 cm diameter tube that is 6.35 cm in length. The esophagus was attached to a 1.27 cm diameter tube, representing the mouth, with an expansion fitting. In the device set-up, a slight curve (flexion) was designed in the upper esophagus and "throat" to simulate the flexion of the neck during a vomiting episode. A pressure gauge was attached to the top of the PVC cap to monitor the pressure at the connection between the esophagus and stomach chamber. The ball valve, representing the LES pressure, was opened when the desired intragastric pressure was reached, allowing the PVC piston to eject the vomitus with some velocity out of the stomach and into the esophagus and mouth.

The vomitus containment chamber (Fig 1B) was a Plexiglas box with dimensions of 30.5 cm x 30.5 cm x 44.5 cm and a hinged lid The edges were sealed with weather proofing tape to ensure a tight seal and prevent aerosols from escaping the chamber. On one side of the chamber, the vomiting device was connected to the "vomiting device port", while on the other side, an SKC© Biosampler (SKC Inc., Eighty Four, PA) was connected to the "biosampler port". After a simulated vomiting incident, a vacuum pump was operated at a flow rate of 12.5 L/min to facilitate capture of aerosolized particles by the biosampler into 4 mL of phosphate buffered saline (PBS). Preliminary studies indicated that the average biosampler efficiency at capturing

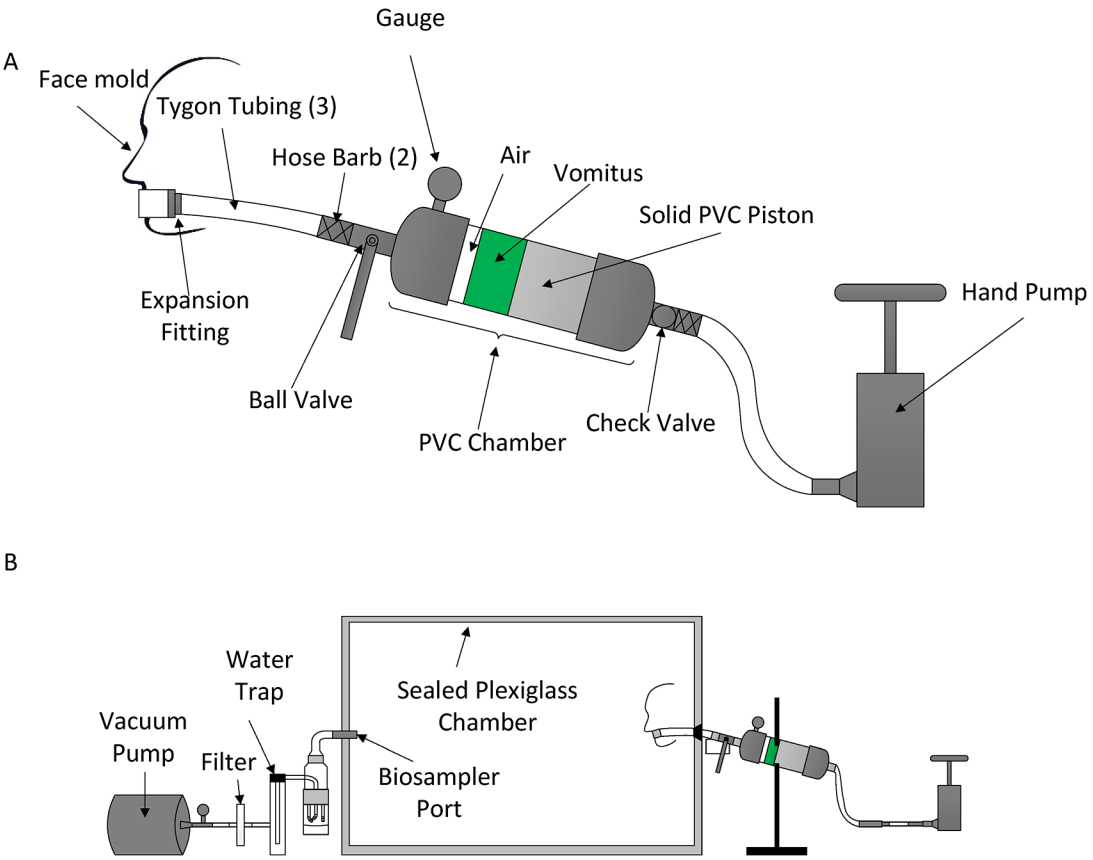

Fig 1. Schematic of Simulated Vomiting Device. (A) Diagram of the simulated vomiting device (B) Experimental set-up for capturing aerosolized virus.

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aerosolized MS2 was 8.5% (data not shown). The biosampler was run for 15 min (221 chamber volumes) after the simulated vomiting event. The entire set-up was further contained in a Biosafety level II hood.

Virus Propagation and Enumeration

Bacteriophage MS2 (ATCC 15597-B1) and its *Escherichia coli* C3000 host (ATCC B-15597) were purchased from the American Type Culture Collection (ATCC, Manassas, VA). To prepare MS2 stock solutions, the protocol described in NSF Standard 55 was used (double agar layer method, described below) [25]. After 10-fold serial dilutions of MS2 were plated, those plates showing complete lysis were flooded with 3 mL of tryptic soy broth (TSB) (Fisher Scientific, Pittsburgh, PA) and the soft agar layer was scraped off into a sterile 50 mL tube. The volume was increased to 40 mL with TSB and then 0.2 g EDTA (Sigma-Aldrich, St. Louis, MO) and 0.026 g lysozyme (Fisher Scientific) were added to each tube. The tubes were then incubated for 2 h at 37°C with shaking. The supernatant was recovered by centrifugation at 9,300 *x g* for 10 min followed by filter sterilization using a 0.22 μm filter (Nalgene, Rochester, NY). Aliquots of this were considered high titer MS2 stock (10^{10} PFU/mL). The low titer stock (10^{8} PFU/mL) was prepared by dilution. Stocks were aliquoted and stored at -80°C until use.

Enumeration of MS2 was also performed using the double agar layer method in accordance with the method of Su and D'Souza (2011) with minor modifications [26]. Briefly, the *E. coli* C3000 host was incubated for 4–6 h with gentle shaking (100 RPM, 37°C, Excella E24

Incubator, New Brunswick Scientific/Eppendorf, Enfield, CT). Simultaneously, 8 mL tubes of 0.6% tryptic soy agar (TSA) (Fisher Scientific) were melted and tempered in a 42°C water bath. Previously prepared petri dishes (Fisher Scientific) containing 1.2% TSA were allowed to warm to room temperature. Then, 10-fold serial dilutions of MS2 (dilutions to achieve countable plates were as high as 10^{-10} for high titer MS2, 10^{-8} for low titer MS2) were prepared. A volume of 0.7 mL of each dilution was added to the tempered 8 mL TSA tube after which 0.3 mL of *E. coli* solution was added, the suspension quickly vortexed and poured on top of the 1.2% TSA plates. Duplicates were done for each dilution. Upon solidification, the plates were inverted, incubated overnight at 37°C and then plaques were counted. Counts were expressed as plaque forming units per milliliter (PFU/mL).

Simulated Vomiting Experiments

Vomitus solutions consisted of MS2 bacteriophage at high (10^{10} PFU/mL) and low (10^{8} PFU/mL) titer were adjusted to high or low viscosity. To prepare the MS2 low viscosity solution (0.1% carboxymethylcellulose (CMC)), 15 mL of MS2 stock was mixed with 0.15 g of high viscosity CMC powder (pre-hydrated Ticalose CMC 6000 powder; Tic Gums, White Marsh, MD). This was used to simulate artificial saliva with a viscosity of 6.24 mPa*s [27]. For the high viscosity vomitus solution (similar to that of egg yolk), a solution of 25% pre-gelatinized starch (PS) was used. To prepare this, 3.75 g of PS (Vanilla flavor Instant pudding, Jell-O, Glenview, IL) was mixed with 15 mL of MS2 stock. Instant pudding was chosen after consultation with Dr. Tyre Lanier (Department of Food, Bioprocessing and Nutrition Sciences, NCSU) because it was easily attainable and did not affect MS2 viability (data not shown). The solution of PS had a viscosity of 177.5 mPa*s. Solutions exceeding this viscosity were too thick to use in the simulated vomiting device.

A total of 13.1 mL (representing a scaled down volume for 800 mL of vomitus) of each solution was pipetted into the stomach chamber of the device, which contained 3.27 mL of air (scaled down from 200 mL in the human body). Using the pump, the stomach was pressurized to 1,283 mmHg (scaled average pressure experienced in the stomach during projectile vomiting), 290 mmHg (scaled maximum pressure experienced in the human stomach), and 115.1 mmHg (minimum pressure for the device) [24]. Pressures greater than 1,283 mmHg were not used because these approached the pressure gauge capacity. Also, the scaled average pressure in the stomach during projectile vomiting (1,283 mmHg) produced a projectile with a force that appeared to be greater than what would be anticipated in a normal vomiting incident. Therefore, the maximum actual pressure observed in the human stomach (290 mmHg) was assumed to be more relevant and used for comparison purposes. Video observation of recorded human vomiting events showed evidence of coughing after the initial vomiting event. The purpose of coughing is to help clear the airway of debris, to prevent aspiration of foreign materials, and to protect the lungs from overextending maximum inspiration [28]. Therefore, a vomiting event followed by four coughs or retches was also simulated using a pressure of 290 mmHg with 4 "coughs" at 233 mmHg each [24].

The components of the vomiting device and chamber were sterilized using 10% bleach for a 5 min exposure followed by rinsing with tap water and wiping with 70% ethanol. The biosampler was autoclaved after each experiment. A negative control with no MS2 was included in all experiments to demonstrate the absence of cross contamination. Immediately before experiments, the entire device was exposed to 254 nm of ultraviolet light for 1 h. Samples collected (by pipet) and analyzed (enumerated for MS2) included: (i) MS2 stock aliquot; (ii) MS2 with thickener (inoculated artificial vomitus solution); (iii) PBS from the biosampler (captured aerosolized virus); (iv) PBS rinse of the biosampler (residual captured aerosolized virus); and (v)

liquid splatter on the bottom of the chamber. Volumes of samples collected and amount of surrogate vomitus remaining in the stomach chamber were also recorded. Previous experiments, in which the chamber was swabbed after a simulated vomiting event, and those swabs enumerated for MS2, confirmed that virus deposition on dry surfaces of the chamber was minimal (cumulatively, <0.1% of total input) (data not shown).

Statistical Analysis

Experiments were performed in triplicate. To calculate the amount of MS2 aerosolized, the concentration of MS2 captured by the biosampler was normalized for both volume and for biosampler capture efficiency (8.5%). The Holm-Sidak multiple comparisons test (SigmaPlot, San Jose, CA) was used for all pairwise comparisons between treatments and pressures. Statistical significance was established at $p<0.05$,$\boldsymbol{\alpha} = 0.05$. For comparing the percent recoveries, the data were not normally distributed; therefore non-parametric Kruskall-Wallis ANOVA by ranks was performed.

Ethics Statement

This research meets all applicable standards for the ethics of experimentation and research integrity.

Results

A snapshot of a simulated projectile vomiting event is shown in Fig 2 and a video recording hosted at (http://youtu.be/jGvqb87DXSI). After each vomiting episode, virtually all of the vomitus solution was deposited at the bottom of the chamber. However, there was evidence of aerosolized MS2 after every simulated vomiting episode (Fig 3). At low initial MS2 inoculum titer (10^8 PFU/mL) suspended in 0.1% CMC (low viscosity), there were statistically significant differences between $\log_{10}$ concentration of MS2 recovered from aerosolized vomitus as a function of pressure (i.e., higher MS2 concentration with higher pressure). The same occurred for high titer (10^{10} PFU/mL), low viscosity experiments, although these differences were not statistically significant. There appeared to be little relationship between pressure and aerosolization for the high titer, high viscosity experiments. The high viscosity, high titer MS2 inoculum was not expelled out of the simulator at the low pressure of 115.1 mmHg, presumably because of the low expulsion force. There was also no statistically significant difference in the

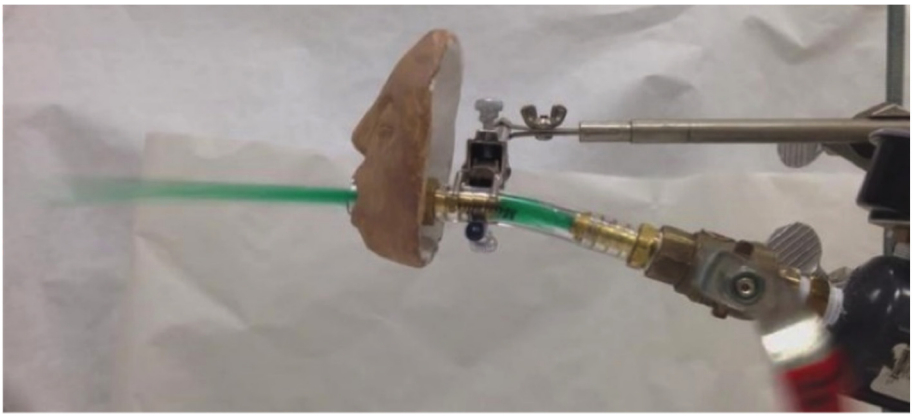

Fig 2. Photo of a Simulated Vomiting Episode. Projectile vomiting of colored simulated vomitus matrix.

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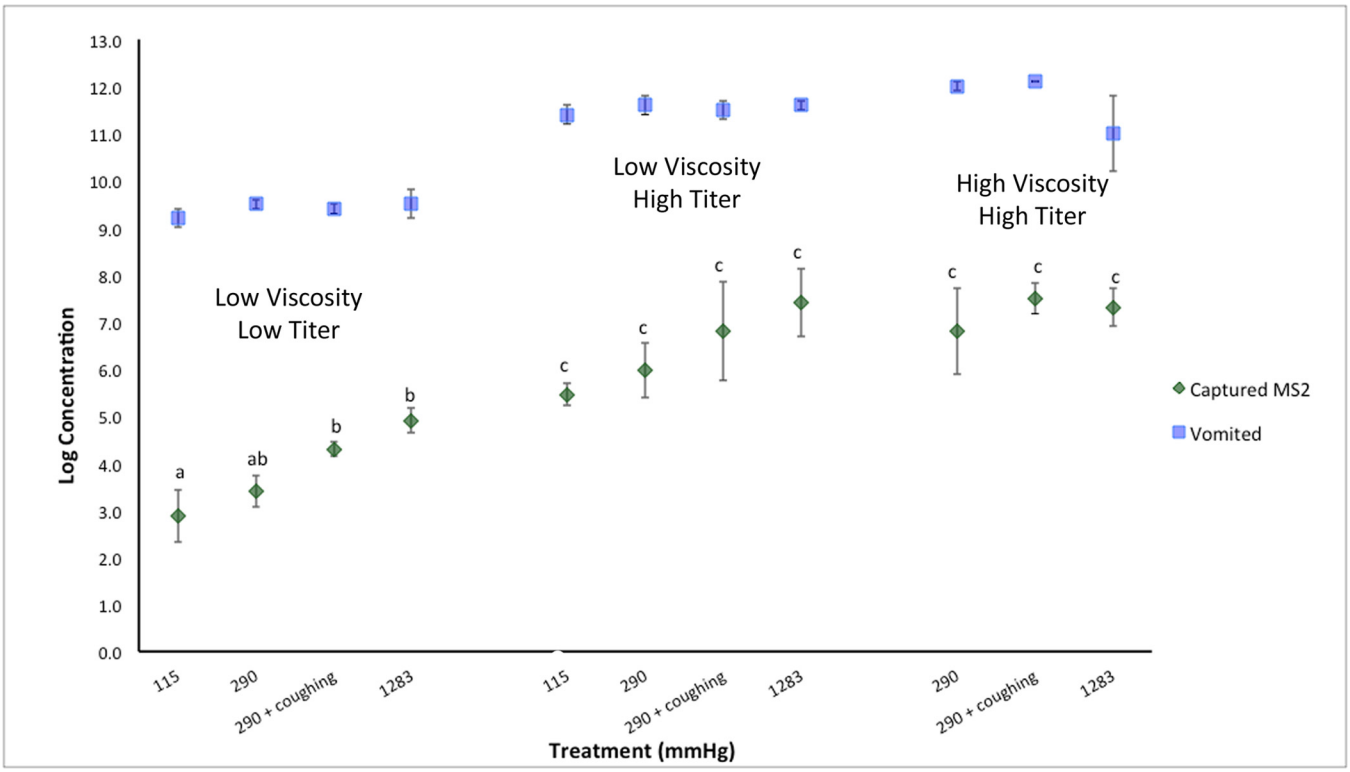

Fig 3. Aerosolization Experiments using bacteriophage MS2. Virus concentration "vomited" is designated by blue squares. Green diamonds show the amount of captured MS2 at designated pressures for simulated vomitus having low and high MS2 titer and of low and high viscosity. Error bars denote one standard deviation above the mean. Shared letters and symbols indicate treatments that were not statistically significantly different within each group.

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concentration of MS2 aerosolized for high viscosity, high titer MS2 solution when compared to low viscosity, high titer MS2 simulated vomitus solution. Although not statistically significant, there appeared to be a slight difference of increased MS2 aerosolization when simulated coughing (at 290 mmHg) was added, regardless of virus titer or simulated vomitus viscosity.

The amount of MS2 aerosolized as a percent of total virus "vomited" ranged from a low of $7.2 \times 10^{-5} \pm 0.00006$ to a high of $2.67 \times 10^{-2} \pm 0.03$ (Table 2). These data were not normally distributed; therefore non-parametric Kruskall-Wallis ANOVA by ranks was performed. There were statistically significant differences between vomiting conditions and degree (%) of MS2 aerosolization ($p<0.01$). When the data were log-transformed and reanalyzed, there were no statistically significant differences when comparing MS2 percent aerosolization at 1,283 mmHg to 290 mmHg with coughing, regardless of virus titer or solution viscosity. There were statistically significant differences when comparing percent aerosolization at pressures of 1,283 mmHg and 115 mmHg ($p<0.05$). The general trend was greater percent aerosolization for high titer MS2 at 1,283 mmHg and 290 mmHg with coughing, than 290 mmHg and 115 mmHg without coughing.

Discussion and Conclusions

By simulating vomiting using a device scaled to human physiological parameters according to similitude principles, this study demonstrated that virus (MS2) aerosolization did indeed occur. These results complement the recent work of Bonifait et al. (2015), who provided the first definitive evidence of NoV bioaerosolization [29]. Specifically, they found evidence of

Table 2. Percent Recoveries of Aerosolized MS2.

Treatment		% Aerosolized	Log % Aerosolized	Statistical Significance
1,283 mmHg	Low Viscosity, Low Titer	$2.8 \times 10^{-3} \pm 0.001$	-2.58 ± 0.21	A B C
	Low Viscosity, High Titer	$1.3 \times 10^{-2} \pm 0.01$	-2.2 ± 0.81	A B
	High Viscosity, High Titer	$2.7 \times 10^{-2} \pm 0.03$	-1.72 ± 0.42	A
290 mmHg	Low Viscosity, Low Titer	$1.1 \times 10^{-4} \pm 0.00005$	-4.02 ± 0.24	C D
	Low Viscosity, High Titer	$4.6 \times 10^{-4} \pm 0.0005$	-3.58 ± 0.63	B C D
	High Viscosity, High Titer	$1.4 \times 10^{-3} \pm 0.001$	-3.29 ± 1.00	A B C D
290 mmHg + coughing	Low Viscosity, Low Titer	$9.6 \times 10^{-4} \pm 0.0005$	-3.06 ± 0.24	A B C D
	Low Viscosity, High Titer	$1.1 \times 10^{-2} \pm 0.02$	-2.55 ± 0.93	A B C
	High Viscosity, High Titer	$3.2 \times 10^{-3} \pm 0.002$	-2.57 ± 0.31	A B C
115 mmHg	Low Viscosity, Low Titer	$7.2 \times 10^{-5} \pm 0.00006$	-4.35 ± 0.63	D
	Low Viscosity, High Titer	$1.33 \times 10^{-4} \pm 0.00009$	-3.93 ± 0.27	B C D

* Shared letters denote treatments with no statistically significant differences at $p>0.05$.

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NoV genogroup II in 8/48 air samples collected; positive samples had concentrations (by RT-qPCR) of 1.4×10^1–2.4×10^3 genome copies per m^3 of air. We, on the other hand, provide evidence that virus aerosols can be produced during the act of vomiting. Together, our work and that of Bonifait et al. (2015) add to the growing evidence that NoV aerosolization occurs by vomiting.

In all cases, <0.03% of the initial concentration of MS2 in the artificial vomitus was aerosolized, though the numbers were quite variable. While a small percentage of the virus released during simulated vomiting was aerosolized, what was released could be enough to cause a significant disease risk. For instance, if an individual vomits at least 50 mL with at least 10^6 particles/mL (numbers from Greenberg et al. (1979)), this would mean 5×10^7 particles would be vomited. Even with the lowest percent of aerosolized virus (7.2×10^{-5}% for 115 mmHg at low titer), approximately 36 virus particles would become aerosolized. In contrast, the highest percent aerosolized (2.67×10^{-2}% shown at 1,283 mmHg for high titer, high viscosity artificial vomitus) would result in aerosolization of >13,000 particles. Interestingly, these numbers are consistent with those estimated for bioaerosols in outbreak settings (1.4×10^1–2.4×10^3 genome copies per m^3 of air) by Bonifait et al. (2015)[29]. Given the low infectious dose of human NoV (20–1300 particles) [5,6], these numbers are clearly enough to make exposed susceptible individuals ill.

Spatial associations and attack rate patterns occurring as a consequence of vomiting incidents support human NoV aerosolization. Marks et al. (2000) demonstrated that attack rates were related to how far individuals sat from the initial vomiting incident in a hotel restaurant: 91% for those sitting at the same table, 56–71% for those at adjacent tables, and 25% for those

seated at the table furthest from the incident [12]. Similarly, Harris et al. (2013) showed that individuals in the same vicinity within a hospital as patients with symptoms of human NoV infection were more likely to become infected than individuals further away [30]. Such spatial associations may be a function of the number and droplet size during vomiting. Smaller droplets may remain in the air for longer periods of time and be subjected to indoor air movements, thus traveling further. On the other hand, larger droplets would be more likely to settle to the surface closer to the initial vomiting incident [31,32].

Pressure was a major parameter investigated in this study. Booth (2014) recently reported on a simulated vomiting system that was used to characterize the extent of splatter occurring in vomiting event [33]. Although that study did not examine aerosolization, an authentic mannequin that is typically used for training adult airway management, with realistic anatomy parts of the upper respiratory tract and an esophagus and stomach (which was replaced with a cylinder containing 1 L of fluid) was used. That study reported that, for their model, a pressure of 6,000 mmHg was required to eject 1 L of water a distance of 1.2 meters. This pressure is significantly greater than the 1,283 mmHg maximum pressure that we used in our simulated vomiting experiments, which was scaled to the average pressure in the human stomach during a vomiting incident as reported by Iqbal et al., 2008 [24]. Assuming that the Booth model was exactly human scale, the pressures required to model vomiting are almost 20 times greater than the average values reported by Iqbal et al., 2008 [24].

Although the amount of virus aerosolized was generally positively correlated with the pressure with which the vomitus was released, this relationship was not always statistically significant. This was partially due to the large standard deviations in the measurements, suggesting high variability in degree of virus aerosolization during vomiting. This implies that even a relatively minor vomiting event may have public health significance. We did not observe a major role for viscosity in the degree of virus aerosolization, despite the fact that others have found that suspension media can play an important role in resistance of virus to aerosolization [19].

Human NoV particles have a diameter of 32 nm and a buoyant density of 1.41 g/cm^3 [12]. Particles this small undergo random Brownian motion and will eventually collide with other particles and coagulate to form larger particles. Based on the parameters above, the settling velocity for a single NoV particle, calculated using Stokes' law, is 4.7 x 10^{-8} m/s. This is very slow, and if left uninterrupted, the virus could remain in the air for months. Of course, it is highly unlikely that virus travel would remain uninterrupted, or that single viruses would be aerosolized without some attachment to the suspending matrix.

Hence, droplets formed as a consequence of a vomiting incident are very important in transmission. Droplet transmission occurs when aerosolized particles are large enough (100–500 μm in diameter) to settle to the ground quickly. For example, a 100 μm droplet, with density of 1.41 g/cm^3 settling in air at 20° C, is predicted to travel 0.46 m/s, meaning that for a distance of 1 meter it will only take the droplet a few seconds to reach the ground [34]. These droplets can also fall on inanimate surfaces, resulting in contamination of fomites.

Consistent with the work of others [35–37], we used the SKC Biosampler for quantifying virus recovery due to aerosolization. This biosampler has been shown to be better for retaining virus infectivity [35], and in comparative studies with other biosamplers, has also been found to be the most efficient at virus capture [19,35,36]. However, there is wide variability in the reported efficiency of virus capture using the SKC Biosampler. For example, Fabian et al., (2009) reported 96% collection efficiency for aerosolized influenza virus particles >1 μm in diameter, and 79% for particles 0.3 μm in diameter using the SKC unit [36]. Others have reported lower capture efficiencies. Hogan et al., 2005 demonstrated <10% efficiency for capturing aerosolized MS2 particles of 30–100 nm in diameter using the SKC Biosampler [37], while Turgeon et al., 2014 found MS2 recovery to be approximately 0.1% as determined by

plaque assay and qPCR [19]. We observed recovery efficiencies similar to these (8.5%) when a nebulizer was used to aerosolize MS2 with the SKC Biosampler.

Although due diligence was taken in model and experimental design, there are a few limitations to this study. For instance, even though the equipment was appropriately scaled, the structural features of the simulated vomiting device were not the same as human anatomy. While the pressures used for simulated vomiting were scaled, the force with which the vomiting occurred using the device sometimes appeared greater than one might expect in real life. Vomitus in nature would undoubtedly contain solids, and the use of solids-free simulated fluids could have impacted the likelihood or degree of virus aerosolization. Based on the model's design, a solids-containing suspension could not be used. The SKC Biosampler has been shown to be more effective at collecting larger airborne particles, but is unable to distinguish particle size. There may potentially be greater aerosolization that could not be detected using the SKC Biosampler, as the efficiency of recovery decreased as size of the particle decreased. Lastly, although MS2 is a logical surrogate virus for human NoV because of its ease of enumeration and safety, it is still necessary to extrapolate the behavior of the surrogate to that of human NoV. Not only has MS2 been a popular surrogate for many pathogenic viruses, it is often used in aerosol studies to examine air samplers and aerosol generation techniques [37,38]. MS2 is also environmentally persistent, like human NoV [39]. Surrogate viruses, like MS2, have been used in other virus aerosolization studies [40–42]. We note that the experimental approach used here, and employing a physical model designed according to similitude principles, may be useful in studies of aerosolization of other viruses during vomiting. For those studies, other surrogate viruses that are similar to size, composition (e.g., lipid envelop or non-enveloped), and other characteristics to the virus being modeled, would be more appropriate.

To our knowledge, this is the first study to document and measure aerosolization of a NoV surrogate in a similitude-based physical model. Relative to the MS2 titers "vomited," the degree of aerosolization was rather minimal (<0.01%). However, based on human NoV infectious dose and estimated virus concentrations in vomitus, even these small percentages of aerosolization would likely result in significant disease risk, as was suggested in the recent findings of Bonifait et al. (2015) [29]. Future studies should focus on characterizing aerosolized particle droplet size as this plays an important role in the settling rate of viruses. The work reported here has implications for better understanding the transmission dynamics of human NoV and for risk modeling purposes, both of which can help in designing effective infection control measures.

Supporting Information

S1 File. Supplementary Material Explaining Concepts and Equations for the Construction of the Vomiting Machine.
(PDF)

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Author Contributions

Conceived and designed the experiments: GTT FL FLD LAJ KK. Performed the experiments: GTT DAL. Analyzed the data: GTT. Contributed reagents/materials/analysis tools: FLD KK LAJ. Wrote the paper: GTT DAL LAJ FLD KK.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-018

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

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Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014 I-021; the recommended solution has been revised.

Title:

Sore Throat with Fever

Issue you would like the Conference to consider:

The 2013 FDA Food Code, section 2-201.13(G) requires a person with sore throat and fever to not return to work until they have medical documentation of being free of *Streptococcus pyogenes* or have received professional medical treatment for same.

This release from exclusion requirement goes above and beyond what is required for other reportable symptoms. Additionally, ***Streptococcus pyogenes*** is not one of the reportable diagnosed illnesses, (e.g. "big six.")

Public Health Significance:

The 2013 Food Code, section 2-201.13(G) requires a person with sore throat and fever to not return to work until they have medical documentation of being free of *Streptococcus pyogenes* or have received professional medical treatment for same.

This release from exclusion requirement goes above and beyond what is required for other reportable symptoms. Additionally, ***Streptococcus pyogenes*** is not one of the big six reportable diagnosed illnesses.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined; language to be deleted is in strikethrough format)*:*

Section 2-201.13

(G) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(G)(1) or (2) if the FOOD EMPLOYEE ~~provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE meets one of the following conditions~~:

1. ~~Has received antibiotic therapy for *Streptococcus pyogenes* infection for more than 24 hours~~ Is ASYMPTOMATIC for at least 24 hours; P or
2. ~~Has at least one negative throat specimen culture for *Streptococcus pyogenes* infection;P~~ The Food Employee provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the Food EMPLOYEE meets one of the following:

(a) Has received antibiotic therapy for *Streptococcus pyogenes* infection for more than 24 hours; P

(b) Has at least one negative throat specimen culture for *Streptococcus pyogenes* infection; P or

(c) Is otherwise determined by a HEALTH PRACTITIONER to be free of a *Streptococcus pyogenes* infection. P

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-019

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

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Issue History:

This is a brand new Issue.

Title:

Plant Food Cooking Time Frame

Issue you would like the Conference to consider:

Addition of a time frame for cooking plant food that will be placed into hot holding

Public Health Significance:

Plant foods which have been subjected to heating become Time Temperature Control for Safety (TCS) since the naturally present competing mircoflora has been changed. Therefore leaving the TCS plant foods within the temperature danger zone for longer than 4 hours, could result in logarithmic growth of pathogenic bacteria, as shown by modeling.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined; language to be deleted is in strikethrough format)*:*

3-401.13 Plant Food Cooking for Hot Holding

Fruits and vegetable that are cooked for hot holding shall be cooked to a temperature of 57ºC (135ºF)~~.~~, within 4 hours.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-020

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

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Issue History:

This is a brand new Issue.

Title:

Plant Food Cooking for Hot Holding

Issue you would like the Conference to consider:

Clarify that plant food includes more than just fruits and vegetables. FDA retail specialists have provided guidance indicating items such as roots, rice and pasta should be considered plant foods.

Public Health Significance:

Roots and grains are Time/Temperature Control for Safety foods (TCS) once heat treated and are often hot held after cooking. A specified minimum cooking temperature is needed to prevent the growth of pathogens and ensure hot holding begins at the proper temperature.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined; language to be deleted is in strikethrough format):

Section 3-401.13

Plant foods, such as ~~F~~fruits, ~~and~~ vegetables, roots and grains, that are cooked for hot holding shall be cooked to a temperature of 57°C (135°F). [Pf]

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-021

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

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Issue History:

This is a brand new Issue.

Title:

Cooking by food temperature

Issue you would like the Conference to consider:

Establishing criteria for a heat transfer medium such as "still dry", "convection" and "high humidity", for various weights of a meat product lacks correlation with the actual temperature of the meat. This code artifact does not accommodate either existing or new and novel cooking technologies. There are many examples of this. Steamers are one example of this misfit. Neither ovens nor steamers are defined in section 1-201.10 (B) of the FDA 2013 Food Code so whatever characteristics you choose to define and differentiate one from the other is a figment of imagination. As it stands, convection steamers do not comply with the 250ºF "air" temperature requirement and arguably - do not cook with air (an insulator) anyway. The maximum temperature attained in a pressureless steamer is that of boiling water at whatever elevation you are at (eg., 212ºF at sea level). Is this to say that you cannot cook a whole meat item to a safe temperature in a steamer? Of course not, as even chicken has a minimum core cooking temperature of 165ºF, well below the temperature of steam and well below the 250ºF minimum established in section 3-401.11 (B)(1).

New, highly advanced food equipment is here and more is on the horizon. They thermally treat meats and other foods from raw to ready to eat by controlling the *enthalpy* of heat ("H") within their cooking zones. They control the rate of energy transfer into the thermal mass (the food). Many if not all of these new cooking technology equipment provide continuous logging and/or event notification enabling food pasteurization - without the pouch and the water bath. This new equipment embraces all of the elements associated with the destruction of pathogenic organisms by controlling energy/mass-flow rates to provide positive control of *boundary layer* and *inertia* effects.

Another novel cooking technology uses long-wave length infrared radiation (900nm-1mm) and can bring a WHOLE meat core temperature to required minimums for required times without ever getting the air temperature anywhere near those shown in the table of Section 3-401.11 (B)(1) of the 2013 FDA FOOD CODE titled "*Oven Temperatures Based on Roast Weight"*. The same can be said of microwave ovens and new hybrid equipment where

microwave is but one of the energy transfer methods. Defining specific criteria for things other than internal food temperatures are short sighted, excessive and limits innovation without adding anything to food safety.

Technology has accelerated dramatically in the past twenty years, and it has now caught up to food equipment, food equipment/processes and ancillary systems. It may be wise for the Conference for Food Protection, the FDA and for licensed operators and their associations to seek liaison with domestic and international food equipment and safety system innovators to ensure that the criteria in the FDA Food Code is relevant to current mainstream equipment systems if not emerging state of the art food equipment processes.

Public Health Significance:

The FDA Food Code should stick with establishing reasonable ***science based*** safety of foods using food criteria such as food temperatures, rather than establishing temperatures for heat transfer mediums that have no direct correlation to the safety characteristics of food. By establishing criteria for one heat transfer medium (air) the code inadvertently restricts innovation. Rather, the code's food based criteria should be specific enough to ensure food safety, but broad enough to encourage investment in innovative food preparation and safety technology.

Like any effective HACCP plan, review is required to reassess the environment in which we operate and changes in technology can have significant impacts on safety and costs.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined)*:*

Section 3-401.11

Remove all of (B) (1) and the corresponding table titled "*Oven Temperatures Based on Roast Weight"* from Section 3-401.11, and amend the language to read

(B) Whole MEAT roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked as specified in the following chart, to heat all parts of the FOOD to a temperature and for the holding time that corresponds to that temperature: P

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-022

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:

Slow Continuous Cooking of Raw Animal Foods

Issue you would like the Conference to consider:

The 2013 FDA Food Code identifies final cooking temperatures for many foods and provides for minimum oven temperature in the case of roasts. However, the problem of slow come up time is not addressed adequately in the code. Temperature controlled for safety (TCS) foods can be allowed to linger at temperatures that allow the proliferation of pathogenic microorganisms and production of heat stable toxins under the existing provisions in the Food Code.

Slow come up times for continuously cooked foods present two specific hazards. First, pathogens that produce heat stable toxins can be allowed to multiply and produce toxins before lethality is reached. The second hazard is that all lethality processes such as those found in USDA Appendix A make assumptions about the number of pathogens present in the food at the beginning of the cooking process. Slow come up times can allow pathogens to replicate to levels where the lethality treatment is not effective.

Slow cooking TCS foods is often seen by food establishment operators as a culinary process providing an enhanced product. The code should restrict the time TCS foods are allowed to dwell in the danger zone. Raw animal and plant foods allowed to linger in the danger zone for extended periods are more likely to produce toxins from *Staphylococcus aureus*, *Clostridium perfringens*, and *Salmonella.* Limiting the amount of time raw animal foods and plant foods can take to stay between the temperatures of 50°F to 130°F will reduce the ability of pathogens to proliferate.

Public Health Significance:

The Food Code Section 3-401.11 provides for minimum final internal product temperatures for raw animal foods, respectively, cooked for hot holding. Section 3-401.11(B) adds requirements for whole meat roast including beef, corned beef, lamb, pork, and cured pork roast such as ham to be placed in a preheated oven at no less than 250° F. The minimum

existing oven temperature of 250ºF is applied to ensure an adequate lethality treatment to these foods.

However, in many establishments meat products are prepared by processes using slow and very slow come up times. In these cases there exists the potential for outgrowth of pathogens that produce heat stable toxins such as *Staphylococcus aureus*, *Clos*. Also, other pathogens may reproduce to a concentration above the ability of the lethality treatment to control.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be modified as follows (language to be added is underlined):

3-401.11 Raw Animal Foods

(A) Except as specified under (B) and in (C) and (D) of this section, raw animal FOODS such as EGGS, FISH, MEAT, POULTRY, and FOODS containing these raw animal FOODS, shall be cooked to heat all parts of the FOOD to a temperature and for a time that complies with one of the following methods based on the FOOD thats being cooked:

(1) 63ºC (145ºF) or above for 15 seconds <u>within 4 hours</u> for : P

(a) Raw Eggs that are broken and prepared in response to a CONSUMER'S order and for immediate service, P and

(b) Except as specified under Subparagraphs (A)(2) and (A)(3) and (B) and in (C) of this section, FISH and MEAT including GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A) (1) and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2);P

(2) 68ºC (155ºF) for 15 seconds <u>within 4 hours</u> or the temperature specified in the following chart that corresponds to the holding tine for RATITES, MECHANICALLY TENDERIZED, and INJECTED MEATS; the following if they are COMMINUTED: FISH, MEAT, GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1), and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2); and raw EGGS that are not prepared as specified under Subparagraph (A)(1)(a) of this section:.P

(3) 74ºC (165ºF) or above for 15 seconds <u>within 4 hours</u> for POULTRY, BALUTS, WILD GAME, as specified under Subparagraphs 3-201.17(A)(3) and (4), stuffed FISH, stuffed MEAT, stuffed pasta, stuffed POULTRY, stuffed RATITES, or stuffing containing FISH, MEAT, POULTRY, or RATITIES.P

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-023

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:

Reheating Commercially Processed TCS Foods in a Microwave for Hot Holding

Issue you would like the Conference to consider:

Clarify that when reheating commercially processed TCS foods in a microwave for hot holding, those foods must be rotated or stirred, covered, and allowed to stand covered for two minutes after reheating. FDA retail specialists have provided guidance indicating the intention is to require "all" TCS foods reheated in a microwave for hot holding to be rotated or stirred, covered, and allowed to stand covered for two minutes after reheating, as specified in Section 3-403.11(B) of the 2013 FDA Food Code. However, 3-403.11(B) specifically states "except as specified under (paragraph) (C) of this section" - paragraph (C) contains the temperature requirement for reheating commercially processed TCS foods in a microwave for hot holding, but does not address the food being rotated or stirred, covered, and allowed to stand covered for two minutes after reheating. Other sections in Chapter 3 that are similarly structured have not been "interpreted" in the same manner by FDA retail specialists; parts of paragraphs have not been applied when an exception is made.

Public Health Significance:

Microwaves do not heat evenly. Inadequate reheating for hot holding could allow pathogen survival/growth.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined; language to be deleted is in strikethrough format):

Section 3-403.11

(A) Except as specified under ¶¶ (B) and (C) and in ¶ ~~(E)~~ (F) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked, cooled, and

reheated for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74ºC (165ºF) for 15 seconds. P

(B) Except as specified under ¶ (C) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD reheated in a microwave oven for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74ºC (165ºF) ~~and the FOOD is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating~~. P

(C) READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that has been commercially processed and PACKAGED in a FOOD PROCESSING PLANT that is inspected by the REGULATORY AUTHORITY that has jurisdiction over the plant, shall be heated to a temperature of at least 57ºC (135ºF) when being reheated for hot holding. P

(D) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD reheated in a microwave oven for hot holding shall be rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating. P

~~(D)~~ (E) Reheating for hot holding as specified under ¶¶ (A) -(C) of this section shall be done rapidly and the time the FOOD is between 5ºC (41ºF) and the temperatures specified under ¶¶ (A) -(C) of this section may not exceed 2 hours. P

~~(E)~~ (F) *Remaining unsliced portions of MEAT roasts that are cooked as specified under ¶ 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under ¶ 3-401.11(B).*

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-024

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

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Issue History:

This is a brand new Issue.

Title:

Separation of Packaged Products Displayed at Retail

Issue you would like the Conference to consider:

Retailers have a desire to cross merchandise certain items for customer convenience at point of sale (e.g. packages of cheese singles displayed adjacent to modified atmosphere packages (MAP) of raw preformed hamburgers, cooked bacon packages near raw bacon packages). Additionally, packaged salads may contain packets of portioned salad dressing within the package of salad greens. The 2013 FDA Food Code Section 3-302.11 has been used as the basis for not allowing this type of product merchandising.

Modern package integrity has improved and is less likely to leak when compared to historical packaging. This improved packaging mitigates the cross-contamination concerns over juices spilling from a package containing one species of meat/poultry onto another package containing another species. Package integrity is a food safety and quality issue and defects are corrected immediately.

Public Health Significance:

The FDA Food Code requires separation of products to protect from cross contamination. While prevention of cross contamination is critical, we are not aware of any documented foodborne illnesses from cross contamination from packaged product in retail stores due to contact with other packaging. In the event that packaging integrity is compromised, products are removed and the area is cleaned and sanitized. Therefore, the public health impact of this provision is minimal and the proposed change would be minimal.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2013 Food Code Section 3-302.11 (A) be amended and for the word "AND" to be changed to an "OR" in section (B) (7) as follows (language to be added is in underline format)

3-302.11

A) FOOD shall be protected from cross contamination by:

(1) Except as specified in (1)(c) and (d) below, separating raw animal FOODS during storage, preparation, holding, and display from:

(a) Raw READY-TO-EAT FOOD including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, or other raw READY-TO-EAT FOOD such as fruits and vegetables, [P] and

(b) Cooked READY-TO-EAT FOOD; [P]

(c) *Frozen, commercially processed and packaged raw animal FOOD may be stored or displayed with or above frozen, commercially processed and packaged, ready-to eat food.*

(d) Food that is adequately packaged to prevent the entry of microbes and other contaminants such as chemicals, and displayed in a manner that would further reduce the likelihood of contamination such as a physical barrier or any other effective means.

(2) *Except when combined as ingredients*, separating types of raw animal FOODS from each other such as beef, FISH, lamb, pork, and POULTRY during storage, preparation, holding, and display by:

(a) Using separate EQUIPMENT for each type, [P] or

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

(c) Preparing each type of FOOD at different times or in separate areas; [P]

(3) Cleaning EQUIPMENT and UTENSILS as specified under ¶ 4-602.11(A) and SANITIZING as specified under § 4-703.11;

(4) Except as specified under Subparagraph 3-501.15(B)(2) and in ¶ (B) of this section, storing the FOOD in packages, covered containers, or wrappings;

(5) Cleaning HERMETICALLY SEALED CONTAINERS of FOOD of visible soil before opening;

(6) Protecting FOOD containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

(7) Storing damaged, spoiled, or recalled FOOD being held in the FOOD ESTABLISHMENT as specified under § 6-404.11; ~~and~~ OR

(8) Separating fruits and vegetables, before they are washed as specified under § 3-302.15 from READY-TO-EAT FOOD.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-025

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

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Issue History:

This is a brand new Issue.

Title:

Separating Raw Animal Food from Unwashed Fruits and Vegetables

Issue you would like the Conference to consider:

Specify that raw animal food must be separated from unwashed fruits and vegetables. Unwashed fruits and vegetables are not considered ready-to-eat. Therefore the separation required between raw animal food and ready-to-eat food does not apply.

Public Health Significance:

Raw animal foods contain naturally occurring bacteria that are eliminated by cooking. Many fruits and vegetables are only washed, not cooked. Washing fruits and vegetables that have been cross contaminated by raw animal foods is not an effective control measure.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined; language to be deleted is in strikethrough format):

Section 3-302.11(A)(1)

(A) FOOD shall be protected from cross contamination by:

(1) Except as specified in (1)~~(c)~~ (d) below, separating raw animal FOODS during storage, preparation, holding, and display from:

(a) Raw READY-TO-EAT FOOD including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, or other raw READY-TO-EAT FOOD such as fruits and vegetables, [P] and

(b) Cooked READY-TO-EAT FOOD; [P]

(c) Fruits and vegetables before they are washed as specified under § 3-302.15.

~~(c)~~ (d) *Frozen, commercially processed and packaged raw animal FOOD may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food.*

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-026

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:

Chemical treatment of water used to wash or crisp raw fruits and vegetables

Issue you would like the Conference to consider:

The consumption of fresh produce has increased in the US while at the same time outbreaks of public health significance related to fresh fruits and vegetables continue to occur. The safety of fresh produce remains a challenge for the food industry. As technologies to enhance the safety of fresh produce become more readily available, they should be utilized by all food establishments.

As specified in the 2013 Food Code in section 3-302.15 Washing Fruits and Vegetables, "...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. [Emphasis added]

Further, in the Food Code paragraph 3-302.15(B), it states, "Fruits and vegetables ***may*** be washed by using chemicals as specified under § 7-204.12." [Emphasis added]

Washing fresh produce, in this context, is required but using treated water is optional. It is well documented that raw agriculture commodities (RACs) may be contaminated with pathogens and, when soaked or submerged in water, there is a risk of cross-contamination. Various chemicals are available that can minimize and/or prevent cross-contamination and, to a lesser degree, reduce pathogen load on fresh produce.

Therefore, the Conference should consider that when produce is washed, crisped, re-hydrated or processed by soaking or submersion, the water used for these purposes shall be chemically treated to minimize the risk of cross-contamination.

Public Health Significance:

The use of chemicals for washing, treatment, storage and processing fruits and vegetables is specified in the Food Code as follows:

7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.

(A) Chemicals, including those generated on-site, used to wash or peel raw, whole fruits and vegetables shall:

(1) Be an approved food additive listed for this intended use in the Code of Federal Regulations, 21 CFR 173, [P] or

(2) Be generally recognized as safe (GRAS) for this intended use, [P] or

(3) Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification), [P] and

(4) Meet the requirements in 40 CFR 156 Labeling Requirements for Pesticide and Devices. [P]

The criteria for using chemicals for washing, treatment, storage and processing fruits and vegetables are designated in the Food Code as priority items. Sufficient controls are already prescribed to ensure the safe and effective use of these chemicals.

Washing raw fruits and vegetables can remove soil and other contaminants. Many food establishments use soaking or submersion as an approved, effective technique for washing produce. This method is often preferred for a variety of reasons, including:

- The contact time is better controlled
- All surfaces come in direct contact with the water
- It reduces the amount of waste water
- It allows for simultaneous washing and re-hydrating
- It helps minimize shrink and extends shelf life
- It improves the appearance of the product
- *And*, when chemicals are added, can provide an antimicrobial treatment for the reduction/prevention of cross-contamination.

It is well documented that pathogenic microorganisms may be present on the exterior surfaces of raw fruits and vegetables. The Food Code Annex 3, Chapter 3, Section 3-302.15 Washing Fruits and Vegetables states that "...more recent studies have demonstrated washing to fall short of their [pathogens] complete removal." There is currently no readily available treatment that can ensure removal or destruction of all pathogens on raw agriculture commodities (RACs) with the possible exception of irradiation.

Using chemically treated water to wash and/or process fresh produce can impact public health by minimizing the risk of cross-contamination and reducing pathogens if they are present. The Food Code Annex 3, Public Health Reasons, supports this position in Section 3-302.15 Washing Fruits and Vegetables as follows:

"All fresh produce, except commercially washed, pre-cut, and bagged produce, must be thoroughly washed under running, potable water or with chemicals as specified in Section 7-204.12, or both, before eating, cutting or cooking. Even if you plan to peel or otherwise alter the form of the produce, it is still important to remove soil and debris first" [Emphasis added] and "It is important to follow practices that minimize pathogens in the water or on the surface of produce." [Emphasis added]

The use of chemicals is equivalent, if not better, than rinsing under running water. Further, the use of chemicals will minimize pathogens in the water. It is estimated (unpublished data) that over three-quarters of grocery stores soak/submerge certain raw produce items to wash, crisp and/or re-hydrate them. Concerns about cross-contamination have led some experts to question the potential risk when soaking produce in untreated water. However, treated water has been shown to be very effective in minimizing/preventing cross-contamination

In January 2014, the Food Marketing Institute published, in collaboration with the Produce Marketing Association and United Fresh Produce Association, *"Produce Safety Best Practices Guide for Retailers*" advising retailers to use sanitizers when soaking/submerging fresh produce. The following guidance was provided to retailers regarding crisping fresh produce:

- If a bath is used, follow sanitizer recommendations
- If using a bath, an appropriate sanitizer should be used in compliance with label directions. [Emphasis added]

(http://www.fmi.org/docs/default-source/food-safety/produce-safety-best-practices-guide.pdf?sfvrsn=2)

Treating produce wash water in the processing sector has been extensively studied. The FDA *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (October, 1998) specifically addresses this issue. In Chapter 2, Section 2.2 it states, "...antimicrobial chemicals in processing water are useful in reducing microbial build-up in water and may reduce microbial load on the surface of produce. Thus, antimicrobial chemicals may provide some assurance in minimizing the potential for microbial contamination."

(www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm064574.htm)

The failure to add antimicrobial chemicals in processing water has also been cited as a contributing factor in foodborne outbreaks attributed to fresh produce. For example, a U.S. House of Representatives, Committee on Energy and Commerce report on an investigation of an outbreak of Listeria monocytogenes in cantaloupe states that FDA officials found several deficiencies including not using an "antimicrobial solution such as chlorine in the water used to wash the cantaloupes."

Additional studies and research support the use of chemicals in water that comes in contact with RACs. For example, a study was conducted in November 2013, comparing 5 different sanitizer options and plain tap water. It was found that sanitizers can have a significant impact on food safety because they are effective in reducing pathogens in the wash water itself, which reduces opportunities for cross-contamination.[1] (attached)

At the 2013 Symposium of the Center for Produce Safety (CPS), a collaborative partnership of industry, government and academic communities, a Key Learning report on wash water concluded, in part:

Many different products are washed, cooled or transported using water. Therefore it is important that the water is treated and maintained properly so that it does not become a source of cross contamination for human pathogens, should they be present. It is equally important to remember that simply washing products is not an effective mechanism for

removing contamination, i.e. it cannot remove or kill pathogens that have had the opportunity to naturally seek out hidden surfaces on products and adhere to them. Therefore our focus is to manage contamination risks throughout production (e.g. GAPs, inspections, hygiene, equipment sanitation, training programs, etc.) and control wash, cooling and transport processes using water so that we do not create cross contamination scenarios. Improper control over wash, cooling or water-based transport systems can do harm, i.e. resulting in large-scale cross contaminations. Dr. Trevor Suslow vividly demonstrated this assertion using an inoculated cilantro load and washing it with un-inoculated parsley on a commercial wash system. The improperly controlled wash system permitted cross contamination onto the parsley demonstrating the potential for cross contamination.

(http://www.centerforproducesafety.org/amass/documents/document/186/Key%20Learnings_2013%20CPS%20Symposium.pdf)

On January 22, 2013, the Center for Produce Safety (CPS) conducted a seminar on post-harvest water disinfection. Among the Key Learnings from this seminar was the following conclusion:

Disinfectants are used in water that contacts produce to prevent cross contamination and not necessarily to kill microorganisms that might be present on the surface of the fruit or vegetable.

If water is not properly treated with active disinfectant, after a period of time the water could become a source of contamination for any fruits or vegetables that are conveyed, cooled or washed in it. Therefore the primary reason for treating water with disinfectants is to keep the water clean of microbial build up. In most systems the level of microbial reduction on the surface of fruits or vegetables is generally thought to be 1-2 logs.

(http://www.pma.com/content/articles/2014/05/cps-wash-water-key-learnings)

The FDA *Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce*, A Report of the Institute of Food Technologists for the Food and Drug Administration published September 30, 2001 provided this summary in Chapter V. Section 1:

It is well established that pathogenic microorganisms associated with whole or fresh-cut produce can cause disease outbreaks, thereby demonstrating the need for improved mitigation efforts to reduce risks associated with these products.

The best method to eliminate pathogens from produce is to prevent contamination in the first place. However, this is not always possible and the need to wash and sanitize many types of produce remains of paramount importance to prevent disease outbreaks. It should be noted that washing and sanitizing are unlikely to totally eliminate all pathogens after the produce is contaminated. Therefore, it is important to use washing and sanitizing protocols that are efficient.

(http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm091363.htm)

Finally, the technology and/or products used to treat water used to wash, crisp, re-hydrate or process fresh produce by soaking or submersion are not proprietary. Several antimicrobial compounds are readily available to the industry. No one product or supplier is advocated. Food establishments have the opportunity to select a water treatment that is

most appropriate to their circumstances. A comprehensive review of these chemicals can be found in the FDA *Preventive Control Measures for Fresh & Fresh-Cut Produce*, Chapter V., Methods to Reduce/Eliminate Pathogens from Produce and Fresh-Cut Produce.

(www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm090977.htm)

[1] Davidson, G., Buchholz, A., Ryser, E. 2013 November*. Efficacy of Commercial Produce Sanitizers against Nontoxigenic Escherichia coli O157:H7 during Processing of Iceberg Lettuce in a Pilot-Scale Leafy Green Processing Line*. Journal of Food Protection; Number 11: pp. 1824-1993, pp. 1838-1845

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that section 3-302.15 of the 2013 Food Code be amended as follows (language to be added is underlined; language to be deleted is in strikethrough format):

3-302.15 Washing Fruits and Vegetables.

(B) Fruits and vegetables ~~may~~ shall be washed by using chemicals as specified under § 7-204.12 when soaked or submerged.

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Supporting Attachments:

- "Efficacy of Commercial Produce Sanitizers against Nontoxigenic Escherichia"

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.

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Efficacy of Commercial Produce Sanitizers against Nontoxigenic *Escherichia coli* O157:H7 during Processing of Iceberg Lettuce in a Pilot-Scale Leafy Green Processing Line

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ABSTRACT

Chemical sanitizers are routinely used during commercial flume washing of fresh-cut leafy greens to minimize cross-contamination from the water. This study assessed the efficacy of five commercial sanitizer treatments against *Escherichia coli* O157:H7 on iceberg lettuce, in wash water, and on equipment during simulated commercial production in a pilot-scale processing line. Iceberg lettuce (5.4 kg) was inoculated to contain 10^6 CFU/g of a four-strain cocktail of nontoxigenic, green fluorescent protein–labeled, ampicillin-resistant *E. coli* O157:H7 and processed after 1 h of draining at ~22°C. Lettuce was shredded using a commercial slicer, step-conveyed to a flume tank, washed for 90 s using six different treatments (water alone, 50 ppm of peroxyacetic acid, 50 ppm of mixed peracid, or 50 ppm of available chlorine either alone or acidified to pH 6.5 with citric acid [CA] or T-128), and then dried using a shaker table and centrifugal dryer. Various product (25-g) and water (50-ml) samples collected during processing along with equipment surface samples (100 cm^2) from the flume tank, shaker table, and centrifugal dryer were homogenized in neutralizing buffer and plated on tryptic soy agar. During and after iceberg lettuce processing, none of the sanitizers were significantly more effective ($P \leq 0.05$) than water alone at reducing *E. coli* O157:H7 populations on lettuce, with reductions ranging from 0.75 to 1.4 log CFU/g. Regardless of the sanitizer treatment used, the centrifugal dryer surfaces yielded *E. coli* O157:H7 populations of 3.49 to 4.98 log CFU/100 cm^2. Chlorine, chlorine plus CA, and chlorine plus T-128 were generally more effective ($P \leq 0.05$) than the other treatments, with reductions of 3.79, 5.47, and 5.37 log CFU/ml after 90 s of processing, respectively. This indicates that chlorine-based sanitizers will likely prevent wash water containing low organic loads from becoming a vehicle for cross-contamination.

In 2009, leafy greens were ranked as the riskiest food category regulated by the U.S. Food and Drug Administration, accounting for 363 outbreaks and 13,568 reported cases of illness *(13)*. Between 1995 and 2006, leafy green–associated outbreaks increased by 38.6%, whereas consumption increased by only 9% *(22)*. The nationwide outbreak of *Escherichia coli* O157:H7 that was traced to baby spinach in 2006 resulted in 205 confirmed infections, 103 hospitalizations, and three deaths *(10, 17)*. Following two additional *E. coli* O157:H7 outbreaks in 2006 linked to shredded iceberg lettuce resulting in 150 illnesses *(12),* at least nine more outbreaks responsible for nearly 300 cases of *E. coli* O157:H7 infection have been documented in the United States through 2012 *(14),* heightening continued safety concerns surrounding fresh-cut leafy greens.

Bacterial pathogens can contaminate leafy greens at any point during the farm-to-fork continuum *(31)*. Major on-farm areas of concern now recognized by the U.S. Food and Drug Administration include agricultural water, biological soil amendments (e.g., manure), domesticated and wild animals, field worker health and hygiene, and the cleanliness of harvesting equipment, tools, and buildings *(47)*. However, leafy greens are also prone to contamination during commercial processing, packing *(8),* distribution, marketing *(51),* and in-home preparation *(35)*. Regarding leafy greens, pathogens are most likely to attach to stomata, irregularities on intact surfaces, cut surfaces, or cracks on the external surfaces *(20, 36, 38, 39, 42)* and can be protected from sanitizers by biofilms *(40)*. Because sanitizers in the wash water cannot be relied upon to inactivate attached or internalized pathogens during processing, it is imperative that growers and harvesters follow good agricultural practices and good handling practices to reduce the likelihood of contamination *(19)*.

Washing of leafy greens remains important for removing soil and debris, decreasing the microbial load, improving quality and appearance, and enhancing product shelf life and safety *(21)*. Numerous small-scale laboratory studies have shown that produce sanitizers reduce pathogen populations only 1 to 3 log CFU on lettuce *(4, 18, 20, 36, 38),* with water alone decreasing *E. coli* O157:H7 levels about 1 log CFU on lettuce during pilot-scale processing *(6)*. Recirculation of this wash water during processing can further magnify the spread of contaminants at large, centralized processing facilities *(21, 28)*. Hence, the

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addition of sanitizers to processing water is imperative to minimize cross-contamination during commercial production of fresh-cut leafy greens *(2, 29, 38, 46)*.

Chlorine-based sanitizers are preferred for commercial flume washing systems because of their relatively low cost compared with other sanitizers and minimal negative impact on end-product quality *(11, 21, 29, 33, 36)*. Since the active component of chlorine, hypochlorous acid (HClO), is most abundant at pH 6.5 to 7.0 *(3)*, the pH of the wash water typically needs to be lowered by adding a weak acid, most commonly citric acid *(21)*. A new, generally recognized as safe acidifying agent composed of phosphoric acid and propylene glycol, known as T-128 (SmartWash Solutions, Salinas, CA), has been developed to improve the stability of chlorine *(25, 29, 33, 41)*. However, chlorine use has raised concerns regarding potentially hazardous by-products, worker safety, environmental damage, and most importantly, decreased efficacy in the presence of an increasing organic load in recirculating flume water, which has heightened interest in other alternatives such as peroxyacetic acid–based sanitizers *(38, 43)*.

Numerous small-scale laboratory studies have assessed sanitizer efficacy against pathogens on leafy greens *(1, 4, 23, 24, 27, 30, 34, 44, 52, 53)*. However, these findings are difficult to extrapolate to large-scale commercial production facilities. Previous work completed by our group was performed without chemical sanitizers to quantify *E. coli* O157:H7 transfer during pilot-plant production of fresh-cut leafy greens *(6, 7)*. Since chemical sanitizers remain the sole intervention strategy to prevent cross-contamination during commercial production of fresh-cut leafy greens, it is imperative that these sanitizers be reevaluated under conditions that more closely resemble commercial operations. Consequently, the objective of this study was to assess the efficacy of five commercial sanitizer treatments against *E. coli* O157:H7 during processing of iceberg lettuce in a pilot-scale leafy green processing line.

MATERIALS AND METHODS

Experimental design. The efficacy of five different sanitizing treatments was assessed in triplicate against *E. coli* O157:H7 by processing a 5.4-kg batch of iceberg lettuce inoculated at 10^6 CFU/g, with sanitizer-free water serving as the control. All lettuce was processed by shredding, conveying, fluming, shaker table dewatering, and/or centrifugal drying, during and/or after which various product, water, and equipment surface samples were collected and quantitatively examined for *E. coli* O157:H7.

Iceberg lettuce. Individually wrapped heads of iceberg lettuce (*Lactuca sativa* L.) (24 heads per case) were obtained from a local wholesaler (Stan Setas Produce Co., Lansing, MI), with the product originating from California or Arizona depending on the growing season. All lettuce was stored in a 4°C walk-in cooler and used within 5 days of delivery.

Bacterial strains. Four nontoxigenic (stx_1^- and stx_2^-) strains of *E. coli* O157:H7 (ATCC 43888, CV2b7, 6980-2, and 6982-2) were obtained from Dr. Michael Doyle at the Center for Food Safety, University of Georgia, Griffin. These strains had been previously transformed with a pGFPuv plasmid containing a green fluorescent protein gene and ampicillin-resistance gene. All four strains were stored at −80°C in tryptic soy broth (Difco, BD, Sparks, MD) containing 0.6% (wt/vol) yeast extract (Difco, BD) (TSBYE) and 10% (vol/vol) glycerol (Sigma Chemical Co., St. Louis, MO) until needed. Working cultures were prepared by streaking each stock culture on tryptic soy agar plates (Difco, BD) containing 0.6% (wt/vol) yeast extract and 100 ppm of ampicillin (ampicillin sodium salt, Sigma Life Science, St. Louis, MO) (TSAYE plus amp). After 18 to 24 h of incubation at 37°C, a single colony was transferred to 9 ml of TSBYE containing 100 ppm of ampicillin (TSBYE plus amp) and similarly incubated.

Lettuce inoculation. A 0.2-ml aliquot of each nontoxigenic *E. coli* O157:H7 strain was transferred to 200 ml of TSBYE with amp and incubated for 18 to 20 h at 37°C. Based on similar growth rates as determined previously *(6)*, the four strains were combined in equal volumes to obtain an 800-ml cocktail, which was added to 80 liters of municipal tap water (~15°C, <0.05 ppm of free chlorine) in a 121-liter plastic container (Rubbermaid, Wooster, OH) to achieve a level of $\sim 10^7$ CFU/ml. Hand-cored heads of iceberg lettuce (~12 heads) were immersed in the *E. coli* suspension for 15 min and then drained or air dried for 1 h at 22°C before being spun in a dewatering centrifuge (described below) to remove residual inoculum from the interior of the heads. Duplicate 25-g samples were then aseptically collected to determine the initial inoculation level at the time of processing.

Lettuce processing line. The same small-scale commercial leafy green processing line consisting of a lettuce shredder, step conveyer, flume tank, shaker table, and dewatering centrifuge was used as previously described in detail by Buchholz et al. *(6)*. For this work, a custom-made stainless steel gate with 1.25-cm-diameter holes spaced 0.65 cm apart (Heinzen Manufacturing, Inc., Gilroy, CA) was added at the end of the 3.3-m-long stainless steel flume tank to retain the product during 90 s of washing.

Wash water. Iceberg lettuce (0.5 kg) was homogenized in 500 ml of Michigan State University tap water using a mechanical blender (model BLC10650MB, Black & Decker, New Britain, CT) and then added to 890 liters of processing water at 12 to 15°C to achieve a low organic load. The following five commercial produce sanitizer treatments were assessed: 30 ppm of peroxyacetic acid (Tsunami 100, Ecolab, St. Paul, MN), 30 ppm of mixed peracid (Tsunami 200, Ecolab), 30 ppm of available chlorine (XY-12, Ecolab) at pH 7.85, 30 ppm of available chlorine (XY-12) acidified to pH 6.50 with citric acid (Sigma-Aldrich, St. Louis, MO), and 30 ppm of available chlorine (XY-12) acidified to pH 6.50 with T-128 (SmartWash Solutions) as measured with a pH probe (pHTestr 30, Oakton, Vernon Hills, IL). Peroxyacetic acid test kit 311 (Ecolab) was used to confirm the peroxyacetic acid and mixed peracid sanitizer concentrations, and chlorine test kit 321 (Ecolab) was used to measure available chlorine. Sanitizer-free Michigan State University tap water (<0.05 ppm of free chlorine) served as the control.

Lettuce processing. Inoculated heads of cored iceberg lettuce (5.4 kg) were hand-fed into the shredder at a rate of about 0.5 kg per s, with the shredded product then step-conveyed at a rate of 2.85 m/s to the top of the conveyor. Processing was then halted for ~10 min to aseptically collect and bag five 25-g lettuce samples in red mesh produce bags (5 lb Header Bag, Pacon Inc., Baldwin Park, CA) for subsequent sampling. Thereafter, processing was resumed with the iceberg lettuce conveyed to the flume tank, washed in 890 liters of recirculating wash water with or without a

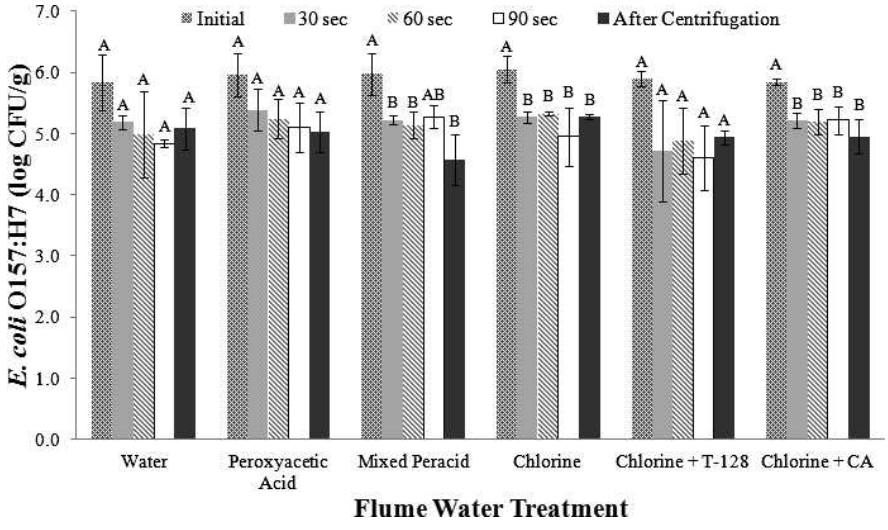

FIGURE 1. *Mean (±SD)* E. coli *O157:H7 populations on the iceberg lettuce inoculated at ~6 log CFU/g during and after processing (*n = *3). Means of the same wash water treatment with different letters are significantly different (*P ≤ *0.05).*

sanitizer for 90 s, partially dewatered on the shaker table, collected in a single centrifugation basket, and centrifugally dried.

Sample collection. During the 90 s of flume washing, three prebagged iceberg lettuce samples (25 g each) were retrieved at the flume gate at 30-s intervals and were immediately added to 100 ml of sterile Difco neutralizing buffer (BD, Franklin Lakes, NJ) in a Whirl-Pak filter bag (Nasco, Fort Atkinson, WI). In addition, nine 50-ml water samples were collected at 10-s intervals in 50-ml centrifuge tubes containing 38× concentrated Difco neutralizing buffer (BD). After shaker table dewatering, product in the basket was dried in the preset 50-lb (110-kg) capacity Spin Dryer (model SD50-LT, Heinzen Manufacturing). During centrifugal drying, four water samples (50 ml each) were similarly collected from the centrifuge drain at 10-s intervals for the first 40 s of the 80-s cycle. After centrifugation, two bagged lettuce samples (25 g each) were also retrieved from the centrifugation basket. Nine product contact areas on the equipment (three flume tank, three shaker table, and three dewatering centrifuge), previously described in detail by Buchholz et al. *(6),* measuring 100 cm^2 as previously identified using Glo Germ (Glo Germ Co., Moab, UT) were sampled immediately after processing as described by Vorst et al. *(48)* using one-ply composite tissues moistened with 1 ml of sterile Difco neutralizing buffer (BD).

Microbiological analyses. All lettuce samples (25 g) were homogenized in a stomacher (Stomacher 400 Circulator, Seward, Worthington, UK) for 1 min at 260 rpm and then either appropriately diluted in sterile 1% (wt/vol) phosphate buffer (8.5 g/liter NaCl, 1.44 g/liter Na_2HPO_4, and 0.24 g/liter KH_2PO_4; J.T. Baker, Mallinckrodt Baker Inc., Phillipsburg, NJ) and plated on TSAYE with amp (calculated minimum detection limit of 40 CFU/g) or processed using 0.45-μm-pore-size membrane filters (Millipore, Millipore Corporation, Billerica, MA) (calculated minimum detection limit of 0.04 CFU/g), which were placed on 60-mm-diameter petri plates containing TSAYE with amp to quantify *E. coli* O157:H7. The one-ply composite tissue samples were added to 15 ml of sterile Difco neutralizing buffer in a Whirl-Pak bag, homogenized for 1 min at 260 rpm, and then plated identically to the lettuce samples, giving a calculated lower detection limit of 1 CFU/100 cm^2. The 50-ml water samples were either appropriately diluted in sterile 1% phosphate buffer and plated on TSAYE with amp or processed by membrane filtration, which gave a calculated minimum detection limit of 0.02 CFU/ml. Following 20 to 24 h of incubation at 37°C, all green fluorescing colonies as seen under UV light (365 nm; Blak-Ray, Ultra-violet Product Inc., San Gabriel, CA) were counted as *E. coli* O157:H7.

Sanitizer neutralization confirmation. Triplicate 1-liter water samples containing 30 ppm of available chlorine (XY-12), 30 ppm of peroxyacetic acid (Tsunami 100), or 30 ppm of mixed peracid (Tsunami 200 ppm) were prepared and confirmed with chlorine test kit 321 or peroxyacetic acid test kit 311. Citric acid (Sigma-Aldrich) and T-128 were used to acidify the chlorine-based sanitizer solution to pH 6.5. A 50-ml centrifuge tube containing 3 ml of 38× concentrated neutralizing buffer (BD) was filled with the sample containing sanitizer, agitated for 5 s, and then immediately assessed for neutralization of the sanitizer as previously described using the appropriate test kit. Preliminary experiments found that a 38× concentration would neutralize various concentrations of the active component of each sanitizing agent used in this study without impacting *E. coli* O157:H7 counts.

Statistical analysis. *E. coli* O157:H7 counts were converted to log CFU per gram, milliliter, or 100 cm^2 and were subjected to analysis of variance using JMP 9.0 (SAS Institute Inc., Cary, NC). Values equaling half the limit of detection were used for samples without *E. coli* O157:H7 counts. The three equipment surface samples from each respective piece of equipment were averaged. A *P* value of ≤0.05 was considered significant for all tests. The Tukey-Kramer honestly significant difference test was used to identify significant differences in *E. coli* O157:H7 populations for individual lettuce, water, and equipment surface samples.

RESULTS

Lettuce. Iceberg lettuce contained an average *E. coli* O157:H7 inoculum of 5.93 log CFU/g at the time of processing (Fig. 1). After shredding, conveying, 90 s of washing, shaker table dewatering, and centrifugal drying, no significant difference ($P > 0.05$) was seen in populations of *E. coli* O157:H7 recovered from the finished product, regardless of sanitizer treatment. Using mixed peracid, *E. coli* O157:H7 populations decreased 1.40 log CFU/g; however, this decrease was not significantly different ($P > 0.05$) compared with the 0.75-log CFU/g reduction seen for water alone. Processing significantly reduced ($P \leq 0.05$) *E. coli* O157:H7 populations on lettuce when mixed peracid, chlorine,

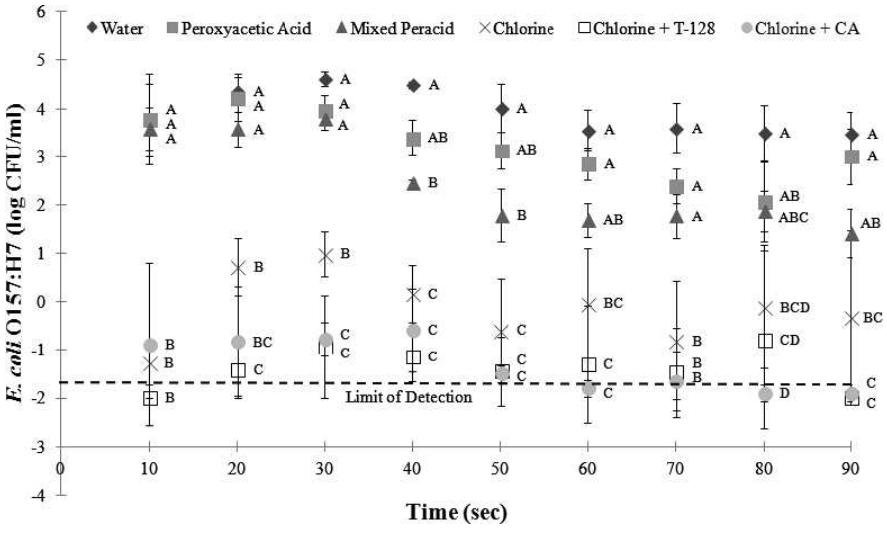

FIGURE 2. *Mean (±SD)* E. coli *O157:H7 populations in flume water during processing iceberg lettuce inoculated at ~6 log CFU/g (n = 3). Half the limit of detection was used to calculate the mean log value when a sample did not yield any colonies by direct plating. Means of the same product type with different letters are significantly different (P ≤ 0.05).*

or chlorine plus CA were used, with reductions of 1.40, 0.77, and 0.89 log CFU/g, respectively. The reductions of 0.75, 0.93, and 0.97 log CFU/g seen for water alone, peroxyacetic acid, and chlorine plus T-128, respectively, were not significant ($P > 0.05$) (Fig. 1).

Flume water. Wash water containing chlorine, chlorine plus T-128, and chlorine plus CA had significantly lower ($P \leq 0.05$) *E. coli* O157:H7 populations at all sampling times (maximum of 0.99 log CFU/ml) compared with 4.61 log CFU/ml in water alone. Using chlorine plus CA and chlorine plus T-128, *E. coli* O157:H7 levels were below the limit of detection of 0.02 log CFU/ml by the end of processing. *E. coli* O157:H7 populations were similar ($P > 0.05$) using water alone and peroxyacetic acid, with respective populations of 3.47 and 3.01 log CFU/ml recovered after 90 s of processing. Similar *E. coli* O157:H7 populations were obtained using mixed peracid ($P > 0.05$) and peroxyacetic acid, with these populations rarely lower ($P \leq 0.05$) than those in water alone (Fig. 2).

Centrifugation water. Using peroxyacetic acid, mixed peracid, or chlorine, wash water exiting the centrifuge drain after spin drying yielded maximum *E. coli* O157:H7 populations of 4.51, 4.36, and 5.48 log CFU/ml, respectively, which were not significantly different ($P > 0.05$) from those in water alone (maximum population of 5.58 log CFU/ml) during the 40-s sampling period. However, chlorine plus CA and chlorine plus T-128 resulted in *E. coli* O157:H7 populations that were lower than those in water alone ($P \leq 0.05$) during the first 20 s of centrifugation. Water samples collected after 40 s of centrifugation yielded *E. coli* O157:H7 populations that were not significantly different for any of the treatments (Fig. 3).

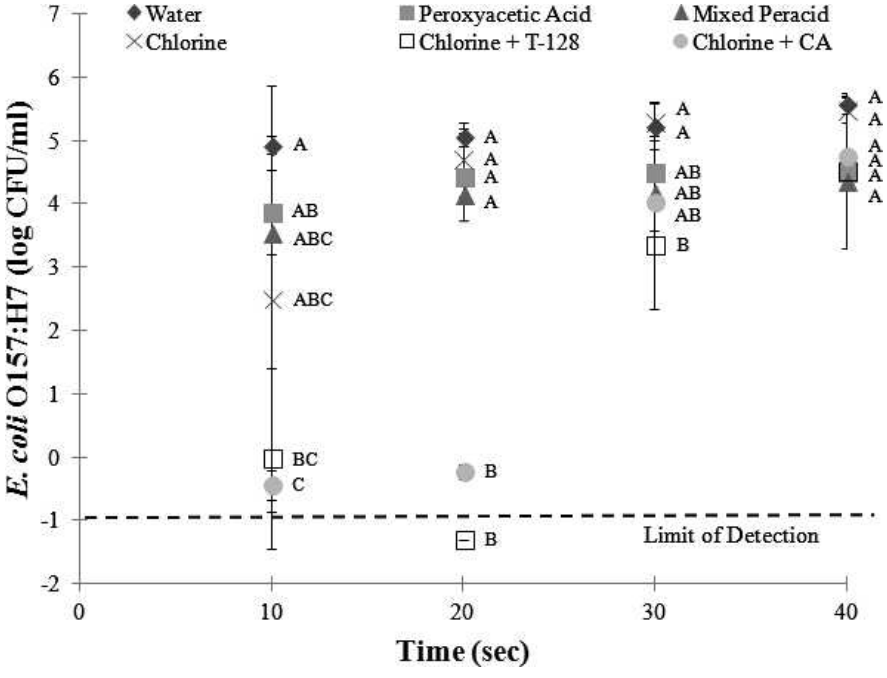

FIGURE 3. *Mean (±SD)* E. coli *O157:H7 populations in spent centrifugation water from iceberg lettuce inoculated at ~6 log CFU/g (n = 3). Half the limit of detection was used to calculate the mean log value when a sample did not yield any colonies by direct plating. Means of the same product type with different letters are significantly different (P ≤ 0.05).*

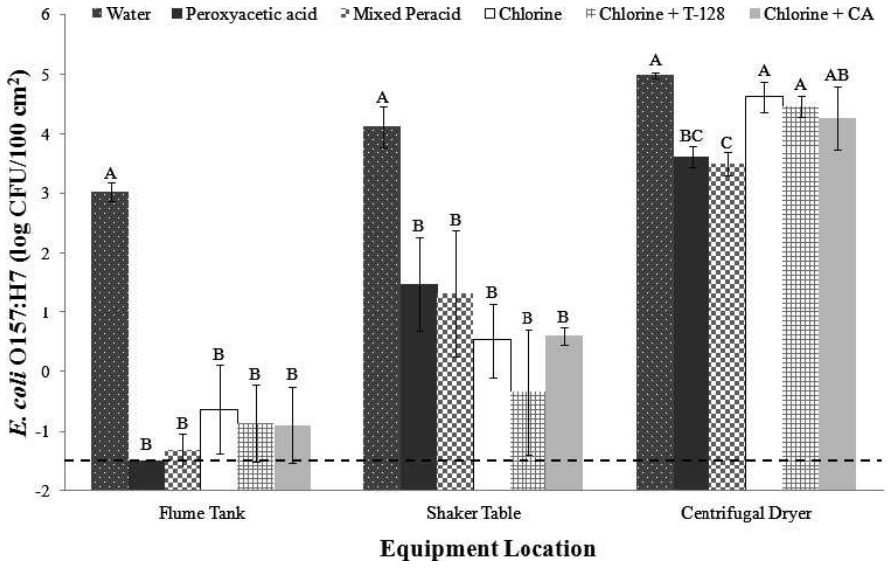

FIGURE 4. *Mean (±SD)* E. coli *O157:H7 populations on equipment surfaces after processing iceberg lettuce inoculated at ~6 log CFU/g* (n = *3). Half the limit of detection was used to calculate the mean log value when a sample did not yield any colonies by direct plating. Means of the same product type with different letters are significantly different (*$P \leq 0.05$*).*

Processing equipment surfaces. After processing iceberg lettuce, all five sanitizer treatments yielded significantly lower ($P \leq 0.05$) *E. coli* O157:H7 populations remaining on the flume tank and shaker table as compared with the water control. Significantly lower ($P \leq 0.05$) *E. coli* O157:H7 populations were recovered on the centrifugal dryer using peroxyacetic acid (3.61 log CFU/100 cm^2) and mixed peracid (3.49 log CFU/100 cm^2) compared with the other treatments, with the highest level (4.98 log CFU/100 cm^2) seen when water alone was used for washing (Fig. 4).

DISCUSSION

Due to the potential production of infectious aerosols during lettuce processing, the same four nontoxigenic strains of *E. coli* O157:H7 were used as in our earlier transfer studies *(6, 7)*. The growth and adherence rates for these four nontoxigenic strains were previously shown to be similar to three strains from the 2006 leafy green outbreaks *(6)*. As previously reported, green fluorescent protein labeling also allowed for easy differentiation of the inoculum from background bacteria *(6, 7, 49)*.

Dip inoculation of the lettuce to contain 6 log CFU/g was crucial to ensure uniform distribution of *E. coli* O157:H7 throughout the heads as well as quantifiable results for subsequent mathematical modeling with this work to be reported elsewhere. Although this inoculation level clearly exceeds levels thought to occur on field-grown lettuce, feces from ''super-shedding'' cows can potentially contain *E. coli* O157:H7 at levels of 6 log CFU/g *(15)*, with such fecal material potentially able to come in contact with lettuce through irrigation water. Preliminary experiments using a mixture of Glo Germ and water showed uniform fluorescence in dipped heads of iceberg lettuce. Additionally, Buchholz and others *(6)* found that *E. coli* O157:H7 populations were statistically similar in iceberg lettuce heads before and after shredding, indicating that the inoculation was homogenous. Dip inoculation of the cored lettuce heads may have allowed internalization of *E. coli* O157:H7 through the damaged tissues, with such cells protected from sanitizers *(37)*. Since all lettuce samples were processed by stomaching, any internalized cells would have gone undetected with only the cells on the surface of the leaves recovered.

Commercial producers of fresh-cut leafy greens use different sanitizers, sanitizer concentrations, and contact times, depending on the design of the processing line. In this study, six different wash treatments were assessed during 90 s of flume washing. Processing inoculated iceberg lettuce resulted in *E. coli* O157:H7 reductions of 0.75 to 1.4 log CFU/g on the finished product. Both during and after processing, no significant differences in sanitizer efficacy ($P > 0.05$) were seen against *E. coli* O157:H7 on iceberg lettuce for any of the treatments, including water alone. However, three wash treatments—mixed peracid, chlorine, and chlorine plus CA—significantly reduced ($P \leq 0.05$) *E. coli* O157:H7 populations after washing. Numerous small-scale laboratory studies have shown similar pathogen reductions (~1 log CFU/g) during washing of various fruits and vegetables with or without sanitizers *(4, 5, 9, 50)*. Using a pilot-scale leafy green processing line, Luo et al. *(29)* also reported an *E. coli* O157:H7 reduction of <1 log after processing inoculated baby spinach *(29)*. Consequently, produce sanitizers cannot be relied upon to ensure end product safety. Chemical sanitizers are routinely added to recirculating wash water to minimize the spread of microbial contaminants during flume washing *(27)*. Regarding their use, peroxyacetic acid–based sanitizers are limited to a maximum of 80 ppm of peroxyacetic acid *(16, 21)*, whereas free chlorine concentrations typically range from 10 to a maximum of 200 ppm *(20, 36, 45)*. However, soil, debris, and vegetable latexes released during shredding of leafy greens will accumulate in the flume water over time *(32)*, decreasing the efficacy of many sanitizers, most notably chlorine *(2, 26, 38, 52)*. The wash water used in this study contained an organic load of ~0.0006% blended iceberg lettuce (wt/vol) to simulate wash water quality during the early stages of processing. Hence, higher *E. coli* O157:H7 populations would have been expected after 90 s of processing if the organic load in the wash water had been

higher, especially for the chlorine-based sanitizer. *E. coli* O157:H7 populations recovered from the wash water were consistently lower ($P \leq 0.05$) using chlorine, chlorine plus CA, and chlorine plus T-128 compared with water alone, peroxyacetic acid, and mixed peracid. Both chlorine plus CA and chlorine plus T-128 treatments yielded *E. coli* O157:H7 levels that were below the limit of detection, which is similar to the findings of López-Gálvez et al. *(27)* using 40 ppm of chlorine.

This study was designed to assess the efficacy of sanitizers during processing, not to assess long-term pathogen persistence in the wash water. Produce sanitizers are primarily used to minimize cross-contamination during flume washing, with their effectiveness dependent on the type of sanitizer, concentration, temperature, and organic load in the wash water. The pilot-scale processing line used in this study was not equipped with a chiller. Therefore, all processing needed to be conducted at our incoming tap water temperature of 12 to 15°C rather than at the targeted commercial temperature of 4°C. Since sanitizer efficacy against *E. coli* O157:H7 is enhanced at temperatures above 4°C *(53),* our *E. coli* O157:H7 reductions likely exceed those that would be expected in commercial operations.

Levels of *E. coli* O157:H7 recovered from spent centrifugation water containing sanitizers were rarely lower than those seen in sanitizer-free water. Similar *E. coli* O157:H7 populations were recovered from centrifugation water containing peroxyacetic acid, mixed peracid, chlorine, or no sanitizer at all four sampling times. The combination of chlorine and citric acid or T-128 was significantly more effective than the other sanitizers ($P \leq 0.05$) against *E. coli* O157:H7 in centrifugation water collected during the first 20 s; however, after 40 s no significant difference was seen compared with the water control ($P > 0.05$). These results indicate that, whereas populations of *E. coli* O157:H7 may be close to or below the limit of detection in flume water, populations in the centrifugation water were not significantly different than the water control by the end of sample collection. Therefore, spent centrifugation water would be best suited for pathogen testing.

E. coli O157:H7 cells recovered from equipment surfaces after processing reflect those that were present in the film of water on the equipment surface. During processing, the flume tank was in continuous contact with the recirculating wash water, with water contact decreasing during shaker table dewatering and centrifugal drying. Numbers of *E. coli* O157:H7 recovered from surfaces in the centrifugal dryer were not significantly different from the water control when any of the three chlorine-based sanitizer treatments were used, indicating that those surfaces may also be well suited for pathogen testing, depending on the particular sanitizer used.

This study was done to assess the efficacy of commercial produce sanitizers against *E. coli* O157:H7 on lettuce, in wash water, and on equipment surfaces during small-scale processing of iceberg lettuce. Whereas none of the sanitizers were more effective than water alone against *E. coli* O157:H7 on iceberg lettuce at any point during or after processing, it is important to reiterate that sanitizers are designed to reduce the microbial load in wash water rather than on the product. Overall, the populations of *E. coli* O157:H7 recovered in wash water containing peroxyacetic acid or mixed peracid were rarely significantly different than those seen in water alone. However, the three chlorine-based treatments were significantly more effective than water alone at reducing *E. coli* O157:H7 populations in wash water during processing. The wash water used in this study replicated a ''best-case'' scenario for processors due to the extremely low organic load and freshly added sanitizers. Similar studies using higher organic loads will be needed to assess sanitizer efficacy against *E. coli* O157:H7 under conditions that more closely simulate commercial processing.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-027

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

All information above the line is for conference use only.

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014-III-27; the recommended solution has been revised.

Title:

Chemicals Used for Washing and Treating Fruits and Vegetables

Issue you would like the Conference to consider:

A revision and clarification to the language of the 2013 Food Code, Section 7-204.12. The current language of Section 7-204.12 of the FDA Food Code *Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria,* does not:

1. Differentiate between two categories of products, one chemical substance providing wash properties only and another substance with antimicrobial treatment properties.
2. Allow for additionally approved antimicrobial treatment chemicals other than Ozone.

Washing chemicals (detergents) *can* be different than treatment chemicals (antimicrobials). Washing chemicals are typically rinsed off after use and do not carry antimicrobial claims. Many other treatment (antimicrobial) chemicals are not rinsed off after use and do carry claims to reduce, control, kill or treat microorganisms in/on Fruits and Vegetables or in wash water. The Food Code combines these uses in Section 7-204.12 and we recommend clearing up confusion and providing guidance for compliance and enforcement.

As technology advances, new methods to wash and treat produce are being developed. New treatment chemicals are being evaluated and cleared by FDA and registered with EPA, if applicable. Treatment chemicals used on fruits and vegetables can be under jurisdiction of FDA, EPA, or both, depending on the use and where the treatment occurs. The complexity of this jurisdiction and the lack of clear guidance may lead to the improper use of these chemicals some of which were not adequately reviewed by health and safety regulating agencies.

A decision tree is available from FDA (and could be included in the Food Code Annex if deemed appropriate) to help explain the EPA-FDA jurisdiction of antimicrobial substances entitled *Determining Regulatory Authority of Antimicrobial Substances* and found at the following link:

http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RegulatoryAuthorityAntimicrobialSubstances/default.htm

Lastly, the Food Code as it is currently written does not allow for antimicrobial treatment chemicals other than Ozone. There are many other antimicrobial chemicals on the market today that have been reviewed and cleared by FDA (and/or registered by EPA). The way the Food Code currently depicts Ozone as a treatment chemical in 7-204.12 suggests that Ozone is the only antimicrobial chemical treatment allowed. Moreover, an update would be needed to the Food Code (or Annex) each instance that a new treatment chemical (i.e. Sodium Dodecylbenzenesulfonate/SDBS in Annex 3) is cleared by FDA. Section 7-204.12 is not all inclusive and should be revised to allow for treatments chemicals other than Ozone without the need to update the Food Code each time new chemistry is developed and approved.

Public Health Significance:

Per Annex 3 of the 2013 FDA Food Code- "*If the chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result".* This improper use of chemicals may also lead to public health issues such as food adulteration and recalls, and/or potentially acute and chronic health effects to both the consumer and the employees within the food retail facilities. The lack of clear and explicit guidance surrounding chemicals used for treating fruits and vegetables creates confusion, and allows for misinterpretation.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the 2013 Food Code Section 7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria be modified as follows (language to be added is underlined; language to be deleted is in strikethrough format):

(A) Chemicals, including those generated on-site, used to wash or peel raw whole fruits and vegetables shall:

(1) Be an approved food additive listed for this intended use in 21 CFR 173, or

(2) Be generally recognized as safe (GRAS) for this intended use, or

(3) Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification), and

(4) Meet the requirements in 40 CFR 16 Labeling Requirement for Pesticide and Devices.

(B) Chemicals ~~Ozone~~, including those generated on-site, used as an antimicrobial agent ~~used~~ in the treatment, storage, and processing of fruits and vegetables in a food establishment shall: ~~meet the requirements of 21 CFR 173.368 Ozone:~~

1. Meet the requirements in 7-204.11 and 7-204.12 (A), and,
2. Be appropriately cleared/registered by FDA or/and EPA and be used in accordance with the EPA - registered label use instructions, or manufacturer's instructions.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-028

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:

Ambient Cooling Pre-chilled TCS Foods

Issue you would like the Conference to consider:

Clarify the 2013 FDA Food Code that ambient cooling also applies to pre-chilled Time Temperature Control for Safety (TCS) food that has risen above 41°F during preparation at ambient temperature.

Public Health Significance:

Section 3-501.14 Annex 3 of the 2013 FDA Food Code states safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of time/temperature control for safety foods has been consistently identified as one of the leading contributing factors to foodborne illness. During slow cooling, time/temperature control for safety foods are subject to the growth of a variety of pathogenic microorganisms.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined; language to be deleted is in strikethrough format)

Section 3-501.14

(A) Cooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled:

(1) Within 2 hours from 57ºC (135ºF) to 21ºC (70°F); [P] and

(2) Within a total of 6 hours from 57ºC (135ºF) to 5ºC (41°F) or less. [P]

(B) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled within 4 hours to 5ºC (41ºF) or less if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna. [P]

(C) Pre-chilled TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that rises above 5°C (41°F) during preparation at ambient temperature, such as sliced deli meats and prepared sandwiches, shall be cooled within 4 hours to 5°C (41°F) or less.

~~(C)~~ (D) Except as specified under ¶ ~~(D)~~ (E) of this section, a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less. P

~~(D)~~ (E) Raw EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less. P

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-029

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

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Issue History:

This is a brand new Issue.

Title:

Acidified Food Date Marking Exemption

Issue you would like the Conference to consider:

In the 2013 FDA Food Code, DATE MARKING is exempt under Section 3-501.17 (G) for specific FOODS prepared and PACKAGED by a FOOD PROCESSING PLANT inspected by a REGULATORY AUTHORITY. For example, this exemption allows for foods such as deli salads manufactured under 21 CFR 110 Current Good Manufacturing Practices and for Preserved FISH products, such as pickled herring and dried or salted cod, and other acidified FISH products defined in 21 Code of Federal Regulation (CFR) 114 Acidified foods, to not require date marking. Although, other canned food items that are manufactured per both 21 CFR 110 and 114 are not included in the list of exemptions. Therefore, it is unclear in the Food Code whether or not food items that are typically known to be acidified or naturally acidic such as fruit juices, canned food vegetables and fruit (olives, jalapenos, pepper rings, etc), and mixed products (salsa, salad dressings, ketchup) labeled as "Keep Refrigerated After Opening" require date marking. The retail food industry and regulators do not have a method to determine whether a food labeled with "Refrigerate after opening" is a quality or safety issue without further proof that these foods meet the Food Code Table A or B under Time/Temperature Control for safety.

Public Health Significance:

With new manufacturing processes, recipes, and formulations, it is not always clear whether or not a manufactured food is defined as TCS and requires date-marking along with temperature control after opening. This is especially true if the packaging contains directions to "Refrigerate after Opening", making it difficult for regulators during routine inspections to determine whether food require both time and temperature control. To avoid the onus of investigating the quality versus safety of time/temperature control to each individual food establishment, an added exemption for date marking acidified foods is warranted. This would lessen the impact to the retail food industry and the inconsistent regulations of these types of food items. The Food Code already exempts certain food items such as deli salads, hard cheeses, semi-soft cheeses, cultured dairy products,

preserved fish products, and other dry fermented or salt-cured meats, which all still require temperature control. Adding Food items that have been prepared and packaged per CFR 114 in a Food Processing Plant inspected by a Regulatory Authority to the date marking exemption would be of no greater public health threat than the previously listed food items under 3-501.17 (G)

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined):

Section 3-501.17 (G):

(G) Paragraph (B) of this section does not apply to the following FOODS prepared and PACKAGED by a FOOD PROCESSING PLANT inspected by a REGULATORY AUTHORITY:

(1) Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR 110 Currentgood manufacturing practice in manufacturing, packing, or holding human food;

(2) Hard cheeses containing not more than 39% moisture as defined in 21 CFR 133 Cheeses and related cheese products, such as cheddar, gruyere, parmesan and reggiano, and romano;

(3) Semi-soft cheeses containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR 133 Cheeses and related cheese products, such as blue, edam, gorgonzola, gouda, and monterey jack;

(4) Cultured dairy products as defined in 21 CFR 131 Milk and cream, such as yogurt, sour cream, and buttermilk;

(5) Preserved FISH products, such as pickled herring and dried or salted cod, and other acidified FISH products defined in 21 CFR 114 Acidified foods;

(6) Shelf stable, dry fermented sausages, such as pepperoni and Genoa; and

(7) Shelf stable salt-cured products such as prosciutto and Parma (ham).

(8) Packaged acidified food items, such as salad dressings, salsas, fruits, vegetables, etc. that have been manufactured in accordance with 21 CFR 114 Acidified Foods.

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2016 Issue Form

Issue: 2016 III-030

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:

Amend Food Code – Clarify sprouting as a specialized process

Issue you would like the Conference to consider:

A recommendation is being made to change the 2013 FDA Food Code Section 3-502.11 (H) to include a clarification on sprouting that requires a variance and Hazard Analysis Critical Control Point (HACCP) plan.

The FDA Food Code Section 3-502.11 discusses specialized processing methods that require a variance from the regulatory authority. A clarification on what is considered "sprouting seeds or beans" is needed to provide both industry and regulatory personnel guidance on proceeding with variance submittal and HACCP Plan development.

Public Health Significance:

The FDA Food Code Annex 3 explains the rationale for FDA Food Code Section 3-502.11 by stating: "specific food processes that require a variance have historically resulted in more foodborne illness than standard processes." Also, these methods require specialized equipment or knowledge by food employees to be done safely, and can present a significant health risk if not done properly[1]. When a variance is required, the FDA Food Code Section 8-201.13 states that a HACCP Plan must be prepared by the permit applicant or permit holder and approved by the regulatory authority. Creation of HACCP Plans by food service establishments can be costly[2], and therefore it is important to eliminate confusion regarding sprouting which requires a HACCP Plan.

Consumption of seed sprouts is a growing trend among the public, with raw seed sprouts being served on many restaurant menus for decades. Raw seed sprouts from manufacturers have been linked to many foodborne illness outbreaks[3]. The contamination seems to come from the seed itself and the dark, warm growing conditions that are present for growth[3, 4]. Because of this, producers of raw seeds sprouts have taken steps to eliminate contamination prior to sproutng[3]. Microgreens are also growing in popularity among high end restaurants, and because they can be grown quickly in small quantities[5], could be produced by the food service establishment for use. Microgreens are grown in soil

and require light to grow[4], which is different from the growing conditions for a raw seed sprout. This means that the high risk associated with the growth of raw seed sprouts would not be the same as the growth of microgreens.

Both microgreens and raw seed sprouts would meet the dictionary definition of sprouting, which is "to produce new leaves[6]." Clarifying that this only applies to sprouting that is done from a raw seed sprout and not microgreens would help to eliminate the development and review of unnecessary HACCP Plans. The clarification needs to be made that the sprouting would be considered a special process only when the intention is for the seed itself to be consumed, since that is where the potential contamination is found.

References:

1. "Annex 3." FDA 2013 Food Code. College Park, MD: U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, 2013. 465. Print.

2. Sharma, A., Roberts, K., & Seo, K. 2010. HACCP Cost Analysis in Retail Food Establishments. Food Protection Trends.

3. Thompson, S., Powell D.A. Risks Associated With The Consumption of Fresh Sprouts. Food Safety Network Technical Report # 16. July, 2000

4. R. Holmer, G. Linwattana, P. Nath, J.D.H. Keatinge, eds. High Value Vegetables in Southeast Asia: Production, Supply and Demand. AVRDC-WorldVegetableCenter, 2013.

5. Treadwell, D., Hochmuth, R., Landrum, L., Laughlin W. Microgreens- A New Specialty Crop. Florida Cooperative Extension Service. April 2010.

6. Sprout [def.1]. In *Marriam-Webster Online*. Retrieved January 8, 2016. http://www.merriam-webster.com/dictionary/sprout.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending the 2013 Food Code be amended to include clarifying language for "sprouting seeds or beans." Recommended language to read (new language is underlined):

3-502.11 Variance Requirement

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before: [Pf]

(H) Sprouting seeds or beans <u>for the purpose of human consumption of both the seed and the sprout, as in raw seed sprouts.</u>

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Supporting Attachments:

- "Microgreens- A New Specialty Crop"

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UF UNIVERSITY of FLORIDA
IFAS Extension

HS1164

Microgreens: A New Specialty Crop[1]

Danielle D. Treadwell, Robert Hochmuth, Linda Landrum, and Wanda Laughlin[2]

Frequently called "vegetable confetti," microgreens are young, tender greens that are used to enhance the color, texture, or flavor of salads, or to garnish a wide variety of main dishes (Figs. 1 and 2). Harvested at the first true leaf stage and sold with the stem, cotyledons (seed leaves), and first true leaves attached, they are among a variety of novel salad greens available on the market that are typically distinguished categorically by their size and age. Sprouts, microgreens, and baby greens are simply those greens harvested and consumed in an immature state. Based on size or age of salad crop categories, sprouts are the youngest and smallest, microgreens are slightly larger and older (usually 2 in. tall), and baby greens are the oldest and largest (usually 3–4 in. tall).

Figure 1. Microgreens in this photo are predominantly in the cotyledon stage and are a few days away from harvest.

Figure 2. Microgreens are often termed "vegetable confetti."

Both baby greens and microgreens lack any legal definition. The terms "baby greens" and "microgreens" are marketing terms used to describe their respective categories. Sprouts are germinated seeds and are typically consumed as an entire plant (root, seed, and shoot), depending on the species. For example, sprouts from almond, pumpkin, and peanut reportedly have a preferred flavor when harvested prior to root development. Sprouts are legally defined, and have additional regulations concerning their production and marketing due to their relatively high risk of microbial contamination compared to other greens. Growers interested in producing sprouts for sale need to be aware of the risks and precautions summarized in the FDA publication

1. This document is HS1164, one of a series of the Horticultural Sciences Department, Florida Cooperative Extension Service, Institute of Food and Agricultural Sciences, University of Florida. Original publication date April 2010. Revised July 2013. Visit the EDIS website at http://edis.ifas.ufl.edu.

2. Danielle D. Treadwell, associate professor, Horticultural Sciences; Robert Hochmuth, Extension agent IV, SVAEC; Linda Landrum, retired Extension agent IV, SVAEC; and Wanda Laughlin, senior ag assistant, SVAEC.

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Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds (FDA 1999).

The crops used for microgreens usually do not include lettuces because they are too delicate and wilt easily. The kinds of crops that are selected for production and sale as microgreens have value in terms of color (like red or purple), unique textures, or distinct flavors. In fact, microgreens are often marketed as specialty mixes, such as "sweet," "mild," "colorful," or "spicy."

Certain crops of microgreens germinate easily and grow quickly. These include cabbage, beet, kale, kohlrabi, mizuna, mustard, radish, swiss chard, and amaranth. Soaking some seeds prior to sowing, such as beets, helps facilitate germination. As many as 80–100 crops and crop varieties have reportedly been used as microgreens (Fig 3). Others that have been used include carrot, cress, arugula, basil, onion, chive, broccoli, fennel, lemongrass, popcorn, buckwheat, spinach, sweet pea, and celery. Growers should evaluate various crop varieties to determine their value as microgreens. Many seed companies are very knowledgeable about the crops and varieties to grow, and a number of them offer organic seed.

Figure 3. A variety of crops can be grown and sold as microgreens.

The commercial marketing of microgreens is mainly targeted toward restaurant chefs or upscale grocery stores. Prices for microgreens generally range from $30 to $50 per pound. The product is packaged in plastic clamshell containers that are typically 4–8 oz by weight but can be sold in 1 lb containers as well.

Production

Microgreens may be grown by individuals for home use. Growing small quantities at home is relatively easy; however, growing and marketing high-quality microgreens commercially is much more difficult. Having the right mix at the perfect stage for harvest is one of the most critical production strategies for success. The time from seeding to harvest varies greatly from crop to crop. When seeding a mixture of crops in a single planting flat, growers should select crops that have a similar growth rate so the entire flat can be harvested at once. Alternatively, growers can seed the various crops singularly and mix them after harvest.

Microgreens can be grown in a standard, sterile, loose, soilless germinating media. Many mixes have been used successfully with peat, vermiculite, perlite, coconut fiber, and others. Partially fill a tray with the media of choice to a depth of 1/2 in. to 1 or 2 in., depending on irrigation programs. Overhead mist irrigation is generally used only through the germination stage in these media systems. After germination, trays should be subirrigated to avoid excess moisture in the plant canopy.

An alternative production system uses one of several materials as a mat or lining to be placed in the bottom of a tray or longer trough. These materials are generally fiberlike and provide an excellent seeding bed. Materials may include burlap or a food-grade plastic specifically designed for microgreens such as those made by Sure to Grow (Beachwood, OH). These mat systems are often used in a commercially available production system using wide NFT-type troughs. The burlap mat may be sufficient alone for certain crops or may require a light topping with a media after seeding. Seeding may be done as a broadcast or in rows. Seeding density is difficult to recommend. Most growers indicate they want to seed as thickly as possible to maximize production, but not too thickly because crowding encourages elongated stems and increases the risk of disease. Most crops require little or no fertilizer, as the seed provides adequate nutrition for the young crop. Some longer-growing microgreen crops, such as micro carrot, dill, and celery, may benefit from a light fertilization applied to the tray bottom. Some of the faster-growing greens, such as mustard cress and chard, may also benefit from a light fertilization because they germinate quickly and exhaust their self-contained nutrient supply quickly. Light fertilization is best achieved by floating each tray of microgreens for 30 seconds in a prepared nutrient solution of approximately 80 ppm nitrogen.

Microgreens are ready for harvest when they reach the first true leaf stage, usually at about 2 in. tall. Time from seeding to harvest can vary greatly by crop from 7 to 21 days. Production in small trays will likely require harvesting with scissors. This is a very time-consuming part of the production cycle and is often mentioned by growers as a major drawback. The seeding mat type of production system has gained popularity with many growers because it facilitates faster harvesting. The mats can be picked up by hand and held vertically while an electric knife or trimmer is used for harvesting, allowing cut microgreens to fall from the mat into a clean harvest container. Harvested microgreens are highly perishable and should be washed and cooled as quickly as possible. Some chefs are asking growers to deliver in the trays or mats and they will cut the microgreens as needed to improve quality. Wash the microgreens using good handling practices for food safety. Microgreens are usually packed in small, plastic clamshell packages and cooled to recommended temperatures for the crops in the mix. Growers should be aware that marketing agreements such as the National Leafy Green Marketing Agreement (NLGMA) have been proposed to reduce the risk of microbial contamination of mature and immature leafy greens. For the current status of the NLGMA, visit http://www.nlgma.org/.

References

Food and Drug Administration. 1999. *Guidance for industry: Reducing microbial food safety hazards for sprouted seeds*. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm120244.htm.

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-031

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

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Issue History:

This is a brand new Issue.

Title:

Amend Food Code – Include Definition for Curing

Issue you would like the Conference to consider:

A recommendation is being made to change the 2013 FDA Food Code Section 1-201.10 (B) to include a definition for "curing."

The FDA Food Code Section 3-502.11 discusses specialized processing methods that require a variance from the regulatory authority. A clear definition of what is considered "curing" is needed to provide both industry and regulatory personnel guidance on proceeding with variance submittal and HACCP Plan development.

Public Health Significance:

The FDA Food Code Annex 3 explains the rationale for FDA Food Code Section 3-502.11 by stating: "specific food processes that require a variance have historically resulted in more foodborne illness than standard processes." Also, these methods require specialized equipment or knowledge by food employees to be done safely, and can present a significant health risk if not done properly[1]. When a variance is required, the FDA Food Code Section 8-201.13 states that a HACCP Plan must be prepared by the permit applicant or permit holder and approved by the regulatory authority. Creation of HACCP Plans by food service establishments can be costly[2], and therefore it is important to eliminate confusion regarding curing which requires a HACCP Plan.

Confusion results from products which may be considered "cured" to establishments due to the addition of curing salt or sodium nitrate but are kept otherwise within the time/temperature parameters outlined in the FDA Food Code Sections 3-501.16 and 3-501.17. The Code of Federal Regulations describes in 21CFR172.175 acceptable levels of sodium nitrite (200 parts per million) and sodium nitrate (500 parts per million) for use as a food additive. Because these products are allowable under 21CFR172.175, the addition of sodium nitrate or sodium nitrite with no other variation in the time/temperature parameters of the FDA Food Code would be regulated as Protection from Unapproved Additives, FDA Food Code Section 3-302.14, and would also be held to the requirements of FDA Food

Code Sections 3-202.12 Additives. Clarification needs to be provided in the FDA Food Code so that food establishments using sodium nitrite or sodium nitrate as a food additive only, without using it for true food preservation, do not use unnecessary resources on HACCP Plan development.

The FDA Food Code Annex 6 describes the process of curing in terms of food processing criteria. United States Department of Agriculture (USDA) has a widely accepted definition of curing that is used for their regulations[3]. This definition is used throughout resources for food establishments[4,5]. Additionally, the use of natural nitrate and nitrites from vegetable powders and juices should be considered in the definition of curing due to the increase popularity of natural foods[6].

References:

1. "Annex 3." FDA 2013 Food Code. College Park, MD: U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, 2013. 465. Print.

2. Sharma, A., Roberts, K., & Seo, K. 2010. HACCP Cost Analysis in Retail Food Establishments. Food Protection Trends.

3. "What Is Curing?" *Ask Karen*. FSIS USDA, 26 Mar. 2009. Web. 28 Dec. 2015.

4. Forest JC, Aberle ED, Hedrick HB, Judge MD, Merkel RA. Principle of meat science. San Francisco: Freeman; 1975.

5. B.A. Nummer and Andress, E.L. 2002. Curing and Smoking Meats for Home Food Preservation Literature Review and Critical Preservation Points. Athens, GA: The University of Georgia, Cooperative Extension Service.

6. Sebranek, Joseph G., Bacus, James N. 2007. Cured meat products without direct addition of nitrate or nitrite: what are the issues? Meat Science.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending the 2013 Food Code be amended to include a new definition under Section 1-201.10 for "curing." Recommended language to read (new language underlined):

1-201.10 Statement of Application and Listing of Terms

(B) Terms Defined As used in this Code, each of the terms listed in ¶ 1-201.10(B) shall have the meaning stated below.

<u>"Curing" means the addition of salt, nitrates or nitrites (either manufactured or naturally occurring), for preservation, color development, and flavor.</u>

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Supporting Attachments:

- "Cured meat products without direct addition of nitrate or nitrite: what are"

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Cured meat products without direct addition of nitrate or nitrite: what are the issues?

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Abstract

The growing popularity of food products marketed in the United States as "natural" and "organic" has resulted in a proliferation of marketing efforts to meet consumer demands for these foods. Because natural and organic foods are not permitted to use chemical preservatives, the traditional curing agents used for cured meats, nitrate and/or nitrite, cannot be added to natural and organic processed meat products. However, alternative processes that utilize ingredients with high nitrate content, such as vegetable-based ingredients, and a nitrate-reducing starter culture can produce processed meats with very typical cured meat properties. Because it is not possible to analytically measure the amount of nitrite produced by this process, several potential issues deserve consideration. Regulations, for example, should permit labeling that accurately reflects the process and products, manufacturing procedures must be standardized to achieve product consistency, marketing efforts should clearly communicate the nature of these products to consumers, product quality must be maintained, and microbiological safety must be assured.
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Keywords: Organic; Natural; Cured meats; Nitrite; Nitrate

1. Introduction

In many parts of the world, natural and organic foods have been experiencing an explosive market growth. Natural and organic processed meats have been a very significant part of that growth, and in the United States, have made up the fastest growing category of natural and organic foods (Mitchell, 2006; Organic Trade Association, 2006). Several studies have documented that consumer preferences for organic and natural foods are based on concerns about antibiotics, pesticides, hormones, genetic modifications in plants and animals, and chemical additives that consumers associate with conventionally produced foods (Bourn & Prescott, 2002; Devcich, Pedersen, & Petrie, 2007; Dreezens, Martijn, Tenbult, Kok, & deVries, 2005; Saher, Lindeman, & Hursti, 2006; Siderer, Maquet, & Anklam, 2005; Winter & Davis, 2006). Consumers are willing to pay significant premiums for organic and natural foods. Premiums of 10–40% for organic foods over conventional products are common (Winter & Davis, 2006) but for meat and poultry, premiums may reach 200% (Bacus, 2006) or even more. In one such example, the average retail price for four brands of organic broilers in the Midwest during April and May, 2006 was $3.19/lb. compared to $1.29/lb. for conventionally produced broilers, a 247% difference (Husak, 2007). The large premiums that consumers are willing to pay for natural and organic foods have resulted in a rapid proliferation of new products and increased marketing by retailers (Petrak, 2005).

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In the US, natural and organic foods must be produced and processed according to United States Department of Agriculture (USDA) regulations that define these products. In most cases, natural and organic foods are very similar to conventional products and do not differ in the typical characteristics expected by consumers. However, in the case of processed meat products such as hams, bacon, frankfurters, bologna and others that are typically cured by addition of sodium/potassium nitrite or nitrate, the requirements for natural or organic labeling do not permit addition of nitrite or nitrate. Nitrite, added directly or derived from nitrate, is a unique, distinctive cured meat ingredient for which there is no substitute, consequently significant process and product changes are necessary to produce natural or organic processed meats that provide consumers with the properties expected of traditional cured meat products. These changes, combined with labeling requirements for these products, have resulted in a category of processed meats in the US that is confusing, and perhaps even misleading, to consumers. Further, because of the essential role that nitrite plays in cured meat quality and safety, changes in the products need to be carefully examined in light of the processing changes that are being introduced for manufacturing natural and organic processed meats. Consequently, several considerations including regulatory, manufacturing, marketing, quality and safety issues need to be addressed.

2. Background

2.1. Definitions of natural and organic processed meats

The requirements for processed meats such as hams, bacon, frankfurters and bologna to qualify as natural or organic in the US have resulted in unique approaches to the development of these products. This is because, while ''natural'' and ''organic'' are two separate and distinct categories of meat and poultry products in terms of USDA regulations and labels, neither of these product categories are permitted to be manufactured with added sodium (or potassium) nitrite or nitrate. However, the USDA permits the manufacture of uncured versions of typical cured meats according to the Code of Federal Regulations (2006), 9 CFR 319.2, which reads:

> ''Any product, such as frankfurters and corned beef, for which there is a standard in this part and to which nitrate or nitrite is permitted or required to be added, may be prepared without nitrate or nitrite and labeled with such standard name when immediately preceded with the term ''Uncured'' in the same size and style of lettering as the rest of such standard name: *Provided*, That the product is found by the Administrator to be similar in size, flavor, consistency and general appearance to such products as commonly prepared with nitrate and nitrite: *And providing further*, That labeling for such products complies with the provisions of 317.17 (C) of this subchapter''.

Thus, there is another category of processed meats, separate from ''natural'' and ''organic'', and that category is ''uncured''. The definitions of natural and organic require that ''uncured'' be included on the label for products labeled with a standardized cured product name (i.e., uncured bacon), but it is important to note that not all products labeled ''uncured'' are natural or organic.

Processed meats that are labeled ''natural'' must comply with the definition of the term provided by the USDA Food Standards and Labeling Policy Book (USDA, 2005). This definition requires that a natural product ...

> ...''does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and the product and its ingredients are not more than minimally processed''.
>
> The term ''minimally processed'' includes
>
> ''...traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or those physical processes which do not fundamentally alter the raw product..., e.g. grinding meat...''. (USDA, 2005).

The definition of natural has been controversial. For example, in the 2005 edition of the USDA Food Standards and Labeling Policy Book, a note was added indicating that sugar, sodium lactate (from a corn source) and natural flavorings from oleoresins or extractives are acceptable for ''all natural'' claims (USDA, 2005). However, because lactate is widely recognized as an antimicrobial ingredient, such use may conflict with the ''no chemical preservatives'' requirement for labeling of a product as natural. This was the basis for a petition submitted to the USDA in October, 2006 after which the Agency removed lactate from the guidance statement provided for natural claims. The USDA will, however, consider use of lactate for natural foods on a case-by-case basis for applications where the ingredient may function as a flavoring rather than a preservative. Further, the Agency is currently planning to initiate new rulemaking processes in the near future for the use of ''natural'' to clarify these uses as well as the use of natural claims relative to livestock production practices (O'Connor, 2006).

Products labeled as organic are much better defined and controlled in the US than the products labeled with natural claims because organic products are governed by the USDA Organic Foods Production Act (OFPA), first established in 1990 as part of the 1990 Farm Bill (Winter & Davis, 2006). The OFPA created a National Organic Standards Board, which established a National List of Allowed and Prohibited Substances, and developed National Organic Program Standards. The standards, implemented in 2002, specify methods, practices and substances that may be used for production, processing and handling of organic foods. Meat, for example, must be raised under

organic management and come from a USDA-certified farm. Ingredients used for processed products are clearly defined as permitted or prohibited in the OFPA National List. Organic products may be labeled as; (1) "100% organic" which must contain only organically produced ingredients; (2) "organic" which must contain at least 95% organically produced ingredients; or (3) "made with organic ingredients" which must have at least 70% organic ingredients. Products with less than 70% organic ingredients are not allowed to be labeled as organic and are permitted only to list those ingredients that are organic on the label. Those products that qualify for the "organic" and "100% organic" labeling are permitted to use the USDA organic seal as part of the label.

2.2. Definitions of cured and uncured processed meats

The term "cured" relative to processed meats is universally understood to mean the addition of nitrite or nitrate with salt and other ingredients to meat for improved preservation (Pegg & Shahidi, 2000). While several ingredients including sugar, spices, phosphates and others are typically included in cured meats, it is the addition of nitrite in one form or another that results in the distinctive characteristics of cured meat (Cassens, 1990). The typical color, flavor, shelf life and safety of ham, bacon, frankfurters, bologna and other cured products are so widely recognized by consumers that these product names are considered "standardized" and "traditional" by the USDA for product labeling and to not require any further clarification to communicate the expected product properties to consumers. On the other hand, products that are similar but made without nitrite or nitrate, must be clearly labeled as "uncured" as described earlier. This is because "uncured" versions of standardized products like ham, bacon, frankfurters and bologna are significantly different from the traditional products that they emulate. At the same time, there are a number of processed meats that are traditionally manufactured without nitrite or nitrate, and that are not labeled as uncured because the standardized product name effectively communicates that the product is not cured. Fresh sausage, such as pork sausage, for example, is not labeled as "uncured" because these products are standardized, traditional and the common name is clearly understood.

The advent of natural and organic processed meat products, both of which prohibit direct addition of nitrite or nitrate, but that also resemble traditional cured meat has made it necessary to require "uncured" as part of the traditional product name. However, because current meat processing technology has developed means by which nitrate and nitrite can be indirectly added to these products to achieve very typical cured meat properties, the labeling designations for these products as uncured is confusing and technically inaccurate. Further, because the indirect addition of nitrate and nitrite to natural and organic processed meats has not been thoroughly investigated in terms of nitrite chemistry and subsequent product properties, a number of important questions remain to be answered, particularly in regard to quality and safety.

3. Review of conventional cured meat ingredients and processes

Conventionally – cured meat products are characterized by addition of nitrate and/or nitrite. While other ingredients, particularly sodium chloride, are essential parts of typical cured meat formulations, it is the nitrate/nitrite that provides the distinctive properties that are common to all cured meat products. The role of nitrate/nitrite is so commonly understood in the meat industry that the term "cure" is used as both a noun and a verb, meaning either nitrate/nitrite as chemical entities, or the addition of these ingredients to meat, respectively.

3.1. Nitrate

Numerous reviews of the history of meat curing have suggested that meat curing originally developed from use of salt contaminated with sodium or potassium nitrate (Binkerd & Kolari, 1975; Cassens, 1990; National Academy of Sciences, 1982; Pegg & Shahidi, 2000; Pierson & Smoot, 1982; Sebranek, 1979).

While it is not clear when saltpeter (potassium nitrate) was first recognized as a curing agent, it is clear that nitrate, either as saltpeter or as a contaminant of sodium chloride, was used to cure meat for centuries before research chemists began to unravel the chemistry of meat curing. In the late 1800s, it was discovered that nitrate was converted to nitrite by nitrate-reducing bacteria, and that nitrite was the true curing agent. The first half of the 20th century brought a gradual shift from nitrate to nitrite as the primary curing agent for cured meats as the advantages of faster curing time for increased production capacity became more important, and as nitrite chemistry became better understood. By the early 1970s, relatively little nitrate was being used for cured meats (Binkerd & Kolari, 1975). The late 1960s and early 1970s also brought a watershed event for the cured meat industry when it became obvious that nitrite could result in formation of carcinogenic n-nitrosamines in cured meat. Subsequent research demonstrated that a significant factor in nitrosamine formation was residual nitrite concentration, and consequently, nitrate was eliminated from most curing processes to achieve better control over residual nitrite concentrations (Pegg & Shahidi, 2000). Today, nitrate is rarely used and then only in a few specialty products such as dry cured hams and dry sausage where long, slow curing processes necessitate a long-term reservoir for nitrite that can be slowly released over the course of the process.

3.2. Nitrite

The chemistry of nitrite in cured meat is an extremely complex mixture of interactive chemical reactions involv-

ing several different reactants. Nitrite is a highly reactive compound that can function as an oxidizing, reducing or a nitrosylating agent, and can be converted to a variety of related compounds in meat including nitrous acid, nitric oxide and nitrate (Honikel, 2004). To further complicate understanding of nitrite chemistry, it has become clear that the formation of nitric oxide (NO) from nitrite is a necessary prerequisite for most meat curing reactions (Møller & Skibsted, 2002). Fortunately, fundamental research on nitric oxide has become one of the most active research areas in biology because nitric oxide has been found to play crucial roles in several physiological functions in living organisms. Fundamental research on nitric oxide in biological systems since the early 1990s has facilitated better understanding of nitrite and nitric oxide in cured meat (Møller & Skibsted, 2002; Stamler & Meissner, 2001).

The most effective way to consider nitrite chemistry in cured meat is to consider the practical effects of the addition of nitrite to meat. The first and most obvious effect is that of cured color development. Close examination of the chemical reactions involved with color development immediately make it obvious that the chemistry of nitrite in meat is a phenomenally complex event. For example, nitrite does not act directly as a nitrosylating (transfer of nitric oxide) agent in meat but first forms intermediates such as N_2O_3 (Honikel, 2004)in the mildly acidic conditions typical of postmortem muscle, and NOCl (Fox, Sebranek, & Phillips, 1994; Møller & Skibsted, 2002; Sebranek & Fox, 1985, 1991) in the presence of salt.

Formation of NO from the intermediates is facilitated by reductants such as ascorbate, and the NO will react with the iron of both myoglobin (Fe^{+2}) and metmyoglobin (Fe^{+3}) to form cured meat pigments and cured color. These reactions demonstrate two of the most important factors governing nitrite reactions in conventionally cured meat products; namely pH and reductants. However, several other nitrite reactions are involved in cured meats and contribute to nitric oxide production. For example, when nitrite is added to comminuted meat, the meat quickly turns brown due to metmyoglobin formation because nitrite acts as a strong heme pigment oxidant and is, in turn, reduced to NO. The NO reacts with metmyoglobin and subsequent reduction reactions convert the oxidized heme to reduced nitric oxide myoglobin for typical cured color following cooking. Further, nitrite can also react with sulfhydryl groups on proteins to release nitric oxide in an oxidation–reduction reaction that results in a disulfide (Pegg & Shahidi, 2000).

In addition to the above reactions of nitrite in meat, all of which affect the rate and/or extent of cured color development, nitrite plays a key role in cured meat as a bacteriostatic and bacteriocidal agent. Nitrite is strongly inhibitory to anaerobic bacteria, most importantly *Clostridium botulinum* and contributes to control of other micro organisms such as *Listeria monocytogenes*. The effects of nitrite and the likely inhibitory mechanism differs in different bacterial species (Tompkin, 2005). The effectiveness of nitrite as an antibotulinal agent is dependent on several environmental factors including pH, sodium chloride concentration, reductants and iron content among others (Tompkin, 2005). While the means by which nitrite achieves microbial inhibition is not clear and many mechanisms have been proposed, all of the factors that impact nitrite inhibitory effects are also important to the known reactions that generate nitric oxide for cured color. Thus, the reaction sequences involving nitric oxide are probably an important part of the antimicrobial role of nitrite in cured meat. For example, some researchers have suggested that nitrous acid (HNO_2) and/or nitric oxide (NO) may be responsible for the inhibitory effects of nitrite (Tompkin, 2005). Because it appears that nitrite reactivity is key to microbial inhibition (one indicator of this is the strong dependence on pH), there has been some question whether ingoing or residual nitrite is most critical to antimicrobial effects. Tompkin (2005) concluded that residual nitrite at the time of product temperature abuse is critical to antibotulinal effects and that depletion of residual nitrite during product storage will reach some point at which inhibitory effects are also depleted.

The nitrite reaction sequences involved with cured color development probably also play a key role in the strong anti-oxidant function of nitrite in cured meat, because proposed mechanisms for the antioxidant effect of nitrite include reaction with heme proteins and metals, and formation of nitroso- and nitrosyl-compounds that have antioxidant properties (Pegg & Shahidi, 2000). It is likely that these proposed mechanisms are dependent upon the same initial reactions of nitrite that form nitric oxide for cured color.

Nitrite is also responsible for the production of characteristic cured meat flavor, though this is probably the least well understood aspect of nitrite chemistry (Pegg & Shahidi, 2000). It is easy to distinguish cooked, cured ham from fresh roast pork on the basis of flavor but the chemical identity of distinguishing flavor components in cured meat has eluded numerous researchers. Some of the flavor difference may be due to the suppression of lipid oxidation by nitrite but other antioxidants do not produce cured meat flavor. If nitrite does, in fact, form some volatile flavor factors, this would represent yet another reaction product of nitrite in cured meat.

In addition to the nitrite reactions which result in cured meat color, microbial inhibition, antioxidant effects and flavor, it has been demonstrated that addition of nitrite to meat results in formation of nitrate and nitrogen gas as well as reaction with carbohydrates and lipids (Honikel, 2004; Pegg & Shahidi, 2000).

The point of this brief discussion of nitrite chemistry and the functions of nitrite in cured meat is to emphasize that nitrite is a highly reactive ingredient when combined with meat, and results in a complex mixture of reaction products. Because nitrite, particularly as nitric oxide, so readily reacts with a wide variety of substrates, reaction kinetics could be an important determinant of how nitrite

is proportioned among the various competitive substrates and reaction products. A slow formation of nitrite (such as from nitrate) in meat might be significantly different in terms of nitrite reaction products than the direct, one-time addition of a full load of nitrite. If, for example, the fastest-reacting substrates consumed a greater share of the nitrite during slow nitrite formation than in the case where nitrite is added directly, then the end products of the more reactive substrates might achieve greater final concentration.

3.3. Past and current safety issues associated with nitrite

Issues that have been raised concerning the safety of using nitrate and nitrite for cured meat have included chemical toxicity, formation of carcinogens in food or after ingestion, and reproductive and developmental toxicity. None of these issues represent relevant concerns for nitrate or nitrite in light at the current regulated levels of use in processed meats. While nitrite is recognized as a potentially toxic compound, and there have been cases where nitrite was mistakenly substituted for other compounds in food or drink at concentrations great enough to induce toxicity symptoms, the normally controlled use of nitrite in processed meats represents no toxicity risk.

However, the issue of carcinogenic nitrosamines formed from nitrite in cured meat was a very serious concern in the 1970s. Fortunately, changes in manufacturing practices and reduced levels of nitrite used in curing solved the problem of nitrosamine formation in cured meat. Yet, a background concern about nitrite has lingered, and in the 1990s, a series of epidemiological studies reported that consumption of cured meat was related to childhood leukemia and brain cancer (Peters et al., 1994; Preston-Martin & Lijinsky, 1994; Preston-Martin et al., 1996; Sarasua & Savitz, 1994). Further, in 1998, nitrite was proposed as a developmental and reproductive toxicant under California's Proposition 65 (Safe Drinking Water and Toxic Enforcement Act). Fortunately, both issues (nitrite as a carcinogen and as a developmental/reproductive toxicant) have been largely resolved by subsequent studies and careful scientific review (Milkowski, 2006).

The issue of ingested nitrate and nitrite first arose in the 1970s when it was recognized that carcinogenic nitrosamines could be formed in the stomach following ingestion. Subsequent work has shown that less than 5% of the nitrite and nitrate typically ingested comes from cured meat, the rest coming from vegetables and saliva (Archer, 2002; Cassens, 1997a; Milkowski, 2006). Nevertheless, in 2006, the International Agency for Research on Cancer (IARC) concluded that "Ingested nitrate or nitrite under conditions that result in endogenous nitrosation is probably carcinogenic to humans" (Coughlin, 2006). While the IARC report is still in progress, the conclusions are likely to ramp up questions and concerns about nitrite as a food additive. In light of the anticipated challenges to nitrite in cured meat, it is imperative that as much information as possible is developed for all processed meat applications where nitrite and/or nitrate have a role.

3.4. Current US regulations on nitrite and nitrate

Current regulations on use of nitrite and nitrate in the United States vary depending on the method of curing used and the product that is cured. For comminuted products, the maximum ingoing concentration of sodium or potassium nitrite is 156 parts per million (ppm) or 0.25 oz. per 100 lbs. (7 g/45.4 kg), based on the green weight of the meat block (USDA, 1995). Maximum ingoing nitrate for these products is 1718 ppm. Sodium and potassium nitrite and nitrate are limited to the same amount despite the greater molecular weight of the potassium salts, which means that less nitrite or nitrate will be included when the potassium salt is used. For immersion cured, and massaged or pumped products, maximum ingoing sodium or potassium nitrite and nitrate concentrations are 200 ppm and 700 ppm, respectively, again based on the green weight of the meat block. Dry cured products are limited to 625 ppm and 2187 ppm of nitrite and nitrate respectively. If nitrite and nitrate are both used for a single product, the ingoing limits remain the same for each but the combination must not result in more than 200 ppm of analytically measured nitrite, calculated as sodium nitrite in the finished product.

Bacon is an exception to the general limits for curing agents because of the potential for nitrosomine formation. For pumped and/or massaged bacon without the skin, 120 ppm of sodium nitrite or 148 ppm of potassium nitrite is required along with 550 ppm of sodium ascorbate or sodium erythorbate which is also required. It is important to note that this is a specifically required amount whereas other nitrite limits are maximum amounts. To accommodate variation in pumping procedures and brine drainage from pumped products, the regulations for pumped and/or massaged bacon permit ±20% of the target concentrations at the time of injecting or massaging. For example, sodium nitrite concentrations within the range of 96–144 ppm are acceptable. Nitrate is not permitted for any bacon curing method. There are two exceptions to these regulations for pumped and/or massaged bacon: first, 100 ppm of sodium nitrite (or 123 ppm of potassium nitrite) with an "appropriate partial quality control program" is permitted and, second, 40–80 ppm of sodium nitrite or 49–99 ppm of potassium nitrite is permitted if sugar and a lactic acid starter culture are included. Immersion cured bacon is limited to 120 ppm of sodium nitrite or 148 ppm of potassium nitrite while dry cured bacon is limited to 200 ppm or 246 ppm, respectively. For bellies cured with the skin on, nitrite and reductant concentrations must be reduced by 10%, based on the assumption that skin comprises approximately 10% of the belly weight.

It is important to note that the regulations also require a minimum of 120 ppm of ingoing nitrite for all cured "Keep Refrigerated" products "unless safety is assured by some

other preservation process, such as thermal processing, pH or moisture control''. The establishment of minimum ingoing nitrite concentration is considered critical to subsequent product safety. This is a significant consideration for natural and organic cured meat products.

On the other hand, for cured products that are processed to ensure shelf stability (stored at ambient temperature and do not require refrigeration), there is no minimum ingoing nitrite level. The USDA Processing Inspector's Calculations Handbook (USDA, 1995) suggests that, for shelf-stable products, ''...40 ppm nitrite is useful in that it has some preservative effect. This amount has also been shown to be sufficient for color-fixing purposes...''.

4. Ingredients used for natural and organic cured meats

Because of the negative perceptions of nitrite-cured meat held by some consumers, the ''uncured'' natural and organic versions of typical cured meats have enjoyed wide-spread market acceptance. A survey of 56 commercial ''uncured'' meat products including bacon, ham, frankfurters, bologna, braunschweiger, salami, Polish sausage, Andouille sausage and snack sticks showed that most of these products demonstrated typical cured meat color and appearance (Sindelar, 2006b). Review of the product ingredient statements showed that sea salt, evaporated cane juice, raw sugar or turbinado sugar, lactic acid starter culture, natural spices or natural flavorings, and celery juice or celery juice concentrate were used in many of the products.

Analyses of samples of four selected commercial brands each of natural or organic bacon, hams and frankfurters showed that all samples except one sample of bacon contained residual nitrite at concentrations ranging from 0.9 ppm to 9.2 ppm. Residual nitrate was found in all products at concentrations of 6.8 ppm to 44.4 ppm (Sindelar, 2006a). Residual nitrite was lower in most of the natural or organic products at the time of sampling than in comparable commercial products made with conventional addition of nitrite. Other cured meat properties including instrumental color, cured pigment concentration, lipid oxidation and sensory properties were, in general, similar for the natural or organic products relative to the conventionally cured products but greater variation in the natural and organic products was obvious. Most notable was low color values, low cured pigment content and low sensory scores for those products that contained little or no residual nitrite. It is important to note that because these were commercial products selected at retail, the time of manufacture and storage history of each was unknown. Nevertheless, these results suggest that: (1) there is wide variation among the natural and organic processed meats that simulate conventionally cured products; and (2) a large majority of natural and organic processed meats demonstrate typical cured meat properties, including cured color, flavor and significant concentrations of residual nitrite and nitrate. Thus, it is clear that nitrite and nitrate are being introduced to these products indirectly as components of other ingredients.

4.1. Unique ingredients in natural and organic processed meats

The most common ingredient observed in review of the product labels of natural and organic processed meats was sea salt. Sea salt is derived directly from evaporation of sea water, unrefined without addition of free-flow additives and retains the natural trace minerals characteristic of the source (Heinerman & Anderson, 2001; Kuhnlein, 1980). Several varieties of sea salt are available and differ depending on the geographical origin of the water used and the mineral content (Saltworks, 2006). While sea salt has been suggested as a likely source of nitrate, limited analytical information suggested that nitrate content of sea salt is relatively low. Herrador, Sayago, Rosales, and Asuero (2005) reported that Mediterranean sea salt contained 1.1 ppm of nitrate and 1.2 ppm of nitrite. Cantoni, Berretta, and Bianchi (1978) analyzed 10 samples each of 3 grades of sea salt and found nitrate and nitrite concentrations of 0.3–1.7 ppm and 0–0.45 ppm, respectively.

The second most common ingredient observed in natural and organic processed meat ingredient lists was raw sugar, most often shown as turbinado sugar. Turbinado sugar is a raw sugar obtained from evaporation of sugar cane juice followed by centrifugation to remove surface molasses. Remaining molasses gives turbinado sugar a light brown color and flavor similar to brown sugar. While it seems possible that raw sugar could include nitrate, there appears to be no evidence of significant nitrate or nitrite concentrations in raw sugar.

Natural flavorings or spices, and celery juice or celery juice concentrate were frequently listed as ingredients, and because these are plant/vegetable products, the potential contribution of nitrate from these sources is very significant. Vegetables are well-known as a source of nitrate with concentrations as high as 1500–2800 ppm (National Academy of Sciences, 1981) in celery, lettuce and beets. Vegetable juices and vegetable powders are commercially available and may be used as ingredients in natural and organic foods. Analysis of some commercially available vegetable juices showed that carrot, celery, beet and spinach juice contained 171 ppm, 2114 ppm, 2273 ppm and 3227 ppm of nitrate respectively (Sebranek, 2006). After 10 days of storage at room temperature, nitrate levels in these juices declined by 14–22%. Nitrite was not detected initially but concentrations of 128–189 ppm of nitrite were found after 10 days at room temperature, probably resulting from bacterial reduction of nitrate. Analysis of commercial celery juice powder indicated a nitrate content of 27,462 ppm or about 2.75%, reflecting the increased concentration following drying (Sindelar, 2006a). Clearly, vegetable products offer the greatest potential to introduce natural sources of nitrate into processed meats. Juices and powders have advantages in supplying nitrate in

concentrated form. Celery juice and celery powder appear to be highly compatible with processed meat products because of very little vegetable pigment (as opposed to beets, for example) and a mild flavor profile similar to raw celery that does not detract greatly from finished product flavor.

A critical ingredient for processed meats with natural nitrate sources is a nitrate-reducing bacterial culture if typical cured meat properties are the final objective. The necessity of bacterial reduction of nitrate to nitrite for meat curing has long been recognized, and nitrate-reducing cultures have been commercially available for several years. Most applications of these cultures have been for dry sausage where a long-term reservoir of nitrite during drying is desirable and where subtle flavor contributions from the culture are considered important (Olesen, Meyer, & Stahnke, 2004). The lactic acid starter cultures used for fermented sausage, primarily *Lactobacillus plantarum* and *Pediococcus acidilactici*, do not reduce nitrate. However, cultures of coagulase-negative cocci such as *Kocuria* (formerly *Micrococcus*) *varians*, *Staphylococcus xylosus*, *Staphylococcus carnosus* and others will reduce nitrate to nitrite. These organisms can achieve nitrate reduction at 15–20 °C but are much more effective at temperatures over 30 °C (Casaburi, Blaiotta, Mauriello, Pepe, & Villani, 2005). The typical recommended holding temperature for commercial nitrate-reducing cultures is 38–42 °C to minimize the time necessary for adequate nitrite formation. Recent research has documented that time is a critical parameter in the development of typical cured meat properties from natural sources of nitrate. Sindelar (2006a) reported that holding time at 38 °C was more critical than the amount of naturally-added nitrate for development of cured meat properties in frankfurters and hams. Time appeared to be more critical for the small diameter frankfurters that reached internal temperature of 38 °C quickly than for the large diameter hams where internal temperature increased to 38 °C more slowly.

Sindelar, Cordray, Sebranek, Love, and Ahn (in press a) evaluated several quality characteristics of frankfurter-style cooked sausages manufactured with starter culture and either 0.2% or 0.4% celery juice powder, each held at 38 °C for either 30 min or 120 min. The products were evaluated during 90 days of refrigerated, vacuum-packaged storage and compared with conventionally processed products manufactured at the same time with added sodium nitrite. Color measurements (Hunter a^+ values reflectance ratios, cured pigment concentrations) indicated that treatments with short incubation time resulted in less cured color/redness than the nitrite-cured control though this difference was not always significant. Cured color/redness was comparable to the nitrite-cured control with the longer incubation time for the first 14 days following manufacturing but the difference became non-significant during extended storage. Residual nitrite following incubation was dramatically different with 5.6 ppm and 7.7 ppm found for the 0.2% and 0.4% celery powder levels, respectively, after 30 min but 24.5 ppm and 46.0 ppm observed after 120 min. No differences were noted for lipid oxidation between any of the treatments and the control. The nitrite-cured control received the highest sensory scores though differences were not significant for all sensory properties.

A similar experiment with hams (Sindelar, Cordray, Sebranek, Love, & Ahn, in press b) was conducted using either 0.2% or 0.35% celery powder and incubation time of 0 min or 120 min. The treatment with no incubation time was included because the extended thermal process (3 hrs., 35 min.) used for hams relative to small diameter frankfurter-style sausage was expected to result in adequate nitrate reduction by the culture. Results showed that there were no treatment differences in objective color measurements or cured pigment concentrations and all products were similar in color properties to the nitrite-cured control. Residual nitrite, following the 120 minute incubation for the 0.2% and 0.35% celery juice powder additions, was 19.5 ppm and 36.1 ppm, respectively. The residual nitrite was significantly less for the hams with celery juice powder (21.0–36.0 ppm at day 0; 7.2–21.3 ppm after 90 days) relative to the nitrite-cured control (63.4 ppm at day 0: 34.1 ppm after 90 days). However, residual nitrite was greater in hams with a greater amount of added celery juice (27.7–36.0 ppm from 0.35% celery powder vs. 19.3–21.0 ppm from 0.20% celery powder at day 0 compared with 11.7–21.3 ppm vs. 7.2–8.8 ppm, respectively, for each after 90 days). Sensory panel evaluation indicated that the greater celery powder treatment (0.35%) resulted in greater vegetable aroma and flavor with less ham aroma and flavor. The treatments with a low level of celery powder (0.2%) were similar to the nitrite-cured control for all sensory properties evaluated.

The authors concluded that the celery juice powder/starter culture treatment was an effective alternative to the direct addition of sodium nitrite to small-diameter, frankfurter-style cured sausage but that incubation time at 38 °C is an important factor for product quality. The celery juice powder/starter culture treatment was also effective for hams but in this case the amount of celery juice powder proved to be more critical. For large diameter products such as hams, it appears that the slow temperature increase that is part of a typical thermal process may provide enough time for the culture to achieve nitrate-to-nitrite reduction. Further, the delicate flavor profile of hams makes these products more susceptible to flavor contributed by vegetable products.

The authors also pointed out that the concentration of celery juice powder used (0.2%, 0.35% and 0.4% – total formulation weight basis) could provide, with 100% nitrate-to-nitrite conversion, maximum ingoing nitrite concentrations of 69 ppm, 120 ppm and 139 ppm (meat block basis), respectively, based on the initial nitrate concentration of 27,462 ppm in the celery powder. Because these nitrite concentrations are, at best, significantly less than the 156–200 ppm normally included in cured comminuted

products or injected products, it seems likely that product quality differences could occur in some circumstances. It is also worth noting that the actual amounts of nitrite formed from nitrate when natural nitrate sources are used could be a concern relative to microbiological safety. The shelf life of processed meats manufactured with natural nitrate sources in generally less than nitrite-cured products because less nitrite is present and other typical preservatives such as phosphates, lactate, curing accelerators and antioxidants are not included (Bacus, 2006).

Ingredients that might be considered as curing adjuncts for natural or organic processed meats include vinegar, lemon juice solids, and cherry powder. Acidulants such as vinegar have potential to accelerate nitrite reactions because of the impact of pH. However, reducing pH in these products is also a concern for reduced moisture retention because phosphates and many of the traditional water binders cannot be used for natural or organic products. Lemon juice solids or powder are typically significant sources of citric acid which could have similar pH effects as vinegar. Cherry powder, on the other hand, is high in ascorbic acid which functions as a strong nitrite reductant but does not have a large impact on product pH.

An evaluation of a cured pork product manufactured with a natural nitrate source (celery powder) and with or without 0.28% cherry powder showed that including the cherry powder reduced residual nitrite by about 50% (Baseler, 2007). Residual nitrite declined from 61 ppm to 32 ppm during 12 weeks of storage for a nitrite-cured control, 18–10 ppm for the celery powder treatment and 10–3 ppm for the celery powder/cherry powder treatment. Addition of cherry powder did not alter the product pH. Other product properties (color, lipid oxidation) were not consistently different though the nitrite-cured treatment showed greater redness (Hunter a^* values) after about 4 weeks of storage.

Natural antioxidants such as rosemary may be used to provide flavor protection and to retard lipid oxidation in processed meats. However, these compounds do not contribute directly to nitrate/nitrite reactions in meat systems. Further, it appears that the nitrite generated from natural nitrate sources as reported by Sindelar et al. (in press a, in press b) was sufficient to provide strong antioxidant effects as typically observed in nitrite-cured meats. Past research has shown that as little as 50 ppm added nitrite has a highly significant effect on lipid oxidation (Morrissey & Techivangana, 1985). Thus, relatively small amounts of nitrite formed from nitrate probably provide an important antioxidant role in natural and organic processed meats.

4.2. Processes for naturally-cured meats

Most processors that utilize ''natural curing'' are following processing procedures that are, in general, similar to those processes that include chemical nitrites and nitrates. Naturally-cured products typically utilize natural sources of nitrate, but some natural ingredients may also contain nitrite. If sufficient nitrite is consistently available from a natural source, no changes in the normal process are required.

Naturally-cured meat products that utilize natural ingredients for a nitrate source need an ingredient that contains a relatively high natural nitrate content. The nitrate ion is much more available, more consistent in concentration and more stable than nitrite, and can be found in a wide variety of natural ingredients. When using a natural nitrate source, conversion of the nitrate to nitrite is required. Typically, this conversion is accomplished by specific microorganisms (with a nitrate reductase enzyme), as described earlier, that are also acceptable food ingredients. When using these microorganisms, the conversion process requires time, with the specific amount of time depending upon the temperature, the environment, and the concentration of the reactants, namely the microorganisms and the naturally-occurring nitrate. The conversion time can be decreased by increasing the reactant concentrations with the amount of starter culture the most critical.

In all natural curing processes, good distribution of both the nitrate source and the starter culture is essential to achieve uniform curing. The natural nitrate source, if dry, is usually either blended with the dry seasoning component for comminuted products, or added directly to curing brines. The starter culture commonly is diluted first with good quality water (i.e. distilled, or low in chlorine or other bacteriocidal chemicals) prior to the addition to comminuted products (the USDA permits a maximum 0.5% combined water and starter culture without labeling the added water) or may also be added directly to curing brines. Also, it is recommended that the starter culture should not be pre-blended with anything that might affect viability (i.e. spices, salt), and thus the nitrate-reducing activity of the culture. The naturally-occurring nitrate is soluble, but the starter culture is not soluble, being water-dispersible, therefore some agitation is recommended for brines to achieve optimal distribution of the culture in the meat product. With curing brines, the pH of the brine is critical to achieving optimal natural curing as well as final product texture, because the phosphates or other buffering agents typically used with nitrite-added products cannot be included for products labeled natural or organic. Generally, low pH brines (i.e. <5.5) are not desirable, thus the pH effect of any added natural ingredients should be considered. With comminuted meat products, the pH effect of directly-added ingredients is not as critical due to the buffering capacity of the meat. Liquid sources of naturally-occurring nitrates (vegetable juices) also are utilized but these ingredients pose some manufacturing issues. Typically, most of these liquids are not shelf stable, and are supplied in frozen form. Secondly, the added water that is a component of the juices must be considered.

For small diameter cooked sausage, formulation and processing are essentially the same as for nitrite-added products, except for the nitrate source and the culture, and a smokehouse process that includes an ''incubation''

period of about 1 h at 42 °C to achieve nitrate reduction prior to a smoke-cook thermal process. For injected products, the physical injection of the brine with the culture is critical because the culture will not migrate significantly from injection sites. Consequently, good distribution by injection is necessary to avoid uncured spots. Increased injection percentage of brine is generally preferred to facilitate better distribution. For thermal processing, no ''incubation'' period is likely to be necessary for large diameter products due to the longer process time involved with relatively slow increase in internal temperature. As product diameter is decreased, the heat process may need to be adjusted to achieve optimal nitrate conversion. With injected bellies, for example, a short ''incubation'' period at 42–46 °C may be necessary prior to the usual heating cycle. Because bacon is not fully cooked, relatively high bacterial counts from the added culture will remain in the finished product. Fermented sausage products do not typically require any adjustments in processing because the fermentation step already incorporated into the process provides adequate nitrate conversion. Because most starter cultures, particularly in the US consist of lactic acid-producing bacteria only, it is imperative to confirm that the added starter culture is composed of a mixed culture including nitrate-reducing organisms as well as those included to ferment the added sugars. Many mixed starter cultures are available to accomplish both functions, or the nitrate-reducing culture can be added ''on top'' of a currently used acid-producing culture.

5. Current issues with natural and organic cured meats

5.1. Regulatory

The current US regulatory requirements concerning ''organic'' meat products are well defined, thus processors desiring to make such products must adhere to a fixed set of regulations outlining permitted ingredients. With ''natural'' meat products, however, the rules for permitted ingredients recently have become more confusing. The petition submitted to the USDA in October, 2006, suggested that the 2005 revisions to the agency's ''natural'' policy created inconsistencies by allowing foods carrying the ''natural'' label to contain synthetic ingredients and preservatives. Much of the concern expressed by the petitioner was the allowance of sodium and potassium lactates in ''natural'' products, since these ingredients would be considered ''chemical preservatives''. The petition to the USDA proposed that extensive rulemaking should be initiated for meat and poultry products labeled as ''natural'' in much the same way that had been done with products labeled as ''organic''. Currently, the USDA has begun the rulemaking process for new regulations on natural products with a public meeting in Washington in December, 2006, and a comment period that concluded in March, 2007.

The issue of lactates as ''chemical preservatives'' also raised the issue of other dual-function ingredients, whereas the ingredient may be considered as a natural ingredient for flavor and/or function, but can also have a dual function as a ''natural'' preservative. The issue of ''natural preservative'' vs. ''chemical preservative'' has not been defined, as yet. Many natural compounds that exist in the environment can serve to inhibit microorganisms, retard oxidation, and thus ''preserve'' the product and would be valuable ingredients in food products that are labeled as ''natural''. Until this issue of ''natural'' vs. ''chemical'' preservatives is resolved, the current US regulatory environment is retarding innovative product development and may compromise food safety as well.

5.2. Manufacturing

When manufacturing ''natural'' and ''organic'' meat products using natural ingredients, the inherent variability of natural ingredients must be considered. In the natural curing process, whereby naturally-occurring nitrates are converted by starter cultures to nitrites, the concentration of the nitrate in the source plus the nitrate-reducing activity of the starter culture will effect the degree of curing achieved. Typically, in products cured with direct addition of sodium nitrite in the US, the ingoing nitrite is limited to 156 ppm in most meat products and 120 ppm in injected bacon. In naturally-cured meat products, the ingoing nitrate level is most often between 40 ppm and 60 ppm, thus there is, at best, significantly less nitrite in these products than in the typical nitrite-cured products. Measurable residual nitrite concentrations in both types of cured products are often similar without major differences in color or color stability. However, product quality will be very dependent upon actual nitrite formation in the product during the nitrate reduction phase of the process. While reduced shelf-life has been observed in naturally-cured meats, a significant part of the change is probably due to the lack of other traditional ingredients that are not permitted in ''natural'' products (i.e. phosphate, ascorbate, erythorbate, citric acid, synthetic antioxidants) as well as reduced concentration of nitrite.

5.3. Marketing

The issue of consumer understanding of what is meant by ''natural'' meat products is difficult to define. Many consumers may not comprehend that natural ingredients often contain naturally-occurring chemicals virtually identical in chemical nature to those chemicals synthetically produced. One of the current concerns with ''naturally-cured'' meat and poultry products is that these products often contain residual nitrate and nitrite, even though labeled as ''no nitrates or nitrites added''. According to the US Code of Federal Regulations (2006) in 9 CFR 319.2, the processor has no choice but to label such products (i.e. ''... to which nitrite or nitrate is permitted or required to be added...'') as ''uncured'' and no ''nitrates or nitrites added'' even though the processor may be utilizing a natural curing process.

To provide the consumer with the most accurate information, more appropriate labeling would be to use a term such as ''naturally-cured'' and eliminate the ''uncured'' and ''no nitrates or nitrites added'' requirement that currently exists in the US.

5.4. Quality

The quality characteristics expected of traditional cured meats that are unique to these products include the reddish-pink color of cooked denatured nitrosylhemochrome, a flavor that is distinct from uncured products, and long-term flavor protection resulting from the strong antioxidant effect of nitrite on meat systems. The fixation of desirable color is the first and most obvious effect of nitrite when added to meat and is considered an essential function because color is a critical component affecting consumer retail purchases (Cornforth & Jayasingh, 2004). As little as 2–14 ppm of nitrite (depending on species) can induce pink coloration in cooked meats, though at these levels the color is often sporadic and likely to fade with time. Extensive research in the 1970s showed that 25–50 ppm of ingoing nitrite was adequate to develop relatively stable cured color (National Academy of Sciences, 1982). While there are indications that cured color may be less intense with 40–50 ppm of nitrite instead of 150–200 ppm depending on product type, 40–50 ppm is generally considered adequate for cured color development in most products. Thus, it would appear that cured color development can be achieved relatively easily in processed meat using natural sources of nitrate and a nitrate-reducing culture. A related question, however, concerns the long-term stability of the cured color formed in these products. One of the difficulties with assessing potential cured color intensity or stability with nitrate-based cures is that the absolute amount of nitrite formed from nitrate cannot be determined due to the reactive nature of nitrite in meat. Sindelar et al. (in press a) reported that for frankfurter-type sausages, products made with celery powder and culture had 9.3–31.9 ppm of residual nitrate remaining when 69 ppm of nitrate was added as part of the celery powder, and 12.2–81.4 ppm when 139 ppm was added. So, if 100% of the nitrate that was depleted was in fact reduced to nitrite, the ingoing nitrite concentrations ranged from 37 ppm to 127 ppm. This is sufficient nitrite to generate desirable cured meat color characteristics in most processed meat products. Similar results were observed for color with hams (Sindelar et al., in press b) where the residual nitrate concentrations suggested formation of nitrite in the range of 45–119 ppm. Thus, the quality of cured color in terms of intensity and stability is not likely to be a major issue in processed meats using natural sources of nitrate if appropriate processing procedures are followed to achieve nitrate reduction, and if adequate packaging (oxygen removal by vacuum or gas flushing and high oxygen-barrier films) is used (Møller et al., 2003).

Cured flavor is an important quality attribute of cured meats that is derived from addition of nitrite, though the chemical nature of the flavor has never been established. It is clear, however, that relatively low concentrations of nitrite result in significant cured flavor. Several researchers have reported acceptable cured meat flavor in products formulated with 40 ppm of ingoing nitrite (Pegg & Shahidi, 2000). In a series of reports, MacDonald, Gray, Stanley, and Usborne (1980), MacDonald, Gray, Kakuda, and Lee (1980) and MacDonald, Gray, and Gibbins (1980) concluded that addition of 50 ppm of nitrite to hams was sufficient to produce significant cured meat flavor and antioxidant protection. Thus, in addition to color, it appears that 40–50 ppm or more of ingoing nitrite will result in a significant flavor contribution to cured meat.

The third quality contribution of nitrite to cured meat is the often-overlooked, but highly effective role of nitrite as an antioxidant, and it is clear that nitrite is again effective at relatively low concentrations. Morrissey and Techivangana (1985), for example, using cooked, ground beef, pork, chicken and fish muscle, reported that 50 ppm of nitrite reduced TBA values by 50–64% for beef, pork and chicken, and about 35% for fish. Nitrite concentrations of 100 ppm resulted in TBA reductions of 57–72%, and 200 ppm reduced TBA values by 87–91%. There was a very clear relationship between saturated:unsaturated fat ratios and the TBA values, with more unsaturated fats resulting in greater TBA values regardless of the nitrite concentration. While nitrite is effective as an antioxidant at 50 ppm, it is more effective at greater concentrations up to 200 ppm. A point to note is that the antioxidant function of nitrite in cured meat, while highly effective, is not as unique as the color and flavor contributions. There are a number of other antioxidants including natural compounds that can protect meat lipids from oxidation and flavor deterioration.

If at least 50 ppm of nitrite is formed from nitrate during processing of meat products with natural nitrate sources, it appears that the typical quality characteristics expected of cured meat (color, flavor, flavor stability) will be achieved. A question that is more difficult to answer is the long-term stability of those quality characteristics. It is well recognized that when nitrite is fully depleted from cured meat, color fading and flavor changes typically occur. Some residual nitrite is essential to maintaining typical cured meat properties during extended product storage, and 5–15 ppm residual nitrite has been reported for commercial cured meats in the US (Cassens, 1997b). It is important to keep in mind that packaging and environmental conditions, particularly temperature and exposure to light, are critical to long-term cured meat quality, and become more critical when residual nitrite is reduced.

5.5. Safety

The safety of processed meats that simulate traditional cured meats by using natural sources of nitrate is a significant issue for two reasons; first, nitrite is a very effective

antimicrobial agent, particularly for preventing toxin production by *C. botulinum* and second; residual nitrite concentration is a well-known risk factor in the potential formation of carcinogenic nitrosamines. In both cases, ingoing and residual nitrite concentrations must be carefully controlled to provide product safety.

The antimicrobial role of nitrite in cured meat has been well documented. While nitrite plays a key role in inhibition of *C. botulinum*, extensive research has demonstrated that pH, reductants (ascorbate and erythorbate), salt, phosphates and thermal processing are all highly interactive with nitrite for achieving inhibitory effects (Tompkin, 2005). It has been suggested that both the amount of added nitrite and the amount of nitrite present as residual nitrite at the time of temperature abuse are important to antibotulinal protection. Because ingoing nitrite is depleted over time in cured meat, the importance of ingoing nitrite is probably due to the increased residual nitrite that results. Christiansen (1980), in a review of botulinal inhibition by nitrite, concluded "that any change in nitrite usage which reduces the level of residual nitrite or increases the rate of nitrite depletion could increase the above mentioned (botulinal) theoretical risk".

The issue for processed meats that utilize natural sources of nitrate is that the true amount of nitrite formed is unknown and impossible to measure because nitrite reacts quickly with meat components. While the amount of detectable residual nitrite in these products is significant, it is often less than that found in nitrite-cured products (Sindelar et al., in press a, in press b) depending on processing conditions. On the other hand, the nitrite reactions means that there are variable pools of nitrite-modified compounds in cured meat that remain available as reactive sources of nitric oxide (Kanner & Juven, 1980; Møller & Skibsted, 2002). Consequently, the microbial safety of processed meats manufactured with natural sources of nitrate is very difficult to assess without microbiological challenge studies. This is a very significant current research need for effectively assessing the safety of these products.

The second potential safety issue that should be considered with these products is the implications of higher-than-usual nitrite concentrations. Sindelar et al. (in press a) found that a frankfurter-style sausage processed with 0.4% celery powder and an extended incubation time resulted in significantly more residual nitrite than a nitrite-cured control throughout 90 days of storage. Elevated residual nitrite in bacon is a potential risk for nitrosamine formation and actual ingoing nitrite concentrations need to be carefully controlled to avoid this potential problem. The nature of the time–temperature relationship for reduction of nitrate to nitrite by a starter culture makes the concentration of nitrite a variable entity. Further, vegetable products are recognized as extremely variable in nitrate content as a result of different environmental conditions that occur during plant growth (National Academy of Sciences, 1981). Consequently, more information is needed on the best means by which to control nitrite formation in processed meats manufactured with natural sources of nitrate to assure that excess concentrations of nitrite do not become a safety issue.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-032

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

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Issue History:

This is a brand new Issue.

Title:

Amend Food Code Annex – Clarifying ROP of fish requirements

Issue you would like the Conference to consider:

A recommendation is being made to clarify the requirements of reduced oxygen packaging (ROP) of fish that does not require a variance as described in 3-502.12 (C).

The 2013 FDA Food Code Section 3-502.12 discusses ROP of fish that does not require a variance. The public health rationale in FDA Food Code Annex 3 needs to clarify what "after packaging" means and why fish packaged using ROP methods in a retail establishment should not be sold that way to the consumer.

Public Health Significance:

The FDA Food Code Annex 3 explains the rationale for FDA Food Code Section 3-502.12 that "using ROP methods in food establishments has the advantage of providing extended shelf life to many foods because it inhibits spoilage organisms that are typically aerobic[1]." For this reason, ROP has become a very popular method of packaging in retail food establishments. Most raw animal foods require a HACCP Plan only, and not a variance, because high levels of competing microorganisms help to control hazards of concern, mainly Listeria monocytogenes. However, ROP of raw fish has additional requirements for storage because of the presence of non-proteolytic C*lostridium botulinum* type E in marine environments. This type of C*lostridium botulinum* can grow at temperatures as low as 37-38F[2]. Given the potency of the toxin that would be created, food products where C*. botulinum* type E is reasonably likely to occur must be stored at frozen temperatures.

The Fish and Fisheries Products Hazard Controls Guidance document outlines that storage temperature for fish products should not exceed 38F at any point while the food is in the reduced oxygen environment. This document also acknowledges that "surveys of home refrigerators indicate that temperatures can exceed 50F[2]." Also, the FDA Food Code Annex 3 describes the need for retail food establishments to remove fish from ROP packaging before thawing when temperature (freezing) of the fish serves as the only barrier to non-

proteolytic C*. botulinum* type E growth[1]. This logic can also be applied to ROP fish that is packaged in the retail food establishment.

There is some difference in interpretation among readers about the meaning of FDA Food Code Section 3-502.12 (C) "Except for FISH that is frozen before, during, and after PACKAGING, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method." The term "after PACKAGING" has been interpreted as only immediately after packaging by some food service operators, leading to misunderstanding about what is allowed per the FDA Food Code. In order to reduce the risk of C*. botulinum* toxin production, ROP fish packaged at a retail level should not be sold directly to the consumer in ROP form. Furthermore, food service employees need to be clear that fish packaged in the food establishment using ROP must be removed from the ROP environment prior to thawing. Stating this clearly in the FDA Food Code Annex 3 for Section 5-502.12 will reduce confusion among industry and regulatory personnel.

References:

1. "Annex 3." FDA 2013 Food Code. College Park, MD: U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, 2013. 465. Print.

2. Fish and Fishery Products Hazards and Controls Guidance Fourth Edition. College Park, MD: U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, 2011.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending the 2013 Food Code Annex 3, Section 3-502.12 be amended to include clarifying language for "after packaging." Recommended language to read (new language is underlined):

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria

Reduced Oxygen Packaging with Fish

Unfrozen raw fish and other seafood are specifically excluded from ROP at retail because of these products' natural association with non-proteolytic C. botulinum (primarily type E) which grows at 3°C (37-38°F). ROP of fish and seafood that are frozen before, during and after the ROP packaging process does not present this hazard. Fish that has been packaged using an ROP method must be removed from the ROP package before thawing process begins in order to fully satisfy the requirement of frozen "after ROP". Due to the fact the food establishment cannot verify that the fish would remain frozen until removed from the package once the product is sold to the consumer, fish that has been packaged using an ROP method must not be sold directly to consumers in the packaging.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-033

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

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Issue History:

This is a brand new Issue.

Title:

Fish Advisory Committee

Issue you would like the Conference to consider:

The FDA recognizes the need to inform consumers of the risk of foodborne illness through the consumption of raw or undercooked meats, poultry, seafood, shellfish, or eggs. They further stipulate consumers should be aware of the eight major allergens that may be contained within a food item. However, it is evident the potential dangers of consuming the chemical contaminates found in certain fish and seafood products is not covered in the Food Code. Currently there is a push by consumers and the US Government to consider sustainable and healthy eating when deciding upon your meal. These farm to fork initiatives influence the consumption habits of consumers that may not be aware of local fish consumption advisories

Public Health Significance:

Toxic substances, such as polychlorinated byphenyls (PCBs), dioxins and methyl mercury can accumulate in the fat or muscle of certain species of fish. Over-consumption of these contaminants may result in chronic debilitating health issues and can potentially be fatal. Our most vulnerable populations, children, children in utero and immune compromised individuals can be in jeopardy of chronic illness or death if accumulation of these toxins occurs. It is quite possible that every day consumers of fish are not receiving the species-specific fish consumption advisories provided for fish caught in individual bodies of water to determine safe consumption practices.
The EPA and FDA agree consumption of certain species of fish and shellfish can result in adverse health effects, therefore they recommend consulting fish and shellfish consumption advisories. However, when dining out or purchasing products to prepare at home, these advisories are not typically available. The point of purchase is the best opportunity to inform consumers that are unaware of the risks of consumption of certain fish products. The only other option to prevent chemical contamination is to assume all consumers have taken the initiative to educate themselves on the dangers of the

consumption of all seafood provided in the restaurant or grocery store where they happen to be shopping.

Recommended Solution: The Conference recommends...:

that a committee be created to discuss, analyze, and make recommendations advising consumers of potential risks associated with chemical contaminants in fish. Committee charges are as follows:

1) Compare existing EPA/FDA guidance on chemical contaminates found in species of fish/fish products.

2) Develop a guidance document that can be easily interpreted by the average consumer; document to include but not be limited to the potential risk for chemical contamination.

3) Determine if a point of sale consumer advisory is needed for fish and fish products

4) Recommend revised Food Code language.

5) Report back the committee's recommendations and findings to the 2018 Biennial Meeting.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-034

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

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Issue History:

This is a brand new Issue.

Title:

Reducing the need for HACCP Plans Under 3-502.12

Issue you would like the Conference to consider:

Re-evaluate the list of foods and activities that require a variance and Hazard Analysis Critical Control Point (HACCP) plan for reduced oxygen packaging in Section 3-502.12 of the 2013 FDA Food Code and remove foods that do not present a hazard that is likely to occur for *Clostridium botulinum* and *Listeria monocytogenes* growth.

Public Health Significance:

The removal of raw meats and raw poultry, hard and semi-soft cheeses, and shelf stable products from the list of foods that require a HACCP plan and variance will be beneficial to both the regulated food establishment and the regulatory authority, without increasing the risk of foodborne illness.

Most foodborne pathogens do not compete well with the other microorganisms. So foods such as raw meat, raw poultry and raw vegetables, that have a high level of spoilage organism do not present a significant hazard from *Clostridium botulinum* or *Listeria monocytogenes*. As identified in the Annex of the Food Code hard, pasteurized and semisoft cheeses "contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C or less...Very few outbreaks have occurred that were associated with cheese."

In foods that are shelf stable (non-time/temperature controlled for safety food) by Table B in the Food Code, *Clostridium botulinum* or *Listeria monocytogenes* are controlled by low water activities, low pH values, or a combination of lower water activities and low pH.

The USDA considers the use of reduced oxygen packaging a protective practice, one that prevents cross contamination between workers and the establishment and the food.

Foods such as raw meats, raw poultry, raw vegetables, hard cheeses, semi soft cheese, and shelf stable foods pose very low risk once they are reduce oxygen packaged at retail. Unnecessary HACCP plans and variances are cumbersome and time consuming for both

the regulatory authority and the food establishment. A reduction in the paper work resulting in stream lining of this process would allow regulators and food establishments alike to focus on higher risk activities.

If *Clostridium botulinum* or *Listeria monocytogenes* are controlled then the risk is low for reduced oxygen packaging

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (new language is underlined;language to be deleted is in strikethrough format)*:*

Section 3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes.* [p]

(B) Except as specified under (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall implement a HACCP PLAN that contains the information specified under 8-201.14 (B) and (D) and that: [pf]

(1) Identifies the FOOD to be PACKAGED; [pf]

(2) Except as specified under (C) -(E) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria: [pf]

(a) Has an AW of 0.91 or less, [pf]

(b) Has a PH of 4.6 or less, [pf]

(c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE, [pf] or

~~(d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables;~~[pf]

(3) Describes how the PACKAGE shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to: [pf]

(a) Maintain the FOOD at 5°C (41°F) or below,[pf] and

(b) Discard the FOOD if within 30 calendar days of its PACKAGING if it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption; [pf]

(4) Limits the refrigerated shelf life to no more than 30 calendar days from PACKAGING to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first; [p]

(5) Includes operational procedures that:

(a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under 3-301.11(B),[pf]

(b) Identify a designated work area and the method by which: [pf]

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination,[pf] and

(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, [pf]and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; and

(6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:

(a) Concepts required for a safe operation, [pf]

(b) EQUIPMENT and facilities, [pf]and

(c) Procedures specified under Subparagraph (B)(5) of this section and 8-201.14 (B) and (D). [pf]

(7) Is provided to the REGULATORY AUTHORITY prior to implementation as specified under ¶ 8-201.13(B).

(C) *Except for FISH that is frozen before, during, and after PACKAGING*, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method. [p]

(D) Except as specified under (C) and (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a cook-chill or sous vide process shall:

(1) Provide to the REGULATORY AUTHORITY prior to implementation, a HACCP PLAN that contains the information as specified under 8-201.14 (B) and (D); [pf]

(2) Ensure the FOOD is:

(a) Prepared and consumed on the PREMISES, or prepared and consumed off the PREMISES but within the same business entity with no distribution or sale of the PACKAGED product to another business entity or the CONSUMER; [pf]

(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under 3-401.11 (A), (B), and (C), [p]

(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4,[p]

(d) Placed in a PACKAGE with an oxygen barrier and sealed before cooking, or placed in a PACKAGE and sealed immediately after cooking and before reaching a temperature below 57°C (135°F), [p]

(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and: [p]

(i) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of PACKAGING;

(ii) Held at 5°C (41°F) or less for no more than 7 days, at which time the FOOD must be consumed or discarded; or [p]

(iii) Held frozen with no shelf life restriction while frozen until consumed or used. [p]

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily, [pf]

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, [pf] and

(h) Labeled with the product name and the date PACKAGED; [pf] and

(3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP PLAN and:

(a) Make such records available to the REGULATORY AUTHORITY upon request, [pf] and

(b) Hold such records for at least 6 months; [pf] and

(4) Implement written operational procedures as specified under Subparagraph (B) of this section and a training program as specified under Subparagraph (B)(6) of this section. [pf]

~~(E) Except as specified under (F) of this section, a FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:~~

~~(1) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;~~

~~(2) Have a HACCP PLAN that contains the information specified under 8-201.14 (B) and (D) and as specified under (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;~~

~~(3) Labels the PACKAGE on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first; and~~

~~(4) Discards the REDUCED OYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.~~

(E)~~(F)~~ A HACCP Plan is not required when a FOOD ESTABLISHMENT uses a REDUCED OXYGEN PACKAGING method to PACKAGE ~~method to package time/temperature control for safety food that is always~~:

(1)~~Labeled with the production time and date~~, A FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables

(2) ~~Held at 5°C (41°F) or less during refrigerated storage, and~~ Cheese

(i) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;

(ii) Labels the PACKAGE on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first; and

(iii) Discards the REDUCED OYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.

(3) ~~Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after PACKAGING.~~ Non-time temperature controlled for safety foods as defined in Table B (Interaction of pH and Aw for control of vegetative cells and spores in food not heat treated of heat treated but not packaged).

(i) Foods packaged limited to those that are commercially manufactured in a food processing plant with no ingredients added in the Food Establishment that would change the nature of the product.

(ii) Non-time temperature controlled for safety foods as defined by Table B, produced in the Food Establishment in accordance with a Variance submitted to the Regulatory authority in accordance with 3-502.11.

(4) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD *that is always:*

(i) Labeled with the production time and date,

(ii) Held at 5°C (41°F) or less during refrigerated storage, and

(iii) Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after PACKAGING.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-035

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

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Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014, III-023; new or additional information has been included or attached.

Title:

Revise Food Code to be Consistent with FSIS Requirements and Guidance

Issue you would like the Conference to consider:

The Food Safety Inspection Service (FSIS) and Food and Drug Administration (FDA) are submitting a joint issue to revise the Food Code to be consistent with FSIS Requirements and guidance. In this proposal FSIS and FDA are recommending adding a new definition in Chapter 1 to the 2013 FDA Food Code for the term INTACT MEAT and to revise the minimum time and temperatures in § 3-401.11 *Cooking* for meat and poultry products to reflect FSIS cooking guidance. Making the Food Code instructions consistent with FSIS regulatory framework and cooking guidance will decrease confusion and help ensure that the products are cooked properly to destroy pathogens that could cause foodborne illness.

FSIS previously submitted this issue in 2010, and the conference recommended that FSIS and FDA work together to bring a proposal to the 2014 meeting to harmonize cooking times and temperatures. The issue was also submitted in 2014, and no action was taken because the conference said that there was no specific request at that time. Since 2014, FSIS and FDA have worked together to develop a joint issue to provide specific recommendations to harmonize the cooking times and temperatures.

Public Health Significance:

The FDA Food Code § 3-401.11(A)(1) applies to fish and meat, including game animals, and specifies that the products can be cooked to 63°C (145°F) for 15 seconds. This time and temperature combination is only appropriate for intact portion cuts of meat, because the contamination is expected to be on the outside of the product, so the product should be safe if the external surface is cooked to 145°F (National Advisory Committee on Microbiological Criteria for Foods, 1997). Although there are exceptions in § 3-401.11(A)(2) for non intact products (mechanically tenderized, injected, or comminuted), it is not clear that the instructions in § 3-401.11(A)(1) only apply to intact products. Therefore FSIS and FDA recommend a new definition for the word INTACT MEAT as follows:

"Intact meat" means a cut of whole muscle(s) MEAT that has not undergone comminution, injection, mechanical tenderization, or reconstruction.

Adding this new definition to the FDA Food Code will clarify which instructions apply to intact meat and which apply to non-intact meat. Making these clarifications would alleviate confusion and ensure that retailers cook meat products using the proper times and temperatures to ensure food safety.

Section 3-401.11(A)(2) applies to mechanically tenderized meats and specifies that they should be cooked at 68°C (155°F) for 15 seconds. However, according to the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks, non-intact products should be held at 68°C (155°F) for 17 seconds. Other time and temperature combinations in the table in § 3-401.11(A)(2) would also provide a 5-log reduction of *Salmonella* in these products. Therefore, FSIS and FDA recommend that the time the product is held is increased from 15 seconds to 17 seconds to be consistent with the table, and the other time and temperature combinations from the table in the FSIS guidance are provided in the Annex.

Section 3-401.11(A)(3) applies to poultry products and recommends that they are cooked at 74°C (165°F) or above for 15 seconds. According to the FSIS guidance in the Time-Temperature Tables for Cooking Ready-to-Eat (RTE) Poultry Products, poultry products can be cooked to 74°C (165°F) instantaneous to achieve a 7-log reduction of *Salmonella*. Therefore, FSIS and FDA recommend deleting the 15 second dwell time from the minimum criteria specified in that subparagraph and changing it to instantaneous. This change is also consistent with CFP Issue # 2002-I-33, which recommended that USDA and FDA work together to establish instantaneous cooking temperatures for animal products that have minimum dwell time of 15 seconds. In addition, FSIS and FDA recommend that retailers have the option of cooking poultry products using the additional time and temperature combinations in the FSIS poultry tables and adding this information in the Food Code Annex.

Section 3-401.11(B) applies to roast beef, corned beef and other products and indicates that they should be cooked using the time and temperature combinations in the table titled "Oven Temperature Based on Roast Weight." These time and temperature combinations are from FSIS Appendix A and achieve a 6.5-log reduction of *Salmonella,* however only some of the time and temperature options have been provided. FSIS and FDA recommend that all of the time temperature options from Appendix A are provided in the Annex.

References:

NACMCF, 1997. Recommendations for Appropriate Cooking Temperatures for Intact Beef Steaks & Cooked Beef Patties for the Control of Vegetative Enteric Pathogens. U.S. Department of Agriculture, Food Safety and Inspection Service, Washington, DC.

FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks, found at: http://www.fsis.usda.gov/wps/wcm/connect/bb25d746-dcb0-4d1b-8833-c4bf1ceb1140/5-log-Temperature-Time-Table-Salmonella.pdf?MOD=AJPERES

Appendix A. Compliance Guidelines for Meeting Lethality Performance Standards For Certain Meat And Poultry Products, found at: http://www.fsis.usda.gov/wps/wcm/connect/212e40b3-b59d-43aa-882e-e5431ea7035f/95033F-a.pdf?MOD=AJPERES

Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products, found at: http://www.fsis.usda.gov/wps/wcm/connect/9ab2e062-7ac8-49b7-aea1-f070048a113a/RTE_Poultry_Tables.pdf?MOD=AJPERES

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending that the 2013 FDA Food Code be modified to reflect the following (language to be added is underlined):

1. Provide a new definition in Chapter 1 Purpose and Definitions for the term INTACT MEAT to read: <u>"Intact meat" means a cut of whole muscle(s) MEAT that has not undergone comminution, injection, mechanical tenderization, or reconstruction.</u>
2. Clarify which criteria apply to INTACT MEAT (cook to 145°F for 15 sec internal temperature).
3. Revise the minimum cooking temperature that applies to mechanically tenderized and injected meats, from 155°F for 15 seconds to 155°F for 17 seconds.
4. Revise the minimum cooking temperature that applies to poultry from 165°F for 15 seconds to 165°F instantaneous.
5. Provide additional time/temperature combinations from Appendix A, the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks and the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products in the Food Code Annexes.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-036

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

This is a brand new Issue.

Title:

“Intended Use” for Raw Beef Source Materials

Issue you would like the Conference to consider:

Federally inspected meat establishments produce whole-muscle, intact beef such as beef primal and subprimal cuts and identify their "intended use" for further preparing or processing into intact or non-intact beef products such as comminuted or mechanically tenderized beef (Refer to Chapter 1 of the 2013 FDA Food Code for definitions). They are required to identify the intended use for consumers of the finished product according to federal Hazard Analysis Critical Control Point (HACCP) regulations 9 CFR 417.2(a)(2). (http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/99-060Npm.htm). Because of these regulations, beef producing establishments have an incentive to communicate and follow-up on how their beef products are used further down the supply chain in order to properly support their HACCP systems. It would also be in the retail facility's best interest to honor the producer's intended use, to avoid possible outbreaks from the product.

Retail establishments can be informed of the intended use from the supplying federal beef establishment in the following ways:

- A letter of intended use available on the supplying federal establishment's company website and references to the letter of intended use on the bills of lading.
- Federally inspected establishments may request that the retail establishment provide letters of guarantee showing that all beef product is used in raw intact product only and maintains on-going communication to verify that all beef product is being processed as raw intact product only.
- A contractual agreement with the receiving firm so the firm has knowledge of the supplying federal establishment intended use or facility's production process.
- Federally inspected establishments may use designated codes to identify the intended use of their production lots.

References:

AskFSIS: http://askfsis.custhelp.com/app/answers/detail/a_id/1884/~/adequate-support-for-the-intended-use-of-beef-primal-and-subprimal-cuts

Public Health Significance:

Since 2008, USDA Food Safety and Inspection Service (FSIS) has noted at least five foodborne illness investigations that involve retail establishments grinding beef that was not intended for grinding. Four of these investigations include illnesses due to *E. coli* O157:H7, while one involved *Salmonella typhimurium* infections. In at least one case, although the intended use was communicated to the retail facility by means of a description on the product invoice, it is unknown whether the store personnel conducting the grinding were aware of the intended use designation or understood the risks and impact associated with producing ground beef from products not intended for grinding.

FSIS has declared Shiga toxin-producing E-coli (STEC) an adulterant only in raw non-intact beef and raw intact beef intended for non-intact use, and as a result, establishments apply more stringent process controls for STEC in beef source materials for non-intact use. Large establishments typically verify these controls through robust lot-by-lot microbiological testing of ground beef source materials. FSIS inspectors also perform specific inspection tasks to verify the establishment's STEC controls.

These additional food safety measures help to mitigate the public health risk of raw non-intact beef to consumers. As a result, when product that was intended for intact beef use ends up as source material in raw non-intact beef products at retail, the food safety measures are undermined. Beef product intended for raw intact beef use typically does not have the benefit of routine FSIS sampling or stringent process controls applied by establishments to control STEC.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the 2013 FDA Food Code be amended as follows (new language underlined):

3-201.11 Compliance with Food Law

(F) WHOLE-MUSCLE INTACT BEEF that is, further processed in a FOOD ESTABLISHMENT and provided information stating that WHOLE-MUSCLE INTACT BEEF are intended for intact use only or not intended for non-intact use, shall be prepared so that it remains INTACT.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-037

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

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Issue History:

This is a brand new Issue.

Title:

Creation of a Mail-Order Food Safety Committee

Issue you would like the Conference to consider:

Many consumers purchase meat, poultry, seafood and other products over the internet and these products are shipped by mail directly to their homes. Although the products are typically packaged with gel packs or dry ice, research has shown they have the potential to be temperature abused (see public health significance below). Therefore, there is a need to provide targeted guidance for food establishments (as defined in the FDA Food Code) that produce perishable food products and ship them to consumers by mail (e.g., by air, ground, or other forms of transport).

A committee should be created to develop guidance addressing proper packaging of products shipped by mail, temperature control during delivery, availability of food safety information, returning compromised and abused products, and other related topics.

Public Health Significance:

The primary challenge when shipping perishable food items is to maintain proper temperatures during steps such as transportation, delivery, and storage. A study by Hallman et. al. found that only 5% of retailers that sell raw meat, poultry and seafood products over the internet require customer signatures upon delivery. This practice may allow packages to be subjected to temperature abuse if proper temperature control is not maintained upon delivery. In addition, more than half (58%) of the retailers studied provided no food safety information on their websites, which could lead to an increased risk for foodborne illness.

The Food Safety and Inspection Service (FSIS) has issued a *Mail Order Food Safety Fact Sheet* for consumers, but it has not developed specific guidance for retailers that ship products by mail. In addition, FSIS has issued the *"FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry, and Egg Products"* and the Food and Drug Administration (FDA) has issued *"Guidance for Industry: Sanitary Transportation of*

Food," however these guidelines do not address transportation of perishable products through the mail.

Specific guidance is needed to address the transportation of perishable food items that are produced at retail food establishments and transported by mail. Although FSIS or the FDA could independently issue revised transportation guidance documents, it is recommended that a CFP committee be formed so that experts from government, state and local health departments, industry, and consumer groups can provide practical recommendations that are most likely to be effective and implemented within the industry.

References:

FSIS Mail Order Food Safety Fact Sheet, found at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/mail-order-food-safety/ct_index

FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry, and Egg Products, found at:
http://www.fsis.usda.gov/shared/PDF/Transportation_Security_Guidelines.pdf

FDA Guidance for Industry: Sanitary Transportation of Food, found at:
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm208199.htm

Hallman, W. K., Senger-Mersich, A., and S. Godwin. Online Purveyors of Raw Meat, Poultry, and Seafood Products; Delivery Policies and Available Consumer Food Safety Information. Food Protection Trends, Vol35, No. 2, p. 80-88.

Recommended Solution: The Conference recommends...:

that a Mail-Order Food Safety Committee be created composed of members from all constituencies in the CFP. The Committee will be charged with:

1. Identifying best practices and existing guidance documents that relate to transportation of perishable food items by mail.
2. Developing a guidance document for food establishments that includes best practices for transportation 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.
3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.
4. Reporting the committee's findings and recommendations to the 2018 Biennial Meeting of the Conference for Food Protection.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-038

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:

Use of pre-formulated sanitizing solutions

Issue you would like the Conference to consider:

Add a new paragraph to the 2013 FDA Food Code Section 4-302.14 that states the availability of a test kit or other device, currently specified in this section, does not apply to pre-formulated hard food-contact surface sanitizing solutions.

Public Health Significance:

Section 7-204.11 *Sanitizers, Criteria* of the 2013 FDA Food Code states that chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 40 CFR (Code of Federal Regulations) 180.940 *Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions)* or 40 CFR 180.2020 *Non-food Determinations.* Section 4-501.114 *Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration and Hardness* indicates that a chemical sanitizer used in a sanitizing solution shall be used in accordance with the U.S. Environmental Protection Agency (EPA) labeling requirements, among other things.

For most sanitizing solutions, a minimum and maximum concentration of the active ingredient has been established. It is specified to ensure sanitizer efficacy and to prevent excessive exposure at a concentration level that exceeds an established maximum concentration and minimize any environmental impact. Food establishment operators use test kits to routinely measure the concentration of sanitizing solutions to ensure they are prepared at the proper use concentration and that the minimum labeled concentration is maintained throughout the sanitizing solution's use as specified in the manufacturer's directions for use.

Currently, Section 4-302.14 *Sanitizing Solutions, Testing Devices* states that a testing kit or other device that accurately measures the concentration of a sanitizing solution shall be provided. However, FDA recognizes that when EPA-registered pre-formulated hard food-contact surface sanitizing solutions are used in accordance to their label instructions, the

need to ensure the concentration of the active ingredient through a testing kit or other device is not necessary.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the 2013 Food Code be amended by adding a new paragraph to Section 4-302.14 as follows (language to be added is underlined; language to be deleted is in strikethrough format):

4-302.14 Sanitizing Solutions, Testing Devices.

(A) Except as specified under ¶(B) of this section, a test kit or other device ~~that~~ shall be provided to accurately measure~~s~~ the concentration in mg/l of sanitizing solutions ~~shall be provided~~. [Pf]

(B) The availability of a test kit or other device specified under ¶(A) of this section, does not apply to pre-formulated sanitizing solutions that are ready-to-use, not diluted or mixed in the food establishment, and are sprayed directly onto food contact surfaces.

Note: italic font is consistent with Food Code formatting; it offers an exception or another possibility and is pursuant to a preceding provision that states a requirement (exception to the rule).

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-039

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:

Surface Cleaning of Utensils and Equipment in Contact with Non-TCS Foods

Issue you would like the Conference to consider:

The 2013 FDA Food Code does not address a clear time frame for the cleaning frequency for all food contact surfaces that come in contact with only non Time Temperature Control for Safety (TCS) foods under Section 4-602.11. Under 4-602.11 (E) the cleaning frequency of surfaces of UTENSILS and EQUIPMENT contacting FOOD that is not Time/Temperature Control for Safety Food shall be cleaned:

1. At any time contamination may have occurred
2. At least every 24 hours for iced tea dispensers and CONSUMER self-service UTENSILS such as tongs, scoops or ladles;
3. Before restocking CONSUMER self-service EQUIPMENT and UTENSILS such as condiment dispensers and display containers; and
4. In EQUIPMENT such as ice bins and BEVERAGE dispensing nozzles and enclosed components of EQUIPMENT such as ice makers, cooking oil storage tanks and distribution lines, BEVERAGE and syrup dispensing lines or tubes, coffee bean grinders, and water vending EQUIPMENT...

   This leaves the cleaning of items in the working kitchen areas that only come in contact with Non-TCS food, such as bakery equipment, toast cutting boards, etc., to have no clearly defined time frequency for cleaning and up to both the industry and regulators to determine when contamination has occurred (which is not always observed). The questions is then why are we so specific about Tea dispensers and consumer items, but not working NON-TCS food contact surfaces throughout the kitchen?

Public Health Significance:

The Public Health significance is the same for all food contact surface that come into contact with non-TCS food items, therefore at a minimum they should be cleaned at a

frequency equal to specific items addressed in the Food Code, such as ice tea dispensers and consumer self-service items.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined; language to be deleted is in strikethrough format)*:*

Section 4-602.11

(E) (1) At any time contamination may have occurred;

(2)~~At least every 24 hours for iced tea dispensers and CONSUMER self-service UTENSILS such as tongs, scoops, or ladles~~; throughout the day, at least once every 24 hours;

(3) Before restocking CONSUMER self-service EQUIPMENT and UTENSILS such as condiment dispensers and display containers; and

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-040

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:

Add a definition for ATP

Issue you would like the Conference to consider:

Adenosine triphosphate (ATP) is well known as the "molecular unit of currency" of all intracellular energy transfer. It is a nucleoside triphosphate (NTP) and is among the nucleotide derivatives necessary for all life comprising the building blocks of nucleic acids, eg., DNA and RNA.

For food safety purposes, the measurement of ATP on surfaces is a measure of the total bioburden (that would otherwise consume the oxidizing character of any approved sanitizer) on the sampled surface. Until now, the entire focus of hygienic operations has been on sanitizing. Incredible sums of money are spent evaluating the efficacy of sanitizers and (to a lesser extent) their toxicological effects. Every approved food contact surface sanitizer found in section 7-204.11 of the 2013 FDA Food Code which references Title 40 of the Code of Federal Regulations, section 180.940 (40 CFR180.940), where it is identified by its chemical identifier which in turn is given its own specific "maximum contamination level" (MCL) for its listed applications. It seems ironic that the U.S.. Congress refers to the sanitizers that they have "approved" as safe within their MCL's, as *contaminants.* Congress did not stop there with their disparaging descriptions these "approved" chemicals. The short title of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) found on its page 3 describes all of the products regulated by FIFRA as *ECONOMIC POISONS.* All of the chemicals regulated by FIFRA are lumped into the genre of "pesticides", whether they are sanitizers, disinfectants, insecticides, fungicides, or rodenticides. What is an *economic poison?* We are told that they are poisons to the vermin and pests that diminish yields which impacts our economy. Unfortunately, these very same products poison us causing myriad of maladies reducing total factor productivity, adding huge health care costs many of which are now paid for by government programs, the results of which is a diminished, poisoned economy.

All of this focus on sanitizers reduces the focus on *clean.* What is "clean" and how do you measure it? Clean "to sight and touch" is very subjective and qualitative, and is of no practical use for food contact surfaces. Edible oils and animal fats can be on surfaces and

be "invisible". We do not "touch" food contact surfaces with our bare hands or fingers, as to do so is to contaminate that surface. Until now, the only quantitative measure used to determine efficacy of a cleaning and sanitizing regime has been the efficacy of the sanitizer alone as tested in a laboratory. Efficacy is expressed in terms of log reductions of American Type Culture Collection (ATCC) test organisms by microbiological assay. New technology for accurate quantitative measure of "clean" is now available from multiple manufacturers in the form of luminometer's that measure the bioluminescence of luciferace. ATP should be defined in the FDA Food Code.

Public Health Significance:

We can improve that which we can measure. ATP is well known and understood to be the molecular unit of energy at the core of all intracellular exchange processes. ATP persists even after the loss of virulence, cellular death, and inactivation or denaturing of microbial cells and NTP. Today, using a new, accurate and affordable technology, we have the opportunity to broaden our understanding of one of the most, if not the most significant of all risk factors for disease transmission; cross-contamination. ATP luminometers effectively measure the bioburden on a surface. This measure enables us to more effectively clean, so that when we sanitize our chances of eliminating the target pathogens is far greater.

References:

http://www.cdc.gov/HAI/toolkits/Appendices-Evaluating-Environ-Cleaning.html
https://en.wikipedia.org/wiki/Adenosine_triphosphate

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined)*:*

Section 1-201.10, Definitions

ATP means adenosine triphosphate. ATP is the molecular unit of currency of all intracellular energy transfer. The amount of ATP on a surface measured in relative light units (RLU's) by an ATP luminometer is indicative of the degree of contamination on a surface. ATP measurements enable reasonable accuracy for cleaning (decontamination) process validation. Clean food contact surfaces are prerequisite to sanitization.

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Conference for Food Protection
2016 Issue Form

Issue: 2016 III-041

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:

Biofilm definition

Issue you would like the Conference to consider:

There are five instances of the word "biofilm" in the 2013 FDA Food Code, all of which are in Annex 3, Public Health rational. Section 1-201.10 of the FDA Food Code provides no definition for this (relatively) new word. Though the word first appeared in literature in the Journal Microbial Ecology, (1975: Mack WN, Mack JP, Ackerson AO, "Microbial film development in a trickling filter," 1975, Volume 2, Issue 3, pp 215-226), it has only come into common parlance over the course of the past ten to fifteen years. It is now well known that biofilms are a problem in food and beverage operations, including potable water and ice handling and dispensing systems in both food and beverage processing and in the retail food industry. This is a Priority foundation item.

Public Health Significance:

Biofilms protect their microbial inhabitants from oxidizing agents and augment their resistance to cleaners and sanitizers. Understanding the characteristics of biofilms, their formation, propagation, growth and the support that they provide to the thriving symbiotic multi-species communities they build is critical to controlling certain risk factors for food borne disease transmission. Now that there are so many publications that identify and characterize biofilms and their myriad microspheres, it is time for the FDA Food Code to be updated to acknowledge biofilms role in food borne disease transmission by providing them with an accurate definition in Section 2-201.10.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is <u>underlined</u>)*:*

Section 1-201.10

"Biofilm" means an assemblage of microbial cells along with inorganic particles (minerals and soils) that bind to surface. Pseudomonas aeruginosa is a pathogen in many if not most biofilms. Other pseudomonads are often in the biofilm brew, some of which have long stalks enabling them to hold-fast the colony. Some common biofilm pseudomonads are motile, using flagella to propel themselves along with any of their attached friends. Protozoa (eg., amoeba) feed on the biofilm chunks that the colony sacrifices and cuts loose once they are no longer needed for processing their mineral and nutrient specialties. Mineral precipitates are an attraction to biofilms, both due to their functional structure, but also because that are necessary for the metabolic survival of the many and varied species of organisms that make the colony. Gentle rinsing of food contact surfaces or sanitization without effective prerequisite cleaning is not effective due to the variable bio-burden and adhesion characteristics of biofilms. Biofilms must be removed from food contact surfaces before the application of an approved food contact surface sanitizer. Plumbing lines that are used to convey liquid foods are especially vulnerable to biofilm propagation due to the inability to inspect, clean and sanitize internal wetted surfaces.

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