Conference for Food Protection
2016 Issue Form

Issue: 2016 I-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 - Plan Review Committee (PRC)

Issue you would like the Conference to consider:

Acknowledge the Plan Review Committee final report and thank its members for completing their charge.

Public Health Significance:

The Plan Review Committee's work provides standards to promote public health and prevent environmental health related illnesses through proper planning of Food Establishment construction.

Recommended Solution: The Conference recommends...:

acknowledgement of the 2014 - 2016 Plan Review Committee final report and thanking its members for completing their charge.

Submitter Information 1:

Name:	Albert Espinoza
Organization:	Plan Review Committee Co-Chair
Address:	HEB5105 Rittiman Road
City/State/Zip:	San Antonio, TX 78218
Telephone:	2108845783
E-mail:	espinoza.albert@heb.com

Submitter Information 2:

Name:	Rebecca Krzyzanowski
Organization:	Plan Review Committee Co-Chair
Address:	Michigan Department of Agriculture525 Allegan Street
City/State/Zip:	Lansing, MI 48909
Telephone:	(517) 719-7919

E-mail: krzyzanowskir@michigan.gov

Content Documents:

- "2014 - 2016 Plan Review Committee Final Report (2016)"
- "Food Establishment Plan Review Manual Cover Sheet"
- "Food Establishment Plan Review Manual (2016)"
- "Appendix A - Plan Review Application"
- "Appendix B - Compliance List (2016)"
- "Appendix C - Copy of Plan Review Model Calculations (2016)"
- "Appendix D - Plan Review Web Links (2016)"
- "Plan Review Committee Roster (2016)"

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: 8/14/2013

Committee Final Reports are considered DRAFT until reviewed and acknowledged by the Executive Board

COMMITTEE NAME: Plan Review Committee (P R C)

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council 1

DATE OF REPORT: January 29, 2016

SUBMITTED BY: Albert Espinoza and Rebecca Krzyzanowski, Co - Chairs

COMMITTEE CHARGE(s):

Re-creating the Plan Review Committee following the CFP 2014 Biennial Meeting to continue its review and update of the following Conference for Food Protection document, Food Establishment Plan Review Guide (2008), and present their findings at the 2016 CFP Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS

Progress on Overall Committee Activities

As of July 24, 2014 we received confirmation from our initial list of committee participants August, 2014 we completed the list with as much a representation of constituency as possible.
In August, 2014 the Co-Chairs reviewed the Plan Review Guide (2008) and shared with our members.
We held a conference call on September 26, 2014 with a proposed agenda.
Conference Call held on Nov. 17 and Nov. 19, 2014 to continue updating the Plan Review Guide
Conference Calls were held on January 16th and February 18, 2015.
During the February 18th conference call our committee decided to have at least 2 members update each of the 12 Sections of the Guide and submit to our Group for discussion, consensus and final update. A webinar resource is requested to provide a VISUAL of the document during our Meetings. Dr. David McSwane later notified our Committee, a webinar resource was available to use.

Per the February 18, 2015 Conference Call, we anticipated progress as the body of *the* Plan Review Guide was broken out into sub groups and offered to our entire group for discussion, consensus and final update. Summer – September, 2015

We held monthly conference calls, in April and May, 2015. During the April conference call subgroups were developed to update the plan review guide as follows:

- Team Leader Rebecca - Sections 1, 2 and 3
- Team Leader Elizabeth – Sections 4, 5, 6
- Team Leader Albert – Sections 7, 8, 9
- Team Leader Liza – Section 10 and Appendix

Our Teams reported their progress on the May 15th, 2015 conference call.

Rebecca Krzyzanowski, Albert Espinoza, Linda Zaziski, Deborah Marlowe, Christopher Sparks and Eric Puente met on July 22nd, 1 p.m. through July 23rd 5 p.m. to update the CFP Plan Review Manual at an on-site workshop at the HEB Quality Assurance, Conference Room, 5105 Rittiman Road, San Antonio, TX.

Our entire Plan Review Committee received the updated Plan Review Manual for final review after our on-site workshop for their comments during our August conference call.

We continued with conference calls every third Friday of the month from June to November,
2015 before submitting our updated Food Establishment Plan Review Manual

- June 19th - Conference Call – Discussion on subgroup progress
- July 22/23 – Group Meeting on-site in San Antonio, Texas. – Food Establishment Plan Review Manual Workshop, Wrap up Webinar held with Committee members unable to attend.
- August 21st – Plan Review Manual, Table of Contents and Appendix A, B available for comment and discussed. Appendix C and D mentioned for our work.
- September 25th, Webinar held with conference call to discuss updates.
- October 16th, Webinar held with conference call, key edits completed per committee member comments.
- November 20th – Webinar held with conference call, final edit review group was formed to complete final edits before the December 11 final webinar and conference call.

December 11th - Final edits to align with the 2013 FDA Food Code were completed and discussed by our committee members. Our final edit review group, Liza Frias, Jessica Fletcher and Catherine Cummins were thanked for their work. Food Establishment Plan Review Manual, Appendix A & B completed. Our FDA Consultant, Veronica Moore was recognized for being present though out our proceedings. Elizabeth Nutt provided the cover sheet. The cover sheet needed one edit and Appendix C & D were to be finalized. A verbal agreement was given/made by the committee to provide a status report to Council Chair, finalize and submit remaining parts by Monday, December 14th, 2015. A follow up email to the committee was provided on Monday, December 14th, 2015 for their vote of approval. Their responses were received by our Committee Co-Chairs for the record.

Our Council Chair received the final packet with the Food Establishment Plan Review Manual, Appendix A – D. This final report and our Formal Voting Committee roster is submitted.

1. Recommendations for consideration by Council:

Conference for Food Protection – Committee Final Report

Template approved: 8/14/2013

Committee Final Reports are considered DRAFT until reviewed and acknowledged by the Executive Board

Our re-created Plan Review Committee's Charge following the CFP 2014 Biennial Meeting was to review and update the Conference for Food Protection document, Food Establishment Plan Review Guide (2008), and present our findings at the 2016 CFP Biennial Meeting. We submit the proposed Food Establishment Plan Review Manual (CFP 2016) for Council Chair consideration to be forwarded to the Conference of Food Protection 2016.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Report – Plan Review Committee Final Report

a. Acknowledgement of 2014-2016 Plan Review Committee Final Report

b. Thank the Committee members for their work on the guidance document

c. Disband the Committee

2. PRC 2- Food Establishment Plan Review Manual

a. Accept the updated Food Establishment Plan Review Manual and Appendix A through D

Attachments:

Content Documents:

1. 2014-2016 Plan Review Committee Final Report
2. Food Establishment Plan Review Manual Cover Sheet
3. Food Establishment Plan Review Manual
4. Appendix A – Plan Review Application
5. Appendix B – Compliance Checklist
6. Appendix C – Copy of Plan Review Model Calculations
7. Appendix D – Plan Review Web Link
8. 2014-2016 Plan Review Committee Roster

COMMITTEE MEMBER ROSTER (attached)

Food Establishment Plan Review Manual

2016 Version

As recommended by the Conference for Food Protection, Plan Review Committee

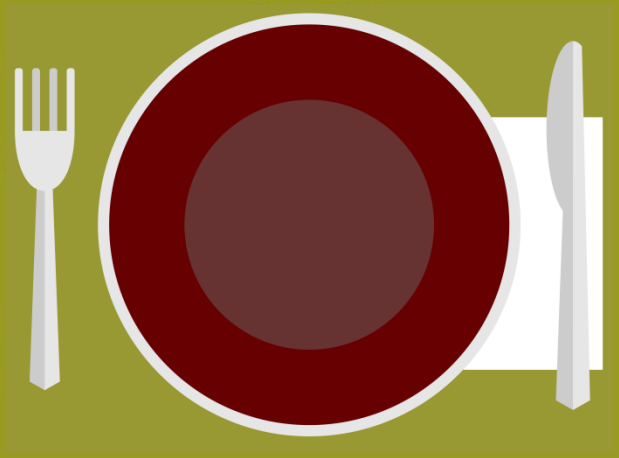


TABLE OF CONTENTS

PREFACE

The FOOD Establishment Plan Review Manual was developed to assist the REGULATORY AUTHORITY and architects, FOOD consultants and other interested professionals in the plan review process when proposing to build or remodel a FOOD ESTABLISHMENT. However, it does not establish regulatory requirements and the recommendations contained herein are not intended to supplant, or otherwise serve as, the rules and regulations applicable to FOOD ESTABLISHMENTs in a given Federal, State, local, or tribal jurisdiction.

- This Manual is intended as a training tool for individuals responsible for conducting plan reviews and can be used in Food and Drug Administration (FDA)-sponsored training courses on Plan Review.
- Is intended to be consistent with the recommendations of the FDA as contained in the FDA 2013 Food Code. The FDA Food Code contains requirements for safeguarding public health and ensuring FOOD is unadulterated and honestly presented when offered to the consumer. Terminology with respect to the word "shall" is based on the recommendations within the FDA Food Code.
- Was developed by the Conference for Food Protection's 2014-2016 Plan Review Committee to update the 2008 Plan Review for Food Establishments Document.

INTRODUCTION

The plan review process presents a unique opportunity to discuss and prepare a proper foundation that will enable a FOOD ESTABLISHMENT to be successful, remain in compliance over time, and protect public health. Quality plan review, process improvement and the dedication to providing excellent customer service are high priorities for this Manual. Plan review assists in providing greater uniformity, technical assistance, and is essential for customer success and avoiding future establishment problems. Poor design, repair, and maintenance will compromise the functionality of the PHYSICAL FACILITIES and its operations. Plan review is intended to ensure PHYSICAL FACILITIES and proposed operational processes are properly designed and sanitary practices implemented in order to serve their intended purposes.

The plan review process provides the REGULATORY AUTHORITY with the opportunity to complete an effective evaluation of a FOOD ESTABLISHMENT's ability to ensure the following:

- Minimum standards are met for the protection of environmental health and safety of the public.
- Prevention of environmental health related illness and promote public health.
- Minimum standards are met for the sanitary design, facility layout, operational and product flow, menus, construction, operation and maintenance of regulated establishments, PREMISES, and surroundings.
- Food Code violations are eliminated prior to construction or implementation.
- Conditions are corrected and prevented that may adversely affect persons utilizing regulated establishments.

- Technical assistance is provided to industry to establish organized and efficient operations.
- Meets consumer expectations for the safe operation of a permitted FOOD ESTABLISHMENT.

No establishment is to be constructed and no major alteration or addition is to be made until detailed plans and specifications for such construction, alteration or addition have been submitted to and APPROVED by the REGULATORY AUTHORITY.

The REGULATORY AUTHORITY may impose specific requirements and provisions in addition to the requirements contained in codes that are authorized by law that are necessary to protect against public health hazards or nuisances. The REGULATORY AUTHORITY shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale.

The function of plan review, construction inspections, pre-operational inspections, and the permit approval process is to provide a comprehensive overview of proposed operations with an emphasis on contents of plans, EQUIPMENT specifications, architectural design, and operational procedures. The end goal of the plan review process is to prevent foodborne illness resulting from poor sanitary facility design and/or floor plans, and, where applicable, when the process is based on menu, FOOD preparation, and FOOD product flow.

DEFINITIONS

The following definitions as used in this document are intended to assist in the understanding of this manual.

Definitions found within the FDA Food Code have been identified in CAPS within this document. A link to the FDA Food Code is included for your reference.
http://www.fda.gov/FOOD/GuidanceRegulation/RetailFOODProtection/FOODCode/ucm374275.htm

"Easily Disassembled Equipment" means EQUIPMENT that is accessible for cleaning and inspection by:

(1) Disassembling without the use of tools, or

(2) Disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.

"Flashing" means an impervious sheet of material placed in construction to prevent water penetration or direct flow of water.

"Service Sink" means a curbed cleaning facility or janitorial sink used for the disposal of mop water and similar liquid wastes.

CONTENTS AND FORMAT OF PLANS AND SPECIFICATIONS

Proper plan review submittal with EQUIPMENT listed and located on floor plans as well as specifications for finish and plumbing schedules will highlight potential problems on paper while allowing for modifications to be made before costly purchases, installations, and construction are performed.

All facilities, systems, processes, and menus, when applicable, will be evaluated to determine minimum operational requirements. Refer to Appendix A for a copy of the Plan Review Application.

The following is a summary of what should be included in the plan submittal:

- Legible plans at minimum of 11 x 14 inches in size drawn to scale (scale - ¼ inch = 1 foot)
- Proposed menu, seating capacity, and projected daily meal volume for the FOOD ESTABLISHMENT.
- Provisions for adequate rapid cooling, including ice baths and refrigeration, and for hot and cold-holding of TIME/TEMPERATURE CONTROL for SAFETY (TCS) FOOD.
- Location of all FOOD EQUIPMENT. Each piece of EQUIPMENT must be clearly labeled, marked, or identified. Provide EQUIPMENT schedule that identifies the make and model numbers and listing of EQUIPMENT that is certified or classified for sanitation by an ANSI accredited certification program (when applicable). Elevation drawings may be requested by the REGULATORY AUTHORITY.
- Location of all required sinks: HANDWASHING SINKS, WAREWASHING sinks, Utility Sink and FOOD preparation sinks (if required).
- Auxiliary areas such as storage rooms, garbage rooms, toilets, basements and/or cellars used for storage or FOOD preparation.
- Entrances, exits, loading/unloading areas and delivery docks.
- Complete finish schedules for each room including floors, walls, ceilings and coved juncture bases.
- Plumbing schedule including location of floor drains, floor sinks, water supply lines, overhead waste-water lines, hot water generating EQUIPMENT with capacity and recovery rate, backflow prevention, and wastewater line connections.
- Location of lighting fixtures.
- Source of water and method of SEWAGE disposal.
- A color coded flow chart may be requested by the REGULATORY AUTHORITY demonstrating flow patterns for:
  - FOOD (receiving, storage, preparation, service);
  - UTENSILS (clean, soiled, cleaning, storage); and
  - REFUSE (service area, holding, storage, and disposal).
- Storage of Employee Personal Items.
- Ventilation.

MENU REVIEW AND FOOD FLOW

The menu review and the flow of FOOD through the FOOD ESTABLISHMENT are integral parts of the plan review process. The menu or a listing of all of the FOOD and beverage items to be offered at the FOOD ESTABLISHMENT must be submitted as part of the plan review application to the REGULATORY AUTHORITY.

As with the inspection process, the plan review process should focus on the FOOD and its flow through receipt, storage, preparation and service. The source and quantity of FOOD to be served should be reviewed along with the preparation and post-preparation operations. It is imperative to have knowledge of this information so that a proper assessment of the PHYSICAL FACILITIES can be made.

The food that flows through retail FOOD ESTABLISHMENT operations can be placed into the 3 following processes:

- **FOOD PROCESSES WITH NO COOK STEP**
  - **Receive – Store - Prepare – Hold – Serve**

  (Other processes may occur, but there is **NO cooking step**)
  - Examples: Salads, deli meats, cheeses, sashimi, raw oysters

- **FOOD PREPARATION FOR SAME DAY SERVICE**
  - **Receive – Store - Prepare - Cook – Hold – Serve**

  (Other processes may occur, including thawing)
  - Examples: Hamburgers, fried chicken, hot dogs

- **COMPLEX PROCESSES**
  - **Receive – Store - Prepare – Cook – Cool – Reheat – Hot Hold – Serve** (Other processes may occur, but the key is repeated trips through the temperature danger zone)
  - Examples: Refried beans, leftovers

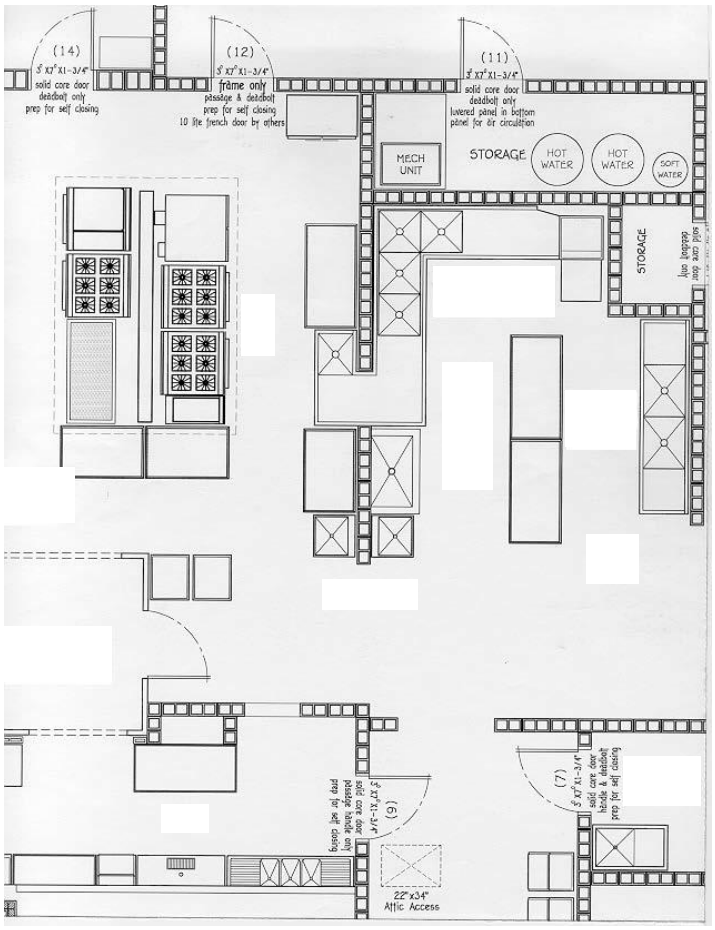
Knowledge of how the FOOD is intended to flow through the FOOD ESTABLISHMNET is very useful since the CRITICAL CONTROL POINTS for each process remain the same regardless of the individual menu ingredients.

Special attention should be given to the review of complex FOOD processes which involve:

- Multiple ingredients being assembled or mixed
- TIME/TEMPERATURE CONTROL FOR SAFETY(TCS) FOODs
- FOODs which will be prepared or held for several hours prior to service

- FOODs requiring cooling and reheating
- Multiple step processing (passing through the Time Temperature Danger Zone, 135˚F - 41˚F more than once)

The process approach can be described as dividing the many flows in a FOOD ESTABLISHMENT into broad categories, analyzing the risks, and placing manager controls on each grouping of FOOD processes. These groupings will also impact the facility design; FOOD flow; and the numbers, types, function and placement of EQUIPMENT.



The drawing above is an example of a fixture plan submitted for plan review. It is a handy tool when following the FOOD process as described by the FOOD ESTABLISHMENT operator or their representative.

Layout, flow and menu (including FOOD preparation processes) should be major considerations to help facilitate an operator's Active Managerial Control (AMC) of the risk factors for foodborne illness. Strategic layout and placing of facilities and EQUIPMENT will separate different FOOD preparation processes, a major step towards preventing contamination of FOOD that may result from poor personal hygiene, contaminated EQUIPMENT, and improper holding temperatures. Adequate and convenient storage will also enhance operations.

The menu for a FOOD ESTABLISHMENT dictates the space and EQUIPMENT requirements for the safe preparation and service of various FOOD items. The menu will determine if the proposed receiving and delivery areas, storage area, preparation and handling areas, and thawing, cooking and reheating areas are available and adequate to handle the types and volumes of FOODs being prepared and served.

When reviewing the menu, it is important to evaluate the flow patterns for the preparation of the FOOD to be sure that the lay-out of the facility provides an adequate separation of raw ingredients from READY-TO-EAT FOODs, and that the traffic patterns are not crossing paths with waste items and other sources of contamination. Cross contamination can be minimized when the flow of FOOD is considered during plan review.

With a proper understanding of the menu and flow, the plans for FOOD ESTABLISHMENTS can be reviewed to help assure that the FOOD items being considered can be protected during all aspects of the FOOD operation.

FOOD Process and Steps Required

	Receive	Store	Prepare	Cook	Cool	Reheat	Hold	Service
NO COOK	X	X	X				X	X
SAME DAY SERVICE	X	X	X	X			X	X
COMPLEX PROCESSES	X	X	X	X	X	X	X	X

Receive	Store	Prepare	Cook	Cool	Reheat	Hold	Serve
Thermometer	**Dry Storage**	**Preparation Tables**	**EQUIPMENT**	**Preparation Sink**	**Fryers**	**Refrigerators**	**Cold Holding Facilities**
	Refrigerated Storage	**Cutting Boards**	**Fryer**	**Ice Bath**	**Oven**	**Ice**	**UTENSILs**
	Frozen Storage	**UTENSILs**	**Oven**	**Blast Chiller**	**Grills**	**Cold Holding**	**Hot Holding Facilities**
	Thermometer	**Hand wash Sinks**	**Broiler**	**Shallow Plans**	**Burners**	**Hot Holding**	
		Preparation Sinks	**Grill**	**Refrigerators**	**Griddle**	**FOOD Warmers**	
		Refrigerators	**Cook Top**	**Chill Sticks**	**Other**	**Thermometer**	
			Griddle	**Thermometer**	**Hand wash Sink**	**Hand wash Sinks**	
			Other	**Hand wash Sink**			
			Thermometer	**Preparation Table**			
			Hand wash Sink	**Other**			

Anticipated EQUIPMENT needs

PREVENTIVE TOOLS FOR THE FOOD ESTABLISHMENT

Active Managerial Control (AMC)

To effectively reduce the occurrence of foodborne illness risk factors, operators of FOOD ESTABLISHMENTs must focus their efforts on achieving active managerial control. The term "active managerial control" is used to describe industry's responsibility for developing and implementing FOOD safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors.

Elements of an effective FOOD safety management system may include the following:

- Certified FOOD protection managers who have shown a proficiency in required information by passing a test that is part of an accredited program
- Standard operating procedures (SOPs) for performing critical operational steps in a FOOD preparation process, such as cooling.
- Recipe cards that contain the specific steps for preparing a FOOD item and the FOOD safety critical limits, such as final cooking temperatures, that need to be monitored and verified.
- Purchase specifications

HACCP

Hazard Analysis and Critical Control Points (HACCP) plays a vital role in proper FOOD ESTABLISHMENT design. However, the risk management tool is not considered a "stand-alone" FOOD safety system. Design and construction are essential pre-requisites and must be put in place prior to the implementation and operation of effective FOOD production practices. The purpose of quality plan review is to ensure that FOOD ESTABLISHMENTs are safe, sanitary, and efficient. Proper design, construction, and HACCP principles work to achieve these purposes and minimize the aforementioned hazards.

Effective HACCP principles are essential to a successful FOOD ESTABLISHMENT and begin with the design and layout of the facility, monitoring the FOOD flow throughout the establishment, from delivery, storage, preparation, cooking, service and consumption. A well-designed progressive FOOD flow system will minimize cross-contamination and maximize efficiency in an establishment.

Good manufacturing policies or practices, standard operating procedures (SOPs), and documentation are essential to an establishment's HACCP-based FOOD safety program and control over potential hazards. HACCP policies specifically address requirements set out in the FDA Food Code. Additional standards or good retail practices are required as foundation for FOOD safety and are detailed in the FDA Food Code. Examples include employee hygiene, employee restriction or exclusion, general sanitation, design, etc. HACCP/VARIANCE under the Plan Review & Construction Program is responsible for the review of HACCP procedures and VARIANCE applications in order for establishments to conduct specialized operations.

The FDA Food Code requires an APPROVED HACCP PLAN to be in place for some specialized processes not listed under §3-502.11. A formal HACCP PLAN review is required and needs to be APPROVED prior to conducting these operations. For information on creating a HACCP PLAN, contact the local regulatory plan reviewer or visit one of these informational hyperlinks: FDA Guidance to Implement HACCP Systems or USDAHACCPGuidelines.

FACILITIES TO MAINTAIN PRODUCT TEMPERATURE

Refrigerators and freezers are required to maintain TCS FOOD at or below 41°F and 0°F (frozen) respectively. It is recommended that refrigerators be maintained between 36°F and 38°F. All refrigeration units must have numerically scaled indicating thermometers accurate to ±3°F. Sufficient refrigeration and freezers shall be provided to support the intended menu. Consideration must be taken with the placement and installation of refrigeration units to allow for adequate ventilation. Air circulation within refrigeration and freezer units should not be obstructed and should allow for an even and consistent flow of cold air throughout the units

Refrigeration and freezer storage involves five major areas:

1. Storage for short-term holding of perishable and TCS FOOD.
2. Long-term storage.
3. Storage space for quick chilling of FOODs.
4. Space for assembling and processing of TCS FOOD.
5. Display storage for customer service.

If TCS foods are prepared a day or more in advance of service, a rapid cooling procedure capable of cooling TCS foods from 135°F to 41°F within 6 hours (135°F to 70°F within 2 hrs.) must be provided. The capacity of the rapid cooling facilities must be sufficient to accommodate the volume of food required to be cooled to 41°F within 6 hours. The location of the rapid cooling facilities (e.g., sinks for ice baths, freezer storage for ice wands, blast chillers) must be identified. Refrigerators and freezers at work stations for operations requiring preparation and handling of TCS foods should be considered. For example, it may be necessary to locate a freezer near the fryer where frozen products will be deep-fried. Refrigeration units, unless designed for such use, should not be located directly adjacent to cooking EQUIPMENT or other high heat producing EQUIPMENT which may adversely impact the cooling system's operation.

A. Refrigeration Storage Calculations

Calculating the amount of refrigeration and freezer space should be based on the menu and expected FOOD volume. The amount and location of refrigeration and freezer EQUIPMENT should complement the FOOD flow of the operation from receiving, storage and FOOD processing, to the point of service.

To plan refrigeration storage, the following items should be considered: menu, type of FOOD operation, number of meals per day, number of deliveries per week, and adequate ventilation in the areas where the refrigeration systems will be located. When assessing the refrigeration needs, shelving space within the refrigeration and freezer units should be designed to prevent the cross-contamination of FOODs. Separating raw meats and poultry from ready-to-eat FOODs such as produce and prepared FOOD items. Thermometers must be conspicuously located in all units. Thermometer sensing elements should be located near the door

Formulas can be used to estimate refrigerated storage space. To calculate, you will need information on number of meals estimated to be served per day, days between deliveries and storage area availability. Links to example calculators can be found in Appendix C.

B. Walk-in Cooler/Freezer Units

Walk-in units should meet an ANSI accredited certification or equivalent, or deemed acceptable by the Regulatory Authority. A walk-in beverage or beer cooler is not recommended for FOOD storage. APPROVED flooring and integral cove bases need to be provided. Quarry tile, ceramic, and galvanized flooring are not recommended flooring materials for walk-in units. All gaps, cracks, penetrations, seams, and plug holes shall be SEALED SMOOTH and flush with the surface material.

Walk-in units should be installed when there is a need for long-term storage of perishable and TCS FOOD or when cooling space is needed for prepared and cooked FOODs. These coolers should be located near delivery or receiving areas. EASILY CLEANABLE curtain strips are recommended at walk-in doors. This not only helps in maintaining the temperature of the walk-in but also leads to an energy cost savings.

Exterior walk-in unit locations shall be properly designed for exterior installation and consideration given varied environmental concerns. Walk-in units should be designed with a roof, APPROVED overhead waterproof protection, and walkways shall be provided for the transportation of FOOD items. Walk-in units shall be APPROVED by the local building official and are evaluated and APPROVED on a case-by-case basis by the REGULATORY AUTHORITY.

If the walk-in floors will be water-flushed for cleaning or receive the discharge of liquid waste or excessive melt water, the floors should be sloped to drain. If the structure of the walk-in is integral with the building, properly installed floor drains may be installed inside the unit.

Each walk-in unit shall be equipped with lighting that provides 10 foot candles of light throughout the unit when it is full of product. Lights must be properly shielded or shatter resistant.

Condensate lines from walk-in units shall drain to APPROVED floor drains or alternative method APPROVED by the REGULATORY AUTHORITY. Without prior approval floor sinks

or floor drain sinks shall not be installed in walk-in units. All walk-in units shall be properly flashed off and SEALED to the ceiling and side walls. Walk-in units are not to be confused with refrigerated FOOD processing rooms. Refer to Item G-Refrigerated Processing Rooms.

C. Reach-in Refrigerators

These units are for short-term storage of perishable and TCS FOODs. These units should be considered to meet the daily storage demands of the kitchen operation. They are to be conveniently located at points of FOOD preparation and FOOD assembly. These units are not to be considered for the quick chilling of cooked and prepared FOODs.

D. Reach-in Freezers

Freezers are for long-term storage. They are not designed to be used as quick-chill units. These units should be located near delivery and DRY STORAGE AREAs.

E. Blast Chillers/Rapid Chill Units

These units are recommended for use when handling large volumes of FOOD that require quick chilling. A blast chiller is an efficient cooling mechanism for any amount of FOOD to be chilled, and where refrigeration cooling space is limited.

F. Refrigerated Worktables

These units are suggested when the menu includes assembling TCS FOODs. These units provide easy access of FOODs from the top of the unit. These units are not designed for long-term storage of FOOD or cooling.

G. Refrigerated Processing Rooms

These areas (e.g. meat cutting rooms) should be considered when there is extensive handling of cold TCS FOOD. APPROVED hand sinks should be located in these areas.

H. Display Storage Refrigerators

These units are designed to display TCS FOOD under refrigeration. Examples of these units are deli display, fresh fish, and meat and poultry cases.

I. Customer Service Display Units/ Cold Buffet Units

These units are designed for holding FOOD under refrigeration for customer access. They are designed for short-term display and are not designed for the cooling of FOOD. Beverage display coolers are not APPROVED for storing open TCS FOODs.

Cold buffets and salad bars are designed for short-term display. They should be mechanically

refrigerated, and have APPROVED sneeze guards with side panel protection.

J. Ice Machines

If ice is to be used as a cooling medium for FOOD and beverage items the unit should be adequately designed and sized to meet all operational needs in an APPROVED location. Ice machines designed for outdoor dispensing will need National Automatic Merchandising Association (NAMA) certification

K. General Cooking and Hot Holding

Cooking and hot holding units are designed to heat FOOD to a required temperature within a required amount of time for FOOD safety. Cooking and reheating temperatures have been determined using scientific analysis. The time and temperature requirements are based on the pathogens that are likely to be present on the product. It is recommended that the units are commercial grade and meet NSF/ANSI standards. Consideration must be taken with the placement and installation of cooking/reheating/hot holding EQUIPMENT to ensure that proper ventilation and sanitation can occur. Construction of these units should be durable and EASILY CLEANABLE

NOTE: The commercial appliances described in this section are placed under a vent hood to evacuate grease, steam, and fumes, which could pose a potential fire or health risk. Refer to the topic on Ventilation of this Manual or your REGULATORY AUTHORITY for specific requirements.

Units used to heat FOOD are divided into two categories:

1. Cooking/Reheating
2. Hot Holding

All units in use must be able to meet the minimum required heated temperatures outlined in the FDA Food Code, Chapter 3-4 Destruction of Organisms of Public Health Concern. http://www.fda.gov/FOOD/GuidanceRegulation/RetailFOODProtection/FOODCode/default.htm

L. Stovetops and Grills

Gas, electric, or wood-burning stoves are used to cook and reheat product in pots or pans. A grill is similar to a stove with the ability to place the FOOD directly over the flame.

M. Ovens

Ovens are thermally insulated chambers used for cooking or reheating FOODs. They can be gas, electric, or wood-burning units.

N. Combination Oven/Steamer (Combi Oven)

A Combi oven/steamer is similar to a convection oven with the ability to produce dry heat, moist heat, or a combination of the two.

O. Rice Cooker/Warmer

The unit is an electric appliance that is capable of cooking rice and then hot holding the rice at 135°F or above. Scoops or ladles for serving may be stored in a running dipper well.

P. Kettle

Kettles are cooking pots used to boil large quantities of FOOD products. The units are generally clean-in-place and should have the necessary tools for sanitation. Adequate floor drains must be present for disposal of spent water.

Q. Rotisserie

Rotisseries are self-contained units that include a heat source and racks for skewers or spits. Beef, pork, or poultry is rotated over the fire to cook the FOOD to the required temperature.

R. Small Appliances

Small appliances (table top) include microwaves, Panini press, broilers, and toasters. These units are used to heat FOOD to the required cook or reheat temperature depending on the application.

S. Fryers

Fryers are cooking devices that use oil heated to a high temperature. The hot oil has a flash point that can result in a fire. Follow the manufacturer's instructions for operation, maintenance and cleaning to prevent a fire incident.

T. Hot Tables

Hot tables are gas or electrically heated units that are design to maintain temperature. They should never be used to cook or reheat TCS FOODs. The design should allow for disassembly and deep cleaning of interior surfaces. These units must be able to maintain a minimum temperature of 135°F.

U. Customer Service Display Units/Hot Buffet Units

These are gas or electrically heated units that are designed to maintain temperature. They should never be used to cook or reheat TCS FOODs. They should be constructed of durable and EASILY CLEANABLE materials. The design should allow for disassembly and deep cleaning of interior surfaces. The design should protect FOOD from contamination that could

occur from the environment or customers by using sneeze shields or covers. The units must be able to maintain a minimum temperature of 135°F

EQUIPMENT AND INSTALLATION

All EQUIPMENT in a FOOD ESTABLISHMENT must comply with the design and construction standards contained in Chapter 4 of the FDA Food Code. FOOD EQUIPMENT that is certified or classified for sanitation by an ANSI accredited program is deemed to comply with Parts 4-1 and 4-2 of the FDA Food Code.

EQUIPMENT including ice makers and ice storage EQUIPMENT, shall not be located under exposed or unprotected sewer lines, open stairwells or other sources of contamination.

The following EQUIPMENT installation recommendations will help ensure proper spacing and sealing allowing for adequate and easy cleaning.

A. Floor Mounted Equipment

EQUIPMENT should be mounted on APPROVED lockable casters, gliders or wheels to facilitate easy moving, cleaning, and flexibility of operation whenever possible. Moveable EQUIPMENT requiring utility services such as gas or electrical connections should be provided with easily accessible quick-disconnects or the utility service lines should be flexible and of sufficient length to permit moving the EQUIPMENT for cleaning. If a flexible utility line is used, a safety chain that is shorter than the utility line must be installed. Check with local fire safety and building codes to ensure that such installations are acceptable.

Floor-mounted EQUIPMENT that is not mounted on wheels or casters with the above utility connections should be:

1. Permanently SEALED to the floor around the entire perimeter of the EQUIPMENT. The sealing compound should be pliable and non-shrinking. It should retain its elasticity and provide a water- and vermin-tight joint; or
2. Installed on a solid, SMOOTH, non-absorbent masonry base. Masonry bases and curbs should have a minimum height of 2" and be coved at the junction of the platform and the floor with at least a 1/4" radius. The EQUIPMENT should overhang the base by at least 1" but not more than 4". Spaces between the masonry base and the EQUIPMENT must be SEALED as above; or
3. Elevated on legs to provide at least a 6" clearance between the floor and EQUIPMENT. The legs shall contain no hollow open ends.
4. For EQUIPMENT not readily moveable by one person, spacing between and behind EQUIPMENT must be sufficient to permit cleaning under and around the unit. EQUIPMENT shall be spaced to allow access for cleaning along the sides, behind and above. At least 6" of clear, unobstructed space under each piece of EQUIPMENT must be provided or EQUIPMENT must be SEALED to the floor.

5. If EQUIPMENT is against a wall and is not movable, the EQUIPMENT must be joined to and/or SEALED to the wall in a manner to prevent liquid waste, dust and debris from collecting between the wall and the EQUIPMENT.
6. When EQUIPMENT is joined together, or spreader plates are used between EQUIPMENT, the resultant joint must be SEALED to prevent liquid waste, dust and debris from collecting between the EQUIPMENT.

Unobstructed and functional aisle and working spaces must be provided. A minimum width of 36" is required by fire and building codes.

All utility and service lines and openings through the floor and walls must be adequately SEALED. Penetrations through walls and floors must be minimized. Exposed vertical and horizontal pipes and lines must be kept to a minimum. The installation of exposed horizontal utility lines and pipes on the floor is prohibited. Any insulation materials used on utility pipes or lines in the FOOD preparation or dishwashing areas must be SMOOTH, non-absorbent, and easy to clean. Electrical units which are installed in areas subject to splash from necessary cleaning operations or FOOD preparation should be water-tight and washable.

B. Counter-Mounted Equipment

COUNTER-MOUNTED EQUIPMENT is defined as EQUIPMENT that is not portable and is designed to be mounted off the floor on a table, counter, or shelf. All COUNTER-MOUNTED EQUIPMENT shall be:

- SEALED to the table or counter; or
- Elevated on APPROVED legs to provide at least a 4" clearance between the table or counter and the EQUIPMENT to facilitate cleaning.

C. Other

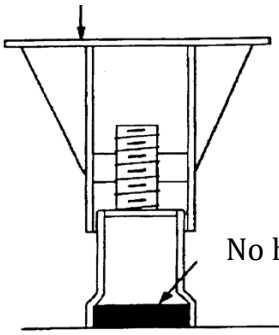
EQUIPMENT that is open underneath, such as drain boards, dish tables, and other tables that are not moveable should be spaced to allow for ease of cleaning or should be SEALED to the wall.

Non-FOOD contact surfaces of EQUIPMENT that are exposed to splash, spillage, or other FOOD soiling or that require frequent cleaning shall be constructed of corrosion-resistant, non-absorbent, and SMOOTH material.

Legs of all EQUIPMENT should not have hollow, open ends.

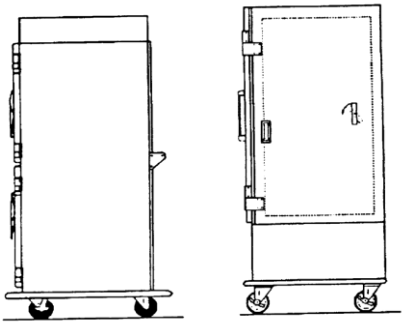
If running water dipper wells are installed, methods for filling and draining the units must be identified.

Equipment sealed to floor



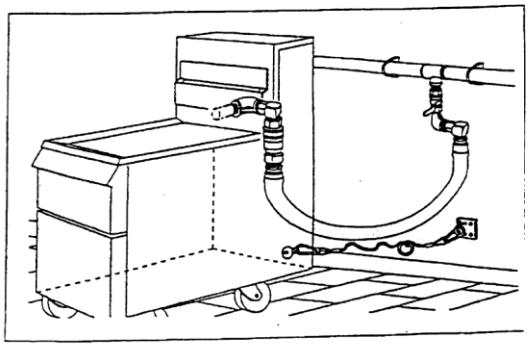
Elevate equipment for effective cleaning.

Sanitary Leg Example



Mobile Kitchen equipment mounted on Castor

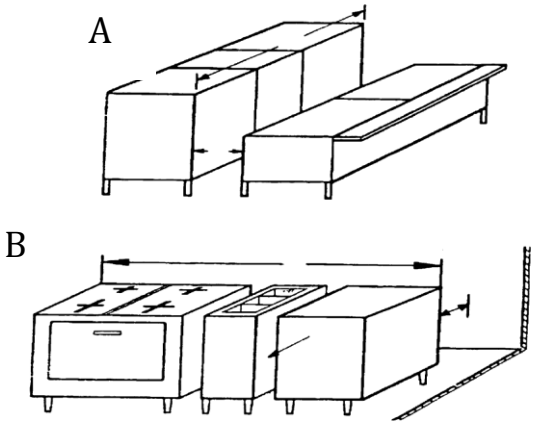
Holding Cabinet & a Reach-in Refrigerator



Refer to your Local Regulatory Authority for Gas Code Requirements

Flexible Gas Connection with Safety Chain

Equipment Spacing



Recommended EQUIPMENT spacing; provided access is available from both ends:

EQUIPMENT Length (A)	Space From Walls and Adjacent EQUIPMENT (B)
4' or less	6"
4' - 8'	12"
8' or more	18

WAREWASHING FACILITIES

The minimum requirement for WAREWASHING in a FOOD ESTABLISHMENT is a three-compartment sink. A mechanical WAREWASHING machine may be installed in addition to the three-compartment sink.

A. Manual Ware washing

For manual WAREWASHING, a stainless steel sink with no fewer than three compartments must be provided, with the exception that a two-compartment sink may be allowed by the REGULATORY AUTHORITY under certain conditions.

- The sink compartments shall be large enough to completely immerse the largest pot, pan or piece of EQUIPMENT to be used in the establishment that will not be cleaned in-place.
- Each compartment shall be supplied with adequate hot and cold potable running water, temperature of the wash solution shall be maintained at not less than 110°F, or the temperature specified on the cleaning agent manufacturer's label instructions.
- Drain boards, UTENSIL racks or tables large enough to accommodate clean and soiled UTENSILs shall be provided. The drain boards shall be self-draining.
- Adequate facilities for pre-flushing or pre-scrapping EQUIPMENT and UTENSILs must be provided.
- If hot water is used to sanitize EQUIPMENT and UTENSILs, the means for heating the water to 171°F in the 3rd compartment must be identified. The racks for the immersion of EQUIPMENT and UTENSIL must be specified.

B. Mechanical Ware washing

WAREWASHING machines shall be installed in accordance with the manufacturer's recommendations and applicable code requirements. If used, the hot water booster for WAREWASHING machines must be identified during plan review.

Adequate facilities shall be provided to air dry washed EQUIPMENT and UTENSILs. Drain boards, UTENSIL racks or tables must be large enough to allow proper and sufficient air drying of EQUIPMENT and UTENSILs.

Storage facilities shall be provided to store cleaned and sanitized UTENSILs and EQUIPMENT at least 6" above the floor; protected from splash, dust, overhead plumbing or other contamination. The plan must specify the location and facilities used for storing all UTENSILs and EQUIPMENT.

PLUMBING

A. Water Supply

The primary concerns relative to the water supply in a FOOD ESTABLISHMENT are:
1. Ensure the facility is supplied with a safe and adequate water supply, including adequate supply of hot water; and
2. Verify that the water can remain safe while it is in the facility.

Safe Source: Start at the water source. Determine if the water is potable or non-potable. The availability of an APPROVED public water supply must be verified. Any use of a non-public water source (well water) shall comply with local, state, and/or federal laws, and construction and testing standards.

Sufficient potable water: Potable water shall be provided from a source constructed and operated according to law that meets the peak water demands of the FOOD ESTABLISHMENT.

B. Hot Water Supply:

The hot water supply shall be sufficient to satisfy peak hot water demands of the FOOD ESTABLISHMENT. Hot water for hand washing and most FOOD ESTABLISHMENT uses shall be at least 100°F. Hot water for mechanical WAREWASHING must be boosted up to 150°F-165°F for washing and 165°F-180°F for sanitizing or according to the manufacturer's data plate on the machine. The temperature of the wash solution for spray-type ware washers that use chemicals to sanitize may not be less than 120°F.
The temperature of the wash solution for manual WAREWASHING must be maintained to not be less than 110°F. The water temperature for manual hot water sanitization must be at least 171°F.

Tank less water heaters shall be installed and used in accordance with the manufacturer's recommendations.

For guidance on calculating Hot Water Requirements see Appendix C – Model Calculations

C. Sewage Disposal, Grease Interceptors/Traps

All SEWAGE including liquid waste shall be disposed into a public SEWAGE system or an individual SEWAGE disposal system constructed and operated according to law. Where individual SEWAGE disposal systems are utilized, the location shall be noted on the plans and certification of compliance with state and local regulations shall be provided.

A grease trap/interceptor is a chamber designed for wastewater to pass through and allow any grease to float to the top for retention as the remainder of the wastewater passes

through. If used, a grease trap shall be located to be easily accessible for cleaning; FOOD solids entering the grease trap/interceptor should be minimized.

It is recommended that waste water from fixtures or drains which would allow fats, oils, and grease to be discharged be directed to a grease trap/interceptor. Local municipalities/jurisdictions will determine the number and size of grease traps, grease interceptors or catch basins. If installed, grease traps shall be properly spaced so they are easily accessible for servicing and cleaning. Refer to the local municipality/jurisdiction for the installation requirements.

D. Backflow Protection

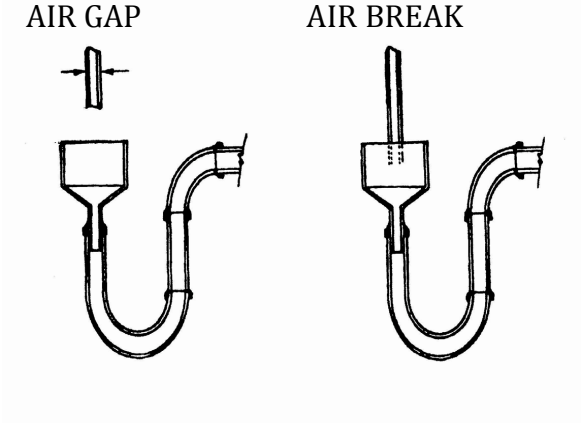
Plumbing shall be sized and installed according to applicable codes. There shall be no cross connections between the potable water supply and any non-potable system or a system of unknown quality. Where non-potable water systems are permitted for purposes such as air conditioning and fire protection, the non-potable water must not contact directly or indirectly: FOOD, potable water or EQUIPMENT that contacts FOOD or UTENSILs. The piping of any non-potable water system shall be durably identified so that it is readily distinguishable from piping that carries potable water.

A connection to a sewer line may be direct or indirect. A direct connection may not exist between the sewerage system and any drains originating from EQUIPMENT in which FOOD, portable EQUIPMENT, or UTENSILs are placed, except if otherwise required by law. When a WAREWASHING machine is located within 5 feet of a trapped floor drain, the dishwasher waste outlet may be connected directly on the inlet side of a properly vented floor drain trap.

An **indirect connection** may be one of two types, air gap or air break:

1. For a potable water supply, an **air gap** means the unobstructed, vertical air space that separates a potable system from a non-potable system.

2. An **air break** is a waste line from a fixture that discharges used water or liquid waste to a drain where the waist line terminates below flood level.



A connection to a sewer line may be direct or indirect. A direct connection may not exist between the sewerage system and any drains originating from EQUIPMENT in which FOOD, portable EQUIPMENT, or UTENSILs are placed, except if otherwise required by law. When a WAREWASHING machine is located within 5 feet of a trapped floor drain, the dishwasher waste outlet may be connected directly on the inlet side of a properly vented floor drain.

HYGIENE FACILITIES

A. Handwashing

Handwashing is a critical factor to prevent contamination of FOODs. Proper handwashing reduces the amount of pathogens that can be transmitted via cross contamination from raw FOODs to READY-TO-EAT-FOODS. It is imperative to have adequate numbers and conveniently placed HANDWASHING SINKS to ensure employees are washing hands. It is important that handwashing be done only at properly equipped HANDWASHING SINKS to help ensure that employees effectively clean their hands and minimize contamination of FOOD and FOOD-CONTACT SURFACES.

A HANDWASHING SINK, hand drying device or disposable towels, hand cleanser and waste receptacle shall be located for convenient use by employees who work in FOOD preparation, FOOD dispensing, and WAREWASHING areas.

Nothing must block the approach to a HANDWASHING SINK.

HANDWASHING SINKS must also be located in or immediately adjacent to toilet rooms.

HANDWASHING SINKS shall be of sufficient number and conveniently located for use by all employees in FOOD preparation, FOOD dispensing, and WAREWASHING areas.

HANDWASHING SINKS shall be easily accessible and may not be used for purposes other than handwashing. Sinks used for FOOD preparation, washing EQUIPMENT or UTENSILs, or service (mop) sinks shall not be used for handwashing.

Each handwashing sink shall be provided with hot and cold water tempered by means of a mixing valve or a combination faucet to provide water at a temperature of at least 100˚F. If used, self-closing, slow-closing or metering faucets shall be designed to provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

Splash from use of a handwashing sink may not contaminate FOOD, FOOD-CONTACT SURFACES, clean EQUIPMENT or UTENSILs. A washable baffle or barrier may be needed if the handwashing sink is located next to a FOOD preparation area, UTENSIL or EQUIPMENT storage, or FOOD-CONTACT SURFACE and if the space between the handwashing sink and FOOD, FOOD preparation, FOOD-CONTACT SURFACES, and clean UTENSILs and

EQUIPMENT does not provide adequate protection.

Similarly, the location of soap and paper towel dispensers at HANDWASHING SINKS must be reviewed during plan review so that their use does not contaminate FOOD, FOOD-CONTACT SURFACES, UTENSILs and EQUIPMENT. In addition, the distance that employees would have to reach the faucet handles, soap and paper towels must be reviewed during plan review to assure that they will have proper access to the HANDWASHING SINKS and will not have to reach across dirty surfaces while washing their hands.

B. Toilet Rooms

Properly functioning toilet facilities must be accessible to employees at all times.

If required by federal, state, local or tribal laws and regulations, toilet facilities must be made available to the customers. If the public toilet facilities are used by employees, separate toilet facilities may not have to be installed for the employees. Toilet facilities must be made accessible in accordance with the Americans with Disabilities Act (ADA) of 1990.

The floors, walls, and ceiling in toilet rooms shall be SMOOTH and EASILY CLEANABLE. The walls around toilets, urinals, toilet paper dispensers, soap dispensers, and paper towel dispensers should be water resistant and durable for frequent cleaning.

The minimum requirements for toilet facilities shall include:

- **Toilet:** At least one toilet and not fewer than the number of toilets required by law shall be provided. If authorized by law, urinals may be substituted for additional toilets in men's toilet rooms.
- **HANDWASHING SINK:** Each HANDWASHING SINK shall be provided with hot and cold water tempered by means of a mixing valve or a combination faucet to provide water at a temperature of at least 100°F. If used, self-closing, slow-closing or metering faucets shall be designed to provide a flow of water for at least 15 seconds without the need to reactivate the faucet.
- **Handwashing cleanser:** Each HANDWASHING SINK or group of two adjacent HANDWASHING SINKS shall be provided with hand cleaning liquid, powder, foam or bar soap. A dispenser shall be provided for handwashing cleanser provided in liquid or powder form.
- **Hand drying facility:** Each HANDWASHING SINK or group of adjacent HANDWASHING SINKS shall be provided with individual, disposable towels; a continuous towel system that supplies the user with a clean towel; heated-air hand drying device; or hand drying device with air-knife, high velocity air at ambient temperatures.
- **Toilet paper:** A supply of toilet paper shall be provided in a dispenser at each toilet.
- **Waste receptacle:** If disposable towels are used, a waste receptacle shall be located at each sink or group of sinks. At least one covered waste receptacle shall be provided in toilet rooms used by females.

- **Ventilation:** Toilet rooms must be vented to the outside. Mechanical Ventilation shall be installed in toilet rooms according to law. If allowed by law, operable screened windows may be used in lieu of mechanical ventilation devices.
- **Toilet room doors:** Toilet room doors shall be tight-fitting and self-closing.
- **Lighting:** At least 215 lux (20 foot candles) shall be provided in toilet rooms.

STORAGE

A. Dry Storage-

The dry storage space needed depends on the menu, number of meals served between deliveries, frequency of deliveries, and the amount and type of SINGLE-SERVICE ARTICLES to be stored. The location of dry storage should be adjacent to the FOOD preparation area and convenient to receiving. Adequate ventilation should be provided. FOOD should not be stored under exposed sewer lines. Similarly, a cabinet that is used for the storage of FOOD, shall not be located under exposed or unprotected sewer lines, open stairwells or other sources of contamination. Stationary shelving needs to have a minimum 6" floor clearance.

Shelving, dollies, racks, pallets and skids shall be corrosion-resistant, non- absorbent and SMOOTH. Pallets, racks and skids used for bulk cased or overwrapped items shall be designed to be moved by hand or by conveniently located hand trucks or forklifts. Shelving, dollies, racks, pallets and skids should be spaced away from walls to allow for cleaning and pest monitoring/inspection.

APPROVED FOOD containers with tight-fitting covers and dollies should be used for storing bulk FOODs such as flour, cornmeal, sugar, dried beans, rice and similar.

B. Dry Storage Calculations

Formulas can be used to estimate the amount of dry storage space that may be needed. To determine, you will need information on number of meals estimated to be served per day, days between deliveries and storage area availability. Links to example calculators can be found in Appendix C.

C. Poisonous or Toxic Materials Storage

Designate an area for POISONOUS OR TOXIC MATERIAL storage that is away from FOOD and clean UTENSILs. These include detergents, sanitizers, related cleaning or drying agents and caustics, acids, polishes and other chemicals. Install cabinets, cages, or physically separate shelves for storing chemicals.

D. Clean Equipment, Utensil and Linen Storage

Designate areas for clean cooking UTENSILs, cutting boards, glassware and dishware. Store them at least 6-inches off the floor in a clean, dry location where they

will be protected from dust and splash.

LIGHTING

A. Intensity

The light intensity shall be at least 108 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry FOOD storage areas and rooms during periods of cleaning.

The light intensity shall be at least 215 lux (20 foot candles) at a surface FOOD is provided for consumer self-service such as buffets and salad bars or where fresh product or packaged FOODS are sold or offered for consumption; inside EQUIPMENT such as reach-in and under-counter refrigerators; at a distance of 75 cm (30 inches) above the floor in areas used for handwashing, WAREWASHING, and UTENSIL storage, and in toilet rooms.

The light intensity shall be at least 540 lux (50 foot candles) at a surface where a FOOD EMPLOYEE is working with FOOD or working with UTENSILs or EQUIPMENT such as knives, slicers, grinders, or saws where employee safety is a factor.

B. Protective Light Shielding

Shielding such as plastic shields, plastic sleeves with end caps, shatterproof bulbs and/or other APPROVED devices shall be provided for all artificial lighting fixtures located in areas where there is exposed FOOD; clean EQUIPMENT, UTENSILs, and LINENS; or unwrapped single-service and single-use articles.

Heat lamps shall be protected against breakage by a shield surrounding and extending beyond the bulb, leaving only the face of the bulb exposed.

FINISHES

A. Floors

Example floor materials are as follows:

- Quarry tile, ceramic tile
- SEALED curbed concrete
- Seamless poured epoxy minimum 3/16-inch thick.
- Commercial-grade sheet vinyl **(no felt backing)**
- Commercial-grade vinyl composition tile (VCT)

Pre-approval from the REGULATORY AUTHORITY should be obtained prior to use of carpet and/or wood.

B. Walls

Example wall materials are as follows:

- Stainless steel
- Ceramic tile
- Aluminum
- Fiber-glassed reinforced panels (FRP)
- SEALED Concrete blocks or bricks
- Epoxy or glazed drywall

Ceilings

Example ceiling materials may include wall finish material listed above along with the following:

- EASILY CLEANABLE, non-absorbent ceiling tiles
- Painted drywall

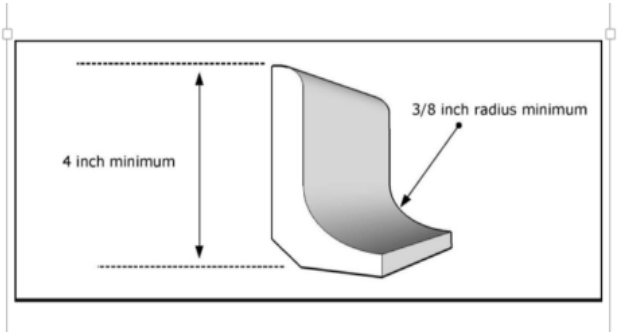
C. Coving

Coving is the floor material found at the base of walls (wall/floor junctures) and is required in most areas of the FOOD ESTABLISHMENT, such as:
FOOD preparation, storage, handling, and packaging areas

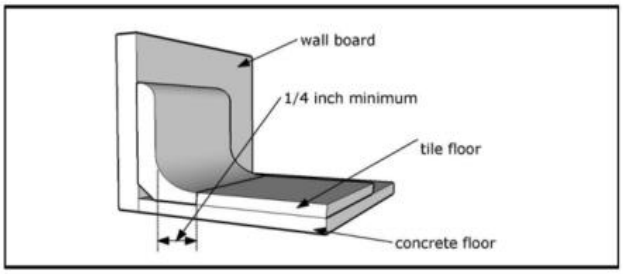
- UTENSIL washing and storage areas
- Interior waste disposal areas (garbage, REFUSE, grease)
- Restrooms
- Hand washing areas
- Janitorial facilities
- Walk-in refrigerator and freezer units (inside and outside)
- Bars (employee side)
- Customer self-serve areas where non-individually prepackaged FOODs or beverages are sold or dispensed (e.g., salad bars, buffets, bulk FOOD sales, beverage stations)
- Employee change and storage areas
- Wait stations

Coved flooring material should extend integrally up the walls. Integral coving is not required in areas used exclusively for dining, point-of-sale, or the storage of UTENSILs or FOODs contained in the original **un-opened** container

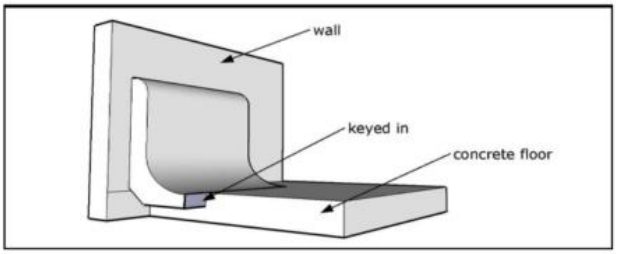
Floor Installation Diagrams



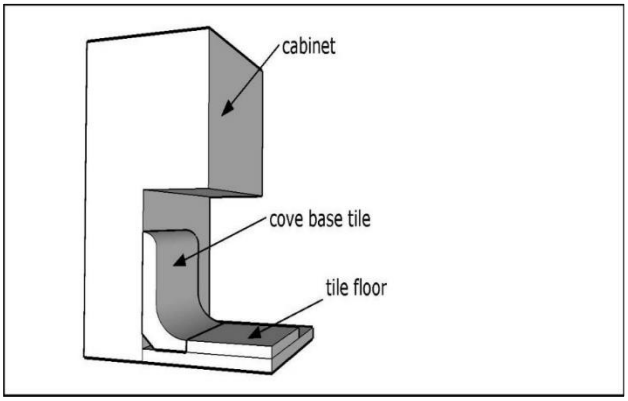
Example of quarry tile cove base.



Example of quarry tile cove base flush with floor.



Example of quarry tile cove base integral to concrete floor.



Example cove base; cabinet toe-kick

PEST CONTROL

All openings to the outside shall be effectively protected against the entrance of insects and rodents. All roller doors, sliding or bi-fold doors, or similar movable wall systems that are not self- closing and create a continuous opening to the exterior must have an effective means of pest control.

Some examples of effective barriers include:

- Solid, tight fitting, self-closing doors.
- Fixed or self-closing screens of #16 mesh or finer.
- Effective air curtains.

Example Air Curtain

This may not apply if a FOOD ESTABLISHMENT opens into a larger completely enclosed structure such as a coliseum, arena, warehouse, shopping mall, superstores, airport, or office building, where the outer openings from the larger structure are protected against the entry of insects and rodents.

A. Building

All masonry or cement foundations must be rodent proof. Seal all openings into the foundation and exterior walls, including openings & penetrations around wall and ceiling penetrations.

Cover all building vents with a minimum #16 mesh screen. Effectively seal all air ducts, skylight, transoms, and other openings to the outside.

B. Windows

Windows that open to the outside must be properly protected with minimum #16 mesh screen, with the exception of service windows.

Drive-thru and walk-up service windows must have effective means to prevent pest entry, to include minimum #16 mesh screens, properly designed and installed air curtains, or other effective means such as self-closing devices (spring-loaded, bump pad, electronic opener, or gravity operated).

C. Delivery, Customer, and Toilet Room Doors

Exterior doors: All outside doors shall be self-closing and tight fitting. Install a door sweep and weather stripping to prevent the entrance of insects and rodents. *Note: Daylight shall not be visible around the perimeter of the door.*

Garage Doors, Roller Doors, and Loading Docks: Garage and roller type delivery doors must be protected against pests. Loading docks shall have properly installed tight fitting dock seals at all loading bays. If the location of one of these doors exposes the kitchen or other FOOD service, air curtains will be required.

Toilet Room (Restroom) doors: All toilet rooms located in or adjacent to a FOOD ESTABLISHMENT shall be provided with tight fitting, self-closing doors. This requirement does not apply to a toilet room that is located outside a FOOD ESTABLISHMENT and does not open directly into the FOOD ESTABLISHMENT such as a toilet room that is provided by the management of a shopping mall.

D. Insect Control Devices, Design and Installation

Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device. These devices must not be located above FOOD preparation areas and installed to prevent the contamination of exposed FOOD, clean EQUIPMENT, UTENSILs, and LINENS, from insect fragments

MECHANICAL VENTILATION

A. Mechanical Ventilation Requirements

Commercial cooking or display EQUIPMENT, which produces smoke, steam, grease, mists, particulate matter, condensation, vapors, fumes, odors, or create sanitation or indoor air quality problems, will require a hood.

Hoods shall be designed and installed to prevent grease and condensation from collecting on walls, ceilings, and dripping into FOOD or onto FOOD contact surfaces. All hoods should comply with the current International Mechanical Code (IMC) and/or all local building and fire safety codes.

Balancing of the exhaust and make-up air must be ensured so that the system can be operated efficiently.

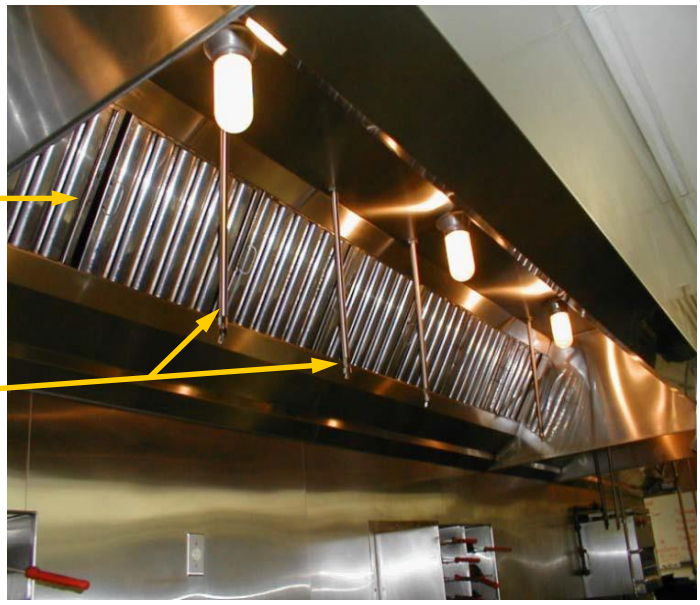
B. Mechanical Ventilation Hood Systems

Type I hoods are required over EQUIPMENT that produce grease, smoke, excessive steam, heat, condensation, particulate matter, odors, or create indoor sanitation or indoor quality problems. Examples of equipment requiring installation under a hood include: Kettles, pasta cookers, hot plates, salamanders, Mongolian-style grills, gas cooking EQUIPMENT, tableside cooking EQUIPMENT, such as Teppanyaki-style cooking, Tandoori ovens, rotisserie units, Panini grills, etc.

Type I Hood over Cook Line

Grease filters

Fire suppression system



The National Fire Protection Association provides a resource for FOOD ESTABLISHMENTS to reduce the potential fire hazard of commercial cooking operations. Refer to the NFPA link below or your local/State Fire Protection regulations.

http://www.nfpa.org/codes-and-standards/document-information-pages?mode=code&code=96

Type II hoods shall be installed over EQUIPMENT that produce steam, heat, mists, condensation, fumes, vapors, and non-grease laden FOODs.

Type II Hood over WAREWASHING Machine

Vapor hood

Vent less Hood Systems or ventilation systems integral to the cooking EQUIPMENT need to be reviewed and APPROVED by the local mechanical code, and other applicable fire safety codes.

Appendix A - MODEL PLAN REVIEW APPLICATION FOR FOOD ESTABLISHMENTS

TYPE OF APPLICATION: □ New □ Remodel □ Conversion	**Projected Start Date:**_____ **Projected Completion Date:** _____
TYPE OF FOOD OPERATION: □ Restaurant □ Institution □ Daycare □ Retail food store □ Other:_____	

FOOD ESTABLISHMENT INFORMATION

Name of Establishment:			
Establishment Address:	**City:**	**State:**	**ZIP:**

OWNERSHIP INFORMATION

Name of Owner:			
Address:	**City:**	**State:**	**ZIP:**
Email:	**Phone Number:**		

APPLICANT INFORMATION (e.g., ARCHITECT/ENGINEER)

Applicant Name:	**Contact Person:**		
Applicant Mailing Address:	**City:**	**State:**	**ZIP:**
Email:	**Phone Number:**		

FOOD OPERATION INFORMATION

Hours/Days of Operation	**Restaurant Seating Capacity**	**Type of Service (check all that apply)**	**Employees**
☐ **Sun:**_____	# of Indoor Seats: _____	☐ On-site consumption	Max per shift:_____
☐ **Mon:**_____	# of Outdoor Seats:_____	☐ Off-site consumption	**Maximum meals to be served**
☐ **Tues:**_____	Square Feet of Facility:	☐ Catering	☐ Breakfast _____
☐ **Wed:**_____	_____	☐ Single-use utensils	☐ Lunch _____
☐ **Thurs:**_____		☐ Multi-use utensils	☐ Dinner _____
☐ **Fri:**_____		☐ Other:_____	
☐ **Sat:**_____			

The following documents must be submitted along with this application:

☐ Proposed menu or complete list of food and beverages to be offered (including seasonal, catering and banquet menus) – ***Standard Operating Procedures or HACCP plans may be required.***

☐ Plans must be clearly drawn to scale (minimum 11 x 14 inches in size) and include these items below:

- The floor plan must identify: food preparation, serving and seating areas, restrooms, office, employee change room, storage, warewashing, janitorial and trash area. Include location of any outside equipment or facilities (dumpsters, well, septic system-if applicable).
- Provide equipment layout and specifications, clearly numbered and cross-keyed with the equipment list. *Elevation drawings may be requested by the Regulatory Authority.*
- Identify handwashing, warewashing and food preparation sinks.
- Provide plumbing layout showing the sewer lines, cleanouts, floor drains, floor sinks, vents, grease trap or grease interceptor, hot and cold water lines, and direction of flow to sanitary sewer.
- Provide exhaust ventilation layout including location of hood and make-up air returns and ducts, if applicable.
- Lighting plan, indicating the exact foot candles for each area as required by the FDA Food Code (§6-303.11).
- Finish schedule showing floor, coved base, wall and ceilings for each area shown on the plans.

Note: A color coded flow chart may be requested by the Regulatory Authority demonstrating flow patterns for: food (receiving, storage, preparation, service); dishes (clean, soiled, cleaning, storage); trash (service area, holding, storage, disposal).

Signature:	**Date:**
Print Name:	**Title:**

Appendix B – REGULATORY COMPIANCE REVIEW LIST

FOOD PREPARATION PROCEDURES

FOOD DELIVERY

1. How often will frozen foods be delivered? □ Daily □ Weekly □ Other: _____
2. How often will refrigerated foods be delivered? □ Daily □ Weekly □ Other: _____
3. How often will dry foods or supplies be delivered? □ Daily □ Weekly □ Other: _____

FOOD STORAGE* - Identify amount of space (in cubic feet) allocated for:

Dry Storage _____; Refrigerated Storage (41°F) _____; Frozen Storage _____; Utensil Storage _____

* Identify on plans where storage will be located.

INSTRUCTIONS: Describe the following with as much detail as possible. Indicate Not Applicable (NA) as appropriate.

PROCESS	IDENTIFY FOOD ITEMS	INDICATE LOCATION AND EQUIPMENT	MEETS CRITERIA (RA to circle and Initial)
Washing Food and Drug Administration (FDA) Food Code §3-302.15			YES/NO
Thawing FDA Food Code §3-501.13			YES/NO
Cooking FDA Food Code §3-401			YES/NO
Hot Holding Hot food maintained at 135°F			YES/NO
Cooling Time/Temperature Control for Safety (TCS) food will be cooled to 41°F within 6 hours; 135°F to 70° in 2 hours			YES/NO
Reheating Food must be reheated to a temperature of 165° for 15 seconds within 2 hours			YES/NO

FINISH SCHEDULE

INSTRUCTIONS: Indicate which materials (quarry tile, stainless steel, fiberglass reinforced panels (RFP), ceramic tile, 4" plastic coved molding, etc.). Indicate Not Applicable (NA) as appropriate.

ROOM/AREA	FLOOR	FLOOR/WALL JUNCTURE	WALLS	CEILING	MEETS CRITERIA (RA to circle and Initial)
Food Preparation					YES/NO
Dry Food Storage					YES/NO
Warewashing Area					YES/NO
Walk-in Refrigerators and Freezers					YES/NO
Service Sink					YES/NO
Refuse Area					YES/NO
Toilet Rooms and Dressing Rooms					YES/NO
Other: Indicate					YES/NO
Identify the finishes of cabinets, countertops, and shelving:					

PHYSICAL FACILITIES

INSTRUCTIONS: Explain the following with as much detail as possible. Indicate Not Applicable (NA) as appropriate.

TOPIC	MINIMUM CRITERIA	MEETS CRITERIA (Circle and Initial)
Handwashing facilities	• Identify number of the handwashing sinks in food preparation and warewashing areas: _____Food Preparation _____ Warewashing Area • Type of hand drying device? Disposable towels □ Hand-drying device □	YES/NO
Warewashing Facilities	**MANUAL DISHWASHING** • Identify the length, width, and depth of the compartments of the 3-compartment sink: _____ • Will the largest pot/ pan fit into each compartment of the 3-compartment sink? □ Yes □ No If No, what will be the procedure for manual cleaning and sanitizing of items that will not fit into sink compartments? _____ • Describe size, location and type (drainboards, wall-mounted or overhead shelves, stationary or portable racks) of air drying space: _____ • What type of sanitizer will be used? □ Chemical Type:_____ □ Hot Water **MECHANICAL DISHWASHING** • Identify the make and model of the mechanical dishwasher:_____ • What type of sanitizer will be used? □ Chemical Type:_____ □ Hot Water • Will ventilation be provided? Yes □ No □	YES/NO

Water Supply	• Is the water supply public or non-public/private? public □ non-public/private □ • If private, has source been approved? Yes □* No □ • Attach copy of written approval and/or permit. • Is ice made on premises or purchased commercially? Made on-site □ Purchased □ • Will there be an ice bagging operation? Yes □ No □	YES/NO
Sewage Disposal	• Is the sewage system public or non-public/private? public □ non-public/private □ • If private, has the sewage system been approved? Yes □* No □ • Attach copy of written approval and/or permit. • Will grease traps/interceptors be provided? Yes □* No □ *Identify location on plan.	YES/NO
Backflow Prevention	• Will all potable water sources be protected for backflow? Yes □ No □ • Are all floor drains identified on the submit floor plan? Yes □ No □	YES/NO
Toilet Facilities	• Identify locations and number of toilet facilities: _____ • Hot and cold water provided? Yes □ No □	YES/NO
Dressing Rooms	• Will dressing rooms be provided? Yes □ No □ • Describe storage facilities for employee personal belongings_____	YES/NO
Linens	• Will linens be laundered on site? Yes □ No □ • If yes, what will be laundered and where? _____ • If no, how and where will linens be cleaned? _____ • Identify location of clean and dirty linen storage:_____	YES/NO

Poisonous/Cleaning Storage	• Identify the location and storage of poisonous or toxic materials • Where will cleaning and sanitizing solutions be stored at workstations? _____ • How will these items be separated from food and food-contact surfaces? _____	YES/NO
Pest Control	• Will all outside doors be self-closing and rodent proof? □ Yes □ No □ NA • Will screens be provided on all entrances left open to the outside? □ Yes □ No □ NA • Will all openable windows have a minimum #16 mesh screening? □ Yes □ No □ NA • Will insect control devices be used? □ Yes □ No □ NA • Will air curtains be used? If yes, where? _____ Note: All pipes and electrical conduit chases must be sealed to prevent rodent access.	YES/NO
Refuse, Recyclables, and Returnables	• Will refuse/garbage be stored inside? □ Yes □ No If yes, where _____ • Identify how and where garbage cans and floor mats will be cleaned? _____ • Will a dumpster or a compacter be used? □ Dumpster □ Compactor • Identify locations of grease storage containers:_____ • Will there be an area to store recyclables? □ Yes □ No • If yes, where _____ • Will there be an area to store returnable damaged goods? □ Yes □ No • If yes, where _____	YES/NO

Food Establishment Plan Review Formulas
Print this sheet and collect the following information from plans. Information will be used to perform calculations.
Facility Name & Address: _____
Hot Water
List each type of plumbing fixture that uses hot water # proposed
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____

Proposed Size: _____ KW or _____ BTU's

Proposed Storage capacity: _____ gallons Thermal Efficiency: _____%

Proposed (for instantaneous water heaters): _____ gallons per minute (gpm) @ _____ degree rise

Proposed dishmachine booster heater:

Refrigerated Storage
By seats: # seats: _____ # meal periods: _____ Drive-Up Window: Y N

By # meals: # meals between deliveries: _____

Walk-in # or Name	Interior Height (ft)	Interior Length (ft)	Interior Width (ft)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Reach-In # or Name	Interior Depth (in)	Interior Width (in)	Interior Height (in)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

_____ _____ _____ _____

Dry Storage

By seats: # seats: _____ # meal periods: _____ Drive-Up Window: Y N

By meals: # meals between deliveries: _____

Storage Rooms

Interior Length (ft)	Interior Width (ft)	Usable room height (ft)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Or

For full height shelves

Total Shelving Length (ft)	Shelving Width (ft)	Usable room height (ft)
_____	_____	_____

Ventilation

Proposed make-up air (MUA) fan volume
MUA1= _____ cfm, MUA2=_____cfm, MUA3=_____cfm

Proposed hood exhaust: hood 1=_____, hood 2=_____, hood 3=_____, hood 4=_____, hood 5=_____ cfm

Required hood exhaust:
Horizontal open perimeter & vertical distance from equipment to hood for each piece of equipment under each hood

Hood 1	**Alternate Formula**		**Main Formula**
Equipment	Vertical Distance (ft)	Open Perimeter (ft)	Area of hood over equip.(sq. ft.)

Hood 2			
Equipment	Vertical Distance (ft)	Open Perimeter (ft)	Area of hood over equip.(sq. ft.)

Hood 3			
Equipment	Vertical Distance (ft)	Open Perimeter (ft)	Area of hood over equip.(sq. ft.)

Hood 4			
Equipment	Vertical Distance (ft)	Open Perimeter (ft)	Area of hood over equip.(sq. ft.)

Hood 5

Equipment	Vertical Distance (ft)	Open Perimeter (ft)	Area of hood over equip.(sq. ft.)

Appendix D Plan Review Web Links

These links are examples of resources available to the Food Establishment Applicant. The required plan, specifications and information must be approved by the Regulatory Authority to receive a permit to operate a food establishment.

Michigan Department of Agriculture and Rural Development

http://www.michigan.gov/mdard/0%2c4610%2c7-125-50772_45851-59764--%2c00.html

Wisconsin Department of Safety and Professional Services

http://www.dsps.wi.gov/Plan-Review

U.S. Food and Drug Administration Food Establishment Plan Review Guide

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm

North Carolina Public Health, Environmental Health Section

http://ehs.ncpublichealth.com/faf/food/planreview/app.htm

Minnesota Department of Agriculture

http://www.mda.state.mn.us/food/business/plan-review.aspx

Conference for Food Protection, Plan Review for Food Establishments

http://www.foodprotect.org/guides-documents/plan-review-for-food-establishments-2008/

Public Health – Seattle and King County

http://www.kingcounty.gov/healthservices/health/ehs/foodsafety/FoodBusiness/permanent.aspx

Harris County Public Health and Environmental Services

http://www.hcphes.org/divisions_and_offices/environmental_public_health/training_and_resources/information_for_food_establishments/food_establishment/

Florida Department of Health in Volusia County

http://volusia.floridahealth.gov/programs-and-services/environmental-health/food-hygiene/food-guide.html

First Name	Last Name	Constituency	Employer	Address	City
Catherine	Cummins	State ReguConsumer	Virginia Department of Health	109 Governor St, 5th Floor	Richmond
Albert	Espinoza	Retail Food Industry	HEB	5105 Rittiman Rd	San Antonio
Jessica	Fletcher	Local Regulator	Mohegan Tribal Health Department	13 Crow Hill Road	Uncasville
Liza	Frias	Local Regulator	City of Pasadena, Public Health Department	1845 N. Fair Oaks Ave, Rm 1200	Pasadena
Beth	Glynn	Retail Food Industry	Starbucks Coffee Company	2401 Utah Ave S, MS S-GQA	Seattle
Michelle	Haynes	State Regulator	DBPR, Division of Hotels and Restaurants	1940 N Monroe St	Tallahassee
Rebecca	Krzyzanowski	State Regulator	MI Department of Agriculture	525 W. Allegan St	Lansing
Michael	MacLeod	Retail Food Industry	Big Y Foods Inc.	2145 Roosevelt Avenue	Springfield
Deborah	Marlow	Local Regulator	Williamson County and Cities Health District	303 S Main Street	Georgetown
Dianna	Pasley	Retail Food Industry	Schnuck Markets, Inc.	11420 Lackland Road	St. Louis
Elizabeth A.	Nutt	Local Regulator	Tulsa Health Department	5051 S. 129th E. Ave	Tulsa
Terrance	Powell	Local Regulator	Los Angeles County Dept. of Public Health	5050 Commerce Drive	Baldwin Park
Daniel	Tew	Food Service Industry	Yum! Brands, Inc.	4612 North Ridge Circle	Crestwood
Karen	Reid	Food Service Industry	Walt Disney World	PO Box 10000	Lake Buena Vista
Christoper	Sparks	State Regulator	TX Dept of State Health Services	8407 Wall St	Austin
Linda	Zaziski	Retail Food Industry	Little Caesers Enterprises	2211 Woodward Avenue	Detroit

FDA Member Consultant	**FDA Alternate**		Email
Veronica Moore	Dan Redditt	Veronica Moore 240-402-1409 Dan Redditt 404-253-1265, x 1265	Veronica.Moore@fda.hhs.gov Joseph.Redditt@fda.hhs.gov

[1] Email addresses: first.last@fda.hhs.gov

State	Zip	Work Phone	Email	Dues Expires
VA	23219	(434) 906-1129	catherine.cummins@vdh.virginia.gov	2016
TX	78218	(210) 884-5783	espinoza.albert@heb.com	2016
CT	06382	(860) 862-6156	jfletcher@moheganmail.com	2016
CA	91103	(626) 744-6062	lfrias@cityofpasadena.net	2016
WA	98134	(206) 318-9255	bglynn@starbucks.com	2016
FL	32399	(850) 717-1734	michelle.haynes@myfloridalicense.com	2016
MI	48909	(517) 719-7919	krzyzanowskir@michigan.gov	2016
MA	01002	(413) 504-4453	mmacleod@bigy.com	2016
TX	78626	(512) 943-3620	dmarlow@wcchd.org	2016
MO	63146	(314) 994-4346	dpasley@schnucks.com	2016
OK	74134	(918) 595-4301	eanutt@tulsa-health.org	2016
CA	91706	(626) 430-5330	tpowell@ph.lacounty.gov	2016
KY	40014	(502) 874-2422	daniel.tew@yum.com	2016
FL	32830	(407) 827-6971	karen.reid@disney.com	2016
TX	78754	(512) 834-6770	christopher.sparks@dshs.state.tx.us	2016
MI	48201	(313) 471-6550	linda.zaziski@lcecorp.com	2016

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-002

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

PRC 2 – Food Establishment Plan Review Manual

Issue you would like the Conference to consider:

A review and acceptance of the updated Food Establishment Plan Review Manual and Appendix A through D (2016).

Public Health Significance:

The Food Establishment Plan Review Manual assists our regulatory authority, architects, food consultants and other interested professionals in the plan review process when proposing to build or remodel a food establishment. Poor design, repair, and maintenance will compromise the physical facility and its operations. This Manual provides standards to promote public health and prevent environmental health related illness.

Recommended Solution: The Conference recommends...:

1) Approval of the Food Establishment Plan Review Manual (including the cover sheet) and Appendix A through D (2016) (documents attached to Issue titled: Report - Plan Review Committee Final Report)

2) Replacing the Plan Review Guide (2008) currently on the CFP website with the final compiled Food Establishment Plan Review Manual in PDF format.

Submitter Information 1:

Name:	Albert Espinoza
Organization:	Plan Review Committee Co-Chair
Address:	HEB5105 Rittiman Road
City/State/Zip:	San Antonio, TX 78218
Telephone:	2108845783
E-mail:	espinoza.albert@heb.com

Submitter Information 2:

Name:	Rebecca Krzyzanowski
Organization:	Plan Review Committee Co-Chair
Address:	Michigan Department of Agriculture525 Allegan Street
City/State/Zip:	Lansing, MI 48909
Telephone:	5177197919
E-mail:	krzyzanowskir@michigan.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-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:

Outdoor equipment guidelines

Issue you would like the Conference to consider:

New and more aggressive outdoor food safety regulations must be considered as the trend in off premise catering and outdoor food events continue to rise.

The CDC states that 1 in 6 Americans will get sick from eating contaminated food. Today's technology in food service equipment for proper heating, holding, transporting, and cooling techniques can greatly reduce this grim statistic.

Offsite events are a challenge to monitor - but as more events arise - the need for better and tighter regulations is necessary. NAFEM (National Association of Foodservice Manufacturers) is an organization which has many resources and qualified companies who have answers for todays challenges. NAFEM companies launch new products each year that meet both sanitation and electrical requirements (Underwriters Laboratories, National Sanitation Foundation, etc.) that keep food at safe serving temperatures in the prep - transport - holding - and serving phases of off premise catered events - without the need for electricity.

Public Health Significance:

Reduction of food borne illnesses from outdoor catered events. The implemention of stricter regulations and increased education on utilizing foodservice equipment appropriate for outdoor use is key to preventing foodborne illness.

Recommended Solution: The Conference recommends...:

that a committee be established to develop recommendations and guidance material regarding outdoor food preparation and service with the following charges:

1. Research available and relevant literature;
2. Explore new technologies in outdoor food equipment;

3. Work with certification organizations to review and revise standards for outdoor equipment;
4. Review existing educational and training materials available from both the public and private sectors;
5. Develop best practice recommendations for outdoor food preparation and service (target audience is both regulatory and industry);
6. Develop recommended language for amending the FDA Food Code; and
7. Report back committee findings and recommendations to the 2018 biennial meeting.

Submitter Information:

Name:	Michael Capretta
Organization:	Cres Cor
Address:	5925 Heisley Road
City/State/Zip:	Mentor, OH 44060
Telephone:	2167806066
E-mail:	mcapretta@crescor.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-004

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

All information above the line is for conference use only.

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014-I-25; new or additional information has been included or attached.

Title:

Report - Oyster Advisory Committee

Issue you would like the Conference to consider:

Issue 2014-I-25 was extracted by the body of State Delegates at the 2014 Biennial Meeting, in Orlando Florida. This action prompted forming an Executive Board Ad Hoc Committee to discuss the extracted no action decision. After discussion, the Executive Board Ad Hoc Committee determined that a Conference Committee should be formed to discuss and provide a recommendation at the 2016 Biennial Meeting.

Public Health Significance:

The Oyster Advisory Committee was tasked with developing recommendations to update the 2013 Food Code Section 3-603.11 Consumer Advisory, as follows, regarding raw molluscan shellfish that have not been treated by a process sufficient to reduce *Vibrio spp*. to an undetectable level, as detected by the *Vibrio vulnificus* testing method in the most current edition of the U.S. Food and Drug Administration Bacteriological Analytical Manual.

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(4) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.

(B) DISCLOSURE shall include:

(1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order)"; or

(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.

(C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request;

(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; or

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the 2014 - 2016 Oyster Advisory Committee Final Report and thanking the committee members for their work.
2. No further action based on:
    - the Interstate Shellfish Sanitation Conference (ISSC) letter dated July 7, 2014 that states the ISSC does not agree that the recommended solution of Issue 2014-I-025 would improve effectiveness or reduce illnesses; and
    - the CFP Oyster Advisory Committee determination that the existing language in Section 3-602.11 of the 2013 FDA Food Code is adequate to address consumer advisory for raw molluscan shellfish.
3. The Oyster Advisory Committee be disbanded as they have completed their charges.

Submitter Information 1:

Name:	Lisa Staley
Organization:	Oyster Advisory Committee Co-Chair
Address:	Maryland Department of Health and Mental Hygiene6 St. Paul Street, Ste 1301
City/State/Zip:	Baltimore, MD 21202
Telephone:	4107678407
E-mail:	lisa.staley@maryland.gov

Submitter Information 2:

Name:	Thomas McMahan
Organization:	Oyster Advisory Committee Co-Chair
Address:	Meijer3040 Remico St, SW
City/State/Zip:	Grandville, MI 49418
Telephone:	616.249.6035
E-mail:	thomas.mcmahan@meijer.com

Content Documents:

- "Oyster Advisory Committee Final Report"
- "2014-2016 Oyster Advisory Committee Roster"

Supporting Attachments:

- "FDA References for Consumer Advisory"
- "ISSC letter July 2014"

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 rev: 06/21/2013

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

COMMITTEE NAME: *Oyster Advisory Committee*

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council I (established by Executive Board Ad Hoc Committee formed from extracted issue 2014-I-25)

DATE OF *REPORT: November 6, 2015*

SUBMITTED BY: *Lisa Staley, Committee Co-Chair, Thomas McMahan, Committee Co-Chair*

COMMITTEE CHARGE(s):

1. Develop recommendations to update Food Code section 3-603.11 Consumer Advisory regarding raw molluscan shellfish that have not been treated by a process sufficient to reduce *Vibrio spp*. to an undetectable level, as detected by the *Vibrio vulnificus* testing method in the most current edition of the U.S. Food and Drug Administration Bacteriological Analytical Manual.

2. Report back to the 2016 Conference for Food Protection Biennial meeting on the committee's work and submit an issue amending the FDA Food Code as recommended by the committee.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

The Oyster Advisory Committee was tasked with developing recommendations to update the 2013 Food Code section 3-603.11 Consumer Advisory, as follows, regarding raw molluscan shellfish that have not been treated by a process sufficient to reduce *Vibrio spp*. to an undetectable level, as detected by the *Vibrio vulnificus* testing method in the most current edition of the U.S. Food and Drug Administration Bacteriological Analytical Manual.

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(4) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.
(B) DISCLOSURE shall include: (1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order)"; or
(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.

(C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states: (1) Regarding the safety of these items, written information is available upon request;
(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; or

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions.

The Oyster Advisory Committee conducted three phone conferences (December 9, 2014, January 13, 2015, and February 26, 2015). A prevailing discussion during the calls was regarding the content contained in the letter from Interstate Shellfish Sanitation Conference (ISSC) dated July 7, 2014 addressed to Kevin Smith, CFSAN and Lori LeMaster, Conference Chair (see attached letter). In the letter, ISSC recommended that CFP take no action on Issue 2014-1-25 as written. This is due to the direct assertion that Council 1 Issue 2014-1-25 would not improve the Food Code consumer advisory effectiveness or reduce illnesses.

At the conclusion of the January 2015 call, the committee members were tasked to compare a side by side comparison of the recommended language from the original Council 1 Issue 2014-I-25 to the current language in section 3-603.11 of 2013 Food Code.

Committee members submitted written feedback that addressed varying positions that either suggested minor revisions to the current language in section 3-603.11 and the importance of having additional employee/consumer education available at establishments that serve raw oysters or took a position that no changes are warranted as the language contained within the committee charge is already covered within 3-603.11. The written feedback was discussed during the February 26, 2015 call. In addition, due to overwhelming discussion that supported a position that no change to the current language in the FDA Food Code is warranted to meet the intent of the charge, committee members asked to vote on whether the issue required further review. As a result of the vote, the committee determined that the current language in 3-603.11 of the 2013 FDA Food Code are sufficient to meet the intent of the charge and no changes to the FDA Food Code Consumer Advisory language are needed at this time.

2. The committee determined that the current language in the section 3-603.11 of the 2013 FDA Food Code is sufficient to meet the intent of the charge and no further discussions were needed.
    a. FUTURE OF THE COMMITTEE: Recommendation that this committee be disbanded and not recreated.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Acknowledgement of the CFP 2014 - 2016 Oyster Advisory Committee Final Report and thanking the committee members for their work.

2. LIST OF SUPPORTING ATTACHMENTS
    a. ISSC Letter dated July 7, 2014
    b. Council 1, 2014-1-025
    c. 3-603.11, 2013 FDA Food Code

COMMITTEE MEMBER ROSTER: See attached CFP Oyster Advisory Committee Roster

Committee Name: Oyster Advisory

Last Name	First Name	Position (Chair / Member)	Constituency	Employer	City	State	Telephone	Email
Staley	Elizabeth	Co-chair	State Regulator	MD Dept of Health and Mental Hygiene	Baltimore	MD	410 767-8407	lisa.staley@maryland.gov
McMahan	Thomas	Co-chair	Retail Food Industry	Meijer	Grandville	MI	616 481-5350	thomas.mcmahan@meijer.com
Marra	Paul	Voting Member	Retail Food Industry	Wegmans Food Markets, Inc.	Rochester	NY	585 328-2550	paul.marra@wegmans.com
Caldwell	Richard	Voting Member	State Regulator	SC DHEC	Columbia	CS	803 896-8995	caldwert@dhec.sc.gov
Henderson	Julie	Voting Member	State Regulator	Virginia Department of Health	Richmond	VA	804 864-7455	julie.henderson@vdh.virginia.gov
Jackson	Keith	Voting Member	Vending and Distribution Food Industry	Performance Food Group	Richmond	VA	804 484-7975	keithjackson@pfgc.com
Nardone	Angela	Voting Member	Food Industry Support	N2N Global	Longwood	FL	407 331-5151	anardone@us.n2nglobal.com
Davis	Douglas	Voting Member	Food Service Industry	Marriott Intenational	Bethesda	MD	301 318-8698	douglas.davis@marriott.com
Nesel	Nancy	Voting Member	Retail Food Industry	Amazon Fresh	San Bernardino	CA	502 641-9314	nesnancy@amazon.com
Ingham	Barbara	Voting Member	Academia	University of Wisconsin	Madison	WI	608 263-7383	bhingham@wisc.edu
Ferko	Francis	Voting Member	Vending and	US Foods	Rosemont	IL	847 232-5896	frank.ferko@usfoods.com
Weddig	Lisa	Voting Member	Processing Food Industry	National Fisheries Institute	McLean	VA	703 752-8886	lweddig@nfi.org
Brown	Robert	Voting Member	Retail Food Industry	Whole Foods Market	Austin	TX	512 944-7405	robert.brown@wholefoods.com
Moore	Michael	Voting Member	State Regulator	MA Food Protection Program	Jamaica Plain	MA	617 983-6754	michaelmoore921b@gmail.com
Adams Hutt	Dr. Catherine	Voting Member	Food Service Industry	National Restaurant Association	Aubrey	TX	630 605-3022	cadams@rdrsol.com
Pilonetti	Therese	Voting Member	State Regulator	Colorado Dept of Public Health & Environment	Denver	CO	303 902-4372	therese.pilonetti@state.co.us
Frappier	Robert	Voting Member	Retail Food Industry	Ahold USA, Inc.	Quincy	MA	617 689-4090	rfrappier@aholdusa.com
Flippens	Bruce	Voting Member	District/Territory Regulator	District of Columbia Department of Health	Washington	DC	202-442-9039	bruce.flippens@dc.gov
Dela Cruz	Hector	Voting Member	Local Regulator	LA County Environmental Health	Van Nuys	CA	818 902-4468	hsdelacruz@gmail.com
Graham	Joe	Voting Member	State Regulator	Washington State Department of Health	Olympia	WA	360 236-3305	joe.graham@doh.wa.gov
Roxanne	Sharp	Voting Member	Local Regulator	Springfield/ Greene County Health Department	Springfield	MO	417 864-1424	rsharp@springfieldmo.gov
Stephens	Martin	Voting Member	District/Territory Regulator	National Park Service / US Public Health Service	Flagstaff	AZ	928 638-7355	martin_stephens@nps.gov
Plunkett	Davie	Voting Member	Consumer	Center for Science in the Public Interest	Washington	DC	202 777-8319	dplunkett@cspinet.org
Ewell	Harold	Non-Voting	Food Industry Support	N2N Global	Longwood	FL	412 418-7018	
Hails	Steve	Non-Voting	Food Industry Support	Sealed Air	Castle Rock	CO	303 910-5571	steve.hails@sealedair.com
Puente	Eric	Non-Voting	Retail Food Industry	Whole Foods Market	Austin	TX	512 415-6617	
Newton	Anna	Non-Voting	Federal Regulatory	CDC			404 639-2839	AENewton@cdc.gov
Cartagena	Mary	Non-Voting	Federal Regulatory	FDA	College Park	MD	240-402-2937	mary.Cartagena@fda.hhs.gov

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(4) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means. Pf

(B) DISCLOSURE shall include: (1) A description of the animal-derived FOODS, such as “oysters on the half shell (raw oysters),” “raw-EGG Caesar salad,” and “hamburgers (can be cooked to order)”; Pf or

(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients. Pf

(C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states: (1) Regarding the safety of these items, written information is available upon request; Pf

(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; Pf or

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions. Pf

Page 405 *Annex 3 – Public Health Reasons/Administrative Guidelines*

3-201.15 Molluscan Shellfish.

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses. Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

Pathogens, such as ***Vibrio vulnificus***, ***Vibrio parahaemolyticus***, ***Vibrio cholerae***, and ***Listeria monocytogenes*** that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependant upon either the month of the year or the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as dinoflagellates. In the U.S., PSP is generally associated with the consumption of molluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, dungeness crabs, tanner crabs, and red rock crabs.

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been identified as a problem in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving Federal and State public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions.[Pf]

ISSC

Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223-1740

July 7, 2014

Kevin Smith
CFSAN
5100 Paint Branch Parkway
College Park, MD 20740

Lori LeMaster
CFP Conference Chair
TN Department of Health
Environmental Health
Andrew Johnson Tower, 4th Floor
Nashville, TN 37234

Dear Kevin Smith and Lori LeMaster

The Interstate Shellfish Sanitation Conference (ISSC) has reviewed the Conference for Food Protection (CFP) action on Issue I-025 and offers the following comments for consideration by the CFP and the USFDA.

The background information included in the Public Health Significance of the Issue is misleading. Recent increases in Vibrio illnesses are not at all related to *Vibrio vulnificus (V.v.)*. The increases are associated with the spread of O4:K12 and O4:Kuntypeable strains of *Vibrio parahaemolyticus (V.p.)*. Historically these strains have caused illnesses in the Pacific northwest, but recently, illnesses have begun to occur on the northeast coast of the United States. The risk of death associated with *V.p.* is overstated. Death from *V.p.* is extremely rare. The rate of illness associated with *V.v,* the species associated with severe illness and death, has not increased and remains stable at approximately 35 illnesses annually.

The ISSC supports the use of consumer advisories and welcomes efforts to improve their effectiveness. However, the ISSC does not agree that the recommended solution of Issue I-025 would improve effectiveness or reduce illnesses.

The ISSC is continuing to focus efforts to better understand the virulent strains of V.p. associated with recent increases in illnesses. The risk of *V.p.* illnesses associated with these virulent strains appears to be a regional problem. There are harvest regions of the U.S. that have not been the source of shellfish associated with increases in reported illnesses. Additionally, the language does not recognize that the risk level is not constant throughout the year. At lower water temperatures the risk of *V.p.* illness greatly diminishes. The proposed language would not be helpful to consumers in identifying raw shellfish that actually pose a higher risk of illness. Additionally, the proposed burden for providing proof of post-harvest processing (PHP) in Section E. is not necessary. Presently the FDA Interstate Certified Shellfish Shippers List (ICSSL) contains the relevant information and shellfish that have been PHP treated are labeled as such. The reference for the analytical method is also inaccurate.

The recommended solution assumes that the relative risk of consumption of raw shellfish is much higher than other animal foods that are consumed raw, undercooked, or not otherwise processed to eliminate pathogens. The recommended solution in the Issue is not the most appropriate way to address relative risk.

Phone 803-788-755 Email issc@issc.org Fax 803-788-7576

The ISSC recommends that the CFP take no action on Issue I-025 as written. The CFP is encouraged to continue to pursue steps to improve the effectiveness of consumer advisory and compliance with existing temperature control, handling and record keeping requirements at retail and food service establishments. The ISSC offers its assistance in any way that you think appropriate.

Sincerely,

Maryanne Guichard
Executive Board Chair

/nsd/ccm

cc: ISSC Executive Board
David McSwane, CFP Executive Director
Paul DiStefano, USFDA

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-005

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 - Ice Maker Equipment Cleaning and Sanitizing Committee (IMC)

Issue you would like the Conference to consider:

The Ice Maker Cleaning and Sanitizing Committee were given 3 key charges:

1. Survey regulatory agencies to determine:

(a) Existing regulatory authority or guidance criteria for ice maker cleaning and sanitizing procedures and frequency.

(b) Determine extent of critical and non-critical inspection violations.

2. Review ice maker manufacturers/owner's manuals to establish their recommended cleaning and sanitizing processing and frequencies and its rationale.

3. Report back to the 2016 biennial meeting with recommendations

Public Health Significance:

Visible ice machine mold and soil appears to be a prevalent issue in commercial ice machines and these biofilms form when cleaning and sanitizing the machine is not performed at a specific frequency to preclude such and/or when the procedure and chemicals used are insufficient to accomplish the intended purpose of preventing microbial growth.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the 2014 - 2016 Ice Maker Equipment Cleaning and Sanitizing Committee Final Report,
2. Thanking the Committee members for their work and completing their charges, and
3. Disbanding the Committee.

Submitter Information:

Name: Peter Voss
Organization: Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address: Ecolab655 Lone Oak Drive
City/State/Zip: Eagan, MN 55121
Telephone: 651-587-6464
E-mail: peter.voss@ecolab.com

Content Documents:

- "Report - Ice Maker Equipment Cleaning and Sanitizing Committee"
- "2014-2016 Ice Maker Equipment Cleaning and Sanitizing Committee Roster"

Supporting Attachments:

- "Attachment A: Ice Machine Manufacturers"

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: Ice Maker Equipment Cleaning and Sanitizing Committee (IMC)

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council I

DATE OF REPORT: January 10, 2016

SUBMITTED BY: Peter Voss & Tim Tewksbary - Co-chairs of the Ice Maker Equipment Cleaning and Sanitizing Committee

COMMITTEE CHARGE(s): Assigned by Issue 2014 I-029

1. Survey regulatory agencies to determine:
    a. Existing regulatory authority or guidance criteria for ice maker cleaning and sanitizing procedures and frequency.
    b. Determine extent of critical and non-critical inspection violations.
2. Review ice maker manufacturers/owner's manuals to establish their recommended cleaning and sanitizing processing and frequencies and its rationale.
3. Report back to the 2016 biennial meeting with recommendations.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The committee formed two (2) working groups to focus on the regulatory and equipment components of the charge.

PROGRESS ON OVERALL COMMITTEE ACTIVITIES:

REGULATORY ACTIVITIES

1. The ice maker regulatory working group prepared a letter and survey which were sent via email to the CFP State Delegates from the 2014 biennial meeting requesting the following information be provided to the committee by the State or inspecting agency (local health districts).
    a. Do your adopted rules relating to ice machine cleaning and/or sanitizing frequency or procedures vary in any significant way from the 2013 FDA Food Code?
    b. Does your agency have any guidance documents for inspectors and/or operators relating to commercial ice makers and/or ancillary ice handling equipment and their cleaning and sanitizing frequency and/or clean in place procedures?
    c. Does your agency have a searchable database of its inspection reports?
    d. If your agency does have a searchable database, please compile a report of your inspection records that will elucidate for us the number of violations associated with contaminated ice machines and related systems, and establish the number of critical to non-critical violations per total number of inspection records.
2. Seventy nine (79) responses were received:
    a. 14 States.
    b. 1 Territory.
    c. 57 Local Health Districts.
    d. 7 No name given.
3. After reviewing the responses submitted:
    a. 98 percent use rules based on the current 2013 FDA Food Code.
    b. 96 percent currently do not have guidance available on the cleaning of ice machines.

c. 62 percent do not have a searchable database because they use paper forms.
d. Only 5 jurisdictions were able to provide inspection records associated with ice machines.

4. The committee reviewed the 5 sets of data provided by the regulatory agencies and came up with the following summary:
    a. 3,763 violations were identified in 2014 related to mold or soil accumulation in the ice bin, bin walls, ice chute, door, and/or gaskets.
    b. 1,427 violations were identified in 2014 related to the ice scoop, personal items being stored in the ice bin, and chemicals being stored over ice.
    c. There were no violations identified regarding the internal components of the ice maker.
5. Based on the findings described, it seems that regulatory agencies are only inspecting areas which could be seen at a quick glance with no ice maker disassembly. This could be attributed to both the design of the equipment and absence of tools needed to open ice makers in the field.

EQUIPMENT ACTIVITIES

1. The ice maker equipment working group generated a list of 33 ice makers Original Equipment Manufacturer (OEMs), and ice vending manufacturers with contact information. A letter was sent via email to the OEMs requesting the following information:
    a. Specific ice machine cleaning and sanitizing procedures with recommended frequency as well as procedures for any ice storage bins and dispensers that may be part of a comprehensive ice delivery system.
    b. Field study and laboratory test data supporting specific recommended ice machine cleaning and sanitizing procedures.
    c. Additional equipment recommended such as water filters etc. that may impact overall equipment cleanliness and sanitation.
2. Manitowoc, Kold Draft and Vogt were the only OEMs that responded and provided limited information that is readily available from their websites. The ice vending manufacturers Arizona Water and Polarmatic responded that they utilize “off the shelf” ice maker equipment and referred us to the OEM’s recommended cleaning and sanitizing procedures. There were no responses or information available online from ice vending machine manufacturers for cleaning/sanitizing procedures or frequency for their comprehensive ice delivery systems.
3. The equipment work group reviewed available online OEM cleaning and sanitizing procedures to determine if there are common generally recommended practices. There was a general lack of uniformity regarding both cleaning/sanitization frequency and type of chemicals to be used. Cleaning frequencies ranged from quarterly, to annually, to “when dirty”. Sanitizing with chlorine and quaternary ammonium compounds (quats) were both suggested without addressing water temperature, while the 2013 Food Code (4-501.114) limits the use of quaternary ammonium compounds at temperatures above 24^{o}C (75^{o}F). Further, many OEMs offer limited cleaning instructions and in some cases they do not indicate that the cleaning methods described must be followed by a sanitizing step. Finally, no test data or field studies to support the recommended cleaning and sanitizing procedures, frequencies and chemicals utilized were provided.
4. Many internal surfaces of commercial ice machines are food contact surfaces and are subject to the ANSI sanitation standards applicable to food equipment. Current ice machine designs which passed the existing performance certification standards are not always accessible for cleaning and inspection and may require tools that are not commonly available to the cleaning personnel or inspectors. Tools listed in the food code (4-202.11) such as “screwdrivers, pliers, open-end wrenches, and Allen wrenches” may be available to maintenance, which is not always at the site during times when the cleaning and sanitization is performed, or when the equipment is inspected. The committee could not find research regarding the possibility of the growth of pathogenic microorganisms in the internal, inaccessible parts of ice machines.

RECOMMENDATIONS FOR CONSIDERATION BY COUNCIL:

1. The Conference for Food Protection request academic research institutions or interested parties to consider conducting research with the objective being a risk assessment which may also necessitate testing and data generation that:
    a. Characterizes the type of microbial contamination and the location of areas of concern within commercial ANSI NSF listed ice machines and factors contributing to their growth rate. Research is needed regarding the surfaces of the interior of ice machines which includes but not limited to ice chutes, cubers, doors, tubing and pumps to determine if there are pathogens of food safety and public health concern.
    b. Establishes data driven cleaning and sanitizing frequency
    c. Develops test methods to enable field verification that internal food contact surfaces are clean and sanitary.
2. In light of the numerous reported soil and mold violations in the accessible food contact surfaces of ice makers and delivery systems, primarily ice bins, chutes and doors, Conference for Food Protection requests FDA change the food code section 4-602.11 Equipment Food Contact Surfaces and Equipment-Frequency (E) (4) language. Proposed additions to existing language are underlined: *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:*
    a. *At a frequency specified by the manufacturer or more frequently, if necessary, to preclude accumulation of soil or mold, or*
    b. *Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold*
3. The Conference for Food Protection request FDA update the Food Establishment marking instructions in Annex 7, Guide 3B under items 16 and 47 to specifically include ice making components that may be inaccessible in addition to ice storage components. Proposed additions to existing language are underlined:
    a. **16. Food-contact surfaces: cleaned and sanitized** - *This item must be marked OUT of compliance when manual and/or mechanical methods of cleaning and sanitizing food-contact surfaces of equipment and utensils are ineffective**;** or if one continuous-use piece of equipment such as an ice machine or one multiuse piece of equipment such as a slicer or can opener is visibly soiled and being used at the time of the inspection.*
    b. **47. Food and non-food-contact surfaces cleanable, properly designed, constructed and used -** *Equipment and utensils including ice machines must be properly designed and constructed, and in good repair to enable ready access to the internal food contact surfaces for cleaning, sanitization and inspection. Proper installation and location of equipment in the food establishment are important factors to consider for ease of cleaning in preventing accumulation of debris and attractants for insects and rodents. The components in a vending machine must be properly designed to facilitate cleaning and protect food products (e.g. equipped with automatic shutoff, etc.) from potential contamination. Equipment must be properly used and in proper adjustment, such as calibrated food thermometers.*
4. The Conference for Food Protection draft a letter to NSF International for the creation of working group to review the existing NSF/ANSI 12 Standard for ice machine cleaning and sanitizing certification with participation of academia and organizations such as AOAC, ASTM with peer review process elements to ensure:
    a. Food contact surfaces are readily accessible for inspection and effective cleaning and sanitization for new equipment.

b. That the performance certification tests methods used for cleanability and sanitization of new equipment food contact surfaces has correlation to cleanability of those same surfaces when in use.

5. The Conference for Food Protection disband the Ice Maker Cleaning and Sanitizing Committee and form a new committee with to address the broader issue of design, cleaning, sanitizing and inspection of food process equipment with inaccessible food contact surfaces. The specific charges for the new committee are addressed in Issue Submittal 6 below.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE

1. Acknowledge the 2014-2016 Ice Maker Cleaning and Sanitizing Committee final report, thank the committee members for their work, and disband the committee.
2. Request Research on Microbial Contamination in Ice Machines
    a. Research is needed to identify the type of microbial growth and location(s) of concern within ANSI NSF listed ice machines. This data will aid in the research to establish cleaning and sanitizing frequencies along with field verification test methods.
    b. The Conference recommends the Conference Chair submit a request to academic research institutions or interested parties to submit grant funding proposals for conducting research with the objective being a risk assessment which may also necessitate testing and data generation that:
        i. Characterizes the type of microbial contamination and the location of areas of concern within commercial ANSI NSF listed ice machines and factors contributing to their growth rate. Research is needed regarding the surfaces of the interior of the ice machine which includes but not limited to ice chutes, cubers, doors, tubing and pumps to determine if there are pathogens of food safety and public health concern.
        ii. Establish data driven cleaning and sanitizing frequency
        iii. Develops test methods to enable field verification that internal food contact surfaces are clean and sanitary.
3. Amend FDA Food Code subparagraph 4-602.11 (E) (4): Equipment Cleaning Frequency
    a. Subparagraph 4-602.11 (E) (4) of the 2013 FDA Food Code states that Equipment should be cleaned at a frequency specified by the manufacturer. Based upon the number of cleaning violations noted in our survey and the lack of guidance provided by manufacturers regarding cleaning frequencies we propose that simply cleaning ice machines based on a manufacturer's recommendations may be inadequate and that it should be combined with reviewing whether the equipment is clean or not.
    b. The Conference for Food Protection recommends that FDA amend the 2013 Food Code subparagraph on Equipment Food Contact Surfaces and Equipment-Frequency, 4-602.11 (E) (4). Proposed additions to existing language are underlined:
    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:
        i. *At a frequency specified by the manufacturer, <u>or more frequently if necessary, to preclude accumulation of soil or mold</u>, or*
        ii. *Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold*
4. Amend FDA Food Code Annex 7, Guide 3B: Food Establishment Marking Instructions
    a. The Ice Maker Equipment Cleaning and Sanitizing committee surveyed the State Delegates of The Conference for Food Protection with regard to the inspection process. The survey results indicated 3,763 violations related to mold or soil accumulation in the visible areas of the ice machines in 2014; however, there were no violations identified

regarding internal components of the ice maker. A specific reminder for the inspection of ice machines including the not readily accessible areas can be included in the Food Establishment marking instructions.

b. The Conference recommends that FDA update the Food Establishment marking instructions in Annex 7 of the 2013 FDA Food Code, Guide 3B under items 16 and 47 to specifically include references to ice making and storage components that may not be readily accessible. Proposed additions to existing language are underlined.

i. **16. Food-contact surfaces: cleaned and sanitized**: *This item must be marked OUT of compliance when manual and/or mechanical methods of cleaning and sanitizing food-contact surfaces of equipment and utensils are ineffective; or if one continuous-use piece of equipment such as an ice machine or one multiuse piece of equipment such as a slicer or can opener is visibly soiled and being used at the time of the inspection.*

ii. **47. Food and non-food-contact surfaces cleanable, properly designed, constructed and used.** *Equipment and utensils including ice machines must be properly designed and constructed, and in good repair to enable ready access to the internal food contact surfaces for cleaning, sanitization and inspection. Proper installation and location of equipment in the food establishment are important factors to consider for ease of cleaning in preventing accumulation of debris and attractants for insects and rodents. The components in a vending machine must be properly designed to facilitate cleaning and protect food products (e.g. equipped with automatic shutoff, etc.) from potential contamination. Equipment must be properly used and in proper adjustment, such as calibrated food thermometers…*

5. Working Group Formation to Update NSF/ANSI 12 Automatic Ice Making Equipment

a. The Ice Maker Equipment Cleaning and Sanitizing committee surveyed Ice Maker Original Equipment Manufacturers and Ice Vending manufacturers as to their specific cleaning and sanitizing procedures and any field study and laboratory test data supporting specific recommended cleaning and sanitizing procedures. The committee found that there was a general lack of uniformity and no test data available to validate the cleaning/sanitizing procedures. .

b. The Committee recommends the Conference for Food Protection send a letter to NSF International requesting the creation of a working group to review and update the existing NSF/ANSI 12 Automatic Ice Making Equipment Standard for cleaning and sanitizing certification with participation of academia and organizations such as Association of Official Analytical Chemists (AOAC), American Society for Testing and Materials (ASTM) with peer review process elements to ensure:

i. Food contact surfaces are readily accessible for inspection and effective cleaning and sanitation for new equipment.

ii. That the performance certification test methods used for cleanability and sanitation of new equipment food contact surfaces has correlation to cleanability of those same surfaces when in use

6. The Conference for Food Protection CIP Committee Formation

a. The Ice Machine Cleaning and Sanitizing committee uncovered a significant discrepancy relating to cleanability of food contact surfaces. The FDA Food Code requires FOOD EQUIPMENT with inaccessible food contact surfaces that depend upon CIP processes for effective cleaning and sanitation to be designed to enable inspection access points for verification purposes, so it cannot be readily determined when cleaning is required. In addition, it is clear from a review of manufacturer's installation and service instructions that there is a lack scientific data for validation of the limited cleaning and sanitizing instructions that are provided.

b. The Conference for Food Protection recommends formation of a Clean in Place (CIP) Committee to carry on the work begun by the Ice Machine committee, but with a broader focus to include all food equipment known to have designs that depend upon CIP processes for safety and do not allow for easy inspection, cleaning and sanitizing access of its food contact surfaces. The committee charges are:
    i. Review ANSI sanitation standards for clean in place processes (CIP).
    ii. Develop specific recommendations for:
        1. Minimum criteria for CIP systems, including suggested revisions to the FDA Food Code.
        2. A mechanism for on-going liaison with ANSI sanitation standards development organizations to reduce likelihood of future gaps in our national food safety, security and control programs.
    iii. Report finding and recommendations to the 2016 biennial meeting of the Conference for Food Protection.

Attachments – Content Documents:

1. Committee Report
2. Committee Roster

Committee Name: Ice Maker Equipment Cleaning and Sanitizing Committee

Last Name	First Name	(Chair/Member/ Non-voting)	Constituency	Employer	City	State	Telephone	Email
Andrews	Christine	Member	Food Industry Support	NSF International	Ann Arbor	MI	(734) 306-0232	candrews@nsf.org
Arbizu	Thomas	Member	State Regulator	TX Dept of State Health Services	Austin	TX	(512) 834-6770	tom.arbizu@dshs.state.tx.us
Bacon	Brenda	Member	Retail Food Industry	Harris Teeter	Matthews	NC	(704) 844-4443	bbacon@harristeeter.com
Buswell	Cheri	Member	Food Service Industry	International Dairy Queen	Minneapolis	MN	(952) 830-0224	cheri.buswell@idq.com
Cavaliero	Kelli	Member	Food Service Industry	Walt Disney Parks and Resorts	Anaheim	CA	(714) 781-4219	kelli.cavaliero@disney.com
Daugherty	Rick	Member	Vending and Distribution Food Industry	National Automated Merchandising Association	Chicago	IL	(630) 921-8650	publichealth100@gmail.com
Fletcher	Jessica	Member	Local Regulator	Mohegan Tribal Health Department	Uncasville	CT	(860) 862-6156	jfletcher@moheganmail.com
Hodge	Lori	Member	Retail Food Industry	BiLo Holdings	Baldwin	FL	(904) 370-8721	lorihodge@biloholdings.com
Johnson	Thomas	Member	Food Industry Support	JDP, Inc.	Mendota Heights	MN	(651) 203-2462	tomj@jdpinc.com
Martin	Charles	Member	Retail Food Industry	Stop & Shop Supermarkets	Purchase	NY	(203) 246-0346	charles.martin@stopandshop.com
McEwen	Jane	Member	Retail Food Industry	International Packaged Ice Association	Tampa	FL	(813) 258-1690	jane@packagedice.com
Morgan	Lisa	Member	Local Regulator	Chatham County Public Health Department	Pittsboro	NC	(919) 545-8309	lisa.morgan@chathamnc.org
Moris	Steven	Member	State Regulator	Kansas Department of Agriculture	Topeka	KS	785-564-6767	Steve.moris@kda.ks.gov
Starobin	Anna	Non-voting	Food Industry Support	Ecolab / Kay Chemical	Greensboro	NC	(336)931-2185	Anna.Starobin@ecolab.com
Sudler	Robert	Member	Regulatory	FDA	College Park	MD	240-402-1943	Robert.Sudler@fda.hhs.gov
Tewksbary	Timothy	Co-Chair	State Regulator	Ohio Department of Agriculture	Reynoldsburg	OH	740-260-9012, 614-867-0056	ttewksbary@agri.ohio.gov
Vergne	Sue	Member	Food Service Industry	Jack in the Box Inc.	San Diego	CA	(858) 571-2171	sue.vergne@jackinthebox.com
Voss	Peter	Co-Chair	Food Industry Support	Ecolab	Eagan	MN	(651) 795-5981	peter.voss@ecolab.com
Yamnik	Dale	Member	Food Service Industry	Yum! Brands, Inc.	Saint Cloud	FL	(407) 593-6181	dale.yamnik@yum.com

Attachment A: Ice Machine Manufacturers

Ice Vending Machine Manufacturers	
Ice House of America	www.icehouseamerica.com
Kooler Ice	www.koolerice.com
Watermill Express	www.watermillexpress.com
Mr. Zippy's Ice and Water	www.riderwash.com
Just Ice	www.just-icellc.com; www.icevendingmachine.net
Polar Station Ice and Water	www.polariceandwater.com
The Ice Cube	www.the-ice-cube.com
Ice Qik	www.icemachinesintl.com
Polarmatic	www.polarmatic.com
Bag of Ice	www.bagofice.com
Akoona Ice	www.akoona.com
Arizona Water and Ice	www.azwatervendors.com
Self Service ice Company	www.self-service-ice-company.it
Texas Snowman	www.txsnowman.com
China vending machine	http://www.globalsources.com/si/AS/Pukui-Hongkong/6008827474514/pdtl/Ice-Vending-Machine/1050711453.htm
Quick Ice USA	www.quickiceusa.com
Fast Ice	www.fastice.com.au
Pure Ice and Water	http://purewater4health.com
Ice Man Ice House	http://bestpriceice.com
The Ice Chest	http://theicechest.net
Ice Machine Manufacturers	
Ice Meister	http://icemeisterusa.com
Hoshizaki	www.hoshizakiamerica.com
Manitowac	www.manitowo**ice**.com
Scotsman	www.scotsman-**ice**.com
Kold Draft	www.kold-draft.com
Ice O Matic	www.**ice**omatic.com
Follett	www.follett**ice**.com
Arctic-Temp	http://holiday-ice.com
A&V	http://www.av-refrigeration.com/en/industrial-ice-machines.html
Vogt Ice	www.vogtice.com
Morris & Associates	www.morris-associates.com
Ice Machine	www.usicemachine.com
Cornelius	www.cornelius.com

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-006

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

IMC 2 – Request Research on Microbial Contamination in Ice Machines

Issue you would like the Conference to consider:

The Ice Maker Equipment Cleaning and Sanitizing committee surveyed Ice Maker Original Equipment Manufacturers and Ice Vending Manufacturers (Attachment A; attached to Issue titled: Report - Ice Maker Equipment Cleaning and Sanitizing Committee) as to their specific cleaning and sanitizing procedures and frequency. In addition, information regarding field study and laboratory test data supporting the specific recommended cleaning and sanitizing procedure and frequency was requested. The committee received a very limited response. The limited response coupled with online research found that there was a general lack of uniformity and no test data available to validate the cleaning/sanitizing procedures, types of chemicals used and frequencies. The committee also surveyed regulatory agencies (detailed in Committee Report) and asked that a database be provided if available of the inspection records of ice machines. Five (5) jurisdictions provided data sets that identified almost 4,000 violations related to mold or soil accumulation in the ice bin and walls. There were no inspection notations documenting that the internal inaccessible parts of the ice machine were inspected. Also, the committee could not find research regarding the possibility of the growth of pathogenic microorganisms in the internal parts of an ice machine. Thus, research is needed to identify the type of microbial growth and location(s) of concern within the American National Standards Institute (ANSI) / National Sanitation Foundation (NSF) listed ice machines. This data will aid in establishing adequate cleaning and sanitizing procedures and frequencies for ice making equipment as well as provide field verification test methods.

Public Health Significance:

When cleaning and sanitizing of ice machines is not performed following procedures specified by the Food Code, microbial and soil accumulation appears to be a common issue in commercial ice machines. Most of the microbiological data available does not include foodborne pathogens and is limited to total bacteria, yeasts, molds and coliform counts. Ice contamination may occur from various sources including but not limited to the

ice machine, water or ice handling practices. The food contact surfaces within the ice machine could be potential areas for pathogen growth and need to be analyzed as to the types of pathogens present and their food safety impact on the public.

Recommended Solution: The Conference recommends...:

that the Conference Chair submit a request to academic research institutions or interested parties to submit grant funding proposals for conducting research with the objective being a risk assessment which may also necessitate testing and data generation that:

1. Characterizes the type of microbial contamination and the location of areas of concern within commercial American National Standards Institute (ANSI) and National Sanitation Foundation (NSF) listed ice machines and factors contributing to their growth rate. Research is needed regarding the surfaces of the interior of the ice machine which includes but is not limited to ice chutes, cubers, doors, tubing and pumps to determine if there are pathogens of food safety and public health concern.
2. Establishes data driven cleaning and sanitizing frequency.
3. Develops test methods to enable field verification that internal food contact surfaces are clean and sanitary.

Submitter Information 1:

Name:	Peter Voss
Organization:	Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address:	Ecolab655 Lone Oak Drive
City/State/Zip:	Eagan, MN 55121
Telephone:	6517955981
E-mail:	peter.voss@ecolab.com

Submitter Information 2:

Name:	Tim Tewksbary
Organization:	Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address:	Ohio Department of Agriculture8995 East Main Street
City/State/Zip:	Reynoldsburg, OH 43068
Telephone:	614-728-6250
E-mail:	timothy.tewksbary@agri.ohio.gov

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-007

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

IMC 3 – Amend Food Code 4-602.11 (E) (4) Equipment Cleaning Frequency

Issue you would like the Conference to consider:

One of the charges of the Ice Machine Equipment Cleaning and Sanitizing Committee was to survey regulatory agencies to determine the 'extent of critical and non-critical inspection violations.'

The committee reviewed 5 sets of data provided by regulatory agencies and came up with the following summary:

- 3,763 violations were identified in 2014 related to mold or soil accumulation in the ice bin, bin walls, ice chute, door, and/or gaskets.

Additionally, the Committee was charged to 'review ice maker manufacturers/owner's manuals to establish their recommended cleaning and sanitizing processing and frequencies and its rationale.'

The equipment work group reviewed available online original equipment manufacturer (OEM) cleaning and sanitizing procedures to determine if there are common generally recommended practices. There was a general lack of uniformity regarding both cleaning/sanitation frequency and type of chemicals to be used. Cleaning frequencies ranged from quarterly, to annually, to "when dirty".

Subparagraph 4-602.11 (E) (4) of the 2013 FDA Food Code states that equipment should be cleaned at a frequency specified by the manufacturer. Based upon the number of cleaning violations noted in our survey and the lack of guidance provided by manufacturers regarding cleaning frequencies, we propose that simply cleaning ice machines based on a manufacturer's recommendations may be inadequate and that it should be combined with reviewing whether the equipment is clean or not.

Public Health Significance:

Visible ice machine mold and soil appears to be a prevalent issue in commercial ice machines and these biofilms form when cleaning and sanitizing the machine is not

performed at a specific frequency to preclude such and/or when the procedure and chemicals used are insufficient to accomplish the intended purpose of preventing microbial growth.

If these soils are not removed in a timely manner they may result in the formation of biofilms which could harbor pathogenic microorganisms such as *Listeria monocytogenes.*

Following the manufacturer's recommended cleaning schedule alone may be inadequate to prevent the growth of these biofilms. Therefore, even if a food establishment is cleaning the ice machine at the manufacturer's recommended cleaning frequency and the ice machine is found to be dirty, it should be cleaned at that time, even if it is prior to the next scheduled cleaning date.

Recommended Solution: The Conference recommends...:

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

Subparagraph on Equipment Food Contact Surfaces and Equipment-Frequency, 4-602.11 (E) (4).

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:

1. At a frequency specified by the manufacturer, <u>or more frequently if necessary, to preclude accumulation of soil or mold</u>, or
2. Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold

Submitter Information 1:

Name:	Peter Voss
Organization:	Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address:	Ecolab655 Lone Oak Drive
City/State/Zip:	Eagan, MN 55121
Telephone:	6515876464
E-mail:	peter.voss@ecolab.com

Submitter Information 2:

Name:	Tim Tewksbary
Organization:	Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address:	Ohio Department of Agriculture8995 East Main Street
City/State/Zip:	Reynoldsburg, OH 43068
Telephone:	614-728-6250
E-mail:	Timothy.tewksbary@agri.ohio.gov

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-008

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

IMC 4 – Amend Annex 7, Guide 3B Food Establishment Marking Instructions

Issue you would like the Conference to consider:

The Ice Maker Equipment Cleaning and Sanitizing committee surveyed the State Delegates of The Conference for Food Protection with regard to the inspection process: "Do your adopted rules relating to ice machine cleaning and/or sanitizing frequency or procedures vary in any significant way from the 2013 FDA Food Code?" and "Does your agency have any guidance documents for inspectors and/or operators relating to commercial ice makers and/or ancillary ice handling equipment and their cleaning and sanitizing frequency and/or clean in place procedures?" Ninety-eight percent use rules based off the current FDA Food Code. Ninety-six percent do not have guidance available on the cleaning of ice machines. Even though the survey results indicated 3,763 violations related to mold or soil accumulation in the visible areas of the ice machines in 2014, there were no violations identified regarding internal components of the ice maker. A specific reminder for the inspection of ice machines including the not readily accessible areas can be included in the Food Establishment marking instructions.

Public Health Significance:

When cleaning and sanitizing of ice machines is not performed following procedures specified by the Food Code, microbial and soil accumulation appears to be a common issue in commercial ice machines. Most of the microbiological data available does not include foodborne pathogens and is limited to total bacteria, yeasts, molds and coliform counts. Ice contamination may occur from various sources including but not limited to the ice machine, water or ice handling practices. The food contact surfaces within the ice machine could be potential areas for pathogen growth. Including a specific reference to ice machines in the Food Establishment marking instructions will reinforce the need for inspectors to evaluate ice machine cleanliness and sanitization on a regular basis.

Recommended Solution: The Conference recommends...:

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

Update the Food Establishment marking instructions in Annex 7, Guide 3B under items 16 and 47 to specifically include references to ice making and storage components that may not be readily accessible.

16. Food-contact surfaces: cleaned and sanitized

...This item must be marked OUT of compliance when manual and/or mechanical methods of cleaning and sanitizing food-contact surfaces of equipment and utensils are ineffective; or if one continuous-use piece of equipment such as an ice machine or one multiuse piece of equipment such as a slicer or can opener is visibly soiled and being used at the time of the inspection.

47. Food and non-food-contact surfaces cleanable, properly designed, constructed and used

Equipment and utensils including ice machines must be properly designed and constructed, and in good repair to enable ready access to the internal food contact surfaces for cleaning, sanitization and inspection. Proper installation and location of equipment in the food establishment are important factors to consider for ease of cleaning in preventing accumulation of debris and attractants for insects and rodents. The components in a vending machine must be properly designed to facilitate cleaning and protect food products (e.g. equipped with automatic shutoff, etc.) from potential contamination. Equipment must be properly used and in proper adjustment, such as calibrated food thermometers....

Submitter Information 1:

Name:	Peter Voss
Organization:	Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address:	Ecolab655 Lone Oak Drive
City/State/Zip:	Eagan, MN 55121
Telephone:	6517955981
E-mail:	peter.voss@ecolab.com

Submitter Information 2:

Name:	Tim Tewksbary
Organization:	Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address:	Ohio Department of Agriculture8995 East Main Street
City/State/Zip:	Reynoldsburg, OH 43068
Telephone:	6147286250
E-mail:	Timothy.tewksbary@agri.ohio.gov

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-009

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

IMC 5 - Working Group Formation to Update NSF/ANSI 12

Issue you would like the Conference to consider:

American National Standards Institute (ANSI) / National Sanitation Foundation (NSF) Standard 12: Automatic Ice Making Equipment sets forth requirements that include specifications regarding the ice machine equipment design, construction and materials of composition. Additionally, the Standard documents the methods and criteria required to show effectiveness of cleaning and sanitizing of the food zone surfaces. "The NSF Mark on a product gives consumers and retailers assurance that the product has been tested and meets the requirements of the Standard".

This Standard is designed to evaluate new equipment and is not aligned to manufacturer cleaning frequency recommendations. The test protocol does not take into account the prolonged use of the equipment in commercial applications and the impact to cleanability.

Based on the 2013 FDA Food Code Section 4-602.11 (E) (4), ice making equipment should be cleaned "at frequency specified by the manufacturer". Survey data collected during the CFP Ice Maker 2014-2016 Committee work suggests that the manufacturer's recommended cleaning frequencies are not supported by research data.

Both the Food Code and NSF/ANSI 12 acknowledge that accessibility to internal food contact surfaces is critical for proper cleaning, sanitizing and inspection. However, it is common that some of the areas of the equipment are difficult to reach without a complicated disassembly process, which limits proper cleaning, sanitization and inspection of the equipment.

Public Health Significance:

Visible ice machine mold and soil accumulation appears to be a prevalent issue in commercial ice machines and may be from a variety of factors:

- Cleaning and sanitizing may not be performed at a specific frequency to preclude accumulation of soil or mold.

- The procedure and chemicals used may be insufficient to accomplish the intended purpose of preventing microbial growth.
- The machine design may be such that internal food contact surfaces are not readily accessible for cleaning, sanitizing and routine inspection.

Many internal surfaces of commercial ice machines are food contact surfaces and are subject to the ANSI sanitation standards applicable to food equipment. Current ice machine designs which passed the existing performance certification standards are not always accessible for cleaning and inspection and may require tools that are not commonly available to the cleaning personnel or inspectors. Tools listed in the Food Code (Section 4-202.11) such as "screwdrivers, pliers, open-end wrenches, and Allen wrenches" may be available to maintenance, which is not always at the site during times when the cleaning and sanitization is performed, or when the equipment is inspected.

Recommended Solution: The Conference recommends...:

that a letter be sent to NSF International recommending the creation of a working group to review and update the existing American National Standards Institute (ANSI) / National Sanitation Foundation (NSF) 12 Automatic Ice Making Equipment Standard for cleaning and sanitizing certification with participation from academia and organizations such as the Association of Official Analytical Communities (AOAC) and the American Society of Testing and Materials (ASTM) with peer review process elements to ensure:

- Food contact surfaces of ice making equipment are readily accessible for inspection and effective cleaning and sanitization.
- That the performance certification test methods used for cleanability and sanitization of new equipment's food contact surfaces has correlation to cleanability and sanitization of those same surfaces when in continuous use in the work place.

Submitter Information 1:

Name:	Peter Voss
Organization:	Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address:	Ecolab655 Lone Oak Drive
City/State/Zip:	Eagan, MN 55121
Telephone:	6517955981
E-mail:	peter.voss@ecolab.com

Submitter Information 2:

Name:	Tim Tewksbary
Organization:	Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address:	Ohio Department of Agriculture8995 East Main Street
City/State/Zip:	Reynoldsburg, OH 43068
Telephone:	6147286250
E-mail:	Timothy.tewksbary@agri.ohio.gov

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-010

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

IMC 6 - Clean in Place (CIP) Committee Formation

Issue you would like the Conference to consider:

The Ice Machine Equipment Cleaning and Sanitizing Committee conducted significant research on the issue of ice machine cleanability. Though ice does not comprise a temperature for safety food, it is identified in the 2013 FDA Food Code as a food. It was generally acknowledged by the committee that internal waterlines and other wetted components in American National Standards Institute (ANSI) / National Sanitation Foundation (NSF) 12 listed ice machines cannot be easily inspected, cleaned and sanitized in place. During our review, it came to light that a similar circumstance exists for other food service equipment, such as dispensing freezers as are commonly used for soft serve ice-cream and yogurt. Because equipment other than ice machines was beyond the scope of our committee's charges, it was decided to defer any discussion beyond ice machines back to the CFP for its possible future deliberation.

Annex 3 of the Food Code contains the public health rationale for cleanability of food contact surfaces. It states; "*Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms"*. Section 4-202-11 CLEANABILITY of Food Contact surfaces states (paragraph (A) (5)) that reusable food contact surfaces shall be:*". . .* accessible for cleaning and inspection by one of the following methods, (a) without being disassembled *Pf,* or, (b) by disassembling without the use of tools *Pf,* or, (c) by easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open end wrenches, and Allen wrenches *Pf."*

Internal water line surfaces in ice machines are not accessible even with "commonly available" tools. Cleaning and sanitizing of food contact surfaces is the function of clean in place systems (CIP). Ice machine manufacturer's equipment manuals make reference to cleaning instructions that (essentially) comprise clean-in-place instructions. FDA FOOD CODE Section 4-202.12 for CIP Equipment states: (A) CIP EQUIPMENT shall meet the characteristics specified under § 4-202.11 and shall be designed and constructed so that: (1) Cleaning and SANITIZING solutions circulate throughout a fixed system and contact all

interior FOOD-CONTACT SURFACES [Pf], and (2) The system is self-draining or capable of being completely drained of cleaning and SANITIZING solutions; and (3) CIP EQUIPMENT that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior FOOD-CONTACT SURFACES throughout the fixed system are being effectively cleaned.

Neither Ice machines nor dispensing freezers have such inspection access ports. FDA Food Code chapter for ACCEPTABILITY; 4-205.10 states *"FOOD EQUIPMENT that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter."*

Note that the preceding ACCEPTABILITY "exemption" for equipment having an ANSI sanitation listing does not relieve FOOD EQUIPMENT from the compliance requirements found in Parts 4-6 and 4-7 of this chapter, which is where criteria for the *OBJECTIVE, FREQUENCY* and *METHODS* for cleaning food contact surfaces are found.

The FDA Food Code requires FOOD EQUIPMENT with inaccessible food contact surfaces that depend upon CIP processes for effective cleaning and sanitation to be designed to enable inspection access points for verification purposes, so that it can be readily determined when cleaning is required. Further the ANSI sanitation standards for performance certification of FOOD EQUIPMENT that depends upon CIP processes lack minimum criteria for cleaning and sanitizing frequency. Lastly, it is clear from the Ice Maker Committee's survey of Original Equipment Manufacturer (OEMs), the recommended cleaning and sanitizing procedures are not based on scientific data.

Public Health Significance:

Many of the manufacturer's equipment manuals reviewed stated that ice machines should be cleaned "as needed". With internal food contact surfaces that cannot be inspected, a reasonable determination for when cleaning and sanitizing is needed cannot be made. The prevention of microbial growth in the form of biofilms, milk-stone and other soils on FOOD EQUIPMENT food contact surfaces of this type is not clearly defined by criteria based on scientific test data and presents a hazard to consumers.

Furthermore, current ANSI sanitation standards test brand new equipment only, before food contact surfaces become worn. There is no test to ensure that the design of ANSI sanitation listed equipment enables easy inspection, cleaning and sanitization of its food contact surfaces across the expected service life of the equipment. None of the ANSI sanitation standards provide any criteria for cleaning frequency or processes. Rather, this subject is left up to manufacturers to provide in their owners manuals and instructions for use.

Recommended Solution: The Conference recommends...:

a Clean in Place (CIP) Committee be formed to expand on the work begun by the 2014 - 2016 Ice Maker Equipment Cleaning and Sanitizing Committee, but with a broader focus to include all food equipment known to have designs that depend upon CIP processes for safety yet do not allow for easy inspection, cleaning and sanitizing access of its food contact surfaces. The charges are:

1. Review ANSI sanitation standards for clean in place processes (CIP).

2. Report back to the CFP at the 2018 Biennial Meeting with specific recommendations for:

(a) Minimum criteria for CIP systems including suggested revisions to the FDA Food Code.

(b) A mechanism for on-going liaison with ANSI sanitation standards development organizations to reduce likelihood of future gaps in our national food safety, security and control programs.

Submitter Information 1:

Name:	Peter Voss
Organization:	Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address:	Ecolab655 Lone Oak Drive
City/State/Zip:	Eagan, MN 55121
Telephone:	6517955981
E-mail:	peter.voss@ecolab.com

Submitter Information 2:

Name:	Tim Tewksbary
Organization:	Co-Chair, Ice Maker Equipment Cleaning and Sanitizing Committee
Address:	Ohio Department of Agriculture8995 East Main Street
City/State/Zip:	Reynoldsburg, OH 43068
Telephone:	6147286250
E-mail:	Timothy.tewksbary@agri.ohio.gov

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-011

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Report - Food Recovery Committee (FRC)

Issue you would like the Conference to consider:

The 2014 Biennial Meeting re-created the retired Food Recovery Committee via Issue 2014-I-035 and charged the committee to review and revise the Comprehensive Guidelines for Food Recovery Programs document (currently posted on the CFP web site) and report back its recommendations to the 2016 CFP Biennial Meeting

Public Health Significance:

The previous version of this document was 2007 and a revision was needed.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the 2014 - 2016 Food Recovery Committee final report;
2. Thank the committee members for their work and efforts on the committee; and
3. Disband the committee.

Submitter Information 1:

Name:	John Marcy
Organization:	Food Recovery Committee Co-Chair
Address:	University of ArkansasO-203 POSC
City/State/Zip:	Fayetteville, AR 72701
Telephone:	(479) 575-2211
E-mail:	jmarcy@uark.edu

Submitter Information 2:

Name:	Susie McKinley
Organization:	Food Recovery Committee Co-Chair
Address:	Florida Restaurant and Lodging Association

City/State/Zip: Tallahassee, FL 00000
Telephone: (850) 508-1139
E-mail: susie@mckinleyhome.com

Content Documents:

- "CFP 2014 - 2016 Food Recovery Committee Final Report 2016"
- "Comprehensive Resource for Food Recovery Programs 2016"
- "CFP 2014-2016 Food Recovery Committee Roster"

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: **Food Recovery Committee (FRC)**

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: **Council I**

DATE OF REPORT: **January 29, 2016**

SUBMITTED BY: **Susie McKinley and John Marcy**

COMMITTEE CHARGE(s):

It was recommended at the 2014 Conference for Food Protection Biennial Meeting that the retired Food Recovery Committee be recreated and assigned with the following charge:

Issue: 2014 I-035
Charge:

Review and revise the *Comprehensive Guidelines for Food Recovery Programs* document (currently posted on the CFP web site) and report back its recommendations to the 2016 CFP Biennial Meeting

.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

a. Potential Food Recovery Committee (FRC) members were recruited and efforts were made to ensure the committee membership met CFP Constitution and Bylaws committee ratio requirements. Committee membership roster was drafted and forwarded to Council I Chair for approval by the Executive Board. The proposed membership roster was amended and approved by the Executive Board during their August 2014 board meeting.

b. The FRC met on a recurring monthly schedule with one meeting every month effective August 2014 with two meetings in November 2015.

c. Work began on the Document with the Committee analyzing the document. We asked for comments and additional issues that needed to be incorporated.

d. The group met with several outside groups who discussed various types of food recovery missions.

e. To break up the charge, the Committee divided into several subcommittees: Date Coding, Wild Game, Food Safety, Small Scale Food Recovery, Food Defense, and Document Outline.

f. Upon completion of the above areas, the compiled revisions and additions to the current *Food Recovery Comprehensive Guidelines* were proposed to the entire Food Recovery Committee for a final vote. The revised *Food Recovery Comprehensive Guidelines* document

was accepted and approved by the FRC and will be submitted as an Issue at the 2016 CFP Biennial Meeting.

g. Attachment A to this Report includes a summary outline of revisions to the document.

2. Recommendations for consideration by Council:

   a. Acknowledge the Food Recovery Committee Final Report and accept the Committee generated guidance document.
   b. Thank the committee members for their work and efforts on the committee; and
   c. Disband the committee.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Report – Food Recovery Committee

   a. Acknowledgement of 2014 – 2016 Food Recovery Committee Final Report.

   b. Thanking the Committee members for their work and efforts on the committee; and

   c. Disbanding the committee

   2. FRC 2 – Comprehensive Resource for Recovery Programs

   a. Accept the revised Food Recovery Comprehensive Guidelines (and supporting appendices) and post on the CFP website in PDF format.

Lists of Attachments –

Content Documents

1. Report – Food Recovery Committee
2. Comprehensive Resource for Food Recovery Program

COMMITTEE MEMBER ROSTER (attached):

Attachment A - Summary Outline of Revisions to the Document

The Comprehensive Guidelines for Food Recovery Programs was very close to being completely rewritten. The document was renamed as the Comprehensive Resource for Food Recovery.

The Committee wanted the Document to be written in clear language, easier to use, less technical so it was written in a voice for users that are not completely familiar with the Food Code. Portions that while accurate, but written for users at a higher level of food safety knowledge, were rewritten for clarity or deleted. Wherever possible, links to web pages were included. As requested by Committee members, whenever possible, charts were provided to assist users.

The following areas were deleted in total:

“About These Guidelines”

The following areas had much deleted:

The Time/Temperature Control for Safety Food” section had all references deleted to potentially hazardous food, the water activity, pH, and the decision tree for TCS food.

The “Planning for Food Defense” section was edited and users were referred to the FDA’s web page for resources.

“Appendix B”

The following areas were updated:

“Definitions” were updated to include new and current/updated definitions of industry terms.

The “Introduction to Food Recovery” section was revised to include current statistics and messaging.

The “Food Recovery Activities” section was updated with current statistics and initiatives. In addition, the references to specific programs were deleted and users are referred to the USDA’s curated list of organizations that conduct food recovery activities.

The “Legal Issues” section was updated and the University of Arkansas’ “A Legal Guide to Food Recovery,” was included for users.

Specific citations to the Food Code were removed and replaced with a general reference to access the Food Code throughout the document.

The “Food Donation” section was rewritten.

The “Foodborne Illness“ section was updated and edited.

The “Food Allergens“ section was updated and edited.

The “Keeping Food Safe“ section was updated and edited.

The “Food Preparation Practices“ section was updated and edited.

The “Maintaining Food Safety During Transportation“ section was updated and edited.

The “Food Recovery Program Responsibilities“ section was updated and edited.

The “Handling Donations of Wild Game Animals“ was updated and edited.

“Appendix C Reference Publications“ was completely rewritten and updated.

“Appendix B“ was moved to “Appendix D“ and was updated.

The following sections /content were added:

A “Donation Program Description“ section was added to “Implementing a Food Recovery Program.”

“Food Safety and Food Recovery“ was added to “Implementing A Food Recovery Program.”

“Understanding Product Code Dating“ was added to Food Donation - Receiving and Storing Food: Evaluating the Condition of the Food.”

“Acceptable Foods and Labeling Requirements“ chart sourced from Feeding America and added to “Food Safety Procedures.”

Active Managerial Control / Food Safety Management System content was added to “Keeping Food Safe.”

A “Reduced Oxygen Packaging“ section was added to “Food Preparation Practices.”

Suggested food transportation methodology was added to “Maintaining Food Safety During Transportation.”

“A Sample Foodhandler / Volunteer Illness Agreement for Reporting Illness“ was added as “Appendix B.”

A “Sample Labels“ section was added to Appendix D.

Comprehensive Resource for Food Recovery Programs

****

Originally developed by the Food Recovery Committee
2000 Conference for Food Protection / Council I

October 2000
Updated January 2004
Updated April 2006
Updated March 2007

This revision April 2016

CONFERENCE FOR FOOD PROTECTION

TABLE of CONTENTS

Executive Summary

The Economic Research Service of the USDA reported in 2012 that 31 percent—or 133 billion pounds—of the 430 billion pounds of the available food supply at the retail and consumer levels in 2010 went uneaten. Retail-level losses represented 10 percent (43 billion pounds) and consumer-level losses 21 percent (90 billion pounds) of the available food supply. At the same time, 14.5% of households (more than 15 million) in the US were food insecure.*

Recovering consumable food and moving it to hunger relief organizations has proven to reduce these numbers and positively impact the lives of millions of people of all ages across America. Numerous organizations, both governmental and private, are involved in this vital work.

The safety of food throughout this recovery process is of critical importance. The population served by hunger relief organizations has a higher percentage of vulnerable individuals. Compounding this concern is the diversity of organizations and agencies acting to insure food safety standards are consistently met.

The Conference for Food Protection offers a forum for the many constituent groups impacted by the processes involved in food recovery, distribution, and service. Its deliberative process to gain consensus and uniformity has been applied to this challenge of reducing hunger in America by increasing the availability of safe food that otherwise would be discarded.

This update of the Comprehensive Resource for Food Recovery Programs is intended to assist all stakeholders, whether new or existing, involved in the recovery, distribution or service of food to people who live their lives insecure about where their next nutrition meal will come from.

*SOURCE: United States Department of Agriculture, Office of the Chief Economist, U.S. Food Waste Challenge, “FAQ’s”, Web. January 8, 2016.

Definitions

Users of this guide please note that many of the terms noted below are industry standard or commonly used definitions. For the purposes of this document, definitions as written in the Food Code are not always used.

A**ctive Managerial Control** is the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors.

Approved Source is an acceptable supplier to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

"Big 6" foodborne illnesses are those that are highly contagious and cause severe symptoms. Employees diagnosed with any of the "Big 6" are excluded from work and can't report to work until cleared by a medical doctor. These illnesses are as follows: non-typhoidal Salmonellosis, Typhoid Fever, Hepatitis A, Shigellosis, Hemorrhagic colitis or Shiga toxin-producing E. coli and Norovirus.

Critical Control Point is a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

Excess Food means any extra wholesome, edible food, including food that was prepared for service, but not served or sold.

Excluded employees are those that have been diagnosed with any of the "Big 6" illnesses and are excluded from working. Employees may not return to work until cleared by a medical doctor.

Field gleaning (gleaning) means the collection of crops from fields that have already been mechanically harvested or on fields where it is not economically profitable to harvest.

Food defense is the collective term used by the Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Department of Homeland Security (DHS), etc., to encompass activities associated with protecting the nation's food supply from deliberate or intentional acts of contamination or tampering. This term encompasses other similar verbiage (e.g., bioterrorism, (BT), counterterrorism (CT))

Food Distribution Organization (FDO) is an organization that accepts donated food and directly distributes it to needy consumers or, in some cases, distributes donated food to another facility (receiving facility) which will then directly distribute it to the consumer. This FDO and the receiving facility may be one and the same.

Food Recovery means the collection of wholesome food for distribution to people in need and is sometimes referred to as food rescue.

HACCP is an acronym that stands for Hazard Analysis and Critical Control Point, a preventionbased food safety management system. HACCP systems are designed to prevent the occurrence of potential food safety problems. HACCP Plan means a written document that delineates the formal procedures for following the Hazard

Analysis Critical Control Point principles developed by the National Advisory Committee on Microbiological Criteria for Foods.

Hazard means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

Perishable foods are meats, dairy products, produce, and bakery items that have been donated from grocery stores, produce distributors, food distributors, etc.

Prepared foods are foods of all descriptions that have been prepared but were never served. This includes cooked items, such as meats, entrees, vegetables, starches, deli trays, and vegetable trays, for example.

Receiving facility means the organization that accepts donated food and directly distributes it to the consumer.

Reclamation Centers are centers operated by retail supermarket chains or wholesale distributors that collect product that will not be sold through the company's normal distribution channels. This may include damaged product or discontinued items being claimed for credit from the vendor/manufacturer.

Reduced oxygen packaging (ROP) provides an environment that contains little or no oxygen in the package. The term ROP can be used to describe any packaging procedure that results in a reduced oxygen level in a sealed package. The term is often used because it is an inclusive term and can include packaging options such as *Cook-chill, Controlled Atmosphere Packaging (CAP), Modified Atmosphere Packaging (MAP)*, and *Sous Vide* (French, *under vacuum*). For additional information, review http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm188201.htm.

Reportable Illnesses are those that require the person-in-charge to exclude or restrict a foodhandler from a food establishment exhibiting symptoms including sore throat with fever, running nose, diarrhea, vomiting, jaundice, pus-filled lesions or draining wounds, and/or diagnosed with hepatitis A, *Salmonella* Typhi, Norovirus, *Shigella*, Shiga toxin-producing *E. coli*, non-typhoidal *Salmonella*. A foodhandler shall report the information to a manager on duty / person-in-charge to reduce the risk of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms.

Restricted employees are those that are exhibiting symptoms of illness and may not work with exposed food or food equipment and food contact surfaces. Symptoms may include: sore throat with fever, running nose, diarrhea, vomiting, jaundice, pus-filled lesions or draining wounds.

Salvage, as a verb, means the act of saving any imperiled property from loss. As a noun, it means the property so saved. Food items may have been subjected to possible damage due to transportation accident, fire, flood, adverse weather, or any other similar cause, which may have rendered the food unsafe or unsuitable for human consumption. As used by food banks, the definition of salvage includes those products processed through reclamation centers. Salvaging involves evaluating the product to determine its fitness for human consumption, reconditioning it, if necessary, in order to place the food back into the distribution system.

Served food is food that has come into contact with the customer. This does not include food on merchandised display.

Time/Temperature Control for Safety (TCS) Food).

(1) **"Time/temperature control for safety (TCS) food**)" is a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation. Most, but not all perishable food and prepared foods are TCS foods.

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

(a) An animal FOOD that is raw or heattreated; a plant FOOD that is heat treated or consists of raw seed sprouts, cut melons, or garlicinoil mixtures that are not modified in a way that results in mixtures that do not support pathogenic microorganism growth or toxin formation; and

(b) Except as specified in Subparagraph (3)(d) of this definition, a food that because of the interaction of its water activity (AW) and PH values is designated as Product Assessment Required (PA) in Tables A and B from the FDA Food Code and provided at the end of the Food Safety Procedures section.1

(3) **"Time/temperature control for safety (TCS) food"** does not include:

(a) An aircooled hardboiled egg with shell intact, or an egg with shell intact that is not hardboiled, but has been pasteurized to destroy all viable salmonellae;

(b) A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

(c) A food that because of its PH or AW value, or interaction of AW and PH values, is designated as a nonTCS food in this definition;

(d) A food that is designated as Product Assessment Required (PA) in Table A or B of the Food Code definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food Is precluded due to:

(a.i) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients,

(a.ii) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen-packaging (ROP), shelf life and use, or temperature range of storage and use, or

(a.iii) A combination of intrinsic and extrinsic factors;

or

(e) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the Subparagraphs (3)(a) (3)(d) of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

Introduction to Food Recovery

In recent years, there has been growing concern about hunger, resource conservation, and the environmental and economic costs associated with food waste. This, in turn, has accelerated public and private efforts to make better use of available food supplies by recovering safe and nutritious food that would otherwise be wasted.

Today, one in ten households in the United States have children that are food insecure. By donating food instead of throwing it out, we are not only helping the lives of hungry families, but we are also saving valuable resources for future generations that went into producing that food as well cutting harmful greenhouse gas emissions that contribute to climate change. And, in 2015, the United States set a goal of a 50 percent reduction national food waste by 2030. This effort will create a new / revitalized partnership with charitable organizations, faith-based organizations the private sector and local, state and tribal governments to reduce food loss and waste in order to improve overall food security and conserve our national's natural resources.

Food recovery programs collect foods from commercial production and distribution channels and redistribute them to people in need. Prepared and processed foods are most often collected from the food service industry. Perishable produce is generally obtained from wholesale and retail sources. There are food recovery efforts carried out by public, private, and nonprofit organizations across the country. The primary goal of food recovery programs is to collect safe and wholesome food donated from commercial sources to meet the nutritional needs of the hungry.

Food recovery is one way to help reduce the problem of hunger in America. Participating in a successful food recovery program has benefits that extend beyond providing food to those who are in need. Participation benefits an establishment's operation, its customers, its employees, and the community. It increases the visibility of a business, and helps build a more cohesive local community.

This document is intended primarily to provide a resource to retail food operators that want to participate in food recovery programs and provide safe food to people in need.

Food Recovery Activities

USDA and EPA Food Recovery Activities

On September 16, 2015, Agriculture Secretary Tom Vilsack and Environmental Protection Agency Deputy Administrator Stan Meiburg announced the United States' first-ever national food loss and waste goal, calling for a 50 percent reduction by 2030. USDA and EPA will work in partnership with charitable organizations, faith organizations, the private sector, and local, state and tribal governments to reduce food loss and waste in order to improve overall food security and conserve our nation's natural resources.

In the United States, food waste is estimated at between 30-40 percent of the food supply. This estimate, based on estimates from USDA's Economic Research Service of 31 percent food loss at the retail and consumer levels, corresponded to approximately 133 billion pounds and $161 billion worth of food in 2010.

In 2013, USDA and EPA joined together to address food waste in America through USDA's Food Waste Challenge and EPA's Food Recovery Challenge to provide a platform to assess and disseminate information about the best practices to reduce, recover, and recycle food loss and waste. By the end of 2014, the joint effort had over 4,000 participants, well surpassing its goal of 1,000 participants by 2020. USDA and EPA are working to grow this list and expand food loss and waste reduction efforts from farm to fork.

*SOURCE: United States Department of Agricutlure "USDA Office of the Chief Economist, Recovery/Donations," US Department of Agriculture, Web. November 22, 2015. http://www.usda.gov/oce/foodwaste/resources/donations.htm

*SOURCE: Environmental Protection Agency "USEPA Sustainable Management of Food, Food Recovery Challenge (FRC)," US Environmental Protection Agency, Web. November 22, 2015. http://www2.epa.gov/sustainable-management-food/food-recovery-challenge-frc

Ongoing Food Recovery Activities

A growing number of organizations--both charitable and for profit--are working to recover wholesome excess food to provide low or no-cost meals to families in need. There are thousands of organizations helping to feed the hungry. The list of organizations presented is not exhaustive. Inclusion on this list does not imply endorsement by the USDA. (If you would like your organization listed, please contact the Office of Chief Economist at FoodWasteChallenge@oce.usda.gov).-The USDA is curating a list of organizations; for more information visit www.usda.gov\oce\foodwaste\resources\donations.htm

Legal Issues

Questions regarding legal issues may primarily be concerned with liability with the donation of food but there may also be other issues based upon both the state and health jurisdiction as well as other regulatory agencies. For a broader discussion, you can access “A Legal Guide to Food Recovery” http://law.uark.edu/documents/2013/06/Legal-Guide-To-Food-Recovery.pdf

Bill Emerson Good Samaritan Food Donation Act

When citizens volunteer their time and resources to help feed hungry people, they are rightfully concerned that they are putting themselves at legal risk. Fortunately, recent legislation provides uniform national protection to citizens, businesses, and nonprofit organizations that act in good faith to donate, recover, and distribute excess food.

Although all states have enacted Good Samaritan laws, one very important consideration for food donors is the issue of food safety and quality. Potential food donors (e.g., restaurants, caterers, cafeterias) are more likely to enter into partnership with food recovery programs if there are assurances that program personnel are trained in safe handling and storage of donated foods. Therefore, program guidance and assurances that emergency food programs operate in accordance with recognized food safety standards help encourage businesses to donate food.

The Bill Emerson Good Samaritan Food Donation Act converts Title IV of the National and Community Service Act of 1990, known as the Model Good Samaritan Food Donation Act, into permanent law, within the Child Nutrition Act of 1966. Congress passed the legislation in late September, 1996, and President Clinton signed the bill into law on October 1, 1996. The Act is designed to encourage the donation of food and grocery products to nonprofit organizations such as homeless shelters, soup kitchens, and churches for distribution to individuals in need.

The Bill Emerson Good Samaritan Food Donation Act promotes food recovery by limiting the liability of donors to instances of gross negligence or intentional misconduct. The Act further states that, absent gross negligence or intentional misconduct, persons, gleaners, and nonprofit organizations shall not be subject to civil or criminal liability arising from the nature, age, packaging, or condition of wholesome food or fit grocery products received as donations. It also establishes basic nationwide uniform definitions pertaining to donation and distribution of nutritious foods and will help ensure that donated foods meet all quality and labeling standards of Federal, State, and local laws and regulations.

Further details may be obtained by contacting the office of the attorney general for the appropriate State. In addition, the Emerson Act does not alter or interfere with State or local health regulations or workers’ compensation laws. Local organizations in each State should also be familiar with the impact upon food recovery projects of State or local health regulations and workers’ compensation laws.

Implementing a Food Recovery Program

There are many ways to contribute to food recovery programs including donating excess prepared foods, donating produce or canned and packaged goods, fundraising, training volunteer food workers, or providing transportation for food from donor to the food distribution organizations (FDOs).

Major aspects of implementing a food recovery program include:

1. choosing a suitable FDO and
2. donor and FDO agreement on the terms of their relationship.

Advice on finding a partner to receive donated foods is available from a number of reliable sources. Among them, the United States Department of Agriculture (USDA), the lead federal agency for food recovery activities, Feeding America, a national network of communitybased, hungerrelief programs; and the National Restaurant Association.

To lay the foundation for a successful partnership and to minimize misunderstandings, the donor and FDO need to plan their joint policies and procedures together. The initial planning meetings should cover at least the following topics:

1. Exchange of basic data such as:
    a. Names of key contacts
    b. Addresses, phone and fax numbers
    c. Anticipated frequency of donations;
2. The types of foods to be donated, for example:
    a. Raw fruits and vegetables
    b. Cold fruit and vegetable salads
    c. Hot foods of animal origin, including mixed dishes like lasagna
    d. Cold cooked foods of animal origin
    e. Hot or cold cooked vegetables
    f. Gravies, creambased soups
    g. Hot or cold grain dishes
    h. Canned and packaged goods that are not potentially hazardous in their packaged form
    i. Beverages, and
    j. Cold or frozen uncooked foods of animal origin, such as raw ground beef;
3. The food transport arrangements including:
    a. Who will transport food from donor to FDO's receiving facility

b. The type of vehicle(s) to be used, temperatureholding equipment (e.g., insulated containers, refrigerated unit)
c. Backup or transportation contingency plan in case of vehicle breakdown or emergency
d. Distance in miles between the donor and the receiving facility
e. Anticipated time in minutes from the donor to receiving facility
f. Anticipated frequency of donations, and
g. Times/dates for pickup of donations;

4. The qualifications of the food manager or personincharge in the donor and receiving facilities such as training and experience;
5. The training provided to staff on hygienic and safe food preparation, food defense procedures, storage, and transporting practices;
6. Preferred time, means and frequency of communication;
7. How unsatisfactory situations will be addressed; and
8. Any other considerations raised by either party.

Early in the planning process, both the donor and FDO operators should familiarize themselves and their staff with the Good Samaritan laws that limit liability to gross negligence and intentional misconduct. Foodhandlers need to fully understand that food safety training, consistent practice of hygienic food preparation practices, and regulatory inspection reports showing favorable performance histories, are factors which help to protect the participants from civil and criminal liability in the good faith donation of apparently wholesome food. Good practices help to provide legal protection for the donor and help ensure the service of safe food to consumers.

Donation Program Description

While donation programs can vary in format, all donated product must be handled correctly to assure that the recipient can have confidence that the product they are receiving has been handled safely.

Typical donation programs include product that is no longer marketable to the donor's primary customer. In many cases the product has a shortened shelf life and must be moved quickly from the donor to end-users or recipients. Donation programs may include shelf-stable food and non-food items as well as perishable products such as meat, deli, dairy, frozen, bakery and prepared foods. As long as these products are handled properly they can still provide wholesome meals to recipients.

Always work with state and local health officials when beginning new programs to ensure that they are in compliance with state and local health codes

Food Safety and Food Recovery

The Center for Disease Control (CDC) estimates that each year 48 million people in the US become ill with 3,000 people dying annually after eating unsafe food.

The Food and Drug Administration (FDA) has identified five major reasons that cause foods to become unsafe to eat:

1. Food from unsafe sources. (Unsafe when obtained and cannot be made safe).
2. Improper holding temperatures. (Temperature abuse of the foods).
3. Inadequate cooking. (Not cooking foods to proper safe temperatures).
4. Contaminated equipment. (Poor cleanliness in the kitchen).
5. Poor personal hygiene. (Sick food handlers and those who do not wash their hands).

Food safety is an integral part of managing food donations and distributions, and it is paramount to minimizing the risk of distributing or serving unsafe foods. The most vulnerable people who will become sick when eating unsafe foods are young children, the elderly, pregnant women and those whose immune systems are compromised, therefore weakened.

It is very important that you make sure the foods you are providing to your clients are safe to be consumed.

These guidelines are to help you to develop a thorough understanding, along with your donors, concerning the foods you will be able to distribute and how they should be safely stored, packaged and transported.

Food Safety Procedures

Introduction

Serving safe food is an essential part of all food recovery activities. In the donor's domain and in the food distribution organization (FDO), all steps need to be taken to ensure that the consumers of the recovered food are receiving a safe product. Certain basic principles of food safety must be incorporated into the program and followed by foodhandlers to provide the consumers protection from foodborne illness.

Food that is directed to those in need is entitled to the same protective measures as food prepared and served to paying consumers. The national food standards at the retail level, as expressed in the FDA Food Code (Food Code), do not differentiate between the protection provided to food consumed by paying consumers and to food consumed by individuals who eat at FDOs.

The Food Code is an excellent reference for minimizing the occurrence of risk factors that contribute to foodborne illness. The standards expressed in the Food Code cover such subjects as:

- manager or Person-In-Charge (PIC) knowledge requirements;
- monitoring the health of foodhandlers;
- foodhandler training and supervision;
- protecting food from pathogens and contaminants from hands and other sources which cause foodborne diseases;
- time and temperature requirements; and
- equipment design and construction and maintenance.

Procedures outlined in this section are based on wellestablished food safety principles and are set forth as guidance for planning and conducting a food recovery program.

Food Donation - Receiving and Storing Food: Evaluating the Condition of the Food

The PersonInCharge (PIC) who accepts the food on behalf of the FDO should ensure the food is from an approved source (i.e., one that meets food safety standards, such as those outlined in this document and the Food Code) and that it is in good condition. Examining foods at the time of receipt is essential to intercept problems that can lead to food contamination, if undetected. Check for evidence of problems, such as the following, and take appropriate action to keep products from being received in an unsatisfactory condition, consumed, or contaminating other product (see Appendix A of this document for additional guidance):

1. Environmental condition of transport, e.g., the vehicle is not clean, pets in the vehicle, evidence of insects or rodents, temperature controls not in use, ready-

toeat foods stored so they can be contaminated by raw foods, toxic compounds are transported in a way that can contaminate food;

2. Cans that are dented in the top or side seams or are leaking or swollen;

3. Insect or rodent infested food e.g., droppings, gnawings, or nesting material. Infested foods, foods that are obviously compromised;

4. Foods of questionable safety should be discarded or isolated from wholesome foods until soundness is determined. In either case, the goal is to keep other foods wholesome and safe and physically separated to ensure sound condition.

Protective measures for prepared foods and whole produce are different from protective measures for canned food, and shelfstable packaged goods. With whole produce and prepared foods, attention should be focused on the packaging and condition of the food and the storage condition in terms of time and temperature. Cut produce such as melons and prepared foods, including cooked entrees and refrigerated foods, need to be kept at correct cold or hot holding temperatures recommended in the Food Code. (*See the Food Preparation Practices section of this document*). With canned food and shelfstable packaged goods, attention should be focused on the condition of the food container.

Once accepted, food should be stored in a manner that protects it from potential contamination such as dripping water, dust, rodents, insects, and other sources of contamination. Canned goods should be organized to prevent damage to the cans and all foods should be organized to allow for proper rotation (i.e., FIFO First In/First Out).

Types of Foods

Foods donated to a food recovery program may include excess prepared food or produce, canned food, wild game and shelf-stable packaged goods. Excess food is any extra wholesome, edible food, including food that was prepared for service, but not served or sold. The charitable donation of food may result because a done has excess or weekly volume of food. Restaurants, grocery stores, office food drives, community food drives or produce culling operations are possible donation sources.

Understanding Product Code Dating

Foods are dated to either ensure quality or safety. Shelf-stable foods generally have dates placed on them that are based on quality. Accepting these foods after these dates is acceptable as the foods are still safe to eat. With one exception, there are no federal laws prohibiting selling, donating or serving shelf-stable foods that have exceeded their dates. The one exception is infant formula, where the US Food and Drug Administration (FDA) requires industry to mark infant formula with “use by” dates to assure the nutritional value of the infant formula up to the marked date and federal law prohibits sale or distribution past the expiration date.

It is not a safe practice to accept ready-to-eat food that requires refrigeration (temperature control for safety food / less than 41°F) to maintain safety, which has

passed its “sell by” or “use by” date, unless the product had been frozen on or before the date(s) noted above and had remained in a frozen state since it was initially frozen. With regards to pasteurized products, such as milk and cheeses, the sell by date is a reference to quality. They are safe to consume until spoilage indicators provide reason to discard.

- **“Sell by”** which is a date defined by the manufacturer or retailer as the last date on which their temperature sensitive foods should be sold;
- **“Use by”** which is a date that has a similar definition for temperature sensitive products but is also used on shelf stable products as a **quality** measurement.
- **“Best by”** which is a date generally used on shelf stable products and is **based on quality not food safety.**
- **“Expiration”** which is a date defined by the manufacturer or retailer and is **based on quality not food safety.**

Freezing foods allows you to keep the donations beyond their “Sell by”, “Use by” and “Best by” dates. Please encourage your donors to freeze donated foods, if possible, so they are frozen solid when picked up.

Foodhandlers - Good Hygienic Practices: Basic Essentials

Handwashing is key to preventing the spread of disease. An infected foodhandler’s poor personal hygiene, followed by contact with food, can result in illness when the food is eaten. Good sanitation, correct handwashing, and no barehand contact with raw, readytoeat (RTE) food help to prevent disease transmission.

Foodhandlers must wash hands and exposed portions of arms, including surrogate prosthetic devices for hands and arms, using soap and running water, vigorously rubbing the hands together to be sure soap contacts all surfaces of the hands, and rinsing under clean, running warm water. Handwashing needs to occur for at least 20 seconds total, with at least 10 to 15 seconds devoted to vigorous rubbing of the hands and arms or surrogate prosthetic devices for hands and arms. Hands and exposed portions of the arms or surrogate prosthetic devices for hands and arms must be washed: immediately before beginning food preparation; during food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks; after using the toilet room; and after engaging in other activities that contaminate the hands. Additional information on when to wash hands can be found in the Food Code.

Acceptable Foods and Labeling Requirements

Food Type	Prepared Foods	Packaged Foods	Fresh Produce
Sources	Hotels Restaurants Institutes Food Service Facilities Bakeries	National and local donors National and local vendors Retail store donations Reclaim and food drives	Any donor or vendor of fresh produce
Examples of foods	Prepared meat, poultry entrees, pasta, pizza, vegetables, chilled foods, etc.	Canned, boxed, or packaged foods Bagged cut produce Dairy Raw shell eggs Meat, poultry, and fish (fresh and frozen)	Whole produce in bins and bags
Label requirement	Fair Packaging and Labeling Act (FPLA) does **not** apply.	Fair Packaging and Labeling Act (FPLA) applies.	Fair Packaging and Labeling Act (FPLA) does **not** apply.
Recommended language for the label to state *See sample labels in Appendix D	1. The name and location of FDO (pre-printed) 2. The name and location of donor 3. The food description 4. The date of donation 5. Allergen disclaimer statement (pre-printed) **WARNING**! This container holds rescued food! This food may contain, have come into contact with, or have been produced in a facility which also produces milk, eggs, peanuts, tree nuts (walnuts, almonds, pecans, hazelnuts/filberts, pistachios, cashews, coconuts, pine nuts, macadamia nuts, and/or Brazil nuts), fish, shellfish (crab, crawfish, lobster, shrimp, mussels, and/or oysters), wheat, soybeans, and/or sesame seeds	1. The common or usual name of the product 2. The name and place of business of the manufacturer, packer, or distributor 3. The net quantity of the contents 4. The common or usual name of each ingredient, listed in descending order of prominence	No label required
Comments	Label is applied to all containers.	These products are assumed to have the proper retail label already on the packaged product when they are received by the member.	

Foodborne Illness

Foodborne illness occurs as a result of exposure of an individual to pathogenic organisms after consuming food that has been contaminated or improperly prepared. CDC estimates more than 48 million cases of foodborne illness, 128,000 hospitalizations and 3,000 deaths occur annually from foodborne illness. Most foodborne outbreaks are caused by viruses and bacteria. Of those outbreaks where a cause could be identified, 65% of these outbreaks involved an infected person handling food.

The 2013 Food Code has identified six foodborne pathogens that are highly infective, easily transmitted and cause very severe illness. The "Big 6" are Norovirus, Typhoid Fever, non-typhoidal Salmonellosis, *Shigella* spp., Enterohemorrhagic / Shigatoxin producing *E. coli* and Hepatitis A. If an employee or volunteer has been diagnosed by a medical doctor with any of the "Big 6", that employee/volunteer must be excluded from the FDO until cleared by a medical professional. There are other foodborne pathogens that should be considered. They are: *Staphylococcus aureus, Clostridium botulinum, Clostridium perfringens, Bacillus cereus,* and S*treptococcus pyogenes*. Foodborne bacteria multiply in food, provided time and temperature controls are inadequate and the appropriate nutrients are present. Viruses and parasites only multiply in human beings or animals. In the case of viruses, any type of food or surface can be the vehicle to transmit the virus. As noted earlier, millions of people contract foodborne illness every year. Most cases are avoidable through the use of safe food preparation and correct sanitation.

Managing Ill Foodhandlers and Volunteers

Most foodborne illness outbreaks in the United States identified ill foodhandlers as a contributing factor. The FDO should strive to prevent the transmission of bacteria and viruses from infected foodhandlers into food. Management, foodhandlers, and volunteers have a responsibility to be aware of the causes of foodborne illness and what their responsibility is to prevent the transmission of bacteria and viruses that cause foodborne illness. The highest level of risk to consumers occurs when foodhandlers and volunteers have specific symptoms (vomiting, diarrhea, jaundice) yet they continue to work.

Risk of transmission is still present if foodhandlers and volunteers have been diagnosed with certain foodborne illnesses, but have recovered from these symptoms or never developed symptoms and also if foodhandlers or employees / volunteers were recently exposed to specific pathogens.

The transmission of foodborne bacteria and viruses can be prevented only when a combination approach is used:

- Restrict or exclude ill food employees / volunteers from working with food,
- Use of correct handwashing procedures whenever necessary, and
- Eliminate bare-hand contact with readytoeat food.

SOURCE: "Estimates of Foodborne Illness in the United States" www.cdc.gov. May 19, 2015. Web. 19 May 2015.

Foodborne Illness Symptoms and Diagnoses:

Vomiting, diarrhea and jaundice serve as indicators that the individual may have a fecaloral route disease and is likely excreting high levels of the infectious agent through stool or vomit. In some cases, these symptoms are indications of other non-infectious conditions such as Crohn's Disease, early stages of pregnancy, irritable bowel syndrome or some liver diseases. The foodhandler or volunteer may continue working if they can show through a medical or other documentation that the symptom is from a noninfectious condition.

Reporting

Management of the FDO must ensure that all foodhandlers and volunteers understand the importance of reporting certain conditions. A sample agreement to explain foodborne illness, specific symptoms, and other high-risk conditions is provided in these guidelines (see Appendix B).

A foodhandler, whether a paid staff member or a volunteer, shares a responsibility for preventing foodborne illness and is obligated to report to the person in charge if they are suffering from the listed symptoms or have been diagnosed with or exposed to one of the Big 6 foodborne pathogens.

For example, if a foodhandler or volunteer has an infected cut, burn or boil on his/her hands and uses a double barrier, that is, a bandage and waterproof, single-use gloves, the foodhandler or volunteer does not have to report the infected lesion to the person in charge. However, if the foodhandler or volunteer does not correctly bandage it, reporting is required. If a foodhandler or volunteer reports an exposure or diagnosis of any Big 6 or symptoms described above, the foodhandler should stop working directly with exposed foods, clean equipment, utensils, and linens, and unwrapped singleservice and singleuse articles until management determines whether the foodhandler may work or not.

In some cases, foodhandlers or volunteers should remain away from the establishment until they are no longer showing symptoms of vomiting, diarrhea, or jaundice for a 24 hour period or provide medical documentation that the foodhandler is free of illness from one of the above listed pathogens or that symptoms result from a noninfectious condition.

After the PIC receives a report of diagnosis of one of the " Big 6" or jaundice from a foodhandler or volunteer, this information must be reported to the Regulatory Authority, for example the health department, either directly or through a headquarters office. Then management must determine what to do based on this report. An additional action the PIC should take along with necessary restrictions and/or exclusions is to refresh all staff and volunteer training with regard to reporting symptoms, diagnosis or exposure to foodborne illnesses, correct handwashing techniques and preventing bare-hand contact with readytoeat food.

Especially Vulnerable Populations

Facilities that serve highly susceptible populations such as hospitals, nursing homes, nursery schools, or senior citizen centers must take extra precautions because these individuals react more severely to foodborne pathogens. Typically these facilities will not receive donated foods because of the greater risk to the vulnerable populations that are served. But when children, the elderly and people with certain medical conditions live outside of a facility setting, they may be the recipients of donated food. While healthy people have a certain resistance to foodborne illness and may only experience mild to moderate symptoms, others who are more susceptible to foodborne illness, can have severe symptoms and complications, and may die.

Among those at increased risk for certain foodborne diseases and their severe manifestations are: older adults, pregnant women, young children, those with weakened immune systems (due to conditions such as AIDS, cancer, chemotherapy treatments, diabetes, or taking steroids), persons with reduced gastric acidity, and those with liver disease.

In food recovery receiving facilities that accept excess prepared food for service to especially vulnerable consumers, extra care must be taken by both parties to ensure the use of sound food safety practices during the continuum from preparation through transportation to receiving and service. Additionally, recovery programs should consider certain precautions noted in the Food Code such as use of pasteurized juice and eggs or egg products that apply to highly susceptible populations.

Training of Foodhandlers or Volunteers

Training of foodhandlers and volunteers in the use of the following control measures will help prevent foodborne illness.

- Cook foods to correct cooking temperatures, for the required amount of time to kill pathogens;
- Cool cooked foods rapidly and hold under refrigeration;
- Maintain all food at correct temperatures at all times.
- Reheat refrigerated foods properly;
- Keep raw and readytoeat foods separated;
- Maintain personal cleanliness during food preparation, including correct handwashing (*See Food Code Chapter 2*);
- Notify foodhandlers of the requirements for maintaining good personal hygiene, proper food preparation practices, and the need to report symptoms of vomiting, diarrhea, jaundice, sore throat with fever, infected wounds or pustular boils; and,
- Maintain a clean establishment, particularly equipment, utensils, and all other surfaces that come into contact with food, to prevent contamination of foods (*See Chapter 4 of the Food Code*).
- Foodborne illness is primarily caused by bacteria, viruses or parasites. Many foodborne illnesses are a result of bacteria, which are microorganisms that occur either naturally in foods or are spread as a result of poor practices such as cross contamination of readytoeat foods or incorrect foodhandler hand contact with food during preparation.

Controlling Biological Hazards Bacteria

Bacteria are present everywhere in soil and air, on the surface of fruits and vegetables, and on and within all animal bodies. Only some bacteria are harmful, but those that cause foodborne illness can result in mild to severe illness, long-term health consequences, or death. *Salmonella*, *Shigella spp.*, *Listeria monocytogenes*, and *E. coli* O157:H7 are some pathogenic bacteria that are transmissible through food.

Bacteria multiply when four factors come together to create the right conditions for growth:

(1) **Nutrients**: foods that nourish bacterial growth, such as high protein foods, milk and dairy products, meat, fish, poultry, cooked pasta and cut produce such as cantaloupe, tomatoes or leafy greens.

(2) **Moisture**: moisture in foods that is available for bacterial growth. This can be moisture that is intrinsically present or that is added to the food (e.g., milk, water, or juice).

(3) **Time**: bacteria need time to reproduce. Some bacteria can double in number approximately every 20 minutes under ideal conditions (room temperature or between 41°F and 135°F). Remember that for some bacteria, very little growth or no growth is necessary to cause illness or to produce a toxin.

(4) **Temperature**: 41°F to 135°F is called the DANGER ZONE! It is within this temperature range that the life and growth of bacteria are supported. Avoid holding foods within this temperature range to prevent bacteria from growing to levels that can cause illness or produce a toxin.

The four factors noted above contribute to foodborne illness. Bacteria that are present everywhere cannot always be eliminated. Nutrients and moisture are always present in certain foods. Time and temperature can be controlled by the foodhandler. Foodhandlers, including paid staff and volunteers, who prepare food should know about the danger zone and be mindful of it during storage, thawing, cooking, cooling, reheating and hot or cold holding for service of foods.

The Food Code addresses time and temperature relationships as a major intervention against foodborne illness. Consult this reference for more information on time and temperature requirements for food safety when cooking, cooling, or reheating foods.

Controlling Biological Hazards – Viruses and Parasites

Foodborne illness can also occur when a person eats food contaminated with certain viruses or parasites. It is important to understand that the mere presence of the virus or parasite in the food can cause illness when the food is ingested. Viruses can contaminate food via infected workers with poor personal hygiene habits who have fecal material on their hands. Viruses, when in or on a food product, do not grow, but may remain in the contaminated food for a long period of time. Hepatitis A virus and Norovirus are viruses transmissible through food that are frequently transmitted by foodhandlers who do not adequately wash their hands after using the toilet. The fecaloral route of pathogens can be interrupted by good handwashing and not working when ill and by eliminating bare hand contact with readytoeat food. See current Food Code for more information.

Parasites do not reproduce as bacteria do, nor is there a need for them to multiply in order to cause illness. Parasites require a host that serves as a source of nutrition and a place to live. Humans serve as hosts for parasites. *Cyclospora* is a parasite that can be transmitted to humans from contaminated food or water.

Controlling Chemical and Physical Hazards

Some foods may contain objects from their production environment such as stones that also could cause injury. For example, foods (such as beans) may be contaminated naturally, from the soil in which they are grown or because of

harvest, storage, or transportation practices. Other foods that have undergone further processing at times, despite best efforts, subsequently become contaminated with materials that could injure consumers of the food. Therefore, operators need to be aware of the hazards associated with different foods and handling practices and take prudent precautions to minimize risks to food recipients.

Chemical hazards can also exist at various stages of food production, transportation, storage, and preparation. When food is stored or held at the FDO, it is imperative that chemical contamination be prevented. Store all toxic cleaners, pest control and other chemicals in an area separate from food storage. All chemicals must be clearly labeled. See current Food Code for more information.

Food Allergens as Food Safety Hazards

According to the Food Allergy Research and Education (FARE) webpage[1], up to 15 million Americans suffer from one or more food allergies. A food allergy is caused by a naturally occurring protein in a food or a food ingredient, which is referred to as an "allergen." For unknown reasons, certain individuals produce immunoglobulin E (IgE) antibodies specifically directed to food allergens. When these sensitive individuals ingest sufficient concentrations of foods containing these allergens, the allergenic proteins interact with IgE antibodies and elicit an abnormal immune response. A food allergic response is commonly characterized by hives or other itchy rashes, nausea, abdominal pain, vomiting and/or diarrhea, wheezing, shortness of breath, and swelling of various parts of the body. In severe cases, anaphylactic shock and death may result.

Many foods, with or without identifiable allergens, have been reported to cause food allergies. There are eight major foods that have consistently been identified as causing serious allergic reactions. These foods are:

- Milk, dairy products
- Egg, egg products
- Fish (such as bass, flounder, or cod)
- Crustacean shellfish (such as crab, lobster, or shrimp)
- Tree nuts (such as almonds, pecans, or walnuts)
- Wheat
- Peanuts
- Soy

To control cross-contamination of food allergens, use a rigorous sanitation regime to prevent cross-contact between allergenic and nonallergenic ingredients.

1 SOURCE: Foodallergy.org – "About Food Allergies" www.foodallergy.org. August 13, 2015. Web. August 15, 2015.

Consumers with food allergies rely heavily on information contained on food labels to avoid food allergens. Each year, the FDA receives reports from consumers who have experienced an adverse reaction following exposure to a food allergen. Frequently, these reactions occur either because product labeling does not inform the consumer of the presence of the allergenic ingredient in the food or because of the crosscontact of a food with an allergenic substance not intended as an ingredient of the food during processing and preparation. Allergen awareness training is necessary for those involved in the preparation, handling and service of food. It is critical that all are aware of how to avoid cross-contact with foods that are not allergens and how to identify an allergic reaction. This is especially important for those FDO serving food, e.g., a soup kitchen.

Labeling is an important aspect of allergen awareness. Here are some recommendations:

- Labeling is required to provide legally required product and ingredient information to the consumer.
- Labeling also allows food to be traced and recalled, should this become necessary.

Cross Contamination

Precautions must be taken to protect food from contamination and to maintain safe food practices during preparation, transportation, storage, and service. Cross-contamination is the transfer of contaminants by way of foodtofood, foodtosurfaceto-food, and by employees contacting both raw foods without proper handwashing or use of suitable utensils. For example, cross- contamination may occur when raw readytoeat vegetables contact a cutting board that had raw chicken on it and was not cleaned and sanitized between uses.

Precautions to prevent cross-contamination include the following:

- Separate raw foods from readytoeat foods;
- Wash, rinse, and sanitize cutting boards and foodcontact surfaces at work stations between uses and when working with different foods, especially when changing from working with raw foods to readytoeat foods; and
- Separating foodhandler tasks to eliminate simultaneous preparation of raw and readytoeat foods.

Keeping Food Safe

All food establishments must strive to integrate food safety practices and active managerial control into an effective food safety management system.

A food safety management system is a program made up of policies, procedures, activities and standards established in a food recovery operation to minimize foodborne illness. The purpose of a food safety management system is to manage areas of

potential risk to prevent foodborne illness. Instilling an active food safety management system into an operation demonstrates a commitment to food safety and provides the framework on which a management system of this type is built.

Active managerial control (AMC) is the most important aspect of an effective food safety management system. AMC is indicated initially by tasking an official of a food recovery agency with the responsibility for food safety. The official must be in a leadership role with the agency and must have the support and commitment of top management. The individual assigned the responsibility for food safety must be held accountable for all food safety activities taken or not taken by the agency. The individual must also understand that in this role food safety concerns must be sought out and remedied. AMC is further defined by establishing, implementing, and managing preventive measures to food safety.

Training is a critical component of any successful food safety management system. All employees handling food should be trained in basic food handling techniques appropriate to the operation and the job duties of the individual. This should be a structured and ongoing program with re-training occurring on a scheduled basis; employees should be exposed to additional training as needed as they move around the operation performing various and additional tasks. Upon completion, an assessment should be conducted by the trainer to demonstrate that learning was achieved. In addition, all operations should have a certified professional food manager on staff that is present during all instances of food handling and preparation. This food manager should be certified utilizing one of the examinations approved by the Conference for Food Protection. For more information, visit the Conference for Food Protection (CFP) or your local health department for information on food manager certification.

A person-in-charge (PIC) must be designated for every shift in the operation. This person must be well trained and knowledgeable about food handling and food safety. The PIC must be able to demonstrate leadership to staff, vendors and guests as needed. The PIC must be proficient in reporting the day-to-day activities to management and in recording all activities as they occur with regards to food safety in the operation. The PIC should be familiar with employee health policies and symptoms and should manage employee health as needed. Both the PIC and certified professional food manager must be familiar with all aspects of active managerial control in controlling the risk factors for foodborne illness.

It is the responsibility of leadership, management staff, and every employee engaged in handling food to provide safe food to the final recipient. Working together to ensure safe food is by far the most effective methodology in achieving this mandate. All must be mindful of the “foodborne illness risk factors” as defined by the U. S. Food and Drug Administration:

- Food from Unsafe Sources
- Inadequate Cooking
- Improper Holding Temperatures
- Contaminated Equipment
- Poor Personal Hygiene

A food safety management system must incorporate preventive measures to reduce risk factors that contribute to foodborne illness. A great way to identify risk factors is to utilize assessment as a tool.The PIC and management personnel must understand and assess the resources accessible to the operation for maintaining food safely. Self-assessment and / or third-party assessment is an important tool of an effective food safety management system. A successful food safety management system must be continually assessed to check hazards, determine resources, understand risks, and to accurately maintain the operation with regards to the critical components of food safety.

An assessment program should verify that the following are in compliance with acceptable food safety standards:

- Exposure to potential food contamination is minimized.
- Are employees familiar with all aspects of an approved source?
- Personal hygiene is correct and strictly adhered to by all personnel.
- Exposure of food to the temperature danger zone is minimized and within standards.
- Documentation of food temperature should be routinely monitored to verify food safety.
- The food handling chain is sufficiently structured so as not to expose food to hazards.
- An effective pest control program is in place, and pests are not permitted inside the operation.
- The cleaning and sanitation program is effective and routine.
- The physical structure is constructed and maintained with food safety in mind.
- Risk versus operating requirements should be explored. Is the operation willing to adopt all food safety management systems to guarantee safe food for the consumer?
- Does the operation manage activities based on a HACCP-based Program?
- Is an effective food safety policy and procedure in place?
- Are corrective action plans in place for any variation from the food safety management system standard?

Corrective action plans can range from minimizing exposure to incorrect temperatures to how to handle a suspected foodborne illness. Is the operation familiar with standard operating procedure should foodborne illness possibly be associated with food from the operation? A procedure should be available and posted for all employees to see should this type of need arise.

For example, Hazard Analysis Critical Control Point (HACCP) is a preventive approach to minimizing the risks from food safety hazards and can be used to ensure safer food products for consumers. The Food Code sets forth parameters (such as time temperature requirements) demonstrated scientifically to control

pathogenic hazards. The Food Code discusses the HACCP approach as well as controlling the introduction of chemical and physical hazards. These parameters provide a solid foundation for developing HACCP plans for individual operations.

Two FDA documents have been developed to assist both the operator and regulator of food service and retail establishments in implementing HACCP into daily operations:

Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments

http://www.fda.gov/downloads/Food/GuidanceRegulation/HACCP/UCM077957.pdf

The Operator's Manual:

- provides operators of such establishments with a stepbystep scheme for designing and voluntarily implementing food safety management systems based on HACCP principles; and,

Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Riskbased Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems

http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006812.htm

The Regulator's Manual:

- provides regulatory authorities with a stepbystep scheme for conducting risk based inspections based on HACCP principles to assist in assessing control of foodborne illness risk factors;
- details intervention strategies that can be developed with the operator to reduce the occurrence of foodborne illness risk factors; and
- provides recommendations for evaluating voluntarily implemented food safety management systems, if asked by industry.

A HACCP system requires the PIC of the food recovery operation to objectively examine the flow of the food, from its receipt to service. This analysis can help the PIC identify the points at which it is critical to impose control in order to keep the food safe. Assistance in applying HACCP principles to food recovery programs is available from regulatory agencies, academia, trade associations, and consultants.

Most operations that prepare food for food recovery recipients fall within these three categories:

1. Food process with no cook step (readytoeat food); (receivestorepreparehold-serve)
2. Examples: fresh vegetables or fruits, tuna salad, coleslaw, sliced sandwich meats
3. Food preparation for same day service; (receivestorepreparecookholdserve)
4. Examples: Hamburgers, hot vegetables, cooked eggs, hot entrees for "specialof-theday"

5. Complex processes (foods prepared in large volume or for next day service); (receivestorepreparecookcoolreheathot holdserve)

Examples: Soups, gravies, sauces, large roasts, chili, taco filling, egg rolls

By tracking the flow of food, critical steps in a specific operation (e.g., cooking and cold holding) and potential cross-contamination points can be identified. Operational procedures and monitoring can be established once the facility identifies the points in its process where food can become contaminated, and where incoming foods that are assumed to be contaminated, such as raw, animalderived foods, must be time/temperature controlled.

Another facet in this proactive and preventive HACCPbased strategy is to anticipate failures in the food recovery program and to predetermine corrective actions. For example, *what will occur if there is a power failure for an extended period of time or the transport vehicle breaks down?* Applying HACCP principles will prompt the personincharge to consider the period of time involved in the power failure, the effect it may have on product temperatures, and whether a reheat would suffice to render a product safe.

It is important to note that HACCP may or may not be a requirement in your jurisdiction. Check with your local regulatory authority to determine if HACCP is required.

To assist in understanding and utilizing a risk-based prevention program, become familiar with HACCP principles. For more information on HACCP, go to the 2013 FDA Food Code at:
http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm

Food Preparation Practices

Thawing: Frozen foods must be thawed according to the Food Code, which allows 4 ways to thaw:

1. under refrigeration of 41°F or less (preferred method);
2. submerged under running water 70°F so that loose particles can float away;
3. through the cooking process; or
4. in a microwave as part of the cooking process.

Cooking: The cooking process is a critical step in controlling potential hazards associated with microorganisms. To kill microorganisms, all parts of the food must reach a sufficient internal food temperature and be held at that temperature for the specified time.

The Food Code prescribes specific times and temperatures for certain foods. The minimum internal food temperatures and times for holding at that temperature are:

135°F: fruits and vegetables cooked for hot-holding, meat and poultry prepared in USDA facilities that were cooked and cooled under USDA supervision

145°F for 15 seconds: raw eggs that are prepared for immediate consumption; solid portions of fish or meat including pork, and commercially raised game animals

155°F for 15 seconds: hamburger and other comminuted meats, fish, and game animals such as deer, elk, and rabbit; ratites; injected meats; and pooled, unpasteurized eggs.

165°F for 15 seconds: wild game animals; poultry; baluts, stuffed fish, meat, ratites; stuffing containing fish, meat, poultry or ratites or reheating TCS foods.

Microwave cooking procedures are also outlined in the Food Code and specify that raw animal foods should be:

- rotated or stirred throughout or midway of cooking to distribute heat through the food;
- covered to help retain moisture;
- heated to at least 165°F in all parts of the food; and
- allowed to stand for 2 minutes after cooking to obtain temperature equilibrium.

The cooking equipment and methods must be adjusted to achieve the desired safe cooking temperatures internally in the final product. The person preparing the food needs to know the required cooking time and temperature and what practices, such as oven temperature and placement of the food within the cooking equipment, are necessary to bring the food to the required temperature. A temperature measuring device should always be used to determine the internal food temperature.

Cooling Methods: Cooling foods from hot temperatures should be done as rapidly as possible and must not take more than 6 hours for all parts of the food to reach the required refrigeration temperature. The recommended time frames to achieve cooling within this 6-hour window are: 2 hours to cool foods from 135°F to 70°F and within a total of 6 hours to cool from 135°F to 41°F. Several methods of cooling are:

- Place the food in shallow pans;
- Separate the food into smaller or thinner portions;
- Use rapid cooling equipment;
- Stir the food in a container placed in an ice-water bath;
- Use containers that facilitate heat transfer, e.g., a metal pan allows food to cool faster than a plastic container; and
- Adding ice as an ingredient.

Reheating: Cooked, cooled foods must be reheated to 165°F for 15 seconds minimum if the food is to be held for hot-holding. Remember, all parts of the food being reheated must reach this temperature.

Time/Temperature Control for Safety (TCS) Food

Time/temperature control for safety (TCS) food is food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. The term does not include foods that do not support growth but may contain a pathogenic microorganism or chemical or physical food safety hazard at a level sufficient to cause foodborne illness or injury. The progressive growth of all foodborne pathogens is considered whether slow or rapid. **For more detailed time and temperature information, please refer to the current Food Code.**

Reduced Oxygen Packaging

Food that is reduced oxygen packaged (vacuum-packaged or modified atmosphere) at retail (restaurants and grocery stores) may be available for donation if removed from the reduced oxygen status by breaking the seal. See the definition of Reduced Oxygen Packaging in this resource.

Equipment

Various types of equipment are used in food operations ovens, steam kettles, food temperature holding equipment, temperature measuring devices (e.g., thermometers, thermocouples) sinks, warewashing machines, refrigerators, and freezers. Usually, additional equipment is necessary for transporting food from donor sites to the receiving facilities, e.g., insulated containers or refrigerated units for maintaining hot or cold temperatures of the food in transport.

Of particular importance to food recovery operations are temperature measuring devices, freezers, refrigerators, sinks, warewashing machines, and food temperature holding equipment.

Safe food depends not only on providing proper equipment of adequate capacity, but operating and maintaining the equipment properly. Foodhandlers need to be trained and must understand the role that cleaning (washing and rinsing) and sanitizing equipment and work stations plays in maintaining a safe operation. Vigilance in maintaining a clean work station and facility promotes hygienic work and food environments and limits the potential for cross contamination of food during preparation.

Maintaining Food Safety During Transportation

Loading for Transport

When food is ready for transport, it must be stored correctly to prevent the contamination of the food while simultaneously keeping the food at the proper temperature. Care must be taken to protect food from contaminants such as, insects, dust, dripping water, or other sources of contamination during transport to the receiving facility. Large batches of food should be separated into several

smaller, covered containers. Stack containers securely and do not pack temperature controlling units beyond their capacity.

Maintaining Food Temperature

Food must be kept hot or cold during transport. Food can be kept at the correct temperature provided the right equipment is available and used correctly. Cold foods be maintained at 41°F or less and hot foods at 135°F or higher. Consult the regulatory authority in your jurisdiction for examples of acceptable methods and temperature requirements for hot and cold holding of foods during transport.

When transporting food, use a visible, active (e.g., refrigerated vehicle) or a passive (e.g., insulated coolers, bags, blankets) temperature retention system for the safe transport of chilled food to maintain foods at no more than 41°F or hot foods at 135°F or above.

Cleaning of the Vehicle for Transport of Food

Vehicles used for transporting food for food recovery programs, whether private vehicles or commercial trucks, need to be routinely cleaned. Cleaning of the vehicle prevents cross-contamination and maintains a sanitary food environment. The interior of the vehicle and especially the section of the vehicle where food containers are stored must be clean and kept free of insects, dirt, animals, leakage and anything else that has the potential to biologically, chemically, or physically contaminate the food.

Receiving Food

Food should be received by a person who is responsible for ensuring that, if the food is not shelfstable or not immediately served to consumers, it is immediately refrigerated or correctly held for later service. It is important to conduct a timely inspection of incoming products and to isolate any suspect foods. See Appendix A for a guidance chart on accessing the food upon receipt.

Record Keeping for Food Safety

Written documentation provides a tracking system to establish accountability, continuously improve the process, spot potential problems, develop strategies for corrective action, ascertain training needs, and validate successful procedures. Donors and receiving facilities must keep records to accomplish these objectives and to maintain a system of checks and balances to document that the food is safely managed. Current and accurate recordkeeping is an essential part of any control system that ensures recipients are provided food that is safe and unadulterated. Also see Appendix B for sample monitoring forms for record keeping.

Emergency Readiness

Many unforeseen situations can occur in an operation that could compromise food safety and the ability to function. Natural disasters can cause disruption for less than a day or for as long as several months. Other disruptions, such as water, gas or power outages, may only be a hardship on the operation and not on the whole community. Finally any illnesses or injuries associated with food products maintained by the food donor or FDO may cause a disruption of operations and require an investigation and a product hold or recall. No matter the length or scope of the disruption, food safety must be a priority.

An emergency preparedness plan is critical to ensure the safety of food provided by food donors or FDOs. An effective emergency preparedness plan must meet the unique situation of the specific operation. Prior preparation, employee training and practicing activities will minimize the surprise element. A successful emergency preparedness plan will ensure the safe storage, production and service of food. A key part of developing and implementing an emergency preparedness plan is assembling a team to develop the plan and an Emergency Response Team (ERT) to oversee and coordinate activities. An ERT should consist of management level employees who are available to respond, manage, make decisions and institute actions that need to be taken in a timely manner.

Several steps will assure the success of the emergency preparedness plan. The plan development team should identify the ERT, construct a directory with contact information and specify the responsibilities of each member in the event of an emergency. To specify these responsibilities, potential disruptions should be determined and actions identified to deal with the disruptions. Identifying the ERT and specifying the actions for disruptions is the heart of the basic emergency preparedness plan. Staff and volunteers should receive training on the plan. Drills to practice the emergency actions should be conducted periodically, and the plan should be reviewed and updated on a regular basis. Also see Appendix D for emergency points of contact and a tool to maintain an updated list of contacts.

Food Recovery Program Responsibilities

A food distribution organization (FDO), as a food recovery participant, has responsibilities including the following:

- Comply with all applicable requirements of the State and/or local regulatory authority. If the jurisdictional regulatory authority does not inspect the program, the program should make a written request for at least an annual inspection.
- Examine, accept and store only those foods that have met the criteria as outlined in this document. See Appendix A chart for guidance on the assessment of donated foods on receipt.
- Implement a comprehensive safe food handling education and training program for all staff and volunteers, including transport drivers. Certification of key staff in safe food preparation and handling is one means to managing the food rescue staff in accordance with current food protection standards. It is recommended that at least one person at all times during operation be a certified professional food manager using an examination approved by the CFP.
- Educate all parties to ensure the food being picked up is safe and can be used to serve your clients. Food recovery programs are run on relationships. Essential to each program's success are the relationships that will develop between the FDOs, other donors and recipients. Make time to meet with all parties to discuss expectations for the program, prior to the start of pick-ups. This starts with working together with the donor to identify surplus food for donation.
- Implement an operational plan review and an ongoing self-inspection program and include, as a minimum: an initial physical plant inspection and at least an annual physical plant review to determine the ability and resources to receive, store, prepare, serve, or perform other food handling activities in compliance with the regulatory agency requirements.

Guidelines for Monitoring Programs

The purpose of this resource document, including the monitoring of facilities to determine if standards are in compliance, is to protect the health of the consumers being served. Use of this document as a resource may increase the confidence of all stakeholders (donors, regulatory authorities, contributors, consumers and a variety of supporters) that every effort is being made to serve a clean, safe product to hungry people, thereby minimizing the risk of foodborne illness.

Food recovery programs may be routinely monitored by the jurisdiction's regulatory agency. In such cases, there will be official inspection protocols and records to record observations, areas of noncompliance and remarks regarding corrections and enforcement.

For nonregulatory monitoring visits by peer reviewers or corporate food safety auditors, the terms and procedures should be in writing and agreed to by both sides. The agreement should include statements regarding:

- Access to the premises;
- Qualifications of the monitor/auditor;
- Procedures for dealing with minor and serious violations observed;
- Oral and written reports of findings during the monitoring visits;
- Specifications for corrective actions for violations observed;

Handling Donations of Wild Game Animals

Wild game may be donated as surplus. In addition to ranch or farm raised game animals that are slaughtered and processed under state inspection or a USDA voluntary inspection program, surplus wild game meat may be available at certain times of the year as a result of herd culling and through programs such as “Hunters for the Hungry.” Examples of wild game animals include mammals such as deer, reindeer, caribou, elk, moose, antelope, bison, rabbits, and squirrels. Other wild game donations may include certain kinds of migratory birds, fish and seafood. The benefit of utilizing wild game is that may provide a low-cost, readily available source of protein. If the meat is frozen, it can be distributed year round.

There is risk associated with wild game. It must be harvested, processed, stored, cooked and served following safe food handling practices to reduce risks posed by bacteria, viruses and parasites. Bacteria, such as *Salmonella* and *E. coli*, may contaminate the meat if the animal is not slaughtered, dressed, transported, and processed under sanitary conditions. Wild animal meat that is known to contain parasites, such as trichinae in bear and walrus, are not recommended for donation. Additionally, wild animals may also contain viruses or prions that can cause disease in humans.

Harvest, processing, donation, receipt, storage, preparation and service of wild game animals must comply with all applicable local regulations. Wild game animals must be legally harvested. While some states allow citizens to harvest and retain road-killed animals, donation of these animals is not recommended. Due to the potential extent of injury and damage to animals caused by vehicle collisions, salvage of meat from various types of animals cannot be adequately addressed in this document. Animals that have been poached or illegally harvested and have been recovered by a wildlife or other enforcement officer may be donated if there is a system in place that ensures the safety of the meat.

Donors must fully understand the requirements of the local donation program before harvesting the animal and presenting it for processing. These steps may include, but are not limited to:

- The maximum time allowed between harvesting and processing
- Requirements for field dressing
- The maximum donation size - whole carcass versus quarters
- Documentation required to be provided or available upon donation and written receipts for tax purposes
- Protection of the carcass during transportation
- Responsibility for processing costs
- Knowledge of which processors are participating in the local donation program

Information for Processors:

The processor must comply with and understand all applicable local regulations for harvesting and processing and of the donation program BEFORE participating in the program. These steps include, but are not limited to:

- Being properly licensed, and/or inspected, or meeting local regulations for exemption to process wild game
- Having a defined process of accepting and rejecting carcasses (examples for rejection may include, if the meat is over 41°F, the carcass is severely damaged, or has any signs of spoilage)
- Knowing what form(s) the recipient organization will accept the meat (whole cuts of meat versus only ground meat, or some combination of these). Further processing of the meat, such as curing, smoking, drying, fermenting or processing into other products, such as sausage, is not recommended and may not be allowed by local regulations.
- Providing appropriate packaging
    - The preferred or maximum package size
    - The preferred packaging material (freezer/butcher paper, secured plastic bags, vacuum packaging)
    - Most recipient organizations prefer to receive the meat frozen for ease in transportation, storage, distribution and to prevent cross-contamination
- Complying with any testing required by local regulations – for example, x-raying of meat taken with metal ammunition, or testing for animal diseases, prior to release of the meat for human consumption
- Labeling – the meat must be labeled to meet all local regulations. Some requirements may include:
    - Uninspected meat may be required to contain the words “NOT FOR SALE” on the label
    - Processing date
    - Processing location - business name, address
    - If applicable, the establishment processing license number, inspection mark and/or plant number
    - Safe food handling instructions:
        - Keep refrigerated or frozen. Thaw in refrigerator or microwave.
        - Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.
        - Cook thoroughly.
        - Keep hot foods hot. Refrigerate leftovers immediately or discard.

- Transport
    - Who is responsible for transporting the meat between the processing facility and the recipient organization
    - Methods to keep the meat cold (below 41°F or frozen) during transport

Information for Recipients:

Receipt

Organizations that receive the donated meat should have guidelines for accepting or rejecting deliveries. The temperature of the meat if it is fresh, should be 41°F or colder. If the meat is received in a frozen state, the packages should be solidly frozen with no evidence of thawing.

If your organization chooses to accept donations of wild game, verify that the local health authority permits donations of this nature.

Storage

There should be adequate refrigeration or freezer capacity to store the estimated volume of meats to be received.

Use

Nutrition information on game animals is available on the USDA National Nutrient Database for Standard Reference at http://ndb.nal.usda.gov/ by using the search function to find information on the species of interest.

Safe Food Handling

Wild game should be cooked to a minimum of 165°F for at least 15 seconds.

Planning for Food Defense

FDA Guidance for Industry: Food Producers, Processors and transporters: Food Security preventive measures guidance:

Food Defense is the effort of preventing intentional contamination of food products by biological, chemical, physical, or radiological agents that are not reasonably likely to occur in the food supply. New federal regulations (FSMA) urge companies to put controls in place to focus efforts on prevention rather than reaction.

The Food and Drug Administration has provided specific food defense information applying to the food industry. It can be accessed at the following link:

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083075.htm

For more information regarding FDA's Food Defense tools and resources, including the Vulnerability Assessment Software and Mitigation Strategies Database, please visit the following resources:

http://www.fda.gov/food/fooddefense/

*SOURCE: Food and Drug Administration, "Food Defense" http://www.fda.gov/food/fooddefense/. January 8, 2016. Web. January 8, 2016.

APPENDIX A Guidance Charts for Assessment of Food on Receipt

FOOD SAFETY GUIDANCE **For products donated directly by an approved donor as defined in "Food Donor Guidance"**

CHART: ASSESSMENT OF FOOD ON RECEIPT			
Food Products	Packaging	Storage Condition	NonAcceptable Conditions
Prepared Foods (Entrees, starches, side vegetables, chilled foods, homemeal replacements)	• Foodgrade packaging in direct contact with food. • Securely closed and separated by food type to avoid cross contamination. • Labeled and dated.	Chilled at no more than 41°F or frozen at 0°F or less.	• Previously reheated foods. • Foods kept in danger zone more than 2 hours. • Food previously served.
Chilled Perishable Prepackaged Foods (Orange Juice)	• Original packaging or foodgrade packaging for all repacked product.	Chilled at no more than 41°F.	• Foods kept in danger zone more than 2 hours. • Damaged or compromised packaging resulting in the loss of sanitary barrier protection. • Outside the "use by" date recommended from the manufacturer.
Meat, Poultry, Fish (Fresh product has a significant chance of leakage and potential cross-contamination therefore fresh animal proteins should be donated to a feeding program that is serving food immediately.)	• Original packaging. • Foodgrade packaging in direct contact with food. • Securely closed and separated by food type (e.g., beef, pork, poultry) to avoid cross contamination. • Labeled and dated as appropriate.	Chilled at no more than 41°F.	• Foods kept in danger zone more than 2 hours. • Nonfoodgrade packaging in direct contact with food.
Meat, Poultry, Fish (Frozen)	• Original packaging. • Foodgrade packaging in direct contact with food. • Labeled and dated as appropriate.	Frozen at 0°F or less.	• Defrosted product. • Damaged or compromised packaging resulting in discoloration of product. • Severe freezer burn.

APPENDIX A Guidance Charts for Assessment of Food on Receipt

CHART: ASSESSMENT OF FOOD ON RECEIPT			
Food Products	Packaging	Storage Condition	NonAcceptable Conditions
Unprocessed Meats (Donated Wild Game)	• Custom exempt or state or federally inspected plant. • Foodgrade packaging. • Labeled and dated with name of game, name and location of plant, “Not an Inspected Product,” “Keep Frozen,” “Cook to 165°F.”	Frozen at 0°F or less.	• Source • Labeling • Defrosted product.
Dairy Products	• Original packaging. • Foodgrade packaging in direct contact with food.	Chilled at no more than 41°F.	• Damaged or compromised packaging, resulting in the loss of sanitary barrier protection.

APPENDIX A Guidance Charts for Assessment of Food on Receipt

CHART: ASSESSMENT OF FOOD ON RECEIPT			
Food Products	Packaging	Storage Condition	NonAcceptable Conditions
Raw Shell Eggs (unpasteurized)	• Original packaging. • Foodgrade packaging in direct contact with food.	Chilled at no more than 41°F.	• Damaged or compromised packaging, resulting in the loss of sanitary barrier protection. • Cracked or broken eggs.
Fresh Produce (Whole)	• Original cartons and bags or foodgrade packaging for all repacked product.	Cool, dry, clean area.	• Significant decay.
Fresh Produce (Chopped)	• Foodgrade packaging securely closed with each vegetable or fruit packed	Chilled at 41°F.	• Food kept in danger zone more than 2 hours.
Frozen Foods (Entrees, starches, vegetables, fruit juices, baked goods)	• Original packaging or foodgrade packaging for all repacked product.	Frozen at 0°F or less.	• Defrosted product. • Damaged or compromised packaging, resulting in the loss of sanitary barrier protection. • Severe freezer burn.
Baked Goods (Fresh or dayold bread, bagels, and other bakery items.)	• Foodgrade packaging in direct contact with food. • Securely closed. • Bread products separately packaged from other baked foods.	Cool, dry, clean area.	• Stale products. • Mold. • Damaged or compromised packaging, resulting in the loss of sanitary barrier protection. • Not packaged in foodgrade packaging.
Prepackaged Foods Nonperishable (Canned)	• Fully intact <u>original cans</u> with labels that must show at a minimum: 1) Product identification 2) Ingredients 3) Net weight, and 4) Distributor 5) Food source for each major food allergen	Cool, dry, clean area.	• Opened, punctured, bulging, or serious can damage, including evidence of leakage, side seam dent, topseam dent, and/or significant rust. • Homecanned products.

APPENDIX A Guidance Charts for Assessment of Food on Receipt

CHART: ASSESSMENT OF FOOD ON RECEIPT			
Food Products	Packaging	Storage Condition	NonAcceptable Conditions
Prepackaged Foods Nonperishable (Shelf-stable boxed/packaged foods)	• Original packaging, boxes or cases. • Foodgrade packaging for all repacked foods. • Labels that must show at a minimum: 1) Product identification 2) Ingredients 3) Net weight, and 4) Distributor	Cool, dry, clean area.	• Opened, punctured, or damaged packing, resulting in the loss of sanitary barrier protection and/or unfavorable environmental exposure. • Damp or stained packages.

Illness

The purpose of this agreement is to assist foodhandlers and volunteers in food recovery operations in notifying the person-in-charge when experiencing any of the conditions listed below so that the person-in-charge can take appropriate steps to prevent the transmission of foodborne illness.

- I agree to report to the person-in-charge if I am experiencing any of the following symptoms: diarrhea, vomiting, jaundice, sore throat with fever, and exposed pus-filled lesions or draining wounds.
- I agree to report to the person-in-charge a future medical diagnosis of any of the following: hepatitis A, Norovirus, typhoid fever, non-typhoidal Salmonellosis, Shigellosis. enterohemorrhagic or shiga-toxin producing *Escherichia coli* (EHEC or STEC infection).
- I agree to report to the person-in-charge any future high-risk conditions such as:
    - Exposure to or suspicion of causing any confirmed outbreak of hepatitis A, Norovirus, typhoid fever, non-typhoidal Salmonellosis, Shigella spp., enterohemorrhagic or shiga-toxin producing *Escherichia coli* (EHEC or STEC infection).
    - A household member diagnosed with hepatitis A, Norovirus, typhoid fever, non-typhoidal Salmonellosis, Shigella spp., enterohemorrhagic or shiga-toxin producing *Escherichia coli* (EHEC or STEC infection).
    - A household member attending or working at a location that has experienced a confirmed outbreak of hepatitis A, Norovirus, typhoid fever, non-typhoidal Salmonellosis, Shigella spp., enterohemorrhagic or shiga-toxin producing *Escherichia coli* (EHEC or STEC infection).

The demonstration of symptoms as noted above and exposure to high-risk conditions as noted above may prevent my participation in acting in a capacity for the food distribution organization. I understand my responsibilities under this agreement to comply with:

1. Reporting requirements noted above involving symptoms, diagnoses, and high-risk conditions specified;
2. Work restrictions or exclusions that are imposed upon me; and
3. Correct hygienic practices.

_____ _____

Name of Foodhandler / Volunteer FDO Representative

Appendix C References

REFERENCE PUBLICATIONS

1. "FDA Food Code," US Food and Drug Administration, Web. 26 October 2015. http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm
2. " Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments - 2006," US Food and Drug Administration, 2006, Web. 26 October 2015. http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006811.htm
3. "Let's Glean! United We Serve TOOLKIT - 2010," US Department of Agriculture, Web. 26 October 2015. http://www.usda.gov/documents/usda_gleaning_toolkit.pdf
4. "Recovery/Donations," U. S. Department of Agriculture, Office of the Chief Economist, Web. 26 October 2015. http://www.usda.gov/oce/foodwaste/resources/donations.htm
5. "Food Waste: Feed Families, Not Landfills," Environmental Protection Agency, Web. 26 October 2015. http://www.epa.gov/foodscraps/fd-donate.htm
6. "Online Marketplace and Retail Food Safety Guidelines," Feeding America, Web. 26 October 2015. http://www.foodbankrockies.org/wp-content/uploads/Online-Marketplace-and-Retail-Food-Safety-Guidelines-July-10-20141.pdf
7. "ServSafe Food Handler Guide for Food Banks," National Restaurant Association, 2014 http://www.restaurant.org/News-Research/News/Guide-offers-tips-on-safe-handling-of-food-at-food
8. "Food Donation: A Restaurateur's Guide – 1997," National Restaurant Association, Web. 26 October 2015. http://infohouse.p2ric.org/ref/12/11907.pdf
9. "The Food Keeper - 2014," Food Marketing Institute, Web. 26 October 2015. http://www.fmi.org/industry-topics/consumer-affairs/food-keeper-food-storage-database
10. "Applications and Perceptions of Date Labeling of Food – 2014", Comprehensive Reviews in Food Science and Food Safety, Institute of Food Science, Web. 26 October 2015. http://onlinelibrary.wiley.com/doi/10.1111/1541-4337.12086/abstract

FOOD DEFENSE RESOURCES

11. "Guidance for Industry: Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance - 2007," US Food and Drug Administration, Web. 26 October 2015 http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm082751.htm
12. "Food Defense," US Food and Drug Administration, Web. 26 October 2015.FDA www.fda.gov/Food/FoodDefense
13. "Food Defense and Emergency Response," US Department of Agriculture, Web. 26 October 2015. www.fsis.usda.gov/wps/portal/fsis/to

EDUCATIONAL RESOURCES

14. http://03507d1.netsolhost.com/TrngWebsite/site/default.html
15. https://austintexas.gov/sites/default/files/files/Health/Environmental/Food_Donation_Guidelines-2.pdf
16. www.recyclingworksma.com/donate
17. www.foodrecoverynetwork.org

Appendix D
Sample Forms for Food Recovery Programs

- Product Temperature Log and Rejection Log
- Agency Receiving and Temperature Log
- Combined Agency Pickup and Delivery Temperature Log
- Refrigerated Storage Daily Temperature Log
- Thermometer Weekly Calibration Log
- Sample Labels

PRODUCT TEMPERATURE LOG AND REJECTION LOG

Donor name and location _____ Date _____

PRODUCT **At Pick-up at Donor** **(Take refrigerated product temperatures only)**	**Temp. @ pickup (<41°F)**	**Temp. Taken by**	**PRODUCTS NOT PICKED UP** a) **Temperature over 41°F.** b) **No label, ingredient list, allergen declaration.** c) **Packaging damaged.** d) **Product did not look or smell good.** e) **Other (Explain)**

1) Take product temperatures at random, not all products need to have their temperature taken.
2) Use an Infrared thermometer or place a digital thermometer probe between 2 packages;
3) Do not insert the thermometer probe into the product.
4) "Temp. Taken by" use the initials of the person taking the temperatures.
5) Use codes **a, b, c, d** for products you do not pick up; if using **e** then give an explanation.
6) Information on unaccepted products at pick-up needs to be discussed with the donor by the Agency not by the Volunteers at pick up.
7) Separate sheet should be used for each donor.
8) Keep these records for 2 years.

AGENCY RECEIVING AND TEMPERATURE LOG

Donor name and location _____ Date _____

Name of Product	Temp. @ delivery (< 41°F)	Temp. Taken by	PRODUCTS NOT ACCEPTED a) Temperature over 41°F. b) No label, ingredient list, allergen declaration. c) Packaging damaged. d) Product did not look or smell good. e) Other (Explain)

1. Take product temperatures at random, not all products need to have their temperature taken.
2. Use an Infrared thermometer or place a digital thermometer probe between 2 packages;
3. Do not insert the thermometer probe into the product.
4. "Temp. Taken by" use the initials of the person taking the temperatures.
5. Use codes **a, b, c, d** for products you do not pick up; if using **e** then give an explanation.
6. Information on unaccepted products at pick-up needs to be discussed with the donor by the Agency not by the Volunteers at pick up.
7. Separate sheet should be used for each donor.
8. Keep these records for 2 years.

COMBINED AGENCY PICKUP AND DELIVERY TEMPERATURE LOG

Donor name and location _____ Date _____

PRODUCT At Pick-up at Donor (Take refrigerated product temperatures only)	Temp. @ pickup (< 41°F)	Temp. @ delivery (< 41°F)	Temp. Taken by	PRODUCTS NOT PICKED UP a) Temperature over 41°F. b) No label, ingredient list, allergen declaration. c) Packaging damaged. d) Product did not look or smell good. e) Other (Explain)

1) Take product temperatures at random, not all products need to have their temperature taken.
2) Use an Infrared thermometer or place a digital thermometer probe between 2 packages;
3) Do not insert the thermometer probe into the product.
4) "Temp. Taken by" use the initials of the person taking the temperatures.
5) Use codes **a, b, c, d** for products you do not accept; if using **e** then give an explanation.
6) Agency needs to relay all product conditions back to the donor; not the "Out of temperature" concerns as that is an Agency transportation issue.
7) Separate sheet should be used for each donor.

8) Keep these records for 2 years.

REFRIGERATED STORAGE DAILY TEMPERATURE LOG

Cooler/Freezer Number_____ Month_____ Year_____

Date.	Temperature F	Taken by.	Date	Temperature F	Taken by.
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

Use a different log for each freezer and for each cooler.

1) "Temp. Taken by" use the initials of the person taking the temperatures.
2) Temperatures need to be taken daily if Agency is open; when not write in space "Closed".
3) Do not take daily temperatures when the unit is in defrost cycle or constantly being opened.
4) Records should have no blanks and need to be done in ink with no white out used. If mistake is made neatly cross out wrong number and write correct number beside it so both numbers are readable.
5) Record Corrective Actions taken when freezer is over 0F and Cooler is over 41°F on the back of this recording form.
6) Keep these records for 2 years.

THERMOMETER WEEKLY CALIBRATION LOG

Food Bank/Agency/Serving Site _____ Week ending _____ Year_____

Thermometer number	Thermometer location	Temperature using Ice/water mixture in F (below 32F acceptable)	Calibration done by	Corrective Action taken (If required) A =Adjusted; D=Discarded.

1) All thermometers (Digital, Infrared and in Coolers/Freezers) need to be checked weekly.

2) Assign a number to each thermometer and where it is located.
(i.e. In a cooler/freezer; assigned to an in-house person; assigned to a driver/volunteer who picks up the food).

3) "Calibrated by" use the initials of the person performing the thermometer temperature checks.

4) Records should have no blanks and need to be done in ink with no white out used.

5) Record Corrective Actions taken as either A (Adjusted) or D (Discarded); leave this column blank if no action needed.

Keep records for 2 years

DONOR NAME AND LOCATION	Ex: **ABC Restaurant 1234 main St, Dallas, TX**
FOOD CHARITY NAME AND LOCATION	Ex: **XYZ Shelter 5678 Main St, Dallas, TX**
FOOD DESCRIPTION (MENU DESCRIPTION):	Ex: **Black Bean Burger**
DATE OF DONATION:	Ex: **11/02/2015**
WARNING! This container holds rescued food! This food may contain, have come into contact with, or have been produced in a facility which also produces milk, eggs, peanuts, tree nuts (walnuts, almonds, pecans, hazelnuts/filberts, pistachios, cashews, coconuts, pine nuts, macadamia nuts, and/or Brazil nuts), fish, shellfish (crab, crawfish, lobster, shrimp, mussels, and/or oysters), wheat, and / or soybeans.	

DONOR NAME AND LOCATION	
FOOD CHARITY NAME AND LOCATION	
FOOD DESCRIPTION (MENU DESCRIPTION):	
DATE OF DONATION:	
WARNING! This container holds rescued food! This food may contain, have come into contact with, or have been produced in a facility which also produces milk, eggs, peanuts, tree nuts (walnuts, almonds, pecans, hazelnuts/filberts, pistachios, cashews, coconuts, pine nuts, macadamia nuts, and/or Brazil nuts), fish, shellfish (crab, crawfish, lobster, shrimp, mussels, and/or oysters), wheat, and / or soybeans.	

Committee Name: 2014 - 2016 Food Recovery Committee								
Last Name	First Name	Position	Constituency	Employer	City	State	Telephone	Email
Ball	James	Member	Retail Food Industry	Walmart	Bentonville	AR	(479) 802-8816	james.ball@wal-mart.com
Baum	Mitzi	Member	Food Service Industry	Feeding America	Chicago	IL	(312) 641-6842	mbaum@feedingamerica.org
Belmont	Jeff	Member	Food Industry Support	National Registry of Food Safety Professionals	Orlando	FL	(407) 352-3830	jbelmont@nrfsp.com
Davis	Eric	at-large	Food Service Industry	Feeding America	Golden	CO	(312) 641-6835	edavis@feedingamerica.org
Deitzel	Diane	at-large	Food Service Industry	Sheetz Inc.	Claysburg	PA	(814) 239-1531	ddeitzel@sheetz.com
Edsall	Jean	Member	Food Service Industry	Compass Group	Charlotte	NC	(330) 401-1143	jean.edsall@compass-usa.com
Eskin	Sandra	Member	Food Service Industry	Pew Charitable Trust	Washington	DC	(202) 540-6407	seskin@pewtrusts.org
Greco	Darby	Member	State Regulator	New York State Department of Health	Albany	NY	(518) 402-7600	djg11@health.state.ny.us
Hancock	Roger	Member	Food Industry Support	Recall Info Link	Boise	ID	(208) 284-1508	roger.hancock@recallinfolink.com
Hodge	Lori	at-large	Retail Food Industry	BiLo Holdings	Baldwin	FL	(904) 266-8029	lorihodge@biloholdings.com
Johnson	Adam	Member	Retail Food Industry	Ecolab	Greensboro	NC	(479) 418-3235	adam.johnson2@ecolab.com
Lamborn	Kim	Member	Retail Food Industry	WinCo Foods	Boise	ID	(208) 672-2332	kim.lamborn@wincofoods.com
Marcy	John	Co-Chair	Academia	University of Arkansas	Fayetteville	AR	(479) 575-2211	jmarcy@uark.edu
Marlow	Deborah	Member	Local Regulator	Williamson County and Cities Health District	Georgetown	TX	(512) 943-3620	dmarlow@wcchd.org
Martin	Charles	Member	Food Service Industry	Ahold USA	Boston	MA	(914)251-2807	Charles.Martin@ahold.com
Martin	David	Member	State Regulator	Oregon Health Authority	Portland	OR	(971) 673-3283	david.c.martin@state.or.us
McGuffey	Charles	at-large	Food Service Industry	7-Eleven Corporate	Dallas	TX	(972) 828-6844	charles.mcguffey@7-11.com
McKinley	Susie	Co Chair	Food Service Industry	Florida Restaurant and Lodging Association	Tallahassee	FL	(850) 224-2250	susie@mckinleyhome.com
Melchert	Chris	Member	Food Service Industry	National Restaurant Association	Washington	DC	(202) 973-3960	cmelchert@restaurant.org
Mellichar	Wayne	at-large	Food Service Industry	Feeding America	Chicago	IL	(312) 629-7263	wmelichar@feedingamerica.org
Mello	Wayne	at-large	Retail Food Industry	Delhaize America/Hannaford	Scarborough	ME	(207) 885-2126	wamello@hannaford.com
Moore	Eric	Member	Retail Food Industry	ACME Markets	Malvern	PA	(610) 889-4005	eric.moore@acmemarkets.com
Oswald	Steve	at-large	Retail Food Industry	Wakefern Food Corporation	Elizabeth	NJ	(908) 527-3624	steve.oswald@wakefern.com
Pasley	Dianna	at-large	Retail Food Industry	Schnuck Markets, Inc.	St. Louis	MO	(314) 994-4346	dpasley@schnucks.com
Pohjola	Carrie	Member	State Regulator	State of WI-DHS	Madison	WI	(715) 579-9487	carrie.pohjola@wi.gov
Roberson	Michael	Member	Retail Food Industry	Publix Super Markets, Inc.	Lakeland	FL	(863) 688-1188	michael.roberson@publix.com
Smith	Aaron	at-large	Retail Food Industry	Ahold USA	Assonet	MA	(508) 977-5201	aaron.smith@stopandshop.com
Spriggs	Sherry	Ex-officio	Federal Regulator	FDA/CFSAN/OFS	College Park	MD	(240) 402-1876	sherry.spriggs@fda.hhs.gov
Sturdivant	Steven	Ex-officio	Regulator	EPA	Dallas	TX	(214) 665-6673	sturdivant.stephen@epa.gov
Wagner	Jim	Member	Retail Food Industry	McClement Management Group	Wheaton	IL	(630) 789-7228	jimwagner123@gmail.com
Williams	Janet	Ex-officio	Federal Regulator	FDA/ORA/DHRD	Rockville	MD	(301) 796-4534	Janet.Williams@fda.hhs.gov
Wilson	Nancy	Member	Food Service Industry	Wawa Inc.	Media	PA	(610) 812-3934	nancy.wilson@wawa.com
Zimmerman	John	Member	Food Service Industry	Sysco	Nashville	TN	(615) 350-1976	zimmermann.john@corp.sysco.com

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-012

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

FRC 2 - Comprehensive Resource for Food Recovery Programs

Issue you would like the Conference to consider:

The 2014 Biennial Meeting re-created the retired Food Recovery Committee via Issue 2014-I-035 and charged the committee to review and revise the Comprehensive Guidelines for Food Recovery Programs document (currently posted on the CFP web site) and report back its recommendations to the 2016 CFP Biennial Meeting

Public Health Significance:

The previous version of this document was 2007 and a revision was needed.

Recommended Solution: The Conference recommends...:

1. Approval of the Food Recovery Committee document titled *Comprehensive Resource for Food Recovery Programs*, including appendices (attached to Issue titled: Report-Food Recovery Committee); and
2. Posting the approved document in PDF format on the CFP website, replacing the previous document *Comprehensive Guidance for Food Recovery Programs* (2007).

Submitter Information 1:

Name:	John Marcy
Organization:	Food Recovery Committee Co-Chair
Address:	University of ArkansasO-203 POSC
City/State/Zip:	Fayetteville, AR 72701
Telephone:	(479) 575-2211
E-mail:	jmarcy@uark.edu

Submitter Information 2:

Name:	Susie McKinley

Organization: Food Recovery Committee Co-Chair
Address: Florida Restaurant and Lodging Association
City/State/Zip: Tallahassee, FL 00000
Telephone: (850) 508-1139
E-mail: susie@mckinleyhome.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-013

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Report - Unattended Food Establishment Committee (UFE)

Issue you would like the Conference to consider:

The 2014 Conference Issue 2014-I-019 created the Unattended Food Establishment Committee and charged the committee with three goals:

1. Develop recommendations on whether and how the Food Code should be modified to address unattended food merchandising operations,
2. Continue to review the "Guidance Document for Unattended Food Establishments" and any existing guidance from FDA and others to update the CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet section 2-101.11 and 2-103.11 of the 2013 Food Code, and
3. Report back at the 2016 Biennial Meeting with a recommendation to Council I.

Public Health Significance:

This committee work was essential to address an increase in the scope and number of unattended food establishments across the country. These three charges were critical to understanding the proper approach for the Conference for Food Protection to consider when addressing these new facilities.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the 2014 - 2016 Unattended Food Establishment Committee final report, and
2. Thank the committee members for their work and efforts on the committee.

Submitter Information:

Name: Chris Gordon, Council I Chair, on behalf of UFE Committee

Organization: Virginia Department of Health
Address: 109 Governor Street13th Floor-Office of the Commissioner
City/State/Zip: Richmond, VA 23219
Telephone: 804-864-7011
E-mail: Christopher.Gordon@vdh.virginia.gov

Content Documents:

- "UFE Final Report"
- "Unattended Food Establishment Committee Roster"
- "Guidance Document for Unattended Food Establishments"

Supporting Attachments:

- "FDA Unattended Food Service Establishments"
- "PIC Duties Unattended Food Service Establishments"
- "NAMA Technical Bulletin-Micro Markets"

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: Unattended Food Establishments

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council I

DATE OF REPORT: January 29, 2016 (Rev 2/11/16)

SUBMITTED BY: Co-Chairs Ric Mathis and Larry Eils

COMMITTEE CHARGE(s): Unattended Food Establishments Issue 2014-I-019

1. Develop recommendations on whether and how the Food Code should be modified to address unattended food merchandising operations.
2. Consider any existing guidance from FDA and others and develop a CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet section 2-101.11 and 2-103.11 of the 2013 Food Code.
3. Report back at the 2016 Biennial Meeting with a recommendation to Council I.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

   The committee's activity began by the Co-chairs emailing the committee information describing and depicting micro markets and their operation in order to familiarize them with this new type of food service. (See attachment "NAMA Technical Bulletin Micro Market" November 2012). After several very productive email meetings, our first conference call was held on February 12, 2015. The committee had a great deal of meaningful discussion. A consensus was reached regarding the initial approach to Food Code Section 2-101.11 in that these establishments would not be required to have a person-in-charge present during all hours of operation.

   Next, the committee sought to develop a name for this type of operation. A lengthy discussion followed about how the operation should be characterized/defined. It was agreed that the Co-chairs along with a sub-committee would use existing information from Indiana (Guidance for Regulation of "Micro Markets" June 6, 2013) and Ohio (3717 Ohio Uniform Food Safety Code, OAC 3717-1-01) and other available resources to develop a composite definition to be discussed during the next call. The agreed upon name was Unattended Food Establishment. Using the composite definition as a template, the committee developed its final definition which is as follows:

   > Unattended Food Establishment means an operation that provides packaged foods or whole fruit using an automated payment system; and has controlled entry not accessible by the general public.
   > Controlled Entry means selective restriction or limitation of access to a place or location.

   After reviewing existing guidance from FDA and other jurisdictions, the committee identified those components or activities indicative of an establishment of this type which were not in the Food Code. These activities were: definitions, plan review, location, nature and source of food and beverages offered for sale, refrigerated display cases, food service equipment limitations, security, routine maintenance, oversight, and designation of responsibilities.

Another sub-committee reviewed Food Code Section 2-103.11 *Person-In-Charge* (PIC) Items (A) through (O) to determine the food safety risk levels of the various responsibilities of the PIC listed in this Section relating to Unattended Food Establishments. (See attached "Person in Charge Duties Unattended Food Service Establishments") It was determined that Item (E) of this attachment was the only activity with a medium risk level for this type of operation if there was no person in charge present. All other designated responsibilities of the Person in Charge were deemed a low or no risk with regards to the operation of an Unattended Food Establishment.

> 2-103-11 Person in Charge (E) Employees are visibly observing FOODS as they are received to determine that they are from Approved sources, delivered at the required temperatures, protected from contamination, UNADULTERED, and accurately presented, by routinely monitoring the EMPLOYEES' observations and periodically evaluating FOODS upon their receipt.

In an Unattended Food Establishment operation the route driver is responsible for the following activities: obtain the food from an approved source (company kitchen or commercial product); maintain the food at 41 F or below from receipt, during transportation and placement in the display refrigerator at the location; all food must be pre-packaged; and all food must be protected from potential sources of contamination from receipt, transportation and their final display at the location. Item (E) covers all these activities done by the route driver.

The committee agreed that Unattended Food Establishments should be addressed in the Food Code and initially sought to identify where and how the Food Code should be modified. However, given the charge of the committee and available time, the members elected to focus on developing a guidance document that could assist state and local agencies when considering the regulation of Unattended Food Establishment. This document contains recommended minimum requirements when approving a waiver or variance for the operation of an Unattended Food Establishment. (See attached "Guidance Document for Unattended Food Establishments") This guidance document completes the second charge given to the committee.

Throughout the committee's work our FDA advisors provided input regarding possible concerns for an operation without a person-in-charge. At the same time they answered the many questions raised by the committee concerning how various sections of the Food Code related to items being included in the guidance document. See attached Memo to FDA National Retail Food Team 12/12/1024 as one example.

2. Recommendations for consideration by Council:
   The Co-chairs, on behalf of the members of the Conference for Food Protection Unattended Food Establishment Committee, recommends:
   1. Acknowledging the work of the Unattended Food Establishment Committee; and
   2. Re-creating the Unattended Food Establishment Committee following the CFP 2016 Biennial Meeting to develop a guidance document and recommendations on how the Food Code should be modified to address Unattended Food Establishments and present their findings at the 2018 CFP Biennial Meeting.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Issues to be submitted:
    a. Title: Report - Unattended Food Establishments

    b. Title: Re-create - Unattended Food Establishments
    Re-creating the Unattended Food Establishment Committee following the CFP 2016 Biennial Meeting to continue the charges assigned in Issue I-019 and:

        1. Develop recommendations on how the FDA Food Code addresses Unattended Food Establishments;

        2. Continue to review the “Guidance Document for Unattended Food Establishments” and any existing guidance from FDA and others to update the CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet section 2-101.11 and 2-103.11 of the 2013 Food Code;

        3. Present their findings at the 2018 CFP Biennial Meeting.

    c. Title: Guidance Document for Unattended Food Establishments

        1. Approval of the Unattended Food Establishment Committee document titled *Guidance Document for Unattended Food Establishments*

        2. Posting the approved document in PDF format on the Conference for Food Protection website.

COMMITTEE MEMBER ROSTER (attached):

Committee Name:

CFP Unattended Foodservice Establishment 2014-16

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Acquista	Robert	Member	Local Regulator	Columbus, OH	Columbus	OH	(614) 371-8773	aacquist@columbus.rr.com
Anderson	Timothy	Member	State Regulator	Wi Ag Dept	Madison	WI	(608) 224-4716	timothy.anderson@wi.gov
Bacon	Brenda	Member	Retail Food Service	Harris Teeter	Matthews	NC	(704) 844-4443	bbacon@harristeeter.com
Balli	Petra	Member	Vending & Distrib.	Aramark	Philadelphia	PA	(215) 413-8745	balli-petra@aramark.com
Branch	Thomas	Member	Retail Food Service	Publix	Marietta	GA	(770) 952-6601 x3663	mac.branch@publix.com
Brizes	Donald	Member	Academic	Johnson & Wales	Charlotte	NC	(980) 598-1481	don.brizes@jwu.edu
Edsall	Jean	Member	Vending & Distrib.	Compass	Charlotte	NC	(330) 401-1143	jean.edsall@compass-usa.com
Eils	Larry	Co-Chair	Vending & Distrib.	NAMA	Chicago	IL	(815) 382-5347	rpeonygarden@gmail.com
Gilliam	Scott	Member	Retail Food Service	Meijer Foods	Grand Rapids	MI	(616)249-6034	scott.gilliam@meijer.com
Grego	Susuan	Member	Vending & Distrib.	Microbac	Pittsburg	PA	412-459-1054	susan.gregro@microban.com
Higley	Jamie	Member	State Regulator	Ohio Dept Health	Columbus	OH	(614) 644-8659	jamie.higley@odh.ohio.gov
Kowalczyk	Suzan	Member	Local Regulator	DuPage County Health Dept	Wheaton	IL	630-221-7396	skowalcz@dupagehealth.org
Krzyzanowski	Rebecca	Member Ad Hoc	State Regulator	MI Dept Ag+E16	Lansing	MI	(517) 719-7919	krzyzanowskir@michigan.gov
Liggans	Girvin	Member Consultant	Consultant	FDA	College Park	MD	240-402-1382	girvin.liggans@fda.hhs.gov
Marlow	Deboral	Member	Local Regulator	Williams CO TX	Georgetown	TX	(512) 943-3620	dmarlow@wcchd.org
Mathis	Ric	Co-Chair	State Regulatory	FL Dept of Health	Tallahassee	FL	(850) 245-4444 x2337	ric.mathis@flhealth.gov

Committee Name:

Narvaez	Nona	Member	Consumer	AFFA	St Paul	MN	(651) 644-5937	nona@minnesotafoodallergy.org
O'Neal	James	Member	Retail Food Service	Delhaize America+E23	Salisbury	NC	(704) 633-8250	james.o'neal@delhaize.com
Patel	Jaymin	Members	Vending & Distrib.	Aramark	Philadelphia	PA	(215) 409-7343	patel-jaymin@aramark.com
Powell	Terrance	Member	Local Regulator	LA County Health	Baldwin Park	CA	(626) 430-5330	tpowell@ph.lacounty.gov
Puente	Eric	Member	Retail Food Service	Whole Foods Markets	Austin	TX	(512) 415-6617	eric.puente@wholefoods.com
Saunders	Doug	Member	Food Industry Support	Coca Cola	Atlanta	GA	(404) 676-5229	ricsaunders@coca-cola.com
Sparks	Christopher	Member At-large	State Regatory	Texas Dept of Health	Austin	TX	(512) 834-6770 x2303	christopher.sparks@dshs.state.tx.us
Steiner	Rebecca	Member	Local Regulator	Kansas City	Kansas City	MO		rebecca.steiner@kcmo.org
Walker	Cynthia	Member	State Regulator	FL Dept Bus	Tampa	FL	(813) 748-9721	cynthia.walker@myfloridalicense.com
Wanucha	Donna	Member Consultant	Alternate Consultant	FDA	College Park	MD	678-616-6500	donna.wanucha@fda.hhs.gov
Whiting	Kelli	Member	Local Regulator	Marion CO IN	Indianapolis	IN	(317) 221-2256	kwhiting@hhcorp.org

Guidance Document
For
Unattended Food Establishments

Prepared by the
Unattended Food Establishment Committee
Conference for Food Protection 2014-2016

Preface

Council I of the Conference for Food Protection (CFP) formed the Unattended Food Establishment Committee which was charged to:

(A) Develop recommendations on whether and how the Food Code should be modified to address unattended food merchandising operations.

(B) Consider any existing guidance from FDA and others and develop a CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that no not meet section 2-101.11 and 2-103.11 of the Food Code.

(C) Report back to the 2016 Biennial Meeting with a recommendation to Council I.

Charge No. 1: Upon completion of the guidance document the Committee was unsure as to where to place the proposed requirements for an unattended food establishment in the Food Code. The proposed requirements cover a number of different sections of the Food Code and some requirements, such as video surveillance, have never been addressed in the Food Code.

Charge No. 2: The CFP Unattended Food Establishment Committee recommends that this information be placed on the CFP website for use as a guidance document. This document is intended to assist regulatory authorities and the foodservice industry in the review, approval and operation of unattended food establishments.

Introduction

A recent innovation in retail operations is the “unmanned food establishment”. This type of operation is typically located in office buildings or restricted break areas where access by the general public is somewhat restricted. While a wide variety of food items may be provided, these operations frequently offer packaged TCS and non-TCS food products that are displayed via refrigeration units, food racks, baskets and/or countertop display units. “Unmanned food establishments” may also be equipped with microwave ovens or offer automatically dispensed hot and cold beverages. The one common characteristic of these operations is that they lack the presence of an onsite person-in-charge.

As these operations have been observed, various jurisdictions have identified them by a variety of names including, but not limited to, micro-markets, self-service food markets and self-service retail convenience stores. Since this type of establishment is not specifically addressed in the FDA 2013 Food Code, impacted jurisdictions have found it necessary to individually address licensing requirements. Except where otherwise indicated in the document, the requirements of the Food Code for food establishments shall apply. For purposes of this guidance document below, such operations will be referred to as Unattended Food Establishments.

The 2014 Conference for Food Protection Biennial Meeting established the “Unattended Food

Establishment Committee" which was tasked to develop a CFP guidance document that could assist states and locals agencies in their regulation of these new entities. The committee proposes the following requirements need to be in place to allow the operation of an unattended food establishment:

Minimum Requirements for an Unattended Food Establishment

A) Definitions

(1) Unattended Food Establishment means an operation that provides packaged foods or whole fruit using an automated payment system; and has controlled entry not accessible by the general public.

(2) Controlled Entry means selective restriction or limitation of access to a place or location.

B) The plan review and food safety operating permit shall be in accordance with the requirements of the local authority having jurisdiction.

C) Unattended Food Establishment Location

(1) The unattended food establishment shall be located in the interior of a building that is not accessible by the general public. Access to the unattended food establishment shall be limited to a defined population (e.g., employees or occupants of the building where the establishment is located).

D) Nature and Source of Food and Beverages Offered for Sale

(1) Only commercially packaged foods properly labeled for individual retail sale (per Food Code definition of packaged and labeled per section 3-201.11(C) are offered).

(2) No unpackaged food is permitted except as provided by section 3-302.11(B) (1), of the Food Code.

(3) Food preparation by consumers is limited to heating/reheating food in a microwave oven.

(4) No dispensing of bulk food.

E) Refrigerated Display Equipment

(1) An unattended food establishment shall be equipped with refrigeration or freezer units that have the following features:

(a) Self-closing doors that allow food to be viewed without opening the door to the refrigerated cooler or freezer; and

(b) Automatic self-locking mechanism that prevents the consumer from accessing the food upon the occurrence of any condition that results in the failure of the refrigeration unit to maintain the internal product temperature specified under section 3-501.16(A) (2) or freezer unit to maintain the product frozen.

F) Food Service Equipment Limitations

(1) Dispenses beverages by individual serving only.

(a) Beverage dispensers connected to the building water supply must be properly equipped with backflow prevention per section 5-203.14, of the Food Code.

(2) Food Contact Surfaces

(a) Multi-use food-contact surfaces shall be cleaned on the frequency consistent with the service per section 4-202. 11, of the Food Code or can be easily removed and replaced with cleaned surfaces.

(b) No multi-use food-contact surfaces intended for use with TCS foods.

G) Security

(1) An unattended food establishment shall provide continuous video surveillance of areas where consumers view, select, handle and purchase products that provides sufficient resolution to identify situations that may compromise food safety or food defense.

(a) Video surveillance recordings shall be maintained and made available for inspection upon request by a representative of a regulatory agency within 24 hours of a request.

(b) Video surveillance recordings shall be held by the establishment for a minimum of fourteen (14) days after the date of the surveillance.

(2) The permit holder takes reasonable steps necessary to discourage individuals from returning food and/or beverages that not have been selected for purchase.

H) Routine Maintenance at an Unattended Food Establishment:

(1) The permit holder shall service the unattended food establishment on a scheduled basis and at a frequency acceptable to the regulatory agency. Service may include, but is not limited to the following:

(a) Checking food supplies and equipment for signs of product damage and/or tampering.

(b) Verifying refrigeration equipment is operating properly including the temperature display and self-locking mechanism.

(c) Rotating foods to better ensure first in/first out of food items.

(d) Cleaning food service equipment and food display areas.

(e) Stocking food and disposable single-use and single-service supplies.

(f) Checking inventory for recalled foods.

(2) Permit holder shall assure:

(a) Food is from an approved source.

(b) Packaged food is provided in tamper-evident packaging.

(c) Food is protected from potential sources of cross contamination.

(d) Food is maintained at safe temperatures during transport and display.

I) Unattended Food Establishment Oversight

(1) Each unattended food establishment shall have a sign readily visible at the automated payment station stating:

(a) The name and mailing address of the business entity responsible for the establishment and to whom complaints and comments should be addressed.

(b) The telephone, email or web information for the responsible business entity, when applicable.

J) Designation of Responsibilities:

(1) The permit holder bears all responsibilities for the operation of the food establishment. Where the permit holder is not the owner or operator of the building where the food establishment is located, a mutual agreement that outlines the responsibilities for cleaning and maintenance of all surfaces and equipment, provision of supportive facilities/services such as janitorial and restroom facilities, pest control and removal of solid waste may be approved by the regulatory agency. This agreement should also outline what actions must be taken by both parties to maintain the establishment in compliance with all requirements.

To: FDA National Retail Food Team
From: Director, Retail Foods and Cooperative Program Coordination Staff - CFSAN
Date: 12/12/2014
Re: Considerations for Permitting Unattended Food Establishments

At the 2014 Biennial Meeting in Orlando, the Conference for Food Protection established an *Unattended Food Establishments Committee (see Issue 2014-I-019)*. The Committee is charged with reporting back to the 2016 meeting with recommendations on "*whether and how the Food Code should be modified to address unattended food merchandising operations*" and to "*consider existing guidance from FDA and others and develop a CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet Sections 2-101.11 and 2-103.11 of the 2013 Food Code."* FDA has appointed a member (Girvin Liggans) and an alternate (Donna Wanucha) to that Committee. We anticipate that the Committee will fulfill its charge and provide sound recommendations to CFP for consideration at the 2016 biennial meeting. FDA will consider all recommendations from the CFP.

Currently, Part 2-1 of the FDA Food Code requires that a food establishment have an appropriate person-in-charge present during all hours of operation. The FDA Food Code does not define specific criteria for the safe operation of unattended food merchandising operations other than those that apply to vending machine locations.

With regard to the potential changes to the Food Code and/or the development of guidance documents for regulatory authorities considering the issuance of a variance or waiver (to Sections 2-101.11 and 2-103.11 of the 2013 Food Code) for unattended food merchandising operations, FDA is recommending that the *CFP Unattended Food Establishments Committee* consider a number of characteristics of unattended food establishments that could impact food safety. FDA is requesting that the Committee consider what, if any, criteria for safe operation should be established with regard to:

1. **The nature and source of food and beverages being offered for sale**
   Food safety risks are dependent on the types of foods being offered for sale. Considerations include:
   - Extent to which sales are limited to packaged foods
   - Extent to which sales are limited to commercially prepared foods
   - Extent to which sales are limited to foods that do not require temperature control for safety
   - Extent to which foods may require on-site preparation by the customer
   - Extent to which foods that are date-labeled for safety or quality are merchandised

2. Display equipment and facility design

The nature of the equipment and the facility design may impact food safety risks. Considerations include:

- Extent to which display equipment is designed and constructed to limit customer access to TCS foods that have been subject to temperature abuse as the result of mechanical failure or other unintended condition
- Extent to which equipment requires connection to a water supply or wastewater connections
- Size and mobility of equipment used in the establishment
- Overall size of the operation
- Availability of seating and other facilities (e.g. restrooms, sinks) for use by customers in the establishment

3. Facility location, oversight and security

The nature of customer access to the location and the level of oversight provided by the operator and others may impact food safety risks.

Considerations include:

- Extent to which the facility is located in a "controlled location" such that access to the food establishment is restricted to a defined group of individuals (e.g. places of employment)
- Extent to which the permit holder or designee is available to service the site, the frequency at which the individual will assess food safety and sanitation and how the permit holder is alerted to problems in the facility that may warrant an immediate response
- Extent to which individuals, including those who may not be employed by the permit holder, are available and authorized to take action if a potential food safety hazard is created in the food establishment (e.g., food spills, cross contamination, vomiting)
- Extent to which surveillance is provided to detect and/or discourage intentional or unintentional acts that may create a food safety hazard
- Extent to which the location is protected from exposure to the outdoors or uncontrolled environments.

Please note that regulatory authorities in some states have already established requirements, either via rulemaking or policy directives, to better define the conditions under which self-service food merchandising operations may operate without the presence of an employee.

Person in Charge as it relates to Unattended Food Service Establishments - October, 2015

2-103.11	Duty of the Person-In-Charge	Applicable to Unattended Market?	Risk Level	Action, Prevention, or Reduction of Risk
(A)	Food operations not conducted in private home, living or sleeping quarters	No		Prepackaged food obtained from commercial, licensed suppliers
(B)	Persons unnecessary to operation are not allowed in food preparation area	No		All foods prepackaged. No food production at unattended market. Only "open" food may be beverages dispensed into a single-use cup.
(C)	People entering the food preparation, storage and warewashing areas comply with the Code.	No		Food is not prepared on-site. Food is stored in secured areas (locked cabinets) or on display in area under continuous electronic surveillance. Entry to unattended market is secured. Warewashing is not done at the unattended market.
(D)	Employees are effectively cleaning their hands. PIC is routinely monitoring the employees' handwashing.	Yes	Low	All food is prepackaged. Hand contact with any food contact surface can be eliminated or minimized. Filling single-service, disposable article dispensers (coffee cups, coffee stirrers, straws) may be accomplished with gloved hands or by using the plastic sleeve wrapping on the cups.
(E)	Employees are visibly observing foods as they are received for • Approved source • Delivered at required temperatures • Protected from contamination • Unadulterated • Accurately presented PIC is to routinely monitor employee observations and periodically evaluate food upon receipt	Yes	Medium	Food is obtained from a safe source (vending branch, commercial, licensed suppliers). Route driver/merchandiser must protect the cold chain of the food from receipt, during transportation, and to the display refrigerator. All foods must be pre-packaged (tamper-resistant or tamper-evident packaging). All foods must be protected from all potential sources of contamination from receipt, transportation and storage.

				All packages of food must be properly labeled for individual retail sale. In all likelihood, the route driver/merchandiser is the person in charge and will not be evaluating other employees.
(F)	Verifying that foods delivered during non-operating hours are from approved sources and are placed into appropriate storage locations, maintained at the required temperatures, protected from contamination, unadulterated, and accurately presented	No		N/A Food is not drop shipped at unattended markets. All food is delivered by the route driver/merchandiser.
(G)	Employees are properly cooking TCS foods and using thermometers	No		N/A Food is not cooked at the unattended market
(H)	Employees are properly cooling TCS foods	No		N/A TCS foods are not prepared using a cooling step at the unattended market
(I)	Consumer advisory is provided	Yes	Low	Any raw animal foods offered for sale (prepackaged sushi) must be properly labeled, including the consumer advisory statement on the individual package label.
(J)	Employees are properly sanitizing cleaned multi-use equipment and utensils before they are reused	Maybe	Low	(1) No multi-use utensils or equipment allowed OR (2) any multi-use utensils or equipment is cleaned and sanitized on a frequency in compliance with applicable sections of the Food Code (either Clean-In-Place or parts are removed during the service visit and replaced with clean parts – soiled parts are properly washed-rinsed-sanitized at the vending branch location)
(K)	Consumers are notified	No		No multi-use tableware is

	that clean tableware is to be used when they return to self-service areas such as salad bars and buffets			provided. *If there is a concern of customers re-using single-service articles, a sign may be recommended….*
(L)	Employees are preventing bare hand contact with ready-to-eat foods	No		All food is prepackaged
(M)	Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties	Maybe	Low	Minimum food safety training for employees of unattended markets would need to be specified. Current Food Code definition of FOOD EMPLOYEE: "Food employee" means an individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES.
(N)	Food employees and conditional employees are informed in a verifiable manner of their responsibility to report in accordance with law, to the person in charge, information about their health and activities as they related to diseases that are transmissible through food	Maybe	Low	Employee health reporting agreement forms (vending companies can use model Forms 1-A, 1-B, 1-C in Annex 7). "RESTICT" already states that the FOOD EMPLOYEE does not work with exposed FOOD, clean EQUIPMENT, UTENSILS, LINENS, or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.
(O)	Written procedures and plans, where specified by this Code and as developed by the food establishment, are maintained and implemented as required.	No		HACCP plans would not be required for unattended markets.

Micro Market – NAMA Technical Bulletin

A New Innovation in Automatic Merchandising

Introduction

Technology is making possible great changes in the food and beverage vending industry. Today you can purchase a Latte or a Cappuccino from a hot beverage machine and enjoy many of the new bottle drinks from a glass front beverage dispenser. You can also make your purchase using a credit/debit card in addition to using bills or coins.

However, the biggest change has been the introduction of the Micro Market. A Micro Market is a self-checkout retail food establishment that replaces a bank of vending machines. In a Micro Market a customer picks up a product from an open rack display, a reach-in refrigerated cooler or freezer or open air cooler, than scans the UPC bar code or an RFID tag for each product at a payment kiosk. The customer pays with a single payment, be it cash, credit card or stored value card. Another unique feature of the Micro Market is that it operates without an employee present, just like vending machines. All Micro Markets are equipped with a 24 hour a day security system monitoring customers as they make their selections and checkout. Micro Markets are designed to be in "closed locations." This refers to a business that has a moderately secured facility for a known group of employees where the Micro Market can be located in a designated area away from heavy public traffic.

Micro Market Products Available

In a typical Micro Market you will find:

- Fresh crisp salads and fruit
- Deli sandwiches, subs, soups and meal options
- Premium beverages, sparkling drinks and juice varieties
- Popular snacks, candies, gum and mints
- Low-calorie, low-fat healthy alternatives
- Breakfast sandwiches, pastries and cereals
- Ice cream and other frozen treats
- Some over the counter medicine and sundry items

Micro Market Equipment

To merchandise all the products available in a Micro Market you will typically find:

- Shelving, be it wall or free standing for popular snacks, candies, gum, mints, low-calorie, low-fat healthy alternative snacks and sundry items

- Single or double door glass front reach-in refrigerators for premium beverages, sparkling drinks and juice varieties
- Single door glass front reach-in refrigerator or open air cooler for fresh crisp salads and

fruit; deli sandwiches, subs, soups and other meal options; breakfast sandwiches, pastries and cereals

Single door glass front reach-in freezer for ice cream and other frozen treats.

Equipment Specification for Handling Potentially Hazardous Foods

All glass front reach-in refrigerators and freezers and open air coolers shall be Listed by the National Sanitation Foundation.

How a Micro Market Works

A Micro Market is serviced on a pre-set schedule by a route driver. The route driver arrives at a location, checks the equipment to be sure it is working correctly, cleans the equipment on a set schedule, check products to be sure they are still "in date" and will be until the next service date, pulls any products that will be "out of date" and then stocks the product shelves and refrigerated and/or freezer units with new product. Through the use of on-line software, the route driver brings only what products are actually needed. The "out of date" products are returned to the warehouse for accountability and proper disposal at the end of day.

Today, government agencies at all levels along with businesses are requesting or mandating that healthier food options be available to their employees. Traditional vending has come a long way to improve its' offerings but is still very limited by column or shelf space size and selections as to what items can be sold in a typical vending machine. A Micro Market expands the number of products that can be sold in the same floor space a typical bank of vending machine would occupy. In addition, a customer can read all the nutrition information on the label of a food product because they can hold it before purchasing.

Public Health Safeguards

Food Safety - Since Micro Markets sell potentially hazardous foods reach-in refrigerated refrigerators maintain a temperature of 41°F and reach-in freezers maintain a temperature of 0°F. All refrigeration equipment have self-closing doors to help maintain the correct temperatures. In addition all refrigeration equipment are equipped with automatic shut-off controls that prevents the equipment from selling food by locking the door when there is a power failure, mechanical failure or other condition that results in an internal temperature greater than 41°F for longer than 30 minutes. Only an authorized service technician or the route driver has the ability to reset the equipment after it is has been determined what caused the temperature failure.

Food Security - Micro Markets are designed to be located in a closed location serving a known set of employees. As mentioned earlier, Micro Markets operate without an employee present. To prevent theft and tampering of food products Micro Markets are equipped with 24/7 surveillance cameras. The time and date products were purchased can

be traced back and matched to the person who made the purchase.

General Sanitation - To perform routine cleaning of the Micro Market the route drive does have access to potable water and a sanitation kit consisting of a cleaning pail, disposable towels, detergent in a spray bottle, sanitizer is a spray bottle and window cleaner.

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-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 issue was submitted for consideration at a previous biennial meeting, see issue: 2014 I-019; new or additional information has been included or attached.

Title:

UFE 2 - Guidance Document for Unattended Food Establishments

Issue you would like the Conference to consider:

At the 2014 Biennial Meeting, the Conference created the Unattended Food Establishments Committee with the following charges:

1. Develop recommendations on whether and how the Food Code should be modified to address unattended food merchandising operations.
2. Consider any existing guidance from FDA and others and develop a CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet section 2-101.11 and 2-103.11 of the 2013 Food Code.
3. Report back at the 2016 Biennial Meeting with a recommendation to Council I.

The committee recommends that the new guidance document for Unattended Food Establishments be approved.

Public Health Significance:

Industry representatives estimate that thousands of unattended food establishments have replaced traditional vending machine operations in the US. However since many jurisdictions do not routinely regulate vending operations, it is not clear how many unattended food establishments would be subject to regulation as a food establishment. Many of the unattended food establishments operations exist in closed environments, such as factories, with a known employee population and with restricted access reducing the threats of accidental or intentional contamination. If the unattended food establishments have installed and are using video surveillance this further reduces the public health impact. Additional precautions need to be implemented, such as failsafe systems for a cooler that cannot maintain TCS product at the required temperature. If none of these

measures exist then the risk to the consumer increases to unacceptable levels and should not be allowed.

Recommended Solution: The Conference recommends...:

1. Approval of the Unattended Food Establishment Committee document titled *Guidance Document for Unattended Food Establishments (*attached to the Issue titled: Report - Unattended Food Establishment Committee); and
2. Posting the approved document in PDF format on the Conference for Food Protection website.

Submitter Information 1:

Name:	Larry Eils
Organization:	Co-chair Unattended Food Establishment Committee
Address:	NAMA8700 Nilsen Ct
City/State/Zip:	Harvard, IL 60033
Telephone:	815-382-3547
E-mail:	rpeonygarden@gmail.com

Submitter Information 2:

Name:	Ric Mathis
Organization:	Co-chair Unattended Food Establishment Committee
Address:	FL Dept of Health4052 Ba;d Cypress Way Bin A08
City/State/Zip:	Tallahassee, FL 32399
Telephone:	850-245-4444 x2337
E-mail:	ric.mathis@flheath.gov

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-015

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:

UFE 3 - Re-create the Unattended Food Establishment Committee

Issue you would like the Conference to consider:

Re-creating the Unattended Food Establishment Committee to continue work on charges set forth in Issue 2014-I-019.

Public Health Significance:

Continuing work on the Unattended Food Establishment Committee is required to meet the charges set forth by Issue 2014-I-019.

Recommended Solution: The Conference recommends...:

Re-create the Unattended Food Establishment Committee to complete the following charges:

1. Develop recommendations on how the FDA Food Code addresses Unattended Food Establishments;
2. Continue to review the "Guidance Document for Unattended Food Establishments" and any existing guidance from FDA and others to update the CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet section 2-101.11 and 2-103.11 of the 2013 Food Code; and
3. Present their findings at the 2018 CFP Biennial Meeting.

Submitter Information:

Name:	Chris Gordon, Council I Chair, on behalf of UFE Committee
Organization:	Virginia Department of Health
Address:	109 Governor Street
City/State/Zip:	Richmond, VA 23219
Telephone:	804-864-7011

E-mail: Christopher.Gordon@vdh.virginia.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-016

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:

Food Establishments With Robotic Operations

Issue you would like the Conference to consider:

New innovative technology is entering the retail food service industry in the form of automated food preparation and process "robots" that not only cook raw foods to ready-to-eat, but combine, garnish, assemble, wrap, package and dispense them. These robots are installed inside of building spaces specifically designed to accommodate their processes. The FDA Food Code should be changed to provide criteria to enable these safe and optimized operational platforms to exist.

Public Health Significance:

New, fully automated *raw* to ready-to-eat (R-RTE) "robotic" food operations in retail food facilities present several critical risk reductions as compared to traditional manual food preparation methods. 1. There are no hands touching R-RTE foods - therefore, no ill employee's are in contact with foods that are being prepared. 2. Every step of the process is continuously controlled, monitored and data logged for time and temperature, along with supervisory analytics and identification of food and ingredient lots, responsible personnel, etc.. 3. R-RTE systems enable automated trace-back and record review of each critical control point (CCP) associated with its hazard analysis critical control point (HACCP) or hazard analysis risk based preventative control (HARPC) program, including corrective action execution, time, date, personnel, etc. and record keeping.

Products begin as raw and are prepared, cooked, garnished, assembled, wrapped, packaged and "dispensed" to a server or to the consumer directly. These new R-RTE food operations that are housed within purpose designed, engineered and built building spaces. They present extreme uniformity and precision for everything from portion size, cook time and temperature and overall quality and their continuous data logs meet evidentiary rule requirements. So too do these systems provide for real time event notification. One of the pioneers for robotic food facilities and the co-presenter of this issue has their food products packed into reusable, sealed, sanitary cassettes (eg., removable, reusable cylindrical

"hoppers") at a licensed food processing facility. These American National Standards (ANSI) sanitation listed cassettes have radio frequency Identification tags (RFID) and track time, temperature and location as products are moved under refrigeration from the food processor through transportation to the food facility. Cassettes that are short-term stored on-site use First-in-First Out (FIFO) control methods and are loaded directly into the robot which opens the hermetically sealed cassette internally, removing the meat cubes, produce, sauce or other food items, ready for preparation and assembly.

Some RTE time/temperature control for safety (TCS) food items may use TIME alone as a public health control. Because of the extreme accuracy of food handling records, time alone as a public health control is easily managed. Products that left temperature control four hours ago are automatically discharged to waste and recorded as such. All of the clean and sanitize in place processes (CSIP) are recorded (logged) some of which are fully automated. A complete flow chart for the flow of food through robotic operation (robop?) is presented to the licensing authority upon application for permit. In addition, a list of the approved sources and the overall food safety plan with standard sanitary operating procedures are provided, including both clean and sanitize in place (CSIP) operations and various manual in place cleaning (IPC) and clean out of place (COP) procedures. In addition to maintenance of an automatic, continuous log of collected critical control point data, there is an overlay to enable supervisory notes from the person in charge relating to the data. Detailed, High Definition (HD) 24/7/365 video surveillance data is over-layed providing a unique data set for each and every daily food operation. The intent of this mechanized process is to provide the safest complex food operation in the world.

Recommended Solution: The Conference recommends...:

1. that a letter be sent to the FDA requesting the 2013 Food Code be amended to include a definition in Section 1-201.11 of the FDA Food Code for food establishments with robotic operations;

and

2. the Conference further recommend that a committee be formed:

A. to establish reasonable criteria and guidance for the new and emerging field of robotic food service operations; and

B. report back with their findings and recommendations to the 2018 Biennial Meeting.

Submitter Information 1:

Name:	Thomas Johnson
Organization:	Johnson Risk Solutions, LLC
Address:	1408 Northland Dr #406
City/State/Zip:	Mendota Heights, MN 55120
Telephone:	651-587-0418
E-mail:	tomj@jdpinc.com

Submitter Information 2:

Name:	Steve Frehn
Organization:	Momentum Machines, LLC
Address:	977 Howard St.

City/State/Zip: San Francisco, CA 94103
Telephone: 651-906-7058
E-mail: steve@momentummachines.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-017

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Revised Term for Animal Foods

Issue you would like the Conference to consider:

The Food Code uses the term "animal food" in several places. This term could be misunderstood as pet food.

Public Health Significance:

Revising the term "animal food" to "animal-origin food" would reduce confusion.

Recommended Solution: The Conference recommends...:

a letter be send to FDA requesting that the term "animal food" be replaced by the term "animal-origin food" throughout the Food Code.

Submitter Information:

Name:	Adam Inman
Organization:	Kansas Department of Agriculture
Address:	1320 Research Park Drive
City/State/Zip:	Manhattan, KS 66502
Telephone:	7855646764
E-mail:	adam.inman@kda.ks.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-018

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Defining Food Establishments—Amend Section 1-201.10(B)

Issue you would like the Conference to consider:

The FDA Food Code recognizes that food establishments should be maintained to ensure sanitary conditions free of rodents, insects, and other pests. The 2013 Food Code, however, defines "food establishments" subject to the code to exclude establishments that offer only prepackaged, shelf-stable foods. States that have adopted the 2013 Food Code's definition of food establishments may not ensure that stores selling only prepackaged, shelf-stable foods meet basic sanitation requirements.

Public Health Significance:

Proper handling, storage, and display of prepackaged foods is necessary to safeguard public health. Establishments that are typically not in the business of selling food -- *such as home goods, hardware, clothing, party supply, and office supply stores* -- should be defined as "food establishments" and required to meet basic sanitation standards. Jurisdictions that inspect such stores have found numerous sanitation violations including the presence of insects, rat and mouse droppings, the presence of a trapped mouse, gnawed food bags, the presence of live birds and a pet dog, improper storage of toxic chemicals, and spoiled food (documentation attached).

Risks posed to consumers may be high for ready-to-eat foods, such as candy bars and chips. These foods are typically eaten directly out of the packaging, with consumers' hands touching both the packaging and the food itself, increasing the likelihood that excrement or toxic chemicals present on the packaging could contaminate the food consumed.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the definition of Food Establishments in the 2013 Food Code section 1-201.10(B) be amended as follows (new language is underlined; language to be deleted is in strikethrough format):

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.

Food Establishment.

(3) "Food establishment" does not include:

~~(a) An establishment that offers only prePACKAGED FOODS that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOODS;~~

(~~b~~a) A produce stand that only offers whole, uncut fresh fruits and vegetables;

(~~c~~b) A FOOD PROCESSING PLANT; including those that are located on the PREMISES of a FOOD ESTABLISHMENT

(~~d~~c) A kitchen in a private home if only FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY;

(~~e~~d) An area where FOOD that is prepared as specified in Subparagraph (3)(~~d~~c) of this definition is sold or offered for human consumption;

(~~f~~e) A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; or

(~~g~~f) A private home that receives catered or home-delivered FOOD.

Submitter Information 1:

Name:	David W. Plunkett
Organization:	Center for Science in the Public Interest
Address:	1220 L Street NW Suite 300
City/State/Zip:	Washington, DC 20005
Telephone:	2027778319
E-mail:	dplunkett@cspinet.org

Submitter Information 2:

Name:	Jessica Almy
Organization:	Center for Science in the Public Interest
Address:	1220 L Street NW Suite 300
City/State/Zip:	Washington, DC 20005
Telephone:	2027778358
E-mail:	jalmy@cspinet.org

Supporting Attachments:

- "Clothing Store 1"
- "Clothing Store 2"
- "Hardware Store 1"
- "Hardware Store 2"
- "Home Goods Store 1"
- "Home Goods Store 2"
- "Home Goods Store 3"
- "Office Supply Store 1"
- "Office Supply Store 2"
- "Party Store 1"
- "Party Store 2"

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

Government of the District of Columbia

Food Establishment Inspection Report

Pursuant to Title 25-A of the District of Columbia Municipal Regulations

DEPARTMENT OF HEALTH Promote. Prevent. Protect.

Bureau of Community Hygiene • Food Safety & Hygiene Inspection Services Division • 899 North Capitol Street, NE-8th Floor • Washington, DC 20002 • food.safety@dc.gov

Establishment Name [redacted] Clothing Store #1

Address [redacted]

City/State/Zip Code Washington, DC 20010

Telephone [redacted] E-mail address

Date of Inspection 04 / 28 / 2015 Time In 10 : 45 AM Time Out 10 : 45 AM

License Holder [redacted]

License/Customer No. [redacted]

License Period 03 / 01 / 2014 - 02 / 28 / 2016 Type of Inspection Complaint

Establishment Type: Food Products Risk Category 1☐ 2☐ 3☐ 4☐ 5☐

Critical Violations	2	**COS**	0	**R**	0
Noncritical Violations	1	**COS**	0	**R**	0

Certified Food Protection Manager (CFPM)

CFPM #:

CFPM Expiration Date: / /

D.C. licensed trash or solid waste contractor: BUILDING

D.C. licensed sewage & liquid waste transport contractor: N/A

D.C. licensed pesticide operator/contractor: [redacted]

FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS

Compliance Status		COS	R
	Demonstration of knowledge		
IN OUT N/A	1.Correct response to questions	☐	☐
	Employee Health		
IN OUT	2 Management awareness; policy present	☐	☐
IN OUT	3 Proper use of restriction and exclusion	☐	☐
	Good Hygienic Practices		
IN OUT N/O	4 Proper eating, tasting, drinking, or tobacco use	☐	☐
IN OUT N/O	5 No discharge from eyes, nose, and mouth	☐	☐
	Preventing Contamination by Hands		
IN OUT N/O	6 Hands clean and properly washed	☐	☐
IN OUT N/A N/O	7 No bare hand contact with ready-to-eat foods or approved	☐	☐
IN OUT	8 Adequate handwashing sinks properly supplied and accessible	☐	☐
	Approved Source		
IN OUT N/A N/O	9 Food obtained from approved source	☐	☐
IN OUT N/A N/O	10 Food received at proper temperature	☐	☐
IN OUT	11 Food in good condition, safe, unadulterated	☐	☐
IN OUT N/A N/O	12 Required records available: shellstock tags, parasite destruction	☐	☐
	Protection from Contamination		
IN OUT N/A N/O	13 Food separated and protected	☐	☐
IN OUT N/A	14 Food-contact surfaces: cleaned & sanitized	☐	☐
IN OUT	15 Proper disposition of returned, previously served, reconditioned, and unsafe food	☐	☐
	Potentially Hazardous Food (TCS Food)		
IN OUT N/A N/O	16 Proper cooking time and temperatures	☐	☐
IN OUT N/A N/O	17 Proper reheating procedures for hot holding	☐	☐
IN OUT N/A N/O	18 Proper cooling time & temperatures	☐	☐
IN OUT N/A N/O	19 Proper hot holding temperatures	☐	☐
IN OUT N/A N/O	20 Proper cold holding temperatures	☐	☐
IN OUT N/A N/O	21 Proper date marking & disposition	☐	☐
IN OUT N/A N/O	22.Time as a public health control: procedures & records	☐	☐
	Consumer Advisory		
IN OUT N/A	23.Consumer advisory provided for raw or undercooked foods	☐	☐
	Highly Susceptible Populations		
IN OUT N/A	24 Pasteurized foods used; prohibited foods not offered	☐	☐
	Chemical		
IN OUT N/A	25 Food additives: approved & properly used	☐	☐
IN OUT N/A	26.Toxic substances properly identified, stored, used	☐	☐
	Conformance with Approved Procedures		
IN OUT N/A	27.Compliance with variance, specialized process, and HACCP plan	☐	☐

GOOD RETAIL PRACTICES

Compliance Status		COS	R
	Safe Food and Water		
N OUT N/A	28.Pasteurized eggs used where required	☐	☐
IN OUT	29.Water & Ice from approved source	☐	☐
N OUT N/A	30.Variance obtained for specialized processing methods	☐	☐
	Food Temperature Control		
IN OUT	31.Proper cooling methods used; adequate equipment for temperature control	☐	☐
N OUT N/A N/O	32.Plant food properly cooked for hot holding	☐	☐
N OUT N/A N/O	33.Approved thawing methods used	☐	☐
IN OUT	34.Thermometers provided & accurate	☐	☐
	Food Identification		
IN OUT	35.Food properly labeled; original container	☐	☐
	Prevention of Food Contamination		
N OUT	36.Insects, rodents, & animals not present	☐	☐
IN OUT	37.Contamination prevented during food preparation, storage, & display	☐	☐
IN OUT	38.Personal cleanliness	☐	☐
IN OUT	39.Wiping cloths: properly used & stored	☐	☐
IN OUT	40.Washing fruits & vegetables	☐	☐
	Proper Use of Utensils		
IN OUT	41.In-use utensils: properly stored	☐	☐
IN OUT	42.Utensils, equipment & linens: properly stored, dried, & handled	☐	☐
IN OUT	43.Single-use/single-service articles: properly stored & used	☐	☐
IN OUT	44.Gloves used properly	☐	☐
	Utensils, Equipment, and Vending		
IN OUT	45.Food and nonfood-contact surfaces cleanable, properly designed, constructed, & used	☐	☐
IN OUT	46.Warewashing facilities: installed, maintained, & used; test strips	☐	☐
IN OUT	47.Nonfood-contact surfaces clean	☐	☐
	Physical Facilities		
IN OUT	48.Hot & cold water available; adequate pressure	☐	☐
IN OUT	49.Plumbing installed; proper backflow devices	☐	☐
IN OUT	50.Sewage & waste water properly disposed	☐	☐
IN OUT	51.Toilet facilities: properly constructed, supplied, & cleaned	☐	☐
IN OUT	52.Garbage & refuse properly disposed, facilities maintained	☐	☐
N OUT	53.Physical facilities: installed, maintained, & clean	☐	☐
IN OUT	54.Adequate ventilation & lighting; designated areas used	☐	☐

IN = in compliance OUT = not in compliance N/O = not observed
N/A = not applicable COS = corrected on-site R = repeat violation

Establishment Name [redacted] Establishment Address [redacted]

OBSERVATIONS	25 DCMR	CORRECTIVE ACTIONS
36 - Rodent droppings and gnawed food product bags observed at areas where food products are sold	3210 1	The premises shall be maintained free of insects, rodents, and other pests The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by: (a) Routinely inspecting incoming shipments of food and supplies; (b) Routinely inspecting the premises for evidence of pests; (c) Using methods, if pests are found, such as trapping devices or other means of pest control as specified in sections 3402, 3410 and 3411; and (d) Eliminating harborage conditions
53 - Cracks and holes observed throughout the walls of the receiving/storage area of establishment	3200 1	The physical facilities shall be maintained in good repair

TEMPERATURES

Item/Location	Temp	Item/Location	Temp	Item/Location	Temp	Item/Location	Temp
Hot Water (Handwashing Sink)	105.0F						

Inspector Comments:
SUMMARY SUSPENSION: IN ORDER FOR LICENSE TO BE RESTORED, A RE-INSPECTION FEE OF $100 [DURING NORMAL BUSINESS HOURS] OR $400 [DURING NON-BUSINESS HOURS] MUST BE PAID PRIOR TO REQUEST AND ALL VIOLATIONS MUST BE ABATED AND APPROVED BY THE DC DOH.

NOTE: AFTER CORRECTING ALL VIOLATIONS, PLEASE HAVE PEST CONTROL SERVICE ESTABLISHMENT AND PROVIDE THE INVOICE/SERVICE REPORT AT THE RESTORATION INSPECTION.

IF YOU HAVE ANY QUESTIONS, CONTACT AREA SUPERVISOR MR. TAYLOR AT (202)442-9037.

Person-in-Charge (Signature) [redacted] (Print) 04/28/2015 Date

Inspector (Signature) Jaime Hernandez (Print) 607 Badge # 04/28/2015 Date

Government of the District of Columbia

Food Establishment Inspection Report

Pursuant to Title 25-A of the District of Columbia Municipal Regulations

DEPARTMENT OF HEALTH Promote. Prevent. Protect.

Bureau of Community Hygiene • Food Safety & Hygiene Inspection Services Division • 899 North Capitol Street, NE-8th Floor • Washington, DC 20002 • food.safety@dc.gov

Establishment Name [redacted] Clothing Store #2

Address [redacted]

City/State/Zip Code WASHINGTON, DC 20015

Telephone [redacted] E-mail address

Date of Inspection 05 / 11 / 2015 Time In 10 : 20 AM Time Out 11 : 15 AM

License Holder [redacted]

License/Customer No.

License Period 11 / 26 / 2014 - 12 / 26 / 2014 Type of Inspection Routine

Establishment Type: Food Products Risk Category 1☐ 2☐ 3☐ 4☐ 5☐

Critical Violations	1	**COS**	1	**R**	0
Noncritical Violations	0	**COS**	0	**R**	0

Certified Food Protection Manager (CFPM)

CFPM #:

CFPM Expiration Date: / /

D.C. licensed trash or solid waste contractor: LAND LORD

D.C. licensed sewage & liquid waste transport contractor: LAND LORD

D.C. licensed pesticide operator/contractor: LAND LORD

FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS

Compliance Status		COS	R
	Demonstration of knowledge		
IN OUT N/A	1.Correct response to questions	☐	☐
	Employee Health		
IN OUT	2 Management awareness; policy present	☐	☐
IN OUT	3 Proper use of restriction and exclusion	☐	☐
	Good Hygienic Practices		
IN OUT N/O	4 Proper eating, tasting, drinking, or tobacco use	☐	☐
IN OUT N/O	5 No discharge from eyes, nose, and mouth	☐	☐
	Preventing Contamination by Hands		
IN OUT N/O	6 Hands clean and properly washed	☐	☐
IN OUT N/A N/O	7 No bare hand contact with ready-to-eat foods or approved	☐	☐
IN OUT	8 Adequate handwashing sinks properly supplied and accessible	☐	☐
	Approved Source		
IN OUT N/A N/O	9 Food obtained from approved source	☐	☐
IN OUT N/A N/O	10 Food received at proper temperature	☐	☐
IN OUT	11 Food in good condition, safe, unadulterated	☐	☐
IN OUT N/A N/O	12 Required records available: shellstock tags, parasite destruction	☐	☐
	Protection from Contamination		
IN OUT N/A N/O	13 Food separated and protected	☐	☐
IN OUT N/A	14 Food-contact surfaces: cleaned & sanitized	☐	☐
IN OUT	15 Proper disposition of returned, previously served, reconditioned, and unsafe food	☐	☐
	Potentially Hazardous Food (TCS Food)		
IN OUT N/A N/O	16 Proper cooking time and temperatures	☐	☐
IN OUT N/A N/O	17 Proper reheating procedures for hot holding	☐	☐
IN OUT N/A N/O	18 Proper cooling time & temperatures	☐	☐
IN OUT N/A N/O	19 Proper hot holding temperatures	☐	☐
IN OUT N/A N/O	20 Proper cold holding temperatures	☐	☐
IN OUT N/A N/O	21 Proper date marking & disposition	☐	☐
IN OUT N/A N/O	22.Time as a public health control: procedures & records	☐	☐
	Consumer Advisory		
IN OUT N/A	23.Consumer advisory provided for raw or undercooked foods	☐	☐
	Highly Susceptible Populations		
IN OUT N/A	24 Pasteurized foods used; prohibited foods not offered	☐	☐
	Chemical		
IN OUT N/A	25 Food additives: approved & properly used	☐	☐
IN OUT N/A	26.Toxic substances properly identified, stored, used	☐	☐
	Conformance with Approved Procedures		
IN OUT N/A	27.Compliance with variance, specialized process, and HACCP plan	☐	☐

GOOD RETAIL PRACTICES

Compliance Status		COS	R
	Safe Food and Water		
N OUT N/A	28.Pasteurized eggs used where required	☐	☐
IN OUT	29.Water & Ice from approved source	☐	☐
N OUT N/A	30.Variance obtained for specialized processing methods	☐	☐
	Food Temperature Control		
IN OUT	31.Proper cooling methods used; adequate equipment for temperature control	☐	☐
N OUT N/A N/O	32.Plant food properly cooked for hot holding	☐	☐
N OUT N/A N/O	33.Approved thawing methods used	☐	☐
IN OUT	34.Thermometers provided & accurate	☐	☐
	Food Identification		
IN OUT	35.Food properly labeled; original container	☐	☐
	Prevention of Food Contamination		
IN OUT	36.Insects, rodents, & animals not present	☐	☐
IN OUT	37.Contamination prevented during food preparation, storage, & display	☐	☐
IN OUT	38.Personal cleanliness	☐	☐
IN OUT	39.Wiping cloths: properly used & stored	☐	☐
IN OUT	40.Washing fruits & vegetables	☐	☐
	Proper Use of Utensils		
IN OUT	41.In-use utensils: properly stored	☐	☐
IN OUT	42.Utensils, equipment & linens: properly stored, dried, & handled	☐	☐
IN OUT	43.Single-use/single-service articles: properly stored & used	☐	☐
IN OUT	44.Gloves used properly	☐	☐
	Utensils, Equipment, and Vending		
IN OUT	45.Food and nonfood-contact surfaces cleanable, properly designed, constructed, & used	☐	☐
IN OUT	46.Warewashing facilities: installed, maintained, & used; test strips	☐	☐
IN OUT	47.Nonfood-contact surfaces clean	☐	☐
	Physical Facilities		
IN OUT	48.Hot & cold water available; adequate pressure	☐	☐
IN OUT	49.Plumbing installed; proper backflow devices	☐	☐
IN OUT	50.Sewage & waste water properly disposed	☐	☐
IN OUT	51.Toilet facilities: properly constructed, supplied, & cleaned	☐	☐
IN OUT	52.Garbage & refuse properly disposed, facilities maintained	☐	☐
IN OUT	53.Physical facilities: installed, maintained, & clean	☐	☐
IN OUT	54.Adequate ventilation & lighting; designated areas used	☐	☐

IN = in compliance OUT = not in compliance N/O = not observed
N/A = not applicable COS = corrected on-site R = repeat violation

Establishment Name [redacted] Establishment Address [redacted]

OBSERVATIONS	25 DCMR	CORRECTIVE ACTIONS
26 - CHEMICALS NOT STORED PROPERLY (Corrected On Site)	3400 1	Poisonous or toxic materials shall be stored so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by: (a) Separating the poisonous or toxic materials by physically separating or partitioning by a wall or structure; and (b) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles This paragraph does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles

TEMPERATURES

Item/Location	Temp	Item/Location	Temp	Item/Location	Temp	Item/Location	Temp
(Refrigerator - beverage)	38.9F						

Inspector Comments:
NO CRITICAL VIOLATIONS WERE OBSERVED. IF YOU HAVE ANY QUESTIONS PLEASE CALL AREA SUPERVISOR MR. RONNIE TAYLOR AT 202-442-9037.

Person-in-Charge (Signature) [redacted] (Print) 05/11/2015 Date

Inspector (Signature) VICTOR CURRIE (Print) 088 Badge # 05/11/2015 Date

FSHISD_2015_3

INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health
1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

[redacted]

Hardware Store #1

[redacted]
LAKE FOREST, CA 92630

[redacted]

Record ID: [redacted]
Inspection Date: 05/03/2013
Reinspection Date:

Type of Facility: 0390-LIMITED PRE-PACKAGED FOOD
25-299 SQ FT-NO PHF
Service: A01-**ROUTINE INSPECTION**

Mailing Address:

ON FILE

V Kenekeo, REHS
ENVIRONMENTAL HEALTH SPEC I
(714) 659-4036
7:30-8:30 a.m.

THE ITEMS NOTED BELOW WERE OBSERVED DURING THE COURSE OF A SITE VISIT. ANY VIOLATIONS OBSERVED MUST BE CORRECTED.

MINOR VIOLATIONS

FC38 - Unsanitary Equipment/Utensil/Linen/Plumbing
Remove dust from the fan covers from the following coolers:
a. Vitamin water
b. Coca Cola
c. Coca Cola at Lawn and Garden
Maintain these areas clean on a regular basis.

FC39 - Evidence of Vermin Activity/Presence of Animals/Insects
Observed a customer with a dog in the facility.
Live animals, birds, and fowl shall not be kept or allowed in any food facility except those that are exempt from California Retail Food Code as described in Section 114259.

COMMENTS

FC99 - NOTES
This inspection report was reviewed with: [redacted] (Assistant manager).
It was agreed that a copy of this report will be e-mailed to the address provided. The person in charge was directed to cal this office if the report is not received within 2 business days. Reports and other valuable information can be found at www.ocfoodinfo.com. SIGNATURE IS NOT REQUIRED; PLEASE RETAIN THIS COPY FOR YOUR FILES.

Change of Ownership: No
Food Temperatures:
NO potentially hazardous foods

Hot water recorded at 120F at the mop sink
Dish/Utensil Sanitation method: N/A
Sanitizer level for wiping cloths: N/A

The “PASS” Notification Seal was posted today in a prominent location.

.

I declare that I have examined and received a copy of this inspection report.

Print Name and Title _____

Signature _____ Date _____

INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health
1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

[redacted]

Hardware Store #2

[redacted]
BREA, CA 92821

[redacted]

Record ID: [redacted]
Inspection Date: 06/20/2014
Reinspection Date:

Type of Facility: 0390-LIMITED PRE-PACKAGED FOOD
25-299 SQ FT-NO PHF
Service: A01-**ROUTINE INSPECTION**

Mailing Address:
ON FILE

L Arellano, REHS
ENVIRONMENTAL HEALTH SPEC I
(714) 823-7046

THE ITEMS NOTED BELOW WERE OBSERVED DURING THE COURSE OF A SITE VISIT. ANY VIOLATIONS OBSERVED MUST BE CORRECTED.

OPENING COMMENTS

FC00 - OPENING COMMENT
Observed 25-199 sq ft of pre packaged non potentially hazardous foods on this date.

MINOR VIOLATIONS

FC38 - Unsanitary Equipment/Utensil/Linen/Plumbing
Clean the tracks inside the soda coolers. Maintain all equipment, utensils and facilities clean, fully operative and in good repair.

FC39 - Evidence of Vermin Activity/Presence of Animals/Insects
Observed live birds inside the facility. Construct, equip, maintain, and operate the food facility so as to prevent the entrance and harborage of insects and rodents. Use any approved method for eliminating insects (i.e. flies, cockroaches) and/or rodents from the facility. A thorough inspection for vermin activity was conducted and no further evidence was observed.

FC40 - Facility not Fully Enclosed/Open Door/Air Curtain
Observed the front doors to be propped open. Maintain the door closed at all times except during immediate passage. Alternatively, if ventilation is desired, provide an approved screen door. Maintain the food facility fully enclosed to preven the entrance and harborage of animals and insects.

COMMENTS

FC99 - NOTES
The report violations were reviewed with: [redacted]
It was agreed that a copy of this report will be sent to the e-mail address provided. The person in charge was directed to call this office if the report is not received within 2 business days. Reports and other valuable information can be found at www.ocfoodinfo.com. SIGNATURE IS NOT REQUIRED; PLEASE RETAIN THIS COPY FOR YOUR FILES.
Change of Ownership: No
Food Temperatures: N/A

F100 - "PASS" SEAL POSTED

I declare that I have examined and received a copy of this inspection report.

Print Name and Title _____

Signature _____ Date _____

Home Goods Store #1

[redacted]

[redacted] *Downey, CA 90242-2659*

3/16/2011

Violation 58

OTHER INSECTS (MINOR) Examples Include: Flies in the delivery staging area only, Gnats in the warewashing area or around floor sink, Flies in a pre-packaged food facility, Ants found on the kitchen floor

Violation 60

SINKS & FIXTURES / SUPPLY LINE - LEAKING / NOT CLEAN / DISREPAIR / UNAPPROVED Examples Include: Leaking faucet at the ware washing sink, Dirty sinks / fixtures, Unapproved rubber hose used as a faucet extension at 3-compartment sink, Faucet unable to reach all compartments of the sink, Cracked sink or sink not secured to wall , Automatic pre-mixing faucet does not stay on for the required minimum 15 seconds, Back flow prevention device is leaking, Hose used to clean floor mats is also used to supply water at wok stove faucet, Leaking water supply line (e.g., inlet valves)

Violation 62

LOW RISK HOT / WARM WATER VIOLATIONS Examples Include: Water throughout the restaurant is measured at 110-119°F, chemically sanitizing multi-use utensils (24 hours to abate), All non critical sinks not meeting the required minimum hot water temperatures (120°F for food prep / mop OR 100°F for handwash sink), Water is less than 120°F at a pre-packaged food facility (24 hours to abate), Water temperature measured at a critical food preparation or mop sink is between 110-119°F or 90-99°F at a critical handwash sink, Manual warewashing solution between

[redacted]

NEARBY RESTAURANTS

Within 2 Miles

[redacted]

[redacted]

100-110°F (Unless otherwise specified by detergent manufacturer's instruction label)

5/18/2010 **Violation 48**

NON-FOOD-CONTACT SURFACES NOT CLEAN (MINOR) Examples Include: Accumulated grease or food debris on the non-food contact surfaces of equipment, shelving, or cabinets, Dirty fan guards or door gaskets in walk-in refrigerator, Dirty shelving in refrigeration unit with no direct food contact

[redacted]

DATA SOURCE

This data was downloaded from the local health department for this restaurant. See our **FAQ** for a full list of our data sources.

Last Updated 3/16/2011 4:00:00 AM

[redacted]

Home Goods Store #2

Government of the District of Columbia

Food Establishment Inspection Report

Pursuant to Title 25-A of the District of Columbia Municipal Regulations

DEPARTMENT OF HEALTH Promote. Prevent. Protect.

Bureau of Community Hygiene • Food Safety & Hygiene Inspection Services Division • 899 North Capitol Street, NE-8th Floor • Washington, DC 20002 • food.safety@dc.gov

Establishment Name [redacted]

Address [redacted]

City/State/Zip Code WASHINGTON, DC 20010

Telephone [redacted] E-mail address

Date of Inspection 02 / 26 / 2015 Time In 01 : 32 PM Time Out 02 : 35 PM

License Holder [redacted]

License/Customer No. [redacted]

License Period 04 / 01 / 2013 - 03 / 23 / 2015 Type of Inspection Routine

Establishment Type: Food Products Risk Category 1☐ 2☐ 3☐ 4☐ 5☐

Critical Violations	0	**COS**	0	**R**	0
Noncritical Violations	2	**COS**	0	**R**	0

Certified Food Protection Manager (CFPM)

CFPM #:

CFPM Expiration Date: / /

D.C. licensed trash or solid waste contractor: Building

D.C. licensed sewage & liquid waste transport contractor: n/a

D.C. licensed pesticide operator/contractor:

FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS

Compliance Status		COS	R
	Demonstration of knowledge		
IN OUT N/A	1.Correct response to questions	☐	☐
	Employee Health		
IN OUT	2 Management awareness; policy present	☐	☐
IN OUT	3 Proper use of restriction and exclusion	☐	☐
	Good Hygienic Practices		
IN OUT N/O	4 Proper eating, tasting, drinking, or tobacco use	☐	☐
IN OUT N/O	5 No discharge from eyes, nose, and mouth	☐	☐
	Preventing Contamination by Hands		
IN OUT N/O	6 Hands clean and properly washed	☐	☐
IN OUT N/A N/O	7 No bare hand contact with ready-to-eat foods or approved	☐	☐
IN OUT	8 Adequate handwashing sinks properly supplied and accessible	☐	☐
	Approved Source		
IN OUT N/A N/O	9 Food obtained from approved source	☐	☐
IN OUT N/A N/O	10 Food received at proper temperature	☐	☐
IN OUT	11 Food in good condition, safe, unadulterated	☐	☐
IN OUT N/A N/O	12 Required records available: shellstock tags, parasite destruction	☐	☐
	Protection from Contamination		
IN OUT N/A N/O	13 Food separated and protected	☐	☐
IN OUT N/A	14 Food-contact surfaces: cleaned & sanitized	☐	☐
IN OUT	15 Proper disposition of returned, previously served, reconditioned, and unsafe food	☐	☐
	Potentially Hazardous Food (TCS Food)		
IN OUT N/A N/O	16 Proper cooking time and temperatures	☐	☐
IN OUT N/A N/O	17 Proper reheating procedures for hot holding	☐	☐
IN OUT N/A N/O	18 Proper cooling time & temperatures	☐	☐
IN OUT N/A N/O	19 Proper hot holding temperatures	☐	☐
IN OUT N/A N/O	20 Proper cold holding temperatures	☐	☐
IN OUT N/A N/O	21 Proper date marking & disposition	☐	☐
IN OUT N/A N/O	22.Time as a public health control: procedures & records	☐	☐
	Consumer Advisory		
IN OUT N/A	23.Consumer advisory provided for raw or undercooked foods	☐	☐
	Highly Susceptible Populations		
IN OUT N/A	24 Pasteurized foods used; prohibited foods not offered	☐	☐
	Chemical		
IN OUT N/A	25 Food additives: approved & properly used	☐	☐
IN OUT N/A	26.Toxic substances properly identified, stored, used	☐	☐
	Conformance with Approved Procedures		
IN OUT N/A	27.Compliance with variance, specialized process, and HACCP plan	☐	☐

GOOD RETAIL PRACTICES

Compliance Status		COS	R
	Safe Food and Water		
N OUT N/A	28.Pasteurized eggs used where required	☐	☐
N OUT	29.Water & Ice from approved source	☐	☐
N OUT N/A	30.Variance obtained for specialized processing methods	☐	☐
	Food Temperature Control		
N OUT	31.Proper cooling methods used; adequate equipment for temperature control	☐	☐
N OUT N/A N/O	32.Plant food properly cooked for hot holding	☐	☐
N OUT N/A N/O	33.Approved thawing methods used	☐	☐
N OUT	34.Thermometers provided & accurate	☐	☐
	Food Identification		
N OUT	35.Food properly labeled; original container	☐	☐
	Prevention of Food Contamination		
N OUT	36.Insects, rodents, & animals not present	☐	☐
N OUT	37.Contamination prevented during food preparation, storage, & display	☐	☐
N OUT	38.Personal cleanliness	☐	☐
N OUT	39.Wiping cloths: properly used & stored	☐	☐
N OUT	40.Washing fruits & vegetables	☐	☐
	Proper Use of Utensils		
N OUT	41.In-use utensils: properly stored	☐	☐
N OUT	42.Utensils, equipment & linens: properly stored, dried, & handled	☐	☐
N OUT	43.Single-use/single-service articles: properly stored & used	☐	☐
N OUT	44.Gloves used properly	☐	☐
	Utensils, Equipment, and Vending		
N OUT	45.Food and nonfood-contact surfaces cleanable, properly designed, constructed, & used	☐	☐
N OUT	46.Warewashing facilities: installed, maintained, & used; test strips	☐	☐
N OUT	47.Nonfood-contact surfaces clean	☐	☐
	Physical Facilities		
N OUT	48.Hot & cold water available; adequate pressure	☐	☐
N OUT	49.Plumbing installed; proper backflow devices	☐	☐
N OUT	50.Sewage & waste water properly disposed	☐	☐
N OUT	51.Toilet facilities: properly constructed, supplied, & cleaned	☐	☐
N OUT	52.Garbage & refuse properly disposed, facilities maintained	☐	☐
N OUT	53.Physical facilities: installed, maintained, & clean	☐	☐
N OUT	54.Adequate ventilation & lighting; designated areas used	☐	☐

IN = in compliance OUT = not in compliance N/O = not observed
N/A = not applicable COS = corrected on-site R = repeat violation

Establishment Name [redacted] Establishment Address [redacted]

OBSERVATIONS	25 DCMR	CORRECTIVE ACTIONS
36 - There is no pest service invoice available (CORRECT VIOLATION WITHIN 5 CALENDAR DAYS)	3210 2	The licensee shall maintain a copy of the establishment's professional service contract and service schedule, which documents the following information: (a) Name and address of its licensed pest exterminator / contractor; (b) Frequency of pest extermination services provided under the contract; and (c) Date pest extermination services were last provided to the establishment
36 - Mice droppings and one trapped mice observed (CORRECT VIOLATION WITHIN 5 CALENDAR DAYS)		The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by: (c) Using methods, if pests are found, such as trapping devices or other means of pest control as specified in sections 3402, 3410 and 3411
37 - Prepackaged foods are stored less than six inches above the ground (CORRECT VIOLATION WITHIN 45 CALENDAR DAYS)	816 1	Except as specified in sections 816 2 and 816 3, food shall be protected from contamination by storing the food: (a) In a clean, dry location; (b) Where it is not exposed to splash, dust, or other contamination; and (c) At least fifteen centimeters (15 cm) or six inches (6 in) above the floor

TEMPERATURES

Item/Location	Temp	Item/Location	Temp	Item/Location	Temp	Item/Location	Temp
Hot Water (Handwashing Sink - toilet room)	102.0F						

Inspector Comments:
CORRECT ITEMS STATED WITHIN 5-DAYS

CORRECT ITEMS STATED WITHIN 45-DAYS

If you have any questions, please call area supervisor Mr. Ronnie Taylor at 202-442-9037.

Person-in-Charge (Signature) [redacted] (Print) 02/26/2015 Date

Inspector (Signature) Douglas Dalier (Print) 082 Badge # 02/26/2015 Date

INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health
1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

Home Goods Store #3

[redacted]
PREPACKAGED FOOD ONLY
[redacted]
HUNTINGTON BEACH, CA 92647

[redacted]

Record ID: [redacted]
Inspection Date: 01/09/2013
Reinspection Date: 01/22/2013

Type of Facility: 0391-PKGD FOOD MKT OR CONFECTIONARY 1-1999 SQ FT
Service: A01-**ROUTINE INSPECTION**

Mailing Address:
ON FILE

B Freeman, REHS
ENVIRONMENTAL HEALTH SPEC II
(714) 981-9070
7:30-8:30 a.m.

THE ITEMS NOTED BELOW WERE OBSERVED DURING THE COURSE OF A SITE VISIT. ANY VIOLATIONS OBSERVED MUST BE CORRECTED.

OPENING COMMENTS

FC00 - OPENING COMMENT
A review of this facility's program element was conducted. This facility was observed not to be selling or storing potentially hazardous food of unpackaged foods. The program element of this facility will be changed to prepackaged non-potentially hazardous food between 25 and 300 feet of food displat.

MINOR VIOLATIONS

FC39 - Evidence of Vermin Activity/Presence of Animals/Insects
Rat droppings were observed on the storage shelving in the storeroom where the prepackaged food is stored. Construct, equip, maintain, and operate the food facility so as to prevent the entrance and harborage of rodents. Use any approved method for eliminating rodents from the facility.
A thorough inspection for vermin activity and contaminated food was conducted and no further evidence was observed.

COMMENTS

FC99 - NOTES

This inspection report was reviewed with: The manager, [redacted]
The management of this facility has provided a current e-mail address and has agreed to receive a copy of this report via e-mail. This report will be sent via e-mail. The person in charge was instructed to contact this office if they do not receive the e-mail.
Change of Ownership: No
Hot water at the mop-sink was good at above 120 F
Retain a copy of the most recent inspection report on the premises available for review at the request of the public.
SIGNATURE IS NOT REQUIRED; PLEASE RETAIN THIS COPY FOR YOUR FILES.
The “Reinspection Due-Pass” Notification Seal was posted today in a prominent

FCC0 - REINSPECTION SCHEDULED

A reinspection is scheduled on the date noted at top of the inspection report. A reinspection notification seal was posted today in a prominent location.
REINSPECTION FEES:
Fees are assessed for second or greater reinspections. The purpose of these fees is to shift costs away from compliant operators and impose fees on those facilities that fail to readily comply with the applicable laws and

I declare that I have examined and received a copy of this inspection report.

INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health
1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

[redacted]

[redacted] -
PREPACKAGED FOOD ONLY
[redacted]
HUNTINGTON BEACH, CA 92647

Record ID: [redacted]
Inspection Date: 01/09/2013

regulations. The amount of the fee is to cover all of the costs associated with the service and the time charged includes travel time. The fees until June 30, 2013 are as follows:

-1st Reinspection: NO FEE
-2nd Reinspection or Greater, during normal work hours:
$25.75 per quarter-hour or fraction thereof
-2nd Reinspection or Greater, during other hours, including weekends and holidays:
$38.63 per quarter-hour or fraction thereof
-Notice of Violation Reinspection: $305.00

I declare that I have examined and received a copy of this inspection report.

Print Name and Title _____

Signature _____ Date _____

Office Supply Store #1

[redacted]

[redacted] *Bellflower, CA 90706-6202*

11/10/2011 **Violation 37**

PURE FOOD / SPOILAGE (MINOR) Examples Include: Meat, fish or poultry products that have the appearance of spoilage (*), PHF oxygen reduced package exceeds a "use by" date, Food-infesting insects (e.g., grain beetles, meal moths, gnats, ants) are observed in food or fruit flies in liquor bottle, Unopened soda can stored in ice bin (customer edible ice), Swollen can or significantly dented can at the rim / seam, Condensate from refrigerator dripping onto raw meat / poultry / uncut fruits and vegetables, Hair found in food, Lining food containers with newspaper

Violation 54

DETERIORATED / UNAPPROVED MATERIALS Examples Include: Missing base coving, floor tiles or grout between tiles, Unapproved floor material (carpet / vinyl tiles) in food areas, Damaged walls (peeling paint / plaster / not smooth / loose FRP / metal flashing), Missing electrical or light-switch cover, Missing or unapproved type of ceiling panels, Deteriorated caulking at the wall and sink junction, Deteriorated floors / walls / ceilings in the walk-in refrigerator(s) (aggregate / gravel exposed), Cardboard or unapproved floor boards used on floors, Holes / cracks in the wall or ceiling that may promote a vermin harborage

Violation 55

NOT CLEAN Examples Include: Accumulated food debris, grease, mold, or dirt on floors, walls, ceilings including inside of walk-in, Make-up air vent / ceiling vent / ceiling fan accumulated

[redacted]

NEARBY RESTAURANTS

Within 2 Miles

[redacted]

with grease or dust, Cockroaches (live or dead) / rodent droppings or urine on floors, walls or ceilings

Violation 67

TOILETS / TOILET ROOM DISREPAIR / INADEQUATE # / DOOR NOT SELF-CLOSING / NOT CLEAN / TOILET TISSUE Examples Include: One of the available toilets is damaged, leaking, clogged or inoperative, Urinal is missing in toilet room of a facility that has on-site liquor consumption, Separate men's and women's toilets are not available in a facility that serves alcohol for on-site consumption, No toilet tissue or missing toilet tissue dispenser, Door removed or propped open at the toilet room, Missing or damaged self-closing device, Unclean toilet facilities

---

7/6/2010

Violation 54

DETERIORATED / UNAPPROVED MATERIALS Examples Include: Missing base coving, floor tiles or grout between tiles, Unapproved floor material (carpet / vinyl tiles) in food areas, Damaged walls (peeling paint / plaster / not smooth / loose FRP / metal flashing), Missing electrical or light-switch cover, Missing or unapproved type of ceiling panels, Deteriorated caulking at the wall and sink junction, Deteriorated floors / walls / ceilings in the walk-in refrigerator(s) (aggregate / gravel exposed), Cardboard or unapproved floor boards used on floors, Holes / cracks in the wall or ceiling that may promote a vermin harborage

---

[redacted]

DATA SOURCE

This data was downloaded from the local health department for this restaurant. See our **FAQ** for a full list of our data sources.

Last Updated 11/10/2011 5:00:00 AM

Office Supply Store #2

[redacted]

[redacted] *Huntington Park, CA 90255-3138*

9/25/2009 **Violation 37**

PURE FOOD / SPOILAGE (MINOR) Examples Include: Meat, fish or poultry products that have the appearance of spoilage (*), PHF oxygen reduced package exceeds a "use by" date, Food-infesting insects (e.g., grain beetles, meal moths, gnats, ants) are observed in food or fruit flies in liquor bottle, Unopened soda can stored in ice bin (customer edible ice), Swollen can or significantly dented can at the rim / seam, Condensate from refrigerator dripping onto raw meat / poultry / uncut fruits and vegetables, Hair found in food, Lining food containers with newspaper

Violation 48

NON-FOOD-CONTACT SURFACES NOT CLEAN (MINOR) Examples Include: Accumulated grease or food debris on the non-food contact surfaces of equipment, shelving, or cabinets, Dirty fan guards or door gaskets in walk-in refrigerator, Dirty shelving in refrigeration unit with no direct food contact

Violation 62

LOW RISK HOT / WARM WATER VIOLATIONS Examples Include: Water throughout the restaurant is measured at 110-119°F, chemically sanitizing multi-use utensils (24 hours to abate), All non critical sinks not meeting the required minimum hot water temperatures (120°F for food prep / mop OR 100°F for handwash sink), Water is less than 120°F at a pre-packaged food facility (24 hours to abate), Water temperature measured at a critical food preparation or mop sink is between 110-119°F or 90-99°F at a critical handwash sink, Manual warewashing solution between

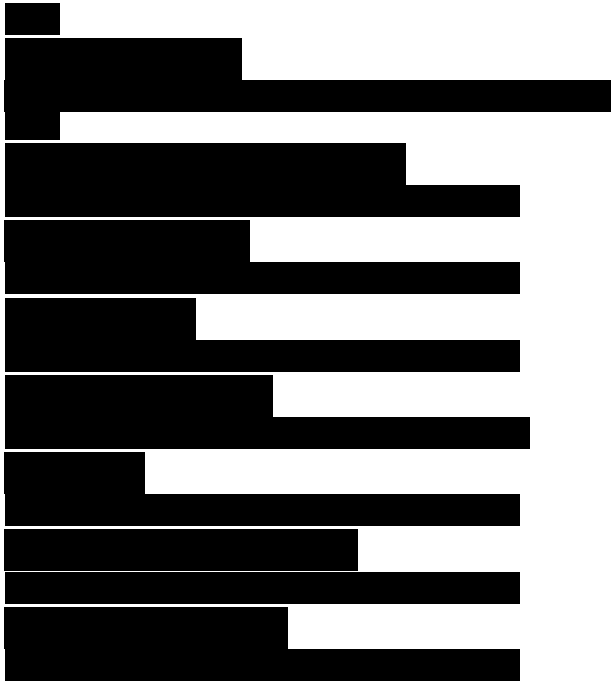
[redacted]

NEARBY RESTAURANTS

Within 2 Miles

[redacted]

100-110°F (Unless otherwise specified by detergent manufacturer's instruction label)



MORE...

DATA SOURCE

This data was downloaded from the local health department for this restaurant. See our **FAQ** for a full list of our data sources.

Last Updated 1/1/2000 5:00:00 AM

INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health
1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

[redacted]

Party Store #1

[redacted]
PREPACKAGED FOOD ONLY
[redacted]
HUNTINGTON BEACH, CA 92647

Record ID: [redacted]
Inspection Date: 01/07/2013
Reinspection Date: 01/14/2013

Type of Facility: 0391-PKGD FOOD MKT OR CONFECTIONARY 1-1999 SQ FT
Service: A01-**ROUTINE INSPECTION**

Mailing Address:
ON FILE

B Freeman, REHS
ENVIRONMENTAL HEALTH SPEC II
(714) 981-9070
7:30-8:30 a.m.

THE ITEMS NOTED BELOW WERE OBSERVED DURING THE COURSE OF A SITE VISIT. ANY VIOLATIONS OBSERVED MUST BE CORRECTED.

OPENING COMMENTS

FC00 - OPENING COMMENT
This facility seems to have changed ownership from [redacted]. Please fill out and provide the new Health Permit application to this Agency.
This facility has on display under 300 feet of non-potentially hazardous food. This facility will have a program element designated as limited Prepackaged food.

MINOR VIOLATIONS

FC39 - Evidence of Vermin Activity/Presence of Animals/Insects
Multiple Rodent droppings were observed on the floor of the storeroom where packaged food is stored. Construct, equip, maintain, and operate the food facility so as to prevent the entrance and harborage of rodents. Use any approved method for eliminating rodents from the facility.
NOTE: A thorough inspection for vermin activity was conducted and no further evidence was observed.

FC40 - Facility not Fully Enclosed/Open Door/Air Curtain
Discontinue propping open the front door to the outside. Maintain the door closed at all times except during passage. Construct, equip, maintain and operate the food facility so as to prevent the entrance and harborage of animals, birds and vermin, including, but not limited to, rodents and insects.

FC43 - Lack of/Improper Handwashing/Handwashing Sup.
No warm water was available from the sink in one of the new restrooms. Handwashing facilities shall be equipped to provide warm water under pressure for a minimum of 15 seconds through a mixing valve or combination faucet.

COMMENTS

FC99 - NOTES
This inspection report was reviewed with: The manager, [redacted]
The management of this facility has provided a current e-mail address and has agreed to receive a copy of this report via e-mail. This report will be sent via e-mail. The person in charge was instructed to contact this office if they do not receive the e-mail.
Change of Ownership: Yes
All food is prepackaged and non-potentially hazardous.
The “PASS” Notification Seal was posted today in a prominent location.
Retain a copy of the most recent inspection report on the premises available for review at the request of the public.
SIGNATURE IS NOT REQUIRED; PLEASE RETAIN THIS COPY FOR YOUR FILES.

FCC0 - REINSPECTION SCHEDULED

I declare that I have examined and received a copy of this inspection report.

INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health
1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

[redacted]

[redacted]
PREPACKAGED FOOD ONLY
[redacted]
HUNTINGTON BEACH, CA 92647

Record ID: [redacted]
Inspection Date: 01/07/2013

A reinspection is scheduled on the date noted at top of the inspection report. A reinspection notification seal was posted today in a prominent location.
REINSPECTION FEES:
Fees are assessed for second or greater reinspections. The purpose of these fees is to shift costs away from compliant operators and impose fees on those facilities that fail to readily comply with the applicable laws and regulations. The amount of the fee is to cover all of the costs associated with the service and the time charged includes travel time. The fees until June 30, 2013 are as follows:

-1st Reinspection: NO FEE
-2nd Reinspection or Greater, during normal work hours:
$25.75 per quarter-hour or fraction thereof
-2nd Reinspection or Greater, during other hours, including weekends and holidays:
$38.63 per quarter-hour or fraction thereof
-Notice of Violation Reinspection: $305.00

I declare that I have examined and received a copy of this inspection report.

Print Name and Title _____

Signature _____ Date _____

INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health
1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

[redacted]

Party Supply Store #2
[redacted]
SANTA ANA, CA 92703

Record ID: [redacted]
Inspection Date: 02/26/2014
Reinspection Date:

Type of Facility: 0391-PKGD FOOD MKT OR CONFECTIONARY 1-1999 SQ FT
Service: A01-**ROUTINE INSPECTION**

Mailing Address:
ON FILE

L Adourian
ENVIRONMENTAL HEALTH SPEC I
(657) 600-7783

THE ITEMS NOTED BELOW WERE OBSERVED DURING THE COURSE OF A SITE VISIT. ANY VIOLATIONS OBSERVED MUST BE CORRECTED.

MINOR VIOLATIONS

FC39 - Evidence of Vermin Activity/Presence of Animals/Insects
A bird in a bird cage was observed to be kept in the employee area in front of the candy aisle. Live animals, birds, and fowl shall not be kept or allowed in any food facility except those that are exempt from California Retail Food Code as described in Section 114259.

FC40 - Facility not Fully Enclosed/Open Door/Air Curtain
Observed the front doors to be propped open. Maintain the door closed at all times except during immediate passage. Alternatively, if ventilation is desired, provide an approved screen door. Maintain the food facility fully enclosed to preven the entrance and harborage of animals and insects.

FC46 - Unapproved Pesticides/Chemicals/Labeling
An insecticide not approved for use in a commercial food facility was observed to be stored in the customer area near the front entrance. Store and use all poisonous substances, detergents, bleach, cleaning compounds, and all other injurious or poisonous materials in a manner that is not likely to cause contamination or adulteration of food.

FC47 - Lack of/Unsanitary/Condition Walls/Floors/Ceilings
1. Accumulated dust, trash, and/or grime was observed beneath the upright cooler. Thoroughly clean and maintain the floors (including the floor sinks and drains), walls, and ceilings in a clean and sanitary manner.

2. A hole was observed in the ceiling in the janitorial room. Effectively seal all crevices (i.e. gaps and cracks) throughout the facility to eliminate potential vermin (including insects) harborage.

3. Sections of base coving were observed to be missing in the janitorial room. Provide an integrally designed base coving with a 3/8-inch radius at the juncture of the floor and wall. The coving must extend up the wall at least 4 inches.

FC49 - Signs/Labels/Menu Board/Trans Fat-Missing/Incorrect/Lack of Food Handler Card
A handwashing sign was not observed to be posted at the handwashing sink in the restroom. Post a legible sign in a conspicuous location at each handwashing sink directing attention to the need to thoroughly wash hands.

*A handwashing sticker was provided on this date.

FC51 - Last Report Unavailable/Consumer Access
The last inspection report was unavailable for review at the public's request. Retain a copy of the most recent inspection report on the premises available for review at the request of the public. A copy of the most recent Health Inspection Report is available at www.ocfoodinfo.com.

COMMENTS

INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health
1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

[redacted]

[redacted]
SANTA ANA, CA 92703

Record ID: [redacted]
Inspection Date: 02/26/2014

FC99 - NOTES Effective January 1, 2014, California Assembly Bill No. 1252 requires the food employees to use suitable utensils, such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment, when contacting ready-to-eat food. For more details, please visit our website at www.ocfoodinfo.com or contact your Environmental Health Specialist.
This inspection report was reviewed with [redacted], owner.
It was agreed that a copy of this report will be mailed to the address provided. The person in charge was directed to call this office if the report is not received within 7 business days. Reports and other valuable information can be found at www.ocfoodinfo.com. A copy of the most recent routine inspection report conducted shall be maintained at the food facility and be made available to a consumer upon request. SIGNATURE IS NOT REQUIRED; PLEASE RETAIN THIS COPY FOR YOUR FILES.

Change of Ownership: No
Food Temperatures:
-upright cooler: packaged milk 45F
Hot water recorded at 120F
Dish/Utensil Sanitation method: n/a
Sanitizer level for wiping cloths: n/a

F100 - "PASS" SEAL POSTED

I declare that I have examined and received a copy of this inspection report.

Print Name and Title _____

Signature _____ Date _____

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-019

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Clean in place (CIP) definition

Issue you would like the Conference to consider:

Clean-in-Place (CIP) is common in liquid food and beverage processing, but is poorly defined and understood in the retail and food service industries. New and novel dispensing equipment and systems being introduced to the industry both in the U.S. and internationally create the need to better define and characterize hazards and reasonable interventions for liquid food preparation and dispensing systems. The process involves more than just rinsing wetted surfaces; it is not just "cleaning" - as the current CIP acronym infers. Chemicals used to clean and sanitize require kinetics in one or many forms to improve efficacy. When food contact surfaces are cleaned and sanitized in a dishwasher, or a three compartment sink, kinetics are added in the forms of high pressure sprays, or scrubbing, or turbulent flows in a power wash type sink. Kinetics (in some form) is also required for plumbed systems that handle liquid foods. Cleaning and sanitizing are discrete sequential steps, where cleaning precedes the application of an approved food contact surface sanitizer on the food contact surface of the equipment. The process is better defined as clean *and sanitize* in place (CSIP), as one cannot sanitize an unclean surface. Pronounced "sea-sip" (two syllables instead of three), CSIP systems are plumbed systems that typically use valves, pumps and control logic to sequentially wash and then sanitize food contact surfaces that are essentially, plumbing lines for liquid foods and beverages.

Public Health Significance:

Due to their plumbing line form, their internal wetted surfaces cannot be readily accessed for inspection or for manual cleaning and sanitizing. This presents a unique hazard to food safety and requires focused safety criteria to ensure reasonable continuous food safety. Using an acronym that has the first letter for each critical sequential step, yet fewer pronounceable syllables can add clarity to its unique safety function without any additional cost to industry or consumers. Further, it is well known that you cannot effectively sanitize contaminated surfaces. Consequently, food contact surfaces must be cleaned before sanitizers are applied. In food and beverage processing, surfactants that may not be

categorized as detergents are often used for the initial cleaning step. Accordingly, instead of calling cleaners "detergents", it is more appropriate use the genus solutions that have reduced surface tensions, known to be more effective than water by itself; *surfactants*. Further, "rinsing" in only needed when the listing and or label instructions indicate it is needed. Some surfactants (and now sanitizers too) are GRAS and others have K1's or are secondary food additives or ingredients and accordingly, require no rinsing after use and before introduction of liquid foods.

References link: https://www.yousendit.com/download/ZWJWR0lVNXZGR0V3anNUQw

CSIP processes comprise a PRIORITY ITEM (^{P}) risk categorization.

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 strike through format)*:*

Section 1-201.10

Clean and sanitize in place (CSIP) ^{P}

(1) "CSIP" means cleaned and sanitized in place by the sequential circulation or forceful flowing by mechanical means through a piping system, of a ~~detergent~~ surfactant solution, water rinse (when required), and SANITIZING solution onto ~~or over EQUIPMENT~~ or through wetted food contact surfaces that require cleaning and sanitizing, such as the method used, in part, to clean and SANITIZE wetted liquid food contact surfaces of food equipment that feature liquid food plumbing lines such as dispensing freezers ~~a frozen dessert machine~~ or milk or juice dispensers and similar equipment.

(2) "CSIP" does not include the cleaning of EQUIPMENT such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CSIP system.

Submitter Information:

Name:	Thomas Johnson, Chief Manager
Organization:	QleanTech Enterprises, LLC
Address:	1408 Northland Dr. #406
City/State/Zip:	Mendota Heights, MN 55120
Telephone:	651-587-0418
E-mail:	tomj@jdpinc.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-020

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Add a definition for In-place cleaning (IPC)

Issue you would like the Conference to consider:

In-place cleaning (IPC) is not the same as clean in place (CIP) or clean and sanitize in place (CSIP). Section 1-201.10 of the 2013 FDA Food Code has a definition for CIP. Section 4-501.112 Part (B) of the FDA Food Code makes reference to in-place cleaning (IPC) which is otherwise not defined in the code. Rather, there is a circular reference made back to CIP. Because they are different processes, IPC needs its own definition.

Public Health Significance:

Having clear, unambiguous definitions for food safety systems is critical to ensuring that everyone has the same idea of what is needed for reasonable safety. This is the reason that section 1-201.10 of the food code is so important and why a new definition needs to be added to the FDA Food Code to differentiate two completely separate concepts that (unfortunately) are known to use the same three words, albeit, in different order.

An *in-place cleaning* (IPC) process is a *manual* cleaning and sanitizing process that is carried out without moving the food equipment or food contact surfaces to a sink or into a dishwasher. Examples here include motorized meat slicers, band saws and grinders, whether for meat or coffee. Another example is a large cutting board or a large food display tray that does not fit into a sink or dishwasher, thus requiring IPC.

Clean in place (CIP) systems have integral plumbing lines for the conveyance of liquid foods. If the internal surfaces of these liquid food or beverage plumbing lines do not have access (inspection) openings to enable inspection, and access to enable manual cleaning and sanitization of its surfaces, then a sequential clean and sanitize in place (CSIP or CIP) system is required. A more accurate description of these system is a *clean* and *sanitize in place* systems, or CSIP (pronounced *"sea-sip" using only two syllables as compared to three syllables for C.I.P.)*. CSIP systems are similar to IPC only in the sense that the food contact surfaces are cleaned and sanitized without moving them to the scullery or into a dish machine. CSIP systems are *plumbed* systems designed to *automatically* or *semi-*

automatically clean and disinfect internal food contact surfaces that are otherwise inaccessible using process validated cleaning and sanitizing protocols. Some equipment can have CSIP integrated into its design and is comprised of a series of valves, pumps and/or control logic with the sequential application of cleaning and then sanitizing solutions, and are free draining. Other CSIP systems depend upon connection to ancillary CSIP equipment that will flush throughout the (food contact surface) plumbing system of the food/beverage equipment, cleaners and sanitizers in sequence, to remove accumulated soils and/or biofilms. These systems are self-draining to carry away dislodged food soils and other contaminants along with the cleaning and sanitizing process solutions. Examples include the internal plumbing and other food contact surfaces in dispensing freezers for soft-serve ice cream, yogurt and similar equipment with inaccessible multi-use food contact surfaces in the form of internal beverage lines, fittings and valves and energy transfer surfaces. Additional examples include internal surfaces of ice machines such as its feed water lines, harvest plates and sumps, and internal and external plumbed beverage lines for food equipment that prepares, processes, packages and/or dispenses milk or milk products, juices, soda, beer, wine and spirits.

IPC comprises a PRIORITY foundation (^{Pf}) item.

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

"In-place cleaning" (IPC) means the *manual* cleaning of Food Equipment and Food Contact surfaces without moving the equipment or food contact surface to the scullery, a dish washer or sink.^{Pf}

Submitter Information:

Name:	Thomas Johnson
Organization:	QleanTech Enterprises, LLC
Address:	1408 Northland Dr. #406
City/State/Zip:	Mendota Heights, MN 55120
Telephone:	651-587-0418
E-mail:	tomj@jdpinc.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-021

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Change abbreviation for CIP to CSIP (clean and sanitize in place)

Issue you would like the Conference to consider:

The acronym "CIP" as defined in section 1-201.10 of the 2013 FDA Food Code could be improved to better articulate the process by reducing one syllable and adding a letter. Instead of having to say each letter aloud, readers can refer to the process with greater descriptive precision by referring to the clean and sanitize in place process as "sea-sip" (CSIP).

Public Health Significance:

Having clear, unambiguous definitions for food safety systems is critical to ensuring that everyone has the same idea of what is needed for reasonable safety. This is the reason that section 1-201.10 of the Food Code is so important and why more descriptive index words should be used whenever possible.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 FDA Food Code modified language be incorporated as follows:

Section 1-201.10 of the FDA food Code is modified to change the index word from CIP to CSIP for the descriptive process of cleaning and then sanitizing the internal liquid food plumbing lines in food equipment.

Submitter Information:

Name:	Thomas Johnson
Organization:	QleanTech Enterprises, LLC
Address:	1408 Northland Dr #406
City/State/Zip:	Mendota Heights, MN 55120
Telephone:	651-587-0418

E-mail: tomj@jdpinc.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-022

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Update the definition of Vending Machines

Issue you would like the Conference to consider:

New payment transaction technology is available whereby products can be dispensed by a vending machine upon completion of a digital transaction. The current definition for "Vending Machines" in the 2013 FDA Food Code section 102.10 (B) needs an update to remain current.

Public Health Significance:

Old-fashioned coin and currency based vending transactions are being replaced with "smart" digital transactions. Safety and convenience conscious consumers are often "cashless" and rely upon new technology for their purchase of goods including food and beverage. Revising the definition to include new payment technologies will reduce confusion as to its acceptability.

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

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, <u>or upon completion of a digital transaction</u> or by optional manual operation, dispenses unit servings of FOOD in bulk or in packages without the necessity of replenishing the device between each vending operation.

Submitter Information 1:

Name:	Thomas Johnson
Organization:	Johnson Risk Solutions, LLC
Address:	1408 Northland Dr. #406

City/State/Zip: Mendota Heights, MN 55120
Telephone: 6515870418
E-mail: tomj@jdpinc.com

Submitter Information 2:

Name: Steve Frehn
Organization: Momentum Machines, LLC
Address: 977 Howard St.
City/State/Zip: San Francisco, CA 94103
Telephone: 650-906-7058
E-mail: steve@momentummachines.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-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:

Shellfish Retail Record Keeping

Issue you would like the Conference to consider:

Enhancing record keeping at retail establishments.

Public Health Significance:

The incidence of *Vibrio parahaemolyticus* (Vp) illness associated with molluscan shellfish consumption is on the increase and continues to be a significant challenge to state and federal health authorities. In 2013 the Interstate Shellfish Sanitation Conference (ISSC) incorporated language into the National Shellfish Sanitation Program requiring increased state regulatory action in response to *V.p.* illnesses. The regulatory response outlined in these new requirements is directly linked to the number of reported *V.p.* illnesses. This approach requires timely investigation of *V.p.* cases by State health officials to determine product source. In many cases, States have been unable to determine the source of the shellfish due to inadequate record keeping as required by Section 3-203.12 of the 2013 FDA Food Code. The National Shellfish Sanitation Program (NSSP) recognizes this requirement as a critical violation. This change would create consistency between the Food Code and the NSSP.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending:

1) Modification of Section 3-203.12(A) of the 2013 FDA Food Code as indicated below from a Priority Foundation to a Priority Violation (language to be added is underlined; language to be deleted is in strikethrough format).

3-203.12 Shellstock, Maintaining Identification.

(A) Except as specified under Subparagraph (C) (2) of this section, SHELLSTOCK tags or labels shall remain attached to the container in which the SHELLSTOCK are received until the container is empty. ~~Pf~~ P

2) The FDA begin discussions with the ISSC and Conference for Food Protection to identify steps that can be taken to enhance implementation and enforcement of shellfish record keeping at retail establishments.

Submitter Information 1:

Name:	Ken Moore
Organization:	ISSC
Address:	209 Dawson RdSuite 1
City/State/Zip:	Columbia, SC 29223
Telephone:	8037887559
E-mail:	issc@issc.org

Submitter Information 2:

Name:	Nancy Daniel
Organization:	ISSC
Address:	209 Dawson RdSuite 1
City/State/Zip:	Columbia, SC 29223
Telephone:	8037887559
E-mail:	issc@issc.org

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-024

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Alignment of the Food Code with the FDA Juice HACCP Retail Definition

Issue you would like the Conference to consider:

The sale of packaged, raw, untreated, or cold pressed juices is allowed under the 2013 FDA Food Code by a retail food establishment. However, the FDA Food Code does not address where a retail food establishment may sell untreated packaged juice. The FDA Juice Hazard Analysis and Critical Control Point (HACCP) regulation and associated guidance does have specific conditions under which packaged untreated juice may be sold under the retail exemption, specifically that any offsite sales must be conducted at a location owned by the retail establishment. Retail regulators operating under FDA Food Code are being challenged by food establishments that want to package untreated juice and then sell it "offsite" via a cooperative arrangement with a health club, health food store or a vending unit as an extension of the retail establishment. A clear link needs to be established in the Food Code & 21 Code of Federal Regulations (CFR) 120 Juice HACCP sections regarding retail sales.

Public Health Significance:

Providing a link between the FDA Food Code and 21 CFR part 120 Juice HACCP requirements for the sale of packaged juice allows for regulators to apply the same criteria when evaluating the safety of a proposed packaged juice process in regards to the retail exemption. Industry benefits from the uniform application of the retail exemption for treated juice by not having differing sets of standards from jurisdiction to jurisdiction. The need to treat packaged juice and the public health risk associated with consumption of untreated packaged juice has been cited in many studies.

Annex 3 of the FDA Food Code in Section 3-801.11 states: There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as Cryptosporidium, Shiga toxin-producing Escherichia coli, Salmonella spp., and Vibrio cholera.

The Summary in *the Federal Register / Vol. 66, No. 13 / Friday, January 19, 2001 / Rules and Regulations for Juice* states the need for the treatment of packaged juice.

"The Food and Drug Administration (FDA or the agency) is adopting final regulations to ensure the safe and sanitary processing of fruit and vegetable juices. The regulations mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of these foods. HACCP is a preventive system of hazard control. FDA is taking this action because there have been a number of food hazards associated with juice products and because a system of preventive control measures is the most effective and efficient way to ensure that these products are safe."

In a September 22, 2005 *Guidance for Industry Letter to State Regulatory Agencies and Firms That Produce Treated (but not Pasteurized) and Untreated Juice and Cider*, the FDA stated the concern regarding continuing outbreaks of foodborne illness associated with the consumption of treated (but not pasteurized) and untreated juice and cider. The letter reminds regulators and industry of actions that the FDA recommends processors take to enhance the safety of these products with the following reason:

"Recent illness outbreaks due to treated (but not pasteurized) and untreated apple cider occurred in Ohio in 2003, and in New York state in 2004. In addition, a multi-state illness outbreak associated with treated (but not pasteurized) orange juice occurred this year. These outbreaks highlight the need for processors to ensure that they are taking all appropriate steps to comply with applicable food safety requirements."

References:

Federal Register CFR 21 Part 120:

https://www.federalregister.gov/articles/2001/01/19/01-1291/hazard-analysis-and-critical-control-point-haacp-procedures-for-the-safe-and-sanitary-processing-and

Guidance for Industry Letter to State Regulatory Agencies and Firms:

http://www.fda.gov/RegulatoryInformation/Guidances/ucm072508.htm

Hazard Analysis Critical Control Point (HACCP), National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Recommendations:

http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm073540.htm

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the 2013 FDA Food Code be amended to include the following (new language is in underline format):

3-404.11 Treating Juice.

JUICE PACKAGED in a FOOD ESTABLISHMENT shall be:

(A) Treated under a HACCP PLAN as specified in ¶¶ 8-201.14(B) -(E) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; [P] or

(B) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance: [Pf]

(1) As specified under § 3-602.11, [Pf] and

(2) As specified in 21 CFR 101.17(g) Food labeling, warning, notice, and safe handling statements, JUICES that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens with the following, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and person with weakened immune systems." Pf

(C) And only at locations that are considered to be retail by the definition of a retail establishment as specified in 21 CFR 120.3 (l) and qualify for the retail exemption as specified in 21 CFR 120.3 (j) (2) (ii).

Submitter Information:

Name:	Sandra D. Craig
Organization:	SC Dept. of Health and Environmental Control
Address:	2600 Bull Street
City/State/Zip:	Columbia, SC 29201
Telephone:	803-896-0614
E-mail:	craigsd@dhec.sc.gov

Supporting Attachments:

- "CFR 120.3"

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.

§120.3 Definitions.

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, §101.9(j)(18)(vi) of this chapter, and parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110 and 117 do not govern such terms where used in this part. The following definitions shall also apply:

(a) *Cleaned* means washed with water of adequate sanitary quality.
(b) *Control* means to prevent, eliminate, or reduce.
(c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.
(d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.
(e) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.
(f) *Culled* means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with §120.24, *culled* means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.
(g) *Food hazard* means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
(h) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.
(i) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.
(j)
(1) *Processing* means activities that are directly related to the production of juice products.
(2) For purposes of this part, processing does not include:
(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and
(ii) The operation of a retail establishment.
(k) *Processor* means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.
(l) *Retail establishment* is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. “Provides” includes storing, preparing, packaging, serving, and vending.
(m) *Shall* is used to state mandatory requirements.
(n) *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.
(o) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.
(p) *Validation* means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.
(q) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

[66 FR 6197, Jan. 19, 2001, as amended at 80 FR 56167, Sept. 17, 2015]

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-025

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Amend Food Code – Nutrition Labeling of Standard Menu Items in Restaurants

Issue you would like the Conference to consider:

The 2013 FDA Food Code should be amended to be consistent with 2010 federal nutrition labeling requirements for foods served or offered for sale in restaurants and similar retail food establishments. The Food, Drug, and Cosmetic Act now requires chain retail food establishments with 20 or more locations to provide calorie and other information for standard menu items (21 U.S. Code § 343(q)(5)(H)(i) to (iii)). Updating the Food Code will encourage state and local food regulatory agencies to implement the law.

Public Health Significance:

Nearly two thirds of adults and one third of children are overweight or obese.[1] Americans consume, on average, one-third of their calories from eating out.[2] Studies link eating out with obesity, higher caloric intake, higher intake of calories, saturated fat and fewer nutrients.[3] Children typically eat almost twice as many calories when they eat out compared to at home.

Studies show that providing nutrition information at restaurants can help Americans make lower calorie choices and spur the reformulation of existing food items and the introduction of nutritionally improved items. A recent Harvard study found restaurant menu calorie labeling could prevent up to 41,000 cases of childhood obesity and could save over $4.6 billion in healthcare costs over ten years.[4]

Americans need nutrition information to manage their weight and reduce the risk of or manage heart disease, diabetes, or high blood pressure, which are leading causes of death, disability, and high health-care costs.

Trade groups, restaurant chains, other food establishments, and over 100 nutrition and health organizations and professionals support menu labeling.

Covered food establishments will be required in 2016 to provide calorie labeling on the menu and menu board for standard menu items, along with a succinct statement on general nutrition advice, and provide additional written nutrition information.

Incorporating this provision in the Food Code will assist regulatory authorities in adding to their restaurant inspections a quick check to determine if the required information is available and presented in a manner that is easy for consumers to see and read (i.e., that it is provided in the required format).

References

[1] CDC/NCHS, National Health and Nutrition Examination Survey, 2012. http://www.cdc.gov/nchs/nhanes.htm

[2] Todd J, et al. The Impact of Food Away from Home on Adult Diet Quality USDA, 2010. http://www.ers.usda.gov/media/136609/err90_1_.pdf

[3] Center for Science in the Public Interest. Research Review: Effects of Eating Out on Nutrition and Body Weight, updated October 2008. https://cspinet.org/new/pdf/lit_rev-eating_out_and_obesity.pdf

[4] Gortmaker SL, et al. Three Interventions That Reduce Childhood Obesity Are Projected to Save More Than They Cost to Implement. November 2015, *Health Affairs*, 34, no. 11 (2015):1304-1311. http://content.healthaffairs.org/content/34/11/1932.full?ijkey=lnFXpx4AIM506&keytype=ref&siteid=healthaff

Recommended Solution: The Conference recommends...:

that 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 3-602.11 Food Labels

(E) FOODS served or offered for sale in restaurants or similar retail FOOD ESTABLISHMENTS not otherwise exempted in the Federal Food, Drug, and Cosmetic Act § 403(q)(5)(H) be labeled according to 21 CFR 101.11.

Annex 3 - Public Health Reasons/Administrative Guidelines

Nutrition Labeling

I. The following foods need not comply with nutrition labeling in the CFR referenced in subparagraph 3-602.11(B)(6) if they do not bear a nutrient claim, health claim, or other nutrition information:

(C) Foods served in ~~food establishments with facilities for immediate consumption such as restaurants, cafeterias, and~~ mobile food establishments;~~, and foods sold only in those establishments;~~

~~(D) Foods similar to those specified in the preceding bullet but that are sold by food establishments without facilities for immediate consumption such as bakeries and grocery stores if the food is:~~

~~(1) Ready-to-eat but not necessarily for immediate consumption,~~

~~(2) Prepared primarily in the food establishment from which it is sold, and~~

~~(3) Not offered for sale outside the food establishment;~~

~~(E) Foods of no nutritional significance such as coffee;~~

(D)~~(F)~~ Bulk food for further manufacturing or repacking; and

(E)~~(G)~~ Raw fruits, vegetables, and fish.

Annex 7 - Model Forms, Guides, and Other Aids

Form 3-A, Food Establishment Inspection Report

37. Food properly labeled; original container; nutrition labeling

Guide 3-B, Instructions for Marking the Food Establishment Inspection....

Food Identification

37. Food properly labeled; original container; nutrition labeling

Packaged foods and foods served or offered for sale in restaurants or similar retail food establishments are required to conform to specific labeling laws unless otherwise exempted.

Submitter Information 1:

Name:	David W. Plunkett
Organization:	Center for Science in the Public Interest
Address:	1220 L Street NW Suite 300
City/State/Zip:	Washington, DC 20005
Telephone:	2027778319
E-mail:	dplunkett@cspinet.org

Submitter Information 2:

Name:	Colin Schwartz
Organization:	Center for Science in the Public Interest
Address:	1220 L Street NW Suite 300
City/State/Zip:	Washington, DC 20005
Telephone:	2027778387
E-mail:	cschwartz@cspinet.org

Supporting Attachments:

- "CSPI Menu Labeling Fact Sheet (Redacted)"
- "Nutrition Labeling on Menus Final Rule 21 CFR Part 101.11"
- "Sample Menu Board 1"
- "Sample Menu Board 2 (Redacted)"

Nutrition Labeling at Restaurants, Supermarkets & Other Food Service Establishments

Congress passed a national law in March 2010 requiring calories to be posted on menus, menu boards, and for food on display at restaurants, supermarkets, convenience stores, and other food service establishments with 20 or more outlets [21 U.S.C. 343(q)(5)(H)].

Menu labeling allows Americans to exercise personal responsibility and make informed choices for a growing part of their diets.

People want nutrition information from food service establishments: **80% of Americans support menu labeling in chain restaurants; 77% want calorie labeling at convenience stores; and 81% favor having supermarkets provide calorie information for their prepared, restaurant-type foods.**[1]

Eating out is a big and problematic part of Americans' diets

Americans consume, on average, one-third of their calories from eating out.[2] Studies link eating out with obesity and higher caloric intakes.[3]

Children typically eat almost twice as many calories when they eat a meal at a restaurant compared to a meal at home.[4] **When eating out, people eat more saturated fat and fewer nutrients**, such as calcium and fiber, than at home.[2,3]

People need nutrition information to manage their weight and reduce the risk of or manage heart disease, diabetes, or high blood pressure, which are leading causes of death, disability, and high health-care costs.

Without nutrition information, it is difficult to compare options and make informed decisions.

2,000 calories per day is used for general nutrition advice. Who would guess…

Large movie theater popcorn from [redacted] without "buttery" topping has over 1,200 cals and 60 g (three days' worth) of saturated fat

A regular order of cheese fries with ranch dressing from [redacted] contains almost 1,800 cals

A pecan roll from [redacted]) has almost double the calories of a chocolate pastry (410 cal)

[redacted]

A side order of jalapeno corn bread fro[redacted] has 690 cals, a side order of fries has 390 cals

A grande hot chocolate from [redacted] contains 320 cals while a cappuccino contains 120 cals

A regular oriental chicken salad from [redacted] contains 1,400 cals while the [redacted] Chicken and Shrimp contains 620 cals

[redacted] red hot beef burrito contains 340 cals

In March 2015, **sales at restaurants and bars surpassed spending at grocery stores for the first time**, making it half of food dollars spent.[5]

On a typical day, 33% of children, 41% of adolescents, and 36% of adults eat at a fast-food restaurant.[6]

A health impact assessment from Los Angeles County estimated **that menu labeling could avert 40% of the 6.75 million pound average annual weight gain** in the county (population aged 5 years and older).[7]

Menu labeling

Though not all studies are able to measure an effect of menu labeling, many show that providing nutrition information at restaurants can help people make lower calorie choices and spur the reformulation of existing food items and the introduction of nutritionally improved items.

- A New York City study found **15% of customers reported using menu labeling and purchased 106 fewer calories in a fast-food lunch** than customers who did not see or use the calorie information.[8]
- A study conducted in New York City [redacted] restaurants found that menu labeling had little effect on beverage calories, but reduced calories in food purchases by 14%. **Together, this is a 6% decrease in calories on average per transaction.** For people buying more calories, the effect was bigger, a 26% decrease.[9]
    - A 6% decrease in calories purchased at chain restaurants would mean a **30 calorie per person per day decrease in intake population-wide.**[9] **Keeping in mind that the obesity epidemic is explained by a less than 100 calorie per day imbalance,**[10] such a change could have a meaningful impact on public health.
- In a restaurant study conducted in Philadelphia, displaying calorie and nutrient labels next to all food-item descriptions and prices resulted in **an average purchase of 151 fewer calories, 224 mg less sodium, and 4 g less saturated fat** relative to unlabeled sites.[11]
- Parents of children 3–6 years old presented with a [redacted] **menu with calorie labeling ordered an average of 100 fewer calories for their children** than did parents who did not receive calorie information.[12]
- A study in King County, Washington found a **significant decrease in calories (41 calories) in entrée items** at 37 chain restaurants after implementation of menu labeling.[13]
- From 2012 to 2013, **newly introduced menu items in the largest U.S. restaurants were 56 calories lower on average** (a decline of 12%).[14]
- Between spring 2010 and spring 2011, **fast-food restaurants decreased children's menu entrees by 40 calories.**[15]
- Between the years of 2005 and 2011, **healthier food options increased from 13% to 20%** at five fast-food chains subject to menu labeling.[16]

[redacted]

For more information, contact the Center for Science in the Public Interest at 202-777-8352 or nutritionpolicy@cspinet.org or visit www.menulabeling.org
Updated July 2015

References

[1]Caravan ORC International. Restaurant Calorie Content: ORC Study 721210, May 2012. Conducted for the Center for Science in the Public Interest. Accessed at <http://cspinet.org/new/pdf/restaurant-calorie-content.pdf>.

[2] Todd J, et al. The Impact of Food Away from Home on Adult Diet Quality USDA, 2010. Accessed at <http://www.ers.usda.gov/media/136609/err90_1_.pdf>.

[3] Center for Science in the Public Interest. Research Review: Effects of Eating Out on Nutrition and Body Weight, updated October 2008. Accessed at <http://cspinet.org/new/pdf/lit_rev-eating_out_and_obesity.pdf>.

[4] Ebbeling CB, et al. Compensation for Energy Intake from Fast Food among Overweight and Len Adolescents. *Journal of the American Medical Association,* 2004, vol. 291, pp. 2828-2833.

[5] Jamrisko M. Americans' Spending on Dining out Just Overtook Grocery Sales for the First Time Ever. *Bloomberg Business*, April 14, 2015. Accessed at <http://www.bloomberg.com/news/articles/2015-04-14/americans-spending-on-dining-out-just-overtook-grocery-sales-for-the-first-time-ever>

[6] Powell NM, et al. Energy Intake from Restaurants: Demographics and Socioeconomics, 2003-2008. *American Journal of Preventative Medicine*, 2012, vol. 43, no. 5, pp. 498-504.

[7] Kuo T, et al. Menu Labeling as a Potential Strategy for Combating the Obesity Epidemic: A Health Impact Assessment. *American Journal of Public Health*, 2009, vol. 9, no. 9, pp.1680-1686.

[8] Dumanovsky T, et al. Changes in Energy Content of Lunchtime Purchases from Fast Food Restaurants after Introduction of Calorie Labeling: Cross Sectional Customer Surveys. *British Medical Journal*, 2011, vol. 343, d4464. doi: 10.1136/bmj.d4464.

[9] Bollinger B, et al. Calorie Posting in Chain Restaurants. *American Economic Journal: Economic Policy*, 2011, vol. 3, no. 1, pp. 91-128.

[10] Hall KD, et al. Quantification of the Effect of Energy Imbalance on Bodyweight. *Lancet*, 2011, vol. 378, pp. 826-837.

[11] Auchincloss A, et al. Customer Responses to Mandatory Menu Labeling May Lead to Lower-Calorie Restaurant Meal Choices for Children. *Pediatrics*, 2010, vol. 125, no. 2, pp. 244-248.

[12] Tandon PS, et al. Nutrition Calorie Labeling May Lead to Lower-Calorie Restaurant Meal Choices for Children. *Pediatrics*, 2010, vol. 125, no. 2, pp. 244-248.

[13] Bruemmer B, et al. Energy, Saturated Fat, and Sodium were Lower in Entrees at Chain Restaurants at 18 Months Compared with 6 Months Following the Implementation of Mandatory Menu Labeling Regulation in King County, Washington. *Journal of the Academy of Nutrition and Dietetics*, 2012, vol. 112, no. 8, pp. 1169-1176.

[14] Bleich SN, et al. Calorie Changes in Chain Restaurant Menu Items: Implications for Obesity and Evaluations of Menu Labeling. *American Journal of Preventative Medicine,* 2015, vol. 48, no. 1, pp. 70-75.

[15] Wu HW, Sturm R. Changes in the Energy and Sodium Content of Main Entrees in US Chain Restaurants from 2010 to 2011. *Journal of the Academy of Nutrition and Dietetics*, 2014, vol. 114, no. 2, pp. 209-219.

[16] Namba A, et al. Exploratory Analysis of Fast-Food Chain Restaurant Menus Before and After Implementation of Local Calorie-Labeling Policies, 2005-2011. *Preventing Chronic Disease*, 2013, vol. 10, E101. doi: 10.5888/pcd10.120224.

§ 101.10 Nutrition labeling of restaurant foods.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., ''low fat, this meal provides less than 10 grams of fat'') may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

[61 FR 40332, Aug. 2, 1996]

EFFECTIVE DATE NOTE: At 79 FR 71253, Dec. 1, 2014, § 101.10 was revised, effective Dec. 1, 2015. For the convenience of the user, the revised text is set forth as follows:

§ 101.10 Nutrition labeling of restaurant foods whose labels or labeling bear nutrient content claims or health claims.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (*e.g.*, ''low fat, this meal provides less than 10 grams of fat'') may serve as the functional equivalent of complete nutrition information as described in § 101.9. For the purposes of this section, restaurant food includes two categories of food. It includes food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments. It also includes food which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in the previous sentence, and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment. For standard menu items that are offered for sale in covered establishments (as defined in § 101.11(a)), the information in the written nutrition information required by § 101.11(b)(2)(ii)(A) will serve to meet the requirements of this section. Nutrient levels may be determined by nutrient databases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

§ 101.11 Nutrition labeling of standard menu items in covered establishments.

(a) *Definitions.* The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this section. In addition, for purposes of this section:

Authorized official of a restaurant or similar retail food establishment means the owner, operator, agent in charge, or other person authorized by the owner, operator, or agent in charge to register the restaurant or similar retail food establishment, which is not otherwise subject to section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act, with FDA for the purposes of paragraph (d) of this section.

Combination meal means a standard menu item that consists of more than one food item, for example a meal that includes a sandwich, a side dish, and a drink. A combination meal may be represented on the menu or menu board in narrative form, numerically, or pictorially. Some combination meals may include a variable menu item or be a variable menu item as defined in this paragraph where the components may vary. For example, the side dish may vary among several options (*e.g.*, fries, salad, or onion rings) or the drinks may vary (*e.g.*, soft drinks, milk, or juice) and the customer selects which of these items will be included in the meal.

Covered establishment means a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, *e.g.*, individual franchises) and offering for sale substantially the same menu items, as well as

a restaurant or similar retail food establishment that is registered to be covered under paragraph (d) of this section.

Custom order means a food order that is prepared in a specific manner based on an individual customer's request, which requires the covered establishment to deviate from its usual preparation of a standard menu item, *e.g.*, a club sandwich without the bacon if the establishment usually includes bacon in its club sandwich.

Daily special means a menu item that is prepared and offered for sale on a particular day, that is not routinely listed on a menu or menu board or offered by the covered establishment, and that is promoted by the covered establishment as a special menu item for that particular day.

Doing business under the same name means sharing the same name. The term ''name'' refers to either:

(i) The name of the establishment presented to the public; or

(ii) If there is no name of the establishment presented to the public (*e.g.*, an establishment with the generic descriptor ''concession stand''), the name of the parent entity of the establishment. When the term ''name'' refers to the name of the establishment presented to the public under paragraph (i) of this definition, the term ''same'' includes names that are slight variations of each other, for example, due to the region, location, or size (*e.g.*, ''New York Ave. Burgers'' and ''Pennsylvania Ave. Burgers'' or ''ABC'' and ''ABC Express'').

Food on display means restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption.

Food that is part of a customary market test means food that appears on a menu or menu board for less than 90 consecutive days in order to test consumer acceptance of the product.

Location means a fixed position or site.

Menu or *menu board* means the primary writing of the covered establishment from which a customer makes an order selection, including, but not limited to, breakfast, lunch, and dinner menus; dessert menus; beverage menus; children's menus; other specialty menus; electronic menus; and menus on the Internet. Determining whether a writing is or is part of the primary writing of the covered establishment from which a customer makes an order selection depends on a number of factors, including whether the writing lists the name of a standard menu item (or an image depicting the standard menu item) and the price of the standard menu item, and whether the writing can be used by a customer to make an order selection at the time the customer is viewing the writing. The menus may be in different forms, *e.g.*, booklets, pamphlets, or single sheets of paper. Menu boards include those inside a covered establishment as well as drive-through menu boards at covered establishments.

Offering for sale substantially the same menu items means offering for sale a significant proportion of menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies, (*e.g.* ''Bay View Crab Cake'' and ''Ocean View Crab Cake''). ''Menu items'' in this definition refers to food items that are listed on a menu or menu board or that are offered as self-service food or food on display. Restaurants and similar retail food establishments that are part of a chain can still be offering for sale substantially the same menu items if the availability of some menu items varies within the chain. Having the same name may indicate, but does not necessarily guarantee, that menu items are substantially the same.

Restaurant or similar retail food establishment means a retail establishment that offers for sale restaurant-type food, except if it is a school as defined by 7 CFR 210.2 or 220.2.

Restaurant-type food means food that is:

(i) Usually eaten on the premises, while walking away, or soon after arriving at another location; and

(ii) Either:

(A) Served in restaurants or other establishments in which food is served for immediate human consumption or

which is sold for sale or use in such establishments; or

(B) Processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in paragraph (ii)(A) of this definition, and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.

Self-service food means restaurant-type food that is available at a salad bar, buffet line, cafeteria line, or similar self-service facility and that is served by the customers themselves. Self-service food also includes self-service beverages.

Standard menu item means a restaurant-type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display.

Temporary menu item means a food that appears on a menu or menu board for less than a total of 60 days per calendar year. The 60 days includes the total of consecutive and non-consecutive days the item appears on the menu.

Variable menu item means a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item.

(b) *Requirements for nutrition labeling for food sold in covered establishments*—(1) *Applicability*. (i) The labeling requirements in this paragraph (b) apply to standard menu items offered for sale in covered establishments.

(ii)(A) The labeling requirements in this paragraph (b) do not apply to foods that are not standard menu items, including:

(*1*) Items such as condiments that are for general use, including those placed on the table or on or behind the counter; daily specials; temporary menu items; custom orders; food that is part of a customary market test; and

(*2*) Self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance.

(B) The labeling requirements of paragraph (b)(2)(iii) of this section do not apply to alcoholic beverages that are foods on display and are not self-service foods.

(2) *Nutrition information*. (i) Except as provided by paragraph (b)(2)(i)(A)(*8*) of this section, the following must be provided on menus and menu boards:

(A) The number of calories contained in each standard menu item listed on the menu or menu board, as usually prepared and offered for sale. In the case of multiple-serving standard menu items, this means the calories declared must be for the whole menu item listed on the menu or menu board as usually prepared and offered for sale (*e.g.*, ''pizza pie: 1600 cal''); or per discrete serving unit as long as the discrete serving unit (*e.g.*, pizza slice) and total number of discrete serving units contained in the menu item are declared on the menu or menu board, and the menu item is usually prepared and offered for sale divided in discrete serving units (*e.g.*, ''pizza pie: 200 cal/slice, 8 slices''). The calories must be declared in the following manner:

(*1*) The number of calories must be listed adjacent to the name or the price of the associated standard menu item, in a type size no smaller than the type size of the name or the price of the associated standard menu item, whichever is smaller, in the same color, or a color at least as conspicuous as that used for the name of the associated standard menu item, and with the same contrasting background or a background at least as contrasting as that used for the name of the associated standard menu item.

(*2*) To the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero.

(*3*) The term ''Calories'' or ''Cal'' must appear as a heading above a column listing the number of calories for each standard menu item or adjacent to the number of calories for each standard menu item. If the term ''Calories'' or ''Cal'' appears as a heading above a column of calorie declarations, the term must be in a type size no smaller than the smallest type size of the name or price of any menu item on that menu or menu board in the same color or a color at least as conspicuous

as that used for that name or price and in the same contrasting background or a background at least as contrasting as that used for that name or price. If the term ''Calories'' or ''Cal'' appears adjacent to the number of calories for the standard menu item, the term ''Calories'' or ''Cal'' must appear in the same type size and in the same color and contrasting background as the number of calories.

(*4*) Additional requirements that apply to each individual variable menu item:

(*i*) When the menu or menu board lists flavors or varieties of an entire individual variable menu item (such as soft drinks, ice cream, doughnuts, dips, and chicken that can be grilled or fried), the calories must be declared separately for each listed flavor or variety. Where flavors or varieties have the same calorie amounts (after rounding in accordance with paragraph (b)(2)(i)(A)(*2*) of this section), the calorie declaration for such flavors or varieties can be listed as a single calorie declaration adjacent to the flavors or varieties, provided that the calorie declaration specifies that the calorie amount listed represents the calorie amounts for each individual flavor or variety.

(*ii*) When the menu or menu board does not list flavors or varieties for an entire individual variable menu item, and only includes a general description of the variable menu item (*e.g.* ''soft drinks''), the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (*e.g.*, ''150/250 calories'') or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of this section where more than two options are available (*e.g.*, ''100–250 calories'').

(*iii*) When the menu or menu board describes flavors or varieties for only part of an individual variable menu item (such as different types of cheese offered in a grilled cheese sandwich (*e.g.*, ''Grilled Cheese (Cheddar or Swiss)''), the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (*e.g.*, ''450/500 calories'') or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of this section where more than two options are available (*e.g.*, ''450–550 calories'').

(*5*) Additional requirements that apply to a variable menu item that is offered for sale with the option of adding toppings listed on the menu or menu board. When the menu or menu board lists toppings that can be added to a menu item (such as pizza or ice cream):

(*i*) The calories must be declared for the basic preparation of the menu item as listed (*e.g.*, ''small pizza pie,'' ''single scoop ice cream'').

(*ii*) The calories must be separately declared for each topping listed on the menu or menu board (*e.g.*, pepperoni, sausage, green peppers, onions on pizza; fudge, almonds, sprinkles on ice cream), specifying that the calories are added to the calories contained in the basic preparation of the menu item. Where toppings have the same calorie amounts (after rounding in accordance with paragraph (b)(2)(i)(A)(*2*) of this section), the calorie declaration for such toppings can be listed as a single calorie declaration adjacent to the toppings, provided that the calorie declaration specifies that the calorie amount listed represents the calorie amount for each individual topping.

(*iii*) The calories for the basic preparation of the menu item must be declared for each size of the menu item. The calories for each topping listed on the menu or menu board must be declared for each size of the menu item, or declared using a slash between the two calorie declarations for each topping where only two sizes of the menu item are available (*e.g.*, ''adds 150/250 cal'') or as a range for each topping in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of this section where more than two sizes of the menu item are available (*e.g.*, ''adds 100–250 cal''). If a slash between two calorie declarations or a range of calorie declarations is used, the menu or menu board must indicate that the variation in calories for each topping arises from the size of the menu item to which the toppings are added.

(*iv*) If the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered for the

menu item (such as is sometimes the case with pizza toppings), the calories for each topping must be declared as single values representing the calories for each topping when added to a one-topping menu item, specifying that the calorie declaration is for the topping when added to a one-topping menu item.

(*6*) Additional requirements that apply to a combination meal. Except as provided in paragraph (b)(2)(i)(A)(*6*)(*iv*) of this section:

(*i*) When the menu or menu board lists two options for menu items in a combination meal (*e.g.*, a sandwich with a side salad or chips), the calories must be declared for each option with a slash between the two calorie declarations (*e.g.*, ''350/450 calories'').

(*ii*) When the menu or menu board lists three or more options for menu items in a combination meal (*e.g.*, a sandwich with chips, a side salad, or fruit), the calories must be declared as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of this section (*e.g.*, ''350–500 calories'').

(*iii*) When the menu or menu board includes a choice to increase or decrease the size of a combination meal, the calorie difference must be declared for the increased or decreased size with a slash between two calorie declarations (*e.g.*, ''Adds 100/150 calories,'' ''Subtracts 100/150 calories'') if the menu or menu board lists two options for menu items in the combination meal, or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of this section (*e.g.*, ''Adds 100–250 calories,'' ''Subtracts 100–250 calories'') if the menu or menu board lists three or more options for menu items in the combination meal.

(*iv*) Where the menu or menu board describes an opportunity for a consumer to combine standard menu items for a special price (*e.g.*, ''Combine Any Sandwich with Any Soup or Any Salad for $8.99''), and the calories for each standard menu item, including each size option as described in paragraph (b)(2)(i)(A)(*6*)(*iii*) of this section if applicable, available for the consumer to combine are declared elsewhere on the menu or menu board, the requirements of paragraphs (b)(2)(i)(A)(*6*)(*i*), (*ii*), and (*iii*) of this section do not apply.

(*7*) Additional format requirements for declaring calories for an individual variable menu item, a combination meal, and toppings as a range, if applicable. Calories declared as a range must be in the format ''xx–yy,'' where ''xx'' is the caloric content of the lowest calorie variety, flavor, or combination, and ''yy'' is the caloric content of the highest calorie variety, flavor, or combination.

(*8*) Exception for a variable menu item that has no clearly identifiable upper bound to the range of calories: If the variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range, *e.g.*, all-you-can-eat buffet, then the menu or menu board must include a statement, adjacent to the name or price of the item, referring customers to the self-service facility for calorie information, *e.g.*, ''See buffet for calorie declarations.'' This statement must appear in a type size no smaller than the type size of the name or price of the variable menu item, whichever is smaller, and in the same color or a color at least as conspicuous as that used for that name or price, with the same contrasting background or a background at least as contrasting as that used for that name or price.

(*9*) Additional requirements that apply to beverages that are not self-service. For beverages that are not self-service, calories must be declared based on the full volume of the cup served without ice, unless the covered establishment ordinarily dispenses and offers for sale a standard beverage fill (*i.e.*, a fixed amount that is less than the full volume of the cup per cup size) or dispenses a standard ice fill (*i.e.*, a fixed amount of ice per cup size). If the covered establishment ordinarily dispenses and offers for sale a standard beverage fill or dispenses a standard ice fill, the covered establishment must declare calories based on such standard beverage fill or standard ice fill.

(B) The following statement designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards:

''2,000 calories a day is used for general nutrition advice, but calorie needs vary.'' For menus and menu boards targeted to children, the following options may be used as a substitute for or in addition to the succinct statement: ''1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years, but calorie needs vary.''; or ''1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years and 1,400 to 2,000 calories a day for children ages 9 to 13 years, but calorie needs vary.''

(*1*) This statement must be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest type size of any calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as that used for the calorie declarations and with the same contrasting background or a background at least as contrasting as that used for the calorie declarations.

(*2*) For menus, this statement must appear on the bottom of each page of the menu. On menu pages that also bear the statement required by paragraph (b)(2)(i)(C) of this section, this statement must appear immediately above, below, or beside the statement required by paragraph (b)(2)(i)(C) of this section.

(*3*) For menu boards, this statement must appear on the bottom of the menu board, immediately above, below, or beside the statement required by paragraph (b)(2)(i)(C) of this section.

(C) The following statement regarding the availability of the additional written nutrition information required in paragraph (b)(2)(ii) of this section must be on all forms of the menu or menu board: ''Additional nutrition information available upon request.''

(*1*) This statement must be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest type size of any calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as that used for the caloric declarations, and with the same contrasting background or a background at least as contrasting as that used for the caloric declarations.

(*2*) For menus, the statement must appear on the bottom of the first page with menu items immediately above, below, or beside the succinct statement required by paragraph (b)(2)(i)(B) of this section.

(*3*) For menu boards, the statement must appear on the bottom of the menu board immediately above, below, or beside the succinct statement required by paragraph (b)(2)(i)(B) of this section.

(ii) The following nutrition information for a standard menu item must be available in written form on the premises of the covered establishment and provided to the customer upon request. This nutrition information must be presented in the order listed and using the measurements listed, except as provided in paragraph (b)(2)(ii)(B) of this section. Rounding of these nutrients must be in compliance with §101.9(c). The information must be presented in a clear and conspicuous manner, including using a color, type size, and contrasting background that render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Covered establishments may use the abbreviations allowed for Nutrition Facts for certain packaged foods in §101.9(j)(13)(ii)(B):

(A)(*1*) Total calories (cal);
(*2*) Calories from fat (fat cal);
(*3*) Total fat (g);
(*4*) Saturated fat (g);
(*5*) *Trans* fat (g);
(*6*) Cholesterol (mg);
(*7*) Sodium (mg);
(*8*) Total carbohydrate (g);
(*9*) Dietary fiber (g);
(*10*) Sugars (g); and
(*11*) Protein (g).

(B) If a standard menu item contains insignificant amounts of all the nutrients required to be disclosed in paragraph (b)(2)(ii)(A) of this section, the establishment is not required to include nutrition information regarding the standard menu item in the written form. However, if the covered establishment makes a nutrient content claim or health claim, the establishment is required to provide nutrition information on the nutrient that is the subject of the claim in accordance with §101.10. For standard menu items that

contain insignificant amounts of six or more of the required nutrients, the declaration of nutrition information required by paragraph (b)(2)(ii)(A) of this section may be presented in a simplified format.

(*1*) An insignificant amount is defined as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrates, dietary fiber, and protein, it must be an amount that allows a declaration of ''less than one gram.''

(*2*) The simplified format must include information, in a column, list, or table, on the following nutrients:

(*i*) Total calories, total fat, total carbohydrates, protein, and sodium; and

(*ii*) Calories from fat, and any other nutrients identified in paragraph (b)(2)(ii)(A) of this section that are present in more than insignificant amounts.

(*3*) If the simplified format is used, the statement ''Not a significant sourceof _____'' (with the blank filled in with the names of the nutrients required to be declared in the written nutrient information and calories from fat that are present in insignificant amounts) must be included at the bottom of the list of nutrients.

(C) For variable menu items, the nutrition information listed in paragraph (b)(2)(ii)(A) of this section must be declared as follows for each size offered for sale:

(*1*) The nutrition information required in paragraph (b)(2)(ii)(A) of this section must be declared for the basic preparation of the item and, separately, for each topping, flavor, or variable component.

(*2*) Additional format requirements for toppings if the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered for the menu item (such as is sometimes the case with pizza toppings). The nutrients for such topping must be declared as single values representing the nutrients for each topping when added to a one-topping menu item, specifying that the nutrient declaration is for the topping when added to a one-topping menu item.

(*3*) If the calories and other nutrients are the same for different flavors, varieties, and variable components of the combination meal, each variety, flavor, and variable component of the combination meal is not required to be listed separately. All items that have the same nutrient values could be listed together with the nutrient values listed only once.

(D) The written nutrition information required in paragraph (b)(2)(ii)(A) of this section may be provided on a counter card, sign, poster, handout, booklet, loose leaf binder, or electronic device such as a computer, or in a menu, or in any other form that similarly permits the written declaration of the required nutrient content information for all standard menu items. If the written nutrition information is not in a form that can be given to the customer upon request, it must be readily available in a manner and location on the premises that allows the customer/consumer to review the written nutrition information upon request.

(iii) The following must be provided for a standard menu item that is self-service or on display.

(A) Calories per displayed food item (*e.g.*, a bagel, a slice of pizza, or a muffin), or if the food is not offered for sale in a discrete unit, calories per serving (*e.g.*, scoop, cup), and the serving or discrete unit used to determine the calorie content (*e.g.*, ''per scoop'' or ''per muffin'') on either: A sign adjacent to and clearly associated with the corresponding food; (*e.g.*, ''150 calories per scoop''); a sign attached to a sneeze guard with the calorie declaration and the serving or unit used to determine the calorie content above each specific food so that the consumer can clearly associate the calorie declaration with the food, except that if it is not clear to which food the calorie declaration and serving or unit refers, then the sign must also include the name of the food, *e.g.*, ''Broccoli and cheese casserole—200 calories per scoop''; or a single sign or placard listing the calorie declaration for several food items along with the names of the food items, so long as the sign or placard is located where a consumer can view the name, calorie declaration, and serving or unit of a particular item while selecting that item.

(*1*) For purposes of paragraph (b)(2)(iii)(A) of this section, ''per displayed food item'' means per each discrete unit offered for sale, for example, a bagel, a slice of pizza, or a muffin.

(*2*) For purposes of paragraph (b)(2)(iii)(A) of this section, ''per serving'' means, for each food:

(*i*) Per serving instrument used to dispense the food offered for sale, provided that the serving instrument dispenses a uniform amount of the food (*e.g.*, a scoop or ladle);

(*ii*) If a serving instrument that dispenses a uniform amount of food is not used to dispense the food, per each common household measure (*e.g.*, cup or tablespoon) offered for sale or per unit of weight offered for sale, *e.g.*, per quarter pound or per 4 ounces; or

(*iii*) Per total number of fluid ounces in the cup in which a self-service beverage is served and, if applicable, the description of the cup size (*e.g.*, ''140 calories per 12 fluid ounces (small)'').

(*3*) The calories must be declared in the following manner:

(*i*) To the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories except that amounts less than 5 calories may be expressed as zero.

(*ii*) If the calorie declaration is provided on a sign with the food's name, price, or both, the calorie declaration, accompanied by the term ''Calories'' or ''Cal'' and the amount of the serving or displayed food item on which the calories declaration is based must be in a type size no smaller than the type size of the name or price of the menu item whichever is smaller, in the same color, or a color that is at least as conspicuous as that used for that name or price, using the same contrasting background or a background at least as contrasting as that used for that name or price. If the calorie declaration is provided on a sign that does not include the food's name, price, or both, the calorie declaration, accompanied by the term ''Calories'' or ''Cal'' and the amount of the serving or displayed food item on which the calorie declaration is based must be clear and conspicuous.

(*iii*) For self-service beverages, calorie declarations must be accompanied by the term ''fluid ounces'' and, if applicable, the description of the cup size (*e.g.*, ''small,'' ''medium'').

(B) For food that is self-service or on display and is identified by an individual sign adjacent to the food itself where such sign meets the definition of a menu or menu board under paragraph (a) of this section, the statement required by paragraph (b)(2)(i)(B) of this section and the statement required by paragraph (b)(2)(i)(C) of this section. These two statements may appear on the sign adjacent to the food itself; on a separate, larger sign, in close proximity to the food that can be easily read as the consumer is making order selections; or on a large menu board that can be easily read as the consumer is viewing the food.

(C) The nutrition information in written form required by paragraph (b)(2)(ii) of this section, except for packaged food insofar as it bears nutrition labeling information required by and in accordance with paragraph (b)(2)(ii) of this section and the packaged food, including its label, can be examined by a consumer before purchasing the food.

(c) *Determination of nutrient content.* (1) A covered establishment must have a reasonable basis for its nutrient declarations. Nutrient values may be determined by using nutrient databases (with or without computer software programs), cookbooks, laboratory analyses, or other reasonable means, including the use of Nutrition Facts on labels on packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act and §101.9, FDA nutrient values for raw fruits and vegetables in Appendix C of this part, or FDA nutrient values for cooked fish in Appendix D of this part.

(2) Nutrient declarations for standard menu items must be accurate and consistent with the specific basis used to determine nutrient values. A covered establishment must take reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(3) A covered establishment must provide to FDA, within a reasonable period of time upon request, information substantiating nutrient values including the method and data used to derive these nutrient values. This information must include the following:

(i) For nutrient databases:

(A) The name and version (including the date of the version) of the database, and, as applicable, the name of the applicable software company and any Web site address for the database. The name and version of a database would include the name and version of the computer software, if applicable;

(B) The recipe or formula used as a basis for the nutrient declarations;

(C)(*1*) Information on:

(*i*) The amount of each nutrient that the specified amount of each ingredient identified in the recipe contributes to the menu item; and

(*ii*) How the database was used including calculations or operations (*e.g.*, worksheets or computer printouts) to determine the nutrient values for the standard menu items;

(*2*) If the information in paragraph (c)(3)(i)(C)(*1*) of this section is not available, certification attesting that the database will provide accurate results when used appropriately and that the database was used in accordance with its instructions;

(D) A detailed listing (*e.g.*, printout) of the nutrient values determined for each standard menu item.

(E) Any other information pertinent to the final nutrient values of the standard menu item (*e.g.*, information about what might cause slight variations in the nutrient profile such as moisture variations);

(F) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(G) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(ii) For published cookbooks that contain nutritional information for recipes in the cookbook:

(A) The name, author, and publisher of the cookbook used;

(B) If available, information provided by the cookbook or from the author or publisher about how the nutrition information for the recipes was obtained;

(C) A copy of the recipe used to prepare the standard menu item and a copy of the nutrition information for that standard menu item as provided by the cookbook; and

(D) A statement signed and dated by a responsible individual employed at the covered establishment certifying that that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined. (Recipes may be divided as necessary to accommodate differences in the portion size derived from the recipe and that are served as the standard menu item but no changes may be made to the proportion of ingredients used.)

(iii) For laboratory analyses:

(A) A copy of the recipe for the standard menu item used for the nutrient analysis;

(B) The name and address of the laboratory performing the analysis;

(C) Copies of analytical worksheets, including the analytical method, used to determine and verify nutrition information;

(D) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(E) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types

and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(iv) For nutrition information provided by other reasonable means:

(A) A detailed description of the means used to determine the nutrition information;

(B) A recipe or formula used as a basis for the nutrient determination;

(C) Any data derived in determining the nutrient values for the standard menu item, *e.g.*, nutrition information about the ingredients used with the source of the nutrient information;

(D) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(E) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(d) *Voluntary registration to be subject to the menu labeling requirements*—(1) *Applicability*. A restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items may voluntarily register to be subject to the requirements established in this section. Restaurants and similar retail food establishments that voluntarily register will no longer be subject to non-identical State or local nutrition labeling requirements.

(2) *Who may register?* The authorized official of a restaurant or similar retail food establishment as defined in paragraph (a) of this section, which is not otherwise subject to paragraph (b) of this section, may register with FDA.

(3) *What information is required?* Authorized officials for restaurants and similar retail food establishments must provide FDA with the following information on Form FDA 3757:

(i) The contact information (including name, address, phone number, and email address) for the authorized official;

(ii) The contact information (including name, address, phone number, and email address) of each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official onsite, such as the owner or manager, for each specific restaurant or similar retail food establishment;

(iii) All trade names the restaurant or similar retail food establishment uses;

(iv) Preferred mailing address (if different from location address for each establishment) for purposes of receiving correspondence; and

(v) Certification that the information submitted is true and accurate, that the person submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act and this section.

(4) *How to register*. Authorized officials of restaurants and similar retail food establishments who elect to be subject to requirements in section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act can register by visiting *http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm217762.htm*. FDA has created a form (Form 3757) that contains fields requesting the information in paragraph (d)(3) of this section and made the form available at this Web site. Registrants must use this form to ensure that complete information is submitted.

(i) Information should be submitted by email by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by email to *menulawregistration@fda.hhs.gov*.

(ii) If email is not available, the registrant can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to 301–436–2804 or

mail it to FDA, CFSAN Menu and Vending Machine Registration, White Oak Building 22, Rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(5) *When to renew the registration.* To keep the establishment's registration active, the authorized official of the restaurant or similar retail food establishment must register every other year within 60 days prior to the expiration of the establishment's current registration with FDA. Registration will automatically expire if not renewed.

(e) *Signatures.* Signatures obtained under paragraph (d) of this section that meet the definition of electronic signatures in §11.3(b)(7) of this chapter are exempt from the requirements of part 11 of this chapter.

(f) *Misbranding.* A standard menu item offered for sale in a covered establishment shall be deemed misbranded under sections 201(n), 403(a), 403(f) and/or 403(q) of the Federal Food, Drug, and Cosmetic Act if its label or labeling is not in conformity with paragraph (b) or (c) of this section.

[79 FR 71253, Dec. 1, 2014]

EFFECTIVE DATE NOTE: At 79 FR 71253, Dec. 1, 2014, §101.11 was added, effective December 1, 2015.

§ 101.12 Reference amounts customarily consumed per eating occasion.

(a) The general principles and factors that the Food and Drug Administration (FDA) considered in arriving at the reference amounts customarily consumed per eating occasion (reference amounts) which are set forth in paragraph (b) of this section, are that:

(1) FDA calculated the reference amounts for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These reference amounts are based on data set forth in appropriate national food consumption surveys.

(2) FDA calculated the reference amounts for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These reference amounts are based on data set forth in appropriate national food consumption surveys. Such reference amounts are to be used only when the food is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, FDA considered the mean, median, and mode of the consumed amount per eating occasion.

(5) When survey data were insufficient, FDA took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the reference amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The reference amount is based on the major intended use of the food (e.g., milk as a beverage and not as an addition to cereal).

(8) The reference amounts for products that are consumed as an ingredient of other foods, but that may also be consumed in the form in which they are purchased (e.g., butter), are based on use in the form purchased.

(9) FDA sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount.

(b) The following reference amounts shall be used as the basis for determining serving sizes for specific products:

BUILD YOUR OWN PIZZA

SELECT YOUR CRUST, SAUCE, TOPPINGS

CRUST

Inspired Hand Tossed
Deep Dish (additional cost)
Crunchy Thin
Brooklyn Style

SAUCE

Robust Inspired Tomato OPTIONAL: White Hearty Marinara BBQ

TOPPINGS

MEAT: Pepperoni • Bacon • Ham • Beef • Salami
Chicken • Philly Steak • Italian or Sliced Sausage

VEGGIES: Green Peppers • Onions • Black Olives
Mushrooms • Banana Peppers • Jalapenos • Tomatoes
Roasted Red Peppers • Fresh Baby Spinach

OTHER: Extra Cheese • Cheddar • Feta
Provolone • Parmesan-Asiago • Pineapple

Cheese Pizza			Additional Toppings (each)		
S	$ 7.99	cal. 910–1390	S	$1.29	cal. 10–270
M	$ 9.99	cal. 1310–2390	M	$1.49	cal. 10–350
L	$11.99	cal. 1620–3230	L	$1.69	cal. 15–500
XL	$12.99	cal. 2450–3500	XL	$1.89	cal. 15–670

All calorie information is for the entire item.


1
Large Popcorn Large Drink
950 - 2030 Cal
13.49
2
Large Popcorn 2 Large Drinks
950 - 3110 Cal
19.19
white CHEDDAR
cinnamon SUGAR
parmesan GARLIC
nacho CHEESE
Add a little extra flavor
to your popcorn
POPC
Large
Medium
Small

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-026

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Frozen Foods Maintained Frozen

Issue you would like the Conference to consider:

Clarifying that Time Temperature Control in both Section 3-202.11(E) and 3-501.11 of the 2013 FDA Food Code is only necessary for Time Temperature Control for Safety Food (TCS) foods and not all frozen foods.

Public Health Significance:

Time Temperature Control in both Section 3-202.11(E) and 3-501.11 of the 2013 FDA Food Code is only necessary for Time Temperature Control for Safety Food (TCS) foods .

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

(E) TIME/TEMPERATURE CONTROL FOR SAFETY ~~A~~ FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen. Pf

and

Section 3-501.11

Stored frozen TIME/TEMPERATURE CONTROL FOR SAFETY FOOD~~S~~ shall be maintained frozen.

Submitter Information 1:

Name:	Ann Johnson
Organization:	FL Department of Agriculture
Address:	3236 Sardenia Terrace
City/State/Zip:	Deltona, FL 32738

Telephone: 407-335-3497
E-mail: anna.johnson@freshfromflorida.com

Submitter Information 2:

Name: Joetta DeFrancesco
Organization: FL Department of Agriculture
Address: 10281 Enoch Lane
City/State/Zip: Bonita Springs, FL 34135
Telephone: 239-206-0260
E-mail: joetta.defrancesco@freshfromflorida.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-027

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Protecting Unwashed Produce From Cross Contamination

Issue you would like the Conference to consider:

The 2013 FDA Food Code does not prohibit storing raw animal foods above or contacting unwashed produce. Washing may not eliminate pathogens from produce exposed to cross contamination. The Food Code should be amended to include unwashed produce in the prohibition of storage under raw animal foods.

Public Health Significance:

Produce that will not be cooked to a specific temperature could cause an illness if exposed to cross contamination.

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):

3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.

(A) FOOD shall be protected from cross contamination by:

(1) Except as specified in (1)(c) 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~~

(b) ~~r~~Raw ~~READY-TO-EAT~~ non-animal FOOD such as fruits and vegetables, P

Submitter Information:

Name:	Adam Inman
Organization:	Kansas Department of Agriculture
Address:	1320 Research Park Drive

City/State/Zip: Manhattan, KS 66502
Telephone: 7855646764
E-mail: adam.inman@kda.ks.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-028

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Amend Returned Food and Re-Service of Food

Issue you would like the Conference to consider:

Request an interpretation from FDA that clarifies the intent of the 2013 Food Code Section 3-306.14(A) allowing for food that is immediately served and in possession of a consumer to be returned for further cooking before being returned to the same consumer.

Public Health Significance:

Food that is returned by the consumer after immediate service for further cooking, would not pose a risk when cooked to a higher temperature and returned to the same consumer.

Any potential contamination would be eliminated by the temperature of the cooking equipment, such as a grill. Separate single use utensils may be used for a returned item and then wash, rinsed, sanitized and air dried.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting an interpretation that clarifies/explains Section 3-306.14(A) of the 2013 Food Code and allows for return of food that is immediately served to a specific consumer back to the same consumer after further cooking. The letter shall also request that FDA post their final interpretation document to the FDA Food Code Reference System.

Submitter Information:

Name:	Christopher Melchert
Organization:	National Restaurant Association
Address:	2055 L Street NWSuite 700
City/State/Zip:	Washington, DC 20036
Telephone:	202-973-3960
E-mail:	cmelchert@restaurant.org

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-029

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Labeling for Food Allergen Cross-Contact

Issue you would like the Conference to consider:

Adding an addendum to the 2013 FDA Food Code subparagraph 3-602.11(B)(5) to include a statement on a product's label, when applicable, that cross-contact with specifically named allergens is possible.

Public Health Significance:

Consumers assume that delis, bakeries, grocery stores, restaurants, and other venues that sell pre-packaged foods (i.e., foods NOT produced and packaged in manufacturing plants that fall under the provisions of the Food Allergen Labeling and Consumer Protection Act, FALCPA) are labeled as stringently for the presence of allergens as manufactured products, and also assume that these venues practice strict allergen control. Because the labels seldom indicate the potential presence of allergens due to cross-contact, reactions have occurred, including food anaphylaxis deaths.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that subparagraph 3-601.11(B)(5) of the 2013 Food Code be amended as follows (language to add is underlined):

3-601.11 Food Labels.

(B) Label information shall include:

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient.[Pf] <u>When applicable, all pre-packaged items will have a label stating that the food may have been in contact with allergens specifically named by the venue preparing and/or packaging the product.</u>

Submitter Information:

Name: Nona Narvaez
Organization: Anaphylaxis and Food Allergy Association of MN (AFAA)
Address: 2200 Hendon Ave
City/State/Zip: St. Paul, MN 55108
Telephone: 6516445937
E-mail: nona@minnesotafoodallergy.org

Supporting Attachments:

- "Suit in Allergy Death: Should Store Bakeries Have to Label? (redacted)"

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.

Suit in Allergy Death: Should Store Bakeries Have to Label?

Posted By *Ishani Nath* On 2015/07/08 @ 9:10 am In Food Allergy

A lawsuit in the death of an Alabama boy, who suffered fatal anaphylaxis from eating a cookie, could have broad implications for supermarket bakeries and food-allergic consumers.

The family of 11-year-old Derek "Landon" Wood filed the lawsuit, in which a crucial aspect is whether a grocery store's bakery should be required to label all of its products, since many of them are made, either entirely or mostly, off the bakery premises.

[redacted], which sold the cookie, takes issue with that interpretation of the U.S. food allergen labeling law, known as FALCPA (Food Allergen Labeling and Consumer Protection Act [2]). It had filed a motion to get the case dismissed.

But on June 11, 2015, a U.S. district judge denied that motion, finding that the family's case has sufficient merit, and allowing the case to proceed.

One thing that no one disputes is that Landon's death was a tragedy and a traumatic experience. The boy, who had multiple food allergies and asthma, and his mother Beth Cline were visiting family in Clarksville, Tennessee on June 3, 2014 when, along with his aunt and cousin, they stopped at a [redacted] store.

In the bakery section, Landon asked his mother to buy him an unlabeled, ready-to-eat "Chocolate Chew" cookie. In the lawsuit, Cline says she spoke to the bakery employee and was assured that the cookie did not contain tree nuts – one of Landon's allergens. (In its legal response, [redacted] denies a bakery employee would have told Cline this.) Cline says it is based on this information that she bought her son the cookie, and a sugar cookie for his cousin.

After returning to the aunt's house, the suit says that Landon had three bites of the cookie, and began saying that his mouth was burning. His mother gave him Benadryl, but the symptoms progressed, with Landon finding it harder to breathe, and his face turning red. His mother administered his epinephrine auto-injector as her sister called an ambulance.

The boy's condition improved briefly during the ambulance ride, but in hospital, even with further medication, his breathing worsened, and he suffered extreme swelling and plummeting blood pressure. Landon was airlifted to Vanderbilt Children's Hospital in Nashville, but his condition could not be stabilized; he died at 10:19 that evening.

The family's lawsuit against the grocery chain calls for "compensation for [redacted]'s negligence and to raise awareness of potential fatal food allergies in American children."

[redacted], for its part, denies the negligence claims. The grocery chain has yet to either agree or deny that a conversation took place between Cline and one its bakery employees. But [redacted] does say that the Chocolate Chew cookies were known by staff to contain tree nuts as an ingredient, and it denies that a bakery employee would have told Cline that these cookies were free of nuts.

As the case moves forward, a key element is the legal interpretation of FALCPA [2], which requires manufacturers to list the Top 8 allergens on the labels of packaged foods, but **exempts foods that are placed in a wrapper or container or prepared on a made-to-order basis** – like a deli sandwich. Further, FALCPA does not cover foods "served in restaurants or other establishments in which food is served for immediate human consumption".

In Landon's death, however, the family argues that these exemptions should not apply, since the [redacted] supermarket that sold the cookie makes most of its finished baked goods at a regional facility, and products are then shipped to in-store bakeries. ([redacted] has not yet answered how Landon's specific cookie was prepared.)

In its response, [redacted] contends that the Chocolate Chew Cookie does not require ingredient labeling because it is "prepared and displayed in a bakery setting and then placed in a wrapper or similar package in response to a consumer's order."

U.S. District Court Judge Aleta Trauger noted that, in attempting to have the family's case dismissed, [redacted] had argued that the cookies that were sold fell within this exception in FALCPA as well as within a similar "immediate consumption" clause in the federal Food, Drug and Cosmetic Act. The judge summarized that the supermarket chain also suggested that the cookie could be considered "made-to-order", making it exempt from labeling requirements.

"[redacted] appears to contend that, because products sold from behind the display case are not packaged and can be sold individually, the products are indistinguishable from cookies sold at a mall cookie counter or a muffin sold at a coffee cart," Trauger wrote.

But in denying the [redacted] motion, she found that, because the cookie did not appear to be served for immediate consumption, nor prepared fresh such as from a food truck, **"the plaintiffs (the family) have sufficiently alleged that the [redacted] bakery was subject to the labeling requirements"**.

"From my perspective, [redacted] the retail store is not operating a bakery," Eddie Schmidt, the attorney representing Landon's family, told Allergic Living. "It's simply a

section of the grocery store." [redacted] would not comment directly to Allergic Living on the continuing lawsuit.

"Part of this lawsuit seeks a declaratory judgment from a federal court that [redacted] cannot use this FDA-interpreted exception to bakeries for not labeling its bakery products," Schmidt said. "If that is accomplished, that will require [redacted], as well as all other grocery stores who are selling bakery products, to identify the food allergens within its products."

Donna Rosenbaum, a consultant with Food Safety Partners, has given the plaintiffs some advice in this suit. She views the in-store bakery labeling issue as an example of how FALCPA has "eroded and evolved over time".

"I would love to see movement from within the industry, and not just from the consumer base; I would love to see people come together on this," she said. "Stores don't want to get sued and consumers certainly don't want to get sick from store products, so it should be a win-win."

She acknowledges, however, that any significant changes will take time. For now, she says the allergic community should look at grocery store bakery products with an added layer of suspicion, and she encourages parents to raise these concerns with grocery store managers, to let them know it's an important issue.

URLs in this post:

[1] Image: **http://allergicliving.com/wp-content/uploads/2015/03/d8b41ce6-9ac5-4d69-aa47-d30db88d49af.jpg**
[2] Food Allergen Labeling and Consumer Protection Act: **http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm**

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-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:

Documenting Food Allergy Labeling Violations

Issue you would like the Conference to consider:

Adding an addendum to the 2013 FDA Food Code Section 8-403.10(B) to include a provision to document on an inspection report form any violation of food allergen labeling on foods pre-packaged and sold by the establishment as required by 3-602.11(B)(5).

Public Health Significance:

Mislabeled pre-packaged foods can cause life-threatening anaphylactic allergic reactions.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2013 Food Code be amended to include a new subparagraph #7 in paragraph 8-403.10(B) (language to be added is underlined):

8-403.10 Documenting Information and Observations.

The REGULATORY AUTHORITY shall document on an inspection report form:

(B) Specific factual observations of violative conditions or other deviations from this Code that require correction by the PERMIT HOLDER including:

<u>(7) Failure of pre-packaged items produced by the establishment to include listed allergens and potential cross-contact with allergens, when applicable</u>.

Submitter Information:

Name:	Nona Narvaez
Organization:	Anaphylaxis and Food Allergy Association of MN (AFAA)
Address:	2200 Hendon Ave
City/State/Zip:	St. Paul, MN 55108
Telephone:	6516445937
E-mail:	nona@minnesotafoodallergy.org

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-031

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Harmonizing a Food Code Labeling Requirement w/ a CFR Labeling Requirement

Issue you would like the Conference to consider:

Subparagraph 3-602.11(B)(4) of the 2013 FDA Food Code requires that food packaged in a food establishment be labeled with the name and address of the manufacturer, packer, or distributor.

However, 21 Code of Federal Regulation (CFR) 101.100(b)(1) exempts a food repackaged in a retail establishment from being labeled with the name of the manufacturer, packer or distributor.

It would seem logical that the same exemption can be reasonably applied to any food packaged or repackaged in a food establishment. Customers have the opportunity to ask the operator about any aspect of the food and decide if their questions are sufficiently answered.

Public Health Significance:

Eliminating Food Code requirements that conflict with Federal food regulations and also provide limited benefit allows resources to be focused on higher risk 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):

Subparagraph 3-602.11

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common

name, an adequately descriptive identity statement;

(2) If made from two or more ingredients, a list of ingredients

and sub-ingredients in descending order of predominance by weight, including a declaration of artificial colors, artificial flavors and chemical preservatives, if contained in the FOOD;
(3) An accurate declaration of the net quantity of contents;
~~(4) The name and place of business of the manufacturer, packer, or distributor; and~~
~~(5)~~ (4) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient. Pf
~~(6)~~ (5) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(g)(3) - (5), nutrition labeling as specified in 21 CFR 101 - Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.
~~(7)~~ (6) For any salmonid FISH containing canthaxanthin or astaxanthin as a COLOR ADDITIVE, the labeling of the bulk FISH container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.
retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.

Submitter Information:

Name:	Adam Inman
Organization:	Kansas Department of Agriculture
Address:	1320 Research Park Drive
City/State/Zip:	Manhattan, KS 66502
Telephone:	7855646764
E-mail:	adam.inman@kda.ks.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-032

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Proposed Revision to Food Code Section 3-401.14, Non-Continuous cooking

Issue you would like the Conference to consider:

Subparagraph 3-401.14 of the 2013 FDA Food Code, together with supporting paragraphs 3-501.14 (A), 3-501.16 (A) (2), 3-401.11 (A-C), 3-501.19 & 3-302.11 (A), deals with very basic food safety principles; cooking, cooling and holding. This section is very prescriptive, lists all necessary steps for safe food preparation and does not require review of any new science to ensure it is being conducted properly.

Developing a non-continuous cooking procedure and providing a copy to the regulatory authority prior to implementation gives notice to the regulatory authority that the food establishment intends to conduct non-continuous cooking operations for raw animal foods and makes it possible for the regulatory authority to verify, if they so desire, that the appropriate non-continuous cooking procedures are being followed and that the requirements of §3-401.14 together with supporting paragraphs 3-501.14 (A), 3-501.16 (A), 3-401.11 (A-C), 3-501.19 & 3-302.11 (A) are being met.

Consequently, we request consideration of changing Section 3-401.14 (F) (1) of the FDA Food Code from requiring a food establishment to obtain pre-approval of a non-continuous cooking process to providing the regulatory authority notice of intent to conduct a non-continuous cooking process along with the procedures the food establishment will use to comply with section 3-401.14 of the FDA Food Code.

Public Health Significance:

This process would not result in any additional public health or food safety risk to consumers. Some of the benefits would include:

1. Developing a non-continuous cooking process and providing a copy to the regulatory authority prior to implementation gives notice to the regulatory authority that the food establishment intends to conduct non-continuous cooking operations for raw animal foods and makes it possible to verify that the appropriate non-

continuous cooking procedures are being followed and that the requirements of §3-401.14 are being met.

2. Subparagraph 3-401.14 deals with very basic food safety principles-heating, cooling and cooking. This section is very prescriptive, lists all necessary steps for safe food preparation and does not require review of any new science or evaluations to ensure it is being conducted properly.
3. This process would allow regulatory agencies to focus on reviews of processes they had concerns on and avoid detailed administrative reviews for complete processes.
4. Encouraging industry to submit their plans for their non-continuous cooking procedures to regulatory agencies for their review without a fear of potential delay that could take weeks or months.
5. Would allow for identification of establishments that needed additional training before implementing a non-continuous cooking process.
6. Reducing the need for overburdened regulatory agencies from needing to conduct a detailed review of each non-continuous cooking process and issuing approvals.
7. Places greater responsibility on industry to ensure their non-continuous cooking plans and procedures are sound and executed properly.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that Subparagraph 3-401.14 (F) (1) of the 2013 Food Code be modified to read (language to be added is underlined; language to be deleted is in strikethrough format):

(F) Prepared and stored according to written procedures that:

1. Have ~~obtained prior Approval from~~ been provided to the REGULATORY AUTHORITY prior to implementation describing the process they will use to comply with section 3-401.14;

Submitter Information:

Name:	Christopher Melchert
Organization:	National Restaurant Association
Address:	2055 L Street NWSuite 700
City/State/Zip:	Washington, DC 20036
Telephone:	202-973-3960
E-mail:	cmelchert@restaurant.org

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-033

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Thawing 3-501.13

Issue you would like the Conference to consider:

With the change in the FDA Food Code to priority, priority foundation and core violations, I believe that the thawing of potentially hazardous food (time/temperature control for safety food (TCS)) should be a priority foundation violation rather than core. It should be a priority foundation violation since improper thawing methods can directly lead to the priority violation of Section 3-501.16.

The definition of a priority foundation violation (per preface page xi, 2013 FDA Food Code) is a provision that "supports, facilitate or enables one or more priority violations."

Public Health Significance:

Improper thawing methods can result in TCS foods being out of temperature control which can lead to bacterial growth and toxin production. Thawing should be viewed in the same manner as improper cooling methods (Section 3-501.15) which is a priority foundation violation. Especially, since many foods being thawed are previously cooked and cooled TCS foods.

The FDA Food Code and most enforcement policies give the regulatory authority the ability to take more immediate action and more progressive enforcement for a priority foundation violation than a core violation.

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)*:*

3-501.13 Thawing.

Except as specified in ¶ (D) of this section, potentially hazardous food (time/temperature control for safety food) shall be thawed:

(A) Under refrigeration that maintains the food temperature at 5°C (41°F) or less[Pf]; or

(B) Completely submerged under running water:

(1) At a water temperature of 21°C (70°F) or below [Pf],

(2) With sufficient water velocity to agitate and float off loose particles in an overflow[Pf], and

(3) For a period of time that does not allow thawed portions of ready-to-eat food to rise above 5°C (41°F)[Pf], or

(4) For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under ¶ 3-401.11(A) or (B) to be above 5°C (41°F), for more than 4 hours including:

(a) The time the food is exposed to the running water and the time needed for preparation for cooking[Pf], or

(b) The time it takes under refrigeration to lower the food temperature to 5°C (41°F)[Pf];

(C) As part of a cooking process if the food that is frozen is:(1) Cooked as specified under ¶ 3-401.11(A) or (B) or § 3-401.12[Pf], or

(2) Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process[Pf]; or

(D) *Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.*

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood Dr
City/State/Zip:	Roscommon, MI 48653
Telephone:	517-719-7919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name:	Karla Horne
Organization:	Great Lakes Conference on Food Protection
Address:	525 W AlleganPO Box 30017
City/State/Zip:	Lansing, MI 48909
Telephone:	231-357-0727
E-mail:	hornek@michigan.gov

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-034

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Interpretation of Food Code Section 3-501.17 (A) & (B)

Issue you would like the Conference to consider:

When a Ready-to-Eat (RTE); Time/Temperature Control for Safety (TCS) food is prepared and held for more than 24 hours, the 2013 FDA Food Code requires that the product be properly Date Marked. It can be held for those 24-hours plus up to six additional days for a total of seven (7) days from the time it was prepared or from the time the original package was opened (in the case of commercially prepared food). By the end of 7-days, the food must either be used or discarded.

The language, "...date or day by which food shall be consumed, sold or discarded when held for a maximum of 7-days," found in Sections 3-501.17 (A) & (B) of the 2013 FDA Food Code is being variously interpreted by regulatory authorities. Consider this example: A facility that is a 24 hour operation prepares a RTE/TCS food at 11:00 pm on 1/1/16. It should not have to discard that food until 11:00 pm on 1/7/16. The product specifically has 24 hours from the precise time it was prepared (or opened) and then six (6) more days before it has to be fully used or discarded. The current language in the 2013 FDA Food Code is being interpreted by some regulators to mean that the food has to be discarded on 1/7/16 without regard to its actual "preparation time." This leads to confusion among operators and the unnecessary premature discard of food that has not yet reached the limit of its full 7-day shelf life.

On this basis, facilities are being given violations on health inspections and food is being wasted. For clarity, the terms "date or day" should be defined in the context of a 24-hour period of time and the calculation of 7-days should include the time-of-day as well as the date or day that the food is prepared or opened.

Public Health Significance:

With the designation of a specific time being placed on the Date Marking Label, it would allow both regulators and the food service facility to have a specific time line in which the RTE/TCS food would have to be properly discarded as required under Section 3-501.17 (A)

& (B) of the 2013 FDA Food Code and therefore less opportunity for miss-information pertaining to time line, date, and possible violation of this section.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting an interpretation that clarifies/explains the terms "date or day" in Section 3-501.17 (A) & (B) of the 2013 Food Code to better define a day as a 24 hour period of time with respect to the protocols for Date Marking. The Conference further requests that that the final interpretation document be posted to the FDA Food Code Reference System.

Submitter Information:

Name:	Christopher Melchert
Organization:	National Restaurant Association
Address:	2055 L Street NWSuite 700
City/State/Zip:	Washington, DC 20036
Telephone:	202-973-3960
E-mail:	cmelchert@restaurant.org

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-035

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Missing reference in 2013 FDA Food Code Section 3-501.19(A)(1)(a)

Issue you would like the Conference to consider:

Section 3-501.19(A)(1)(a) of the 2013 FDA Food Code should reference 3-501.19(B)(1)-(4), not just (1)-(3). This would be consistent with its reference to the equivalent requirement in (C)(5).

3-501.19(B)(4) requires that, when using time without temperature control as the public health control, foods that are not marked or have exceeded the time are discarded. Adding (B)(4) to the reference in 3-501.19(A)(1)(a) will require that discarding such food be addressed in the required written procedures.

Public Health Significance:

Requiring disposal to be included in the time as a public health control procedures will help prevent unsafe food from being served or sold.

Recommended Solution: The Conference recommends...:

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*):*

3-501.19 Time as a Public Health Control.

(A) Except as specified under ¶ (D) of this section, if time without temperature control is used as the public health control for a working supply of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD before cooking, or for READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is displayed or held for sale or service:

(1) Written procedures shall be prepared in advance, maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request that specify: [Pf]

(a) Methods of compliance with Subparagraphs (B)(1)-(~~3~~4) or (C)(1)-(5) of this section; [Pf]

Submitter Information:

Name:	Adam Inman
Organization:	Kansas Department of Agriculture
Address:	1320 Research Park Drive
City/State/Zip:	Manhattan, KS 66502
Telephone:	7855646764
E-mail:	adam.inman@kda.ks.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-036

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:

Clarifying Date Marking Disposition

Issue you would like the Conference to consider:

Subparagraph 3-501.18(A)(3) of the 2013 FDA Food Code refers to a food that is "appropriately marked with a date or day that exceeds" date marking timeframes. The word "appropriately" is confusing.

Public Health Significance:

Clarifying the Food Code can help with compliance.

Recommended Solution: The Conference recommends...:

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

3-501.18 Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition.

(A) A FOOD specified in ¶ 3-501.17(A) or (B) shall be discarded if it:

(3) Is ~~appropriately~~ marked with a date or day that exceeds a temperature and time combination as specified in ¶ 3-501.17(A). P

Submitter Information:

Name:	Adam Inman
Organization:	Kansas Department of Agriculture
Address:	1320 Research Park Drive
City/State/Zip:	Manhattan, KS 66502
Telephone:	7855646764
E-mail:	adam.inman@kda.ks.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-037

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 - Additional Requirements for Consumer Advisories

Issue you would like the Conference to consider:

Amending Section 3-603.11 of the 2013 FDA Food Code to include training and verbal communication of risk.

Public Health Significance:

An *E. coli* O157:H7 outbreak occurred in May 2014, in which 12 became ill and 7 were hospitalized after eating hamburgers in restaurants in 4 different states (CDC, 2014). Initially, the Michigan Department of Health reported that undercooked ground beef eaten at several different restaurants was a suspected source (WILX News, 2014). A recall of 1.8 million pounds of ground beef products suspected of contamination by *E. coli* O157:H7 was subsequently issued (CDC, 2014; Erb, 2014). Interviews with the sickened individuals revealed that eight of the twelve had ordered their hamburgers cooked rare or medium rare (Andrews, 2015). Four of the five illnesses reported in Ohio were traced to a restaurant chain. Epidemiological investigation revealed that all of the cases were tied to one strain of *E. coli* O157:H7, but could not reveal whether the risk of consuming undercooked hamburgers had been communicated with consumers (Andrews, 2015; CDC, 2014). The outbreak highlights several issues. First, it reveals the riskiness of undercooked hamburgers and the restaurant culture of ordering undercooked hamburgers. It also shows that using terms such as "medium rare" are not effective in describing how well-cooked a hamburger will be.

Measuring the temperature of a hamburger with a thermometer is the only reliable method to determine that it has reached a safe temperature; color is not a reliable indicator of doneness. Hamburgers can brown at temperatures well below the recommended endpoint temperature (Hague *et al*., 1994, Lyon *et al.*, 2000). Premature browning is related to the oxidative state of the meat (Hunt *et al*, 1999). The form of myoglobin at the time of cooking directly correlated to the visual and instrumental analysis results; hamburger patties that contained deoxymyoglobin (DMb) had more pink color when cooked than those that

contained oxymyoglobin (OMb) and metmyoglobin (MMb) (Hunt *et al*, 1999). Numerous other factors can contribute to the color of ground beef. Cooking pre-frozen hamburger patties results in more premature browning than allowing patties to thaw before cooking (Hunt *et al*, 1999). pH played a direct role in the thermostability of the different myoglobin forms; as pH increased, OMb and MMb became more stable (Hunt *et al*, 1999). Hamburger containing less fat takes longer to cook than hamburgers with a higher fat content (Troutt *et al*., 1992). Meat from older carcasses showed a higher rate of premature browning than meat taken from younger carcasses (Marksberry, 1990).

Chefs and other culinary specialists cite methods of determining doneness other than temperature, such as color and touch (Levine and Chapman, 2014). A local food writer and chef writes about cooking hamburgers, "With practice, you can check doneness by touch: a little give for medium and just barely firm for well-done. Until you get good enough at that, though, the best bet is to peek. Make a small slit in a thicker part of the burger. The interior will be light pink for medium or just browned all the way through, but still juicy, for well-done." (Washington Post, 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):

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(4) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means, <u>supplemented with verbal confirmation</u>. Pf

<u>Those who are communicating to consumers must be trained in the hazards and risks associated with consuming raw or undercooked animal foods not otherwise processed to eliminate hazards and how to convey risk messages verbally to consumers.</u>

(B) DISCLOSURE shall include:

(1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order)"; Pf or

(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients. Pf

<u>(3) State there is a risk for foodborne illness associated with what they are ordering</u>

<u>(4) provide a safe temperature guideline so the consumer can request that temperature if desired, with a statement of how to significantly reduce risk (i.e., ordering cooked to above a certain endpoint temperature).</u>

(5) State that color is not an indicator of doneness.

(C) REMINDER shall be conducted verbally include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request; Pf

(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness;Pf or

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne Pf illness, especially if you have certain medical conditions.

(4) The verbal statement must include that ordering /purchasing raw undercooked product increases risk of foodborne illness. All references to determining safety and doneness of a product should be made to temperature, not color or other indicators that are not reliable.

Submitter Information:

Name:	Dr. Ben Chapman
Organization:	NC State University
Address:	Campus Box 7606
City/State/Zip:	Raleigh, NC 27695
Telephone:	919 809 3205
E-mail:	benjamin_chapman@ncsu.edu

Supporting Attachments:

- "Of course I know what I'm talking about: Assessment of Risk Communication a"

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.

IN REVIEW – JOURNAL OF FOOD PROTECTION

Of course I know what I'm talking about: Assessment of Risk Communication about Undercooked Hamburgers by Restaurant Servers

Ellen M. Thomas[1,a], Benjamin Chapman[2], Douglas Powell[3], Andrew Binder[4], Dana Hanson[1], Lee-Ann Jaykus[1], Anne McLaughlin[5]

1. North Carolina State University; Department of Food, Bioprocessing, and Nutrition Sciences. Raleigh, NC 27607.
2. North Carolina State University; Department of Youth, Family, and Community Sciences. Raleigh, NC 27607.
3. Dr. Douglas Powell; powellfoodsafety.com; barfblog.com
   skype: dpowell29
   0478 222 221(cell)
4. North Carolina State University; Department of Communication. Raleigh, NC 27607.
5. North Carolina State University; Department of Psychology. Raleigh, NC 27607.

· Author for correspondence. Phone: 919-541-1282, Email: ethomas@rti.org
[a] RTI International, 3040 Cornwallis Road, Durham NC, 27709

KEY WORDS: hamburger safety, measuring doneness in hamburgers, risk communication

ABSTRACT

According to the U.S. Food and Drug Administration 2013 Model Food Code, it is the duty of a food establishment to disclose and remind consumers of risk when ordering undercooked food such as ground beef. The purpose of this study was to explore actual risk communication activities of food establishment servers. Secret shoppers visited restaurants (n=265) in seven geographic locations across the U.S., ordered medium rare burgers, and collected and coded risk information from chain and independent restaurant menus and from server responses. The majority of servers reported an unreliable method of doneness (77%) or other incorrect information (66%) related to burger doneness and safety. These results indicate major gaps in server knowledge and risk communication, and the current risk communication language in the Model Food Code does not sufficiently fill these gaps. Furthermore, should servers even be acting as risk communicators? There are numerous challenges associated with this practice including high turnover rates, limited education, and the high stress environment based on pleasing a customer. If it is determined that servers should be risk communicators, food establishment staff should be adequately equipped with consumer advisory messages that are accurate, audience-appropriate, and delivered in a professional manner so as to help their customers make more informed food safety decisions.

Introduction

Ground beef is a vehicle for human pathogens and its consumption has been identified as a risk factor for foodborne illness *(7*). Various pathogenic bacteria may be found in the gut of cattle (and on hides) and can contaminate meat during slaughtering and processing (*5, 10*). One of the pathogens commonly associated with ground beef is *Escherichia coli* O157:H7. Other serotypes of *E. coli* have also resulted in foodborne illness associated with ground beef (*1*). If ground beef is contaminated, two risk-reduction steps have been shown to be achieve a 5-log reduction: cooking to 155°F for 15 seconds or 160°F for <1 second, and avoiding cross-contamination (the transfer of pathogens from one surface to another post-processing). Sensory qualities such as color or texture, and/or cook time, are not reliable indicators of pathogen risk reduction on a hamburger, but are often cited by culinary professionals as indicators of doneness (*8*).

The U.S. FDA 2013 Model Food Code stipulates that when a food of animal origin (such as beef, eggs, fish, lamb, milk, poultry, or shellfish) is served raw, undercooked, or has been insufficiently processed to eliminate pathogens, the restaurant shall disclose and remind consumers of risk (*6*). Disclosure is defined as including a description of the animal-derived food (such as, “hamburger can be cooked to order”) and stating that the food is served undercooked, which is typically identified by an asterisk.

The reminder is to asterisk the food with a footnote stating that "consuming raw or undercooked meat, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness." The consumer advisory may also include the distinction that this risk is especially increased if an individual has a particular medical condition, and that additional safety information is available upon request (*6*). However, there is little research to illustrate whether disclosure and reminder of risk is actually occurring, and what the role of restaurant servers is in the process.

The goal of this project was to investigate the process of risk disclosure and reminder in restaurants, on both the menu and by the server. It was hypothesized that there would be numerous gaps and inconsistencies in how risk is communicated in restaurants.

MATERIALS AND METHODS

Recruitment. Forty-four secret shoppers were recruited and trained to collect data in seven locations: Raleigh, NC; Blacksburg, VA; College Station, TX; Manhattan, KS; Lincoln, NE; Davis, CA; and Philadelphia, PA. Geographic locations were selected for convenience based on where project collaborators were located nationally, and to represent multiple regions of the United States. Restaurants were selected by using an online restaurant directory for each geographic location. Locations were classified according to the U.S. Census Bureau standards, which include urbanized areas (UA), which are defined as a densely developed territory (at least 1,000 people per square mile) of 50,000 people or more, or urbanized clusters (UC), which are defined as a densely developed territory between 2,500 and 50,000 people (*12*).

Secret shopper training was standardized and consisted of an in-person meeting between trainer and trainee at the sampling location. The secret shoppers were presented a brief background of the rationale for the project, followed by a walk-through of the script, which included an explanation of Likert scale coding, designed to rank degree of agreement or disagreement with certain statements. Likert scales were used to rank the level of correctness or incorrectness of server responses about undercooked hamburgers.

Data collection was primarily conducted during lunchtime on a weekday, and for convenience, the restaurant sample was limited to a radius of approximately 10 miles from the secret shopper's work location. Exceptions included Virginia and Kansas, where secret shoppers visited other cities in the state to reach the restaurant quota. A sample list was generated by randomly selecting from online regulatory catalogs of permitted food premises. A chain restaurant was defined as a franchised restaurant that included 10 or

more locations; less than 10 locations was classified as an independent restaurant. Each secret shopper was assigned a random number, restaurants generated from the sample list were assigned a number, and restaurants were randomly assigned to the secret shoppers.

Data Collection. Two secret shoppers visited each restaurant. First, secret shoppers captured pictures of the consumer advisory messages on the restaurant menu(s). Secret shoppers then ordered lunch to eat at the restaurant site, specifically not a hamburger. During the meal, secret shoppers ordered two hamburgers to go: one was ordered cooked medium rare, and the other, well done. The secret shopper ordering the medium rare hamburger ordered first. When ordering the medium rare burger, if the server did not proactively provide any risk information, the secret shopper ordering the well-done burger interjected to ask:

- Is that safe to eat?
- How do you determine doneness (whether it is safely cooked or not?)?

Secret shoppers occasionally went off script based on server responses and how the conversation progressed. Server responses to the questions were documented by the secret shoppers, in most cases as text on a cell phone.

Coding. Data were segmented by server response to secret shopper questions for each restaurant, and a codebook was developed to analyze these responses. Five categories were used to examine the different aspects of server communication. Specifically, server responses were coded for (1) availability of medium rare ordering; (2) method of determining doneness; (3) whether safety information was mentioned; (4) whether incorrect information was mentioned; and (5) appearance of server confidence.

The question of availability of medium rare burgers was addressed by coding for whether servers allowed medium rare to be ordered.

- **Yes** was coded when servers allowed burgers to be ordered
- **No** was coded when servers cited restaurant policy that did not allow medium rare to be ordered.

One of the primary goals of this research was to capture the method of doneness cited by the server; more specifically, how many restaurant servers communicate an unreliable indicator of doneness to consumers. After review of the data, six codes emerged to describe types of "doneness" as described by servers. Some data units were double-coded or even triple-coded in cases when servers mentioned more than one method of determining doneness.

- **Temperature** was coded when a thermometer use was referenced, or when a specific temperature was mentioned. Temperature was sometimes double-coded with color.
- **Color** was coded when mentioned by the server. Color was often double-coded with touch, and sometimes double-coded with temperature.
- **Touch** was coded when a textural quality was mentioned, or when words such as "warm" or "cold" were used. Touch was often double-coded with color.
- **Time** was coded when any unit of time was mentioned or implied.
- **Cooks know** was coded when cook experience was used as the criteria for judging degree of doneness.
- **I don't know** was coded when the server stated that he or she did not know or was not sure.

The third category addressed the question: Is safety information provided by the server? Because servers frequently referred to factors that were more directly related to quality, but believed them to be safety related, such statements were also coded as safety information.

- **Yes** was coded when the risk for foodborne illness was stated; when the consumer was told directly whether it was safe or not to consume medium rare burgers; when the health department or Food Code was mentioned; or when a quality factor was mentioned as an answer to a safety question, implying that the two are related.
- **No** was coded when the above information was not provided. Some servers provided a method of doneness, but made no statements about safety. These instances were also coded under this category.

The fourth category further addressed the question of risk information by coding for whether incorrect information was provided.

- **Yes** was coded when any incorrect information was stated. Incorrect information included any method to determine doneness other than temperature; statements about quality that implied a correlation with safety; and/or a direct statement of safety if the temperature was stated to be below 160°F.
- **No** was coded when all information provided was correct.

The fifth category was the appearance of confidence of the server: positive or negative.

- **Positive** was coded with the use of "to be" verbs, indicative mood, no hedging, and overall apparent confidence of the server as noted by direct observation by the secret shopper.
- **Negative** was coded with the use of conditional language or hedging, and overall appearance of little confidence as observed by the secret shopper.

Code reliability was confirmed by determining simple reliability and Cohen's kappa using a second coder for the initial 40 restaurants visited. Both values for each code are listed in Table 1. Because Cohen's kappa values were all within the range of acceptability, refinement of codes was not necessary.

Likert scales were also developed to score the risk messages found on the menus and to provide a comprehensive score for server responses. This was done because there were varying degrees of correct or incorrect information provided, as well as depth of information, and the need to characterize such variations quantitatively. There were a total of four scales used: a menu scale; an initial server response scale (assigned to each server response that dictated whether it was subsequently scored as correct or incorrect information; a correct server response scale (used when the response contained correct information); and an incorrect server response scale (used when the response contained incorrect information). Each site visited was assigned a score from three of the four scales. Scores ranged from a low of 1 to a high of 7. For the menu and initial server scales, incorrect information received scores between 1 and 3, and correct information received scores between 4 and 7. The correct and incorrect scales were used to further quantify the type of information that was shared by the server. Secret shoppers and an additional coder scored the data based on these scales.

The three most recent inspection reports were collected from those restaurants for which they were available. Inspection frequencies varied, but inspection typically occurred once per year. The information from inspection reports about posted consumer advisory messaging [in compliance (I), out of compliance (O), or N/A] were collected from each report.

Data Analysis. Data were analyzed using SAS 9.4 software (SAS Institute, Cary, NC). Analysis consisted of running a GLIMMIX procedure to determine a p value for each comparison and compare differences in code frequencies and Likert scores between states, restaurant type, and restaurant location. A Spearman correlation was performed on secret shopper Likert scores for menu and server response scores to test the consistency of training and ensure validity.

RESULTS

Coding. A total of 265 restaurants were visited (132 chain, 133 independent); 87.6% of them were in urbanized areas, while 12.4% were in urban clusters. Based on the coding explained above, six subcodes were used to describe servers' reporting of method used to determine doneness: temperature, color, touch, time, cooks know, or server stated that they did not know. In some instances, servers did not mention a method of doneness; some servers listed more than one method of doneness in a conversation. A total of 296 responses were obtained, exclusive of 66 instances in which the server did not mention a method of doneness and inclusive of server responses in which more than one subcode was cited. Response rate to this question was 74.0% (n = 199) and Figure 1 illustrates the overall percentage of each method of doneness mentioned by a server. The majority of server respondents cited a single subcode, but 23.6% (n = 47), 4.0% (n = 8), and 0.5% (n = 1) provided double coding, triple coding, or quadruple coding. The most frequent instances for which multiple methods of doneness were mentioned were for temperature and color, color and touch, or all three.

Overall, 74.1% of restaurants (n = 196) allowed medium rare burgers to be ordered. There was not a significant difference between states or population area, but significantly more independently owned restaurants allowed secret shoppers to order medium rare burgers than did chain restaurants ($p = 0.0007$).

In 50.7% of the conversations (n = 134), servers mentioned safety information (both correct and incorrect information). There was a difference between states, with California having the highest rate of safety information sharing, and significantly differing from Kansas, Nebraska, and Pennsylvania ($p = 0.0095$, 0.0316, 0.0014,

respectively). There was not a difference between type of restaurant ($p = 0.6183$) or population area ($p = 0.1952$) relative to servers discussing safety.

For those instances in which servers shared information, that information was incorrect in 66.7% of the interactions ($n = 177$). There were significant state-to-state differences; Pennsylvania had the highest rate of incorrect information shared ($p = 0.0051$). There was no difference when comparing information sharing by type of restaurant or population area. Approximately 70% of servers appeared confident ($n = 189$). There was not a significant difference in appearance of confidence by state ($p = 0.5776$), restaurant type (0.6321), or population area ($p = 0.9737$).

Likert Scoring. A Spearman's correlation was run on secret shopper and control Likert scores to ensure that they were a consistent standard, and that the secret shopper training was valid. The scores that were generated confirmed validity (menu $= 0.741$, initial server $= 0.612$, correct server $= 0.354$, incorrect server $= 0.388$).

The Likert scale data are summarized in Tables 3, 4, and 5. Virginia had the highest menu scores, while California scored the lowest. Similar results were observed for the initial server scores, although Pennsylvania and Texas also scored low. Chain restaurant menu and initial server scores were significantly higher than independent restaurant scores ($p < 0.001$). Urbanized clusters scored significantly higher than urbanized areas for menu scores ($p < 0.001$) but not for initial server scores.

Thirty-five percent of server interactions ($n = 93$) qualified to be scored on the correct server response Likert scale, while 67% of server interactions qualified to be scored on the incorrect server response Likert scale. There was wide variability in these scores when comparing states. There was not a significant difference for restaurant type

for either types of server response (correct p = 0.6705, incorrect p = 0.7950). However, urbanized areas scored higher than urbanized clusters for the correct server response scoring (p = 0.0080), but not for incorrect server response (p = 0.0752).

Inspection Reports. Not all of the inspection reports were available to access for each restaurant (0% missing for Nebraska; 46% missing for Pennsylvania). Based on those available, the majority of restaurants were reported to be in compliance with consumer advisory messaging in inspection reports (Table 6). North Carolina had the highest rate of noncompliance. For all of the other states, there was at least one round of inspections in which noncompliances related to written consumer advisories were absent.

Server Responses. Posing questions to servers yielded a wide array of responses related to safety of the product, determining doneness, and servers' personal opinions. Particularly notable responses included stating that undercooked burgers were safe even for pregnant women, just the outside of burgers are where the bad bacteria lives, and the cook just knows if the burger is done by feeling it. These types of responses highlight the major gaps and inconsistencies in the information that servers provide to consumers.

DISCUSSION

Beef hamburgers are a favorite of Americans, and despite their association with some high profile foodborne illness outbreaks and the scientific consensus that temperature is the only reliable indicator of doneness, consumers continue to eat burgers that are not thoroughly cooked as a result of personal and cultural preferences. Consumer messaging can take many forms, both written and oral. The purpose of this study was to determine whether restaurant servers discuss risks of consuming undercooked hamburgers with consumers, and if so, what information they share. Identifying current practices helps determine inconsistencies in the risk information that is being communicated, and to make recommendations as to what information would most effectively communicate risk so that consumers can make an informed decision. A secret shopper study design was chosen, in which data collectors posed as restaurant patrons and collected information from servers while actually ordering medium rare hamburgers. While more expensive than a national survey of servers in which they self-report their behaviors, this design allowed for direct communication with the servers and the opportunity to present the data in both qualitative and quantitative manners. A previous secret shopper study conducted in 13 supermarkets in Ontario revealed that store employees appeared confident in the advice they offered, but it was incorrect; poor food handling practices were also observed (*9*). Points of particular interest were the methods used to determine hamburger doneness; whether ordering undercooked hamburgers was allowed; and whether the information shared by servers was correct. Information on written menu messages and inspection reports were provided as a framework for comparison.

While inspection reports for the restaurants visited showed a high rate of compliance with Food Code-recommended consumer advisory messaging, the Likert scores for menu messaging and server response were not always consistent, and servers frequently provided contradictory information. For example, servers used a wide array of unreliable factors when discussing burger doneness, particularly color. In some cases, this was simply because the server did not know the temperature ranges used to cook hamburgers. This lack of knowledge suggests poor communication between the kitchen staff and serving staff, as well as the possibility that thermometers are not being used by kitchen staff. This is consistent with the literature (*2*). When servers did mention temperature, it was often in conjunction with another qualitative factor, such as color or time.

Similarly, the majority of restaurants were in compliance relative to consumer advisory messaging on inspection reports. Nonetheless, servers frequently contradicted the risk information found on the menu by citing qualitative indicators of doneness (as described above); assuring consumers that undercooked hamburgers were safe to consume; or by listing temperatures that are not sufficient to kill pathogens. For the servers that did share correct information, the average Likert scores show that prompting by the secret shopper was still required to get any risk information, which was part of the secret shopper ordering protocol if servers did not volunteer risk information. The inconsistency between inspection reports and server risk messaging illustrates a major drawback of the former, in that formal inspections can miss the impact of personal communication in risk management. Stressing the importance of consumer advisory in the process of inspections would be one step towards a more positive risk communication

culture in restaurants. Adding this component not only fills the gap in investigating how a restaurant communicates risk, but also serves to emphasize its importance to those administering and receiving the inspection.

The Likert scoring revealed some differences between states and restaurant type with respect to the quality of risk information that was shared by servers. For example, California scored the lowest for menu and initial server score. North Carolina, which adopted the 2009 FDA Food Code shortly before the secret shopper study began, had high scores. Chain restaurant servers consistently scored higher than independent restaurant servers. This is to be expected, as chain restaurants typically have standardized food safety programs that include employee training and appropriate messaging.

The data presented here demonstrate a gap in server knowledge about food safety risks and the communication of that risk to consumers. But should servers be risk communicators? Placing them in this role presents challenges: (i) high turnover and low pay; (ii) limited education; (iii) high stress and fast-paced environment; and (iv) pressure to "please" the consumer and provide a pleasurable dining experience. If we were to rely on servers for food safety communication, the data presented here suggests the need for a more formal food safety curriculum specifically aimed towards servers, with the ultimate goal of improving risk messaging to consumers. Risk communication literature demonstrates that consumers need to understand the context of a risk in order to identify and remember it (*4*). Familiarity also plays a strong role in consumer perception of a risk, as does trust (*11*). Behavior and risk communication are more likely to be impacted when targeting both knowledge and individual intention. Food servers may be in the unique position of providing accurate food safety information to consumers. Identifying

additional roadblocks and determining server receptivity to training interventions focused on risk communication is the next step moving forward from this study.

ACKNOWLEDGMENTS

This research would not have been possible without the work of the secret shoppers: Katrina Levine, Matt Agle, Nicole Arnold, Lily Yang, Stephanie Pollard, Mary Blodgett, Ashley Searing, Courtney Crist, Nick Sevart, Donka Milke, Elizabeth Stone, Liz Holmgren, Nick Baumann, Anteelah Phebus, Danny Unruh, Eric Oliver, Sherri Pitchie, Michael Pitchie, Hannah Hamilton, Gentry Lewis, Ashley Hallowell, Brad Shoyer, Laura Shane, Nelly Osoria, John Luchansky, Anna Porto-Fett, Elba Arias, Jessie Hudson, Tamra Tolen, Alana Bryant, Mariana Villarreal, Keila Perez, Yicheng Xie, Songsirin Ruengvisesh, Katie Kirsch, Zahra Mohammed, Christine Bruhn, Myat Aye, Rachelle Woods, Yaohua Feng, Thu Tran. I am grateful to David Marx of University of Nebraska at Lincoln, who provided a great deal of support with statistical analysis throughout the course of the project. This research was supported by Agriculture and Food Research Initiative Competitive Grant no. 2012-68003-30155 from the USDA National Institute of Food and Agriculture.

REFERENCES

1. Batz, M. B., Hoffmann, S., and J. G. Morris. 2012. Ranking the disease burden of 14 pathogens in food sources in the United States using attribution data from outbreak investigations and expert elicitation. *Journal of Food Protection* 75(7): 1278–91.

2. Bogard, A. K., Fuller, C. C., Radke, V., Selman, C. A., and K. E. Smith. 2013. Ground Beef Handling and Cooking Practices in Restaurants in Eight States. *Journal of Food Protection* 76(12): 2132–2140.

3. Center for Disease Control and Prevention. Foodborne Outbreak Online Database (FOOD). Accessed from: http://wwwn.cdc.gov/foodborneoutbreaks/

4. Cope, S., Frewer, L. J., Houghton, J., Rowe, G., Fischer, A. R. H., and J. de Jonge. 2010. Consumer perceptions of best practice in food risk communication and management: implications for risk analysis policy. *Food Policy* 35(4): 349-57.

5. Elder, R. O., Keen, J. E., Siragusa, G. R., Barkocy-Gallagher, G. A., Koohmaraie, M., and W. W. Laegreid. 2000. Correlation of entero- hemorrhagic Escherichia coli O157 prevalence in feces, hides, and carcasses of beef cattle during processing. Proc. Natl. Acad. Sci. USA 97:2999–3003.

6. Food and Drug Administration. 2013. FDA Food Code 2013. U.S. Department of Health and Human Services. Accessed from: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm

7. Interagency Food Safety Analytics Collaboration project report. 2015. Foodborne illness source attribution estimates for *Salmonella, Escherichia coli* O157 *(E. coli* O157*), Listeria monocytogenes (Lm),* and *Campylobacter* using outbreak surveillance data. Accessed from http://www.cdc.gov/foodsafety/pdfs/ifsac-project-report-508c.pdf

8. Levine, K. and B. Chapman. Evaluation of food safety messages in popular cookbooks. Presented at: Food & Nutrition Conference & Expo; October 20, 2014; Atlanta, GA.

9. Mathiasen, L. and D. Powell. 2005. Secret shopper: grocery store employee food handling practices from a customer's perspective. *Food Protection Trends* 25(8): 626-636.

10. McEvoy, J. M., Doherty, A. M., Sheridan, J. J., Thomson-Carter, F. M., Garvey, P., McGuire, L., Blair, I. S., and D. A. McDowell. 2003. The prevalence and spread of Escherichia coli O157:H7 at a commercial beef abattoir. *Journal of Applied Microbiology* 95:256–266.

11. Slovic, P. 1987. Perception of risk. *Science* 236(4799): 280-285.

12. United States Census Bureau. 2010 Census Urban and Rural Classification and Urban Area Criteria. Accessed from: https://www.census.gov/geo/reference/ua/urban-rural-2010.html

FIGURE LEGENDS

Figure 1. Overall percentages of method of doneness mentioned by server (n = 296).

Table 1. Simple reliability and Cohen's kappa for secret shopper codes.

Code	**Simple reliability**	**Cohen's kappa**
Medium rare allowed	100%	1
Method of doneness	72%	0.65
Safety information provided	89%	0.75
Incorrect information	85%	0.68
Appearance of server confidence	93%	0.82

Table 2. Likert scores for menu, initial server, correct server, and incorrect server by state. An asterisk designates when there was a significant difference between state scores. The highest and lowest score for each category is in bold.

State	Menu* (n = 276)	Std. dev.	Initial Score* (n = 269)	Std. dev.	Correct score* (n = 105)	Std. dev.	Incorrect score* (n = 191)	Std. dev.
California	**3.19**	0.83	2.89	1.25	4.25	-	4.84	1.95
Kansas	3.84	0.85	3.44	1.39	2.60	1.22	**5.24**	1.71
Nebraska	3.83	0.88	3.31	1.37	3.53	1.48	4.77	1.74
North Carolina	3.99	0.59	3.24	1.46	2.95	1.16	4.81	1.54
Pennsylvania	3.86	0.88	2.86	0.99	**2.14**	0	4.50	2.06
Texas	3.64	0.84	**2.82**	1.57	**4.33**	1.83	4.23	1.99
Virginia	**4.08**	0.91	**3.84**	1.63	3.46	0.94	**2.88**	1.78
Total	3.79	0.88	3.22	1.42	3.19	1.34	4.60	1.90

Table 3. Likert scores for menu, initial server, correct server, and incorrect server by restaurant type. An asterisk designates when there was a significant difference between chain and independent scores.

Restaurant Type	Menu* (n = 276)	Std. dev.	Initial Score* (n = 269)	Std. dev.	Correct score (n = 105)	Std. dev.	Incorrect score (n = 191)	Std dev.
Chain	4.09	0.94	3.40	1.45	3.21	1.78	4.68	1.92
Independent	3.52	0.66	3.03	1.38	3.17	1.78	4.52	1.89

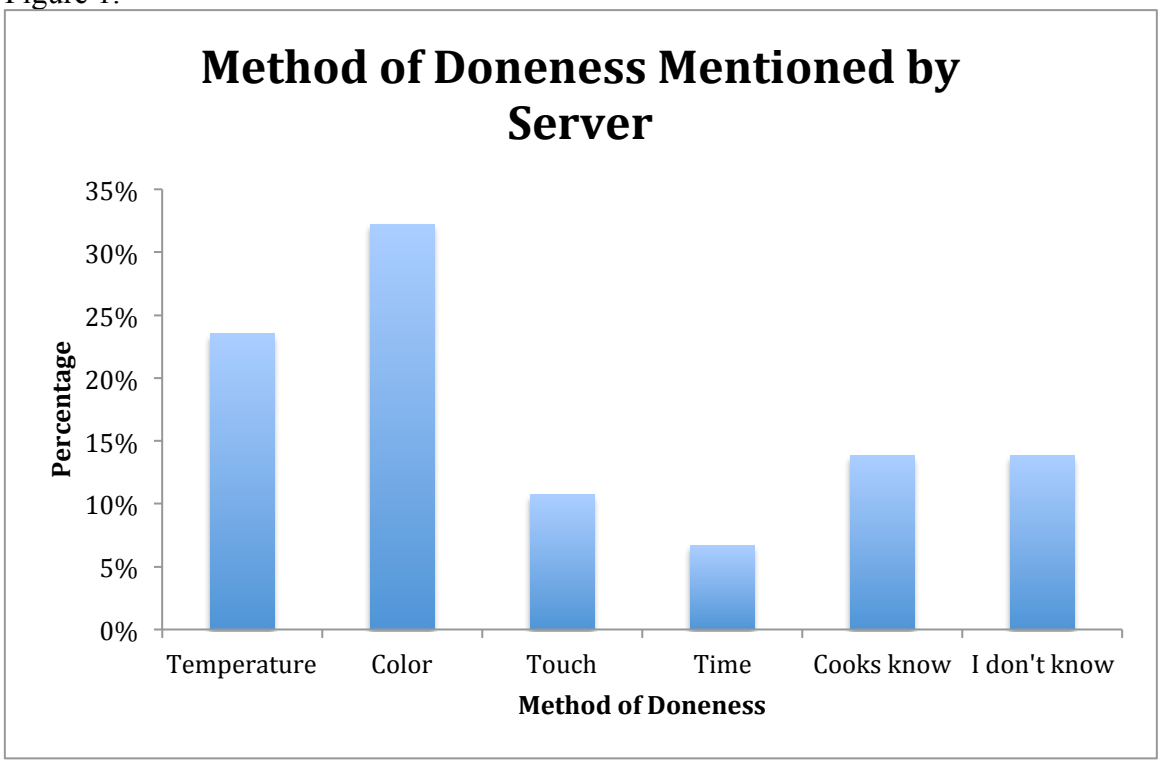
Table 4. Likert scores for menu, initial server, correct server, and incorrect server by population area. An asterisk designates when there was a significant difference between urbanized area and urbanized cluster scores.

Population Area	Menu* (n = 276)	Std. dev.	Initial Score (n = 269)	Std. dev.	Correct score (n = 105)	Std. dev.	Incorrect score* (n = 191)	Std. dev.
Urbanized Area	3.76	0.83	3.18	1.42	3.22	1.85	4.76	1.83
Urbanized Cluster	4.09	0.98	3.56	1.40	3.05	1.43	2.67	1.63

Table 5. Average rate of compliance with consumer advisory messaging in restaurants visited for past 3 inspections.

Compliance category	Percentage
In compliance	68%
Out of compliance	9%
N/A	23%

Figure 1.


Method of Doneness Mentioned by Server
35%
30%
25%
20%
15%
10%
5%
0%
Percentage
Temperature
Color
Touch
Time
Cooks know
I don't know
Method of Doneness

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-038

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:

Raw Animal Foods – Consumer Advisory

Issue you would like the Conference to consider:

Section 3-401.11(D) and 3-401.11(D)(3) in the 2013 FDA Food Code allow:

"3-401.11(D) A raw animal food such as raw egg, raw fish, raw-marinated fish, raw Molluscan shellfish, or steak tartar; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in ¶ (C) of this section, may be served or offered for sale upon consumer request or selection in a ready-to-eat form if:"

"3-401.11(D)(3) the CONSUMER is informed as specified under 3-603.11 that to insure its safety, the FOOD should be cooked as specified under (A) or (B) of this section;"

However, Section 3-603.11 does not require that the food establishment provide language informing the consumer how to request or select the animal food cooked as specified under 3-401.11(A)(B)

Since section 3-603.11 does not require the food establishment to provide language for how consumers can request or select animal food cooked as specified under 3-401.11(A)(B) people who want to order their animal food cooked safely may accidentally receive it partially cooked.

Food establishments that utilize the consumer advisory should have to have an ordering system in place that informs the consumer what to say to request or select their animal cooked as specified under 3-401.11(A)(B). Ordering animal food raw or partially cooked should be a willful act on the part of the consumer. Serving an animal food raw or partially cooked should be an intentional act on the part of the food establishment.

If, for example, a food establishment uses the terms rare, medium-rare, medium, medium-well and well done for placing an order they need to be able to convey to the consumer and the regulatory authority, in writing and upon request, which of those terms will result in the food being cooked pursuant to 3-401.11(A)(B).

By adding a new section to 3-603.11 it will:

1. Still enable consumers to request or select animal foods raw or partially cooked.
2. Allow consumers to order animal foods that are subject to the consumer advisory to be cooked safely.
3. Allow each food establishment that utilizes the consumer advisory to use their own ordering language to comply with this requirement.
4. Give regulators a way to hold the permit holder more accountable to the temperature requirements of section 3-401.11(A)(B) for those menu items that have a consumer advisory.

Public Health Significance:

The 1993 E. coli O157:H7 outbreak linked to a popular fast food restaurant chain fundamentally changed how beef is slaughtered, processed, distributed, and cooked in the United States. The outbreak, which sickened over 500 people and caused the death of four children was the catalyst for:

- E. coli O157:H7 and Hemolytic Uremic Syndrome (HUS) being added to the federal list of reportable diseases by the Center for Disease Control (CDC) in 1995,
- The Food and Drug Administration (FDA) raising their recommended internal temperature of cooked hamburgers to 155 degrees Fahrenheit in 1993,
- The United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) declaring E. coli O157:H7 to be an adulterant in raw ground beef in 1994. (In 2011 six additional strains of E. coli were declared to be adulterants.)
- The USDA initiating a monitoring program for E. coli O15:H7 in raw ground beef,
- FSIS initiating a program to encourage better testing and controls by industry and,
- FSIS began requiring safe food handling labels on all raw meat and poultry.

Those measures, along with systematic changes in critical control points in processing by the beef industry, were intended to minimize E. coli contaminated beef from entering the food supply. However, the approximately 1.8 million pound recall of ground beef tied to E. coli O157:H7 in 2014; separate 5.3 million pound and 1.36 million pound recalls in 2008; a 21.7 million pound recall in 2007; and a 25 million pound recall in 1997 highlight the continued risk of contaminated beef reaching the consumer. The risk associated with E. coli is of particular concern as there is still no effective way to prevent the onset of HUS in those patients that contract a Shiga toxin-producing E. coli infection.

There are many other pathogens associated with raw and partially cooked animal foods. Poultry, Pork, Egg and Seafood Producers as well as the producers of other amenable and non-amenable meats all have challenges similar to the Beef Producers and yet unique to their own industries. Hepatitis A, Listeria monocytogenes, Clostridium botulinum, Clostridium perfringens, Campylobacter jejuni, Staphylococcus spp., Salmonella spp., Shigella spp., Vibrio spp., and Norovirus are among those diseases that are transmissible from raw animal foods. The risk of these illnesses being transmitted is increased when the animal foods associated with these pathogens are served raw or partially cooked.

At a food establishment, a consumer should be able to order animal foods- cooked safely- to minimize the risk of getting sick from these foodborne pathogens. Given the current

language of the FDA Food Code, if there is a consumer advisory present on the menu, there is often no effective means for the consumer to order food cooked safely.

The annex of the 2013 FDA Food Code states "the requirements specified under 3-401.11(D) acknowledge the rights of an informed consumer to order and consume foods as preferred by that consumer based on the consumer's health status and understanding of the risks associated with eating raw or partially-cooked animal foods."

However, I do not believe that 3-401.11 and 3-603.11, as written, adequately protect the rights of the consumers who want their animal foods cooked pursuant to 3-401.11(A)(B). Those consumers often have no effective means to order animal food cooked safely in those food establishments that choose to provide a consumer advisory.

It also has caused the unintended consequence that the regulatory community is not able to hold a food establishment accountable for accidentally undercooking animal food when there is a consumer advisory present on the menu.

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 3-603.11

(A): Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(4) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means. Pf table tents, placards, or other effective written means; and provide an effective means for ordering as specified in (D) of this section.

(D) the FOOD ESTABLISHMENT has, in writing and available to the CONSUMER and REGULATORY AUTHORITY, ordering information that will give the CONSUMER an effective means of requesting or selecting the animal FOOD cooked pursuant to 3-401.11(A)(B)[Pf]

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood Dr
City/State/Zip:	Roscommon, MI 48653
Telephone:	5177197919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name:	Karla Horne
Organization:	Great Lakes Conference on Food Protection

Address: 525 W AlleganPO Box 30017
City/State/Zip: Lansing, MI 48909
Telephone: 231.357.0727
E-mail: hornek@michigan.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-039

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:

Addition of new Food Code section: Grinding Logs

Issue you would like the Conference to consider:

This proposal requests the addition of a requirement for retail food establishments to comply with regulations issued by the Food Safety and Inspection Service (FSIS) that require certain retail food establishments that grind raw beef products to maintain records of the source for the materials they use, date and time the beef was ground, and date and time when grinding equipment was cleaned and sanitized. At the retail level, state and local governments provide for regulatory oversight and enforcement. The purpose of this proposal is to provide in the 2013 FDA Food Code a requirement for retail food establishments to comply with 9 CFR (Code of Federal Regulations) 320.

Public Health Significance:

The Food Code recognizes that consumers are at risk of foodborne illness from undercooked or improperly cooked meat items, particularly ground beef. Some retail food establishments may grind intact beef to produce ground beef "in house". While this practice is lawful, it may present an increased risk of foodborne illness to consumers because grinding intact beef "in house" may spread pathogenic contamination from the exterior of an intact product throughout the resulting ground beef, or, may serve as a source of cross-contamination of grinding equipment. Further, consumers may mistakenly believe that ground beef produced "in house" in this way is fresher or safer, and thus may undercook such products, which is insufficient to kill pathogens.

FSIS in promulgating the rule on "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" has recognized that when illnesses occur, it is necessary to have complete records for purposes of tracing the contaminated product to its source. The Association of Food and Drug Officials (AFDO) requested FSIS to submit the rule to the Conference for Food Protection for adoption into the Food Code to address issues of oversight and enforcement.

It would thus serve public health for the Conference to act on AFDO's recommendation.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2013 Food Code be amended with the addition of the following language to the appropriate section or paragraph of Part 3-2, Sources, Specifications, and Original Containers and Records (language to be added is underlined):

Grinding Log.

As required under 9 CFR 230, a grinding log shall be maintained for any beef products that are ground on the premises of a food establishment, and such log shall be open and available for inspection upon request of a duly authorized inspector.

Submitter Information:

Name:	David W. Plunkett
Organization:	Center for Science in the Public Interest
Address:	1220 L Street NW Suite 300
City/State/Zip:	Washington, DC 20005
Telephone:	2027778319
E-mail:	dplunkett@cspinet.org

Supporting Attachments:

- "Official Comments from the Association of Food and Drug Officials"
- "Final Rule: Records to be Kept by Official Establishments and Retail Stores"

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.

Association of Food and Drug Officials

2550 Kingston Road, Suite 311, York, PA 17402
Telephone (717) 757-2888 ● Fax (717) 650-3650
E-Mail: afdo@afdo.org ● Internet: www.afdo.org

Official Comments from the Association of Food and Drug Officials

Date:	9/19/2014
Subject:	Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products
Docket ID:	FSIS-2009-0011
RIN:	0583-AD46
CFR Citation:	9 CFR Part 320

The Association of Food & Drug Officials [AFDO] is a national organization that represents state, local, and federal government food, drug, and medical device safety regulatory officials. Within the food protection arena, AFDO is well known for promoting uniformity and cooperation among the regulatory community and has participated in numerous collaborative projects to advance these objectives. AFDO's vision for an integrated food safety system nearly two decades ago remains a foundational goal today for improving government's oversight of our global and domestic food supply. Additionally, AFDO continues to develop a host of model codes and guidance documents that state and local regulatory agencies can utilize for promulgating their own specific regulations and for improving their field staff's inspection skills. Because of AFDO's strong allegiance to state and local food safety programs, we routinely intervene in matters we feel are important to government regulators and which can have an important impact on public health.

The USDA's Food Safety and Inspection Service has proposed amending 9 CFR Part 320 by including a rule designed to improve the traceability of ground beef by requiring all producers of these products to keep extensive records. Under the proposed new requirements, ground beef producers would have to record the source, supplier and names of all materials used in producing ground beef. FSIS officials have indicated that ground beef sold at retail is often produced by combining cuts from multiple beef sources, which becomes problematic during foodborne illness investigations when the agency attempts to identify the source of the illness outbreak.

As the proposed rule would apply to both official processing establishments and retail facilities, its application is most significant at the retail area where FSIS does not maintain an oversight presence. Government oversight at retail facilities is conducted by state and local government agencies that license or permit, conduct inspection and investigation, and collect and test food products for safety. All of these agencies are, therefore, impacted by this proposed rule. The proposed rule, if finalized, will require such facilities to maintain clear records identifying the source, supplier, and names of all materials used in the preparation of raw ground beef products.

AFDO is pleased to offer the following comments on the proposed new requirements:

It appears USDA/FSIS is seeking to broaden its regulation of retail-exempt facilities, which have traditionally come under the purview of state and local regulatory authorities. If adopted, this rule could very well set a precedent for USDA/FSIS to expand its regulatory activities with regard to retail and grocery facilities that are not currently subject to ongoing federal inspection. AFDO would not be supportive if this were to be true but would welcome a more collaborative system of addressing FMIA requirements in retail-exempt establishments through Memorandums of Understanding [MOU's] or Cooperative Agreements with state or local food safety regulatory agencies.

FSIS should indicate how they plan to enforce the requirements of the proposed rule should they be approved. Will FSIS have their Compliance staff conduct inspections at retail, and, if so what types of enforcement actions would they take for non-compliant retail establishments? Here, again, AFDO believes FSIS should consider collaborating with state and local agencies on enforcement activities since these agencies currently license and permit them to operate.

It would seem appropriate for FSIS to submit the proposed rule to the Conference for Food Protection [CFP] for adoption into the FDA Food Code and eventually into state rules.

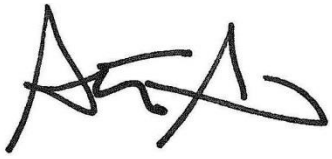
The proposed rule would provide access to records by FSIS personnel because of the importance of these records during foodborne illness investigations. FSIS investigators, however, are seldom the first responders to illness outbreaks. Local and state health officials are the first to respond and generally conduct the majority of the illness investigation in the early stages. While AFDO supports the proposed requirement for providing FSIS investigators access to records, we would strongly recommend the wording be amended in such a way to provide record access by state and local officials as well. If this proposed rule is truly intended to impact foodborne illness by helping to improve effective trace-back and trace-forward activities at retail establishments, this amended language is necessary, in our view.

Under 9 CFR 320.2, a person or business that conducts business at multiple locations are allowed to maintain required records at the business's office location. Since these records are critical in foodborne illness and recall investigations, we believe the proposed rule should require the records to be maintained at the business where ground beef is produced. In a number of circumstances, major retail grocery chains operate in multiple states with their main offices located in one location. It is not unreasonable to expect the records to be maintained at the location of production which could help speed any investigation that might occur.

AFDO is very supportive of the proposed rule as we believe it will assist regulators in the oftentimes difficult task of identifying contaminated product. Furthermore, our experience with voluntary recordkeeping indicates it is ineffective and not uniformly accepted. This proposed rule can have an impact on creating improved investigation and identification capabilities for regulatory officials.

AFDO appreciates the opportunity to comment on this important proposed rule.

Respectfully submitted,



Stephen Stich
AFDO President

Rules and Regulations

Federal Register
Vol. 80, No. 244
Monday, December 21, 2015

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 320

[Docket No. FSIS–2009–0011]

RIN 0583–AD46

Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its recordkeeping regulations to require that all official establishments and retail stores that grind raw beef products for sale in commerce maintain the following records: The establishment numbers of establishments supplying material used to prepare each lot of raw ground beef product; all supplier lot numbers and production dates; the names of the supplied materials, including beef components and any materials carried over from one production lot to the next; the date and time each lot of raw ground beef product is produced; and the date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized. These requirements also apply to raw beef products that are ground at an individual customer's request when new source materials are used.

DATES: Effective June 20, 2016.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; Telephone: (202) 205–0495; Fax (202) 720–2025.

SUPPLEMENTARY INFORMATION:

Executive Summary

This rule requires official establishments and retail stores that grind raw beef for sale in commerce to maintain specific information about their grinding activities. This rule is necessary to improve FSIS's ability to accurately trace the source of foodborne illness outbreaks involving ground beef and to identify the source materials that need to be recalled. The recordkeeping requirements in this final rule will greatly assist FSIS in doing so.

FSIS has often been impeded in its efforts to trace ground beef products back to a supplier because of the lack of documentation identifying all source materials used in their preparation. On July 22, 2014, FSIS published a proposed rule (79 FR 42464) to require official establishments and retail stores to maintain records concerning their suppliers and source materials received. Having reviewed and considered all comments received in response to the proposed rule, FSIS is finalizing the rule and making several changes in response to comments. Most of the proposed requirements are retained in this final rule. This final rule requires establishments and retail facilities that grind raw beef to keep the following records: The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef; all supplier lot numbers and production dates; the names of the supplied materials, including beef components and any materials carried over from one production lot to the next; the date and time each lot of raw ground beef is produced; and the date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized. These requirements also apply when official establishments and retail stores grind new source materials at an individual customer's request.

In response to comments, FSIS is not adopting two proposed requirements. First, under this final rule, establishments and retail stores that grind raw beef products will not have to maintain records concerning the weight of each source component used in a lot of ground beef. After considering comments, FSIS concluded that weighing each component in a lot of ground beef was time-consuming and offered little food safety benefit because contamination in a lot of ground beef is not dependent on the weight of any contaminated component. FSIS is also not requiring that establishments and stores that grind raw beef products maintain records of the names, points of contact, and phone numbers of each official establishment supplying source material because FSIS already has this information in its Public Health Information System (PHIS). Any marginal benefit presented by these two proposed requirements would be outweighed by the time burden associated with recording the information. In response to comments, this rule also differs from the proposed rule in terms of the place where the records must be maintained and the retention period. Under the proposed rule, based on existing recordkeeping requirements (9 CFR 320.1), establishments and retail stores would have been allowed to keep the required records at a business headquarters location if the grinding activity is conducted at multiple locations. In response to comments, however, this rule requires the grinding records to be kept at the location where the beef is ground. This change in the final rule will save investigators valuable time and will reduce the risk that records will be lost or misplaced. Finally, in response to comments, for purposes of this rule, FSIS is including the definition of a lot as set out in the regulatory text at the end of this document (9 CFR 320.1(b)(4)(iii)).

Under the proposed rule, based on existing regulations (9 CFR 320.3(a)), the required grinding records would have been required to be maintained for up to three years. However, in response to comments, FSIS concluded that because the records required by this rule are needed primarily to investigate foodborne illness outbreaks, their utility diminishes over time. FSIS consulted with its investigators and public health experts and determined that the records would rarely be needed after one year. Considering this fact and comments concerning the burden of keeping records on-site, particularly at retail stores, FSIS shortened the retention period in the final rule to one year after the date of the recorded grinding activity.

The final rule will result in storage and labor costs to official establishments and retail stores that grind raw beef for sale in commerce. Benefits will accrue

in terms of averted foodborne illnesses, less costly outbreaks and recalls, and increased consumer confidence when purchasing ground beef. These costs and benefits are listed in Table 1.

TABLE 1—EXECUTIVE SUMMARY TABLE

Costs:	
Labor	▪ $56.6 million annually ($45.8 million to $67.4 million).
Storage	▪ $2.7 million annually.
Unquantified Costs	▪ Non-labor costs associated with recordkeeping for customer-requested grinds. ▪ Potential for slight costs to consumers in the form of ground beef price increases.
Benefits:	
Unquantified Benefits	▪ Benefits to consumers in the form of averted foodborne illnesses as a result of contaminated ground beef. ▪ Benefits to retailers and official establishments grinding raw beef in the form of less costly food safety events, such as outbreaks and recalls. ▪ Benefits to official establishments supplying ground beef components in the form of less costly recalls and insulation from costly spillover effects during food safety events.

Background

Under the authority of the Federal Meat Inspection Act (FMIA) and its implementing regulations (9 CFR 329.1 and 329.6), FSIS investigates reports of consumer foodborne illness associated with FSIS-regulated products. FSIS investigators and other public health officials use records kept at all levels of the food distribution chain, including the retail level, to identify the sources of outbreaks.

FSIS has often been impeded in these efforts when an outbreak involves ground beef because of a lack of documentation identifying all source materials used in its preparation (79 FR 42464). In some situations, official establishments and retail stores have not kept adequate records that would allow effective traceback and traceforward activities. Without such records, FSIS cannot conduct timely and effective consumer foodborne illness investigations and other public health activities throughout the stream of commerce.

As FSIS also explained in the proposed rule, official establishments and retail stores that grind raw beef products for sale in commerce must keep records that will fully and correctly disclose all transactions involved in their business that are subject to the FMIA (*see* 21 U.S.C. 642) (79 FR 42465). Businesses must also provide access to, and permit inspection of, these records by FSIS personnel.

The proposed rule also explained that under 9 CFR 320.1(a), every person, firm, or corporation required by 21 U.S.C. 642 to keep records must keep records that will fully and correctly disclose all transactions involved in the aspects of their business that are subject to the FMIA. Records specifically required to be kept under 9 CFR 320.1(b) include, but are not limited to, bills of sale, invoices, bills of lading, and receiving and shipping papers. With respect to each transaction, the records must provide the name or description of the livestock or article, the number of outside containers, the name and address of the buyer or seller of the livestock or animal, and the date and method of shipment.

The recordkeeping requirements contained in the FMIA and 9 CFR part 320 are intended to permit FSIS to trace product, including raw ground beef product associated with consumer foodborne illness, from the consumer, or the place where the consumer purchased the product, back through its distribution chain to the establishment that was the source of the product. Having this information available will make it easier to determine where the contamination occurred. Investigators should also be able to conduct effective traceforward investigations so as to identify other potentially contaminated product that has been shipped from the point of origin of its contamination to other official establishments, retail stores, warehouses, distributors, restaurants, or other firms. FSIS must be able to carry out these investigations using records that should be kept routinely by official establishments and retail stores.

In the proposed rule, FSIS explained past efforts it has made to ensure that official establishments and retail stores that produce raw ground beef maintain necessary records. For example, the proposal explained that in 2002, FSIS published a **Federal Register** notice that listed the data that FSIS intended to collect when any samples of raw ground beef produced at an official establishment tested positive for *E. coli* O157:H7 (67 FR 62325, Oct. 7, 2002). FSIS also listed the information it intended to gather from retail stores at the time it collected a sample of raw ground beef for *E. coli* O157:H7 testing.

In the proposed rule in the present rulemaking, FSIS explained that shortly after issuing the 2002 **Federal Register** notice, the Agency began collecting the information listed in the **Federal Register** notice from official establishments and retail stores (79 FR 42465).[1] However, as the proposal explained, some retail stores and official establishments still did not maintain records sufficient for traceback, and some retail stores did not document or maintain supplier information at times other than when FSIS collected samples of ground raw beef product from the stores for *E. coli* O157:H7 testing.[2] As a result, FSIS was, and remains, disadvantaged in its foodborne disease investigations.

In 2009, FSIS provided guidance to a retail industry association, which was made available on the FSIS Web site, stating that retail stores should keep appropriate records to aid in investigations involving FSIS-regulated products associated with foodborne illnesses and other food safety incidents.

To further address the issue, on December 9–10, 2009, the Food and Drug Administration (FDA) and FSIS held a public meeting to discuss the essential elements of product tracing systems, gaps in then-current product tracing systems, and mechanisms to enhance product tracing systems for food.[3] This meeting was followed on

[1] FSIS Notice 47–02, November 20, 2002, ''FSIS Actions Concerning Suppliers that may be Associated with Escherichia coli (E. coli) 0157:H7 Positive Raw Ground Beef Product.''

[2] On June 4, 2012, FSIS implemented routine verification testing for six Shiga toxin-producing *E. coli* (STEC), in addition to *E. coli* O157:H7, in raw beef manufacturing trimmings. See *Shiga Toxin-Producing Escherichia coli in Certain Raw Beef Products* (77 FR 31975, May 31, 2012).

[3] Comments from this hearing are available at: *http://www.regulations.gov/#!searchResults;rpp=10;po=0;s=FDA-2009-N-0523;dct=PS*. A transcript of this meeting is

March 10, 2010, by an FSIS public meeting that discussed its procedures for identifying suppliers of source material used to produce raw beef product that FSIS found positive for *E. coli* O157:H7. FSIS sought input from meeting participants on ways to improve its procedures for identifying product that may be positive for *E. coli* O157:H7.

Despite these actions, as explained in the proposed rule, some official establishments and retail stores still did not keep and maintain the records necessary for effective investigation by FSIS. With this history in mind, FSIS conducted a retrospective review of 28 foodborne disease investigations from October 2007 through September 2011 in which beef products were ground or re-ground at retail stores.[4] When records were available and complete, enabling FSIS to identify specific production in an official establishment, the Agency was able to request a recall of product from the supplying establishment in six of eleven investigations. In contrast, when records were not available or incomplete, FSIS was able to request a product recall only two of seventeen times. These results confirmed FSIS's experience in specific cases where the presence of records at the retail level was often instrumental in identifying the source of an outbreak, as well as the implicated products that should be recalled. The proposed rule includes a fuller description of this review, including specific examples (79 FR 42464).

Since the review in the proposed rule, FSIS has completed nine ground beef outbreak investigations. Of these nine investigations, grinding records were available and complete in four of them and incomplete or not available in five. When records were available and complete, FSIS was able to request a recall of product from the supplying establishment in one of four investigations. For the remaining three, two led to store level recalls. For these two, FSIS did not request recalls at supplier establishments because in one investigation, the trim for retail product had over ten suppliers, and in the other, FSIS was not able to narrow down the list of suppliers because the retailer did not clean up in between grinding different products. FSIS did not request a recall for the third case in which records were available and complete because there were multiple products and multiple federal establishments involved, and FSIS was not able to identify the product associated with the illnesses or the supplying establishment. In the five investigations where records were not available or incomplete, FSIS was unable to request a recall from a supplying establishment.

The investigations reviewed in the proposed rule, and those reviewed since the proposed rule, confirm the Agency's findings that the records kept by official establishments and retail stores vary in type and quality and are often incomplete or inaccurate. Overall, FSIS has concluded that voluntary recordkeeping by retail stores that grind raw beef has been insufficient, as evidenced by continuing outbreaks linked to pathogens in raw ground beef that FSIS cannot trace back to the source. The lack of specific information about supplier lot numbers, product codes, production dates, and the cleaning and sanitizing of grinding equipment has prevented or delayed FSIS in identifying the source of outbreaks, as well as other product that might be adulterated. The cleaning and sanitizing of equipment used to grind raw beef is important because it prevents the transfer of *E. coli* O157:H7 and other bacteria from one lot of product to another.

Proposed Rule

On July 22, 2014 (79 FR 42464), FSIS proposed to amend the Federal meat inspection regulations to require that all official establishments and retail stores that grind raw beef for sale keep records disclosing the following: The names, points of contact, phone numbers, and establishment numbers of suppliers of source materials used in the preparation of each lot of raw ground beef; the names of each source material, including any components carried over from one production lot to the next; the supplier lot numbers and production dates; the weight of each beef component used in each lot (in pounds); the date and time each lot was produced; and the date and time when grinding equipment and other related food-contact surfaces were cleaned and sanitized. FSIS also proposed that official establishments and retail stores would have to comply with these requirements with respect to raw beef products ground at an individual customer's request when new source materials are used.

FSIS posted the sample grinding log record below (Table 2) on its Web site in late 2011 and included it with the 2009 guidance and the proposed rule. FSIS proposed requiring the items in the sample record marked with asterisks. The proposed rule specifically stated that the information under the other column headings would not be required, but that some official establishments and retail stores might choose to keep and maintain this information.

available at: *http://www.regulations.gov/#!searchResults;rpp=10;po=0;s=FDA-2009-N-0523;dct=O.*

[4] Ihry, T., White, P., Green, A., and Duryea, P. Review of the Adequacy of Ground Beef Production Records at Retail Markets for Traceback Activities During Foodborne Disease Investigations. Poster presented at: Annual Conference of the Council of State and Territorial Epidemiologists; 2012, June 4–6; Omaha, NE. A copy of this document is available at: *http://www.fsis.usda.gov/wps/wcm/connect/87caa3f9-0c76-45c7-be4e-84d73151ed9e/RD-2009-0011-072114.pdf?MOD=AJPERES.*

Table 2: Grinding log record that FSIS posted (2009)

NEW WAVE STORE

123 Main Street

Anytown, USA, Zip Code

FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST

Employee Name_____ Today's Date_____

Date and Time of Grind*	Lot/Batch # (lot = same source material)	Exact Name/ Type of Product Produced	Package Size of Product Produced	Amount (in lbs) of Source Material Used in Each Lot, including Carryover*	Production Code of Product Produced	Manufacturer Name of Source Material Used for Product Produced*	Supplier Lot #s, Product Code and/or Pack Date of Source Material Used*	Estab. Info. from Label of Source Material Used (Est. #, ph #, contact info)*	Date and Time Grinder and Related FCSs Cleaned and Sanitized*	Comments

_____

Signature of Store Management Reviewer Date

*Information that would have been required by the proposed rule.

Final Rule

As stated above, the final rule is mostly consistent with the proposed rule. It requires official establishments and retail stores that grind raw beef products to maintain the following records: The establishment numbers of the establishments supplying the material used to prepare each lot of raw ground beef; all supplier lot numbers and production dates; the names of the supplied materials, including beef components and any materials carried over from one production to the next; the date and time each lot is produced; and the date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized. These requirements also apply to raw ground beef products that are prepared at an individual customer's request when new source materials are used. If new source materials are not used, there is no reason to record the customer-requested grind separately.

The final rule will not require records concerning the names, points of contact, and phone numbers of each official establishment supplying source material or the weight of each source component. In consideration of comments that it received, FSIS has concluded that the records concerning the names, points of contact, and phone numbers of each official establishment supplying source material were unnecessary given that FSIS already possesses this information through the establishment profiles in PHIS. In addition, FSIS concluded, in response to the comments submitted, that weighing each component in a lot of ground beef was time-consuming and offered little food safety benefit. Contamination occurs in a lot of ground beef regardless of the weight of the contaminated component.

In conformance with these changes, FSIS has updated its sample grinding log as pictured in Table 3 below to reflect the requirements of this final rule.

The final rule also differs from the proposed rule with respect to the place of maintenance and the retention period of the required records. Based on 9 CFR 320.2, the proposed rule would have required records to be kept at the place

Table 3: Sample Grinding log with final rule requirements.

NEW WAVE STORE

123 Main Street

Anytown, USA, Zip Code

FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST

Employee Name_____ Today's Date_____

Date and Time of Grind	Manufacturer Name of Source Material Used for Product Produced	Supplier Lot #s, Product Code and/or Pack Date of Source Material Used	Est. Number(s) of Est. providing source material	Date and Time Grinder and Related FCSs Cleaned and Sanitized	Comments

_____

Signature of Store Management Reviewer Date

where the business, in this case the grinding activity, is conducted, unless the business is conducted at multiple locations, in which case the proposal would have allowed the records to be maintained at a business's headquarters office. In response to comments, FSIS has concluded that keeping the required information at the location where the beef is ground will save investigators time and reduce the risk that records are misplaced when they are moved. This rule, therefore, establishes a new 9 CFR 320.2(b), which requires that all the information required by this final rule be kept at the location where the beef is ground.

Based on 9 CFR 320.3(a), the proposed rule would have required that the proposed grinding records be retained for a period of two years after December 31 of the year in which the transaction giving rise to the record (grinding) occurred. In response to comments discussed below, FSIS concluded that because the vast majority of ground beef is consumed within several months of its production, a one-year retention period is adequate to trace the source of any foodborne disease outbreak involving raw ground beef. Accordingly, this final rule creates a 9 CFR 320.3(c) which requires that official establishments and retail stores covered by this rule retain the required records for one year.

The final rule also makes technical changes to 9 CFR 320.2 and 320.3 to improve readability.

Summary of Comments and Responses

FSIS received 40 comments on the proposed rule from individuals, retailers, beef producers and processors, beef industry and retail trade groups, consumer advocacy groups, an organization representing food and drug officials, a State department of agricultural and rural development, a food technology company, and two members of Congress. Most of the commenters supported the proposed rule. Industry groups supported recording information for effective investigation in the event of a foodborne illness outbreak but stated that the costs of compliance were higher than estimated, and that several pieces of information were unnecessary or overly burdensome. A summary of the relevant issues raised by the commenters and the Agency's responses follows.

1. Covered Entities

Comment: Consumer and retail trade groups stated that the rule should apply to supermarkets, grocery stores, meat markets, warehouse clubs, cooperatives, supercenters, convenience stores, wholesalers, and restaurants.

Response: This final rule applies to all official establishments and retail stores that grind raw beef products for sale to consumers in normal retail quantities. The rule covers supermarkets and other grocery stores, meat markets, warehouse clubs, cooperatives, supercenters, convenience stores, and wholesalers, if they grind raw beef product.

FSIS is not applying this final rule to restaurants. Only a small percentage of all raw beef grinding occurs at restaurants and only on a very small scale. It is thus likely that any outbreak traced to a restaurant that grinds its own raw beef will be traceable to a specific supplier.

2. Content of Records

Comment: Retail organizations, a food technology company, and a beef brand recommended reducing costs by removing from the proposed rule the requirement to weigh each source component. These commenters stated that the proposed requirement was time-consuming, disruptive to workflow, unfeasible with current equipment, and offered no public health benefit.

Response: FSIS agrees that the requirement to weigh each source component is not necessary. If a foodborne illness outbreak occurs, the weight of a source component in a lot of ground beef is not significant in tracing the material back to the suppliers. Also, any amount of adulterated source material in a lot of ground beef would adulterate the product. Accordingly, FSIS has removed this provision from the final rule and has adjusted the paperwork burden estimates and costs accordingly.

Comment: An independent grocers' trade group suggested removing the requirement to record supplier lot numbers and production dates.

Response: Supplier lot numbers and production dates are necessary to identify product at a supplier's location that may be associated with an outbreak. By including supplier lot numbers and production dates, investigators can more easily and quickly determine the source of a foodborne illness outbreak and limit the amount of product recalled.

Comment: Industry groups generally opposed recordkeeping for customer-requested grinds. They stated that it was impractical to clean grinding equipment between customer requests, meat case items usually lack supplier information, and public health benefits from logging these grinds would be limited. One meat industry trade group suggested only requiring the proposed recordkeeping provisions for customer-requested grinds over thirty pounds. A retail trade group recommended that its members perform customer-requested grinds at the end of the day or during a clear production cycle break.

Response: Customer-requested grinds present the same food safety risk as other raw ground beef. Retailers should keep customer-requested grinds separate and must record the information required in this rule when new source materials are used for customer-requested grinds. It is also in the store's interest to perform a clean up before and after customer-requested grinds. If the source is not clear, or if there is no clean up, traceback to the supplier will be impossible. The retailer would have produced the product associated with the outbreak, and in such circumstances, FSIS will have to request that the retailer recall product. Also, if the source is not clear, FSIS will likely have to request that the retailer recall more product than would be necessary if the retailer had recorded the necessary information.

FSIS agrees that customer-requested grinds present unique challenges but estimates that the benefits of being able to rapidly identify a customer-grind associated with an outbreak outweigh the recordkeeping and clean-up costs.

Comment: Two food-safety non-profits, a grocery store chain, and a consumer group stated that the name of the retail product should be recorded to assist in identifying product subject to recall. One individual and a food-safety non-profit stated that retail products should include specific day or production lot codes to assist in tracing products back to specific grinding lots.

Response: FSIS does not believe that including retail product names on records listing source materials used to produce those products is practical. Products from different source materials may have the same name, *e.g.,* 80/20 Ground Chuck. In addition, products from the same source materials may be marketed differently. For example, packages of ''Bob's Ground Beef'' and ''Jan's Ground Beef'' may originate from the same lot of source materials, despite bearing different retail names.

FSIS is also not requiring official establishments and retail stores to label retail products with timestamps or production lot codes to identify them with the specific lot or lots of ground beef from which they were produced. Retail ground beef products can usually be traced back to their specific grinding lots through stores' inventory data, the product's date and time of sale, and information stored on customers' shopper cards. Once a retail product is traced back to the grinding lot or lots,

the records required by this final rule will enable FSIS investigators to identify the source materials, suppliers, and production lots from which the product was produced.

Comment: Industry groups opposed recording the names, points of contact, and phone numbers of suppliers because FSIS already has this information through PHIS.

Response: FSIS agrees that the names, points of contact, and phone numbers of official establishments supplying source materials are already located in the establishment profiles within PHIS. Therefore, the establishment numbers of suppliers provide sufficient information to FSIS, and FSIS has removed those pieces of information from the recordkeeping requirements, leaving the requirement that official establishments and retail stores keep the establishment number of their suppliers of source materials. FSIS has updated its paperwork burden and costs estimates to reflect this change.

3. Use of Sample Grinding Log

Comment: A consumer group recommended that FSIS provide a sample grinding log containing all of the required information. A grocery store chain and retail trade group stated that grinders should be able to create their own logs, so long as all required information is included. A retail trade group questioned whether grinders would be required to use the sample log shown above.

Response: While FSIS has provided a sample grinding log that is depicted above, FSIS is not specifying in the final rule how official establishments and retail stores must record the required information. Entities may record the required information as they see fit, so long as the records of the required information are maintained in accordance with 9 CFR 320.2 and 320.3.

4. Imports

Comment: One individual stated that the proposed rule should apply to imported beef.

Response: FSIS' regulations do not apply directly to establishments in foreign countries, and retail stores in foreign countries are not eligible to export product to the United States. To be eligible to export raw beef product to the United States, countries must maintain an equivalent inspection system for beef. Therefore, in the event of *Salmonella* or shiga-toxin producing *E. coli* (STEC) outbreaks, countries that ship beef to the United States will need to have traceback and traceforward systems for beef products that allow the country to identify the source of contamination. Countries that export beef to the United States may choose to establish recordkeeping requirements consistent with this rule. However, they may also have other means to track the necessary information.

5. Other Species

Comment: Individual commenters and food safety groups believed that the rule should apply to ground product produced from swine, poultry, lamb, and turkey.

Response: FSIS issued the proposed rule to address deficiencies in recordkeeping that hampered investigations into foodborne illness investigations involving raw ground beef. Between 2007 and 2013, FSIS investigated 130 outbreaks of human illness. Of those, 31 (24 percent) were linked to beef ground at a retail venue. FSIS did not propose that new records be maintained for ground products other than beef because the Agency is most often impeded in its efforts to trace back and identify sources of human illness when beef ground in retail stores is the vehicle for those illnesses. FSIS considers the comments requesting similar requirements for other ground product to be outside the scope of this rule.

6. Consumer Education

Comment: A meat processor, a meat products company, and two individuals stated that more outreach was needed to educate consumers on how to properly handle and cook meats.

Response: FSIS promotes consumer awareness of food safety issues and encourages proper food preparation practices. For example, FSIS posts consumer food safety information on its Web page.[5] The posted information includes the kind of bacteria that can be found in ground beef, specific information as to why the *E. coli* O157:H7 bacterium is of special concern in ground beef, and the best way to handle raw ground beef when shopping and when at home. This Web page also contains the *Food Safe Families Campaign* guidelines to keep food safe, which tells consumers to cook ground beef to a safe minimum internal temperature of 160 °F (71.1 °C) as measured with a food thermometer. FSIS also provides food safety education in other forms (*e.g.,* FSIS has continued to work with the Ad Council to launch food safety public service announcements, and FSIS staff provide in-person food safety education through the mobile Food Safety Discovery Zone).

Nonetheless, recordkeeping by retail establishments will more quickly and efficiently address the concerns (*i.e.,* traceback and identifying sources of human illness when beef ground in retail stores is the vehicle for those illnesses) raised in this final rule.

7. Supplier Process Control Actions

Comment: One individual urged official establishments to improve contamination control at slaughter. A meat products company that did not support the rule believed that suppliers cannot control *E. coli,* but that the answer is not more recordkeeping because that does not address the core problem, which is the interdependent relationship between animals and *E. coli.*

Response: FSIS is continuing to address process control actions that should be taken by beef suppliers to control *E. coli.* For example, FSIS made available updated guidance on testing and high event periods[6] in 2013 and implemented new traceback activities in 2014.[7] However, while better process control may reduce the incidence of *E. coli* O157:H7-adulterated ground beef, it will not address the issue of official establishments and retail stores not keeping adequate records that allow effective traceback and traceforward activities. Without the records required by this final rule, FSIS cannot conduct timely and effective consumer foodborne illness investigations and other public health activities through the stream of commerce.

8. Implementation

Comment: An independent grocers' trade group recommended a two-year delayed effective date for small businesses to comply with the rule. Alternatively, the commenter stated that small businesses should be exempt from the rule's requirements altogether. Similarly, a retail trade group believed that small retailers would need more time for outreach and training and that implementation would take longer than anticipated by the proposed rule

[5] FSIS food safety guidance for meat preparation, available at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation.*

[6] Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers, available at: *http://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-9026-4e1e-a0c2-1ac60b836fa6/Compliance-Guide-Est-Sampling-STEC.pdf?MOD=AJPERES.*

[7] FSIS Directive 10,010.3, Traceback Methodology for Escherichia Coli (E. Coli) 0157:H7 in Raw Ground Beef Products and Bench Trim, available at: *http://www.fsis.usda.gov/wps/wcm/connect/ae5e81d0-c636-4de1-93f3-7a30d142ae69/10010.3.pdf?MOD=AJPERES.*

because of the need to create or modify records forms.

Response: FSIS has provided sample grinding logs in this rule and the proposed rule. Small businesses may use these logs, or any other recordkeeping system they wish, to record the required information. FSIS believes that the recordkeeping requirements are straightforward and do not require extensive training or guidance materials. FSIS has also not adopted the proposed requirements that grinders record and maintain records of the weight of each source material used in a grinding lot, and the names, points of contact, and phone numbers of each official establishment supplying source material.

In addition, as is discussed above, FSIS has advised official establishments and retailers to maintain these types of records since 2002. Nonetheless, in response to comments, this final rule provides that retailers and official establishments will have 180 days from the date of publication of this final rule to comply with its requirements. This effective date should provide industry sufficient time to comply with the requirements because FSIS has simplified the requirements originally proposed, and FSIS will ensure that establishments and retailers are aware of the new requirements through the outreach activities discussed below and through partnering with the States and other organizations, such as retail organizations.

9. Training

Comment: One consumer group recommended face-to-face contact by FSIS with entities that grind raw beef to explain the rule's requirements. A beef producers' trade group encouraged FSIS to conduct outreach through webinars and by attending industry meetings. One individual stated that operators should be trained to understand the risks of *E. coli* in grinding. Another individual suggested more training on keeping logs, proper attire, and hand-washing. A State agriculture department believed it would incur costs associated with responding to questions from grinders and training State personnel to field such questions appropriately.

Response: As noted above, the recordkeeping requirements in the final rule are straightforward and do not require extensive training or guidance materials. FSIS will update its Sanitation Guidance for Beef Grinders,[8] which includes sample grinding logs and instructions, and will hold webinars to explain the requirements of this final rule and answer questions from official establishments, retailers, and other organizations. FSIS will also provide guidance to small businesses through its Small Plant Help Desk and *Small Plant News* newsletter, and at industry conferences, exhibitions and workshops.

10. Retention and Maintenance of Records

Comment: A food-safety non-profit organization suggested that records required under this rule be retained for at least ninety days. A grocery store chain believed six-to-twelve months would be adequate. A retail trade group believed six months was appropriate. The latter two commenters mentioned that frozen beef should be consumed within three to four months.

Response: While ground beef is safe indefinitely if kept frozen, it will lose quality over time. FSIS recommends consuming fresh ground beef within two days and frozen ground beef within four months.[9] These recommendations suggest that records documenting the grinding of raw beef need only be kept for a short period of time. However, the Agency is aware that consumers do not always follow such recommendations, sometimes keeping ground beef in their freezers for up to a year, for example. FSIS is therefore requiring in the final rule that official establishments and retailers maintain the prescribed records for one year (9 CFR 320.3).

Comment: A trade group representing food safety officials stated that records should always be maintained at the location where the beef was ground.

Response: This final rule amends 9 CFR 320.2 to require that official establishments and retail stores maintain the required records at the place where the raw beef is ground. This approach, along with the shorter record retention period being required in 9 CFR 320.3, balances the burden on retailers of storing records for the necessary period of time with the needs of investigators to have such records available at the grinding location.

11. Enforcement

Comment: Three individuals stated that FSIS should assess additional fines or penalties to enforce the final rule's requirements. A consumer group recommended FSIS perform verification checks at retailers to monitor compliance. A trade group representing food safety officials asked how FSIS would enforce the rule and urged FSIS to work more cooperatively with State and local food safety agencies. The commenter also recommended that local officials have access to the new records, as they are often involved at the earliest stages of an outbreak.

Response: The FMIA provides FSIS with authority to require specified persons, firms, and corporations to keep records that will fully and correctly disclose all transactions involved in their businesses subject to the FMIA and to provide access to facilities, inventory, and records (21 U.S.C. 642). If official establishments do not maintain the required records, FSIS will issue noncompliance records. FSIS may also take any regulatory control actions as defined in 9 CFR 500.1(a), including the tagging of product, equipment, or areas.

FSIS personnel conduct in-commerce surveillance related to wholesomeness, adulteration, misbranding, sanitation, and recordkeeping.[10] When this rule becomes final, FSIS compliance investigators will verify that retail grinders meet the recordkeeping requirements. If compliance investigators find they do not, they may issue a Notice of Warning to the retail store.

If FSIS personnel find noncompliance at an official establishment, the Agency could issue non-compliance reports, letters of warning, or request the Department of Justice to initiate a civil proceeding in Federal court to enjoin the defendant from further violations of the applicable laws and regulations. If FSIS personnel find noncompliance at a retail facility, the Agency may issue notices of warning or request the Department of Justice to initiate a civil proceeding to enjoin the defendant from further violations of the applicable laws and regulations.

States with their own meat and poultry inspection (MPI) programs will need to be aware of the requirements of this rule and are required to enforce requirements ''at least equal to'' the Federal inspection program. Therefore, they will need to require that establishments under State inspection maintain records consistent with what FSIS is requiring.

FSIS will also explore ways to partner with States, with or without MPI programs, so that State employees can provide information about the recordkeeping requirements to grocery stores, help them to keep logs in the most efficient and effective way

[8] Available at: *http://www.fsis.usda.gov/shared/PDF/Sanitation_Guidance_Beef_Grinders.pdf.*

[9] FSIS Ground Beef and Food Safety, available at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation/ground-beef-and-food-safety/CT_Index.*

[10] FSIS Directive 8080.1, Rev. 4, *Methodology for Conducting In-Commerce Surveillance Activities,* April 24, 2014.

possible, and provide other information that will enhance the efficiency and effectiveness of store efforts. FSIS intends to provide information to State officials about the grinding logs requirement during regular monthly Webinars that FSIS conducts for State MPI Directors and State HACCP Contacts and Coordinators.

FSIS also routinely cooperates with State and local authorities to conduct effective foodborne illness investigations, including by sharing epidemiological data, records, and investigative resources. FSIS intends to provide information to State and local authorities during the course of these illness investigations about the role that grinding logs can play in facilitating these investigations.

12. Grinding Frequency and Time Burden

Comment: To reduce costs, a grocers' trade group stated that FSIS should require records only for all source materials used in grinds during a single production day, requiring a new log for production that would begin only after the end-of-day full cleaning of the grinding equipment. Several commenters also stated that many retail stores grind several times per day and may use several different suppliers, significantly increasing recordkeeping costs.

Response: In the proposed rule, FSIS considered requiring documentation of information on a weekly basis, but rejected this approach because it would be difficult to differentiate between lots ground from different suppliers throughout the week (79 FR 42469). The same holds true for daily logs. In either situation, investigators would be unable to effectively conduct traceback and traceforward activities in the event of an outbreak because of limited detail. FSIS is not dictating how often the required information must be physically recorded. Under the final rule, the required information must be recorded whenever any of the information required for the lot of product being ground changes. For example, if an entity uses the same source material for multiple grinds throughout the day, it would only need to record the source material information (9 CFR 320.1(b)(4)(i)(A)–(C)) once but would need to record the date and time of each grind (9 CFR 320.1(b)(4)(i)(D)). However, if a store or establishment were to start using a different supplier or lot number during the day, it would need to document that change (9 CFR 320.1(b)(4)(i)(B)). This approach minimizes the recordkeeping burden but preserves the information needed by investigators.

Comment: A grocery store chain disagreed with FSIS's estimates of grinds per day and average number of suppliers at retail, suggesting that beef is ground every day, several times per day as needed, and with several different cases of raw material. A retail trade group estimated more average grinds at retail per day than FSIS's estimate, stating that its average member grinds four times per day. A State agriculture department and a beef producers' trade group urged further study of the economic impact of the rule on small businesses, including feedback from industry. A retail trade group estimated that the time needed for the proposed recordkeeping is much higher per respondent per year than estimated by FSIS, suggesting that a conservative estimate would be 214 hours per year.

Response: FSIS has taken into account comments on the amount of time required for recordkeeping and made adjustments to its cost estimate. For the final estimates, FSIS adjusted the average number of recordkeeping tasks per day at official establishments and retail stores from one to a range of four-to-five-and-a-half, plus an additional task if an entity conducts a grind composed of only trim. FSIS also adjusted the assumed time required to complete a record at official establishments and retail stores to account for multiple source materials, from 30-to-90 seconds to one minute for grinds not including trim, two minutes for grinds including trim and other ground beef components, and six-to-ten minutes for trim-only grinds. Trim-only grinds are usually composed of trim from different suppliers and production lots. Therefore, more time is needed to document the required information as compared to other grinding activities. In updating these estimates, FSIS has taken into account, in addition to the comments, the changes in the final rule concerning required records. Specifically, FSIS is using the low end of time estimates from the comments because, for the final rule, FSIS has significantly reduced the information required to be kept compared to the proposed rule.

13. Waste

Comment: Two individuals and an independent grocers' trade group stated that retailers would simply throw out bench trim to avoid the recordkeeping requirements.

Response: In its proposed rule, FSIS considered a 2008 study that found that recording grinding information is already prevalent among official establishments and retail stores that grind raw beef. The 2008 study found that 74 percent of chain retail stores and 12 percent of independent retail stores kept grinding logs. Of the stores that kept grinding logs, the study reported that 78 percent of those logs were incomplete (79 FR 42471). Although insufficient voluntary recording is one impetus for this rule, FSIS is not aware of any instance when official establishments and retail stores that were keeping necessary records discarded source material in lieu of recording necessary records. Therefore, FSIS concludes that the costs of recordkeeping will rarely be greater than the costs of discarding bench trim, and that the amount of product discarded as a result of the rule should be negligible.

14. Effect on Small Businesses

Comment: An independent grocers' trade group stated that the proposed rule would have a significant economic impact on a substantial number of small entities, and, therefore, FSIS must conduct an initial regulatory flexibility analysis.

Response: While the rule will affect a substantial number of small businesses, the cost of complying with the proposed regulations will be relatively small on a per firm basis. FSIS has provided guidance and a sample grinding log, which FSIS will update as appropriate. Similar guidance is available from other providers, including industry associations.[11] Entities can use these materials to minimize the costs of their recordkeeping programs. In addition, as is discussed above, FSIS will hold webinars to provide small businesses additional information on the rule and will publish information through its Small Plant Help Desk and *Small Plant News* newsletter. The fact that a number of small firms already maintain adequate grinding records suggests that the cost of the practice is not prohibitive to doing business.

15. Definition of a Lot of Ground Beef

Comment: A beef industry trade group commented that some ground beef producers have different definitions for ''lots'' or ''batches'' of ground beef.

[11] Food Marketing Institute, Comprehensive Guide Meat Ground at Retail Recordkeeping and Sanitation, available at: *http://www.fmi.org/docs/default-source/food-safety-best-practice-guides/meat-ground-at-retail-comprehensive-guide.pdf?sfvrsn=6.* Conference for Food Protection, Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments, available at: *http://www.foodprotect.org/media/guide/CFP%20Beef%20Grinding%20Log%20Template%20Guidance%20Document%20-%208-8-2014.pdf.*

Response: FSIS did not propose a definition for a ''lot'' of ground beef in the proposed rule. In response to this comment, and for the sake of consistency in implementing this final rule, FSIS has added a new 9 CFR 320.1(b)(4)(iii), which defines a lot.

Implementation

All retailers and official establishments will have 180 days from the date of publication of this final rule to comply with its requirements.

As is discussed above, this rule does not prescribe the method by which official establishments and retail stores must keep the required information but does require that the information be kept at the location where the beef is ground. The records must be retained for one year after the transaction giving rise to the record (grinding) occurred. FSIS will update its Sanitation Guidance for Beef Grinders,[12] which currently includes sample grinding logs and instructions, and hold webinars to explain the requirements of the final rule and answer questions from official establishments, retailers, and other organizations. FSIS will also provide information to small businesses through its Small Plant Help Desk and *Small Plant News* newsletter. FSIS will provide guidance to State MPI programs on the requirements of this rule and seek to partner with States to ensure that the requirements of this rule are communicated to official establishments inspected by State MPI programs and to retail stores that grind raw beef. FSIS will also work with States and universities around the nation to conduct outreach workshops targeted to retailers and official establishments to explain the requirements of the rule. Records of the required information must be made available to authorized USDA officials upon request (9 CFR 300.6(a)(2)). These officials may examine and copy such records (9 CFR 320.4). At official establishments, FSIS inspection personnel will verify compliance. As is discussed above, if FSIS personnel find noncompliance at an official establishment, the Agency could issue non-compliance reports, letters of warning, or request the Department of Justice to initiate a civil proceeding in Federal court to enjoin the defendant from further violations of the applicable laws and regulations. At retail stores, FSIS compliance investigators will verify that retail grinders meet the recordkeeping requirements. If compliance investigators find they do not, the Agency may issue notices of warning or request the Department of Justice to initiate a civil proceeding to enjoin the defendant from further violations of the applicable laws and regulations.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a ''non-significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget.

In updating the preliminary regulatory impact analysis of the proposed rule, FSIS has made several changes in response to public comments and newly available information. Specifically, FSIS has made the following changes in the final regulatory impact analysis:

- Increased the number of retail firms in the baseline using new U.S. Census Bureau data;
- Added assumptions about the percentage of retail firms that grind raw beef;
- Incorporated new distributions relating to source materials used to reflect the complexity of grinding operations;
- Adjusted the time estimates for recordkeeping activities, the frequency of recordkeeping tasks, and the number of active grinding days per week based on comments received;
- Added estimates of labor to incorporate recordkeeping for grinds, including pieces of trim and customer-requested grinds;
- Updated the wage rate and benefits factor for firm employees that record or maintain required records based on the newest available information;
- Added discussion about unquantified costs associated with maintaining records for customer-requested grinds; and
- Expanded the benefits discussion to include benefits not previously addressed, such as the mitigation of costly spillover effects from foodborne illness outbreaks, and the incentive traceability provides to produce safe product.

Need for the Rule

During investigations of foodborne illness outbreaks attributed to ground beef, grinding records are an important part of the traceback and traceforward processes. Without accurate records, it is difficult to identify where ground beef components originated. If investigators cannot identify a source, it is likely that adulterated product will remain in commerce and more consumers will eat the product and become ill. Delays in identifying the source of contamination can also negatively affect sales of ground beef due to loss in consumer confidence. Despite efforts by FSIS, industry associations, and other regulators to provide retailers and official processing establishments with guidance and examples of best practices, the current level of recordkeeping is still less than what is needed for timely and accurate traceability investigations.

Traceability systems are a potential way to lessen the costs of foodborne illness outbreaks and other food safety events. In the case of private regulation, each firm will ultimately decide what level of traceability to implement on the basis of costs and potential benefits, such as smaller losses of reputation and reduced liability costs during foodborne illness outbreaks.[13] Some firms may decide not to invest at all. Insufficient traceability, however, is not optimal for the industry as a whole.[14] In some cases industry associations and third parties can influence firms to adopt traceability measures, but in the case of grinding records, these efforts have not achieved an acceptable level.[15]

Forms of private regulation, such as those currently in place for raw beef grinding entities, are vulnerable to firms that do not invest their fair share to the detriment of others, commonly referred to as the ''free rider'' problem.[16] In the event of a foodborne illness outbreak

[12] Available at: *http://www.fsis.usda.gov/shared/PDF/Sanitation_Guidance_Beef_Grinders.pdf.*

[13] Hobbs, Jill E., (2004) ''Information Asymmetry and the Role of Traceability Systems,'' *Agribusiness,* Vol. 20 (4), 397–415, available at: *http://onlinelibrary.wiley.com/doi/10.1002/agr.20020/pdf.*

[14] McEvoy, David M. and Souza-Monteiro, Diogo M., (2008) ''Can an Industry Voluntary Agreement on Food Traceability Minimize the Cost of Food Safety Incidents?'' *12th Congress of the European Association of Agricultural Economists,* Gent, Belgium, July 26–29, available at: *http://ageconsearch.umn.edu/bitstream/43860/2/397.pdf.*

[15] Gould, Hannah L. et al. (2011) ''Recordkeeping Practices of Beef Grinding Activities at Retail Establishments,'' *Journal of Food Protection,* Vol. 74 (6), 1022–1024, available at: *http://www.ncbi.nlm.nih.gov/pubmed/21669085.*

[16] Havinga, Tetty, (2006) ''Private Regulation of Food Safety by Supermarkets,'' *Law and Policy,* Vol. 28 (4), 515–533, available at: *http://www.ru.nl/publish/pages/552245/havingasupermarketslapo2006.pdf.*

attributed to ground beef, if traceback is conducted at an entity that maintains adequate records, there is a strong chance that the source of contamination will be identified. When this happens, losses in reputation, consumer confidence, and sales are generally limited to the firm supplying the adulterated product. Other firms, such as the retailers (both those that invest in traceability and those that do not), are to some degree insulated from negative spillover effects. In this case, free-rider firms—those that do not invest in traceability—benefit from the investments of others.

If, however, traceback occurs at a firm that does not invest in recordkeeping, the chances of investigators successfully tracing adulterated product to its source are low. An illness outbreak attributed to ground beef in which the source is unidentified will negatively affect ground beef producers and retailers indiscriminately. In this case, firms that have invested in traceability will bear costs that could have been avoided were it not for the free-rider firm. Mandatory recordkeeping requirements will help to eliminate insufficient traceability systems and therefore mitigate the free rider problem.

Inadequate traceability systems can also contribute to moral hazard, which, in the case of ground beef, is a lack of incentives to produce a safe product.[17] Producers of ground beef components endeavor to produce safe product because the consequences of producing unsafe product are great. However, if adulterated ground beef is often unable to be traced back to its source, producers face less risk when the components they produce are unsafe. Mandatory recordkeeping requirements can help to reduce moral hazard by increasing the chances that adulterated product is traced back to its source, thereby strengthening the incentives for fabricators of ground beef components to supply the safest product that they can produce.

Industry Baseline

FSIS has identified four groups of businesses that will be subject to the final rule.

1. Official, federally-inspected establishments that grind beef: FSIS used information from PHIS to determine the number of federally inspected establishments subject to FSIS sampling of ground beef product for *E. coli* O157:H7 and *Salmonella* in the past calendar year (2014). To ensure that only those establishments that receive ground beef components from a supplier are included in the total, FSIS excluded those establishments that also slaughtered beef in the past calendar year.[18] Using the Hazard Analysis and Critical Control Point (HACCP) size categories available in PHIS, FSIS determined that there are 12 large establishments and 1,132 small (including HACCP size small and HACCP size very small) establishments that fall into this category.

2. Supermarkets and other grocery stores that grind beef: FSIS used data from the U.S. Census Bureau to determine the number of grocery stores in the U.S. Specifically, FSIS used the 2012 Statistics of U.S. Business (SUSB) data set[19] to determine the number of stores under the North American Industry Classification System (NAICS) code 445110—Supermarkets and Other Grocery (except Convenience) Stores. FSIS found that there are 21,543 stores owned by large firms (≥500 employed), and 44,504 stores owned by small firms (<500 employed). FSIS is aware that not all supermarkets and grocery stores grind beef in store. However, for the purposes of the cost estimate, FSIS assumed that 100 percent of supermarkets and grocery stores grind beef. While this results in a minor overestimate, FSIS lacks the data needed to support a different assumption.

3. Meat markets that grind beef: FSIS used the 2012 SUSB Census data to determine the number of stores under the NAICS code 445210—Meat Markets. FSIS found that there are 123 stores owned by large firms, and 5,105 stores owned by small firms. The NAICS code for meat markets includes six subcategories, three of which do not grind beef, including Baked Ham Stores, Frozen Meat Stores, and Poultry Dealers. To account for these stores, FSIS assumed that 50 percent of large stores and 50 percent of small stores in this category grind beef.

4. Warehouse clubs and supercenters that grind beef: FSIS used the 2012 SUSB Census data to determine the number of stores under the NACIS code 452910—Warehouse Clubs and Supercenters. FSIS determined that there are 5,124 such stores owned by large firms, and 40 stores owned by small firms. FSIS is aware that not all warehouse clubs and supercenters grind beef in store. To account for this, FSIS assumed that 20 percent of large stores and 100 percent of small stores grind beef.[20]

TABLE 4—ENTITIES THAT GRIND RAW BEEF

Entity type	Total entities		Percent grinding		Entities grinding	
Establishment type	Large	Small	Large	Small	Large	Small
Official Establishments	12	1,132	100	100	12	1,132
Supermarkets and Other Grocery Stores	21,543	44,504	100	100	21,543	44,504
Meat Markets	123	5,105	50	50	62	2,553
Warehouse Clubs and Supercenters	5,124	40	20	100	1,025	40
Total	26,802	50,781			22,641	48,229

Values in Table may not sum to totals because of rounding.

[17] Starbird, S. A., Amanor-Boadu, V., and Roberts, T. (2008) ''Traceability, Moral Hazard, and Food Safety,'' *12th Congress of the European Association of Agricultural Economists,* available at: *http://ageconsearch.umn.edu/bitstream/43840/2/EAAE_0398.pdf.*

[18] If an official establishment slaughters beef, then it is likely the only source of components for its own ground beef production, and therefore it would not need to keep records pertaining to suppliers. While it is possible that some official establishments both slaughter beef and receive components from other official establishments for grinding, the number of such establishments is likely very small.

[19] U.S. Census Bureau, (2012), Statistics of U.S. Businesses, accessed January 28, 2015, available at: *http://www.census.gov/econ/susb/.*

[20] FSIS was able to determine that the majority of large stores in this category do not grind beef in store because two large firms which account for approximately 80 percent of supercenters have ceased this practice. These firms purchase beef pre-ground and pre-packaged from federally inspected establishments or have it shipped from one of their other branded chains.

To estimate the number of entities that are already maintaining adequate records, FSIS used a Centers for Disease Control and Prevention (CDC) study of ground beef recordkeeping practices at retail stores and applied the distributions in the study to the entities that grind raw beef. The study found that 74 percent of chain retail stores and 12 percent of independent retail stores kept grinding logs. Of the stores that kept grinding logs, the study reported 78 percent of those logs as incomplete.[21] For the purposes of this estimate, FSIS used the chain stores surveyed in the study as a proxy for large retailers and official establishments, and the independent stores as a proxy for small retailers and official establishments. Therefore, the recordkeeping distribution of large entities based on the survey results is approximately 16 percent complete (74 percent*(1–78 percent)), 58 percent incomplete (74 percent*78 percent), and 26 percent no records. For small entities, the distribution is approximately 3 percent complete (12 percent*(1–78 percent)), 9 percent incomplete (12 percent*78 percent), and 88 percent no records. FSIS applied these distributions to the set of all grinding entities in Table 4, above. The current recordkeeping practices of beef grinding entities are displayed in Table 5.

TABLE 5—BASELINE RECORDKEEPING PRACTICES AT ENTITIES THAT GRIND RAW BEEF

Entity size	Recordkeeping	Distribution (percent)	Entities
Large	Complete	16	3,686
	Incomplete	58	13,069
	No Records	26	5,887
	Total		22,641
Small	Complete	3	1,273
	Incomplete	9	4,514
	No Records	88	42,441
	Total		48,229

Values in table may not sum to Totals because of rounding.

Alternative Regulatory Approaches

FSIS considered a number of alternatives designed to achieve the regulatory objective outlined in the Need for the Rule section. The final rule was chosen as the least burdensome, technically acceptable regulatory approach to ensure that adequate grinding records are maintained for the purposes of outbreak investigation and product trace back. While some alternatives would result in lesser costs to industry, and some alternatives would result in more complete information for outbreak investigators, in FSIS's judgment the final rule is the alternative that maximizes net benefits. Cost estimates were developed for the final rule but not for the rejected alternatives because the costs for these alternatives are discernibly higher or lower because of the amount of time spent on recordkeeping.

Alternatives Considered

(1) Encouraging rather than requiring grinding records: FSIS provided industry voluntary guidelines (see Table 2) in 2009. As stated previously, the Agency has concluded that a policy of voluntary guidelines for recordkeeping has not ensured that all official establishments and retail stores maintain complete records that will ensure quick identification of contaminated product.

(2) Regulated Daily Recordkeeping Program: FSIS considered requiring that retail stores and official establishments maintain grinding records such that each producer recorded grinding activities once per day, and information on all suppliers that were used during that day but not on when during the day those suppliers were used. Daily recording may have been sufficient if entities typically cleaned their equipment once a day, rarely changed suppliers, and conducted few grinds per day, but FSIS has found that the majority of retailers grind product and clean their equipment multiple times per day. A single daily recordkeeping task is, therefore, insufficient to provide the necessary information for traceback and could inhibit FSIS's ability to identify suppliers during ongoing outbreaks. In addition, the time savings of daily recordkeeping over per-grind recordkeeping is likely low since most of the same information will need to be kept. Therefore, FSIS rejected this alternative.

(3) The Final Rule: The chosen alternative requires that retail stores and official establishments maintain grinding records such that each producer must record the required information whenever any of the required information for the lot of product being ground changes. To minimize the burden placed on these entities, FSIS has removed certain pieces of information from the requirements that were included in the proposed rule, ensuring that only the necessary information for traceability is maintained. Requiring records that pertain to each individual grind guarantees that investigators will be able to identify the components included in an adulterated package of ground beef, creating a narrower list of potential sources of adulterated product and increasing the chances that the source of contamination is identified. FSIS has determined that this alternative is the least burdensome option that achieves the regulatory objective.

(4) More Detailed Recordkeeping Program: FSIS also considered expanding the proposed recordkeeping requirements to include all fields suggested in the 2009 FSIS guidance (all fields in the Table 2 sample log). This approach would provide FSIS with more detailed records to use during an investigation, which may improve traceability slightly. However, the small improvement in the trace back process provided by the additional level of detail would place an unnecessarily large burden on those entities that grind product and must keep records. Any such small improvement would not outweigh the costs incurred for keeping the more detailed records. For this reason, FSIS decided to require that only the most critical information be recorded. Other information, including

[21] See footnote 3.

that which appears on the sample log, is voluntary.

The costs and benefits of the final rule and each regulatory alternative are displayed in Table 6.

TABLE 6—REGULATORY ALTERNATIVES CONSIDERED

Alternative	Costs	Benefits
(1) Encouraging Voluntary Recordkeeping.	No additional costs	No additional benefits.
(2) Regulated Daily Recordkeeping.	Slightly less costly alternative to industry due to small time savings over per-grind recordkeeping.	Improvement over voluntary recordkeeping because records are required and must be created every day of grinding, but the records will in most cases not be detailed enough to facilitate traceability. Therefore, any benefits that can realistically be expected will be minimal, and the objective of facilitating traceability will not be met.
(3) The Final Rule	$59.3 million ($48.5 million to $70.2 million) annual costs to the industry, plus additional costs associated with recording the source of trim and customer-requested grind components. Potential slight costs to consumers.	Achievement of regulatory objective resulting in benefits to consumers in the form of averted foodborne illness, to retailers and official establishments grinding components from suppliers in the form of less costly outbreaks and recalls, and to official establishments supplying ground beef components in the form of less costly recalls and insulation from costly spillover effects during food safety events.
(4) More Detailed Recordkeeping.	Most costly alternative to industry	Achievement of regulatory objective resulting in the benefits described above. Potential for small increase in traceback speed and therefore small increase in avoided illnesses.

Expected Costs of the Final Rule

Costs to Industry

Retailers and official establishments that grind raw beef will incur costs to comply with the final rule. These include the labor cost of employees who record and maintain the records, storage costs, and those costs associated with trim and customer-requested grinds. FSIS has attempted to estimate the cost of labor and storage using information obtained from industry associations, the U.S. Census Bureau, the U.S. Bureau of Labor Statistics, a commercial real estate services firm report, and public comments.

In order to keep adequate records when grinding trim, entities will need to keep track of the source of each cut of beef from which the trim was separated. If not all of the trim is ground in a single batch, then entities will need to record each lot in which the trim is used. Similarly, if retail stores grind beef at the request of customers, they will need to record the required information for that small grind if new source materials are used. How entities choose to deal with the requirements will differ, and the costs associated with these requirements will vary greatly because of differences in firm size, component ordering practices, and grinding practices. FSIS used labor-time estimates from a grocery store chain's public comments to estimate additional costs related to grinding trim. FSIS left additional costs related to customer requested grinds unquantified because of the many variations in how retail stores will deal with the requirements and the relatively small number of customer grinds that take place.

Entities may incur other costs for training and investment should they choose to implement complex recordkeeping systems. Electronic recordkeeping options exist, which are likely more expensive than paper records but provide additional benefits such as improved accuracy, lower labor requirements, useful reporting and recall management tools, and supply-side management functions. Firms will decide individually whether these systems are suitable to their needs, and the proportion of those choosing more complex systems is uncertain. For the purposes of the cost estimate, FSIS has only estimated costs and benefits of the basic, paper-based system of recordkeeping. FSIS assumes that if firms choose to invest more in their recordkeeping systems, they will do so because the benefits achieved outweigh the costs.

Model records are available in the preamble of this final rule, on the FSIS Web site,[22] and on the Web sites of industry associations. Best practices and guidance for beef grinders are also available from a number of sources.[23] Therefore, FSIS does not anticipate that entities will incur significant costs for the development of records and standard operating procedures. FSIS also believes that training for recordkeeping can be done informally, on the job, and will therefore result in minimal costs. Also, as noted above, FSIS will conduct webinars and provide guidance to help inform industry of the new requirements, which will help minimize training costs.

To estimate the labor costs associated with recordkeeping, FSIS divided the entities keeping no records and incomplete records into categories based on three basic types of grinding activities:

1. No trim—grinds in which no trim is used, only chubs of ground beef;
2. With trim—grinds in which trim is added to chubs of ground beef; and
3. Trim-only—grinds consisting only of trim.

Using distributions from the CDC recordkeeping study, FSIS was able to estimate the number of official establishments and retail stores that do not use trim in their grinds (no trim), that use trim in their grinds (with trim), and that use no trim in some grinds and

[22] FSIS, (2012) Sanitation Guidance for Beef Grinders, available at: *http://www.fsis.usda.gov/wps/wcm/connect/b002d979-1e1e-487e-ac0b-f91ebd301121/Sanitation_Guidance_Beef_Grinders.pdf?MOD=AJPERES.*

[23] Food Marketing Institute, (2013) ''Comprehensive Guide Meat Ground at Retail Recordkeeping and Sanitation,'' accessed February 12, 2015, available at: *http://www.fmi.org/docs/default-source/food-safety-best-practice-guides/meat-ground-at-retail-comprehensive-guide.pdf?sfvrsn=6.* Beef Industry Food Safety Council, (2005) ''Best Practices For Retailer Operations Producing Raw Ground Beef,'' accessed February 12, 2015, available at: *https://www.bifsco.org/CMDocs/BIFSCO/Best%20Practices/bestpracticesforretail4-05.pdf.*

only trim in others (trim-only). While there are likely other combinations of practices, and not all entities will fall into the three defined categories, these categories are sufficient for the purposes of the cost estimate. The categorization of entities is displayed in Table 7.

TABLE 7—ENTITIES CATEGORIZED BY TYPES OF GRINDING PERFORMED

Size	Recordkeeping	Entities	Trim or no trim	Trim practices	Entities
Large ...	Incomplete	13,069	Using Trim (91%)	Trim-Only (90%)	10,703
				With Trim (10%)	1,189
			No Trim (9%)	.....	1,176
	No Records	5,887	Using Trim (91%)	Trim-Only (90%)	4,821
				With Trim (10%)	536
			No Trim (9%)	.....	530
Small	Incomplete	4,514	Using Trim (61%)	Trim-Only (52%)	1,432
				With Trim (48%)	1,322
			No Trim (39%)	.....	1,761
	No Records	42,441	Using Trim (61%)	Trim-Only (52%)	13,462
				With Trim (48%)	12,427
			No Trim (39%)	.....	16,552

Values in table may not sum to Totals because of rounding.

FSIS assigned time estimates for each of the three types of grinds based on public comments. For no trim grinds, FSIS assumed that recordkeeping would take approximately 1 minute per grind.[24] For with trim grinds, FSIS assumed that the number of components would approximately double, and therefore recordkeeping would take about 2 minutes. For trim-only grinds, FSIS assumed that recordkeeping would vary depending on the number of sources and take approximately 6 to 10 minutes per grind.[25] If an entity is keeping complete records, FSIS assumed that it would not incur any additional costs; if an entity is keeping no records, it would incur costs associated with the full labor time estimate, and if an establishment is keeping incomplete records, FSIS assumed it would incur costs associated with half of the labor time estimate.

FSIS also relied on public comments to estimate the number of grinding activities completed per day. FSIS consequently estimated that the average entity grinds 4 to 5.5 times per day,[26] with the exception of those that do trim-only grinding. For those entities, FSIS estimated that they would complete no trim grinds 4 to 5.5 times per day and then perform an additional trim-only grind (for a total of 5 to 6.5 per day). Further, FSIS estimated that approximately 90 percent of retailers perform customer-requested grinds, and that those grinds make up 1 percent of the total grinds.[27] FSIS estimated that the recordkeeping for customer-requested grinds would take about 1 minute. Customer-requested grinds were not applied to official establishments. Finally, FSIS estimated that the average retailer grinds 6 days per week.[28]

To illustrate the time estimate, FSIS has provided the following example of a retail store that does trim-only grinds, performs customer-requested grinds, and has incomplete records:

- Low Estimate: [4 grinds per day × 1 min per grind (no trim) + 1 grind per day × 6 min per grind (trim-only) + {5 grinds (no trim + trim-only) * 1/99[29]} grinds per day × 1 min per grind (customer request)] × 6 days per week × 50 percent (incomplete records) = 30.2 minutes per week.
- High Estimate: [5.5 grinds per day × 1 min per grind (no trim) + 1 grind per day × 10 min per grind (trim-only) + {6.5 grinds (no trim + trim-only) * 1/99} × 1 min per grind (customer request)] × 6 days per week × 50 percent (incomplete records) = 46.7 minutes per week.

If the store in the example above started with no records, the 50-percent factor would be removed, increasing the time burden to 60.3 to 93.4 minutes per week. If instead the store were an official establishment, the customer grinds would be removed, resulting in a burden of 30 to 46.5 minutes per week.

Time estimates were calculated for each entity in Table 7 and then multiplied by 52 weeks for an annual estimate. To calculate the cost of this added labor, FSIS estimated that the recordkeeping would be performed by an employee paid at the Bureau of Labor Statistics ''Butchers and Meat Cutters'' (occupation code 51–3021) mean hourly wage rate of $14.40.[30] To account for benefits paid to these employees, such as paid leave and retirement contributions, FSIS applied a benefits factor of 1.412 [31] to the wage rate, resulting in a total compensation rate of $20.33 per hour. FSIS then multiplied the labor time estimates by the total compensation rate estimate to get the total annual cost of labor, displayed in Table 8.

[24] ''60 seconds to fill each grind log entry''—Docket ID# FSIS–2009–0011–0035, available at: *http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0035.*

[25] ''8 minutes per day to log beef trim,'' ± 2 minutes to account for varying number of components—Docket ID# FSIS–2009–0011–0035, available at: *http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0035.*

[26] Low estimate: ''Grinds raw beef 4x per day''—Docket ID# FSIS–2009–0011–0034, available at: *http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0034.* High estimate: Midpoint of ''3–8 batches a day''—Docket ID# FSIS–2009–0011–0040, available at: *http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0040.*

[27] ''90 percent of the retailers that grind beef in store perform grinds at a consumer's request . . . the figure is 1 percent or less''—Docket ID# FSIS–2009–0011–0047, available at: *http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0047.*

[28] ''6x per week''—Docket ID# FSIS–2009–0011–0034, available at: *http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0034.*

[29] (1/99) is the factor used to calculate the number of customer-requested grinds as 1 percent of the total grinds.

[30] Bureau of Labor Statistics, May 2013 National Occupational Employment and Wage Estimates, accessed February 2, 2015, available at: *http://www.bls.gov/oes/current/oes_nat.htm.*

[31] Bureau of Labor Statistics, Employer Costs for Employee Compensation, September 2014, accessed February 2, 2015, available at: *http://www.bls.gov/news.release/ecec.t06.htm.* Wages and salaries as a percentage of total compensation are estimated at 70.8% for all service-providing industries, with total benefits accounting for the other 29.2%. To estimate total compensation, FSIS applied a benefits factor of (29.2%/70.8% + 1) = 1.412 to the hourly wage rate.

TABLE 8—ANNUAL LABOR COSTS

Entity size	Low estimate ($mil)	High estimate ($mil)	Midpoint estimate ($mil)
Large	12.24	18.70	15.47
Small	33.54	48.74	41.14
Total	45.78	67.44	56.61

Values in table may not sum to Totals because of rounding.

To account for record storage costs, FSIS again used distributions of recordkeeping practices from the aforementioned CDC study.[32] According to the study, 36 percent of retailers that maintain records keep them for greater than 1 year, 39 percent keep records for 6 months to 1 year, and 25 percent keep records for less than 6 months. FSIS assumed that grinding records for a full year could be kept in 3 square feet of storage space, and that the cost of that storage would be approximately $15.50 annually.[33] FSIS then assumed that those retail stores that already kept records, but for less than 6 months, would incur $46.50 in costs for a full year of storage (3 sq. ft. × $15.50), and those entities that already kept records for 6 months to 1 year would pay half the annual cost, or $23.25. Those entities keeping records for greater than 1 year would have no additional costs because they are already maintaining records at the minimum level.

The distribution from the CDC study was applied to the number of retail stores keeping complete or incomplete records, and then multiplied by the assumed annual cost of storage. The retail stores that do not keep records will incur the $46.50 in costs for a full year of storage.

For official establishments, FSIS assumed that those already maintaining records would be keeping those records for at least 2 years, as required by 9 CFR 320.3(a). For these establishments there would be cost savings associated with one year of reduced storage time equivalent to $46.50. For official establishments not maintaining records, there would be an additional cost of $46.50. FSIS applied the cost savings to those official establishments keeping records and the additional costs to those official establishments keeping no records, and added those costs and savings to the recordkeeping costs estimated for retail stores. The results are displayed in Table 9.

TABLE 9—ANNUAL RECORD STORAGE COSTS

Entity size	Affected entities	Storage costs ($mil)
Large	16,613	0.62
Small	46,194	2.08
Total	62,807	2.70

Values in table may not sum to Totals because of rounding.

The total cost to industry was calculated as a sum of the previously estimated costs. The results of the annual industry cost estimate are displayed in Table 10.

TABLE 10—TOTAL ANNUAL INDUSTRY COSTS

Entity size	Low estimate ($mil)	High estimate ($mil)	Midpoint estimate ($mil)	Unqualified costs
Large	12.86	19.32	16.09	Additional costs associated with the grinding of trim and customer requested grinds.
Small	35.63	50.83	43.23	
Total	48.48	70.15	59.32	

Values in table may not sum to Totals because of rounding.

Cost to Consumers

This rule will not result in any direct costs to consumers. It is possible that retailers and official establishments that grind raw beef will pass on a portion of the increased cost of grinding to consumers. In most cases these costs should be small. In the case of customer-requested grinds, consumers may end up paying a small fee, as is presently customary at some retail stores. While this practice may discourage some consumers, the facts that customer-requested grinds are so infrequent, and fees are already applied at some locations, suggest that fees will not cause major disruptions to ground beef sales. Therefore FSIS expects that

[32] See footnote 3.

[33] Cassidy Turley, National Retail Review Winter 2014, accessed February 3, 2015, available at: *http://dtz.cassidyturley.com/DesktopModules/CassidyTurley/Download/Download.ashx?contentId=3926&fileName=Cassidy_Turley_National_Retail_Review_Winter_2014.pdf.* FSIS used the national average quoted rate for Community/Neighborhood/Strip Shopping Centers (see page 11) to approximate the cost of storing records at a retail store.

any indirect costs to consumers will be minimal.

Cost to Agency

FSIS does not anticipate that the Agency or other regulators will incur additional costs as a result of this rule. FSIS has provided guidance to retailers that grind raw beef and will continue outreach efforts to ensure that retailers are aware of the rule and are able to comply. FSIS will also hold webinars and provide guidance on the new recordkeeping requirements.

FSIS will conduct a retrospective analysis to quantify what effects, if any, the final rule has on Agency resources. To do so, FSIS will examine the following:

- Number, length, and outcome of recall effectiveness checks.
- Regulatory noncompliance citations at official establishments for the proposed revisions to 9 CFR 320.1(b)(4).

We determined to not examine the overtime hours for enforcement, district office, and recall staff on a per-outbreak basis, as suggested in the proposed rule. The overtime hours cannot directly link to outbreaks.

Expected Benefits of the Final Rule

Public Health Benefits

Mandatory grinding logs with a minimum level of necessary information will improve FSIS investigators' ability to trace implicated product to its source, recommend timely and accurate recalls, remove adulterated product from commerce, and prevent illnesses at later stages of outbreaks.[34]

Mandatory grinding logs will increase the likelihood that adulterated product is able to be traced back to its source. When FSIS identifies official establishments producing adulterated product, it takes steps to assess their production processes through comprehensive food safety assessments and follow-up evaluations. In doing so, FSIS is able to identify poor practices and deficiencies in process control and to require changes to resolve these issues. In some cases these assessments lead to findings that are valuable to industry as a whole, and the lessons learned can be documented and disseminated in the form of guidance. Improvements to production practices and process control, whether at implicated official establishments or other establishments that have benefited from lessons learned, will result in reductions in foodborne illness outbreaks.

Firms that supply ground beef components will have incentives to apply the guidance developed as a result of previous outbreak investigations and to improve the safety of their product in general. As traceability systems improve as a result of better recordkeeping, liability for food safety events will be shifted from retailers to suppliers. This shift will reduce the prevalence of moral hazard—explained previously in the Need for the Rule section—thereby incentivizing supplier firms to produce safer product through the potential for adverse consequences of supplying unsafe product, such as reputation loss and litigation.[35] Therefore, by improving traceability through better recordkeeping, this rule has the potential to promote a safer supply of ground beef for consumers.

Benefits to Retailers and Official Establishments That Grind Raw Beef

Retailers and official establishments that grind raw beef products purchased from a supplier will benefit from mandatory recordkeeping because investigators have a better chance of tracing the adulterated product back to the supplier. Investigations that end at the retail level often result in recalls that are very costly for retailers because they bear the burden of product loss and compensating customers for returned product. These recalls can also negatively affect the brand of the store or chain, resulting in a loss in consumer confidence and a loss in sales. In some cases outbreak investigations that end at the retail level could result in exposure to legal liability.[36] Accurate records increase the likelihood that contaminated product is traced to its source, lessening the impact of recalls on retailers and official establishments that purchase ground beef components from suppliers.

For retailers that are already maintaining accurate records, there will be benefits from the reduction in free rider firms, as explained previously in the Need for the Rule section. Fewer free rider firms will decrease the chances that outbreak investigations go unresolved, which can greatly reduce the cost to retailers. When a source is not identified, an outbreak may indiscriminately affect firms selling and producing ground beef. The fresh spinach outbreak in 2006 is a prime example of the consequences of an outbreak where the source of contamination is in doubt. Bagged spinach was associated with infections of *E. coli* O157:H7, but because no individual processor could be identified as having been the source of the outbreak, FDA and CDC issued a public alert advising consumers not to eat bagged spinach and eventually advised consumers not to eat all fresh spinach. Six companies issued voluntary recalls in September 2006. Sales of spinach plummeted from $14.3 million in September to $3.7 million in October and did not recover fully until January 2008.[37] An outbreak caused by a single firm, which was identified weeks after public warnings and recalls took place, ended up causing serious losses to the entire industry. Mandatory recordkeeping increases the chances that an investigator identifies the source of contamination, thereby increasing the chances that an outbreak will have minimal impact on uninvolved firms.

Benefits to Official Establishments That Supply Ground Beef Components

Official establishments supplying retail stores and processing establishments with ground beef components will also benefit from the increased ability of FSIS investigators to identify sources of contamination. When individual establishments are found to be suppliers of adulterated product, other uninvolved establishments are insulated from large spillover effects such as those illustrated in the spinach recall described above. Identifying the source establishment will likely be even more significant for official establishments because ground beef components make up a greater portion of their sales than ground beef would at a retail store. Mandatory recordkeeping could help to preserve consumer confidence and ground beef sales in the event of a foodborne illness outbreak, benefiting all firms that are uninvolved in the outbreak, while penalizing the establishment that supplied the adulterated product.

Another potential benefit for official establishments is a reduction in the scope of ground beef recalls. All else being equal, more accurate grinding records should result in the

[34] For a visual representation of the potential for averted illnesses due to quicker investigations and an earlier recall, please refer to Figure 1 of the FDA *Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* final rule, available at: *https://federalregister.gov/a/04-26929/#p-674.*

[35] See footnote 9.

[36] See *Financial Exposures* section of: Grocery Manufacturers Association (GMA), Covington & Burling, and Ernst & Young ''Capturing Recall Costs,'' 2011, accessed January 15, 2015, available at: *http://www.gmaonline.org/file-manager/images/gmapublications/Capturing_Recall_Costs_GMA_Whitepaper_FINAL.pdf.*

[37] University of Minnesota Food Industry Center, (2009) ''Natural Selection: 2006 *E. coli* Recall of Fresh Spinach,'' accessed January 20, 2015, available at: *http://ageconsearch.umn.edu/bitstream/54784/2/Natural%20Selection.pdf.*

identification of specific lots of implicated product and therefore a narrower recall.[38] Smaller recalls will result in lower costs from product loss and reimbursement and recall execution costs such as advertising and public relations management. In some cases, smaller recalls as a result of better recordkeeping could even minimize sales losses, because a recall could be limited to a smaller geographical region thereby reducing losses in consumer confidence.

Finally, official establishments will benefit from lessons learned during recalls and follow-up assessments at entities linked to foodborne illness outbreaks. As recordkeeping practices at retail and official processing establishments improve, more outbreaks will be able to be traced to their source. This traceback will initiate further examination of current practices and could lead to the identification of significant issues that, if corrected, would benefit official establishments generally.

Net Benefits of the Final Rule

The total costs and benefits achieved as a result of the final rule are displayed in Table 11.

TABLE 11—NET BENEFITS OF THE FINAL RULE

Costs:	
Labor	$56.6 million annually ($45.8 million to $67.4 million).
Storage	$2.7 million annually.
Unquantified Costs	Non-labor costs associated with recordkeeping for the grinding of trim and customer requested grinds.
	Potential slight costs to consumers in the form of ground beef price increases.
Benefits:	
Unquantified Benefits	Benefits to consumers in the form of averted foodborne illnesses as a result of contaminated ground beef.
	Benefits to retailers and official establishments grinding raw beef in the form of less costly food safety events, such as outbreaks and recalls.
	Benefits to official establishments supplying ground beef components in the form of less costly recalls and insulation from costly spillover effects during food safety events.

Regulatory Flexibility Analysis

The FSIS Administrator certifies that, for the purpose of the Regulatory Flexibility Act (5. U.S.C. 601–602), the final rule will not have a significant economic impact on a substantial number of small entities in the United States. While the rule does affect a large number of small businesses, the average per entity annual cost is relatively low, at approximately $905 (746 to 1,064). This estimate does not include unquantified costs associated with customer-requested grinds. These costs will vary by retail store, but the total cost of compliance across the industry will be low because of the relatively small number of customer requested grinds. Table 12 provides a summary of the small entities affected by the final rule and the average annual cost.

TABLE 12—TOTAL COSTS AND AVERAGE COST PER ENTITY FOR SMALL BUSINESSES

Entity type	Entities	Total annual cost ($mil)	Average annual cost ($)
Retailer	46,649	42.22	905.16
Official	1,132	1.00	885.63
Total	47,781	43.23	904.70

Values in table may not sum to Totals because of rounding.

There is a multitude of guidance already available that small businesses can use, and FSIS has provided a sample grinding log in this final rule that can be used. These resources will help to keep the cost of implementing a new recordkeeping program low. In general, as the size of the business and the amount of ground product sold gets smaller, so too will the number of suppliers and components used, and the number of grinds performed. The smaller scale of production should contribute to lower average costs for smaller businesses. Moreover, the fact that some small firms are already maintaining adequate records shows that the cost of the practice is not prohibitive to doing business.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the new information collection requirements included in this final rule have been submitted for approval to the Office of Management and Budget (OMB).

Title: Records to be Kept by Official Establishments and Retail Stores that Grind Raw Beef Products.

Type of Collection: New.

Abstract: Under this final rule, all official establishments and retail stores that grind raw beef products for sale in commerce, including products ground at a customer's request, will have to maintain certain records.

The required records will have to include the following information:

(A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product,

(B) All supplier lot numbers and production dates,

(C) The names of the supplied materials, including beef components

[38] Resende-Filho, Moises A. and Buhr, Brian L. ''Economics of Traceability for Mitigation of Food Recall Costs,'' prepared for presentation at the *International Association of Agricultural Economists (IAAE) Triennial Conference,* Foz do Iguaçu, Brazil, 18–24 August, 2012, available at: *http://ageconsearch.umn.edu/bitstream/126193/2/IAAE_2012_Paper.pdf.* This paper presents simulation results of a model that indicated that that presence of a traceability system decreased volumes of recalls by over 90 percent (see Table 3).

and any materials carried over from one production lot to the next,

(D) The date and time each lot of raw ground beef product is produced, and

(E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

In response to comments, FSIS removed requirements for entities covered by this rule to provide names, points of contact, and phone numbers for official establishments. Also in response to comments, the Agency eliminated the requirement that the weight of each source component used in a lot of ground beef be kept. However, in response to other public comments, FSIS increased the time estimates for recordkeeping activities, the frequency of recordkeeping tasks, and the number of active grinding days per week. FSIS also increased the number of retail stores that will be affected by the rule. These changes resulted in a significant increase in the number of burden hours initially estimated in the proposed rule.

Estimate of Burden: FSIS estimates that it would take a maximum of 50.33 hours per respondent annually.

Respondents: Official establishments and retail stores that grind raw beef products.

Estimated Number of Respondents: 65,911.

Estimated Maximum Annual Number of Responses per Respondent: 1,878.

Estimated Maximum Total Annual Recordkeeping Burden: 3,317,493 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Ave. SW., Room 6065 South Building, Washington, DC 20250–3700; (202) 720–5627.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Food Safety and Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication 1400 Independence Avenue SW., Washington, DC 20250–9410

Fax: (202) 690–7442

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

List of Subjects in 9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, FSIS is amending 9 CFR part 320, as follows:

PART 320—RECORDS, REGISTRATION, AND REPORTS

■ 1. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53

■ 2. Amend § 320.1 by adding paragraph (b)(4) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(4)(i) In the case of raw ground beef products, official establishments and retail stores are required to keep records that fully disclose:

(A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;

(B) All supplier lot numbers and production dates;

(C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;

(D) The date and time each lot of raw ground beef product is produced; and

(E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

(ii) Official establishments and retail stores covered by this part that prepare ground beef products that are ground at an individual customer's request must keep records that comply with paragraph (b)(4)(i) of this section.

(iii) For the purposes of this section of the regulations, a lot is the amount of ground raw beef produced during particular dates and times, following clean up and until the next clean up, during which the same source materials are used.

* * * * *

■ 3. Revise § 320.2 to read as follows:

§ 320.2 Place of maintenance of records.

(a) Except as provided in paragraph (b) of this section, any person engaged in any business described in § 320.1 and required by this part to keep records must maintain such records at the place where such business is conducted, except that if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records must be kept in a safe place at the prescribed location in accordance with good commercial practices.

(b) Records required to kept under § 320.1(b)(4) must be kept at the location where the raw beef was ground.

■ 4. Revise § 320.3 to read as follows:

§ 320.3 Record retention period.

(a) Except as provided in paragraphs (b) and (c) of this section, every record required to be maintained under this part must be retained for a period of 2 years after December 31 of the year in which the transaction to which the record relates has occurred and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such records under this part.

(b) Records of canning as required in subpart G of part 318 of this chapter, must be retained as required in § 318.307(e); except that records required by § 318.302(b) and (c) must be retained as required by those sections.

(c) Records required to be maintained under § 320.1(b)(4) must be retained for one year.

Done in Washington, DC, on: December 14, 2015.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2015–31795 Filed 12–18–15; 8:45 am]

BILLING CODE 3410–DM–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 348 and 390

RIN 3064–AE20

Removal of Transferred OTS Regulations Regarding Management Official Interlocks and Amendments to FDIC's Rules and Regulations

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Federal Deposit Insurance Corporation (''FDIC'') is adopting a final rule to rescind and remove from the Code of Federal Regulations the transferred OTS regulation entitled ''Management Official Interlocks.'' This subpart was included in the regulations that were transferred to the FDIC from the Office of Thrift Supervision (''OTS'') on July 21, 2011, in connection with the implementation of applicable provisions of title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''). The requirements for State savings associations in the transferred OTS regulation are substantively similar to those in the FDIC's regulation, which is also entitled ''Management Official Interlocks'' and is applicable for all insured depository institutions (''IDIs'') for which the FDIC has been designated the appropriate Federal banking agency.

DATES: The final rule is effective on January 20, 2016.

FOR FURTHER INFORMATION CONTACT: Jennifer Maree, Counsel, Legal Division, (202) 898–6543; Mark Mellon, Counsel, Legal Division, (202) 898–3884; Karen Currie, Senior Examination Specialist, (202) 898–3981.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Dodd-Frank Act

The Dodd-Frank Act [1] provided for a substantial reorganization of the regulation of State and Federal savings associations and their holding companies. Beginning July 21, 2011, the transfer date established by section 311 of the Dodd-Frank Act, codified at 12 U.S.C. 5411, the powers, duties, and functions formerly performed by the OTS were divided among the FDIC, as to State savings associations, the Office of the Comptroller of the Currency (''OCC''), as to Federal savings associations, and the Board of Governors of the Federal Reserve System (''FRB''), as to savings and loan holding companies. Section 316(b) of the Dodd-Frank Act, codified at 12 U.S.C. 5414(b), provides the manner of treatment for all orders, resolutions, determinations, regulations, and advisory materials that had been issued, made, prescribed, or allowed to become effective by the OTS. The section provides that if such materials were in effect on the day before the transfer date, they continue to be in effect and are enforceable by or against the appropriate successor agency until they are modified, terminated, set aside, or superseded in accordance with applicable law by such successor agency, by any court of competent jurisdiction, or by operation of law.

Section 316(c) of the Dodd-Frank Act, codified at 12 U.S.C. 5414(c), further directed the FDIC and the OCC to consult with one another and to publish a list of the continued OTS regulations that would be enforced by the FDIC and the OCC, respectively. On June 14, 2011, the FDIC's Board of Directors approved a ''List of OTS Regulations to be Enforced by the OCC and the FDIC Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act.'' This list was published by the FDIC and the OCC as a Joint Notice in the **Federal Register** on July 6, 2011.[2]

Although section 312(b)(2)(B)(i)(II) of the Dodd-Frank Act, codified at 12 U.S.C. 5412(b)(2)(B)(i)(II), granted the OCC rulemaking authority relating to both State and Federal savings associations, nothing in the Dodd-Frank Act affected the FDIC's existing authority to issue regulations under the Federal Deposit Insurance Act (''FDI Act'') and other laws as the ''appropriate Federal banking agency'' or under similar statutory terminology. Section 312(c) of the Dodd-Frank Act amended the definition of ''appropriate Federal banking agency'' contained in section 3(q) of the FDI Act, 12 U.S.C. 1813(q), to add State savings associations to the list of entities for which the FDIC is designated as the ''appropriate Federal banking agency.'' As a result, when the FDIC acts as the designated ''appropriate Federal banking agency'' (or under similar terminology) for State

[1] Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376 (2010).

[2] 76 FR 39247 (July 6, 2011).

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-040

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:

FOOD guard criteria comprise a CORE item, not a PRIORITY ITEM.

Issue you would like the Conference to consider:

Section 3-306.11 of the 2013 FDA Food Code describes FOOD guards as a PRIORITY ITEM ("P"). "Preface x" of the code defines a PRIORITY ITEM as ". . . *a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness. . ."*

We looked for data to support the categorization of FOOD GUARDS as PRIORITY ITEMS. A review of scholarly articles and discussions with epidemiologists at various agencies, including Dr. Aron Hall at the CDC did not turn up any evidence of food borne disease transmission being associated with the lack of FOOD GUARDS, or their being out of position in some way. Frankly, we were surprised as retail grocery stores merchandise produce without FOOD GUARDS, and we had assumed that if there was data it would likely be associated with these large and numerous open food display areas. Instead, Dr. Hall responding in writing to our inquiry, stated that he was not aware of any data indicating a relationship between FOOD GUARDS and disease transmission. Section 3-306.11 "FOOD DISPLAY" is designated as a PRIORITY ("P") item, and requires food on display to be protected by various means, one of which is by the use of FOOD GUARDS, which are also known as "sneeze guards". The American National Standards Institute (ANSI) sanitation standard for FOOD GUARD's extremely granular and its specified measurements for the food guard based upon the anthropometrics of "the average person" whereby the guard or shield, must intercept the straight line from the "average" persons mouth to the food on display. If a regulatory authority determines that a ANSI sanitation listed FOOD GUARD is slightly out of place given its installation on the counter and the location of the food on display, the operator is cited for a critical violation. The entire premise of using these precise measurements for the "average" persons anthropometrics lacks substance. Designing a functional, compliant food guard is often an impossible feat as consumers can range in height from 4' tall in elementary school, to 6'8" tall and taller in high school, or in a corporate cafeteria or any other commercial food service operation. Because compliant FOOD GUARDS are often (if not always) an obstruction to reach-in

access for many above or below average persons, patrons have to contort themselves to reach their desired items, and in so doing can touch with hands or articles of clothing - other foods. Touching ready to eat foods with hands is a known contributing factor to food borne disease transmission. Food Guards being in or out of position to intercept the direct line from the average persons mouth to the food on display, is not a contributing factor to food borne disease transmission. We maintain that function takes precedence over form and that when FOOD GUARDS are provided, they must enable convenient access of food for the self-service guest. Further, there is no critical need for the food guard to intercept the line from the average persons mouth to the food on display as theorized and assumed as is evidenced by the ANSI sanitation standards precise measurement criteria.

Public Health Significance:

PRIORITY ITEM ("P") designations are supposed to be reserved for critical safety criteria for hazards known to contribute to food borne disease and injury. Assigning this designation to items that lack criticality such as FOOD GUARD'S, is wasteful and does nothing to promote food safety. The mis-categorization of this risk adds confusion and diminishes the importance of other to Priority designations due to its arbitrary, non-scientific categorization. Further, because ("P") item criteria comprise the highest risk categorization in the FDA Food Code, inspection agencies and design professionals are persuaded to waste thousands if not millions of hours every year complying with the arbitrary ANSI sanitation standards specified measurements because of the sections Priority designation. The cost of of compliance with section 3-306.11 is staggering, especially in light of the fact that it does nothing to improve public health and safety and instead wastes valuable time and money that could instead be used to mitigate risk factors known to contribute to food borne disease transmission.

There are some other reasons one might want a FOOD GUARD. For example, it could be used as a barrier or heat shield adjacent to a griddle or a broiler, or perhaps a hot food well or baines marie. But the ANSI sanitation measurements for a FOOD GUARD's are irrelevant for these examples - as the function of the FOOD GUARD here is actually to be a patron or child guard to reduce likelihood that they could be burned. Surely no reasonable person would think that the FOOD GUARD provides any microbial risk mitigation in these examples, as the thermal mass of the hot food would destroy any aerosolized organism from a cough or sneeze on contact. One could argue that such a guard protects from physical hazards. But foods on display are there for a short amount of time, and there is no data to suggest a physical or chemical hazard exists whether there is a FOOD GUARD used or not.

When the ANSI sanitation standards precise measurement requirements for FOOD GUARDS result in them becoming an obstacle to easy access to food, a documented hazard to the food is created; the inadvertent bare hand contact with ready to eat foods. The logical risk based preventative control for this hazard is to require convenient access to foods for all consumers, even those that are above or below "average", or handicapped. FOOD GUARDs that are obstacles to food access cause many patrons to simply choose not to reach for the item, diminishing the sales opportunity for the operator and the nutritional choice of the consumer. This is especially true with children and the handicapped.

Lacking scientific data that FOOD guards effectively protect food from contamination, the PRIORITY ITEM designation in section 3-306.11 of the FOOD CODE is arbitrary and inappropriate. This is not to say that FOOD guards cannot or should not be used. Rather, when FOOD GUARDS are used, form must follow function. Finally, FOOD GUARDS comprise a Core item, not a Priority item nor a Priority foundation item.

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 3-306.11 Food Display.

~~Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the CONSUMER before consumption,~~ FOOD on display ~~shall~~ can be ~~protected from contamination~~ shielded by the use of PACKAGING; counter, service line, or salad bar FOOD guards; display cases; or other ~~effective~~ means [P]. When FOOD guards are used, they shall be installed and maintained in a manner that allows self-serve consumers convenient access to the displayed foods.

Section 4-204.12 Equipment Openings, Closures and Deflectors

(E) When FOOD guards are provided, they shall be installed and maintained in a manner that self-service consumers are allowed convenient access to the food in order to reduce the risk of inadvertent hand or clothing contact with other foods on display.

Submitter Information 1:

Name:	Thomas Johnson, Chief Manager
Organization:	Johnson Risk Solutions, LLC
Address:	1408 Northland Dr #406
City/State/Zip:	Mendota Heights, MN 55120
Telephone:	651-587-0418
E-mail:	tomj@jdpinc.com

Submitter Information 2:

Name:	Steve Carlson, President
Organization:	Rippe Associates
Address:	6117 Blue Cir Dr, Suite 100
City/State/Zip:	Minnetonka, MN 55343
Telephone:	952-933-0313
E-mail:	scarlson@rrippe.com

Supporting Attachments:

- "CDC Food Guards (2015)"

Subject: RE: Food borne disease transmission/contributing factors
Date: Monday, December 7, 2015 at 10:17:02 Eastern Standard Time
From: Hall, Aron (CDC/OID/NCIRD) <esg3@cdc.gov>
To: Tom Johnson <tomj@jdpinc.com>

Dear Tom,

I am not aware of any such data.

Kind Regards,

Aron J. Hall, DVM, MSPH, DACVPM
CDC Division of Viral Diseases
ajhall@cdc.gov

From: Tom Johnson [mailto:tomj@jdpinc.com]
Sent: Friday, December 04, 2015 8:21 AM
To: Hall, Aron (CDC/OID/NCIRD) <esg3@cdc.gov>
Cc: Hall, Aron (CDC/OID/NCIRD) <esg3@cdc.gov>
Subject: Food borne disease transmission/contributing factors

Dear Aron,

I am conducting research on behalf of a client and in preparation for the 2016 Conference fo Food Protection.

Does CDC have any data relating to the transmission of a food borne disease associated with a cough or sneeze?

ANSI sanitation requirements have very specific and detailed requirements for food shields based on myriad of anthropometrics and various risk theories and opinions. Interpretation and enforcement of these criteria cost the industry tens of millions of dollars every year and also impact access to food by the public.

We seek data that may indicate that pathogenic species such as Listeria monocytogenes, Salmonella, E.Coli, Staph, Hep A have been transmitted because of the lack of a food shield, or that due to misuse or positioning, a cough or sneeze may have transmitted one of the target organisms of concern.

Please advise.

Thank You and Best Regards,

Thomas Johnson, Chief Manager
Johnson Risk Solutions, LLC
Insightful HACCP/Technology & Risk Mitigation Integrations
1408 Northland Dr. #406
Mendota Heights, MN 55120
dir: 651-203-2462 cell: 651-587-0418
tomj@jdpinc.com jrsrisk.com
https://www.linkedin.com/pub/tom-johnson/4/42a/379

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-041

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:

Food equipment cleanability and design

Issue you would like the Conference to consider:

Contaminated food contact surfaces of food equipment are known to be a contributing factor to food borne disease transmission. At a minimum, food contact surfaces should be designed and formed of materials conducive to their effective cleaning and sanitation across their entire service life, not just the first day they were placed into service. At a minimum, these surfaces should have recommended cleaning and sanitizing protocols that include frequency, methods and means.

American National Standards Institute (ANSI) performance certification standardized tests are only performed on brand new (virgin) equipment, the surfaces of which are free of any wear and/or food residue/biofilm accumulation at the time of certification testing. There are no current ANSI Sanitation performance certification test methods to ensure that equipment food contact surfaces can be effectively cleaned and sanitized beyond the food equipment's first use.

Matrices of soils, including inorganic and organic matter accumulates on food contact surfaces, if not cleaned and sanitized with a specific frequency using effective methods can harbor opportunistic microorganisms of many species. These include the spoilers along with pathogenic bacteria and virus. A discipline of focused and continuous effort to clean and then sanitize these surfaces is needed to ensure a reasonable standard of care, especially in those operations that serve highly susceptible persons. The artifact definition of CLEAN (*to sight and touch*) is not sufficient for food contact surfaces that are inaccessible to sight or touch.

Equipment that requires clean and sanitize in place (CIP, or CSIP) processes to clean and sanitize food contact surfaces that are not readily accessible for inspection present the greatest risk from this gap in ANSI sanitation performance certification testing. Examples include internal food contact surfaces in ice machines such as its harvest plates, sumps and the potable lines interconnecting them. Risk is amplified when a carbon filter is placed upstream from the ice machine, which is often the case. The reference link #3 below

presents a table showing growth rates for biofilms in drinking water lines where there is no residual chlorine. Since carbon filters remove chlorine, this chart has direct correlation to wetted surfaces leading into and within an icemaker. Other reference links below provide evidence of growth and propagation of biofilms even in ice waters.

Other examples of food equipment that are dependent upon CIP processes that are ill defined in the code and within ANSI sanitation standards include the interior surfaces of product lines used to deliver jumpable Time Temperature for Safety Food 9TCS0 products from a walk-in refrigerator (for example) to a dispenser (or dispensing freezer); or condiments from a bag-in-the-box to the point of application, along with soda and juice dispensers.

Section 4-205.10 of the FDA Food Code states that equipment listed to an ANSI sanitation standard is deemed to comply with chapters 4-1 and 4-2. Such a listing *does not* however relieve the operator of their duty to comply with everything else in chapter 4 beyond 4-2, such as section 4-6 and 4-7 and the remainder of the code. It is unfortunate that Section 4-602.11 (E) (4) (a) and (b) introduce an arbitration in the science based safety of the code. Here is the current text:

(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:

(a) At a frequency specified by the manufacturer, or

(b) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

Coffee bean grinders, and cooking oil storage tanks have little in common with the other examples listed in this food codes criteria section as they do not relate to equipment designed to prepare, hold or convey liquid food products. This inconsistency creates an arbitrary circumstance that obfuscates hazards associated with food equipment with internal or external liquid food plumbing lines that otherwise lack inspection ports or access openings for all or most of the equipment's wetted food contact surfaces.

Section 4-205.10 (4) (a) (above) infers that following a manufacturers instruction for use of their equipment will ensure a reasonable standard of care. This is inaccurate. Though it is true that the manufacturer is strictly liable for their equipment design, this liability does not ensure food-safe equipment design. Few manufacturers of food equipment have conducted any kind of professional risk analysis, whether internally or a third party of the potential hazards to foods prepared or processed using their equipment across the life of their equipment.

Generally speaking, the industry pursues product certification to a large extent because it is the shortest well-traveled path to obtaining local approvals, nationwide. Their overall goal is compliance with local interpretations of adopted rules and regulations, and they rely upon the codes and standards development organizations to have their acts together to ensure reasonable minimum safety. We have let them down with this issue.

It is well known today that though a surface may appear "clean" to sight and touch it can still be contaminated with fats, oils and other invisible organic matter that both inactivates sanitizers and shields pathogens. In food equipment dependent upon clean and sanitize in

place (CSIP/CIP), surfaces can be coated with P*seudomonas spp* (biofilms) and with them myriad other microorganisms. *Pseudomonas aeruginosa* is a gram negative, rod shaped pathogen common in almost all biofilms and is particularly dangerous to highly susceptible persons with diminished immune systems. *Pseudomonas fluorescens,* though less common and considered less virulent is known to continue to grow in waterlines and other fluid food lines at temperatures as low as 4 degrees Celsius (4ºC/39.2ºF).

Because the internal surfaces of small bore water lines and tubing common in liquid foodservice and beverage equipment (which includes foods such as potable water, ice, coffee, tea, juice, beer, wine, soda, etc) are inaccessible, there is no way of visually determining if biofilms are present. Without competent risk analysis as is now required in the Food Safety Modernization Act (FSMA) as described in the hazard analysis risk based preventative control (HARPC) regimes, there is no reasonable way to ensure that the manufacturers recommended cleaning and sanitizing protocols and frequency are adequate to ensure continuously sanitary food contact surfaces.

Hazard analysis critical control point (HACCP) regimes with their prerequisite programs (PRP's) and the new Hazard Analysis and Risk-based Preventive Controls (HARPC) programs with their Sanitation Standard Operation Procedures (SSOPs) provide a method by which reasonable interventions are put in place to mitigate risks to food. The fact that there are food contact surfaces that cannot be accessed for inspection, cleaning and sanitation by itself should be enough for any reasonable person concerned about public health and safety, to seek answers to the questions of risk, and to pursue improvement in poorly designed equipment with food contact surfaces that cannot be effectively inspected, cleaned and sanitized, or verified to be clean and sanitary. What is needed for equipment with inaccessible food contact surfaces is a risk based preventative control approach to ensure food safety.

Public Health Significance:

Failure to properly clean and sanitize food contact surfaces has been identified as a significant contributing factor to food borne disease transmission. Because the ANSI sanitation standards do not exist for testing food contact surfaces across their service life for continuous cleanability and sanitation suitability, the FDA Food Code needs to add new minimum safety criteria to fill the gap.

Section 4-602.11 has been used as a kind of catch-all waste basket for criteria that did not fit well in other sections of the code, or for things that are or were considered to be of lesser importance. For example, this section not only covers equipment used with liquid foods, some of which are TCS, but also coffee grinders and other equipment systems that lack similar microbiological risks. For these reasons we recommend that coffee grinders and the (hot) cooking oil systems be removed from this section entirely and replaced with examples of food service equipment with liquid food plumbing lines that depend upon a clean and sanitize in place (CSIP or CIP) capabilities to ensure clean and sanitary food contact surfaces. From a risk analysis, categorization and prioritization perspective, it is more appropriate that coffee grinders, meat saws, large cutting boards and other food equipment food contact surface too large to be cleaned out of place (COP) in a sink or dish washer should be subjected to in place cleaning (IPC) protocols, pursuant to their listings and the manufacturers instructions.

Reference links -

1. Control of Biofilm Growth in Drinking Water Distribution Systems http://infohouse.p2ric.org/ref/15/14291.pdf

2. Phylogenetic and Functional Heterogeneity of Sediment Biofilms along Environmental Gradients in a Glacial Stream http://aem.asm.org/content/67/2/799.full

3. Water Contamination Emergencies Managing the Threats (see last page discussion) - http://tinyurl.com/ntah4mg

4. Spread of *Pseudomonas fluorescens* Due to Contaminated Drinking Water in a Bone Marrow Transplant Unit: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3122780/

5. Contaminated feeding bottles: the source of an outbreak of Pseudomonas aeruginosa infections in a neonatal intensive care unit: http://www.ncbi.nlm.nih.gov/pubmed/19059675

6. Other peer reviewed publications: https://www.yousendit.com/download/ZWJWR0lVNXZtNEs1eDhUQw

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 strike through format):

Section 4-602.11

(A) through (D) remain unchanged.

(E) Except when dry cleaning methods are used as specified under § 4-603.11, surfaces of UTENSILS and EQUIPMENT contacting FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cleaned and sanitized:

(1) At any time when 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, ice bins; and

(E)(4) In EQUIPMENT ~~such as ice bins and BEVERAGE dispensing~~

~~nozzles and with enclosed~~ with enclosed liquid food plumbing line components ~~of EQUIPMENT~~ such as dispensing freezers ice makers and dispensers, ~~cooking oil storage tanks and distribution lines~~, BEVERAGE, syrup and condiment dispensing lines or tubes, ~~coffee bean grinders and~~ water vending EQUIPMENT and similar enclosed liquid food contact surfaces that depend upon CSIP processes for safety:

1. *At a frequency of once a week or more frequently as may be necessary to ~~preclude accumulation of soil or mold~~ prevent accumulation of soils or the formation of biofilms, molds and other foreign contaminants.*
2. *Or at a frequency as recommended by the manufacturer when publicly available third party process validation test data supports their recommended cleaning and sanitizing frequency and protocols given their equipment's intended use and expected service life.*

Submitter Information:

Name:	Thomas Johnson, Managing Director
Organization:	QleanTech Enterprises, LLC
Address:	1408 Northland Dr. #406
City/State/Zip:	Mendota Heights, MN 55120
Telephone:	651-587-0418
E-mail:	tomj@jdpinc.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-042

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:

Towel Drying Exception For Equipment Removed From High-Temp Dish Machines

Issue you would like the Conference to consider:

Wet stacking of equipment and utensils is a common issue and cause of concern in many food service establishments. Most facilities lack the space or time to adequately air dry utensils and equipment; therefore, stacking items while wet is frequently observed.

Single-use disposable towels, if used and stored appropriately, are sanitary. A single-use disposable towel could be used to dry equipment and then be discarded. Towel drying would also give the employee another chance to discern whether the items may need to be rewashed.

Public Health Significance:

Wet stacking prevents equipment from drying and increases the potential for bacterial growth. When food particles are not sufficiently removed in the washing process, the equipment, utensils, and food contact surfaces stacked wet support the growth of microorganisms, thus risking the public's health.

When utilizing a high-temperature sanitizing warewashing machine that reaches a temperature of at least 71°C(165°F) for a stationary rack warewashing machine or 82°C(180°F) for all other mechanical hot water sanitizing machines, the final rinse of the high temperature sanitizing warewashing machine should not exceed 90°C(194°F). If the high temperature sanitizing warewashing machine is operating according to manufacturer's specifications, and temperature limits have been met according to 4-501.112 to ensure surfaces of multiuse utensils and equipment accumulate enough heat to destroy pathogens, then single-use disposable towels used to remove remaining moisture should not pose a public health risk.

Recommended Solution: The Conference recommends...:

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

[4-901.11] Equipment and utensils, ~~Air-drying required,~~ Drying

After cleaning and sanitizing, equipment and utensils:

(A)Shall be air-dried or used after adequate draining as specified in the first paragraph of 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions), before contact with food. Stacking of wet items shall be prohibited; *OR*

(B)May not be cloth dried except that UTENSILS have been air-dried may be polished with cloths that are maintained clean and dry, *OR*

(C)May be hand-dried using individual, single-use disposable towels after removal from a high-temperature sanitizing warewashing machine operated as specified under 4-501.112

Submitter Information 1:

Name:	Megan Calahan
Organization:	Tulsa City-County Health Department
Address:	5051 S 129th E Ave
City/State/Zip:	Tulsa, OK 74134
Telephone:	918-595-4311
E-mail:	mcalahan@tulsa-health.org

Submitter Information 2:

Name:	DeBrena Hilton
Organization:	Tulsa City-County Health Department
Address:	5051 S 129th E Ave
City/State/Zip:	Tulsa, OK 74134
Telephone:	918-595-4302
E-mail:	dhilton@tulsa-health.org

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-043

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:

Harmonizing Direct Drain Connection Allowances with Plumbing Codes

Issue you would like the Conference to consider:

Paragraph 5-402.11(C) of the 2013 FDA Food Code allows a direct drain connection from warewashing machines if certain conditions exist. Various plumbing codes require direct drain connections for warewashing machines and warewashing sinks. However, in the absence of a plumbing code, food establishments are subjected to unnecessary requirements.

The 5-402.11(C) allowance should be extended to warewashing sinks that are not used for food preparation if the installation conditions specified in 5-402.11(C) are met.

Public Health Significance:

Eliminating Food Code requirements that conflict with other regulatory requirements, when the level of public health protection is not compromised, reduces difficulties faced by food code regulatory agencies.

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):

Paragraph 5-402.11(C)

(C) *If allowed by LAW, a WAREWASHING machine <u>or WAREWASHING sink</u> may have a direct connection between its waste outlet and a floor drain when the machine <u>or sink</u> is located within 1.5 m (5 feet) of a trapped floor drain and the machine <u>or sink</u> outlet is connected to the inlet side of a properly vented floor drain trap.*

Submitter Information:

Name: Adam Inman
Organization: Kansas Department of Agriculture

Address: 1320 Research Park Drive
City/State/Zip: Manhattan, KS 66502
Telephone: 7855646764
E-mail: adam.inman@kda.ks.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-044

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:

Hot Water Provided at Service Sink

Issue you would like the Conference to consider:

Clarify that hot water is required to be provided at a service sink. Currently, this violation is cited under 5-501.18 using the ambiguous reference in Annex 3 of "proper equipment and supplies must be made available to accomplish thorough and proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated". While some public health jurisdictions may be able to require hot water at a service sink through their local plumbing codes, others cannot.

Public Health Significance:

An accumulation of greasy food residue left behind after cleaning waste receptacles, mops and mop buckets with only cold water can create a harborage area for pathogens and contribute to the breeding of pests.

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 5-203.13(A)

(A) At least 1 service sink or 1 curbed cleaning facility equipped with a floor drain <u>and equipped to provide water a temperature of at least 38°C (100°F)</u> shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

Submitter Information 1:

Name:	Ann Johnson
Organization:	FL Department of Agriculture
Address:	3236 Sardenia Terrace

City/State/Zip: Deltona, FL 32738
Telephone: 407-335-3497
E-mail: anna.johnson@freshfromflorida.com

Submitter Information 2:

Name: Joetta DeFrancesco
Organization: FL Department of Agriculture
Address: 10281 Enoch Lane
City/State/Zip: Bonita Springs, FL 34135
Telephone: 239-206-0260
E-mail: joetta.defrancesco@freshfromflorida.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-045

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:

Consolidating Chemical Storage Provisions in the Food Code

Issue you would like the Conference to consider:

The chemical storage provisions in the 2013 FDA Food Code should be combined into one section.

In earlier versions of the code the respective paragraphs (A) were "Swing" violations, which made the division necessary. However, both storage above and immediately adjacent are classified as Priority violations.

Public Health Significance:

Simplifying the Food Code can help with compliance.

Recommended Solution: The Conference recommends...:

a letter be sent to FDA recommending consolidating Sections 7-201.11 and 7-301.11 and paragraphs of the FDA 2013 Food Code into one section and deleting Section 7-301.11 (language to be inserted is underlined; language to be deleted is in strikethrough format):

7-201.11 Separation.

POISONOUS OR TOXIC MATERIALS shall be stored<u>, handled and displayed, whether for use in the food establishment or for retail sale,</u> so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLESERVICE and SINGLE-USE ARTICLES by~~:~~

~~(A) S~~<u>s</u>eparating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning~~; P~~ and

~~(B) L~~<u>l</u>ocating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES. *This paragraph does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if*

the materials are stored to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES. P

"POISONOUS OR TOXIC MATERIALS shall be stored, handled and displayed, whether for use in the food establishment or for retail sale, so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLESERVICE and SINGLE-USE ARTICLES by separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning and locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES. *This paragraph does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if the materials are stored to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.* P"

Submitter Information:

Name:	Adam Inman
Organization:	Kansas Department of Agriculture
Address:	1320 Research Park Drive
City/State/Zip:	Manhattan, KS 66502
Telephone:	7855646764
E-mail:	adam.inman@kda.ks.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-046

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:

Removing the Reference to Restricted Use Pesticides in 7-202.12(B)(2)

Issue you would like the Conference to consider:

Section 7-202.12(B)(2) of the 2013 FDA Food Code provides basic requirements to prevent pesticide contamination in food establishments. However, the requirements are limited Restricted Use Pesticides. Most pesticides being used in food establishments are not Restricted Use Pesticides, as labeled per EPA regulations.

Although pesticides labeled for use in food establishments will have use directions that require taking these precautions, having the requirements in the Food Code eliminates the need to document the label use directions in instances where the precautions are not taken.

Public Health Significance:

Extending the pesticide use requirements in Section 7-202.12(B)(2) to include General Use Pesticides will further reduce the chance of pesticide contamination of food.

Recommended Solution: The Conference recommends...:

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

7-202.12 Conditions of Use.

POISONOUS OR TOXIC MATERIALS shall be:

(A) Used according to:

(1) LAW and this Code,

(2) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a FOOD ESTABLISHMENT, [P]

(3) The conditions of certification, if certification is required, for use of the pest control materials, [P] and

(4) Additional conditions that may be established by the REGULATORY AUTHORITY; and

(B) Applied so that:

(1) A HAZARD to EMPLOYEES or other PERSONS is not constituted, [P] and

(2) Contamination including toxic residues due to drip, drain, fog, splash or spray on FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES is prevented, and ~~for a RESTRICTED USE PESTICIDE,~~ this is achieved by: [P]

(a) Removing the items, [P]

(b) Covering the items with impermeable covers, [P] or

(c) Taking other appropriate preventive actions, [P] and

(d) Cleaning and SANITIZING EQUIPMENT and UTENSILS after the application. [P]

Submitter Information:

Name:	Adam Inman
Organization:	Kansas Department of Agriculture
Address:	1320 Research Park Drive
City/State/Zip:	Manhattan, KS 66502
Telephone:	7855646764
E-mail:	adam.inman@kda.ks.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-047

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:

Temporary Food Establishment Inspection Intervals

Issue you would like the Conference to consider:

The 2013 FDA Food Code Section 8-401.10(C) states that:

The regulatory authority shall periodically inspect throughout its permit period a temporary food establishment that prepares, sells, or serves unpackaged potentially hazardous food (time/temperature control for safety food) and that:

(1) Has improvised rather than permanent facilities or equipment for accomplishing functions such as handwashing, food preparation and protection, food temperature control, warewashing, providing drinking water, waste retention and disposal, and insect and rodent control; or

(2) Has inexperienced food employees.

While this is a nondebitable code provision the use of the word "shall" means that the act is "imperative" and constitutes a command to the regulatory authority. However, based on risk, it may not be necessary for the regulatory authority to inspect a temporary food establishment (TFE) more than once even if the conditions stated in 8-401.10(C)(1) or (2) exist.

I propose changing the word shall to may.

Public Health Significance:

I do not believe there is a public health rationale for the use of the word "shall" in 8-401.10(C). By changing it to "may" it would still permit/allow the regulatory authority to conduct more than one inspection of the TFE during the operational period if they determine it is necessary.

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 8-401.10

(C) The REGULATORY AUTHORITY ~~shall~~ may periodically inspect throughout its PERMIT period a TEMPORARY FOOD ESTABLISHMENT that prepares, sells, or serves unPACKAGED TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and that:

(1) Has improvised rather than permanent facilities or

EQUIPMENT for accomplishing functions such as

handwashing, FOOD preparation and protection, FOOD

temperature control, WAREWASHING, providing DRINKING

WATER, waste retention and disposal, and insect and

rodent control; or

(2) Has inexperienced FOOD EMPLOYEES.

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood DR
City/State/Zip:	Roscommon, MI 48653
Telephone:	5177197919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name:	Karla Horne
Organization:	Great Lakes Conference on Food Protection
Address:	525 Allegan StPO Box 30017
City/State/Zip:	Lansing, MI 48909
Telephone:	2313570727
E-mail:	hornek@michigan.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 I-048

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: 2012 I-038; new or additional information has been included or attached.

Title:

Inclusion of Inspection Result Posting in Food Code

Issue you would like the Conference to consider:

Rigorous health inspections are a critical component of an effective food safety system. The 2013 FDA Food Code recognizes that the results of restaurant inspections are public documents and should be available for public review. However, complex rules regarding public access create difficulty for consumers who wish to consider inspection results.

Public Health Significance:

Consumer access to the results of these inspections plays an important role in maintaining the efficacy and credibility of the inspection system, and allows consumers to consider critical food safety information when making restaurant choices. Recent data show that nearly half of all foodborne illnesses are contracted from food prepared outside the home. Although food establishments are routinely inspected, the results of those inspections are not readily available to consumers-who thus have no way of minimizing their risk by knowing how an establishment performed on its most recent food safety assessment. This proposal was submitted previously to CFP and since that time, numerous jurisdictions have adopted requirements for restaurants to post inspection results and published articles highlighting this practice's benefits to public health *(see supporting attachments to this Issue)*.

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):

8-4 Inspection and Correction of Violations

<u>8-403.51 Public Posting.</u>

The REGULATORY AUTHORITY shall make available the results of the inspection report by requiring the timely posting of the most recent inspection results in the entrance, front window, or similarly prominent consumer-accessible area of the FOOD ESTABLISHMENT. Results may be posted in the form of a letter grade, numerical score, or other form as determined by the REGULATORY AUTHORITY.

Submitter Information:

Name:	David W. Plunkett
Organization:	Center for Science in the Public Interest
Address:	1220 L Street NW Suite 300
City/State/Zip:	Washington, DC 20005
Telephone:	2027778319
E-mail:	dplunkett@cspinet.org

Supporting Attachments:

- "Letter Grading and Transparency Promote Restaurant Food Safety in New York"
- "Study of Retail Food Establishment Inspection Scoring and Grading Systems"
- "Impact of a Letter-Grade Program on Restaurant Sanitary Conditions (Part I)"
- "Impact of a Letter-Grade Program on Restaurant Sanitary Conditions (Part 2)"
- "Poster: Feasibility of Restaurant Letter Grading in Utah"

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.

DIRECT FROM CDC ENVIRONMENTAL HEALTH SERVICES BRANCH

Wendy McKelvey, MS, PhD

Melissa R. Wong, MPH

Bailey Matis, MPH

New York City Department of Health and Mental Hygiene

Letter Grading and Transparency Promote Restaurant Food Safety in New York City

Editor's Note: NEHA strives to provide up-to-date and relevant information on environmental health and to build partnerships in the profession. In pursuit of these goals, we feature a column from the Environmental Health Services Branch (EHSB) of the Centers for Disease Control and Prevention (CDC) in every issue of the *Journal*.

In these columns, EHSB and guest authors share insights and information about environmental health programs, trends, issues, and resources. The conclusions in this article are those of the author(s) and do not necessarily represent the views of CDC.

Wendy McKelvey is principal investigator for two CDC grants that promote environmental public health—one from the Environmental Health Specialists Network (EHS-Net) and the other from the Environmental Public Health Tracking Program. Melissa Wong had been project director for the NYC EHS-Net Program for the past five years. Bailey Matis is the current project director.

Each year in New York City (NYC), more than 6,000 people end up hospitalized for foodborne illness (New York City Department of Health and Mental Hygiene, 2014). Although the proportion of illness caused by food prepared away from the home is uncertain, the food service setting is associated with 68% of nationally reported foodborne illness outbreaks where food was prepared in one place (Gould et al., 2013). New Yorkers eat out nearly one billion times a year (New York City Department of Health and Mental Hygiene, 2011), and two-thirds eat meals from a restaurant, deli, coffee shop, or bar at least once per week, so the potential public health impact of unsafe food handling practices in NYC restaurants is enormous (Wong et al., 2015).

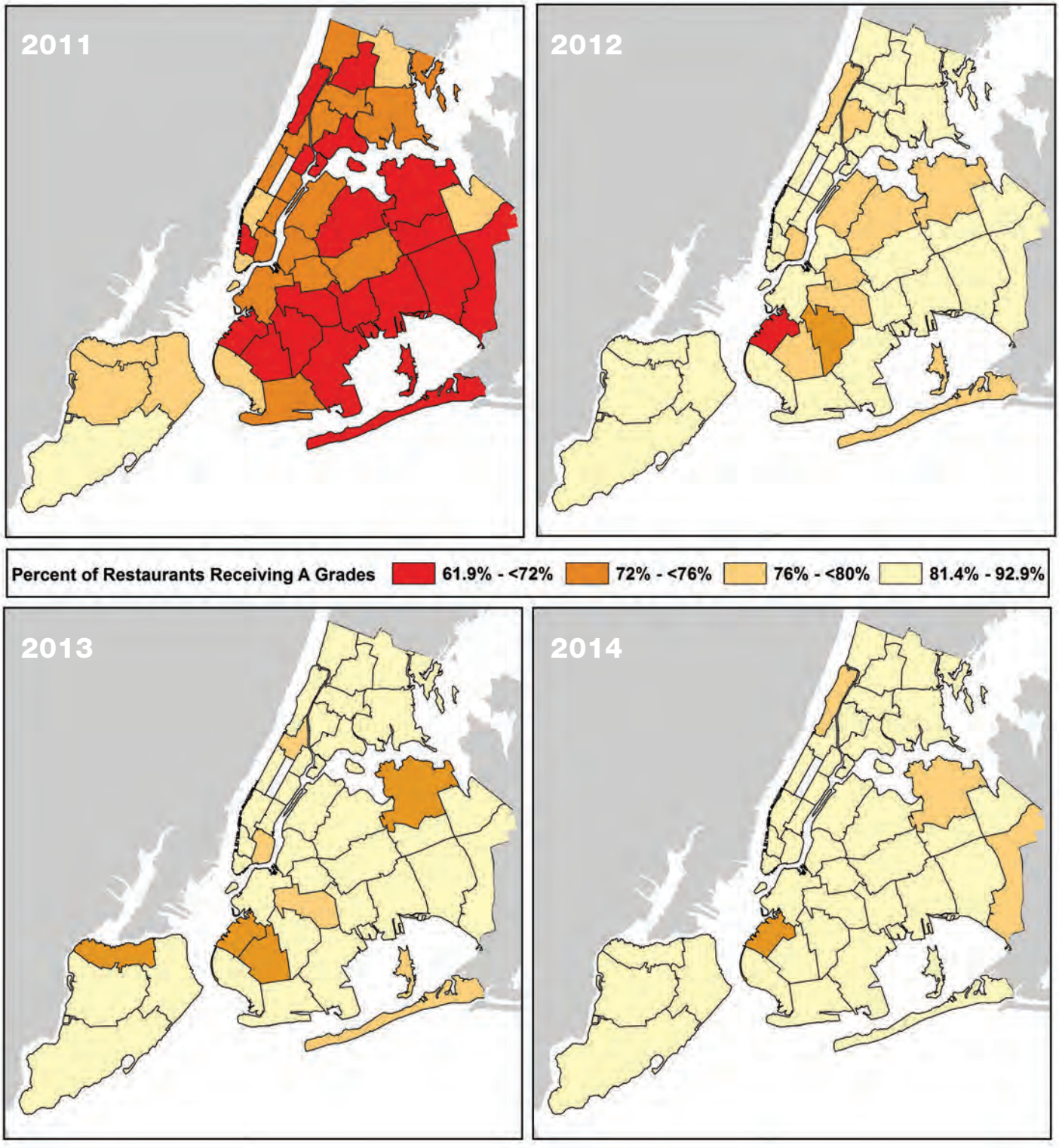
Improving food handling practices across the approximately 24,000 restaurants that operate in NYC on any given day can reduce risks of foodborne illness. Not having a certified kitchen manager on site, employees working while ill, limited food handler knowledge of food safety, and food workers touching food with their bare hands have been identified as factors that increase the risk of restaurant-related foodborne illness (Gould et al., 2013; Hedberg et al., 2006). In an effort to prevent these and other unsafe food handling practices, the New York City Department of Health and Mental Hygiene launched the restaurant letter grading program in July 2010. The program requires restaurants to post a letter grade that reflects their most recent sanitary inspection results in a visible window location. It also targets the poorest performers with more frequent inspections.

The premise of the NYC letter grading program is that consumer access to inspection results will encourage restaurant operators to better comply with food safety rules. In addition to a conspicuously posted letter grade, the NYC Health Department has increased the transparency of restaurant inspection results by making them available in detail on a searchable Web site and a free smartphone app ("ABCEats," available for download on iTunes and Google Play). Both of these data resources provide maps and street views of establishments and allow users to filter restaurants by zip code, cuisine type, and grade.

The NYC letter grading program also supports industry by using a dual inspection approach that allows restaurants to improve before being graded. If a restaurant does not earn an A grade on its initial unannounced inspection, it receives a reinspection approximately 7–30 days later, at which point the grade is issued. Restaurants that earn an A grade at initial or reinspection do not pay fines for sanitary violations cited. Those that do not earn an A grade have the

FIGURE **1**

Percentage of Restaurants Achieving A Grades by New York City Neighborhood, 2011–2014



right to contest their grade and fines at an administrative tribunal.

As a part of the Centers for Disease Control and Prevention's Environmental Health Specialists Network (EHS-Net) cooperative agreement, we evaluated the impact of the NYC restaurant letter grading program on health hazard reduction (Wong et al., 2015). We tracked scores on initial inspection before and after grading began in July 2010 and measured a 35% increase in the probability of a restaurant practicing A-grade hygiene by 2013. Specifically, we observed more food safety certified managers on site, better worker hygiene, more restaurants with proper hand washing stations, and fewer restaurants with mice. We also measured public response to restaurant letter grades in two population-based telephone surveys conducted 12 and 18 months after the program began. In both surveys, more than 90% of respondents said they approved of restaurant letter grading, and 88% said they considered the grades in dining decisions.

Restaurant sanitary conditions have been steadily improving in NYC since implementation of letter grading (Figure 1). In 2011, 72% of restaurants were posting A grades, and by 2014, after four years, 85% were posting A grades (New York City Department of Health and Mental Hygiene, 2015). Findings from our evaluation suggest that increasing transparency of restaurant inspection results and providing the public with these results in the form of an easily interpreted letter grade posted at the point of consumer decision making is an effective regulatory approach.

Corresponding Author: Wendy McKelvey, Director of Environmental Health Surveillance, Bureau of Environmental Surveillance and Policy, New York City Department of Health and Mental Hygiene, 125 Worth St., 3rd floor, CN-34E, New York, NY 10013.
E-mail: wmckelve@health.nyc.gov.

References

Gould, L.H., Rosenblum, I., Nicholas, D., Phan, Q., & Jones, T.F. (2013). Contributing factors in restaurant-associated foodborne disease outbreaks, FoodNet sites, 2006 and 2007. *Journal of Food Protection, 76*(11), 1824–1828.

Gould, L.H., Walsh, K.A., Vieira, A.R., Herman, K., Williams, I.T., Hall, A.J., & Cole, D. (2013). Surveillance for foodborne disease outbreaks—United States, 1998–2008. *Morbidity and Mortality Weekly Report Surveillance Summaries, 62*(SS 2), 1–34.

Hedberg, C.W., Smith, S.J., Kirkland, E., Radke, V., Jones, T.F., & Selman, C.A. (2006). Systematic environmental evaluations to identify food safety differences between outbreak and nonoutbreak restaurants. *Journal of Food Protection, 69*(11), 2697–2702.

New York City Department of Health and Mental Hygiene. (2011). *Community health survey*. New York: Author. Retrieved from http://www.nyc.gov/html/doh/html/data/survey.shtml

New York City Department of Health and Mental Hygiene. (2014). *Foodborne illness hospitalizations among New York City residents, 2000–2012* (unpublished data).

New York City Department of Health and Mental Hygiene. (2015). *NYC environment and health data portal*. Retrieved from http://www.nyc.gov/health/trackingportal

Wong, M.R., McKelvey, W., Ito, K., Schiff, C., Jacobson, J.B., & Kass, D. (2015). Impact of a letter-grade program on restaurant sanitary conditions and diner behavior in New York City. *American Journal of Public Health, 105*(3), e81–e87.

Did You Know?

The U.S. Environmental Protection Agency's third annual SepticSmart Week is September 21–25. Check out www.epa.gov/septicsmart for planned activities and valuable educational materials.

NACCHO
National Association of County & City Health Officials
The National Connection for Local Public Health

[RESEARCH BRIEF]
September 2014

Study of Retail Food Establishment Inspection Scoring and Grading Systems

Introduction

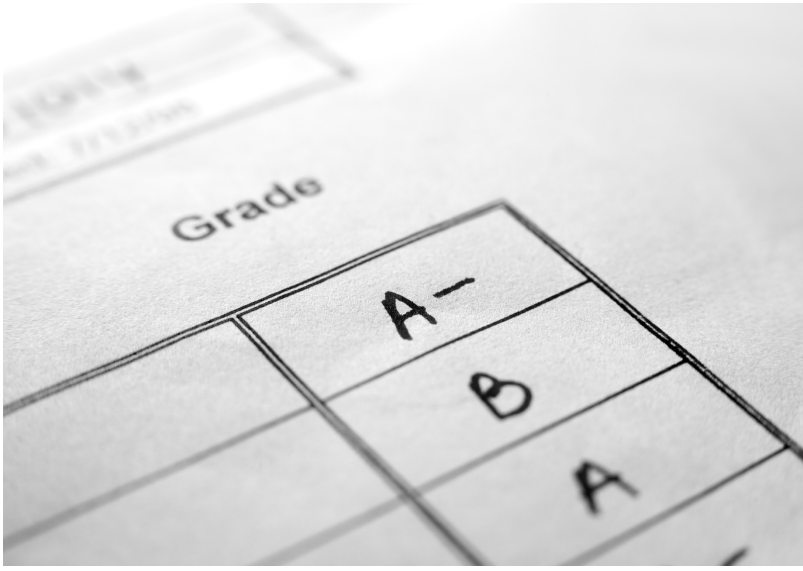
Local health departments (LHDs) play a major role in ensuring the food people eat every day is safe. In the United States, approximately 3,000 entities regulate food safety. The vast majority of these entities are LHDs, with more than 75% of the 2,800 LHDs in the United States educating, inspecting, or licensing retail food establishments.

Through a cooperative agreement with the Food and Drug Administration (FDA), in 2012, the National Association of County and City Health Officials (NACCHO) studied the way that LHDs use scores or grades to convey the results of their retail food establishment[1] inspections.

While food establishment inspection grading and scoring (FISG) systems vary throughout the United States, generally numerical scores, letters, colors, graphics/symbols, or any combination thereof are used to systematically quantify or illustrate the inspection performance of a retail food establishment. Gaining a better understanding of the use, composition, successes, and shortcomings of FISG systems could help additional LHDs implement their own systems. This research brief presents findings from NACCHO's survey to learn more about retail FISG systems implemented by LHDs, including the following:

- National prevalence of LHDs that assign a score or grade to an inspection of licensed food establishments;
- Distribution of different types of scoring and grading systems;
- Relationship between scoring/grading systems and other food safety practices; and
- Potential areas for further research or in-depth case studies.

Local health departments play a major role in ensuring the food people eat every day is safe.



Methodology

Informed by the NACCHO-FDA Food Safety Advisory Group, NACCHO developed, piloted, and executed an electronic quantitative survey instrument in 2012 to a sample of 2,565 LHDs. A stratified random sample of 531 LHDs was selected from this sample. The strata included 48 states and the District of Columbia (excluding Rhode Island and Hawaii). The sample included approximately 20% of LHDs from each state.

The survey included key elements and questions intended to ascertain the following:

- Presence of any scoring or grading system;
- Type of score or grade assigned (e.g., numerical score, letter score, color, or graphic);
- Communication to the public;
- Perceived impact on food safety;
- Implementation year and changes since implementation;
- Regulations, licensing, inspections, and penalties; and
- Geographic barriers and staffing challenges.

Findings and Results

General Information

The survey had a response rate of 39% (208).[2] Non-response includes both survey non-contact[3] and refusal;[4] differentiation between these non-response types is not possible. Among the responses, 183 were from LHDs in states where statewide requirements for how inspections were scored or graded were not present. Twenty-five responses were from states with a statewide requirement for how inspections were scored or graded.

To better understand the prevalence of states with statewide inspection scoring or grading systems, NACCHO contacted the National Conference of State Legislatures (NCSL) to assist with the post-hoc identification. NCSL identified 10 states with a statewide policy regarding how inspection scores or grades were determined and communicated. Fifty LHDs that did not respond to the survey were located in one of those 10 states, so NACCHO concluded that the non-respondents also had a statewide system; however, these LHDs were not imputed into the results.

Prevalence of FISG Systems

NACCHO asked respondents to indicate their use of FISG systems. Nearly 38% (79) of respondents answered "yes" when asked if their LHD jurisdiction, either entirely or within some political subunits, provided licensed food establishments an overall food grade, score, or graphic after an inspection.

Type of FISG System in Use

The following findings were true of the 79 LHDs that responded that they used an FISG system (Figure 1):[5]

- 75% indicated use of a numerical score, 4.5 times greater than the next most frequently used type—letter grade, which 16.5% of respondents reported using;
- 10% indicated use of a color or other graphic to describe an inspection result;
- 11% indicated use of another, unspecified type of FISG system;
- 77% indicated using only one FISG type; and
- 16% indicated using two or more FISG types in combination.

75% of respondents indicated use of a *numerical score*, 4.5 times greater than the next most frequently used type—*letter grade*

Communication

NACCHO asked respondents to provide data on the methods used to communicate grading or scoring of food establishment inspections to the public. The questionnaire allowed respondents to select more than one method of communication. The following findings were true of the 79 respondents who reported using a scoring or grading system:

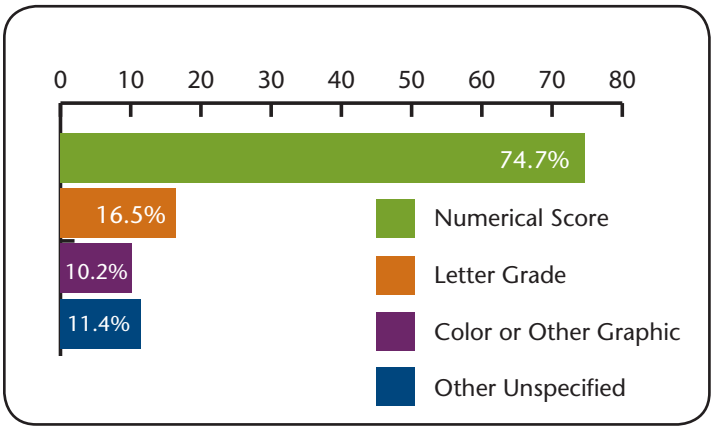
- 62% indicated that the LHD made inspection scores or grades available upon request by the public, making this method the most prevalent among those investigated;
- 41% indicated that inspection scores or grades appeared in local print or broadcast media;
- 37% indicated that inspection scores or grades were made available on the Internet; and
- 35% indicated that inspection scores or grades were posted on the premises of the food establishment.

Perceptions

NACCHO asked respondents to provide information about their perception of how FISG systems impacted food safety within the regulated establishment and the manner in which regulatory inspections were conducted. Respondents were equally divided that FISG systems impacted the manner in which inspectors conducted inspections. The following findings were true of the 79 respondents who reported use of a FISG system:

- 67% perceived that an FISG system had no impact on how operators shared information during an inspection;
- 66% either agreed (52%) or strongly agreed (14%) that an assigned score or grade was perceived as correlated with an establishment's control of risk factors;
- 59% perceived that an FISG system had impacted how much attention operators paid to food safety; and
- 58% perceived an improved impact on food safety.

FIGURE 1. TYPE OF FISG SYSTEM IN USE



n=79; percentages do not total 100 because respondents may have selected more than one choice

Next Steps and Future Research Questions

NACCHO plans to conduct six to eight case studies with LHDs to explore key questions and hypotheses determined through the data analysis. LHDs selected for case studies will vary based on perceived impact of FISG system, maturity of FISG system, public access to grades or scores, and degree of urbanization, among other considerations.

NACCHO will develop the case studies through record review, open-ended questions, and telephone interviews with key informants (e.g., food establishment operators, board of health representatives, municipality supervisors, and LHD professionals). Through case studies, NACCHO intends to explore further the following questions:

- Does any particular approach to scoring and grading have a greater impact than others on the control of foodborne illness risk factors in retail food establishments?
- Does any particular approach to scoring and grading have a greater impact than others on consumer attitudes and behavior?
- Does the presence of an FISG system affect the behavior of health inspectors?
- Does the presence of an FISG system affect the behavior of establishment operators?
- Does the method used to communicate inspection results to the public affect the perceived impact or value of FISG systems?
- What motivates LHDs to employ FISG systems?
- Are LHDs in areas with strong local media more likely to use FISG systems or report violation results openly and routinely to the public?

[RESEARCH BRIEF]

September 2014

Notes

1. A retail food establishment generally refers to operations that (1) store, prepare, package, serve, vend food directly to the consumer; or (2) provide food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank.
2. With an assumed population of 2,565 LHDs, a response sample of 335 was needed to reach a confidence level of 95% and confidence interval of +/-5.
3. Inability to contact units selected for the survey.
4. Refusal of selected unit to participate and provide some or all of the information requested.
5. To have a requirement for scoring and grading and imputed as affirmative responses when asked if their LHD jurisdiction, either entirely or within some political subunits, provided licensed food establishments an overall food grade, score, or graphic after an inspection.

Acknowledgments

This project was made possible through the support of the Food and Drug Administration, cooperative agreement #5U50FD004334-04. NACCHO is grateful for this support. The views expressed within do not necessarily represent the official views of the sponsor.

FOR MORE INFORMATION, PLEASE CONTACT:

Justin Snair, MPA
Senior Program Analyst
Critical Infrastructure & Environmental Health Security
jsnair@naccho.org

Amy Chang, MS
Program Analyst
Environmental Health
achang@naccho.org

Jennifer Li, MHS
Director
Environmental Health/Health and Disability
jli@naccho.org

Andrew Roszak, JD, MPA, EMT-P
Senior Director
Environmental Health, Pandemic Preparedness,
and Catastrophic Response
aroszak@naccho.org

NACCHO
National Association of County & City Health Officials
The National Connection for Local Public Health

Public Health
Prevent. Promote. Protect.

www.naccho.org

The mission of the National Association of County and City Health Officials (NACCHO) is to be a leader, partner, catalyst, and voice with local health departments.

1100 17th St, NW, 7th Floor Washington, DC 20036

P 202-783-5550 F 202-783-1583

Study of Retail Food Establishment
Inspection Scoring and Grading Systems

Appendix A—Univariate Data Tables

Uses Food Grading and Scoring System			
	Freq.	**Percent**	**Cum.**
No	129	62.02	62.02
Yes	79	37.98	100.00
Total	208	100.00	

Uses Letter Grade			
	Freq.	**Percent**	**Cum.**
No	66	83.54	83.54
Yes	13	16.46	100.00
Total	79	100.00	

Uses Numerical Score			
	Freq.	**Percent**	**Cum.**
No	20	25.32	25.32
Yes	59	74.68	100.00
Total	79	100.00	

Uses Other Image			
	Freq.	**Percent**	**Cum.**
No	78	98.73	98.73
Yes	1	1.27	100.00
Total	79	100.00	

Uses Other Graphic			
	Freq.	Percent	Cum.
No	72	91.14	91.14
Yes	7	8.86	100.00
Total	79	100.00	

Uses Other			
	Freq.	**Percent**	**Cum.**
No	70	88.61	88.61
Yes	9	11.39	100.00
Total	79	100.00	

Number of Types Used in Combination			
	Freq.	**Percent**	**Cum.**
0	5	6.33	6.33
1	61	77.22	83.54
2	11	13.92	97.47
3	2	2.53	100.00
Total	79	100.00	

Assigned Score or Grade is Correlated with Establishment Control of Risk Factors			
	Freq.	Percent	Cum.
Strongly Agree	10	13.70	13.70
Agree	38	52.05	65.75
Neither	15	20.55	86.30
Disagree	7	9.59	95.89
Strongly Disagree	3	4.11	100.00
Total	73	100.00	

System has Impacted How Much Operators Pay Attention to Food Safety			
	Freq.	Percent	Cum.
No	32	40.51	40.51
Yes	47	59.49	100.00
Total	79	100.00	

System has Impacted How Operators Share Information during Inspections			
	Freq.	Percent	Cum.
No	53	67.09	67.09
Yes	26	32.91	100.00
Total	79	100.00	

System has Impacted Manner in which Inspectors Conduct Inspections			
	Freq.	Percent	Cum.
No	39	49.37	49.37
Yes	40	50.63	100.00
Total	79	100.00	

Perceived Impact on Food Safety			
	Freq.	Percent	Cum.
No Impact	4	5.56	5.56
Improved Impact	42	58.33	63.89
Unclear Impact	26	36.11	100.00
Total	79	100.00	

Year Implemented Food Grading and Scoring System			
	Freq.	Percent	Cum.
Before 2000	49	67.12	67.12
2000	1	1.37	68.49
2001	3	4.11	72.60
2002	1	1.37	73.97
2006	1	1.37	75.34
2007	2	2.74	78.08
2008	4	5.48	83.56
2009	2	2.74	86.30
2010	3	4.11	90.41
2011	3	4.11	94.52
2012	4	5.48	100.00
Total	73	100.00	

Inspection Report Posted on Premises			
	Freq.	**Percent**	**Cum.**
No	50	63.29	63.29
Yes	29	3.71	100.00
Total	79	100.00	

Inspection Report Available upon Request			
	Freq.	**Percent**	**Cum.**
No	11	13.92	13.92
Yes	68	86.08	100.00
Total	79	100.00	

Inspection Report Available on the Internet			
	Freq.	**Percent**	**Cum.**
No	53	67.09	67.09
Yes	26	32.91	100.00
Total	79	100.00	

Grades or Scores Posted on the Premises			
	Freq.	**Percent**	**Cum.**
No	51	64.56	64.56
Yes	28	35.44	100.00
Total	79	100.00	

Grades or Scores Available upon Request			
	Freq.	**Percent**	**Cum.**
No	30	37.97	37.97
Yes	49	62.03	100.00
Total	79	100.00	

Grades or Scores Available on the Internet			
	Freq.	**Percent**	**Cum.**
No	50	63.29	63.29
Yes	29	36.71	100.00
Total	79	100.00	

Grades, Scores, Violations Appear in Local Print or Broadcast Media			
	Freq.	**Percent**	**Cum.**
No	47	59.49	59.49
Yes	32	40.51	100.00
Total	79	100.00	

Food Safety

Impact of a Letter-Grade Program on Restaurant Sanitary Conditions and Diner Behavior in New York City

Melissa R. Wong, MPH, Wendy McKelvey, PhD, Kazuhiko Ito, PhD, Corinne Schiff, JD, J. Bryan Jacobson, MPH, and Daniel Kass, MSPH

Objectives. We evaluated the impact of the New York City restaurant letter-grading program on restaurant hygiene, food safety practices, and public awareness.

Methods. We analyzed data from 43 448 restaurants inspected between 2007 and 2013 to measure changes in inspection score and violation citations since program launch in July 2010. We used binomial regression to assess probability of scoring 0 to 13 points (A-range score). Two population-based random-digit-dial telephone surveys assessed public perceptions of the program.

Results. After we controlled for repeated restaurant observations, season of inspection, and chain restaurant status, the probability of scoring 0 to 13 points on an unannounced inspection increased 35% (95% confidence interval [CI] = 31%, 40%) 3 years after compared with 3 years before grading. There were notable improvements in compliance with some specific requirements, including having a certified kitchen manager on site and being pest-free. More than 91% (95% CI = 88%, 94%) of New Yorkers approved of the program and 88% (95% CI = 85%, 92%) considered grades in dining decisions in 2012.

Conclusions. Restaurant letter grading in New York City has resulted in improved sanitary conditions on unannounced inspection, suggesting that the program is an effective regulatory tool. (*Am J Public Health.* 2015;105:e81–e87. doi:10.2105/AJPH.2014.302404)

Restaurant food safety is increasingly important, with almost half of the US food dollar spent on restaurant food[1] and about one third of caloric intake from foods prepared outside the home.[2] In New York City (NYC), residents eat out nearly 1 billion times each year.[3] Although most diners do not get sick, foodborne pathogens cause millions of preventable illnesses in the United States annually.[4] The exact proportion of restaurant-attributable foodborne illness is unknown, but national surveillance in the United States found that two thirds of reported foodborne outbreaks from 1998 through 2008 occurred in the restaurant or deli setting,[5] and consumption of food prepared outside the home has been linked to an increased risk of sporadic foodborne diseases.[6]

Regular inspection of restaurants for food safety is a core function of local health authorities, guided by the US Food and Drug Administration (FDA) Food Code.[7] Although all states have sanitation codes modeled after the FDA Food Code,[8] implementation methods vary by jurisdiction. The NYC Department of Health and Mental Hygiene (hereafter, Health Department) is charged with inspecting restaurants, coffee shops, bars, nightclubs, employee or university cafeterias, bakeries, and fixed-site food stands (hereafter, restaurants). Its inspection program uses a scoring system to measure compliance with the NYC Health Code, which is updated regularly to maintain consistency with the FDA Food Code and the New York State Sanitary Code. Restaurants are entitled to an impartial review of inspection results by an administrative tribunal, which can improve an assigned score and reduce associated monetary fines.

Before letter grading, the Health Department aimed to inspect restaurants at least once per year and imposed monetary fines for violations cited at inspections. Inspection results were available on the Health Department Web site. However, financial disincentives and the Web site posting were insufficient to drive improvements across the industry, with most restaurants cited for multiple public health hazards. Mean inspection scores and restaurant sanitary conditions were stagnant (D. Kass, email communication, February 2009).

In an effort to improve restaurant food safety and increase transparency of inspection information, the Health Department launched its letter-grade program on July 27, 2010. The program uses public disclosure of inspection scores in the form of letter grades at point of decision-making; a more finely tuned, risk-based inspection schedule; and financial incentives to encourage high food-safety standards. It began after an 18-month planning process that included a public announcement of the intent to begin letter grading; meetings with restaurant industry representatives, food safety experts, and regulators from a jurisdiction with a restaurant sanitary grade program; promulgation of 2 regulations subject to notice and comment; and training and education for restaurateurs. The process was covered by the media, and by July 2010, restaurateurs were aware of the program and anticipating the launch.[9,10]

We evaluated the impact of the restaurant letter-grade program by assessing (1) hygiene and food-safety practices as characterized by inspection outcomes before and after program implementation and (2) public response to the program measured by 2 population-based telephone surveys.

METHODS

The NYC restaurant inspection program has been using a point system to score inspections since 2005.[11] Presence and severity of violations contribute to an inspection score. Under the grading program, an inspection score of 0 to 13 points is in the A-range; 14 to 27 points is in the B-range; and 28 or more points is in the C-range. Restaurants scoring 0 to 13 points on the first inspection of their inspection cycle (initial inspection) are issued an A grade. Restaurants not earning an A grade on initial

inspection receive a full reinspection no less than 7 days later. The grade card is issued based on the reinspection score. The initial inspection and any reinspection together are an "inspection cycle." Upon completion of an inspection cycle, there is an interval before the next cycle. Restaurants earning an A grade on initial inspection of a cycle are inspected in 11 to 13 months. Restaurants scoring 28 or more points on either initial or reinspection of a cycle have a 3- to 5-month interval. The remaining restaurants scoring 14 to 27 points on either initial inspection or reinspection of a cycle have a 5- to 7-month interval.

Before the grading program was launched, the Health Department aimed to conduct at least 1 inspection in all restaurants annually. Restaurants scoring 28 or more points received a follow-up compliance inspection about 1 month later. A score of 28 points or higher could result in a restaurant being placed on a twice-yearly inspection schedule. Administrative violations (e.g., expired permit) were included in the scoring system before implementation of letter grading, but they are not included under the grading program.

Health Department inspectors cite violations with standardized forms on handheld computers. They also collect data on restaurant descriptors such as cuisine, service method to customer (e.g., wait service, counter service), venue description (e.g., restaurant, bar), and chain status (15 or more national outlets). Inspectors are trained in the classroom and under an experienced inspector in the field before they are allowed to work independently.

Data Analysis

We analyzed preadjudicated inspection scores and points for violations cited on initial or reinspections conducted between July 27, 2007, and July 26, 2013. We subtracted administrative violation points from pregrading inspection scores to make pregrading scores more comparable with postgrading.

We calculated measures that used "most recent initial inspection" among restaurants in business as of July 27 in each year. "Most recent initial inspection" is used in crude analyses to depict a restaurant's usual sanitary conditions closest to the specified period end date. We consider initial inspections of a cycle the best indicator of usual sanitary conditions because they occur at the longest interval after the previous inspection and they are unannounced to operators. Crude metrics were percentage of restaurants scoring in the A-, B-, or C-range; percentage scoring 40 points or higher (85th percentile score on initial inspection in the program's first year); median inspection score; and average points for specific violations or violation groups. Average violation points characterize both presence and severity of violations over time.

We assessed performance on reinspection of a cycle by calculating percentage of restaurants scoring in the A-range on reinspection among those with B-range or C-range initial inspection scores. We tracked the percentage of restaurants with A, B, or C grades on a cycle that went on to earn an A grade on their next cycle.

We modeled the probability of scoring 0 to 13 points (A-range score) across all initial inspections in all 43 448 restaurants by fitting a binomial regression model that included 5 indicators of time: 13 to 36 months before grading (reference), 0 to 12 months before grading, 0 to 12 months after grading, 13 to 24 months after grading, and 25 to 36 months after grading. We fit restaurant random intercepts to account for repeated observations and variation across individual restaurants. We used indicator variables to adjust for potential confounding by season of inspection (January–March, April–June, July–September, October–December), because pest and holding temperature–related violations increase during the warmest season and the distribution of inspection date varied over time.[12] We did not think chain restaurant status was a potential confounder because the distribution before and after grading remained constant, but we included it to estimate the probability that a chain restaurant scored 0 to 13 points relative to a nonchain. We also ran the fully adjusted model for the subset of restaurants with inspections in the first and last year of the study ($n = 7059$) to evaluate whether improvement differed among the most stable restaurants.

To assess whether an excess or deficit in the frequency of inspection scores around grade cut-offs could have biased our results, we estimated the underlying (unbiased) smooth frequency distribution of scores by fitting a generalized additive model with penalized splines[13] and used the smoothed distribution to estimate the "bias-corrected" percentage of A-range scores in the postgrading period. The percentage of A-range scores across initial inspections in the postgrading period dropped only slightly from 30.7% to 27.4% upon correction. We therefore deemed it unnecessary to correct for potential bias resulting from an excess or deficit of scores around grade cut-offs.

We conducted analyses in SQL Management Studio 2008 R2 (Microsoft, Redmond, WA), SAS version 9.2 (SAS Institute, Cary, NC), and R version 3.0.1 (R Project, Vienna, Austria).

Public Perception Surveys

The Health Department worked with Baruch College Survey Research (BCSR) to conduct 2 English/Spanish bilingual telephone surveys in July 2011 and February 2012 to assess public perceptions of the grading program. Landline samples on a random-digit-dial design and respondents were selected randomly within the household; cell phones were randomly selected from a mobile number database for NYC county telephone numbers. Respondents were screened for NYC residency and age of 18 years or older.

In July 2011 and January 2012, 502 and 511 adults completed surveys, respectively. Based on the American Association for Public Opinion Research (AAPOR) standard definitions,[14] response rates were 26% and 22%, and cooperation rates were 60% and 51%, respectively. AAPOR response rates incorporate estimates of the proportion of respondents of unknown eligibility that might have been eligible. Data were weighted to the US Census 2009 American Community Survey to ensure the samples represented the age, gender, race, Hispanic origin, and borough distribution of NYC adults. Confidence intervals (CIs) for proportions were calculated with SAS version 9.3 (SAS Institute, Cary, NC).

RESULTS

Approximately 24 000 restaurants operate in NYC on any given day. A total of 43 892 restaurants were in business at some point between July 2007 and July 2013, and 46% (20 005) of those were in operation at some point both before and after grading. During the 3 years before grading, 31 226 restaurants

operated. Of those, 41% were newly opened for business and 36% went out of business. In the 3 years since grading began, 32 700 restaurants operated. Of those, 39% were newly opened for business and 27% went out of business (Table 1). The distribution of restaurant types was nearly identical before and since grading was instituted.

Inspections

The percentages of A-range scores on recent unannounced initial inspection were similar during the 3 years before grading and have improved since grading. The proportion of restaurants with A-range scores went from 28% in July 2008 to 31% in July 2010, with an additional increase to 46% by July 2013 (Figure 1). With more restaurants achieving A-range scores after grading, the median initial inspection score went from 21 points as of July 2008 and 20 points as of July 2010 to 17 points as of July 2013.

After we controlled for chain status, season of inspection, and correlation within restaurants, the probability of attaining an A-range score on an unannounced initial inspection among all restaurants increased 26% (success ratio [SR] = 1.26; 95% CI = 1.22, 1.31) by the 2-year mark (Table 2). The SR increased at the 3-year mark to 1.35 (95% CI = 1.31, 1.40). Compared with the warmest season (July–September), the other seasons exhibited higher SRs, with the highest (SR = 1.30; 95% CI = 1.26, 1.35) in the coldest season (January–March). The SRs for the subset of restaurants in business during the whole period (data not shown in Table 2) were slightly higher—1.32 (95% CI = 1.25, 1.40) and 1.41 (95% CI = 1.33, 1.49) for the 2- and 3-year mark, respectively. Chain restaurants showed a high SR for both all restaurants (SR = 3.46; 95% CI = 3.31, 3.61) and the subset of restaurants operating during the whole period (SR = 3.79; 95% CI = 3.54, 4.07).

TABLE 1—Restaurant Characteristics Before and After Grading: New York City, NY, 2007–2013

Characteristic	Operating Between July 27, 2007, and July 26, 2010 (n = 31 226), No. (%)	Operating Between July 27, 2010, and July 26, 2013 (n = 32 700), No. (%)
Borough		
Bronx	3 267 (10)	3 222 (10)
Brooklyn	7 538 (24)	8 047 (25)
Manhattan	11 828 (38)	12 584 (38)
Queens	7 307 (23)	7 552 (23)
Staten Island	1 286 (4)	1 295 (4)
Chain restaurants		
Yes	3 393 (11)	3 627 (11)
No	27 833 (89)	29 073 (89)
Restaurant type[a]		
Wait service restaurant or diner	8 589 (31)	10 564 (33)
Quick-service establishment with take-out or limited seating	12 706 (46)	14 443 (45)
Baked goods, ice cream, or cafe only	3 539 (13)	4 050 (13)
Bar or wine bar	1 206 (4)	1 289 (4)
Cafeteria and banquet-style service or deli buffet	992 (4)	1 236 (4)
Food service at attraction	534 (2)	662 (2)
Missing	3 660	456

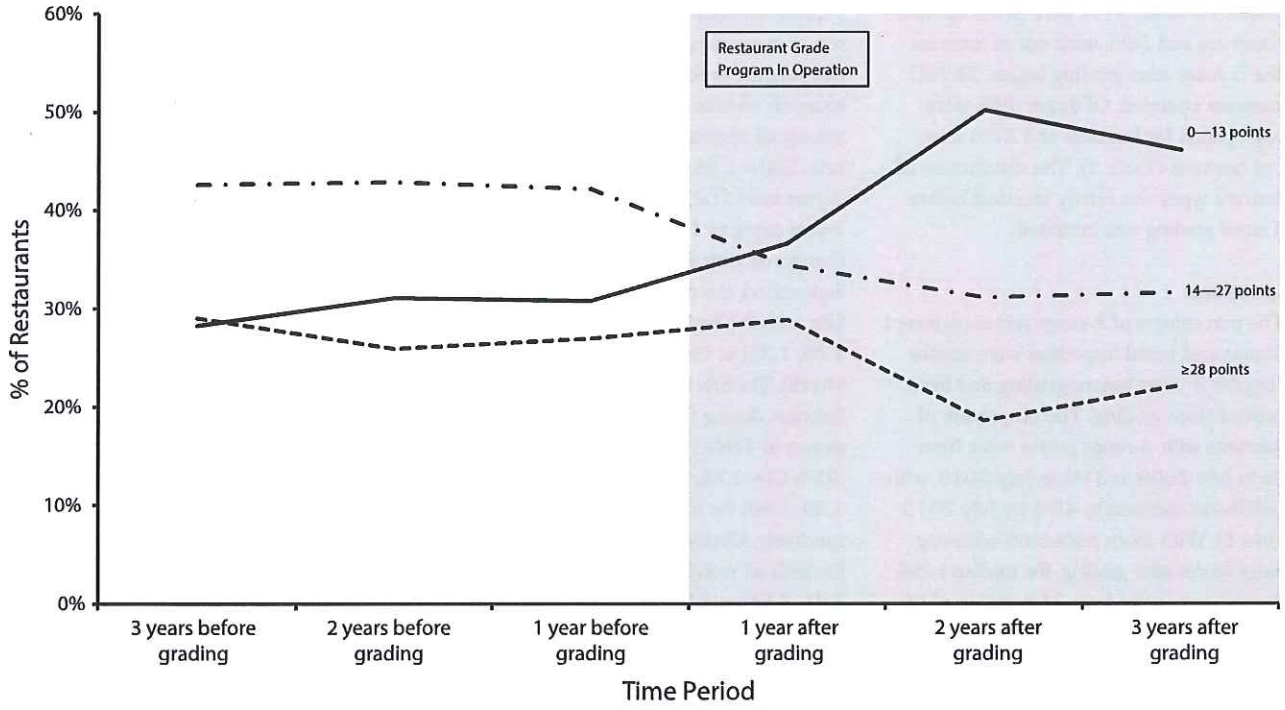
Note. The city restaurant letter-grading program began on July 27, 2010. All gradable restaurants (or pregrading equivalent) in operation between July 27, 2007, and July 26, 2013, included.
[a]Percentage excludes missing values.

Certain critical food safety violations contributed fewer average points in July 2013 compared with the 2 years before grading (Table 3). In July 2012, the average points given to all restaurants declined substantially for evidence of any type of vermin (rats, mice, flies, or roaches), inadequate hand-washing facilities, and no food safety–certified supervisor on-site. Points given for improper storage or use of equipment or utensil and inadequate food worker hygiene also declined to a lesser extent. These overall point reductions were maintained in July 2013. Meanwhile, average points increased for improperly maintained food contact surfaces, and the points given for inadequate protection of food from contamination, cross contamination, and holding food at improper temperatures increased slightly (Table 3). Although average points for temperature and cross-contamination violations increased slightly, average severity of cited violations decreased (data not shown).

We observed inverse trends for C-range scores on recent initial inspection over time. The proportion of C-range scores decreased from 29% as of July 2008 and 27% as of July 2010 to 22% as of July 2013 (Figure 1). The percentage of extreme C-range (≥ 40 points)–scoring restaurants dropped from 14% in the year before grading to 13% in July 2011, dropping to 7% in July 2012, and increasing to 9% in July 2013, while the 80th percentile decreased from 36 points in July 2008 to 30 points in July 2013.

Three years after grading, more restaurants corrected unsanitary conditions observed on initial inspection of most recent inspection cycle. In July 2013, 45% of restaurants requiring reinspection earned A grades upon reinspection, up from 34% in July 2011. Likewise, there was a decrease in the proportion of poorly performing restaurants that did not improve on reinspection (28+ point scores on both initial and reinspection). The proportion of restaurants that scored poorly on both initial and reinspection dropped from 28% as of July 2009 to 22% as of July 2013.

When we tracked performance from inspection cycle to inspection cycle, we found that 80% and 79% of A-grade restaurants maintained their A grade on their next cycle at 2 and 3 years after grading, respectively. Among B-grade restaurants, 53% and 54%



Note. The city restaurant letter-grading program began on July 27, 2010. Pre-adjudicated score from initial inspection closest to end of each period for unique restaurants was included in the analysis. For the time before the letter grading program began, inspection scores before grading were adjusted to remove points given for nonsanitary administrative violations.

FIGURE 1—Inspection score category on recent initial restaurant inspection: New York City, NY, 2007–2013.

improved to an A grade on the next cycle as of the 2- and 3-year mark, respectively.

Public Perception Surveys

Results from 2 independent telephone surveys suggested that New Yorkers dine out frequently and support and use letter grades to help them decide where to eat. Among NYC adults, 67% (95% CI = 63%, 71%) and 68% (95% CI = 63%, 72%) reported eating meals from a restaurant, deli, coffee shop, or bar at least once per week at the 1-year and 18-month mark, respectively. At the 1-year mark, 90% (95% CI = 87%, 93%) approved of the program and 71% (95% CI = 66%, 74%) had seen a grade card in restaurant windows. At 18 months, support remained at 91% (95% CI = 88%, 94%) and 81% (95% CI = 77%, 84%) had seen grade cards. Among those who had seen grade cards, 88% (95% CI = 85%, 92%) considered them in their dining decisions at the 1-year and 18-month mark.

Results suggested that grades reassure diners about food safety; 76% (95% CI = 71%, 80%) felt more confident in a restaurant's food safety when an A grade was posted. An estimated 70% (95% CI = 66%, 74%) expressed concern about getting sick from eating from restaurants, delis, and coffee shops, with 38% (95% CI = 34%, 43%) being very concerned. A majority of 88% (95% CI = 85%, 91%) supported more frequent inspections for restaurants that do not earn an A grade.

DISCUSSION

The NYC Health Department launched the restaurant letter-grading program to motivate restaurants to improve food safety, inform the public about inspection results, and reduce illness associated with dining out. The program introduced multiple changes to the enforcement landscape, including the mandatory posting of letter grades summarizing sanitary inspection scores, a fine-tuned risk-based inspection schedule, and a revised policy on financial penalties. Survey results suggest that New Yorkers approve of the program and use it when making dining decisions. Our restaurant hygiene analysis suggests that the program provided an effective incentive for operators to comply with regulations and improve practices. We also found that there is an incentive to maintain hygiene practices, with the majority of A-grade restaurants earning A grades on their next inspection cycle.

Our ultimate goal is to reduce foodborne illness, but evaluating the impact of 1 program on such a multifactorial outcome is challenging. Past foodborne illness studies have noted that case finding suffers from underreporting and potential misclassification.[4,15] Among cases that are identified, it can be difficult to know if exposures occurred in a restaurant. Certain hygiene and food-safety conditions monitored in restaurants are known risk factors or environmental antecedents for foodborne illness outbreaks,[7,16,17] so we think measurement of sanitary conditions alone serves as a good proxy for public health risks.

TABLE 2—Estimated Success in Scoring in the A-Range on Initial Inspection in Restaurants: New York City, NY, July 2007-July 2013

Indicator	Inspections, No.	Model I,[a] SR (95% CI)	Model II,[b] SR (95% CI)
Time period			
13-36 mo before grading (Ref)	42 016	1.00	1.00
0-12 mo before grading	26 200	1.05 (1.01, 1.09)	1.05 (1.01, 1.09)
0-12 mo after grading	32 594	0.86 (0.83, 0.89)	0.87 (0.84, 0.90)
13-24 mo after grading	38 339	1.24 (1.20, 1.29)	1.26 (1.22, 1.31)
25-36 mo after grading	32 918	1.33 (1.29, 1.38)	1.35 (1.31, 1.40)
Season			
July-September (Ref)	36 598	. . .	1.00
October-December	41 697	. . .	1.20 (1.16, 1.24)
January-March	45 825	. . .	1.30 (1.26, 1.35)
April-June	47 947	. . .	1.20 (1.16, 1.24)
Chain restaurant			
No (Ref)	151 374	. . .	1.00
Yes	20 693	. . .	3.46 (3.31, 3.61)

Notes. CI = confidence interval; SR = success ratio. The city restaurant letter-grading program began on July 27, 2010. Preadjudicated initial inspection scores for all restaurants in operation between July 27, 2007, and July 26, 2013, included. A-range is equivalent to ≤ 13 points.
[a]Model includes random intercepts for unique restaurants.
[b]Model includes random intercepts for unique restaurants and adjusts for chain restaurant status and season of inspection.

Improvement in hygiene conditions appeared to be driven by certain categories of violations. Having a certified kitchen manager on site is important because it has been associated with fewer critical violations on inspection[18,19] and identified as an important factor for preventing foodborne outbreaks.[20] Decreases in violations for inadequate handwashing facilities and worker hygiene and improper storage or use of equipment or utensils are also likely to decrease risk for foodborne illness.[21] Decreases in presence and severity of vermin violations contributed in large part to improvements in inspection scores, but vermin violations remain the largest average contributors to inspection score on initial inspection, suggesting a need for more restaurant operator education on this topic. The increase in average violation points related to food contact surface maintenance was likely an artifact related to a tendency for inspectors to cite this violation under a "miscellaneous" section before grading.

Although overall inspection performance improved in the second and third year of grading, A-range scores (0–13 points) decreased slightly in the first year of grading compared with the year before. We believe this decrease reflects the method in which the program was rolled out. The first restaurants inspected under the grading program were those that scored poorly under pregrading program rules. These poorer-performing restaurants were overrepresented during year 1.

We call attention to the strong association between chain restaurant status and A-range score on initial inspection. This finding is consistent with other studies that reported better sanitary conditions (i.e., fewer critical violations) in chain restaurants compared with nonchains.[18,22,23] It is instructive to consider the mechanisms used by chains to ensure food safety, such as use of standardized procedures, specialized equipment, and additional worker training and internal mock inspections, when conducting educational outreach among nonchains.

New York City is not alone in requiring public disclosure of restaurant inspection results at the point of decision-making. This type of disclosure program is becoming more common in North America at the state, county, and local level and several jurisdictions have published program evaluation findings. Similar to our results, the Toronto and Los Angeles evaluations found their disclosure programs were used by consumers and led to improved restaurant sanitary practices.[24–26] Jin and Leslie[24] found that mandatory posting of grade cards in Los Angeles County improved inspection scores after they controlled for restaurant characteristics. Similar to our findings, Toronto Public Health found overwhelming program approval by diners and that diners felt safer making purchases with their program.[25] Both of these evaluations were also able to detect decreases in foodborne illness after program implementation.[15,27]

A previous study of the NYC restaurant grading program analyzed a public-use restaurant inspection data set and concluded that the program was not associated with an improvement in scores.[28] However, the analysis included only 17 complete months of inspection data after grading. We identified improvements in sanitary conditions only after the 2-year mark, which may partially explain the inconsistency in results. The previous analysis also did not account for overrepresentation of poorer-performing restaurants resulting from more frequent inspection for poorer performers after grading. By contrast, our regression analysis addressed oversampling by including random intercepts for individual restaurants.

Limitations

This study has certain limitations. We compared inspection performance across time among inspected restaurants. In our earliest period (July 2007–July 2008), about 25% of restaurants were uninspected because of reduced staffing and other inspectional priorities. Because initial inspection assignment before grading was random, we believe inspections during this period were not biased toward poorer-performing restaurants. Use of inspection scores over time may have also been problematic. Subtracting administrative violation points from pregrading inspection scores to make them comparable with grading scores may have underestimated inspection scores pregrading, because the scoring system did not always include points from every violation to calculate inspection score. The impact would be an underestimate of the success of the program. We were unable to find an adequate comparison group (e.g., nongraded jurisdiction) because of jurisdictional differences in food-safety regulations and inspection scoring systems, but we used time and within-restaurant analysis as controls to isolate the impact of the program over time.

TABLE 3—Average Points per Inspection for Specific Violations Cited on Recent Initial Inspections in Restaurants: New York City, NY, 2008–2013

Violations	From 24 Mo to 13 Mo Before Grading (n = 21 208)	From 12 Mo Before to Start of Grading (n = 22 313)	From 13 Mo to 24 Mo After Grading (n = 24 942)	From 25 Mo to 36 Mo After Grading (n = 24 681)
Facility and worker violations				
Critical violations				
Improperly maintained food contact surfaces[a]	0.69	0.98	1.31	1.53
Inadequate worker hygiene	0.51	0.47	0.36	0.35
Public health hazards[b]				
No food safety-certified supervisor on site	1.29	1.37	0.84	0.79
Inadequate hand-washing facilities	1.81	1.45	0.65	0.58
Food handling and holding violations				
Critical violations[c]				
Improper storage of in-use utensil	0.83	0.76	0.62	0.58
Inadequate protection of food from contamination during storage, preparation, display, service	1.03	1.01	1.20	1.16
Public health hazards				
Food not held cold enough	2.40	2.59	2.52	2.75
Food not held hot enough	1.28	1.39	1.28	1.36
Cross-contamination of foods	0.69	1.05	0.80	0.82
Pest violations: all vermin violations[d]	3.47	3.33	2.97	2.95

Notes. The city restaurant letter-grading program began on July 27, 2010. Each time period covers 12 months. Preadjudicated results from initial inspection closest to the end of each period for unique restaurants. Average points per violation cited on all recent initial inspections used to quantify the severity of violation conditions.
[a]Violation citation practices changed when grading started. Before grading, violation was cited in a miscellaneous violation category.
[b]Public health hazards point range is 7 to 28 points, except for "inadequate hand-washing facilities," which is 10 or 28 points, and "no food safety certified supervisor on-site," which is 10 points.
[c]Critical violation range is 5 to 8 points.
[d]Vermin includes rats, mice, cockroaches, or flies; all vermin violations range from 5 to 28 points. Points were bundled together for multiple vermin types.

Finally, the NYC restaurant grading program involved multiple changes to the enforcement landscape—more nuanced risk-based inspection frequency, greater exposure of restaurants to the risk of fines, grade posting, improvements to online resources, and additional training opportunities.[29] We cannot tease out which factors contributed most to improving hygiene or grades.

Conclusions

The results from our analysis indicate that the NYC restaurant letter-grading program exhibited a positive impact on restaurant hygiene, food-safety practices, and public awareness, suggesting that the program is an effective tool for improving food safety. Our analysis also identified violation areas that can be targeted for improvement in future program operations. ■

About the Authors

Melissa R. Wong, Wendy McKelvey, Kazuhiko Ito, and J. Bryan Jacobson are with the Bureau of Environmental Surveillance and Policy, New York City Department of Health and Mental Hygiene, New York, NY. Corinne Schiff and Daniel Kass are with the Division of Environmental Health, New York City Department of Health and Mental Hygiene.

Correspondence should be sent to Melissa R. Wong, MPH, Bureau of Environmental Surveillance and Policy, New York City Department of Health and Mental Hygiene, 125 Worth St, 3rd Floor, CN 34E, New York, NY 10013 (e-mail: mwong2@health.nyc.gov). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

This article was accepted October 17, 2014.

Contributors

M. R. Wong contributed to program evaluation design, performed analysis, and drafted the article. W. McKelvey contributed to program evaluation design and assisted with drafting the article. K. Ito and J. B. Jacobson conducted the analysis and assisted with drafting the article. C. Schiff and D. Kass conceptualized the program and assisted with drafting the article. All authors helped to interpret findings and review drafts of the article.

Acknowledgments

This work was supported by federal funds from the Centers for Disease Control and Prevention (grants 5U01EH000692 and 1U38EH000939).

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

Human Participant Protection

The New York City Department of Health and Mental Hygiene institutional review board determined that the program evaluation protocol was not human participant research in accordance with 45 CFR Part 46.

References

1. National Restaurant Association. Facts at a glance. 2013. Available at: http://www.restaurant.org/News-Research/Research/Facts-at-a-Glance. Accessed July 19, 2013.

2. Lin BH, Guthrie JF. *Nutritional Quality of Food Prepared at Home and Away From Home, 1977–2008.* Washington, DC: US Department of Agriculture, Economic Research Service; 2012.

3. *Community Health Survey.* New York, NY: New York City Department of Health and Mental Hygiene; 2011.

4. Scallan E, Hockstra RM, Angulo FJ, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis.* 2011;17(1):7–15.

5. Gould LH, Walsh KA, Vieira AR, et al. Surveillance for foodborne disease outbreaks—United States, 1998–2008. *MMWR Surveill Summ.* 2013;62(suppl 2):1–34.

6. Jones TF, Angulo FJ. Eating in restaurants: a risk factor for foodborne disease? *Clin Infect Dis.* 2006; 43(10):1324–1328.

7. *Food Code: 2013 Recommendations of the United States Public Health Service and Food and Drug*

Administration. College Park, MD: US Department of Health and Human Services; 2013: 1–698.

8. US Food and Drug Administration. Real progress in Food Code adoptions. 2013. Available at: http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FederalStateCooperativePrograms/UCM230336.pdf. Accessed September 30, 2014.

9. Collins G. A stir over plan to grade New York City's restaurants. *New York Times*. February 25, 2009. Available at: http://www.nytimes.com/2009/02/26/nyregion/26inspect.html?hp=&pagewanted=all. Accessed February 26, 2009.

10. Collins G. City seeks comments on plan for restaurant letter grades. *New York Times*. December 17, 2009. Available at: http://dinersjournal.blogs.nytimes.com/2009/12/17/city-seeks-comments-on-plan-for-restaurant-letter-grades. Accessed January 6, 2014.

11. *Inspection Scoring System for Food Service Establishments*. New York, NY: New York City Department of Health and Mental Hygiene; 2005.

12. City of New York. New York City restaurant inspection results. NYC open data. Available at: https://nycopendata.socrata.com. Accessed October 10, 2014.

13. Wood SN. Stable and efficient multiple smoothing parameter estimation for generalized additive models. *J Am Stat Assoc*. 2004;99:673–686.

14. *Standard Definitions: Final Dispositions of Case Codes and Outcome Rates for Surveys*. 6th ed. Deerfield, IL: The American Association for Public Opinion Research; 2009.

15. Simon PA, Leslie P, Run G, et al. Impact of restaurant hygiene grade cards on foodborne-disease hospitalizations in Los Angeles County. *J Environ Health*. 2005;67(7):32–36, 56; quiz 59–60.

16. Irwin K, Ballard J, Grendon J, Kobayashi J. Results of routine restaurant inspections can predict outbreaks of foodborne illness: the Seattle–King County experience. *Am J Public Health*. 1989;79(5):586–590.

17. Petran RL, White BW, Hedberg CW. Health department inspection criteria more likely to be associated with outbreak restaurants in Minnesota. *J Food Prot*. 2012;75(11):2007–2015.

18. Kassa H, Silverman GS, Baroudi K. Effect of a manager training and certification program on food safety and hygiene in food service operations. *Environ Health Insights*. 2010;4:13–20.

19. Cates SC, Muth MK, Karns SA, et al. Certified kitchen managers: do they improve restaurant inspection outcomes? *J Food Prot*. 2009;72(2):384–391.

20. Hedberg CW, Smith SJ, Kirkland E, Radke V, Jones TF, Selman CA. Systematic environmental evaluations to identify food safety differences between outbreak and nonoutbreak restaurants. *J Food Prot*. 2006;69(11):2697–2702.

21. US Food and Drug Administration, National Retail Food Team. *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types*. 2009. Available at: http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224682.pdf. Accessed November 6, 2014.

22. Harris KJ, DiPietro RB, Murphy KS, Rivera G. Critical food safety violations in Florida: relationship to location and chain vs. non-chain restaurants. *Int J Hospit Manag*. 2014;38:57–64.

23. Jin GZ, Leslie P. Reputational incentives for restaurant hygiene. *Am Econ J Microeconomics*. 2009;1(1):237–267.

24. Jin GZ, Leslie P. The effect of information on product quality: evidence from restaurant hygiene grade cards. *Q J Econ*. 2003;118(2):409–451.

25. Toronto Public Health. *Food Premises Inspection and Disclosure System. Evaluation Report*. Toronto, ON: Healthy Environments Services; 2002.

26. Thompson S, de Burger R, Kadri O. The Toronto Food Inspection and Disclosure System: a case study. *Br Food J*. 2005;107(3):140–149.

27. Arthur A, Gournis E, McKeown D, Yaffe B. *Foodborne Illness in Toronto*. Toronto, ON: Toronto Public Health; 2009.

28. Ho DE. Fudging the nudge: information disclosure and restaurant grading. *Yale Law J*. 2012;122(574):574–688.

29. *Restaurant Grading in New York City at 18 Months*. New York, NY: New York City Department of Health and Mental Hygiene; 2012.

Feasibility of Restaurant Letter Grading in Utah

By: Breanna Peltekian, Heather Stuart, Ry Mount, and Lauren Martinez
Public Health Program, Westminster College - Spring 2015

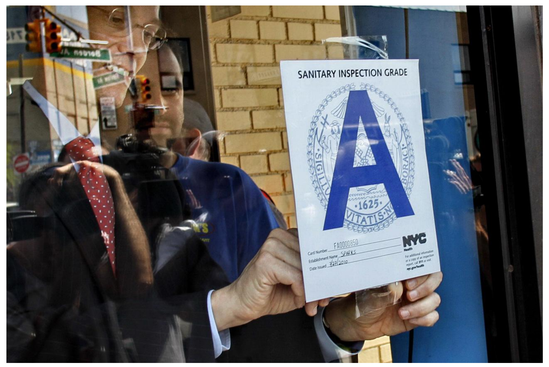
Introduction

Utahns are in need of a transparent identification system to determine which restaurants are sanitary, based on the grade assigned by the health department, which would be conveyed to the public in a simplified format. This will create market pressure to improve safety and sanitation and to reduce the incidence of foodborne illness through informed consumer choice.

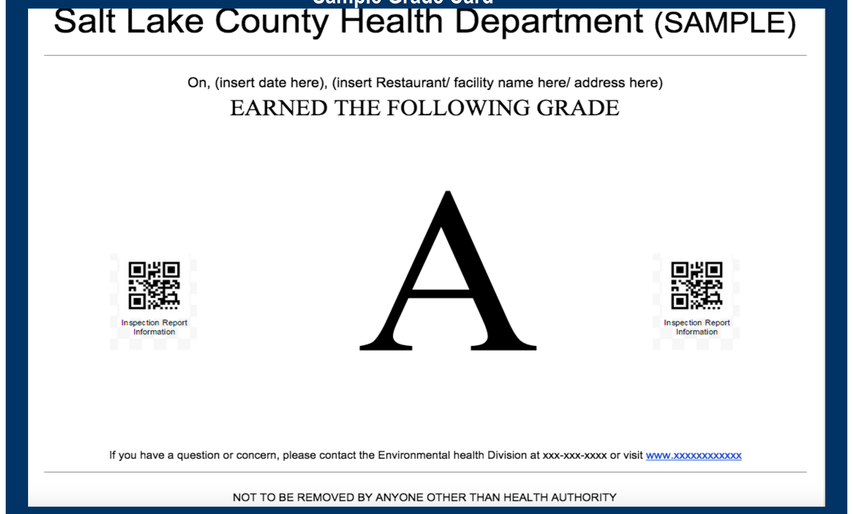
Overall, this proposal's main objective is to determine the feasibility of implementing a restaurant letter grading system in Utah. To achieve this objective, there are several sub-objectives:

- Survey the general public on their opinions and acceptance of the letter grading system
- Assess cost-effectiveness and success of other states' restaurant letter grading programs
- Discuss with health professionals the feasibility and limitations of our proposal
- Receive feedback from the Utah Restaurant Association and/or restaurant owners to determine the limitations of our proposal

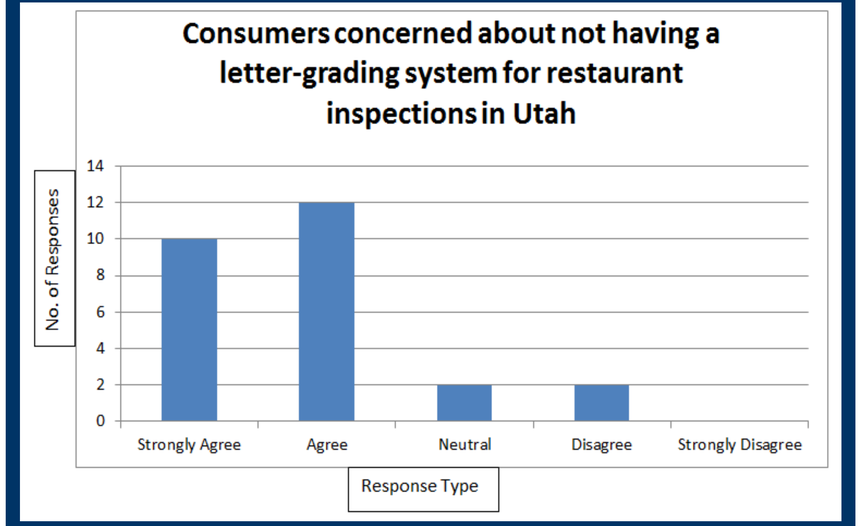
Up to 70% of FBI is linked to food prepared at foodservice establishments (WHO, 2007). Determining the feasibility of this proposal is important to Public Health because implementing the letter grading system will potentially decrease the amount of foodborne illnesses and provide the public with information to help determine the health and safety of what they will be eating.



Sample Grade Card



Results



Literature Cited

Estimates of Foodborne Illness in the United States. (2014, January 8). In *Centers for Disease Control and Prevention*. Retrieved January 15, 2015, from http://www.cdc.gov/foodborneburden/

Filion, K., & Powell, D. A. (2009). The use of restaurant inspection disclosure systems as a means of communicating food safety information. *Journal Of Foodservice*, *20*(6), 287-297. doi: 10.1111/j.1748-0159.2009.00151.x

Food Illness Down, Restaurant Revenue Up Since Letter Grading Began. (2012, March 6). In *Mike Bloomberg*. Retrieved from http://www.mikebloomberg.com/index.cfm?objectid=E9222A8B-C29C-7CA2-FC40BFE0CF8B9A33

Simon, P., Leslie, P., Run, G., Jin, G., Reporter, R., Aguirre, A., & Fielding, J. (2005, March). Impact of Restaurant Hygiene Grade Cards on Foodborne-Disease Hospitalizations in Los Angeles County. *DRUM*.

Zimmer, B. (2014, October 9). Florida restaurants fight inspection letter grades. Retrieved April 3, 2015, from http://www.wtsp.com/story/news/2014/10/08/florida-restaurant-industry -fights-health-inspection-letter-grades-ratings-dbpr/16945213/

Acknowledgments

We would like to express our sincere thanks to everyone who has been a contribution to developing our proposal: Environmental Health Professionals Brian Cowan, Royal Delegge, and Phil Bondurant for their opinions and expertise on health inspections and how to overcome the limitations to a letter grading system; Rose Henderson from the Southern Nevada Health Department for her knowledge and experience with a live letter grading system and grade cards; Ryan Glenn and Michelle Serrano for providing us with restaurant owners' perspectives; Representative LaVar Christensen for his guidance and interest in our plan for implementation; the participants from our survey for taking time out of their day; and last but definitely not least, Han Kim for his expertise and knowledge of public health research and policy projects and his continued support of our success.

Materials and Methods

Environmental health professionals, restaurant owners, and the general public were interview/surveyed. First, environmental health scientists discussed the process used in their specific Utah counties for food inspections and how the current food inspection scores are determined. They also gave their opinion on our letter-grading proposal and they answered, with their experience, if they believe restaurant letter grading would be effective in Utah.

Next, twenty five restaurant-goers from the general public were surveyed to determine if they would benefit from the restaurant letter grades being easily displayed. A Likert Scale was used to assess the opinions and desires from the public. Finally, restaurant owners were interviewed to see what their main concerns are in regards to letter grading and to answer any questions that they had. In the end, political feasibility will be determined by speaking with a Utah State Legislator, LaVar Christensen, who is interested in sponsoring and passing a bill regarding restaurant letter grading in Utah.

The letter grading systems that other states utilize were closely examined. It was researched whether the other states' systems are beneficial to reducing the incidence of foodborne disease, as well as improve business for the restaurants.The letter grading system in other states allowed us to compare Utah's system to theirs, to see the limitations that they faced, if any, and how they overcame those limitations.

Conclusion

By surveying the public and researching foodborne illness in Utah, it was determined that the existing programs that are implemented in Utah are insufficient in protecting the public. The programs in place now provide limited access to the public for them to see the results of inspections and to understand the risks they are taking when dining out. This research supports that a letter grading system would aid in lowering the rates of restaurant contracted food borne illnesses. It would not just come from simply changing the format of the grade card, but with the accountability that comes with this awareness. The letter grade would make consumers more aware of inspection reports and more selective in their choices.

This selectivity would make restaurant cleanliness a part of a business plan. It would mean that restaurants are no longer only being held accountable by the health department, but also by consumers. If a restaurant knows that their potential customers would be put off by a poor grade, it would be crucial to the business's survival to make sure that they were up to code. This would by default lower food borne illness rates and is why Utah should be in support of a restaurant letter grading system.

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-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 and Re-create - Employee Food Safety Training Committee

Issue you would like the Conference to consider:

Acknowledge the Food Employee Food Safety Training Committee report and re-create the committee for the 2016-2018 biennium.

Public Health Significance:

Food employees trained in food safety have the potential to decrease incidents of foodborne illness in foodservice establishments. The existence of many variations of food safety training requirements in many jurisdictions throughout the United States makes it difficult for foodservice establishments that have more than one location to have a consistent food employee food safety training program. Foodservice establishments could more readily and efficiently offer effective food employee training if consistent national food employee training standards were created. Such standards would encourage more food employee training in food safety and could improve public health.

Recommended Solution: The Conference recommends...:

acknowledging the Employee Food Safety Training Committee report and thanking the committee members for their efforts.

The Conference further recommends re-creating the Employee Food Safety Training Committee to continue the work initiated during the 2014-2016 biennium and to complete the original charges from Issue 2014-II-011; specific committee charges for the 2016-2018 biennium are to:

1. Identify what a food employee should know about food safety, prioritized by risk.
2. Develop a guidance document to include recommendations for appropriate operator, regulator, and/or third-party food safety training program(s); including the criteria for the program and learning objectives.

3. Report Committee findings and recommendations to the 2018 Conference for Food Protection Biennial Meeting.

Submitter Information 1:

Name:	Ben Chapman
Organization:	Employee Food Safety Training Committee
Address:	NC State UniversityCampus Box 7606
City/State/Zip:	Raleigh, NC 27695
Telephone:	9198093025
E-mail:	benjamin_chapman@ncsu.edu

Submitter Information 2:

Name:	Chuck Catlin
Organization:	Employee Food Safety Training Committee
Address:	Food safety Rx2276 E. Clinton Street
City/State/Zip:	Phoenix, AZ 85028
Telephone:	602.769.1418
E-mail:	chuck.catlin@foodsafetyrx.com

Content Documents:

- "Employee Food Safety Training committee report"

Supporting Attachments:

- "CFP-employee-training-committte-1-8-15"
- "Literature on evaluating food handler training programs:"
- "FDA Risk Factor Study 1998, 2003 and 2008 comparison"
- "Employee Food Safety Training Committee Meeting Minutes"
- "CFP Food Employee Training Committee Training Component Draft"
- "Employee Food Safety Training Topics"

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: Employee Food Safety Training Committee

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council II

DATE OF REPORT: January 15, 2016

SUBMITTED BY: Ben Chapman and Chuck Catlin

COMMITTEE CHARGE(s): Created by Council II at the 2014 biannual meeting, in response to issue 011, the Employee Food Safety Training Committee was given the following charges:

1. Make recommendations to the Conference for Food Protection in regard to :
    a. What a food employee should know about food safety, prioritized by risk.
    b. A guidance document to include recommendations for appropriate operator, regulator, and/or third-party food safety training program(s); including the criteria for the program and learning objectives.
2. Report Committee recommendations to the 2016 Conference for Food Protection Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:
    a. December 2014 kick off for charges and initial discussions
    b. March 18, 2015, Face-to-face meeting Chicago

We divided our members into three subcommittees so that each could dig deeply into the subject matter to review and compile information to help make decisions on what to include in our final committee recommendations.

Subcommittee 1 - Industry non-regulatory delivery of food handler training

Subcommittee 1 focused on the main sources of information from existing programs that the retail and food service industry have implemented. Pertinent questions to answer included:

- What is common between the programs (content, practices, approach)?
- What is unique about any of the programs?
- Are there particular emphases?
- Delivery modes?
- Evaluation?

Subcommittee 2 - Review current state requirements and local (e.g., CA, IL, FL)

Subcommittee 2 focused on the main sources of information will be gleaned from states that currently require some sort of food handler training. Pertinent questions to answer included:

- What is common between the programs (content, practices, approach)?
- What is unique about any of the programs?
- Are there particular emphases?
- Lessons learned from the process (where did the programs/requirements start, where did they end up what were the sticky points)?
- Delivery modes?

Subcommittee 3 - FDA Risk Factor related employee activities and research

Subcommittee 3 focused on reviewing and analyzing existing sources of data. These included:

- FDA Retail Risk Factor Study results. (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm230313.htm)
- Information gleaned from the 2013 Food Code that relates to food handlers.
- Peer reviewed literature and other pertinent research on food handler practices and behaviors.

c. Sub committees met three times via call and one time as a whole group in person (minutes available in attachments).

June 17, 2015 Phone
July 27, 2015, in Portland concurrent with IAFP (in person)
August 12, 2015 Phone
October 2, 2015 Phone

d. Also produced was a comparison of risk factor compliance issues taken from FDA's Risk Factor Studies. This information was used to ensure the risk-based nature of the committee's decision making, as well as provide a framework for charge #2 (A guidance document to include recommendations for appropriate operator, regulator, and/or third-party food safety training program(s); including the criteria for the program and learning objectives) to be carried out in future years. The document is entitled, ***FDA Risk Factor Study 1998, 2003 and 2008 comparison.*** In addition, the subcommittee compiled a list of relevant literature related to evaluating food employee training materials, entitled, ***Literature on evaluating food employee training programs*** (attached)

e. Through reviewing the outputs from each of the subcommittees, in mid-October 2015, a draft of a compiled list of what a food employee should know about food safety was distributed to the entire committee for review, (attached, entitled, ***CFP Food Employee Training Committee Training Component Draft)***

f. On November 6, 2015, a call was held to discuss the compiled matrix. Quorum was not met so a vote was conducted via email. Attached final document, entitled, ***Employee Food Safety Training Topics*** detailing consensus-reached topics (two 'no' votes). This

document is a first-step tool for the committee to use to complete the charge provided by the Council. It is not meant to be adopted for any official action but provides a framework going forward if the Council wishes the committee to complete the charges.

2. Recommendations for consideration by Council:
   a. **Future of the committee: Re-create the Committee through 2018**

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Acknowledge the committee report, thank the committee members, and re-create the committee for the 2016-2018 biennium with the following charges:
   a. What a food employee should know about food safety, prioritized by risk.
   b. A guidance document to include recommendations for appropriate operator, regulator, and/or third-party food safety training program(s); including the criteria for the program and learning objectives.
   Report Committee recommendations to the 2018 Conference for Food Protection Biennial Meeting.

COMMITTEE MEMBER ROSTER (attached):

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Atkins	Hugh	member	State Regulator	TN Department of Health	Nashville	TN	(615) 741-8535	hugh.atkins@tn.gov
Bhatt	Chirag	member	Food Service Industry	Bloomin Brands, Inc	Tampa	FL	(813) 892-8641	ChiragBhatt@BloominBrands.com
Catlin	Chuck	Co-chair	Support	Food Safety RX	Mountain View	CA	(602) 769-1418	catlin@google.com
Chapman	Ben	Co-chair	Academia	North Carolina State University	Raleigh	NC	(919) 809-3205	benjamin_chapman@ncsu.edu
Eisenbeiser	Ashley	member	Retail Food Industry	Food Marketing Institute	Arlington	VA	(202) 220-0689	aeisenbeiser@fmi.org
Feazell	Susan	member	Food Industry Support	National Registry of Food Safety Professionals	Orlando	FL	(800) 446-0257	sfeazell@nrfsp.com
Graham	Joe	member	State Regulator	WA State Department of Health				joe.graham@DOH.WA.GOV
Green	Elizabeth	member	Local Regulator	Mid-Ohio Valley Health Department	Parkersburg	VA	(304) 420-1471	elizabeth.s.green@wv.gov
Grooters	Susan	member	Consumer	KAW Coalition	Washington	DC	(802) 223-6303	susangrooters@gmail.com
Jensen	Joyce	member	Local Regulator	Lincoln-Lancaster County Health Department	Lincoln	NE	(402) 441-8033	jjensen@lincoln.ne.gov
King	Hal	Member	Food Service Industry	Chick-fil-A Inc.	Atlanta	GA	(404) 765-2508	hal.king@chick-fil-a.com
Lang	Jeffrey	member	Local Regulator	Lane County Envirionmental Health	Eugene	OR	(541) 682-3636	jeffrey.lang@co.lane.or.us
Lee	Aimee	member	Retail Food Industry	Publix Super Markets, Inc.	Charlotte	NC	704-424-5017	aimee.lee@publix.com
Luebkemann	Geoff	member	Food Service Industry	Florida Restaurant and Lodging Associaton	Tallahassee	FL	(850) 224-2250	gluebkemann@frla.org

Mull	Monique	member	Local Regulator	Mesa County Health Department	Grand Junction	CO	(970) 248-6962	monique.mull@mesacounty.us
Nelson	Laura	member	Food Industry Support	Alchemy Systems	Austin	TX	(512) 637-5100	laura.nelson@alchemysystems.com
Rosenwinkel	Ken	member	Retail Food Industry	Jewel-Osco	Itasca	IL	(630) 948-6787	ken.rosenwinkel@jewelosco.com
Tabata	Christina	member	Food Service Industry	Taco Bell (Yum!)	Irvine	CA	(949) 863-4327	christina.gallegos@tacobell.com
Taylor	Alan	member	State Regulator	Maryland Stae Department of Health	Balitmore	MD	(410) 767-8447	alan.taylor@maryland.gov
Weichelt	William	member	Food Service Industry	National Restaurant Association	Chicago	IL	(312) 715-5388	wweichelt@restaurant.org
Coleman	Eric	CDC Advisor (non-voting member)	Advisory	CDC			(404) 488-3438	EColeman@cdc.gov
Hughes	Stephen	FDA member consultant	Advisory	FDA	College Park	MD	(240) 402-2833	stephen.hughes@fda.hhs.gov
Tart	Alan	Alternate	Advisory	FDA	Atlanta	GA	(404) 253-1267	alan.tart@fda.hhs.gov
Non-Voting Members:								
Buchanon	Janice	non- voting member	Food Industry Support	The Steritech Group	Charlotte	NC	(704) 971-6565	janice.buchanon@steritech.com
Buswell	Cheri	non- voting member	Food Service Industry	International Dairy Queen	Minneapolis	MN	(952) 830-0224	cheri.buswell@idq.com
Chong	Korey	non- voting member	Food Industry Support	Premier Food Safety	Fullerton	CA	(714) 451-0075	korey@premierfoodsafety.com

Costa	Cynthia	non- voting member	State Regulator	CT Department of Public Health	Hartford	CT	(860) 509-7297	cynthia.costa@ct.gov
Deslauriers	Susan	non- voting member	Retail Food Industry	Big Y Foods	Springfield	MA	(413) 504-4452	deslaurs@bigy.com
Eckhardt	Christina	non- voting member	Food Industry Support	Aramark	Philadelphia	PA	(267) 939-4894	eckhardt-christina@aramark.com
Eisenbeiser	Ashley	non- voting member	Retail Food Industry	Food Marketing Institute	Arlington	VA	(202) 220-0689	aeisenbeiser@fmi.org
Eisenberg	Miriam	non- voting member	Food Industry Support	Ecosure, A Division of Ecolab	Lincolnshire	IL	(847) 597-9848	miriam.eisenberg@ecolab.com
Espinoza	Albert	non- voting member	Retail Food Industry	HEB	San Antonio	TX	(210) 884-5783	espinoza.albert@heb.com
Follett	Emilee	non- voting member	Food Industry Support	StateFoodSafety.com	Orem	UT	(801) 805-4679	efollett@statefoodsafety.com
Kim	James	non- voting member	Food Industry Support	Premier Food Safety	Fullerton	CA	(714) 451-0075	james@premierfoodsafety.com
Lewis	Christie H.	non- voting member	Food Industry Support	StateFoodSafety.com	Orem	UT	(801) 805-1872	chl@statefoodsafety.com
Maeson	Jordon	non- voting member	Food Industry Support	Safer Dining LLC	St. Petersburg	FL	(727) 422-7392	Jordon@SaferDining.com
McMahan	Thomas	non- voting member	Food Retail/Industry	Meijer	Grandville	MI	(616) 249-6035	thomas.mcmahan@meijer.com
Nakamura	George	non- voting member	Food Industry Support	StateFoodSafety.com	Orem	UT	(801) 494-1879	gmlnaka@comcast.net
Turner	Brian	non- voting member	Food Service Industry	Sodexo	Downers Grove	IL	(847) 682-5672	brian.turner@sodexo.com
Tyjewski	Susan	non- voting member	Food Service Industry	CKE Restaurants Holdings, Inc.	Anaheim	CA	(714) 254-4552	styjewski@ckr.com

Literature on evaluating food handler training programs:

Studies of training programs

- ServSafe programs
  - York et al., 2009: http://www.ncbi.nlm.nih.gov/pubmed/19699837
    - Abstract: The number of foodborne illnesses traced to improper food handling in restaurants indicates a need for research to improve food safety in these establishments. Therefore, this 2-year longitudinal study investigated the effectiveness of traditional ServSafe (National Restaurant Association Educational Foundation, Chicago, IL) food-safety training and a Theory of Planned Behavior intervention program targeting employees' perceived barriers and attitudes toward important food-safety behaviors. The effectiveness of the training and intervention was measured by knowledge scores and observed behavioral compliance rates related to food-safety practices. Employees were observed for handwashing, thermometer usage, and proper handling of work surfaces at baseline, after receiving ServSafe training, and again after exposure to the intervention targeting barriers and negative attitudes about food-safety practices. Repeated-measures analyses of variance indicated training improved handwashing knowledge, but the intervention was necessary to improve overall behavioral compliance and handwashing compliance. Results suggest that registered dietitians; dietetic technicians, registered; and foodservice managers should implement a combination of training and intervention to improve knowledge and compliance with food-safety behaviors, rather than relying on training alone. Challenges encountered while conducting this research are discussed, and recommendations are provided for researchers interested in conducting this type of research in the future.
  - Roberts et al., 2008: https://krex.k-state.edu/dspace/bitstream/handle/2097/806/RobertsFPTApr2008.pdf;jsessionid=EBCE1BAFFD47F3A77D6DE777F3D36203?sequence=1
    - **Abstract:** Statistics show that 59% of foodborne illnesses are traced to restaurant operations. Food safety training has been identified as a way to assure public health, yet evidence supporting the effectiveness of training has been inconclusive. A systematic random sample of 31 restaurants in three midwestern states was selected to assess the effect of training on food safety knowledge and behavior. A total of 402 employees (242 pretraining and 160 post-training)

participated in this study. Pre and post-training assessments were conducted on knowledge and behavior related to three key food safety practices: cross contamination, poor personal hygiene, and time/temperature abuse. Overall knowledge ($P \geq .05$) and compliance with standards of behavior ($P \geq .001$) improved significantly between pre- and post-training. When each practice was examined independently, only handwashing knowledge ($P \geq .001$) and behavior ($P \geq .001$) significantly improved. Results indicated that training can improve knowledge and behaviors, but knowledge alone does not always improve behaviors.

- Non-ServSafe or multi-program studies
  - Ehiri, Morris, and McEwen, 1997: http://www.sciencedirect.com/science/article/pii/S0956713597000054
    - Abstract: This paper reports the findings of a study which investigated the effectiveness of a food hygiene training course in Scotland, and discusses the implications these may have for food safety control in the UK and elsewhere. One hundred and eighty-eight individuals who undertook the elementary food hygiene training course of the Royal Environmental Health Institute of Scotland (REHIS), and a comparison group comprising two hundred and four employees of a City Council were surveyed by means of a structured self-completion questionnaire. Food hygiene knowledge, attitudes and opinions of the course participants were assessed before and after training, and compared with those of the comparison group. The training course evaluated by the study is typical of many certificated training courses applied in the food industry. After training, no significant improvements were observed in course participants' pre-course knowledge of a number of crucial aspects of food safety, including food storage, cross contamination, temperature control, and high risk foods. The findings highlight problems likely to arise from reliance on training designs which primarily emphasise the provision of information that seldom translates into positive attitudes and behaviours. This suggests a need for the adoption of approaches which take account of social and environmental influences on food safety, thus, ensuring that food hygiene training is seen, not as an isolated domain which sole purpose is to produce certificated personnel, but as part of an overall infrastructure for effective food safety control.
- Online programs
  - Croker and Liu, 2006 (dissertation): http://dl.acm.org/citation.cfm?id=1168405

        - Abstract: The purpose of the study was to identify preferences among foodservice employees for traditional classroom or computer-based training (CBT) based upon age, gender, and educational level; examine how employee preferences toward traditional classroom training or CBT differ in two franchise restaurant types, fast food restaurants and full service restaurants; explore learning preferences among foodservice employees toward using traditional classroom training or CBT; and analyze the possible relationships between age, gender, educational level, type of restaurant, and learning style in the attitudes toward CBT among foodservice employees in Southeastern Idaho. A self-reporting inventory was designed to collect data. Results of this study showed that older employees were less comfortable with CBT than younger employees, females were less comfortable with CBT than males, and employees in full service restaurants were also less comfortable than those in fast food restaurants. Employees with a diverger learning style more often preferred traditional classroom training than CBT. As to the attitudes among foodservice employees toward CBT, the results revealed that female and older employees, employees with lower education levels, employees in full service restaurants and employees with a diverger or an assimilator learning style had more negative attitudes toward CBT in terms of format, presentation, confidence, learning motivation, and usefulness of CBT. These findings might contribute to a better understanding of employee preferences for different training methods, employee attitudes toward CBT and examine CBT usage and programs.
    - Hislop and Keara, 2009 (food safety knowledge retention): http://www.ingentaconnect.com/content/iafp/jfp/2009/00000072/00000002/art00030
        - Abstract: Foodborne illness in Canada is an ongoing burden for public health and the economy. Many foodborne illnesses result from improper food handling practices. If food handlers had a greater knowledge of what causes foodborne illness, perhaps these illnesses would have less of an impact on society. This study gave researchers the opportunity to examine the current food safety knowledge of food handlers by using a standardized questionnaire. Questionnaires were distributed by environmental health officers to food handlers working in the food service industry during on-site inspections, and responses were used to evaluate immediate knowledge of key food safety issues. Both certified and noncertified food handlers were evaluated. Information also was collected on the number of years since food safety

certification was achieved and the number of years experience noncertified food handlers had in the food service industry. Results indicated that certified food handlers had a greater knowledge of food safety information than did noncertified food handlers. The highest failure rates were observed among noncertified food handlers with more than 10 years of experience and less than 1 year of experience. The results support the need for mandatory food safety certification for workers in the food service industry and for recertification at least every 10 years. Although the study was not sufficiently rigorous to evaluate existing food safety courses, data collected provided valuable insight into what issues should be emphasized in existing food safety courses and which should be targeted by future food safety initiatives.

- Worsfold, Griffith, and Worsfold, 2004 (Enviro Health officer's views on food hygiene training effectiveness): http://www.emeraldinsight.com/doi/full/10.1108/00070700410515208
  - Abstract: In both their enforcement and training role environmental health officers (EHOs) may influence businesses' attitudes to hygiene training. A survey was conducted to examine EHOs' experience and perceptions of the provision and effectiveness of food hygiene training in small food businesses. The results indicate that officers had concerns about the content and the delivery of hygiene courses and about the quality of other hygiene trainers. Officers use the industry guides to advise on training but receive limited guidance on the assessment of hygiene training in the workplace. The checking of training records was considered to be less important than the use of observation and questioning for assessing hygiene training effectiveness. Environmental factors, such as supervisor support and situational aids were judged by officers to be important factors in the implementation of workplace hygiene training. They reported low levels of formal refresher training and active support of training by management.
  - See Methods section for survey details
- **Medeieros et al. 2011 (Food Control, Volume 22, Issue 8, August 2011, Pages 1136–1144) Assessment of the methodological strategies adopted by food safety training programmes for food service workers: A systematic review**
  http://www.sciencedirect.com/science/article/pii/S0956713511000569
- Abstract: This is a systematic review conducted to identify and assess the methodological strategies used in training programmes designed to enhance food safety in food services. Fourteen original articles

were selected from the Scopus, Scielo and Medline digital databases. The topics most dealt with in the educational programmes were personal hygiene, food safety and best practices. The resources most widely used during the training courses were interactive media, audiovisual materials, videos, lectures and recreational activities. In addition to being low cost, hand washing activities yield positive results in food safety. Employee training assessment is carried out by using questionnaires, analytical monitoring, a check list and the Likert scale. Hand washing is the most assessed item. The activities most widely accepted by the employees during training courses are interactive media and hands-on activities. These activities contribute toward the enhancement of employees' skills and knowledge, and encourage changes in attitude and behaviour.

Studies on evaluation

- Ko, 2010: http://www.sciencedirect.com/science/article/pii/S0956713509002199
    - Abstract: This study investigates food safety perceptions and agricultural food handling practices, as well as satisfaction with the work performance of such handlers. Data are collected from 333 food handlers at agricultural food processing companies or restaurants. Data is analyzed by SPSS, with statistical analyses including descriptive statistics, *t* tests and regression analyses. **Dimensions pertaining to food safety perception and practices include personal sanitation, pre-handling food preparation, food preparation and after food preparation.** The scales of food safety perception during analysis are higher than what are typically found in practice, and some gaps are identified. Analysis results indicate that food preparation and after food preparation dimensions have significantly higher mean values than those associated with pre-food handling and personal sanitation. Regression analysis further demonstrates that satisfaction with work performance can accurately predict food safety perception and practice components. Moreover, their handling practices mediate how perception affects satisfaction with work performance of food handlers.
- Medeiros et al., 2001: http://www.sciencedirect.com/science/article/pii/S1499404606600675
    - Abstract: Traditionally, nutrition educators have used a fairly global approach to teach food safety by teaching a broad range of safe food handling behaviors in the expectation that this will lead to the avoidance of foodborne illness. This approach can be confusing and lead to evaluation data that are difficult to interpret. This article suggests that food safety education and evaluation in the future be organized around five behavioral constructs: practice personal

hygiene, cook foods adequately, avoid cross-contamination, keep foods at safe temperatures, and avoid food from unsafe sources. These five constructs are derived from data on actual outbreaks and estimated incidences of foodborne illness. **Research is needed to establish reliable and valid evaluation measures for these five behavioral constructs. Evaluation instruments can be tailored to fit specific education programs. If evaluation instruments focus on these five behavior areas, the result will be meaningful evaluation data that can be more easily summarized across food safety education programs for consumers.**

- Deniston, Rosenstock, and Getting, 1968: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1891042/
    - Old study on evaluating the effectiveness of public health programs

FDA Risk Factor Study 1998, 2003 and 2008 comparison

% Out of Compliance

Risk Factors	1. Food from Unsafe Sources	2. Inadequate Cooking	3. Improper Holding Time/Temper-ature	4. Contaminated Equipment/Protection from Contamination	5. Poor Personal Hygiene	6. Other (Chemical Contamination)	Notes
Hospitals	4.7	2.3	36.2	17.6	17.1	14.6	
Nursing Homes	2.1	9.6	29.2	16.8	16.0	12.5	
Elementary Schools	3.7	11.8	27.5	14.7	14.9	13.4	
Fast Food	2.4	7.4	38.2	17.4	24.2	31.4	
Full Service	12.0	15.4	54.7	35.0	40.9	25.2	
Delis	4.3	9.4	50.8	18.8	20.5	28.4	
Meat & Poultry	2.3	-#	19.9	17.0	6.8	14.1	#low observations
Seafood	11.4	-#	32.5	13.6	8.9	9.6	#low observations
Produce	1.5	-#	34.7	16.1	15.1	10.2	

The highest percentage out of compliance for all 9 types of facilities that were visited was Improper Holding Time/Temperature.

Study also found all 9 types of facilities did not have adequate written employee health policies. All had greater than 50% out of compliance.

FDA Risk Factor Study

1998, 2003 and 2008

Data Items in Need of Priority Attention for Each Risk Factor

Risk Factor	Data Items
Food from Unsafe Sources	Shellstock tags retained for 90 days;
Inadequate Cooking	Rapid reheating; poultry, stuffed fish, meat, pasta cooked;
Improper Holding Time/Temperature	cooling; cold-holding; hot holding; date-marking; discarding of foods; time alone used as a public health control;
Contaminated Equipment/Protection from Contamination	Surface/utensils cleaned/sanitized; separation of raw/RTE foods; protection from contamination; raw animal foods separated
Poor Personal Hygiene	Proper, adequate handwashing; handsink convenient/accessible; good hygienic practices; prevention of contamination of hands; handsink, cleanser/drying device;
Other (Chemical Contamination)	Poisonous or toxic materials properly identified, stored and used

FDA Risk Factor Study

1998, 2003 and 2008

Recommendations

For Whom	Task	Including
Industry Managers	Develop and Implement SOPs	Detail monitoring & corrective action for time/temperature control; training should be covered in employee orientation and in refreshers
Industry Managers	Provide necessary resources, equipment, and supplies	Thermocouples, temperature logs, hand soap & towels, chemical sanitizers, test kit
Industry Managers	Verify employees are following monitoring procedures	Daily oversight; provide employees with necessary knowledge & skills
Industry Managers	Identify methods to routinely assess effectiveness of SOPs	Could be based on internal review; regulatory inspections, or third party evaluation; risk factor violations noted during inspections should motivate managers to respond with active managerial control
Industry Managers	Overall – active managerial control over the risk factors	High out of compliance percentages of data items related to handwashing, bare-hand contact with ready to eat foods, time/temperature control, and contaminated equipment indicate needed improvement in those areas
Regulatory Programs	Conduct quality, risk-based inspections	Spend more time observation employee practices – handwashing, food handling, cooling of foods, and clean-up procedures; provide inspection tools; consider alternate working schedules to allow inspections at different times – observe cooling when it is occurring
Regulatory Programs	Providing onsite education and achieving voluntary compliance	Make use of existing training programs; establish open dialogue; obtain immediate corrective action; assist operators with SOPs and risk control plans; develop intervention strategies
Regulatory Programs	Implementing consistent and effective enforcement protocol	Develop procedures and strategies; look for active managerial control over risk factors; ensure credibility by applying enforcement actions uniformly
Regulatory Programs	Continuous program improvement	Self-assessment outlined in Program Standards

"…it is important to note that the risk factors and data items in need of priority attention remain the same as in previous data collection periods for each of the facility types. This is an indication that more action is needed by the industry and regulatory bodies." FDA Risk Factor Study, page 150

Employee Food Safety Training Committee Meeting Minutes

Date: Wednesday, December 17, 2014

Time: 3:00 p.m. (EST)

Facilitator: Hal King

Introduced himself as Chair and Ben as Vice Chair. . . Ben is not on the call due to illness.

1. Thanked everyone for agreeing to be a participant on the committee and explained that there is a lot of work to do
2. 19 voting members, Linda Catalan will not participate due to change in job duties
3. 18 participants on the call. Hal allowed the pragmatic system to announce callers.
4. Hal read the Antitrust Statement (conference for Food Protection, Inc.). Wants to be clear that everyone has a copy and understands.
5. Read the Committee Charge

   1. Make recommendations to the Conference for Food Protection in regard to:
      a. What a food employee should know about food safety, prioritized by risk.
      b. A guidance document to include recommendations for appropriate operator, regulator, and/or third-party food safety training program(s); including the criteria for the program and learning objectives.
   2. Report Committee recommendations to the 2016 Conference for Food Protection Biennial Meeting.

6. Ken Rosenwinkel – thanked Hal for being committee chair. Committee has one year as opposed to two years to complete the charge.
   - Hal stated that he wants to make sure that every voice is heard, and solicits everyone's input

7. The process of gathering information will allow to "close the gaps" in standards of food safety.
   - Christina. . .likes how process is layed out. Question: What can we gain from the training??
   - William. . .not a regulated thing from gov't perspective. It is a requirement for food safety training.
   - Chirag. . .understands that the focus is retail food protection and not the manufacturing side.
8. We are only talking about "line" employees. Don't want miss what we can learn from other sectors. The goal is to make sure that the food handler is ready.
9. Alan – Does anyone have a job that is based on Job Task Analysis (JTA)? Wants to prevent any assumptions as to what a food worker should know. The committee should decide what a food handler should really know. He and Hal have been through the JTA process. It would be great to stay as close to the JTA process as possible.
10. Take a look across the board at processes in different states (William). Agreed to be a part of this process and get ASTM standard information. Want to compare the states that are represented, just to see if there is a gap in what states are using.
11. Next call can be based on reports of gaps by members. Will collect info via email prior to call.
12. Steven (FDA) made suggestion to first figure out where programs are. Then look at them as a committee to agree on the actual gaps.
13. Aimee volunteered to get info on the grocery/retail side. Ben will search on the academic side.
14. Janice suggested to start at the state level.
15. Jeff Lang willing to serve with Ben on the academic sector.
16. Regardless of industry, there should not be that big of a difference.

17. A little confusion as to what the motive or goal is. As a baseline, it was suggested to start with the ASTM standard.
18. Hal thanked everyone for the comments and suggestions. The next call should take place at the end of January. Send emails or templates to Hal to assist. The goal is to make more progress.
19. Scheduling of future calls – suggested to preset calls. Select dates that will work for Hal and Ben. Then to send committee to vote on those dates. FDA can't use doodle. Meeting Wizard works best for FDA. Suggested to have calls more frequently.
20. Call ended at 4:25 p.m.

CFP Food Service Employee Training Committee Meeting
Chicago, IL - March 18, 2015
Minutes of the Meeting

Attendance (see below)

1. Introductions
The members introduced themselves and their interest in this committee.

2. An industry and regulatory perspective on the process (Chuck Catlin)
Co-Chair Chuck Catlin presented an overview of perspectives for the Committee to consider as it frames its work. It was noted that the typical food employee sees their activity as "low risk," a dangerous perspective. Catlin also reminded the members that consensus is important, and asked them to leave personal and business biases aside, and deliberate with open-mindedness.

3. Framing behavior-based training (Ben Chapman)
Co-Chair Ben Chapman suggested that the Committee could work on "knowledge based" guidance, but miss the opportunity to focus on changing behavior. Looking at the food safety requirements and risk factors viewed through the "why" of best practices, in a "behavior based" frame might yield greater impact. Identifying desirable behaviors and advancing their adoption and implementation is the opportunity. Chapman went on to present some academic background information for the members' consideration, including:

- A good analogy for our work is to consider employees that clean hospital rooms: its known that they care, and understand that their interventions (sanitizing to control infection) matters.

- For our purposes, how do we ensure that food employees care? Teaching and showing them that people get sick when they fail to adhere to standards, and that is largely preventable by food employees. Training must show them how to do this, and getting them talking to each other about this is essential to its successful adoption.
- Methods that matter:
    1. Using stories more than numbers
    2. Putting the info into relatable context for the employee
    3. Generating surprise
    4. Generating ongoing dialog

4. Review of the committee charge, clarification of scope

Charge 1
Make recommendations to the Conference for Food Protection in regard to:

a. What a food employee should know about food safety, prioritized by risk.
b. A guidance document to include recommendations for appropriate operator, regulator, and/or third-party food safety training program(s); including the criteria for the program and learning objectives.

Charge 2
Report Committee recommendations to the 2016 CFP Biennial Meeting.

Chapman asked Council II member Brain Turner to perspective on this Committee's genesis, and about what audience we should focus on. Turner explained that discussion about forming this Committee centered on the need for consistent criteria for "frontline" training, and how to provide value (impact) to that training.

Discussion ensued regarding the jobs/people this Committee should focus on impacting, and it was suggested that while position-specific information might be useful, starting with the Food Code definition of "food employee" is a better, more general, and broader reaching start. Consensus of the Committee is to use the Food Code definition of "food employee." Discussion ensued regarding the study and creation of JTAs, and consensus reached that this would not be undertaken by the Committee.

Chapman then asked the Committee to consider clarifying its understanding of the term "prioritized" in the charge, and consensus was reached that this means starting with the known risk factors and prioritizing their importance in training content. Chapman will communicate this "reading" of the prioritization charge to the CFP Executive Board.

Additional consensus was reached by the Committee that:

- the Committee's work will apply to employees in any place the Food Code applies to.
- the learning objectives in the Committee charge are from section a) of the charge (with perspective provided from Council II by Brian Turner).

5. Review cataloged documents/data sources

- Job Task Analysis (JTA) and the process
- Current industry outlines
- Compliance/behavior change literature related to employee food safety training
- FDA risk factor study insights

Chapman overviewed documents that Committee members were provided, and asked for others to be submitted. Differentiation was established between "certificate" (that uses learning objectives), and "certification" (that uses a JTA) work. Committee consensus is to proceed based on learning objectives, rather than JTAs.

Discussion ensued regarding CA and IL programs, and their basis in ASTM 2659, which does require a JTA, and consensus reached that what the Committee produces must be "measurable and reportable," and provide a template for national consistency.

Opposition was voiced to moving in any way toward ASTM 2659 and/or employee testing. It was pointed out that demonstration of knowledge via employee questions currently exists in the Food Code. Steven Hughes, FDA consultant to the Committee, pointed out that three main areas exist in our review: Content, Mechanics (implementation), and Food Code relativity, and suggested the Committee focus on the Content mission.

6. Establish subcommittees for each group

Chapman reviewed three proposed subcommittees scopes of work:

1. Review current Industry non-regulatory delivery
2. Review current state requirements (i.e., CA, IL, FL)
3. FDA Risk Factor related employee activities (FC sec. 203.11; "must haves" and "nice to haves").

The Committee Co-Chairs will call for volunteers to subcommittees, then when formed those groups will select their chairs.

Catlin pointed out that the Committee should be creative in its objectives and activity, not simply use existing "check boxes," and be aware of the opportunity to create work product based in or derived from something that does not yet exist.

7. Milestone setting

- Co-Chairs set March 27 as the deadline for subcommittee sign up.
- Subcommittees will meet at their own direction, and once empanelled the Committee Co-Chairs will establish reporting deadlines for the reminder of the CFP 2014-16 cycle.
- Committee Co-Chairs will poll Committee members for three proposed Committee meetings moving forward, with integration of the subcommittee schedules. Potential dates:
  - May 2015, in Chicago concurrent with the NRA show
  - July 24-27, 2015, in Portland concurrent with IAFP

November, 2015, week 1, details TBD

8. Adjourn

With unanimous consent the Committee adjourned at 1:40 PM.

Food Handler Training subcommittee: Industry non-regulatory delivery of food handler training
June 15
12pm ET- 1pm ET

Attending: Ben Chapman, Suzanne Feazell, Susan Delauris,Chirag Bhatt, Chuck Catlin, Aimee Lee, Stephen Hughes

- Reviewed the charge and approved the charge subcomponents.

- Quick thoughts on the charge, focused on generating a common outline capturing the elements of current programs.
- Suggestion to create a matrix, using risk factors as a foundation, in order to compare 'apples to apples' of different programs. What elements were similar?

- Discussion on recognizing that specific departments may result in specific requirements: produce department and pizza are different.

- Specific to job tasks should be recognized, not in the generic outline.
- Lets focus on the common knowledge, skills and behaviors.

- We need to try to achieve that the syllabus is universal as the baseline knowledge, skills and understanding

- Suggestion to align the matrix by the suggested inspection code

- Additional resources for this group: Brian Chapman State Food Safety & Kate Piche with NRA

Action 1 : Reach out to William on NRAs members looking like
Action 2: Susan Feazell - create a template to compare apples to apples - Susan to send to Ben
Action 3: Chirag to send to a quick email to restaurants food service to

gather FMI info.
Action 4: Chuck to reach out to additional resources noted above

CFP Employee Training Committee Meeting
IAFP Conference – Portland, OR
July 8, 2015
Conference call

Jordan Mason -FL
Ken Rosenwinkel - IL
Joe Graham - WA
Joyce Jensen

Ben talked about the charge, what we need to do.

Introductions

Expectations were confirmed – review state programs and discuss common elements

Allergens were discussed as a hot topic as they relate to food handlers - need to take into consideration and what's out there and not being used

Joe for context - states that already have it that go into the code interesting conversation, code requirement

Ken Shared: IL - Contentious issues were not really even within scope of content but related to implementation of assessment.

Some very basic criteria food employee training/food handler
Little of basic components - cleaning and sanitizing, temperature controls, personal hygiene
Should it be ANSI approved or not
* IL rule as a compromise - two classifications of training (restaurant vs non-restaurant) no such thing as restaurant vs. non-restaurant component

In IL - Certficates that required after three years

Joe from WA shared:

30 min training requirement as a minimum
Every two years
Food allergy awareness is included
Manual
36 questions are provided in the assessment they are risk based and weighted
Offered in 7 languages - not required in the code

Actions: Joe to send us a food handler info an populate the matrix. (completed)

Food employees

ANSI landminds

FL experience from Allergens Safe Staff
GA requirements
JTAs
Jordan – shared that there are not JTAs available from Florida

Wrap-up and next meeting confirmed for August 12, 2015.

CFP Employee Training Committee Meeting
July 8, 2015
Conference call

Attendees:
Tom McMahan
Susan Feazell
Ashley Eisenbeiser
Chirag Bhatt
Ben Chapman
Stephen Hughes

Chirag provided details on a few programs:
Cracker Barrel
Waffle House and Starbucks, to be added to matrix

Susan's discussed the matrix including common competencies and unique foci

Pest control - brief of and concise - inform supervisor as - control measures related to pest control

Tom suggested that cleaning and sanitizing - is a core item (specifically the difference between cleaning and sanitizing)

Identifying core items - pest control/cleaning and sanitizing should that maybe be required under.

Some discussion around allergens - potential around adding allergens for food handler core

Focused some discussion of knowledge of a food handler diseases:

Reportable illnesses

- Knowledge know and understand the 6 reportable illnesses
- Shouldn’t come to work if they are feeling sick
- Obligation when they have certain symptoms
- Some kind of documentation and a diagnosis is a manager
- If they are throwing up with diarrhea - because of the symptoms
- The problem with the anecdote, is that the indicated pathogens
- Sort of need to know why they are reporting it
- Teach them the symptoms vs. the pathogen
- Need to make sure that the knowledge

Wrap Up

CFP Employee Training Committee Meeting
IAFP Conference – Portland, OR
Monday, July 27, 2015
Portland Convention Center

A meeting of the CPF Training Committee was called to order by Chairman Ben Chapman at noon on July 27, 2015. Those in attendance were Ben Chapman, Susan Feazell, Hal King, Geoff Luebkemann, William Weichelt, Chuck Catlin, Davene Sarrocco-Smith, Bryan Chapman, George Nakamura, Jeff Lang, Joe Graham, ……

Chairman Chapman explained that the purpose of the meeting was to report on the progress of the work of the three subcommittees and clarify any matters.

Subcommittee 1: Looking at current Industry Practices with regard to food safety employee training.
There was some discussion regarding the different levels of training across the food service industries and the differing categories of food industries – grocery, restaurant, wholesale, etc. It was noted that the subcommittee should not describe in detail what is in the training program but that a subject matter is present.

Subcommittee 2: Looking at State Food Service Employee Training Programs.
It was noted that there appears to be little consistency between State food service training programs and requirements. A request went out for more state program information.

Subcommittee 3: Looking at Risk Factors as they relate to food safety employee training.
In reviewing the literature, it appears that there are five common risk factors being addressed across several training programs. They include Cross Contamination, Personal Hygiene/Hand Washing, Temperature Control, Employee Illness Reporting, and Cleaning/Sanitizing. There was some discussion regarding clarification of terms of employee illness reporting with regard to exclusion/restriction, reportable disease and symptom reporting. It was felt that symptom reporting was key to the discussion.

It was reported that some of the outliers being noted were issues like Pest Control, Allergens, etc.

It was noted that an important factor in evaluating training programs for the food serving employee would be to access the learning level of the population. It was also noted that when putting in place the California statutes for food training there were political hurdles which needed to be overcome and should be considered when making recommendations to Council. Two new committee members volunteered to work with Subcommittee 2 in looking at state programs.

It was reported that all three subcommittees were collecting data and information and building matrixes for the purpose of comparison and concluding recommendations.

Chairman Chapman advised that what we would be submitting to Council would be “guidelines” for what should be in any food server training program.

The subcommittees will be meeting by conference call monthly to complete their matrixes and will attempt to schedule a call of the full committee around the Thanksgiving time frame. Chairman Chapman thanked everyone in attendance and those on the phone.

CFP Food Employee Training Committee
Training Component Draft (October 2, 2015)

1. Introduction To Food Safety; What it is and the impact on health

Burden of foodborne illness

- Number of illnesses
- Cost of illnesses
- Consequences Pathogens of most concern – Add highly susceptible populations very quickly – and a possible example from the oral

What is food safety
What is foodborne illness
Who gets it, CDC risk factors

Other hazards – include it Chemical/Physical

Ben 10/2/2015 11:49 AM
Formatted: Indent: Left: 0"

2. Reportable Symptoms, Illnesses, Causes; Food Handler Role

Supervision

- Person in Charge

Employee Health

- Reportable Symptoms
    - Vomiting
    - Diarrhea
    - Jaundice
    - Sore throat with fever
    - Lesion containing pus or infected wound that is open and draining.

- Stay home if sick – if you have these symptoms -

- Reportable Illnesses
    - Norovirus

- Shiga Toxin-Producing Escherichia Coli or Shigella
- Salmonella spp.
- Salmonella Typhi
- Hepatitis A

- Exclusion/Restrictions

Labeling

- Consumer advisory

Ben 10/2/2015 11:54 AM
Comment [1]: Move – labeling is also not the correct – move it to allergens

Highly Susceptible Populations

Compliance with Approved Procedures

- HACCP Plans

Ben 10/2/2015 11:51 AM
Comment [2]:

3. Avoiding Contamination and Cross-contamination

Preventing contamination

- Ice
- Equipment
  - Utensils
- Consumers
- Produce Washing
- Animals
- Pasteurized Eggs
- Ventilation
- Vending Machines
  - Auto shutoff
- Equipment Certifications (NSF, UL)
- Single Service Use Items
- Proper Storage of Food
  - Locations
  - Storage levels

4. Time and Temperature Control PHF/TCS

Food

- Receiving

    - Condition
    - Temperatures
    - Shellfish
- Shellfish Tags
- Juicing

Destruction of organisms of public health Concern
- Cooking
- Freezing
    - Parasite destruction
- Reheating
- Raw Animal Foods

Limiting Growth Of Organisms of Public Health Concern
- Hot holding
- Cold holding
- Chilling
- Time as a public health control
- Thawing
- Date Marking (TCS RTE foods)

5. Personal Hygiene and Hand Washing

Good Hygienic Practices
- Clean Clothing
- Washing Hands and arms
- Fingernails
- Jewelry
- Proper eating, drinking and Tobacco use

Preventing Contamination from hands
- Food Contamination Prevention
- Hair Restraints
- Glove use
- Hand washing
- Facilities for hand washing
- No bare hand contact with RTE’s

6. Cleaning and Sanitizing

Chemical Use and Storage

- Chlorine
- Quaternary Ammonia
- Iodine
- Pesticides

Cleaning and Sanitation (Food & Non-food Contact Surfaces)

- Wiping Cloths
- Dish Washing
- Manual Cleaning
- Hot Water

Responding to Contamination Events

- Bodily Fluids clean up (Vomit, Diarrhea)

7. Pest Control

Insect control devices that are used to electrocute or stun fling insects must be designed to retain the insect within the device.

- Control devices shall not be located over food prep areas.
- Dead insects and fragments must be prevented from falling on exposed food or clean equipment or other food contact surfaces.
- Exposed food or food contact surfaces must be protected from contamination by insects, rodents or other vermin.

Poisonous or toxic materials shall be stored in a manner that prevents contamination of food, or food contact surfaces.

8. Hazard Identification & Control (receiving, storing and preparing)

Identify harbors for microorganisms

- Niches
- Foods to pay attention to
-

Identify control measures for some specific foods as they relate to risk factors

9. Allergen Control

Allergens are proteins that react negatively in some people triggering an immune system response that can be life threatening. Anaphylaxis is a severe allergic reaction of rapid onset affecting many body systems and is the most dangerous to the victim. More than 160 foods have been identified as sources of allergic reactions in humans. However, 90 percent of these reactions are caused by eight main food categories.
The 8 main categories of food containing allergens are milk, eggs, finfish, crustacean shellfish, peanuts, tree nuts, wheat and soy.

- Food services must post emergency contact numbers to provide a quick reference in an emergency.
- Call 911 if a guest or employee is having a serious allergic reaction.
- Ask the person, who is having the reaction, if they carry an EpiPen. **Do not inject the allergic victim.** The allergic person or medical personnel are the only people authorized to administer medicine.

Note: an EpiPen is a small medical device often carried by people that have severe allergic reactions. The device delivers a measured dose (or doses) of epinephrine (also known as adrenaline) using autoinjector technology.

Compliance With Laws

- Permits
- Regulatory Agencies
- Inspection and Correction of Violations

Facilities

- Approved Water Sources
- Hand wash sinks
- Hand drying provisions
- Plumbing
    - Airgap
    - Backflow prevention

- Mobile Food Trucks
- Toilet Rooms
- Lighting

Terms
(NOTE this is not the list of things that food employees should know, this is a list of terms that we would want to use for consistency within the content areas)

(1) "Food additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.3(e)(1).

(2) "Color additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.3(f).

"Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.

"Approved" means acceptable to the REGULATORY AUTHORITY based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

Asymptomatic.
(1) "Asymptomatic" means without obvious symptoms; not showing or producing indications of a disease or other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice.
(2) "Asymptomatic" includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

"aw " means water activity which is a measure of the free moisture in a FOOD, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol AW .
"Balut" means an embryo inside a fertile EGG that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.

"Beverage" means a liquid for drinking, including water. "Bottled drinking water" means water that is SEALED in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

"Casing" means a tubular container for sausage products made of either natural or artificial (synthetic) material.

"Certification number" means a unique combination of letters and numbers assigned by a SHELLFISH CONTROL AUTHORITY to a MOLLUSCAN SHELLFISH DEALER according to the provisions of the National Shellfish Sanitation Program.

"CFR" means CODE OF FEDERAL REGULATIONS. Citations in this Code to the CFR refer sequentially to the Title, Part, and Section numbers, such as 40

CFR 180.194 refers to Title 40, Part 180, Section 194. CIP.

(1) "CIP" means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and SANITIZING solution onto or over EQUIPMENT surfaces that require cleaning, such as the method used, in part, to clean and SANITIZE a frozen dessert machine.
(2) "CIP" does not include the cleaning of EQUIPMENT such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system. 3

"Commingle" means:
(1) To combine SHELLSTOCK harvested on different days or from different growing areas as identified on the tag or label, or
(2) To combine SHUCKED SHELLFISH from containers with different container codes or different shucking dates.

Comminuted. (1) "Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing.
(2) "Comminuted" includes FISH or MEAT products that are reduced in size and restructured or reformulated such as gefilte FISH, gyros, ground beef, and sausage; and a mixture of 2 or more types of MEAT that have been reduced in size and combined, such as sausages made from 2 or more MEATS.

"Conditional employee" means a potential FOOD EMPLOYEE to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential FOOD EMPLOYEES who may be

suffering from a disease that can be transmitted through FOOD and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

"Confirmed disease outbreak" means a FOODBORNE DISEASE OUTBREAK in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the FOOD as the source of the illness.

"Consumer" means a PERSON who is a member of the public, takes possession of FOOD, is not functioning in the capacity of an operator of a FOOD ESTABLISHMENT or FOOD PROCESSING PLANT, and does not offer the FOOD for resale.

Core Item. (1) "Core item" means a provision in this Code that is not designated as a PRIORITY ITEM or a PRIORITY FOUNDATION ITEM.
(2) "Core item" includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

"Corrosion-resistant material" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the FOOD to be contacted, the normal use of cleaning compounds and SANITIZING solutions, and other conditions of the use environment.

"Counter-mounted equipment" means EQUIPMENT that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

"Critical control point" means a point or procedure in a specific FOOD system where loss of control may result in an unacceptable health RISK.
"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CRITICAL CONTROL POINT to minimize the RISK that the identified FOOD safety HAZARD may occur.

“Cut leafy greens” means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term “leafy greens” includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach,

cabbage, kale, arugula and chard. The term “leafy greens” does not include herbs such as cilantro or parsley.

"Dealer" means a PERSON who is authorized by a SHELLFISH CONTROL AUTHORITY for the activities of SHELLSTOCK shipper, shucker-packer, re-packer, re-shipper, or depuration processor of MOLLUSCAN SHELLFISH according to the provisions of the National Shellfish Sanitation Program.

"Disclosure" means a written statement that clearly identifies the animal-derived FOODS which are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

Drinking Water.
(1) "Drinking water" means water that meets criteria as specified in 40 CFR 141 National Primary Drinking Water Regulations.
(2) "Drinking water" is traditionally known as "potable water.
(3) "Drinking water" includes the term "water" except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.

"Dry storage area" means a room or area designated for the storage of PACKAGED or containerized bulk FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and dry goods such as SINGLE-SERVICE items.

Easily Cleanable.
(1) "Easily cleanable" means a characteristic of a surface that: (a) Allows effective removal of soil by normal cleaning methods; (b) Is dependent on the material, design, construction, and installation of the surface; and (c) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into FOOD based on the surface's APPROVED placement, purpose, and use.

(2) "Easily cleanable" includes a tiered application of the criteria that qualify the surface as EASILY CLEANABLE as specified in Subparagraph (1) of this definition to different situations in which varying degrees of cleanability are required such as:

(a) The appropriateness of stainless steel for a FOOD preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for CONSUMER dining; or
(b) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the CONSUMER dining area.

"Easily movable" means:
(1) Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of EQUIPMENT for cleaning; and
(2) Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the EQUIPMENT to be moved for cleaning of the EQUIPMENT and adjacent area.

Egg.
(1) "Egg" means the shell EGG of avian species such as chicken, duck, goose, guinea, quail, RATITES or turkey.
(2) "Egg" does not include:
(a) A BALUT;
(b) The egg of reptile species such as alligator; or
(c) An EGG PRODUCT.

Egg Product.
(1) "Egg Product" means all, or a portion of, the contents found inside EGGS separated from the shell and pasteurized in a FOOD PROCESSING PLANT, with or without added ingredients, intended for human consumption, such as dried, frozen or liquid eggs.
(2) "Egg Product" does not include FOOD which contains EGGS only in a relatively small proportion such as cake mixes.

"Employee" means the PERMIT HOLDER, PERSON IN CHARGE, FOOD EMPLOYEE, PERSON having supervisory or management duties, PERSON on the payroll, family member, volunteer, PERSON performing work under contractual agreement, or other PERSON working in a FOOD ESTABLISHMENT.

"EPA" means the U.S. Environmental Protection Agency.

Equipment.

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

"Exclude" means to prevent a PERSON from working as an EMPLOYEE in a FOOD ESTABLISHMENT or entering a FOOD ESTABLISHMENT as an EMPLOYEE.

"FDA" means the U.S. Food and Drug Administration.

Fish.
(1) "Fish" means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption.
(2) "Fish" includes an edible human FOOD product derived in whole or in part from FISH, including FISH that have been processed in any manner.

"Food" means
(1) a raw, cooked, or processed edible substance, ice, BEVERAGE, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum. "Foodborne disease outbreak" means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common FOOD.

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

"Food employee" means an individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES

Food Establishment.
(1) "Food establishment" means an operation that: (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides FOOD for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or FOOD bank; and (b) relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(2) "Food establishment" includes: (a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the REGULATORY AUTHORITY; and (b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.

(3) "Food establishment" does not include:
(a) An establishment that offers only prePACKAGED FOODS that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOODS;
(b) A produce stand that only offers whole, uncut fresh fruits and vegetables;
(c) A FOOD PROCESSING PLANT; including those that are located on the PREMISES of a FOOD ESTABLISHMENT
(d) A kitchen in a private home if only FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, is prepared for sale or service at a function such as a religious or charitable organization’s bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY;

(e) An area where FOOD that is prepared as specified in Subparagraph (3) (d) of this definition is sold or offered for human consumption;

(f) A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; or

(g) A private home that receives catered or home-delivered FOOD. Food Processing Plant.
(1) "Food processing plant" means a commercial operation that manufactures, packages, labels, or stores FOOD for human consumption, and provides FOOD for sale or distribution to other business entities such as FOOD PROCESSING PLANTS or FOOD ESTABLISHMENTS.
(2) "Food processing plant" does not include a FOOD ESTABLISHMENT.

Game Animal.
(1) "Game animal" means an animal, the products of which are FOOD, that is not classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2 Definitions, or as Poultry, or FISH.
(2) "Game animal" includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.
(3) "Game animal" does not include RATITES.

"General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175 Pesticides classified for restricted use. "Grade A standards" means the requirements of the United States Public Health Service/FDA "Grade A Pasteurized Milk Ordinance" with which certain fluid and dry milk and milk products comply.

"HACCP plan" means a written document that delineates the formal procedures for following the HAZARD Analysis and CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

Handwashing Sink.

(1) "Handwashing sink" means a lavatory, a basin or vessel for washing, a wash basin, or a PLUMBING FIXTURE especially placed for use in personal hygiene and designed for the washing of the hands.
(2) "Handwashing sink" includes an automatic handwashing facility.

"Hazard" means a biological, chemical, or physical property that may cause an unacceptable CONSUMER health RISK.

"Health practitioner" means a physician licensed to practice medicine, or if allowed by LAW, a nurse practitioner, physician assistant, or similar medical professional.

"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned FOODS, to maintain the commercial sterility of its contents after processing.

"Highly susceptible population" means PERSONS who are more likely than other people in the general population to experience foodborne disease because they are:
(1) Immunocompromised; preschool age children, or older adults; and
(2) Obtaining FOOD at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

"Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:
(1) The number of potential injuries, and
(2) The nature, severity, and duration of the anticipated injury.

"Injected" means manipulating MEAT to which a solution has been introduced into its interior by processes that are referred to as "injecting," “pump marinating,” or "stitch pumping”.

Juice.

(1) "Juice" means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or purée.
(2) "Juice" does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as BEVERAGES or ingredients of BEVERAGES.

"Kitchenware" means FOOD preparation and storage UTENSILS.

"Law" means applicable local, state, and federal statutes, regulations, and ordinances.

"Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves. Major Food

Allergen.
(1) "Major food allergen" means: (a) Milk, EGG, FISH (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or (b) A FOOD ingredient that contains protein derived from a FOOD, as specified in Subparagraph (1)(a) of this definition.
(2) "Major food allergen" does not include: (a) Any highly refined oil derived from a FOOD specified in Subparagraph (1)(a) of this definition and any ingredient derived from such highly refined oil; or (b) Any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282).

"Meat" means the flesh of animals used as FOOD including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except FISH, POULTRY, and wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (4).

Mechanically Tenderized.
(1) "Mechanically tenderized" means manipulating meat with deep penetration by processes which may be referred to as “blade tenderizing,” “jaccarding,” “pinning,” “needling,” or using blades, pins, needles or any mechanical device.

(2) "Mechanically tenderized" does not include processes by which solutions are INJECTED into meat. "mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

"Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

Non-Continuous Cooking.
(1) "Non-continuous cooking" means the cooking of FOOD in a FOOD ESTABLISHMENT using a process in which the initial heating of the FOOD is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service.
(2) "Non-continuous cooking" does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

Packaged.
(1) "Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether PACKAGED in a FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT.
(2) "Packaged" does not include wrapped or placed in a carry-out container to protect the FOOD during service or delivery to the CONSUMER, by a FOOD EMPLOYEE, upon CONSUMER request.

"Permit" means the document issued by the REGULATORY AUTHORITY that authorizes a PERSON to operate a FOOD ESTABLISHMENT.

"Permit holder" means the entity that:
(1) Is legally responsible for the operation of the FOOD ESTABLISHMENT such as the owner, the owner's agent, or other PERSON; and
(2) Possesses a valid PERMIT to operate a FOOD ESTABLISHMENT.

"Person" means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

"Person in charge" means the individual present at a FOOD ESTABLISHMENT who is responsible for the operation at the time of inspection.

Personal Care Items.
(1) "Personal care items" means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a PERSON'S health, hygiene, or appearance.
(2) "Personal care items" include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

"pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

"Physical facilities" means the structure and interior surfaces of a FOOD ESTABLISHMENT including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

"Plumbing fixture" means a receptacle or device that:
(1) Is permanently or temporarily connected to the water distribution system of the PREMISES and demands a supply of water from the system; or
(2) Discharges used water, waste materials, or SEWAGE directly or indirectly to the drainage system of the PREMISES.

"Plumbing system" means the water supply and distribution pipes; PLUMBING FIXTURES and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the PREMISES; and water-treating EQUIPMENT.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in 4 categories:
(1) Cleaners and SANITIZERS, which include cleaning and SANITIZING agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;
(2) Pesticides, except SANITIZERS, which include substances such as insecticides and rodenticides;

(3) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and PERSONAL CARE ITEMS that may be deleterious to health; and
(4) Substances that are not necessary for the operation and maintenance of the establishment and are on the PREMISES for retail sale, such as petroleum products and paints.

"Poultry" means:
(1) Any domesticated bird (chickens, turkeys, ducks, geese, guineas, RATITES, or squabs), whether live or dead, as defined in 9 CFR 381.1 Poultry Products Inspection Regulations Definitions, Poultry; and
(2) Any migratory waterfowl or game bird, pheasant, partridge, quail, grouse, or pigeon, whether live or dead, as defined in 9 CFR 362.1 Voluntary Poultry Inspection Regulations, Definitions.

"Premises" means:
(1) The PHYSICAL FACILITY, its contents, and the contiguous land or property under the control of the PERMIT HOLDER; or
(2) The PHYSICAL FACILITY, its contents, and the land or property not described in Subparagraph (1) of this definition if its facilities and contents are under the control of the PERMIT HOLDER and may impact FOOD ESTABLISHMENT personnel, facilities, or operations, and a FOOD ESTABLISHMENT is only one component of a larger operation such as a healthcare facility, hotel, motel, school, recreational camp, or prison.

"Primal cut" means a basic major cut into which carcasses and sides of MEAT are separated, such as a beef round, pork loin, lamb flank, or veal breast.

Priority Item.
(1) "Priority item" means a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.
(2) "Priority item" includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and
(3) "Priority item" is an item that is denoted in this Code with a superscript P-P .

Priority Foundation Item.

(1) "Priority foundation item" means a provision in this Code whose application supports, facilitates or enables one or more PRIORITY ITEMS.
(2) "Priority foundation item" includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and
(3) "Priority foundation item" is an item that is denoted in this Code with a superscript Pf - Pf .

"Public water system" has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.

"Ratite" means a flightless bird such as an emu, ostrich, or rhea.

Ready-to-Eat Food.
(1) "Ready-to-eat food" means FOOD that:
(a) Is in a form that is edible without additional preparation to achieve FOOD safety, as specified under one of the following: ¶ 3-401.11(A) or (B), § 3-401.12, or § 3-402.11, or as specified in ¶ 3-401.11(C); or
(b) Is a raw or partially cooked animal FOOD and the consumer is advised as specified in Subparagraphs 3-401.11(D)(1) and (3); or
(c) Is prepared in accordance with a variance that is granted as specified in Subparagraph 3-401.11
(D) (4); and(d) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.
(2) "Ready-to-eat food" includes:
(a) Raw animal FOOD that is cooked as specified under § 3-401.11 or 3-401.12, or frozen as specified under § 3-402.11;
(b) Raw fruits and vegetables that are washed as specified under § 3-302.15;
(c) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;
(d) All TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked to the temperature and time required for the specific FOOD under Subpart 3-401 and cooled as specified under § 3-501.14;

(e) Plant FOOD for which further washing, cooking, or other processing is not required for FOOD safety, and from which rinds, peels, husks, or shells, if naturally present are removed;
(f) Substances derived from plants such as spices, seasonings, and sugar;
(g) A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for FOOD safety;
(h) The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured MEAT and POULTRY products, such as prosciutto ham, country cured ham, and Parma ham; and dried MEAT and POULTRY products, such as jerky or beef sticks; and
(i) FOODS manufactured as specified in 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

Reduced Oxygen Packaging.
(1) "Reduced oxygen packaging" means:
(a) The reduction of the amount of oxygen in a PACKAGE by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and
(b) A process as specified in Subparagraph (1)(a) of this definition that involves a FOOD for which the HAZARDS Clostridium botulinum or Listeria monocytogenes require control in the final PACKAGED form.
(2) "Reduced oxygen packaging" includes:
(a) Vacuum PACKAGING, in which air is removed from a PACKAGE of FOOD and the PACKAGE is HERMETICALLY SEALED so that a vacuum remains inside the PACKAGE;
(b) Modified atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the PACKAGING material or the respiration of the FOOD. Modified atmosphere PACKAGING includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;
(c) Controlled atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that until the PACKAGE is opened, its composition is different from air, and continuous control of that atmosphere

is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, non-respiring FOOD, and impermeable PACKAGING material;
(d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or
(e) Sous vide PACKAGING, in which raw or partially cooked FOOD is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

"Refuse" means solid waste not carried by water through the SEWAGE system.

"Regulatory authority" means the local, state, or federal enforcement body or authorized representative having jurisdiction over the FOOD ESTABLISHMENT.

"Reminder" means a written statement concerning the health RISK of consuming animal FOODS raw, undercooked, or without otherwise being processed to eliminate pathogens.

"Re-service" means the transfer of FOOD that is unused and returned by a CONSUMER after being served or sold and in the possession of the CONSUMER, to another PERSON.

"Restrict" means to limit the activities of a FOOD EMPLOYEE so that there is no RISK of transmitting a disease that is transmissible through FOOD and the FOOD EMPLOYEE does not work with exposed FOOD, clean EQUIPMENT, UTENSILS, LINENS, or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.
"Restricted egg" means any check, dirty EGG, incubator reject, inedible, leaker, or loss as defined in 9 CFR 590.

"Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

"Risk" means the likelihood that an adverse health effect will occur within a population as a result of a HAZARD in a FOOD.

"Safe material" means:
(1) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any FOOD;
(2) An additive that is used as specified in § 409 of the Federal Food, Drug, and Cosmetic Act; or
(3) Other materials that are not ADDITIVES and that are used in conformity with applicable regulations of the Food and Drug Administration.

"Sanitization" means the application of cumulative heat or chemicals on cleaned FOOD-CONTACT SURFACES that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

"Sealed" means free of cracks or other openings that allow the entry or passage of moisture.

"Service animal" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

"Servicing area" means an operating base location to which a mobile FOOD ESTABLISHMENT or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding FOOD.

"Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

"Shellfish control authority" means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of MOLLUSCAN SHELLFISH harvesters and DEALERs for interstate commerce.

"Shell stock" means raw, in-shell MOLLUSCAN SHELLFISH.

"Shiga toxin-producing Escherichia coli" (STEC) means any E. coli capable of producing Shiga toxins (also called verocytotoxins). STEC infections can be asymptomatic or may result in a spectrum of illness ranging from mild non-bloody diarrhea, to hemorrhagic colitis (i.e., bloody diarrhea), to hemolytic uremic syndrome (HUS - a type of kidney failure). Examples of serotypes of STEC include: E. coli O157:H7; E. coli O157:NM; E. coli O26:H11; E. coli O145:NM; E. coli O103:H2; and E. coli O111:NM. STEC are sometimes referred to as VTEC (verocytotoxigenic E. coli) or as EHEC (Enterohemorrhagic E. coli). EHEC are a subset of STEC which can cause hemorrhagic colitis or HUS.

"Shucked shellfish" means MOLLUSCAN SHELLFISH that have one or both shells removed. "Single-service articles" means TABLEWARE, carry-out UTENSILS, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one PERSON use after which they are intended for discard.

Single-Use Articles.
(1) "Single-use articles" means UTENSILS and bulk FOOD containers designed and constructed to be used once and discarded.
(2) "Single-use articles" includes items such as wax paper, butcher paper, plastic wrap, formed aluminum FOOD containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications under §§ 4-101.11, 4-201.11, and 4-202.11 for multiuse UTENSILS.

"Slacking" means the process of moderating the temperature of a FOOD such as allowing a FOOD to gradually increase from a temperature of -23o C (-10o F) to -4o C (25o F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen FOOD such as shrimp.

"Smooth" means:

(1) A FOOD-CONTACT SURFACE having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel;
(2) A non-FOOD-CONTACT SURFACE of EQUIPMENT having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and
(3) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

"Tableware" means eating, drinking, and serving UTENSILS for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

"Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of FOOD, air, or water.

"Temporary food establishment" means a FOOD ESTABLISHMENT that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

Time/Temperature Control for Safety Food (formerly “potentially hazardous food” (PHF)).
(1) "Time/temperature control for safety food" means a FOOD that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.
(2) "Time/temperature control for safety food" includes:
(a) An animal FOOD that is raw or heat-treated; a plant FOOD that is heat treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and
(b) Except as specified in Subparagraph (3)(d) of this definition, a FOOD that because of the interaction of its AW and PH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

Table A. Interaction of PH and AW for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

A_W values	pH: 4.6 or less	pH: > 4.6 - 5.6	pH: > 5.6
≤0.92	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - 0.95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD
** PA means Product Assessment required

Table B. Interaction of PH and AW for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_W values	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	non-TCS food*	Non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD
** PA means Product Assessment required

(3) "Time/temperature control for safety food" does not include:
(a) An air-cooled hard-boiled EGG with shell intact, or an EGG with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;
(b) A FOOD in an unopened HERMETICALLY SEALED CONTAINER that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;
(c) A FOOD that because of its PH or AW value, or interaction of AW and PH values, is designated as a non-TCS FOOD in Table A or B of this definition;
(d) A FOOD that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that FOOD Is precluded due to:

(i) Intrinsic factors including added or natural characteristics of the FOOD such as preservatives, antimicrobials, humectants, acidulants, or nutrients,
(ii) Extrinsic factors including environmental or operational factors that affect the FOOD such as packaging, modified atmosphere such as REDUCED OXYGEN PACKAGING, shelf life and use, or temperature range of storage and use, or
(iii) A combination of intrinsic and extrinsic factors; or

(e) A FOOD that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the Subparagraphs (3)(a) - (3)(d) of this definition even though the FOOD may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

"USDA" means the U.S. Department of Agriculture.

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

"Variance" means a written document issued by the REGULATORY AUTHORITY that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the REGULATORY AUTHORITY, a health HAZARD or nuisance will not result from the modification or waiver.

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of FOOD in bulk or in packages without the necessity of replenishing the device between each vending operation.

"Vending machine location" means the room, enclosure, space, or area where one or more VENDING MACHINES are installed and operated and includes the storage areas and areas on the PREMISES that are used to service and maintain the VENDING MACHINES.

"Warewashing" means the cleaning and SANITIZING of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT.

"Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

Employee Food Safety Training Topics Adopted Dec 1, 2015			
Topic	**Category**	**Short Description**	**Risk Delineation**
I	Introduction To Food Safety	Burden of foodborne illness	
		Pathogens of most concern	Risk Factors
		CDC risk factors	Risk Factors
		Highly susceptible populations	Priority
II	Reportable Symptoms, Illnesses, Causes; Food Handler Role	Stay home if sick	Priority
		Reportable symptoms (food code)	Priority
		Reportable illnesses (food code)	Priority Foundation
III	Personal Hygiene and Hand Washing	Clean clothing	
		Washing hands and arms: How, When, Facility needs	Priority
		Fingernails	Priority Foundation
		Jewelry	
		Proper eating, drinking and tobacco use	
		Hair restraints	
		Glove use	Priority Foundation
		Bare hand contact with ready-to-eat foods	Priority Foundation
IV	Avoiding Contamination and Cross-contamination	Preventing contamination: ice	Priority
		Preventing contamination: equipment, utensils	
		Preventing contamination: produce washing	
		Preventing contamination: proper food storage (location, storage hierarchy)	Priority
V	Allergen Control	8 main categories	
		Major symptoms	
VI	Time and Temperature Control PHF/TCS	Cooking	Priority
		Cooling	Priority Foundation
		Thawing	
		Reheating	Priority
		Hot holding	Priority
		Cold holding	Priority

		Date marking	Priority Foundation
VII	Cleaning and Sanitizing	Chemical use and storage (sanitizers)	Priority Foundation
		Chemical use and storage (chemicals)	Priority Foundation
		Wiping cloths	
		Dish washing: Mechanical, Manual	Priority Foundation
		Hot water	Priority Foundation

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-002

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Report- Demonstration of Knowledge (DoK) Committee

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) Demonstration of Knowledge Committee seeks Council II's acknowledgment of the committee's final report.

Public Health Significance:

Demonstration of knowledge is identified as one of the five key public health interventions to protect consumer health. The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard Analysis and Critical Control Point (HACCP) principles, and Code requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Code requirements, and to take appropriate preventive and corrective actions. A dialogue with the person in charge during the inspection process will also reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the 2014-2016 Demonstration of Knowledge (DoK) Committee Report and attachments, and
2. Acknowledgement of the committee members for their participation on the conference calls, surveys and work completed.

Submitter Information 1:

Name:	Michelle Haynes
Organization:	2014-2016 Demonstration of Knowledge Committee
Address:	DBPR, Hotels and Restaurants1940 N Monroe St.

City/State/Zip: Tallahassee, FL 32399-1011
Telephone: 850.717-1734
E-mail: michelle.haynes@myfloridalicense.com

Submitter Information 2:

Name: Eric Moore, Committee Co-Chair
Organization: 2014-2016 Demonstration of Knowledge Committee
Address: ACME Markets75 Valley Stream Parkway
City/State/Zip: Malvern, PA 19355
Telephone: 267.971.0916
E-mail: eric.moore@acmemarkets.com

Content Documents:

- "2014-2016 DoK Committee Final Report"
- "Attachment I 2014-2016 DoK Roster"
- "Attachment II 2014-2016 DoK Meeting Record"
- "Attachment III 2014-2016 DoK Pro Con Table 2-102.11 Template"
- "Attachment IV 2014-2016 DoK Pro Con Listing 2013 Food Code 2-102.11 (A)"
- "Attachment V 2014-2016 DoK Pro Con Listing 2013 Food Code 2-102.11 (C)"
- "Attachment VI 2014-2016 DoK Alternative Methods of Demonstrating Knowledge"
- "Attachment VII 2014-2016 DoK Final Survey Results"

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

COMMITTEE NAME: Demonstration of Knowledge Committee (DoK)

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council II

DATE OF REPORT: January 31, 2016

SUBMITTED BY: Michelle Haynes and Eric Moore, Co-Chairs

COMMITTEE CHARGE(s):

1. Review the current methods in Food Code Section 2-102.11 for demonstrating knowledge.
2. Identify the pros and cons of the existing methods in Food Code Section 2-102.11(A) and 2-102.11(C) for the Person in Charge to demonstrate knowledge.
3. In lieu of Food Code Section 2-102.11(A) and 2-102.11(C), identify methods that could be used to demonstrate knowledge if/when the Certified Food Protection Manager (CFPM) is not onsite.
4. Identify the pros and cons of alternative methods to demonstrate knowledge if/when the CFPM is not onsite. Although not limited to the following areas, the committee should assess the pros and cons of each alternative method in light of the following areas:
    a. Differentiation between knowledge and application;
    b. Emphasis on risk factors;
    c. Ease of uniform assessment by regulators and industry;
    d. Enabling the Person in Charge to demonstrate knowledge even when there is language barrier;
    e. What corrective action should be taken when there is not a demonstration of knowledge from the Certified Food Protection Manager or the Person In Charge.
5. Report back to the 2016 Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall DoK Committee Activities:
    a. The DoK Committee began actively addressing the charges starting with the first of many web conference calls in November 2014. Meeting records are detailed in Attachment II 2014-2016 DoK Meeting Record. After an initial review of the relevant Food Code section in question, committee members contributed their suggestions of pros, cons and alternative methods via email. The compilation was shared and vigorously discussed among the members during monthly web conference calls. Customized online surveys (see Attachment VII) were used to determine the selected statements that would be included in the final report.
    b. The DoK committee was able to successfully complete the majority of its charges except Charge 4.
        i. Charge 1, completed: "*Review the current methods in Food Code Section 2-102.11 for demonstrating knowledge."*
            1. The review of Food Code Section 2-102.11 was completed by having committee members fill out a form (*Attachment III DoK Pro & Con Table*

2-102.11) that classified each article in Food Code Section 2-102.11 as a pro or con.

2. Each member was requested to provide an explanation for each article in section 2-102.11 for both pro and con point of view.
3. This form was then compiled in to one list for use in completing Charge 2 and 3.

ii. Charge 2, completed: "*Identify the pros and cons of the existing methods in Food Code Section 2-102.11(A) and 2-102.11(C) for the Person in Charge to demonstrate knowledge."*

1. Member feedback from charge 1 was then compiled into two separate pro and cons documents:
    a. Attachment IV 2014-2016 DoK Pro Con Listing 2013 FDA Food Code 2-102.11(A)
        i. This document identifies the Pros and Cons determined by the committee through consensus that would be used to develop the DoK Final Survey that would be used to support the committee's recommendations to the conference.
        ii. Should the conference grant re-formation of the Demonstration of Knowledge Committee this document is recommended for use.
    b. Attachment V 2014-2016 DoK Pro Con Listing 2013 FDA Food Code 2-102.11(C)
        i. This document identifies the Pros and Cons determined by the committee through consensus that would be used to develop the DoK Final Survey that would be used to support the committee's recommendations to the conference.
        ii. Should the conference grant re-formation of the Demonstration of Knowledge Committee this document is recommended for use.
2. Consensus for all pros and cons was reached by the Demonstration of Knowledge Committee

iii. Charge 3, complete: "*In lieu of Food Code Section 2-102.11(A) and 2-102.11(C), identify methods that could be used to demonstrate knowledge if/when the CFPM is not onsite."*

1. Member feedback obtained from charge 1 was then compiled into Attachment VI 2014-2016 DoK Alternative Methods to Demonstrating Knowledge.
    a. This document provides 10 methods which food establishments are able to demonstrate knowledge in the absence of a CFPM.
    b. These methods were determined through committee consensus.
    c. Also included are is suggested alternative Food Code language for Section 2-102.11.
    d. Should the conference grant re-formation of the Demonstration of Knowledge Committee this document is recommended for use.

iv. Charge 4, incomplete. "*Identify the pros and cons of alternative methods to demonstrate knowledge if/when the CFPM is not onsite. Although not limited to the following areas, the Committee should assess the pros and cons of each alternative method in light of the following areas:*

a. Differentiation between knowledge and application;
b. Emphasis on risk factors;
c. Ease of uniform assessment by regulators and industry;
d. Enabling the Person in Charge to demonstrate knowledge even when there is a language barrier;
e. What corrective action should be taken when there is not a demonstration of knowledge from the Certified Food Protection Manager or the Person in Charge?"

1. Due to time constraints, the DoK Committee was unable to address Charge 4. It is the Committee's desire to be re-created and charged with completing this charge from the 2014 CFP Biennial Meeting using the methods outlined in Attachment VI Alternative Methods for Demonstrating Knowledge.

2. Recommendations for consideration by Council II:
   a. The committee recommends that the Council II acknowledge the final report, including Attachments I-VII.
   b. The DoK Committee will submit an issue to recommend re-creation of the committee in order to complete the charges originally assigned during the CFP 2014 Biennial Meeting, utilizing Attachments II-VII as reference documents.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. **Report – Demonstration of Knowledge Committee**
   The committee seeks acknowledgement of the DoK Committee report including the Attachments I-VII and thanks the committee members for their work.
2. **Re-Create – Demonstration of Knowledge Committee**
   Recreate the Demonstration of Knowledge (DoK) Committee following the CFP 2016 Biennial Meeting with the following charges:
   a. Review findings of 2014-2016 DoK Charge 2 "*Identify the pros and cons of the existing methods in Food Code Section 2-102.11(A) and 2-102.11(C) for the Person in Charge to demonstrate knowledge."* using the following:
      i. Attachment IV 2014-2016 DoK Pro Con Listing 2013 FDA Food Code 2-102.11(A)
   b. Attachment V 2014-2016 DoK Pro Con Listing 2013 FDA Food Code 2-102.11(C)Continue evaluation of 2014-2016 DoK Committees original Charge 4:. "*Identify the pros and cons of alternative methods to demonstrate knowledge if/when the CFPM is not onsite. Although not limited to the following areas, the Committee should assess the pros and cons of each alternative method in light of the following areas:*

a. Differentiation between knowledge and application;
b. Emphasis on risk factors;
c. Ease of uniform assessment by regulators and industry;

d. Enabling the Person in Charge to demonstrate knowledge even when there is a language barrier;
e. What corrective action should be taken when there is not a demonstration of knowledge from the Certified Food Protection Manager or the Person in Charge?" using the following:
i Attachment VI 2014-2016 DoK Alternative Methods to Demonstrating Knowledge

c. Propose alternative methods as recommended FDA Food Code language
d. Present their findings at the CFP 2018 Biennial Meeting.

ATTACHMENTS:

I. 2014-2016 DoK Roster
II. 2014-2016 DoK Meeting Record
III. 2014-2016 DoK Pro Con Table 2-102.11 Template
IV. 2014-2016 DoK Pro Con Listing 2013 FDA Food Code, section 2-102.11(A)
V. 2014-2016 DoK Pro Con Listing 2013 FDA Food Code, section 2-102.11(C)
VI. 2014-2016 DoK Alternative Methods of Demonstrating Knowledge
VII. 2014-2016 DoK Final Survey Results

2014-2016 Demonstration of Knowledge Committee Roster

Committee Name: Demonstration of Knowledge

Last	First	Position	Constituency	Employer	City	State	Telephone	Email
Bogard	April	Member	State Regulator	Minnesota DOH	St Paul	MN	(651) 201-5076	april.bogard@state.mn.us
Brown	Robert	Member	Industry	Whole Foods Market	Austin	TX	(512) 944-7405	robert.brown@wholefoods.com
Buck	Francie	Member	Industry	Sealed Air(Diversey)	Racine	WI	(505) 610-3818	francie.buck@sealedair.com
Crabtree	Deborah	Member	Local Regulator	Fairfax County Health Dept	Fairfax	VA	(703) 246-8431	deborah.crabtree@fairfaxcounty.gov
Dela Cruz	Hector	Member	Local Regulator	LA County Environmental Health	Los Angeles	CA	(818) 672-2230	hdelacruz@ph.lacounty.gov
Earnest	Mark	Member	Industry	Captain D's	Nashville	TN	(615) 231-2089	mark_earnest@captainds.com
Ford	Lisa	Member	Industry	Brinker International	Dallas	TX	(972) 770-9627	lisa.ford@brinker.com
Gilliland	Robert	Member	Local Regulator	Kansas City, MO Health Department	Kansas City	MO	(816) 513-6181	rob.gilliland@kcmo.org
Haynes	Michelle	Co-Chair	State Regulator	DBPR, Division of Hotels & Restaurants	Tallahassee	FL	(850) 717-1734	michelle.haynes@myfloridalicense.com
Huang	Yao-Wen	Member	Academia	University of Georgia	Athens	GA	(706) 542-1092	huang188@gmail.com
Hughes	Stephen	FDA Advisor	Federal Regulator	FDA	College Park	MD	(240) 402-2833	stephen.hughes@fda.hhs.gov
Hults	Julie	Member	Local Regulator	City of Milwaukee	Milwaukee	WI	(414) 286-5746	jhults@milwaukee.gov
James-Davis	Lucia	Member	Industry	The Seritech Group	Charlotte	NC	(321) 287-1394	lucia.james-davis@steritech.com
Lively	Shanna	Member	State Regulator	TN Department of Agriculture	Nashville	TN	(615) 837-5176	shanna.lively@tn.gov
Marcello	John	FDA Advisor	Federal Regulator	FDA	Tempe	AZ	(480) 829-7396	john.marcello@fda.hhs.gov
Miklos	Mark(Mick)	Member	Industry	National Restaurant Association	Buford	GA	(770) 868-7422	mmiklos@restaurant.org
Moore	Eric	Co-Chair	Industry	ACME Markets	Malvern	PA	(267) 971-0916	eric.moore@acmemarkets.com
Morris	Sheri	Member	State Regulator	PA Dept. of Agriculture	Harrisburg	PA	(717) 787-5289	shmorris@pa.gov
Peters	Brad	Member	Industry	HRBUniversal LLC	Birmingham	AL	(855) 447-2864	bpeters@hrbuni.net
Sylvis	Christine	Member	Local Regulator	Southern Nevada Health District	Las Vegas	NV	(702) 759-1251	sylvis@snhdmail.org
Taylor	Todd	Member	Industry	Ecolab	Greensboro	NC	(336) 931-2200	todd.taylor@ecolab.com
Yamnik	Dale	Member	Industry	Yum! Brands, Inc.	Saint Cloud	FL	(407) 593-6181	dale.yamnik@yum.com
Zaziski	Linda	Member	Industry	Little Caesers Enterprises; Inc.	Detroit	MI	(313) 471-6550	linda.zaziski@lcecorp.com
Radke	Vince	CDC Advisor	Federal Regulator	CDC			(770) 488-7065	vradke@cdc.gov
Balli	Petra	At Large Member	Industry	Aramark	Philadelphia	PA	(215) 413-8745	balli-petra@aramark.com
Deslauriers	Susan	At Large Member	Industry	Big Y Foods	Springfield	MA	(413) 504-4452	deslaurs@bigy.com
Erwin	Rob	At Large Member	Local Regulator	Fairfax County Health Department	Fairfax	VA	(703) 246-8430	robert.erwin@fairfaxcounty.gov
Eckhardt	Christina	At Large Member	Industry	Aramark	Philadelphia	PA	(267) 939-4894	eckhardt-christina@aramark.com
Nelson	Laura	At Large Member	Industry	Alchemy Systems	Austin	TX	(512) 637-5100	laura.nelson@alchemysystems.com
Paster	Tara	At Large Member	Industry	Paster Training, Inc.	Gilbertsville	PA	(610) 970-1776	tara.paster@pastertraining.com
Tyjewski	Susan	At Large Member	Industry	CKE Restaurants Holdings, Inc.	Anaheim	CA	(714) 254-4552	styjewski@ckr.com
Wood	Sharon	At Large Member	Industry	HEB Grocery Company	San Antonio	TX	(210) 938-6511	wood.sharon@heb.com

2014 - 2016 CFP
Demonstration of Knowledge Committee

Teleconference: 1
Friday, November 14, 2014 **Call-In Number: 877-394-5901**
1:00pm – 3:00p.m. EST **Access Code: 2995496#**

Co-Chairs: Eric Moore, Michelle Haynes
FDA Advisors: John Marcello Stephen Hughes
CDC Advisor: Vince Radke
Scribe: *Eric Moore*

AGENDA ITEMS:

1. Welcome, Roll-Call,	Eric & Michelle	**X**
2. Conference for Food Protection, Inc. Antitrust Statement	**Eric**	**X**
3. Review of CFP Committee Membership Expectations a. *CFP Biennial Meeting/Conference Procedures 2014,Part VIII* b. Participation and feedback expectations	**Michelle**	**X**
4. Demonstration of Knowledge Committee Charges	**Eric**	**X**
5. Food Code provisions review	**Stephen Hughes**	**X**
6. Review of issue "As Submitted" at 2014 CFP	**April Bogard**	**X**
7. Review CFP Timeline for Committee Work	**Michelle**	**X**
8. Work Plan Recommendations (Please be prepared to identify the charges in which you are most interested in the event of subgroup formation)	**All**	**X**
9. Other Items/General Discussion	**All**	**X**
10. Regular Monthly Meeting Dates (Please have your calendar's available)	**All**	**X**

Attendance:

April	Bogard	X	Sheri	Morris	X
Robert	Brown	X	Stephen	Hughes	X
Deborah	Crabtree	X	Vince	Radke	X
Hector	Dela Cruz	X	Susan	Deslauriers	X
Mark	Earnest	X	Christina	Meinhardt	X
Robert	Gilliland	X	Laura	Nelson	X
Michelle	Haynes	X	Tara	Paster	X
Julie	Hults	X	Susan	Tyjewski	X
Lucia	James-Davis	X	Linda	Zaziski	X
Shanna	Lively	X	Todd	Taylor	X
Mark(Mick)	Miklos	X	Christine	Sylvis	X
Eric	Moore	X	Dale	Yamnik	X

Meeting Minutes:

- Welcome and introductions completed, each member provided a brief history and why he/she were interested in the DoK Committee
- Recorded attendance

  Read and reviewed the following CFP documents:
  - Antitrust statement
  - Committee member participation expectations
  - DoK Committee Charges
- FDA Advisor (Steven Hughes) provided Food Code provisions review

2014 - 2016 CFP
Demonstration of Knowledge Committee

    - Food Code sections: *2-102.11, 2-102.20, 2-103.11, & Annex 3 Public Health Reasons/Administrative Guidelines*
- Representative of Issue submitter (April Bogard) provided overview of why the issue was submitted to 2014 CFP
- Committee starting late and may require short timelines for feedback
- Next meeting to be scheduled for 12/5/14

Action Items for Committee:

1. Review of the following documents:
    a. Demonstration of Knowledge issue as submitted at 2014 CFP
    b. Food Code sections: *2-102.11, 2-102.20, 2-103.11, & Annex 3 Public Health Reasons/Administrative Guidelines*
    c. Demonstration of Knowledge Committee Charges
2. Identify the pros and cons of the existing methods in Food Code Section 2-102.11(A) and 2-102.11(C) for the Person in Charge to demonstrate knowledge.
    a. Report all feedback on *2014 DoK Committee Feedback Template*
3. In lieu of Food Code Section 2-102.11(A) and 2-102.11(C), identify methods that could be used to demonstrate knowledge if/when the CFPM is not onsite.
    a. Report all feedback on *2014 DoK Committee Feedback Template*

2014 - 2016 CFP
Demonstration of Knowledge Committee

Teleconference: 2

Friday, December 05, 2014
1:00pm – 3:00p.m. EST

Call-In Number: 877-394-5901
Access Code: 2995496#

Co-Chairs: Eric Moore, Michelle Haynes
FDA Advisors: John Marcello Stephen Hughes
CDC Advisor: Vince Radke
Scribe: *Susan Tyjewski*

AGENDA ITEMS:

1. Welcome, Call to Order	Eric	
2. Roll-Call,	Eric	
3. Conference for Food Protection, Inc. Antitrust Statement	Eric	
4. Approval of minutes (*voting members*)	Eric	
5. Review CFP Timeline for Committee Work	Michelle	
6. Review of member submitted pros and cons of Food Code Section 2-102.11(A) and 2-102.11(C) for PIC to demonstrate knowledge	Michelle	
7. Review of member summited proposed methods to demonstrate knowledge if/when the CFPM is not onsite	Eric	
8. Open discussion	All	
9. Determine next meeting date & action items	All	

ATTENDENCE:

April	Bogard	
Robert	Brown	X
Francie	Buck	
Deborah	Crabtree	X
Hector	Dela Cruz	
Mark	Earnest	X
Lisa	Ford	X
Robert	Gilliland	X
Michelle	Haynes	X
Yao-Wen	Huang	
Julie	Hults	X
Lucia	James-Davis	X
Shanna	Lively	X
Mark(Mick)	Miklos	X
Eric	Moore	X
Sheri	Morris	X
Linda	Zaziski	
Dale	Yamnik	X
Todd	Taylor	X

Christine	Sylvis	X
Stephen	Hughes	
John	Marcello	X
Vince	Radke	X
Petra	Balli	
Susan	Deslauriers	
Rob	Erwin	
Christina	Eckhardt	
Laura	Nelson	
Tara	Paster	X
Susan	Tyjewski	
Sharon	Wood	
Brad	Peters	X
David	Lawrence	X

Meeting Minutes:

- Meeting opened and roll call
- CFP committee report timeline reviewed
- Discussed individual committee member submitted pros & cons

2014 - 2016 CFP
Demonstration of Knowledge Committee

- Determined that most efficient method to review all pros & cons would be to compile all feedback provided by members and conduct on-line poll for members to review and vote on.

Teleconference: 3

Friday, January 23, 2015
1:00pm – 3:00p.m. EST

Call-In Number: 877-394-5901
Access Code: 2995496#

Co-Chairs: Eric Moore, Michelle Haynes
FDA Advisors: John Marcello Stephen Hughes
CDC Advisor: Vince Radke
Scribe: *Susan Tyjewski*

AGENDA ITEMS:

1. Welcome, Call to Order	Eric	
2. Roll-Call,	Eric	
3. Conference for Food Protection, Inc. Antitrust Statement	Eric	
4. Review of member submitted pros and cons of Food Code Section 2-102.11(A) and 2-102.11(C) for PIC to demonstrate knowledge	Michelle	
5. Review of member summited proposed methods to demonstrate knowledge if/when the CFPM is not onsite	Michelle	
6. Open discussion	All	
7. Determine next meeting date & action items	All	

ATTENDENCE:

April	Bogard	X
Robert	Brown	X
Francie	Buck	
Deborah	Crabtree	X
Hector	Dela Cruz	X
Mark	Earnest	
Lisa	Ford	
Robert	Gilliland	X
Michelle	Haynes	X
Yao-Wen	Huang	X
Julie	Hults	X
Lucia	James-Davis	X
Shanna	Lively	X
Mark(Mick)	Miklos	X
Eric	Moore	X
Sheri	Morris	X
Linda	Zaziski	X
Dale	Yamnik	X
Todd	Taylor	X

Christine	Sylvis	X
Stephen	Hughes	X
John	Marcello	
Vince	Radke	X
Petra	Balli	
Susan	Deslauriers	
Rob	Erwin	
Christina	Eckhardt	
Laura	Nelson	
Tara	Paster	
Susan	Tyjewski	X
Sharon	Wood	
Brad	Peters	
David	Lawrence	X

2014 - 2016 CFP
Demonstration of Knowledge Committee

Meeting Minutes:

- Welcome and Roll-Call
- Discussion of pros and cons survey results
- Food Code Section 2-102.11(A)
    - Pro 1 Accepted alternate languag**e**
    - Pro 2 Accepted as is
    - Pro 3 Accepted as is
    - Pro 4 Amend alternate language – In 2nd sentence change is after "compliance" to may and take out "designed to Achieve Managerial Control"
    - Pro 5 Amend alternate language – replace "food employees" with PIC
    - Con 1 Accepted alternate language
    - Con 2 Accepted 1st alternate language
    - Con 3 Accepted 1st alternate language and agreed on taking 2nd sentence from original Con (language barriers) and create Con 6
    - Con 4 Accepted as is
    - Con 5 Omit, Con 2 sufficiently covers
- Food Code Section 2-102.11(C)
    - Pro 1 Accept the 1st alternate language with the code citation removed
    - Pro 2 Use the alternate language of Pro 5
    - Pro 3 Accept alternate language
    - Pro 4 Accept alternate language
    - Pro 5 At the end of the sentence of the original language, add – pertaining to their operation.
    - Pro 6 Accept the 2nd alternate language with adding the word customized before the word questions…
    - Pro 7 Accept as is
    - Pro 8 Amend the alternate language – replace restaurant with food establishment
    - Con 1 Accept alternate language with removing the last sentence
    - Con 2 Amend alternate language to read – Questions not asked while inspection is being conducted may take extra time or be forgotten
    - Con 3 Begin next call with this item

Action Item:

1. The Pros & Cons discussed today will be distributed with the agreed upon changes included.

Wrap Up

- First report from the Chair to the CFP Board is due in March, 2015
- Next call will be on Feb. 9 at the same time and discussion will begin with Con 3 of Food Code Section 2-102.11(C).

2014 - 2016 CFP
Demonstration of Knowledge Committee

Teleconference: 4

Monday, February 9, 2015
1:00pm – 3:00p.m. EST
Call-In Number: 877-394-5901
Access Code: 2995496#

Co-Chairs: Eric Moore, Michelle Haynes
FDA Advisors: John Marcello Stephen Hughes
CDC Advisor: Vince Radke
Scribe: *Susan Tyjewski*

AGENDA ITEMS:

1. Welcome, Call to Order	Eric	
2. Roll-Call,	Eric	
3. Continue discussion of Pros & Cons	All	
4. Determine next meeting date & action items	All	

ATTENDENCE:

April	Bogard	X
Robert	Brown	X
Francie	Buck	X
Deborah	Crabtree	X
Hector	Dela Cruz	X
Mark	Earnest	X
Lisa	Ford	
Robert	Gilliland	X
Michelle	Haynes	X
Yao-Wen	Huang	X
Julie	Hults	X
Lucia	James-Davis	X
Shanna	Lively	X
Mark(Mick)	Miklos	X
Eric	Moore	X
Sheri	Morris	X
Linda	Zaziski	X
Dale	Yamnik	X
Todd	Taylor	X

Christine	Sylvis	X
Stephen	Hughes	X
John	Marcello	
Vince	Radke	X
Petra	Balli	
Susan	Deslauriers	
Rob	Erwin	
Christina	Eckhardt	
Laura	Nelson	
Tara	Paster	
Susan	Tyjewski	X
Sharon	Wood	
Brad	Peters	X
David	Lawrence	X

Meeting Minutes:

- Welcome and Roll-Call
- Review of minutes from January 23 meeting
- Discussion of pros and cons survey results continued

2014 - 2016 CFP
Demonstration of Knowledge Committee

- Food Code Section 2-102.11(C)
    - Con 3 Submitter withdraws
    - Con 4 Omit – this is covered in Con 10
    - Con 5 Omit – it is combined with Con 9
    - Con 6 Alternate language accepted
    - Con 7 The agreed upon language for Con 7 is the 2nd sentence from the 2nd alternate language of Con 9. "Regulators need to ensure only questions relevant to the operation are asked and that answers given for a facilities procedure that exceeds the minimum requirement (such as temperatures) are not debited for."
    - Con 8 Accepted as is
    - Con 9 Use the 1st alternate language for now. This can be re-evaluated when the form with amended verbiage is circulated.
    - Con 10 Eric and Michelle will make changes with a focus on nerves, intimidation, ability to communicate, etc. Will start the next call with this item.
    - Con 11 Submitter removes
    - Con 12 Submitter removes because the core is covered in #7.
- Action Item 3
- In lieu of Food Code Section 2-102.11(A) and 2-102.11(C), identify methods that could be used to demonstrate knowledge if/when the CFPM is not onsite.
    - #1 Strike this one. It is not aligned with the committee's charge.
    - #2 Strike this for #11.
    - #11 Discussion on amending #11 to include organizations that have their own program that matches an ANSI-ASTM accredited program.

Wrap Up

During the discussion of food safety training in #11 it was mentioned there is another CFP committee that is working on employee food safety training standards. Susan Quam will contact the chairs, Chuck Catlin and Ben Chapman for a possible meeting with Eric and Michelle to discuss the overlap of this topic between the two committees.

Next Meeting

The following was provided by Julie Hults to be incorporated into suggestion #3 for discussion.

Language from the WI version of the food code 2-102.11 (C):

(C) Demonstrating FOOD safety principles based on the PERMITTED/LICENSED establishment's specific FOOD operations. The areas of knowledge include:

Next meeting is scheduled for February 27, 2015 at 1:00 pm Eastern time.

Discussion should start with Con 10 of Food Code Section 2-102.11(C)

2014 - 2016 CFP
Demonstration of Knowledge Committee

Teleconference: 5

Monday, March 23, 2015
1:00pm – 3:00p.m. EST
Call-In Number: 877-394-5901
Access Code: 2995496#

Co-Chairs: Eric Moore, Michelle Haynes
FDA Advisors: John Marcello Stephen Hughes
CDC Advisor: Vince Radke
Scribe: *Susan Tyjewski*

AGENDA ITEMS:

5. Welcome, Call to Order	Eric	
6. Roll-Call,	Eric	
7. Continue discussion of Action Item 3	All	
8. Determine next meeting date & action items	All	

ATTENDENCE:

April	Bogard	
Robert	Brown	
Francie	Buck	X
Deborah	Crabtree	X
Hector	Dela Cruz	X
Mark	Earnest	X
Lisa	Ford	
Robert	Gilliland	X
Michelle	Haynes	X
Yao-Wen	Huang	
Julie	Hults	X
Lucia	James-Davis	
Shanna	Lively	X
Mark(Mick)	Miklos	X
Eric	Moore	X
Sheri	Morris	X
Linda	Zaziski	
Dale	Yamnik	X
Todd	Taylor	

Christine	Sylvis	
Stephen	Hughes	X
John	Marcello	
Vince	Radke	
Petra	Balli	
Susan	Deslauriers	
Rob	Erwin	
Christina	Eckhardt	
Laura	Nelson	
Tara	Paster	
Susan	Tyjewski	X
Sharon	Wood	
Brad	Peters	
David	Lawrence	

Meeting Minutes:

- Welcome
- Review and approval of minutes from February 9 meeting
- Announcements

  - Eric & Michelle haven't connected with the other CFP committee – Food Safety Training. They will discuss off line with Susan if that should still be done.
  - The Chair and Co-Chair were notified last week that Miss Bogard has to resign from the committee, she is leaving her position. We are in the process of identifying a substitute regulatory representative to take her position as a voting member of the committee. We are appreciative of all the work she has done and wish her luck in her future endeavors.
- Roll-Call
- Discussion began on Action Item 2 –Identify the pros and cons of the existing methods in Food Code Section 2-102.11(A) and 2-102.11(C) for the Person in Charge to demonstrate knowledge. - Con 7
  - Modify to clearly address the state of mind of the worker and eliminate all other concerns because they are covered in Con 5. Submitter of Con 7 agrees.
    - Michelle proposed new wording that was accepted regarding nervousness, intimidation and anxiety.
  - Discussion regarding whether this Con speaks to the problem of even asking questions to determine compliance.
    - Yes it does and there are 2 other methods that can be utilized. Agreement that this is not the right place to make a statement on this.
- Continued discussion on Action Item # 3, In lieu of Food Code Section 2-102.11(A) and 2-102.11(C), identify methods that could be used to demonstrate knowledge if/when the CFPM is not onsite. - #3
  - Mick Miklos opposes this one and gave an industry perspective about increasing the # of options allowed to demonstrate knowledge not reduce them.
  - Stephen Hughes with the FDA added that there was a lot of effort that went into developing what constitutes the appropriate body of knowledge for a manager. There would be some concern if it were suggested a second and different certification process (food handler) be introduced into that section.
  - There was clarification on the intent of #3 and that was to change the requirement of having to meet one of the three options to having to meet two of the three.
    - Sherry Morris pointed out there is a difference of opinion between industry and regulators on whether to change the # of options required to meet the determination.
  - Agreement that the voting members of this committee should vote on #3 again.
    - Bullet points should be incorporated so when there is a vote it will be clear what the issues are. Various members will contribute their comments and Michelle will add them to the documentation.

Next Meeting

We will begin the next meeting with Julie Hults having the opportunity to give her perspective on Action Item 3 and the following language from the WI version of the food code 2-102.11 (C):

2014 - 2016 CFP
Demonstration of Knowledge Committee

“Demonstrating FOOD safety principles based on the PERMITTED/LICENSED establishment’s specific FOOD operations. The areas of knowledge include:”

Eric will send out different dates to choose from for our next meeting.

2014 - 2016 CFP
Demonstration of Knowledge Committee

Teleconference: 6

Monday, April 17, 2015
1:00pm – 2:30p.m. EST
Call-In Number: 877-394-5901
Access Code: 2995496#

Co-Chairs: Eric Moore, Michelle Haynes
FDA Advisors: John Marcello Stephen Hughes
CDC Advisor: Vince Radke
Scribe: *Susan Tyjewski*

AGENDA ITEMS:

9. Welcome, Call to Order	Eric	
10. Roll-Call,	Eric	
11. Continue discussion of Action Item 3	All	
12. Determine next meeting date & action items	All	

ATTENDENCE:

April	Bogard	
Robert	Brown	
Francie	Buck	X
Deborah	Crabtree	X
Hector	Dela Cruz	X
Mark	Earnest	X
Lisa	Ford	X
Robert	Gilliland	X
Michelle	Haynes	X
Yao-Wen	Huang	
Julie	Hults	X
Lucia	James-Davis	
Shanna	Lively	
Mark(Mick)	Miklos	X
Eric	Moore	X
Sheri	Morris	X
Linda	Zaziski	X
Dale	Yamnik	X
Todd	Taylor	X
Christine	Sylvis	X
Stephen	Hughes	X
John	Marcello	
Vince	Radke	X
Petra	Balli	
Susan	Deslauriers	
Rob	Erwin	X
Christina	Eckhardt	

2014 - 2016 CFP
Demonstration of Knowledge Committee

Laura	Nelson	
Tara	Paster	
Susan	Tyjewski	
Sharon	Wood	
Brad	Peters	
David	Lawrence	

Meeting Min:

Julie Hults: WI version of the food code 2-102.11 (C):

“Demonstrating FOOD safety principles based on the PERMITTED/LICENSED establishment’s specific FOOD operations. The areas of knowledge include:”

Demonstrating in place of

2014 - 2016 CFP
Demonstration of Knowledge Committee

Teleconference: 7

Friday, June 19, 2015
1:00pm – 3:00p.m. EST
Call-In Number: 877-394-5901
Access Code: 2995496#

Co-Chairs: Eric Moore, Michelle Haynes
FDA Advisors: John Marcello Stephen Hughes
CDC Advisor: Vince Radke
Scribe: *Susan Tyjewski*

AGENDA ITEMS:

13. Welcome, Call to Order	Eric	
14. Roll-Call,	Eric	
15. Continue discussion of Action Item 3	All	
16. Determine next meeting date & action items	All	

ATTENDENCE:

Robert	Brown	✓
Francie	Buck	✓
Deborah	Crabtree	
Hector	Dela Cruz	
Mark	Earnest	
Lisa	Ford	
Robert	Gilliland	
Michelle	Haynes	✓
Yao-Wen	Huang	
Julie	Hults	
Lucia	James-Davis	✓
Shanna	Lively	✓
Mark(Mick)	Miklos	✓
Eric	Moore	✓
Sheri	Morris	✓
Linda	Zaziski	✓
Dale	Yamnik	✓
Todd	Taylor	✓

Christine	Sylvis	✓
Stephen	Hughes	✓
John	Marcello	
Vince	Radke	
Petra	Balli	
Susan	Deslauriers	
Rob	Erwin	✓
Christina	Eckhardt	
Laura	Nelson	
Tara	Paster	
Susan	Tyjewski	✓
Sharon	Wood	
Brad	Peters	
David	Lawrence	

Meeting Minutes:

- Welcome
- Antitrust Statement Reminder
- Are there any comments on the minutes of March 23? No
- Discussion begins with Action Item 3, # 14.

2014 - 2016 CFP
Demonstration of Knowledge Committee

- Mic reads language he has suggested.
    - Consider recommending that Section 2-102.11 of the Food Code be deleted rather than amended.
        - Section 2-102.11(A) The lack of priority violations may be accidental and not a true demonstration of knowledge.
        - Section 2-202.11(B) The presence of a CFPM is already required in Section 2-102.12(A).
        - Section 2-102.11(C) The risk based inspection identifies whether an establishment is being well run and whether knowledge is being demonstrated. The list of 17 questions could be moved to Annex 5 as guidelines for dialogue with PICs.

- There is discussion with Stephen Hughes on clarification of the requirement of a CFPM in Section 2-102.11 and 2-102.12.

- Mic comments the inspection itself shows if the facility is well run proving demonstration of knowledge. The 2 sections are like “double dipping”.
    - Mic meant for # 14 to be a blanket suggestion to change the Food Code in place of all Action Items.

- There is discussion on how the committee will proceed with input to CFP.

- Mic and Sheri Morris will further modify and refine the suggested language of #14 to incorporate what was discussed and submit to Eric and Michelle.

- Eric and Michelle will reformat the survey and use the information for the upcoming report due by 7/2.

- After the report is submitted the action item feedback will be circulated for final review by the committee.

- Eric will send invitations to the next meeting.

2014 - 2016 CFP
Demonstration of Knowledge Committee

Teleconference: 8

Wednesday September 30, 2015
2:00pm – 3:30p.m. EST
Call-In Number: 877-394-5901
Access Code: 2995496#

Co-Chairs: Eric Moore, Michelle Haynes
FDA Advisors: Stephen Hughes
CDC Advisor: Vince Radke
Scribe: *Susan Tyjewski*

AGENDA ITEMS:

1. Welcome, Call to Order	Michelle	
2. Roll-Call,	Michelle	
3. Review of last meeting's minutes	All	
4. Discussion will begin with # 14 amended language	All	
5. Brief overview of entire PDF document	Michelle	
6. Review voting process and timeline	Michelle	

ATTENDENCE:

Robert	Brown	
Francie	Buck	✓
Deborah	Crabtree	✓
Hector	Dela Cruz	
Mark	Earnest	
Lisa	Ford	
Robert	Gilliland	✓
Michelle	Haynes	✓
Yao-Wen	Huang	
Julie	Hults	✓
Lucia	James-Davis	✓
Shanna	Lively	
Mark(Mick)	Miklos	✓
Eric	Moore	✓
Sheri	Morris	✓
Linda	Zaziski	✓
Dale	Yamnik	✓
Todd	Taylor	✓

Christine	Sylvis	✓
Stephen	Hughes	✓
John	Marcello	
Vince	Radke	
Petra	Balli	
Susan	Deslauriers	
Rob	Erwin	✓
Christina	Eckhardt	
Laura	Nelson	
Tara	Paster	
Susan	Tyjewski	✓
Sharon	Wood	✓
Brad	Peters	
David	Lawrence	

Meeting Minutes:

- Welcome
- Antitrust Statement Reminder

2014 - 2016 CFP
Demonstration of Knowledge Committee

- Are there any comments/changes to the minutes of June 19? No

- Discussion begins - There are three tables that summarize our committee work.

    - Mic refers to Method 12 which is a recommendation to replace demonstration with duties. He acknowledges Dale and Sherry for their input.
    - Stephen clarifies that section 2.102.11 requires someone to be on site with knowledge. Section 2.102.12 requires someone on staff to be a CFPM but does not require them to be on site.
        - The FDA would be reluctant to eliminate section B.
        - This may not be the charge of the committee which is to recommend alternate methods.
    - Sherry comments that the charge of the committee is to list alternative methods discussed whether they are viable or not.
    - Mic will take a look at the language in the 2nd bullet in view of Stephen's comments.

- Going to the beginning – discussion on improving how the Pros & Cons are written.

    - Dale volunteers to provide improved wording on
        - Page 1 – Pro 1
        - Page 2 – Con 1
        - Page 2 – Con 2
        - Minor changes to Con 3 & Con 4 are offered and accepted.
    - Michelle reads modified language for Page 2 Pro 1. It is accepted.

- Returning to the Alternative Methods.
    - Mic proposes that we strike Method 3 because that is not the committee's charge. Agreed.
    - Method 4 – wording modified during call.
    - Clarification on Method 11 – food safety principles be demonstrated instead of responding to questions.
    - Discussion on how some methods are thematically the same but the order should be changed. For voting the order will be
        - Method 2
        - Method 10
        - Method 9
        - Method 12
    - Discussion on whether Method 5 should be removed because it's covered in other methods. Dale offers to improve wording on this for voting.
    - Remove Method 7 – it refers to computer tablets.

- **Next Steps**
- All adjusted wording will be submitted to Michelle on Monday by noon.
- The link to the survey will be sent out on Tuesday and you'll have one week to review.
- We will have another meeting after the results of the survey are analyzed so the final report can be discussed.

2014 - 2016 CFP
Demonstration of Knowledge Committee

Teleconference: 9

Friday November 6, 2015
2:00pm – 3:30p.m. EST
Call-In Number: 877-394-5901
Access Code: 2995496#

Co-Chairs: Eric Moore, Michelle Haynes
FDA Advisors: Stephen Hughes
CDC Advisor: Vince Radke
Scribe: *Susan Tyjewski*

AGENDA ITEMS:

1. Roll call	Michelle	
2. Reminder on anti-trust statement	Michelle	
3. Review of last meeting's minutes	Michelle	
4. Review of remaining timeline for report submission	Michelle	
5. Discussion of survey results	All	
6. Proposal of issues that the committee would like to submit for 2016 CFP	All	

ATTENDENCE:

Robert	Brown	✓
Francie	Buck	✓
Deborah	Crabtree	
Hector	Dela Cruz	✓
Mark	Earnest	✓
Lisa	Ford	
Robert	Gilliland	
Michelle	Haynes	✓
Yao-Wen	Huang	
Julie	Hults	✓
Lucia	James-Davis	✓
Shanna	Lively	✓
Mark(Mick)	Miklos	
Eric	Moore	
Sheri	Morris	✓
Linda	Zaziski	✓
Dale	Yamnik	✓
Todd	Taylor	✓

Christine	Sylvis	
Stephen	Hughes	✓
John	Marcello	
Vince	Radke	✓
Petra	Balli	
Susan	Deslauriers	✓
Rob	Erwin	✓
Christina	Eckhardt	
Laura	Nelson	
Tara	Paster	✓
Susan	Tyjewski	✓
Sharon	Wood	v
Brad	Peters	
David	Lawrence	

Meeting Minutes:

- Welcome
- Antitrust Statement Reminder

2014 - 2016 CFP
Demonstration of Knowledge Committee

- Review of minutes of Sept. 30 meeting. Any comments or questions? - No
- Timeline for report submissions
    - Final report must be turned in to Susan Quam by Dec. 4.
    - The following volunteered to help with the final report.
        - Tara
        - Dale
        - Linda
        - Hector
    - The Issues must be submitted by Jan. 15.

- Discussion on the Survey Results

- Dale recommended that the questions be put in order by the % of agreement with the high on top and the low at the bottom. Also questions with the level of agreement split closely be removed.
    - A comment was made that only 12 out of the 21 voting members participated by voting. There will be a reminder sent out with a survey deadline.

- Discussion continued on questions where the % of agreement was close and if they should be deleted.
    - There was a motion to eliminate Q1 because Q2 is a restatement.
        - The motion was seconded and no one opposed.
            - Q1 will be removed.
    - There was a motion to eliminate Q20 in favor of Q21.
        - The motion was seconded and no one opposed.
            - Q20 will be removed.
    - There was a motion to eliminate Q3.
        - The motion was seconded and no one opposed.
            - Q3 will be removed.
    - Discussion on Q39 and Q40 determined that they were not exactly the same. Q39 recommends eliminating the code section and Q40 recommends modifying. They will both stay.

- Proposal for the issue submission
    - Recommend the acceptance of the final report
    - This committee did not complete the complete charge.
        - Item # 4 of the original charge.
            - Identify the pro's and con's of alternative methods to demonstrate knowledge if/when the CFPM is not onsite. Although not limited to the following areas, the committee should assess the pro's and con's of each alternative method in light of the following areas:
                a. Differentiation between knowledge and application.
                b. Emphasis on risk factors;
                c. Ease of uniform assessment by regulators and industry;
                d. Enabling the Person in Charge to demonstrate knowledge even when there is a language barrier.

e. What corrective action should be taken when there is not a demonstration of knowledge from the Certified Food Protection Manager or the Person in charge.

- Recommend the committee be re-formed to complete the charge and also list the alternative methods to be evaluated by the new committee.
  - Recommend the committee propose either to change the language in the food code or provide an alternative method.

- It was agreed that the committee will request a meeting time at the CFP on Friday afternoon and also present a report on Sunday morning.

- The final report will be prepared and submitted to Susan Quam by Dec. 4.

- Meeting adjourned.

2014 - 2016 CFP

Demonstration of Knowledge Committee

2-102.11 Demonstration.

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:

Regulation	Pro	Con
(A) Complying with this Code by having no violations of PRIORITY ITEMS during the current inspection; Pf		
(C) Responding correctly to the inspector's questions as they relate to…(1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE; Pf		
(C) Responding correctly to the inspector's questions as they relate to… (2) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease; Pf		
(C) Responding correctly to the inspector's questions as they relate to… (3) Describing the symptoms associated with the diseases that are transmissible through FOOD; Pf		

2014 - 2016 CFP

Demonstration of Knowledge Committee

Regulation	Pro	Con
(C) Responding correctly to the inspector's questions as they relate to… (4) Explaining the significance of the relationship between maintaining the time and temperature of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and the prevention of foodborne illness; Pf		
(C) Responding correctly to the inspector's questions as they relate to… (5) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, EGGS, and FISH; Pf		
(C) Responding correctly to the inspector's questions as they relate to… (6) Stating the required FOOD temperatures and times for safe cooking of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD including MEAT, POULTRY, EGGS, and FISH;Pf		
(C) Responding correctly to the inspector's questions as they relate to… (7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;Pf		

2014 - 2016 CFP

Demonstration of Knowledge Committee

Regulation	Pro	Con
(C) Responding correctly to the inspector's questions as they relate to… (8) Describing the relationship between the prevention of foodborne illness and the management and control of the following: (a) Cross contamination, Pf (b) Hand contact with READY-TO-EAT FOODS, Pf (c) Handwashing, Pf and (d) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair; Pf		
(C) Responding correctly to the inspector's questions as they relate to… (9) Describing FOODS identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction. Pf		
(C) Responding correctly to the inspector's questions as they relate to… (10) Explaining the relationship between FOOD safety and providing EQUIPMENT that is: (a) Sufficient in number and capacity, Pf and (b) Properly designed, constructed, located, installed, operated, maintained, and cleaned; Pf		

2014 - 2016 CFP

Demonstration of Knowledge Committee

Regulation	Pro	Con
(C) Responding correctly to the inspector's questions as they relate to… (11) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT; Pf		
(C) Responding correctly to the inspector's questions as they relate to… (12) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections; Pf		
(C) Responding correctly to the inspector's questions as they relate to… (13) Identifying POISONOUS OR TOXIC MATERIALS in the FOOD ESTABLISHMENT and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to LAW; Pf		
(C) Responding correctly to the inspector's questions as they relate to… (14) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code; Pf		

2014 - 2016 CFP

Demonstration of Knowledge Committee

Regulation	Pro	Con
(C) Responding correctly to the inspector's questions as they relate to… (15) Explaining the details of how the PERSON IN CHARGE and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this Code, or an agreement between the REGULATORY AUTHORITY and the FOOD ESTABLISHMENT; Pf		
(C) Responding correctly to the inspector's questions as they relate to… (16) Explaining the responsibilities, rights, and authorities assigned by this Code to the: (a) FOOD EMPLOYEE, Pf (b) CONDITIONAL EMPLOYEE, Pf (c) PERSON IN CHARGE, Pf (d) REGULATORY AUTHORITY; Pf		
(C) Responding correctly to the inspector's questions as they relate to… (17) Explaining how the PERSON IN CHARGE, FOOD EMPLOYEES, and CONDITIONAL EMPLOYEES comply with reporting responsibilities and EXCLUSION or RESTRICTION of FOOD EMPLOYEES.		

Alternative Method to Demonstrate Knowledge if/when CPM is Not Onsite	Pro	Con
1.		

Pro/Con Listing for 2-102.11(A)

2-102.11 Demonstration
Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:
A) Complying with this Code by having no violations of PRIORITY ITEMS during the current inspection; Pf

Pro 1: This is a good way to show knowledge because it allows the PIC to demonstrate operational controls as they relate to Food Code requirements.
Pro 2: Having no PRIORITY ITEMS allows both regulators and industry to easily know when a food establishment is in compliance with the demonstration of knowledge requirements. It also allows both the inspector and industry to know which sections of the Food Code to focus training on.
Pro 3: Easy for the inspector to evaluate.
Pro 4: If you accept the assumption that performance is a direct reflection of the PIC's level of knowledge, then the absence of Priority Item violations is indicative of the individual's knowledge. Additionally, full compliance may be indicative that the principles and the elements of a food safety management system are in place to control risk.
Con 1: Inspections capture conditions at a facility at a given point in time, and as such, may miss some systemic failures that are present and ongoing but not detectable at the moment. Although the desired end is the elimination of risk factors and full compliance with this Code works to that end, it might be argued that this subsection is Demonstration of Compliance rather than Demonstration of Knowledge.
Con 2: Could be subjective in the day to day reality of conducting inspections. Relies on regulator's judgment resulting in lack of consistency.
Con 3: The undue focus on Priority Items to the exclusion of Priority Foundation and Core violations could overlook potential threats to Food Safety.
Con 4: Studies have shown that knowledge and behavior do not always go hand-in-hand.
Con 5: Language barriers may cause a loss of effective communication between inspectors and operators.

Pro/Con Listing for 2-102.11(C)

2-102.11 Demonstration
Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:
C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include…….

Pro 1: This gives the inspector the opportunity to ask customized questions directly related to operation being observed; not just utilizing standard questions.
Pro 2: This gives the PIC the opportunity to explain the processes performed in their food establishment which can often be validated with operations manuals and other training tools.
Pro 3: Gives a clear understanding for regulators and industry of the requirements and rationale to demonstrate Food Code knowledge as it pertains to their operations.
Pro 4: PIC is able to demonstrate food safety knowledge by successfully answering questions pertaining to their operation.
Pro 5: It addresses the importance of the PIC having knowledge of the risks and how they relate to foodborne illness.
Pro 6: If completely and correctly answered, the PIC can establish him/herself as properly trained, knowledgeable and engaged in the management of food safety in the establishment. It reflects that systems for managing food safety are in place even if momentary execution might be lacking.
Pro 7: Through Q&A the inspector is able to determine training needs.
Pro 8: This essentially amounts to an abbreviated CFPM oral exam. If the PIC is able to successfully answer all questions posed, they clearly have a solid understanding of basic food safety principals pertaining to their operation.
Con 1: Inspector's questions could be easily misunderstood by a PIC, especially if the inspector is not properly trained on asking appropriate questions relevant to the establishment's operation. This could also result in a degree of inconsistency based on the types and numbers of questions asked of the PIC by the inspector. For instance, there is no standard for how many questions a PIC must answer correctly to demonstrate knowledge.
Con 2: Inspector may focus on the questions and may not make observations of behaviors a higher priority.

Con 3: Regulators need to ensure only questions relevant to the operation are asked and that answers given for a food establishment's procedures that exceed the minimum requirement (such as temperatures) are not debited if in compliance with food establishment's standards.
Con 4: If a PIC is not accompanying an inspector at the time the inspector has a question, the inspector may need to take extra time at the end of the inspection to return to an area with the PIC to question the food establishment's procedure, thereby adding additional time for completion of the inspection. In some cases, if the PIC is not with the inspector, the inspector may have entirely forgotten the question he had regarding that process by the time the PIC rejoins the inspection.
Con 5: The number of questions asked and the percent that must be answered correctly in order to "pass" these criteria for demonstration of knowledge is not standardized resulting in inconsistent application from one inspector to another.
Con 6: The quality of an interview is as much a function of the interviewer's ability as it is the interviewee's competence. If the inspector does not ask questions properly/clearly, then the PIC's ability to successfully answer them will be limited. This "oral exam" also assumes that the inspector is a subject matter expert, has no competency issues, and knows the correct answers to the questions posed. On a more practical level, in many establishments English is not the primary language of the PIC or kitchen staff. Clearly, communication barriers are difficult to overcome in these situations. CFPM classes/exams overcome this by way of bilingual instructors and translated study materials/exams; however, it is far more challenging to overcome this in an on-site interview with an inspector.
Con 7: Nervousness, intimidation, and anxiety are all factors that may affect the employee's ability to relay accurate answers to the regulator's questions.

Alternative Methods for Demonstrating Knowledge

Method 1: The person in charge can demonstrate Food Code knowledge through practical means such as showing how they take temperatures, calibrate a thermometer, mix or test sanitizer, showing a posted employee health policy or list of major food allergens, etc.

Method 2: Establishment is in compliance with 2-103.11.

Method 3 : Recommend *modifying* Section 2-102.11 of the Food Code as follows:

Section 2-102.11 (B) would remain as currently written in the Food Code and would be followed by this:

- **If the Certified Food Protection Manager is not present, and because the distinction between knowledge and application is vague and difficult to articulate which often leads to frustration between operators and regulators, the PIC shall be a food handler certificated through an ANSI-ASTM accredited program or its equivalent. The PIC shall substantiate knowledge through direct application of (A) through (O) of the Duties Section of the Food Code (2-103.11.) The successful completion of these tasks should adequately demonstrate the PIC's knowledge.**
    - **Eliminate Section 2-102.11 (A). The number of times that an establishment has no priority violations is statistically insignificant. There is also the suspicion among regulators that a lack of priority violations could be accidental and not a true reflection of demonstration of knowledge.**
    - **Eliminate Section 2-102.11 (C). The Food Code already articulates the duties of a PIC in Section 2-103.11. In addition, the entirety of the risk based inspection identifies whether an establishment is controlling risk and, by extension, whether knowledge is being demonstrated through application. The current list of 17 questions found in 2-102.11 (C) could be moved to Annex 5 as guidelines for inspectors who wish to have dialogue with PICs.**

Method 4: Employees are completing tasks correctly.

Method 5: Having one or more food handlers who are certificated through an ANSI-ASTM accredited program or equivalent and who comply with section 2-103.11 of this Code, thus applying practical means knowledge to the successful completion of tasks.

Method 6: The PIC can show evidence of demonstration of knowledge through the use of job aides or other means.

Method 7: Change the Demonstration of Knowledge criteria. Instead of meeting one of the three options to be in compliance, change it to having to meet two of the three options to be in compliance.

Method 8: The establishment has a food handler certificated program through an ANSI-ASTM program or equivalent and one or more employees is certificated through the program.

Method 9: Change the code language in 2-102.11 (C) to: "Demonstrating food safety principles based on the specific food operation. The areas of knowledge include:..".

Method 10: Recommend *eliminating* Section 2-102.11 within the Food Code as follows:

This method seeks to replace the Demonstration Section, in its entirety with reliance instead on the Duties Section as it might be performed by ANSI-ASTM accredited food handlers:

Allow the Duties Section of the Food Code (2-103.11) to substantiate demonstration of knowledge in lieu of the Demonstration Section (2-102.11). The distinction between knowledge and application is vague and difficult to articulate and this can lead to frustration between operators and regulators. Having one or more food handlers certificated through an ANSI-ASTM accredited program or equivalent and who comply with (A) through (O) of Section 2-103.11 by applying practical knowledge to the successful completion of tasks should adequately demonstrate knowledge of the PIC.

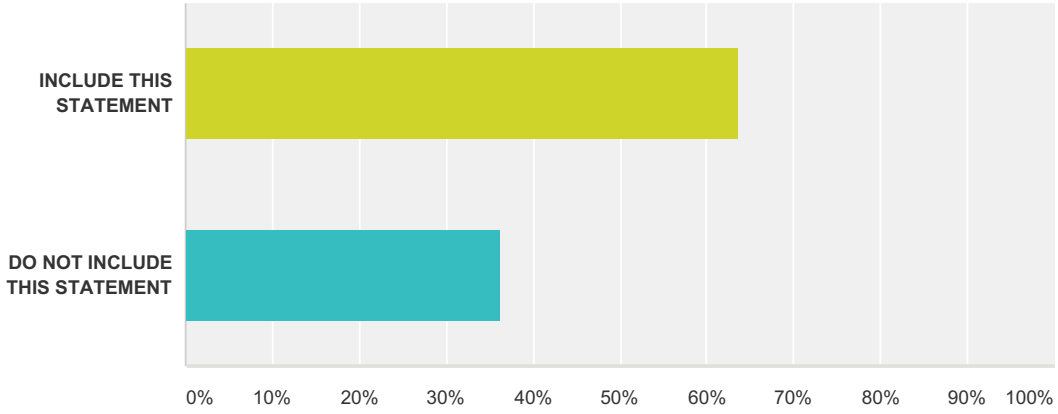
• Eliminate Section 2-102.11 (A). The number of times that an establishment has no priority violations is statistically insignificant. There is also the suspicion among regulators that a lack of priority violations could be accidental and not a true reflection of demonstration of knowledge.

• Eliminate Section 2-102.11 (B). The Food Code already requires the presence of a CFPM in Section 2-102.12 (A). The FDA Risk Factor Study correlates the presence of a CFPM with better control of risk factors and provides justification for the requirement in the Food Code to have at least one CFPM per establishment.

• Eliminate Section 2-102.11 (C). The Food Code already articulates the duties of a PIC in Section 2-103.11. In addition, the entirety of the risk based inspection identifies whether an establishment is controlling risk and, by extension, whether knowledge is being demonstrated through application. The current list of 17 questions found in 2-102.11 (C) could be moved to Annex 5 as guidelines for inspectors who wish to have dialogue with PICs.

Q1 Pro 1: Good easy to follow expectation for both the regulator and industry representativeto know the criteria to be in compliance and the rationale. Requirement is easy to providetraining to both the regulator and industry.

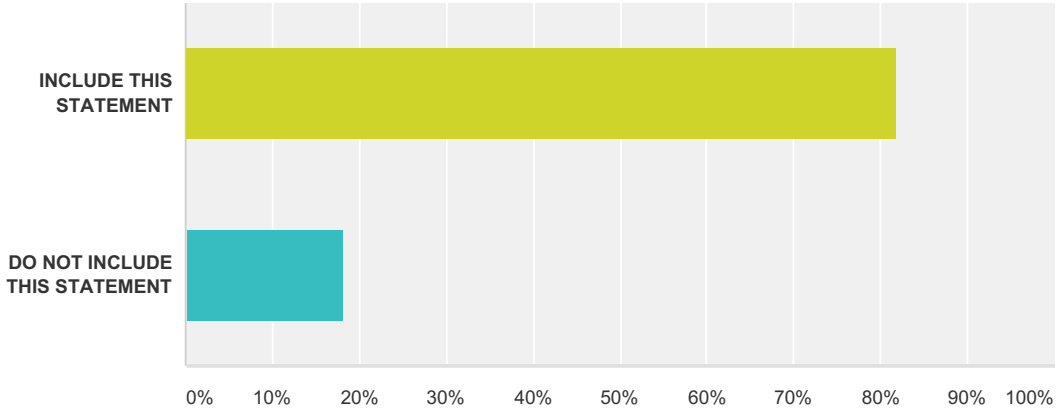
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	63.64%	7
DO NOT INCLUDE THIS STATEMENT	36.36%	4
Total		11

Q2 Pro 1.1: Having no PRIORITY ITEMS allows both regulators and industry to easily knowwhen a food establishment is in compliance with the demonstration of knowledgerequirements. It also allows both the inspector and industry to know which sections ofthe Food Code to focus training on.

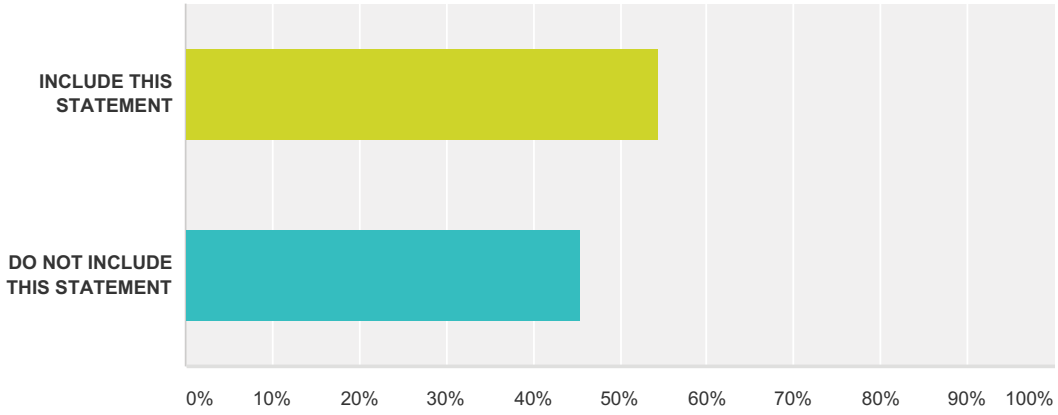
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	81.82%	9
DO NOT INCLUDE THIS STATEMENT	18.18%	2
Total		11

Q3 Pro 2: The establishment demonstrates knowledge through compliant operations.

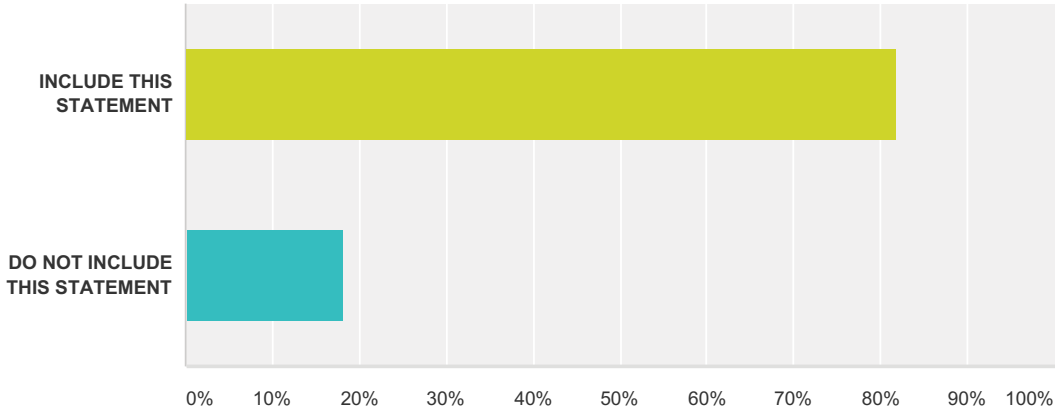
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**54.55%**	6
DO NOT INCLUDE THIS STATEMENT	**45.45%**	5
Total		**11**

Q4 Pro 3: Easy for the inspector to evaluate.

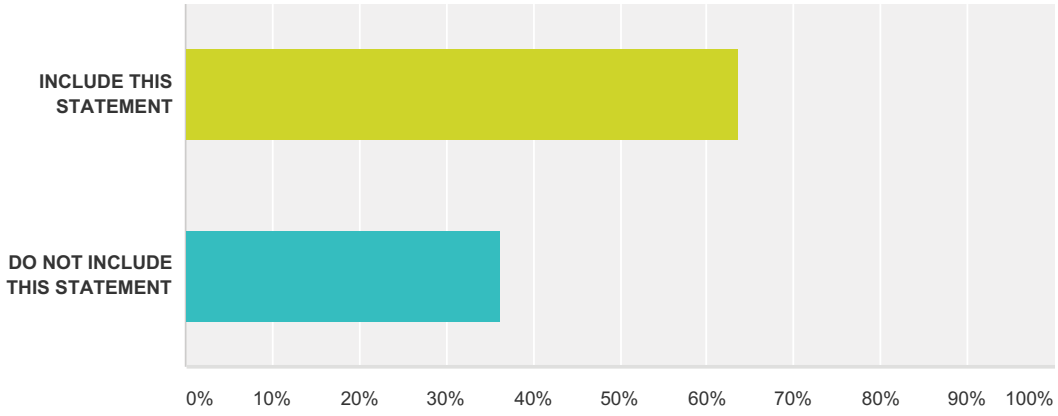
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**81.82%**	9
DO NOT INCLUDE THIS STATEMENT	**18.18%**	2
Total		**11**

Q5 Pro 4: If you accept the assumption that performance is a direct reflection of the PIC'slevel of knowledge, then the absence of Priority Item violations is indicative of theindividual's knowledge. Additionally, full compliance may be indicative that the principlesand the elements of a food safety management system are in place to control risk.

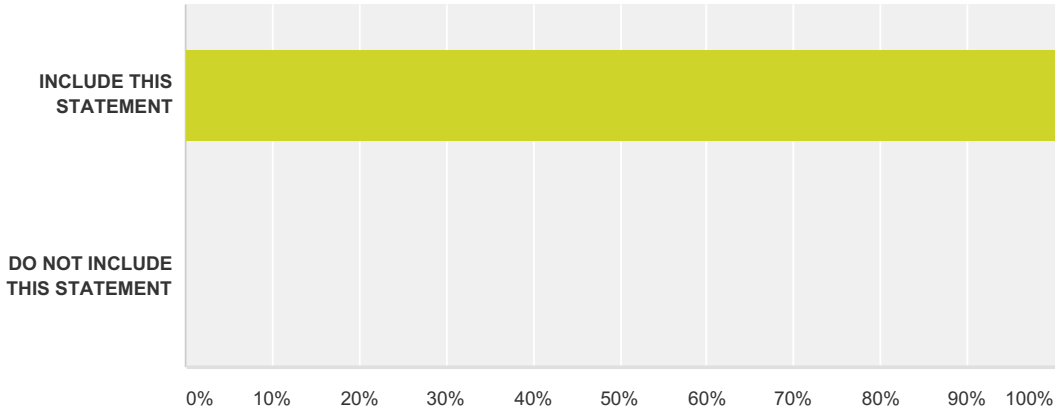
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**63.64%**	7
DO NOT INCLUDE THIS STATEMENT	**36.36%**	4
Total		**11**

Q6 Pro 5: This is a good way to show knowledge because it allows the PIC to demonstrateoperational controls as they relate to Food Code requirements.

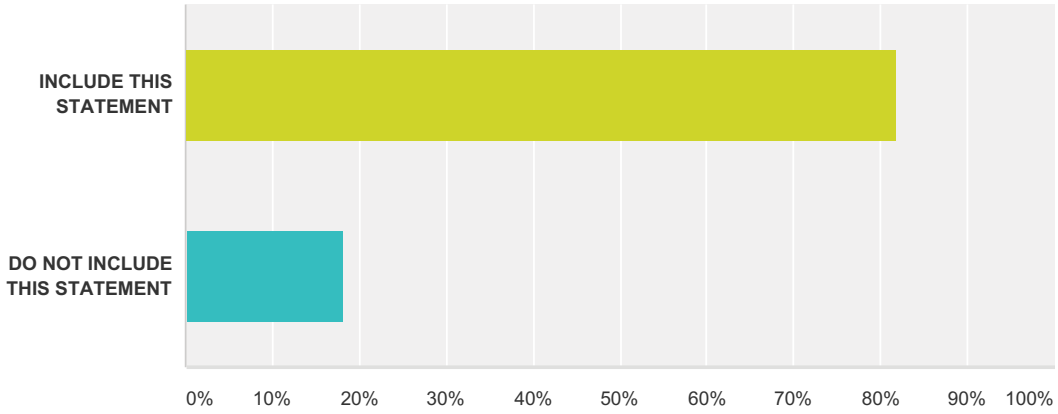
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**100.00%**	11
DO NOT INCLUDE THIS STATEMENT	**0.00%**	0
Total		**11**

Q7 Con 1: Could be subjective in the day to day reality of conducting inspections. Relies onregulator's judgment resulting in lack of consistency.

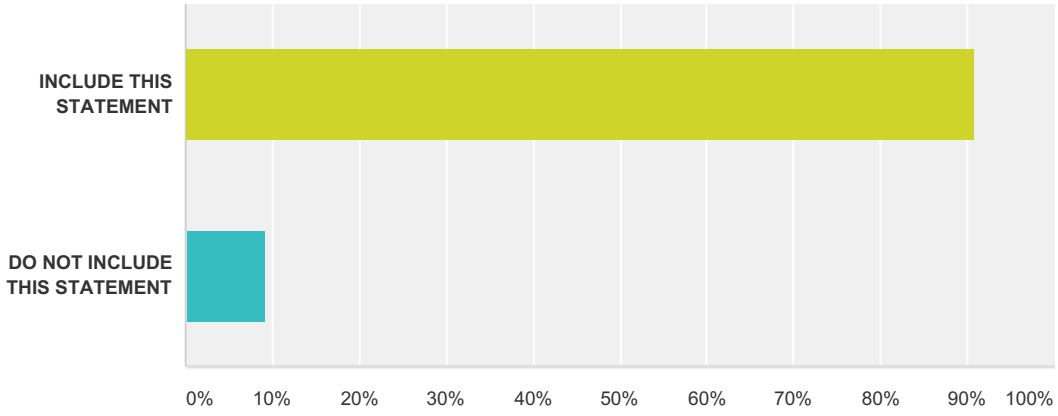
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**81.82%**	9
DO NOT INCLUDE THIS STATEMENT	**18.18%**	2
Total		**11**

Q8 Con 2: Inspections capture conditions at a facility at a given point in time, and as such,may miss some systemic failures that are present and ongoing but not detectable at themoment. Although the desired end is the elimination of risk factors and full compliancewith this Code works to that end, it might be argued that this subsection isDemonstration of Compliance rather than Demonstration of Knowledge.

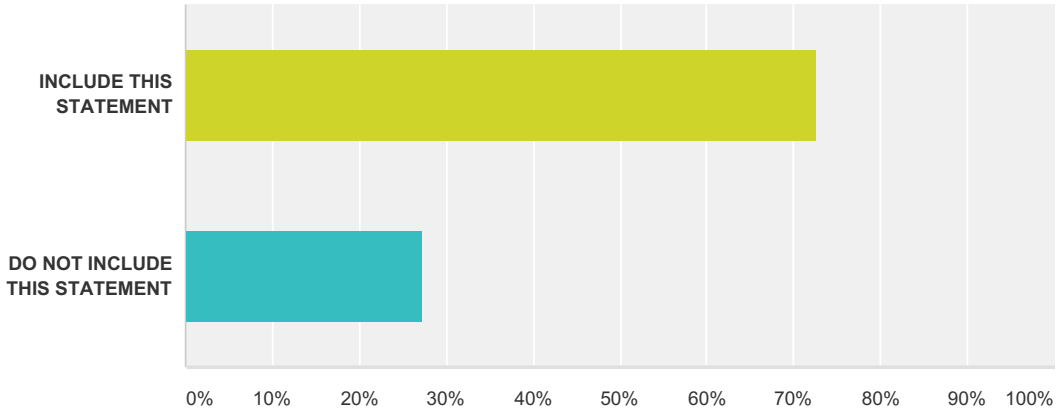
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**90.91%**	10
DO NOT INCLUDE THIS STATEMENT	**9.09%**	1
Total		**11**

Q9 Con 3: The undue focus on Priority Items to the exclusion of Priority Foundation andCore violations could overlook potential threats to Food Safety.

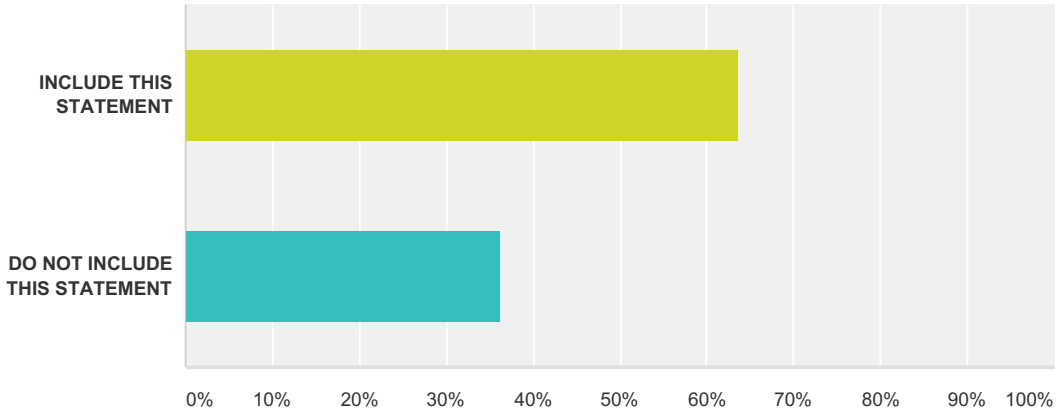
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**72.73%**	8
DO NOT INCLUDE THIS STATEMENT	**27.27%**	3
Total		**11**

Q10 Con 4: Studies have shown that knowledge and behavior do not always go hand-in-hand.

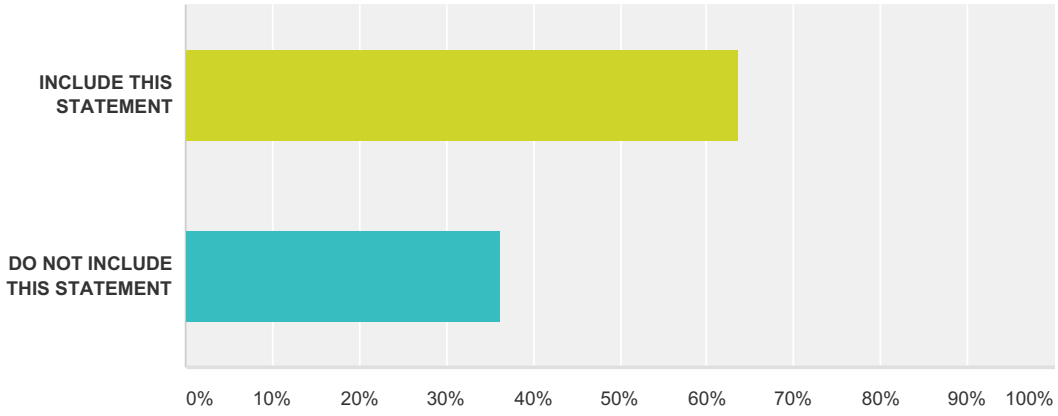
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**63.64%**	7
DO NOT INCLUDE THIS STATEMENT	**36.36%**	4
Total		**11**

Q11 Con 5: Language barriers may cause a loss of effective communication betweeninspectors and operators.

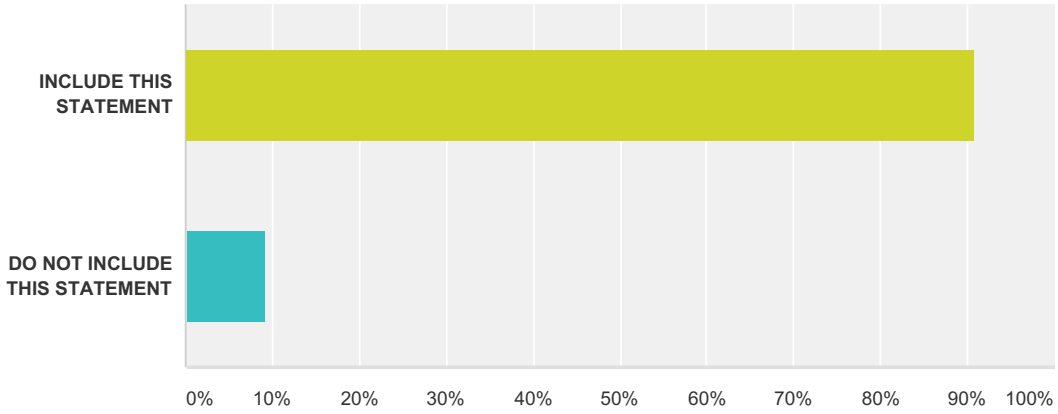
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**63.64%**	7
DO NOT INCLUDE THIS STATEMENT	**36.36%**	4
Total		**11**

Q12 Pro 1: Gives a clear understanding for regulators and industry of the requirements andrationale to demonstrate Food Code knowledge as it pertains to their operations.

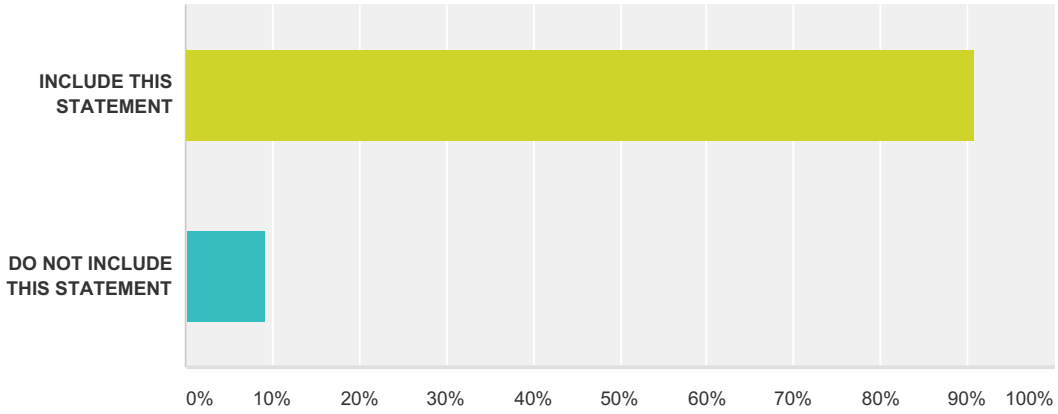
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**90.91%**	10
DO NOT INCLUDE THIS STATEMENT	**9.09%**	1
Total		**11**

Q13 Pro 2: PIC is able to demonstrate food safety knowledge by successfully answeringquestions pertaining to their operation.

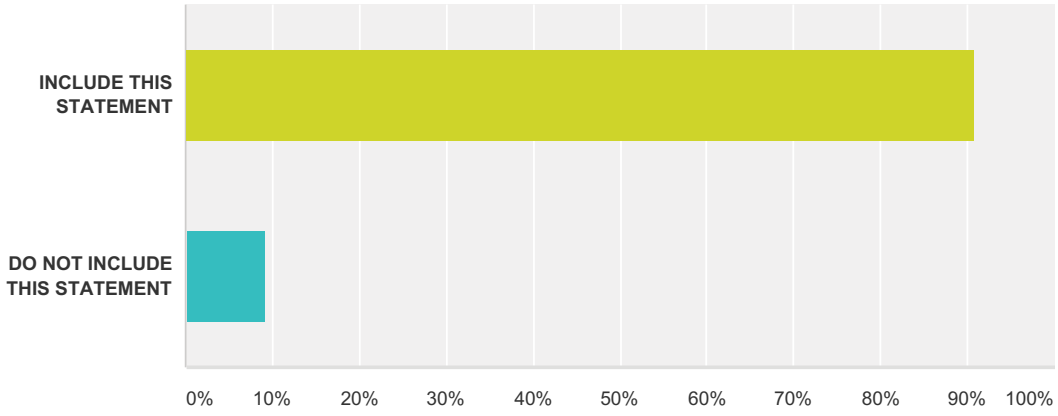
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**90.91%**	10
DO NOT INCLUDE THIS STATEMENT	**9.09%**	1
Total		**11**

Q14 Pro 3: It addresses the importance of the PIC having knowledge of the risks and howthey relate to foodborne illness.

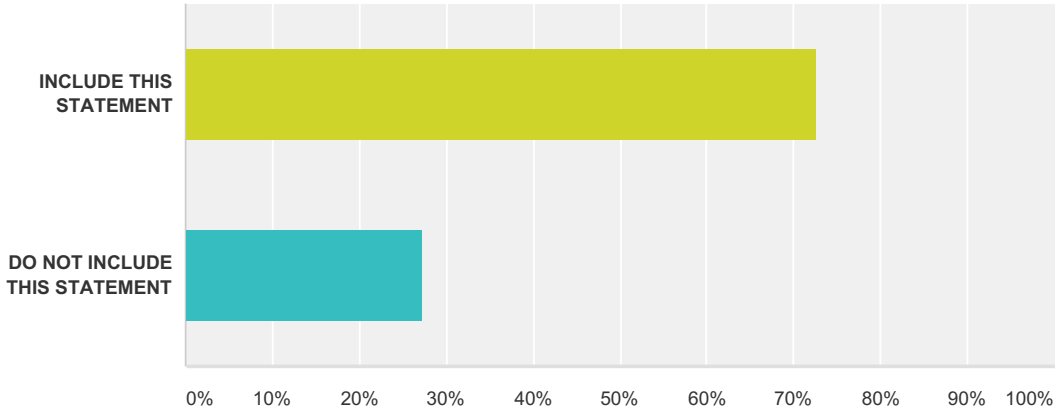
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**90.91%**	10
DO NOT INCLUDE THIS STATEMENT	**9.09%**	1
Total		**11**

Q15 Pro 4: Through Q&A the inspector is able to determine training needs.

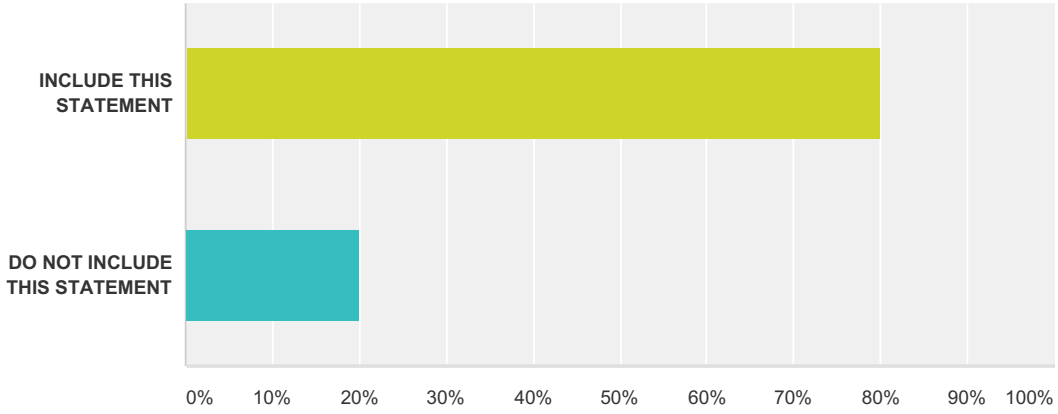
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**72.73%**	8
DO NOT INCLUDE THIS STATEMENT	**27.27%**	3
Total		**11**

Q16 Pro 5: This essentially amounts to an abbreviated CFPM oral exam. If the PIC is able tosuccessfully answer all questions posed, they clearly have a solid understanding ofbasic food safety principals pertaining to their operation.

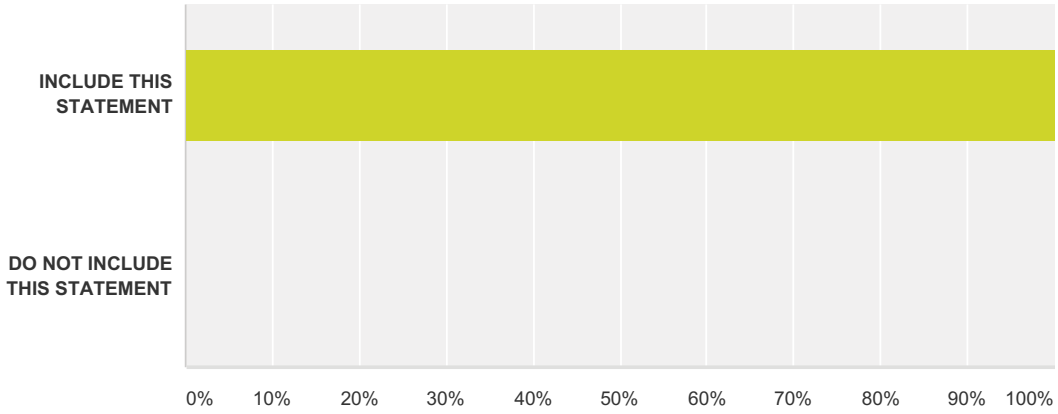
Answered: 10 Skipped: 2



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**80.00%**	8
DO NOT INCLUDE THIS STATEMENT	**20.00%**	2
Total		**10**

Q17 Pro 6: This gives the inspector the opportunity to ask customized questions directlyrelated to operation being observed; not just utilizing standard questions.

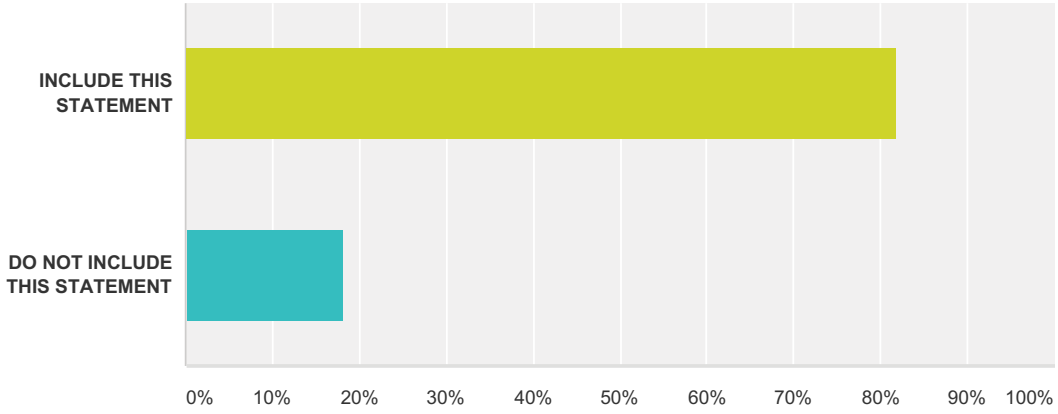
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**100.00%**	11
DO NOT INCLUDE THIS STATEMENT	**0.00%**	0
Total		**11**

Q18 Pro 7: If completely and correctly answered, the PIC can establish him/herself asproperly trained, knowledgeable and engaged in the management of food safety in theestablishment. It reflects that systems for managing food safety are in place even ifmomentary execution might be lacking.

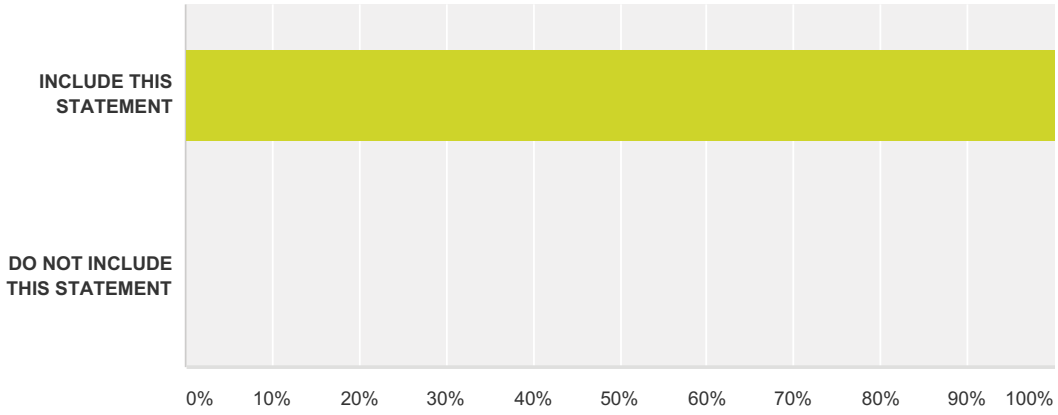
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**81.82%**	9
DO NOT INCLUDE THIS STATEMENT	**18.18%**	2
Total		**11**

Q19 Pro 8: This gives the PIC the opportunity to explain the processes performed in theirfood establishment which can often be validated with operations manuals and othertraining tools.

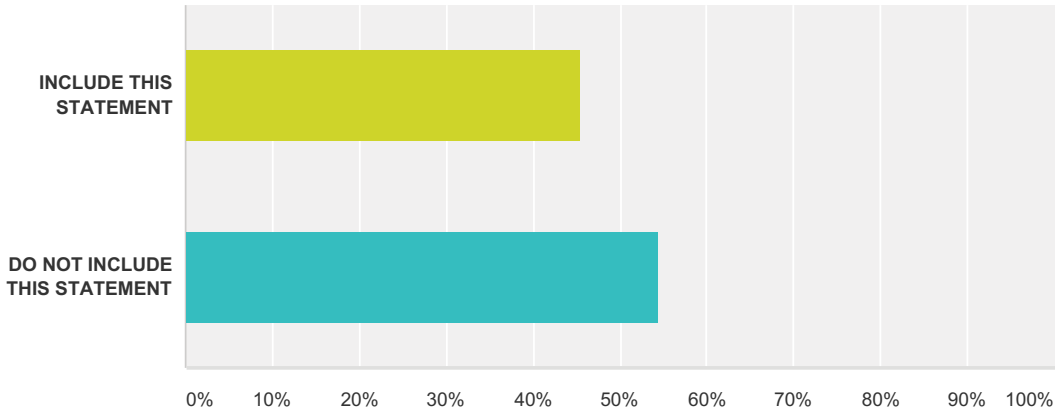
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**100.00%**	11
DO NOT INCLUDE THIS STATEMENT	**0.00%**	0
Total		**11**

Q20 Con 1: Could be easily misconstrued by regulators if not properly trained on askingappropriate questions based on the establishment's operation. Resulting in a level ofconsistency being lost. Pertaining to how many questions not answered correctly resultsin being marked OUT for Demo of Knowledge.

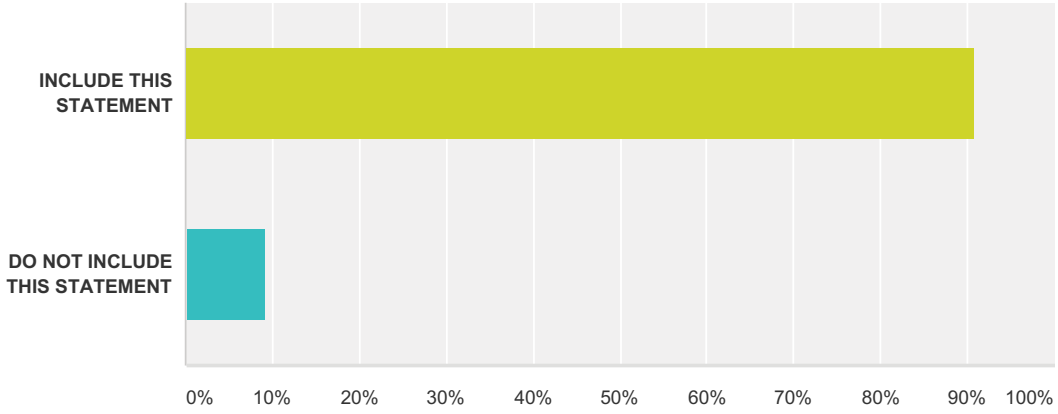
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**45.45%**	5
DO NOT INCLUDE THIS STATEMENT	**54.55%**	6
Total		**11**

Q21 Con 1.1: Inspector's questions could be easily misunderstood by a PIC, especially if theinspector is not properly trained on asking appropriate questions relevant to theestablishment's operation. This could also result in a degree of inconsistency based onthe types and numbers of questions asked of the PIC by the inspector. For instance,there is no standard for how many questions a PIC must answer correctly to demonstrateknowledge.

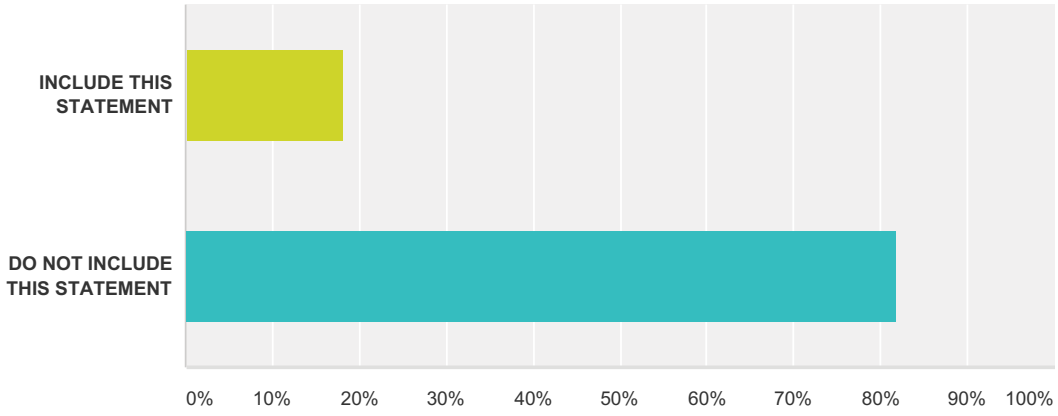
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**90.91%**	10
DO NOT INCLUDE THIS STATEMENT	**9.09%**	1
Total		**11**

Q22 Con 2: Questions not asked during the course of the inspection take extra time or maybe forgotten entirely.

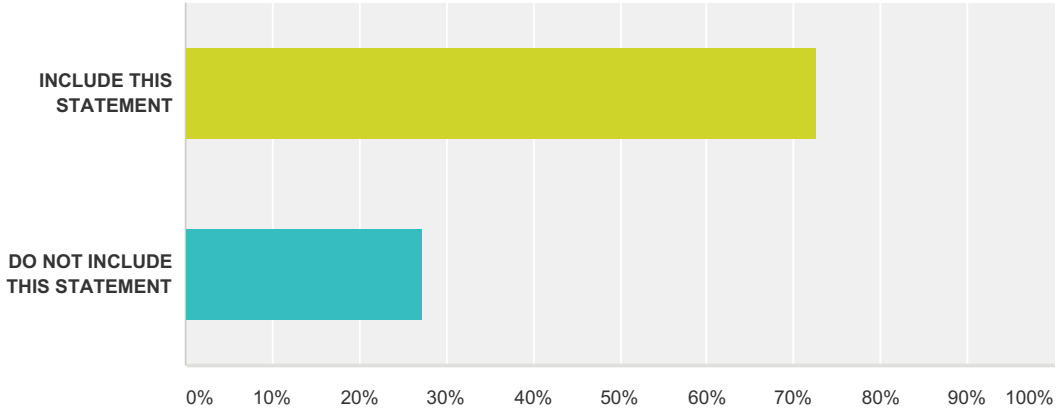
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**18.18%**	2
DO NOT INCLUDE THIS STATEMENT	**81.82%**	9
Total		**11**

Q23 Con 2.1: If a PIC is not accompanying an inspector at the time the inspector has aquestion, the inspector may need to take extra time at the end of the inspection to returnto an area with the PIC to question the food establishment's procedure, thereby addingadditional time for completion of the inspection. In some cases, if the PIC is not with theinspector, the inspector may have entirely forgotten the question he had regarding thatprocess by the time the PIC rejoins the inspection.

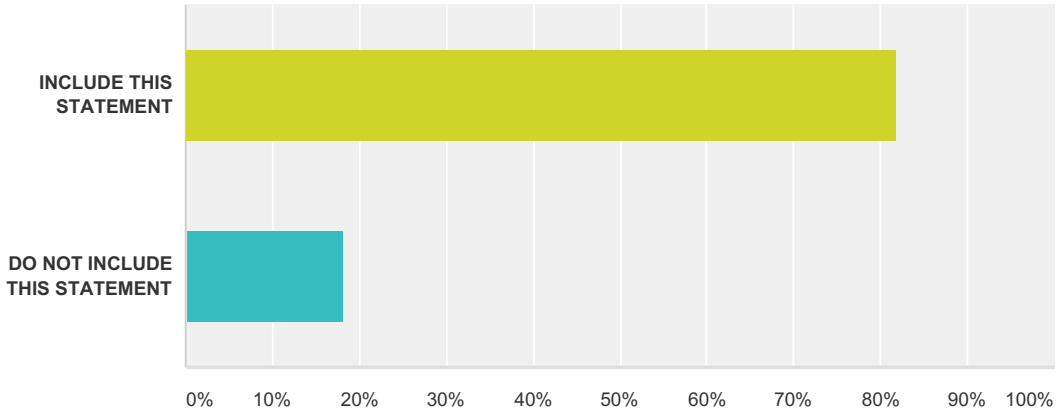
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	72.73%	8
DO NOT INCLUDE THIS STATEMENT	27.27%	3
Total		11

Q24 Con 3: Inspector may focus on the questions and may not make observations ofbehaviors a higher priority.

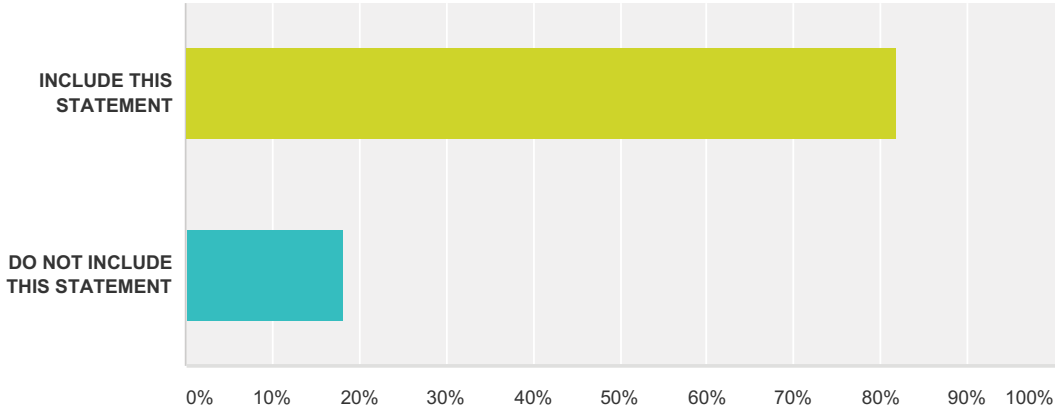
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**81.82%**	9
DO NOT INCLUDE THIS STATEMENT	**18.18%**	2
Total		**11**

Q25 Con 4: Regulators need to ensure only questions relevant to the operation are asked andthat answers given for a food establishment's procedures that exceed the minimumrequirement (such as temperatures) are not debited if in compliance with foodestablishment's standards.

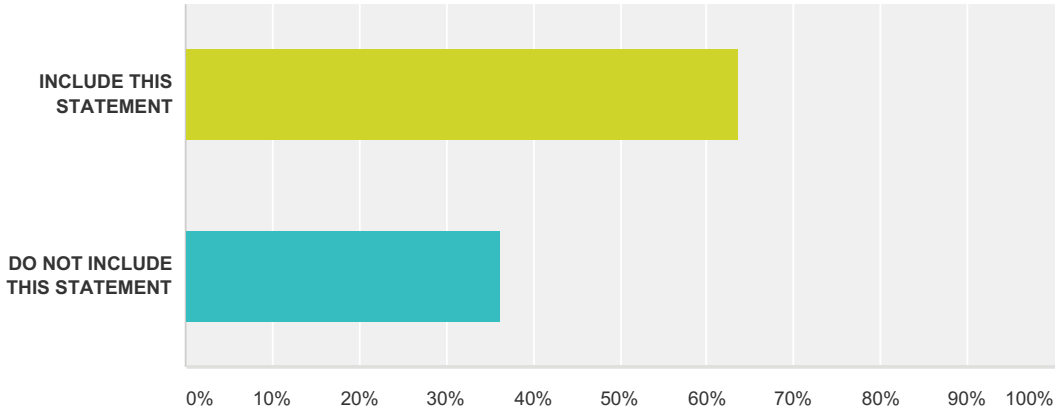
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**81.82%**	9
DO NOT INCLUDE THIS STATEMENT	**18.18%**	2
Total		**11**

Q26 Con 5: The quality of an interview is as much a function of the interviewer's ability as it isthe interviewee's competence. If the inspector does not ask questions properly/clearly,then the PIC's ability to successfully answer them will be limited. This "oral exam" alsoassumes that the inspector is a subject matter expert, has no competency issues, andknows the correct answers to the questions posed. On a more practical level, in manyestablishments English is not the primary language of the PIC or kitchen staff. Clearly,communication barriers are difficult to overcome in these situations. CFPMclasses/exams overcome this by way of bilingual instructors and translated studymaterials/exams; however, it is far more challenging to overcome this in an on-siteinterview with an inspector.

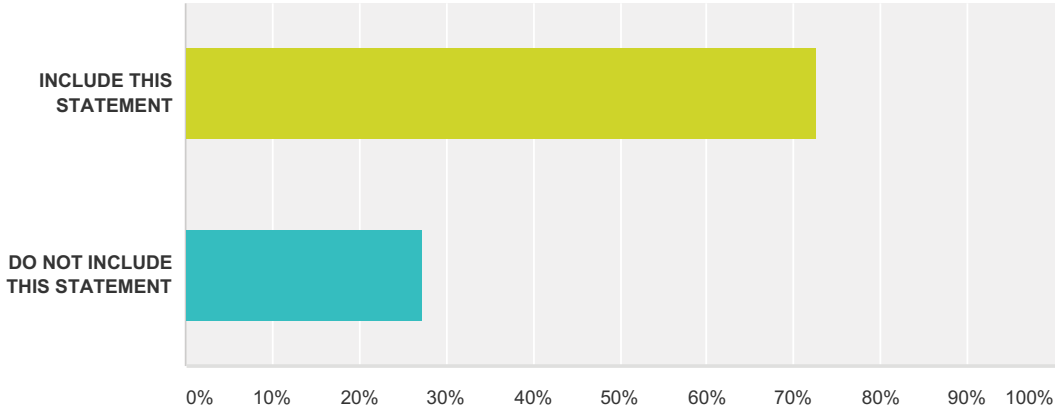
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	63.64%	7
DO NOT INCLUDE THIS STATEMENT	36.36%	4
Total		11

Q27 Con 6: The number of questions asked and the percent that must be answered correctlyin order to "pass" these criteria for demonstration of knowledge is not standardizedresulting in inconsistent application from one inspector to another.

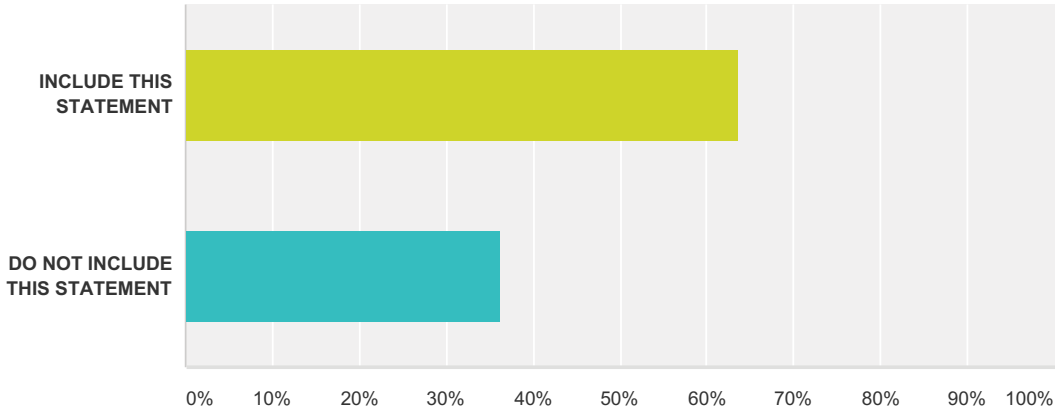
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**72.73%**	8
DO NOT INCLUDE THIS STATEMENT	**27.27%**	3
Total		**11**

Q28 Con 7: Nervousness, intimidation, and anxiety are all factors that may affect theemployee's ability to relay accurate answers to the regulator's questions.

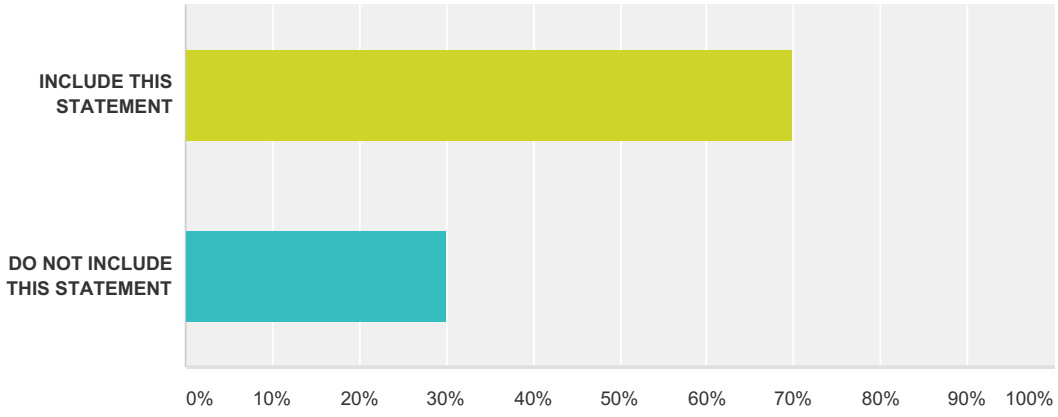
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**63.64%**	7
DO NOT INCLUDE THIS STATEMENT	**36.36%**	4
Total		**11**

Q29 Method 1: Change the Demonstration of Knowledge criteria. Instead of meeting one ofthe three options to be in compliance, change it to having to meet two of the threeoptions to be in compliance.

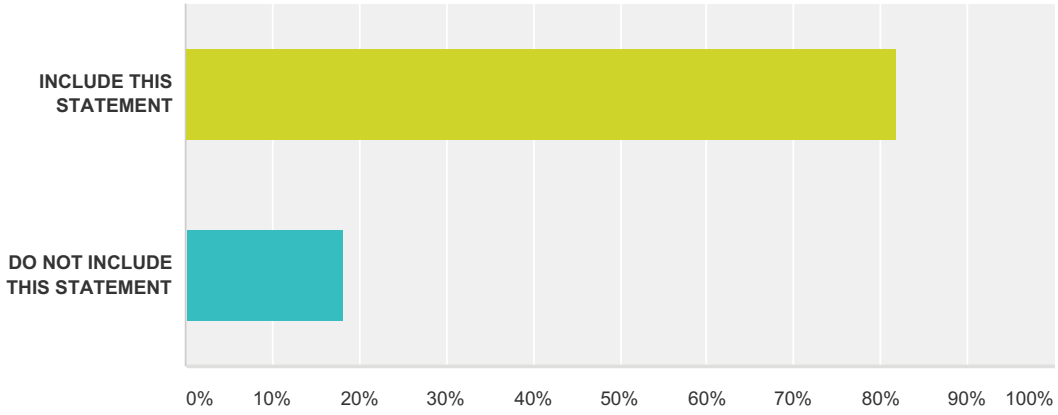
Answered: 10 Skipped: 2



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**70.00%**	7
DO NOT INCLUDE THIS STATEMENT	**30.00%**	3
Total		**10**

Q30 Method 2: Establishment is in compliance with 2-103.11.

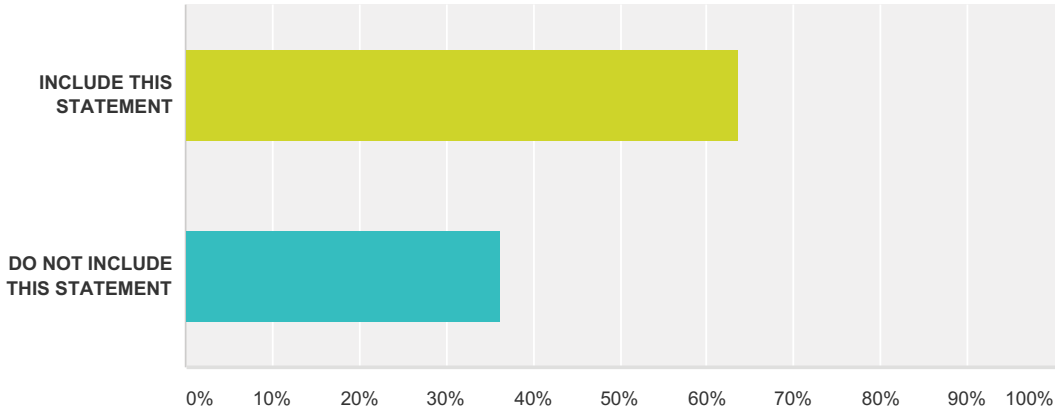
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**81.82%**	9
DO NOT INCLUDE THIS STATEMENT	**18.18%**	2
Total		**11**

Q31 Method 4: The PIC can show evidence of demonstration of knowledge through the use ofjob aides or other means.

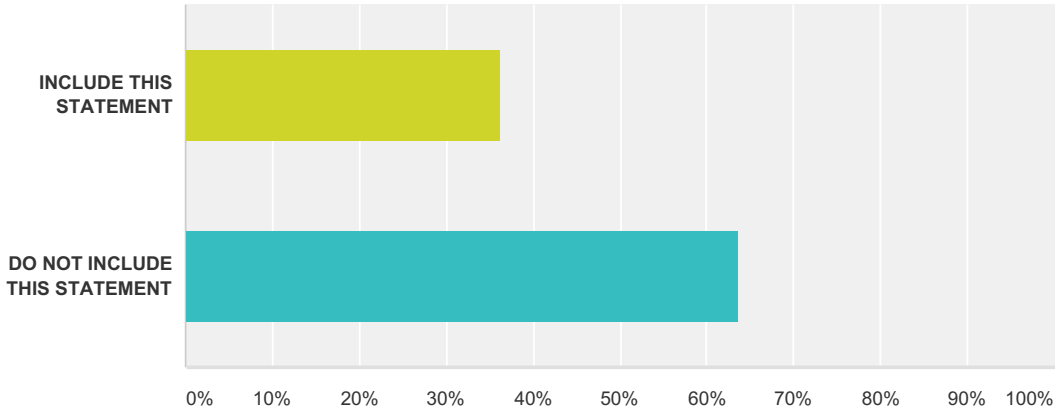
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**63.64%**	7
DO NOT INCLUDE THIS STATEMENT	**36.36%**	4
Total		**11**

Q32 Method 5: PIC/designee can demonstrate through practical means knowledge.

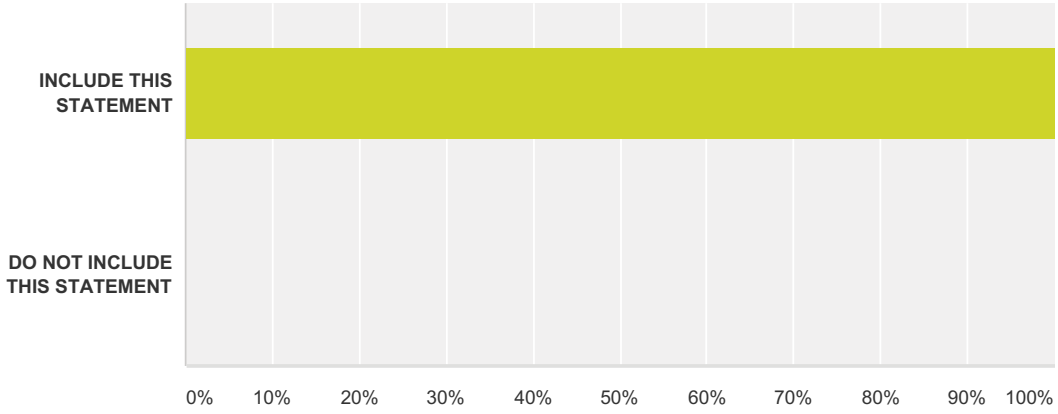
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**36.36%**	4
DO NOT INCLUDE THIS STATEMENT	**63.64%**	7
Total		**11**

Q33 Method 5.1: The person in charge can demonstrate Food Code knowledge throughpractical means such as showing how they take temperatures, calibrate a thermometer,mix or test sanitizer, showing a posted employee health policy or list of major foodallergens, etc.

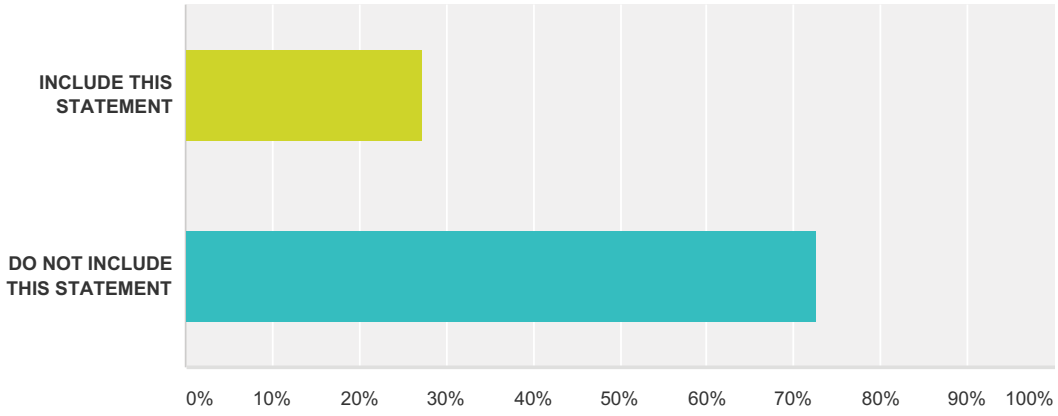
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**100.00%**	11
DO NOT INCLUDE THIS STATEMENT	**0.00%**	0
Total		**11**

Q34 Method 6: Develop standardized questions covering all areas of knowledge enumeratedin sub-section (C).

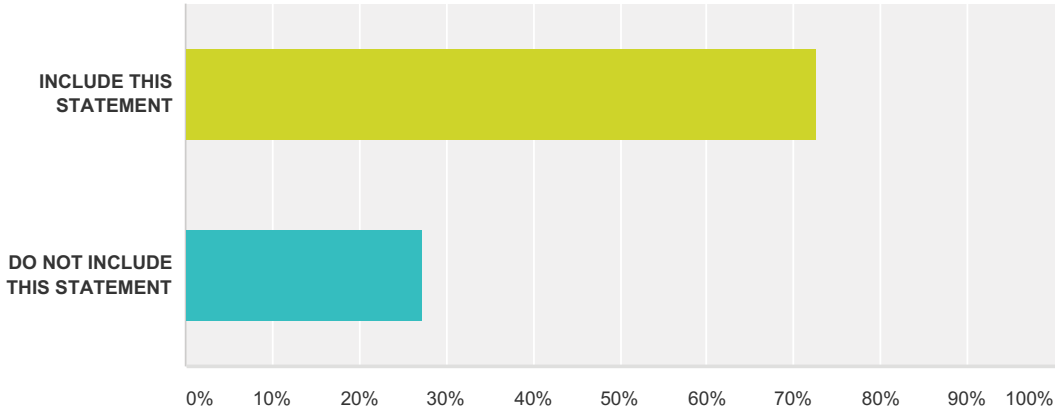
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**27.27%**	3
DO NOT INCLUDE THIS STATEMENT	**72.73%**	8
Total		**11**

Q35 Method 8: Employees are completing tasks correctly.

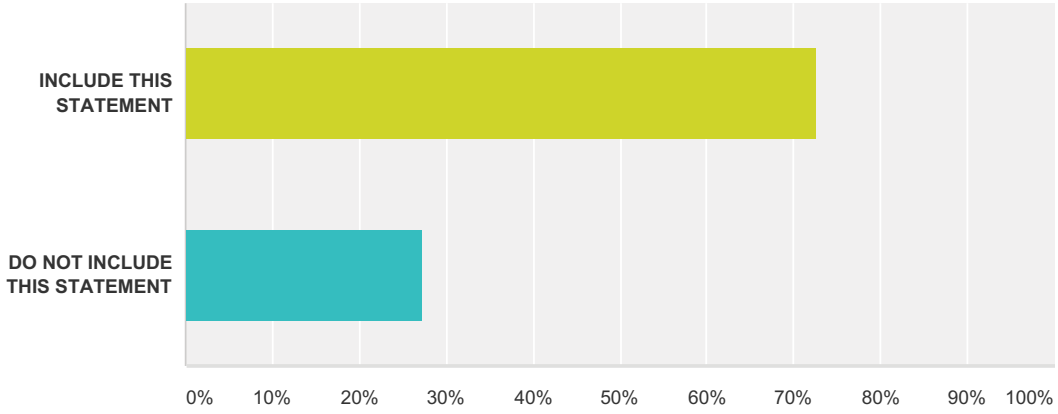
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**72.73%**	8
DO NOT INCLUDE THIS STATEMENT	**27.27%**	3
Total		**11**

Q36 Method 9: Having one or more food handlers who are certificated through an ANSI-ASTMaccredited program or equivalent and who comply with section 2-103.11 of this Code,thus applying practical means knowledge to the successful completion of tasks.

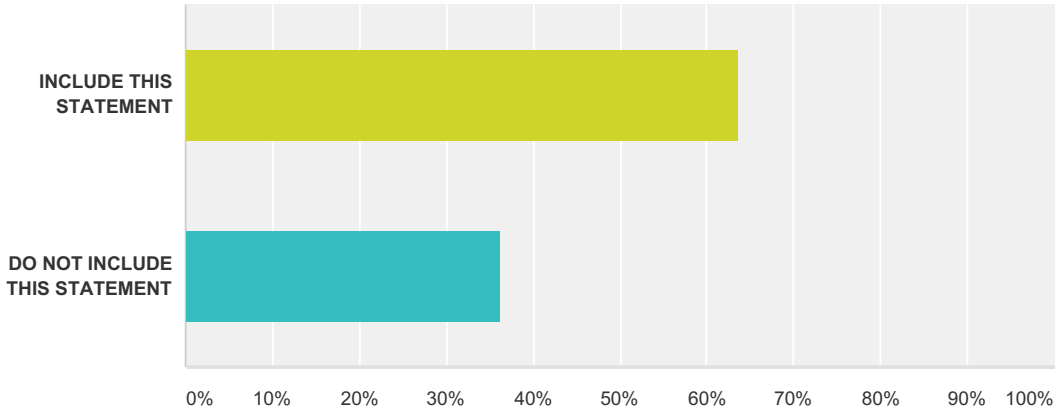
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**72.73%**	8
DO NOT INCLUDE THIS STATEMENT	**27.27%**	3
Total		**11**

Q37 Method 10: The establishment has a food handler certificated program through an ANSIASTMprogram or equivalent and one or more employees is certificated through theprogram.

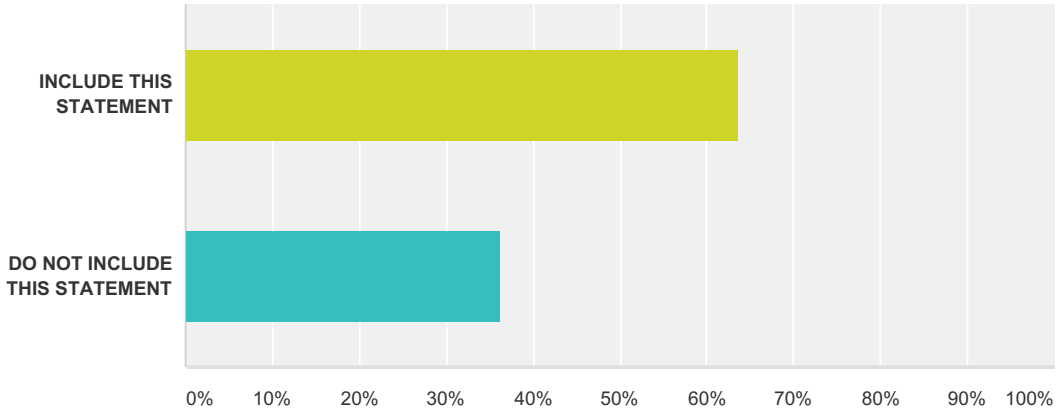
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**63.64%**	7
DO NOT INCLUDE THIS STATEMENT	**36.36%**	4
Total		**11**

Q38 Method 11: Change the code language in 2-102.11 (C) to: “ Demonstrating food safetyprinciples based on the specific food operation. The areas of knowledge include: …..”.

Answered: 11 Skipped: 1

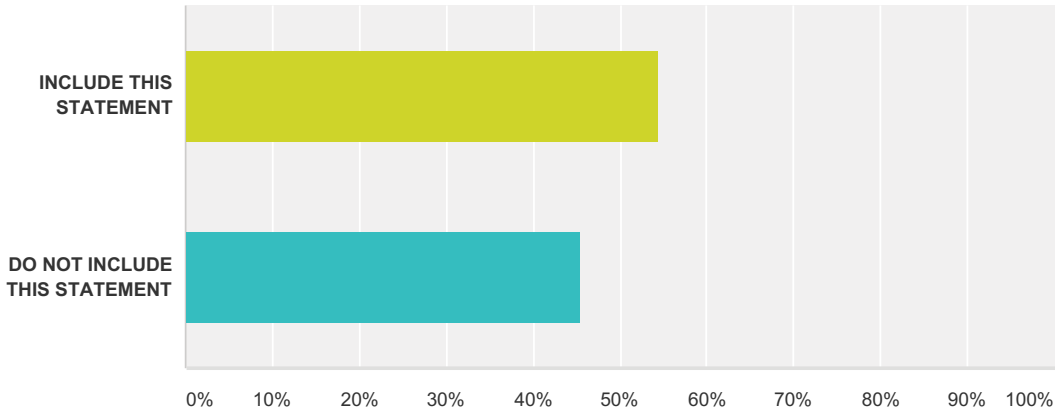


Answer Choices	Responses	
INCLUDE THIS STATEMENT	**63.64%**	7
DO NOT INCLUDE THIS STATEMENT	**36.36%**	4
Total		**11**

Q39 Method 12: Recommend eliminating Section 2-102.11 within the Food Code as follows:Allow the Duties Section of the Food Code (2-103.11) to substantiate demonstration ofknowledge in lieu of the Demonstration Section (2-102.11). The distinction betweenknowledge and application is vague and difficult to articulate and this can lead tofrustration between operators and regulators. Having one or more food handlerscertificated through an ANSI-ASTM accredited program or equivalent and who complywith (A) through (O) of Section 2-103.11 by applying practical knowledge to thesuccessful completion of tasks should adequately demonstrate knowledge of the PIC.• Eliminate Section 2-102.11 (A). The number of times that an establishment has nopriority violations is statistically insignificant. There is also the suspicion amongregulators that a lack of priority violations could be accidental and not a true reflection ofdemonstration of knowledge.• Eliminate Section 2-102.11 (B). The Food Code already requires the presence of a CFPMin Section 2-102.12 (A). The FDA Risk Factor Study correlates the presence of a CFPMwith better control of risk factors and provides justification for the requirement in theFood Code to have at least one CFPM per establishment.• Eliminate Section 2-102.11 (C). The Food Code already articulates the duties of aPIC in Section 2-103.11. In addition, the entirety of the risk based inspection identifieswhether an establishment is controlling risk and, by extension, whether knowledge isbeing demonstrated through application. The current list of 17 questions found in 2-102.11 (C) could be moved to Annex 5 as guidelines for inspectors who

wish to havedialogue with PICs.

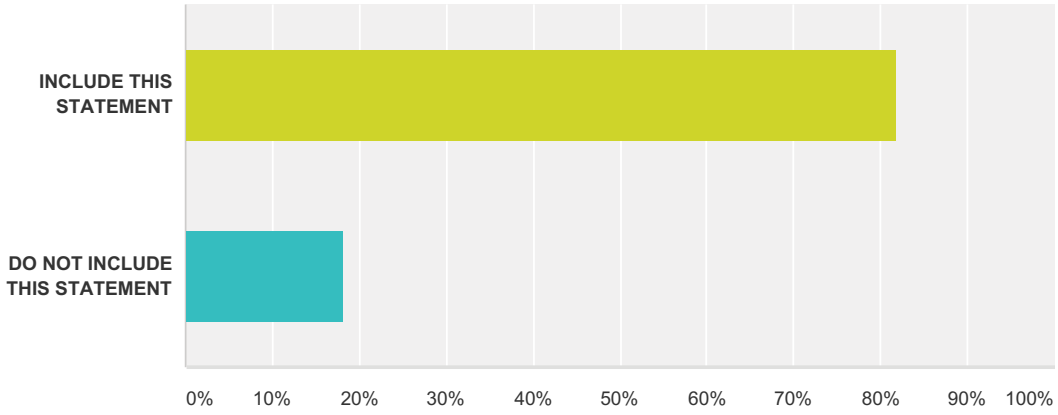
Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**54.55%**	6
DO NOT INCLUDE THIS STATEMENT	**45.45%**	5
Total		**11**

Q40 Method 12.1: Recommend modifying Section 2-102.11 of the Food Code as follows:If the Certified Food Protection Manager is not present, and because thedistinction between knowledge and application is vague and difficult to articulatewhich often leads to frustration between operators and regulators, the PIC shallbe a food handler certificated through an ANSI-ASTM accredited program or itsequivalent. The PIC shall substantiate knowledge through direct application of (A)through (O) of the Duties Section of the Food Code (2-103.11.) The successfulcompletion of these tasks should adequately demonstrate the PIC's knowledge.o Eliminate Section 2-102.11 (A). The number of times that an establishmenthas no priority violations is statistically insignificant. There is also thesuspicion among regulators that a lack of priority violations could beaccidental and not a true reflection of demonstration of knowledge.o Eliminate Section 2-102.11 (C). The Food Code already articulates theduties of a PIC in Section 2-103.11. In addition, the entirety of the riskbased inspection identifies whether an establishment is controlling riskand, by extension, whether knowledge is being demonstrated throughapplication. The current list of 17 questions found in 2-102.11 (C) could bemoved to Annex 5 as guidelines for inspectors who wish to have dialoguewith PICs.

Answered: 11 Skipped: 1



Answer Choices	Responses	
INCLUDE THIS STATEMENT	**81.82%**	9
DO NOT INCLUDE THIS STATEMENT	**18.18%**	2
Total		**11**

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-003

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Re-create - Demonstration of Knowledge (DoK) Committee

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) Demonstration of Knowledge Committee (DoK) requests that the committee be re-created to continue evaluation of the methods of demonstrating knowledge found in the 2013 FDA Food Code Section 2-102.11.

Public Health Significance:

Demonstration of knowledge is identified as one of the five key public health interventions to protect consumer health. The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard Analysis and Critical Control Point (HACCP) principles, and Code requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Code requirements, and to take appropriate preventive and corrective actions. A dialogue with the person in charge during the inspection process will also reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

Recommended Solution: The Conference recommends...:

the Demonstration of Knowledge (DoK) Committee be re-created following the 2016 CFP Biennial Meeting to continue work originally assigned in Issue 2014-II-016 with the following charges:

1. Identify and evaluate the pros and cons of *Alternative Methods to Demonstrating Knowledge*, a document created by the 2014-2016 DoK Committee (Attachment VI to the DoK Committee Report). Although not limited to the following areas, the committee will assess the pros and cons of each alternative method in light of the following areas:
   a) Differentiation between knowledge and application

b) Emphasis on risk factors
c) Ease of uniform assessment by regulators and industry
d) Enabling the Person in Charge to demonstrate knowledge even when there is a language barrier
e) What corrective action should be taken when there is not a demonstration of knowledge from the Person in Charge

2. Recommend alternative methods of demonstrating knowledge as new or amended Food Code language.
3. Report back committee outcomes and recommendations to the 2018 CFP Biennial Meeting.

Submitter Information 1:

Name:	Michelle Haynes
Organization:	2014-2016 Demonstration of Knowledge Committee
Address:	DBPR, Hotels and Restaurants1940 N Monroe St.
City/State/Zip:	Tallahassee, FL 32399
Telephone:	850-717-1734
E-mail:	michelle.haynes@myfloridalicense.com

Submitter Information 2:

Name:	Eric Moore, Committee Co-Chair
Organization:	2014-2016 Demonstration of Knowledge Committee
Address:	ACME Markets75 Valley Stream Parkway
City/State/Zip:	Malvern, PA 19355
Telephone:	267.971.0916
E-mail:	eric.moore@acmemarkets.com

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-004

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

All information above the line is for conference use only.

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014-I-032; new or additional information has been included or attached and the recommended solution has been revised.

Title:

Imminent Health Hazard: Modify Enforcement & PIC Duties

Issue you would like the Conference to consider:

Modify both the enforcement action and the duties of the Person in Charge in the FDA Food Code relative to "Imminent Health Hazard" so that a facility 1) with a written emergency operating plan that is preapproved by the regulatory authority; and that 2) takes immediate corrective action to eliminate, prevent or control a risk or hazard in accordance with that written and preapproved emergency operating plan; and that 3) informs the regulatory authority of the risk or hazard having occurred and the written preapproved emergency operating plan having been implemented should not have to cease operations.

Public Health Significance:

As stated in CFP's 2014 Emergency Action Plan for Retail Food Establishments, "All retail food establishments are vulnerable to a potential emergency or disaster that could impact the safety of the food and products they sell or serve to consumers. Yet, in times of crises, these facilities can also serve the community and provide valuable resources." During crisis, industry and public health are partners with a common purpose; to restore normalcy to the community quickly while protecting the public health in the process. Industry is the expert at feeding people, not emergency management agencies. The sooner food establishments can get operating; the sooner communities can return to normal. Pre-approval of emergency operating plans enables facilities to remain in operation and the regulatory authority to deploy their limited resources more efficiently, starting with establishments that don't have emergency operating plans, because delays in re-opening hurt all stakeholders; customers, employees and first responders.

The proposed language for Food Code Section 2-103.11(P) is modeled after language in the State of Georgia Rules & Regulations Governing Food Service, 511-6-1 effective November 1, 2015, found in a supporting attachment accompanying this Issue.

In the following link, "Emergency Action Plan for Retail Food Establishments", CFP 2014, note in particular Localized Emergency or Event #s 2, 3 & 4 located on pages 4-5. Also note planning for Response to an Emergency paragraphs 1, 2 & 3 located on page 7. Also see chart I on page 17; Procedures for Handling Refrigerated TCS Foods during a Power Outage.

http://www.foodprotect.org/media/guide/Emergency%20Action%20Plan%20for%20Retail%20food%20Est.pdf

In the following link, "Lessons Learned: Food Safety Preparedness before the Next Natural Disaster" in Food Safety Magazine, August/September 2014, note in particular, authors Kalis & Blake (CDC), Hatch (AL DPH) & Corby (AFDO) on the value of preapproved emergency operating plans. Kalis & Blake add that in a crisis, food service providers with preapproved emergency operating plans become part of the infrastructure that protects public health.

http://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2014/lessons-learned-food-safety-preparedness-before-the-nest-natural-disaster/

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the 2013 Food Code be amended by adding new paragraphs to Sections 8-404.11 and 2-103.11 as follows (underline format used for new language):

Section 8-404.11. Ceasing Operations and Reporting.

(A) Except as specified in ¶ (B) and (C) of this section, a PERMIT HOLDER shall immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, SEWAGE backup, misuse of POISONOUS OR TOXIC MATERIALS, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.

(B) A PERMIT HOLDER need not discontinue operations in an area of an establishment that is unaffected by the IMMINENT HEALTH HAZARD.

(C) A PERMIT HOLDER need not discontinue operations if the facility has experienced an interruption of water service or an extended interruption of electrical service for two or more hours so long as the facility has a specific written emergency operating plan that has been preapproved by the regulatory authority and if the Person in Charge takes immediate corrective action to eliminate, prevent or control the risk or hazard in accordance with the specific written preapproved emergency operating plan and if the Person in Charge informs the regulatory authority of the specific risk or hazard having occurred and of the specific written preapproved emergency operating plan having been implemented. [Pf]

Section 2-103.11. Person in Charge

The Person in Charge shall ensure that:

(P) Imminent Health Hazard. If an imminent health hazard exists because of an emergency such as a fire, flood, interruption of electrical or water service for two or more hours, sewage malfunction, misuse of poisonous or toxic materials, onset of an apparent

foodborne illness outbreak, gross unsanitary occurrence or condition, or other circumstances that may endanger public health, then operations are immediately discontinued and the Health Authority is notified.[P] If, however, the Imminent Health Hazard consists of an interruption of water service or an extended interruption of electrical service for two or more hours, the establishment may continue to operate under a specific written emergency operation plan that has been preapproved by the Health Authority prior to the occurrence of the specific emergency event provided the Person in Charge notifies the Health Authority that the specific emergency event has occurred and the preapproved specific written emergency operation plan is being implemented. [Pf]

Submitter Information:

Name:	Mark "Mick" Miklos
Organization:	National Restaurant Association
Address:	175 West Jackson Blvd.Suite 1500
City/State/Zip:	Chicago, IL 60604
Telephone:	770-868-7422
E-mail:	mmiklos@restaurant.org

Supporting Attachments:

- "Rules & Regulations Governing Food Service for the State of Georgia"

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.

Below are the Rules & Regulations Governing Food Service (Food Code) for the State of Georgia, effective November 1, 2015. Note Section 511-6-1.03 (2) (n), Management & Personnel, Responsibilities of the Person in Charge (PIC), Imminent Health Hazard which is highlighted in yellow.

511-6-1-.03 Management and Personnel

(1) Demonstration of Knowledge. Based on the risk of foodborne illness inherent to the food service operation, during inspections and upon request, the person in charge shall demonstrate to the Health Authority knowledge of foodborne disease prevention, application of the Hazard Analysis Critical Control Point principles, and the requirements of this Chapter. The person in charge shall demonstrate this knowledge in one of the following ways:

(a) Compliance with Chapter. Complying with this Chapter by having no violations of Priority Items during the current inspection; [Pf]

(b) Certified Food Service Manager. Being a certified food service manager who has shown proficiency of required information through passing a test that is part of an accredited program; [Pf] or

(c) Correct Answers to Food Safety Questions. Responding correctly to the inspector's questions as they relate to the specific food operation. The areas of knowledge include:

1. Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee; [Pf]

2. Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease; [Pf]

3. Describing the symptoms associated with the diseases that are transmissible through food; [Pf]

4. Explaining the significance of the relationship between maintaining the time and temperature of time/temperature control for safety food and the prevention of foodborne illness; [Pf]

5. Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish; [Pf]

6. Stating the required food temperatures and times for safe cooking of time/temperature control for safety food including meat, poultry, eggs, and fish; [Pf]

7. Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of time/temperature control for safety food; [Pf]

8. Describing the relationship between the prevention of foodborne illness and the management and control of the following:
(i) Cross contamination, [Pf]

(ii) Hand contact with ready-to-eat foods, [Pf]

(iii) Handwashing, and [Pf]

(iv) Maintaining the food service establishment in a clean condition and in good repair;[Pf]

9. Describing foods identified as major food allergens and the symptoms major food allergen could cause in a sensitive individual who has an allergic reaction; [Pf]

10. Explaining the relationship between food safety and providing equipment that is:

(i) Sufficient in number and capacity, and [Pf]

(ii) Properly designed, constructed, located, installed, operated, maintained, and cleaned; [Pf]

11. Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment; [Pf]

12. Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections; [Pf]

13. Identifying poisonous or toxic materials in the food service establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law; [Pf]

14. Identifying critical control points in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Chapter; [Pf]

15. Explaining the details of how the person in charge and food employees comply with the HACCP plan if a plan is required by the law, this Chapter, or an agreement between the Health Authority and the food service establishment; [Pf]

16. Explaining the responsibilities, rights, and authorities assigned by this Chapter to the:

(i) Food employee, [Pf]

(ii) Conditional employee, [Pf]

(iii) Person in charge, [Pf]

(iv) Health Authority; [Pf] and
17. Explaining how the person in charge, food employees, and conditional employees comply with reporting responsibilities and exclusion or restriction of food employees. [Pf]

(2) Responsibilities of the Person in Charge (PIC). There must be a person in charge on the premises of the food service establishment at all times. The person in charge shall ensure compliance with the following:

(a) Operations Not Conducted in Private Home. Food service establishment operations are not conducted in a private home or in a room used as living or sleeping quarters; [Pf]

(b) Authorized Personnel Access. Persons unnecessary to the food service establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles are protected from contamination; [Pf]

(c) Authorized Persons Compliance. Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, and warewashing areas comply with this Chapter; [Pf]

(d) Employee Handwashing. Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing; [Pf]

(e) Monitoring of Receiving. Employees are visibly observing and verifying delivered foods as they are received to determine that they are from approved sources and are placed into appropriate storage locations, as required by this Chapter, such that they are received and maintained at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the employees' observations, maintaining receiving/corrective action records for deliveries during non-operating hours, and periodically evaluating foods upon their receipt as specified within DPH Rule 511-6-1-.04(3)(m);[Pf]

(f) Proper Cooking Techniques. Employees are properly cooking cold/hot holding, and reheating for hot holding time/temperature control for safety food, being particularly careful in cooking, reheating, and holding those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats, through daily oversight of the employees' routine monitoring of the cooking, holding, and reheating for hot holding temperatures using appropriate temperature measuring devices properly scaled and calibrated. [Pf]

(g) Proper Cooling Methods. Employees are using proper methods to rapidly cool time/temperature control for safety food, that are not held hot or are not for consumption within four hours, through daily oversight of the employees' routine monitoring of food temperatures during cooling; [Pf]

(h) Consumer Food Safety. Consumers who order raw or partially cooked ready-to-eat foods of

animal origin are informed that the food is not cooked sufficiently to ensure its safety; [Pf]

(i) Proper Sanitizing. Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing; [Pf]

(j) Clean Tableware. Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets; [Pf]

(k) Bare Hand Contact. Unless the conditions specified in DPH Rule 511-6-1-.04(4)(a)4 are met, employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment; [Pf]

(l) Food Safety Training. Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties; [Pf]

(m) Reporting Responsibilities. Food employees and conditional employees are informed in a verifiable manner of their responsibility to report in accordance with the Chapter, to the person in charge, information about their health and activities as they relate to diseases that are transmissible through food; [Pf] and

(n) Imminent Health Hazard. If an imminent health hazard exists because of an emergency such as a fire, flood, interruption of electrical or water service for two or more hours, sewage malfunction, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross unsanitary occurrence or condition, or other circumstances that may endanger public health, then operations are immediately discontinued and the Health Authority is notified. [P] However, establishments may continue to operate under an emergency operation plan that has been approved by the Health Authority prior to the occurrence of such emergency events.[Pf]

(o) Procedures and Plans. Written procedures and plans, where specified by this Chapter and as developed by the food service establishment, are maintained and implemented as required.[Pf]

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-005

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:

Demonstration of Knowledge regarding Food Allergen Labeling

Issue you would like the Conference to consider:

Adding an amendment to the 2013 FDA Food Code section 2-102.11(C)(9) to include describing proper food allergen labeling for products, when applicable, produced by the venue.

Public Health Significance:

Pre-packaged products from bakeries, delis, restaurants, and other venues often are not labeled with allergens that they contain (a violation of the Food Code section 3-602.11(B)(5)), nor the potential allergens that may have been in contact with the products. This poses a serious risk to allergic consumers who may experience anaphylaxis as a result of exposure to the allergens.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that Subparagraph 2-102.11(C)(9) of the 2013 Food Code be amended as follows (new language is underlined):

2-102.11 Demonstration.

(C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include:

(9) Describing FOODS identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction. Describe proper food allergen labeling for pre-packaged products produced by the establishment.[Pf]

Submitter Information:

Name: Nona Narvaez
Organization: Anaphylaxis and Food Allergy Association of MN (AFAA)

Address: 2200 Hendon Ave
City/State/Zip: St. Paul, MS 55108
Telephone: 6516445937
E-mail: nona@minnesotafoodallergy.org

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-006

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Report – Program Standards Committee (PSC)

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) Program Standards Committee seeks Council II's acknowledgment of the committee's final report.

Public Health Significance:

The Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) were developed to serve as a guide for regulatory retail food program managers in the design, management, and execution of a retail food program with the public health outcome of reducing foodborne illness risk factors. The Program Standards Committee is a standing committee reporting to the CFP Executive Board. The Committee provides ongoing input to the FDA on issues that arise with the Retail Program Standards. The Committee serves the Conference by indirectly assisting Retail Program Standards enrollees in making progress towards meeting the Retail Program Standards. The Committee continues to work with the FDA internal Program Standards working group and the FDA Clearinghouse Workgroup to clarify and address issues that arise with the Retail Program Standards.

Recommended Solution: The Conference recommends...:

1. Acknowledgment of the 2014 - 2016 Program Standards Committee Final Report, and
2. Thanking the Committee members for their work and dedication during the 2014 - 2016 biennium.

Submitter Information 1:

Name: David Lawrence, Chair
Organization: Program Standards Committee

Address: Fairfax County Health Department10777 Main Street, Suite 111
City/State/Zip: Fairfax, VA 22030
Telephone: (703) 246-8435
E-mail: David.Lawrence@fairfaxcounty.gov

Submitter Information 2:

Name: Debbie Watts, Co Vice-Chair
Organization: Program Standards Committee
Address: Tulsa Health Department5051 South 129th East Avenue
City/State/Zip: Tuls, OK 74134
Telephone: (918) 595-4305
E-mail: Dwatts@tulsa-health.org

Content Documents:

- "2014-2016 Program Standards Committee Final Report"
- "2014-2016 CFP Program Standards Committee Membership Roster"
- "Retail Program Standards - Competency of Inspectors Infographic"

Supporting Attachments:

- "Verification Audit Survey Tool"
- "Industry Support for Standards 2, 4 and 7 Survey Tool"
- "Verification Audit Survey Results"
- "Industry Support for Standards 2, 4 and 7 Survey Results (FMI Summary)"
- "Industry Support for Standards 2, 4 and 7 Survey Results (NRA Summary)"

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: Program Standards

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Executive Board

DATE OF REPORT: 12/18/2015

SUBMITTED BY: David Lawrence, Chair
Caroline Friel, Co Vice-Chair
Debbie Watts, Co Vice-Chair

COMMITTEE CHARGE(s):

The charges to the 2014 – 2016 Program Standards Committee were designated as follows in two 2014 CFP issues:

Issue #: 2014 II-005:
Charges:

1. Identify areas where the Voluntary National Retail Food Regulatory Program Standards can be changed or improved to enhance enrollment and implementation; and
2. Work on a project to recognize levels of performance of Program Standards enrollees that will demonstrate the progress of enrollees in a meaningful way and acknowledging the enrollees for taking the necessary incremental steps toward meeting the Program Standards. As part of this project:
   a. Provide a Cost/Benefit Analysis for recognizing partial achievement of the Retail Program Standards;
   b. Identify different approaches that could be used to recognize partial achievement of the Retail Program Standards that would not require additional resources to perform or administer; and
   c. Examine whether there is an additional burden placed on enrollees or FDA (in time, money, or added complexity of the Standards) associated with development of a system to ensure that jurisdictions are uniformly recognized for partial achievement of the Standards.
3. Review the current verification audit requirement and:
   a. Identify strengths of the current verification audit requirement;
   b. Identify weaknesses of the current verification audit requirement, with emphasis on any barriers that may result from the current requirement; and
   c. Determine whether there are potential changes to the requirement, or the administration of the requirement, that could maintain the credibility of the Retail Program Standards while reducing barriers to achievement that may result from the current verification audit requirement.
4. Serve as a sounding board for FDA with respect to ideas generated during collaboration with the other entities such as NACCHO, PFP, AFDO.
5. Formulate resolutions to issues brought before the committee and report back at the 2016 CFP Biennial Meeting.

Issue #: 2014 II-003:
Charges:
To solicit the support of industry to:

1. Identify the benefits to industry for regulatory authorities to achieve Standard 2, Standard 4, and Standard 7 of the Voluntary National Retail Food Regulatory Program Standards.
2. Examine methods to support regulatory efforts to achieve Standard 2, Standard 4, and Standard 7 of the Voluntary National Retail Food Regulatory Program Standards.

3. Report back at the 2016 CFP Biennial Meeting with recommendations on how the Conference can collaborate with industry to facilitate enrollment and achievement of the Voluntary National Retail Food Regulatory Program Standards.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:
   a. The Program Standards Committee membership included recruitment efforts to gain additional food industry and local regulatory members across the CFP regions. Per the Constitution and Bylaws, a balanced ratio of regulatory to industry members has been maintained. In April 2015, the Executive Board approved an updated roster that maintains this ratio by listing eight (8) regulatory and eight (8) food industry representatives as voting members. Any CFP members who expressed interest in the committee but who were not selected as voting members were designated as either electives or "at large" members. These electives and "at large" members have been included in all committee activities.
   b. The first full committee call was held on September 17, 2014. The committee chair and co vice-chairs presented the recommendation that the charges be worked on at a subcommittee level to stay ahead of the Executive Board's due dates and to complete the charges by December 2015 or sooner. The committee members supported the recommendation. Two subcommittees were formed: (1) **Issue 2014 II-003 Subcommittee** with co-leads Caroline Friel (food service industry) and Todd Mers (regulatory - state), and (2) **Issue 2014 II-005 Subcommittee** with co-leads Debbie Watts (regulatory - local) and Angie Cyr (regulatory - state). Each full committee member expressed their interest in serving on either or both subcommittees.
   c. Meetings were held via conference call and using GoToMeeting and Adobe Connect (arranged by the FDA consultants) to share reference documents online. To facilitate work on the current charges, a familiarization of all members with the Voluntary National Retail Food Regulatory Program Standards (hereafter referred to as Retail Program Standards) was established by ensuring access to the FDA resources. The full committee has met seven times (September 17, 2014 kick-off call; April 15, 2015; May 20, 2015; June 17, 2015; July 22, 2015; August 19, 2015; and September 23, 2015). During the initial meetings, time was allocated to introduce new members to the historical perspective of the committee. Subcommittee updates were provided as part of the full committee calls. Work on requests from the FDA regarding proposed revisions to Standards 4, 7 and 9 were conducted by the full committee.

2. Progress on Issue 2014 II-003 Activities:
   a. The **Issue 2014 II-003 Subcommittee** (hereafter referred to as Competency of Inspectors Subcommittee) met via phone conferencing (October 15, 2014, November 12, 2014, January 14, 2015, February 11, 2015, March 11, 2015, April 8, 2015, and May 13, 2015) and by email from October 2014 until September 2015. The Subcommittee developed and distributed a survey questionnaire (*see Industry Support for Standards 2, 4 and 7 Survey Tool attached to this repor*t) to assess industry's opinion regarding the benefits, if any, of having regulatory authorities achieve Standard 2, Standard 4, and Standard 7 of the Retail Program Standards. The Subcommittee gathered information from industry stakeholders regarding the value to industry of having a regulatory agency involved with the Retail Program Standards and provided recommendations to support regulatory efforts to achieve the Retail Program Standards.
   b. This part of the Program Standards Committee's final report outlines the disposition of issues worked on by the Competency of Inspectors Subcommittee and its recommendations to the Conference. Along with being a foundation and system upon which all regulatory programs can build through a continuous improvement process, the Retail Program Standards provide a template of what a quality regulatory food establishment program needs. Per the specific charges, this report will refer to only Standards 2, 4, and 7.
      i. Standard 2 provides the essential elements of a training program for regulatory staff.

ii. Standard 4 pertains to implementing an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and consistency among the regulatory staff.
iii. Standard 7 relates to enhancing communication with industry and consumers through forums designed to solicit input to improve the food safety program.

c. *Charge 1: To solicit the support of industry to identify the benefits to industry for regulatory authorities to achieve Standard 2, Standard 4, and Standard 7 of the Voluntary National Retail Food Regulatory Program Standards.* The 2011 Food Safety Modernization Act (FSMA) requires the FDA to partner with state and local food safety regulatory agencies to build a national Integrated Food Safety System (IFSS). The goal of a national IFSS is to develop a seamless partnership and operation of federal, state, and local food safety regulatory agencies to meet the public health mission of achieving a safer food supply.

The benefits of having a regulatory authority meet the Retail Program Standards contributes to an IFSS by improving the confidence in the food safety work being conducted by other agencies, focusing efforts on the reduction of risk factors known to contribute to foodborne illness, and encouraging retail food establishments to implement active managerial control over these risk factors.

The Competency of Inspectors Subcommittee developed and distributed the Industry Support for Standards 2, 4 and 7 Survey Tool to assess industry's opinion regarding the benefits to industry, if any, of having regulatory authorities achieve Standard 2, Standard 4, and Standard 7 of the Retail Program Standards:

i. The original survey was disseminated to the Food Marketing Institute (FMI) and the National Restaurant Association (NRA). 133 responses were received. Incomplete surveys were removed and the remaining 116 surveys were combined and analyzed.
ii. Most respondents were food service operations/restaurants (n=55) and retail food establishments (n=49). Wholesale distribution and national grocery stores were represented one time each, and there were 10 respondents who did not respond to the self-identification question.
iii. The Subcommittee analyzed the survey responses and identified that the most important benefits to industry of having regulatory authorities achieve the Retail Program Standards are that the Standards:
    1. Support a consistent approach to inspections;
    2. Focus inspector and industry time on the true risk factors to reduce foodborne illness versus focusing time, money and limited resources on Good Retail Practices that have little impact on preventing foodborne illnesses;
    3. Enable "apple to apple data analyses" on a National basis; and
    4. Enable trend analysis for identifying opportunities and long-term solutions.
iv. The Subcommittee's analysis of survey responses found that the most important benefits to industry of having regulatory authorities achieve Standard 2 are:
    1. Supporting a consistent, credible approach to inspections;
    2. Providing more time for industry to focus on food safety rather than disputing improper citations or managing non-uniform regulations;
    3. Focusing both industry and regulators on solving complex public health problems; and
    4. Increasing consumer confidence.
v. The Subcommittee's analysis of survey responses found that the most important benefits to industry of having regulatory authorities achieve Standard 4 are:
    1. Quality assurance is needed due to the diversity in inspector competency;

2. Quality assurance drives uniformity in the inspection process. This is important with the increased use of inspection information by media to report results to the public; and
3. Standard 4 criteria help to drive continuous improvement.

vi. The Subcommittee's analysis of survey responses found that the most important benefits to industry of having regulatory authorities achieve Standard 7 are:
1. The more collaboration industry and regulatory authorities have, the better off we are – as we are on the same team;
2. Standard 7 criteria enable free, open communication and sharing to align priorities;
3. Relationship building is of the utmost importance as it enables problem solving and improvement; and
4. Standard 7 promotes the establishment of partnerships to facilitate swift responses to future outbreaks and crises.

vii. The Subcommittee identified the following trends after compiling the survey data:
1. There is a positive correlation between the length of time in business and the perceived value of Standards 2, 4, and 7.
2. Having a larger number of employees was statistically associated with perceived value of Standard 2.

d. *Charge 2: To solicit the support of industry to examine methods to support regulatory efforts to achieve Standard 2, Standard 4, and Standard 7 of the Voluntary National Retail Food Regulatory Program Standards.* The Retail Program Standards offer a systematic approach to, through a continuous improvement process, enhance retail food regulatory programs. They define and provide a framework designed to accommodate both traditional and emerging approaches of a regulatory food safety system. To address the charge, the Subcommittee interviewed regulatory agencies enrolled in the Retail Program Standards, mostly those who had achieved Standards 2, 4, and 7 and who conduct direct (not contracted) inspections, to examine and provide methods to support regulatory efforts to achieve Standard 2, Standard 4, and Standard 7.

e. Recommendations from Issue 2014 II-003. Based on the work done by the Competency of Inspectors Subcommittee, the Program Standards Committee has the following recommendations (**in bold**) for consideration by Council (*See Issue PSC 2*):

i. Develop a roadmap. When an enrolled regulatory agency implements the Retail Program Standards correctly, there is a cultural transition in the agency that supports continuous improvement. **The committee recommends that the FDA develops a Retail Program Standards guide or template to help regulatory agencies to enroll in the Retail Program Standards, realize what they are getting involved in prior to enrollment, provide recommendations about where an enrollee should begin, and provide a roadmap to allow management to plan for proper staffing and resources to actually complete and sustain the activities associated with the Retail Program Standards.**

ii. Involve industry in the funding and benchmark achievement processes. While the committee does not support an agency enrolling in the Retail Program Standards solely to receive accolades, there is reason to celebrate along the way as an agency progresses through meeting various levels of the Retail Program Standards. Industry members of this committee made it very clear that industry would like to be a formal part in developing a recognition process but feel that development of such a process is beyond the scope of the current Issue 2014 II-003 charges. The committee recommends the continuation of charge 2 of Issue 2014 II-005 by the 2016 - 2018 Program Standards Committee with support from the FDA to further examine a process for recognizing partial achievement of the Retail Program Standards. *Note: This recommendation will be made in Issue PSC 3.*

iii. Recognize that meeting the Retail Program Standards is a primary means to reducing foodborne illness within enrolled jurisdictions. One regulatory agency with 47,000 food establishments reports that implementation of the Retail Program Standards within their agency was instrumental in achieving a 90% reduction in foodborne illness outbreaks within their jurisdiction since 1997. The committee recommends that the FDA seek forums for enrollees to share their success stories that correlate with the implementation of the Retail Program Standards. *Note: This recommendation has redundancy with the recommendation presented below in viii.*

iv. Provide extra points on the grant application to encourage the regulatory agencies who are actively achieving the Retail Program Standards. While the different funding mechanisms are not a prerequisite for enrollment in the Retail Program Standards, only the top-scoring eligible proposals in each FDA Region are awarded grants. The committee found that those applicants who are actively achieving the Retail Program Standards are treated no differently than a regulatory agency who is applying for the first time. This existing approach may encourage more agencies to enroll in the Retail Program Standards but it does not encourage completion of the Retail Program Standards. Those actively enrolled in the Retail Program Standards should receive extra points on the application process. This would financially facilitate an agency's progress in achieving and sustaining the Retail Program Standards. **This committee recommends that the FDA reward achievement of the Retail Program Standards by giving extra credit during the application review and scoring process for grants.**

v. Establish and conduct regularly scheduled meetings, conferences, and/or webinars of state or FDA regional workgroups that will encourage regulatory agencies in their efforts with the Retail Program Standards. Trying to meet the Retail Program Standards without having someone to mentor you along the way can be an arduous task. The Retail Program Standards have been around since 2001. The FDA reports that as of October 2015, 119 enrollees have completed self-assessments AND have met three or more Standards. However, there are only 14 regulatory agencies that conduct direct inspections and have achieved Retail Program Standards 2, 4 and 7. **This committee recommends that the FDA establish additional formal networks to complement the existing NACCHO Program Standards Mentorship Program (e.g., workgroups in each state or by FDA region with routinely scheduled webinars, conference calls) to assist regulatory agencies in their efforts with the Retail Program Standards.**

vi. Promote the utilization of FoodSHIELD. The Retail Program Standards requires the creation of many documents, many of which can be obtained from others already enrolled in the Retail Program Standards. FoodSHIELD provides a means where federal, state and local governmental regulatory agencies may share documents by creating a workgroup and inviting others to see/review such documents. FoodSHIELD was designed to facilitate collaboration among the federal regulatory agencies, laboratories, state and local government entities, military branches, and academics involved in protecting the food supply and responding to foodborne illness outbreaks and safety concerns. The upcoming FoodSHIELD Program Standards Resource Center should further provide additional help for program managers who are developing the Program Standards within their agency. **The committee recommends that the FDA engages in a promotion of the FoodSHIELD Program Standards Resource Center when it goes live.**

vii. Ensure that FDA Regional Retail Food Specialists are highly knowledgeable regarding the Retail Program Standards. The FDA has 25 Regional Retail Food Specialists located throughout the United States and are assigned to one of the five FDA regions. The Specialists work with their assigned state, local, tribal, and territorial regulatory agencies to provide technical assistance. Any wisdom that can be shared along the way

with enrollees is invaluable. Testimonials describing the competency and proficiency of their Regional Retail Food Specialist regarding the Retail Program Standards were mixed. However, the successful retail food regulatory programs reportedly had very supportive Regional Retail Food Specialists. Having FDA Regional Retail Food Specialists who provide accurate and timely answers helps maintain momentum as one moves through the Standards. **The committee recommends that the FDA provides a means to ensure that each of the FDA Regional Retail Food Specialists has a minimum level of knowledge regarding implementation of the Retail Program Standards.**

viii. Champion the cause of implementing the Retail Program Standards. It is very unlikely a regulatory agency will successfully sustain meeting the Retail Program Standards without first getting the full support of management and then authorizing someone to responsibly drive forward the discussions regarding the Standards. All of the success stories shared with the committee spoke of one or two individuals who constantly championed the cause of implementing the Retail Program Standards. They always required the decision makers to ask the question, "How will this activity/initiative further achievement of the Retail Program Standards?" **The committee recommends that the FDA seeks the expansion of existing forums (e.g., NACCHO sharing sessions, NEHA AEC Retail Program Standards Workshop, and cooperative agreements with NACCHO and AFDO) for enrollees to share their success stories with the Retail Program Standards.** Note: This recommendation will encompass the recommendation made in iii.

Note: The Competency of Inspectors Subcommittee would like to acknowledge and thank Elvir Begic, MPH and Genevieve Weseman, MPH of the Saint Louis County Department of Public Health for extrapolating and conducting the analysis of the survey data in this report and for designing and producing the Retail Program Standards - Competency of Inspectors infographic attached to this report.

3. Progress on Issue 2014 II-005 Activities:
   a. The **Issue 2014 II-005 Subcommittee** (hereafter referred to as the Retail Program Standards Subcommittee) met via phone conferencing (October 31, 2014; December 3, 2014; January 23, 2015; April 15, 2015; August 19, 2015; and September 23, 2015) and conducted additional business by email and phone. The Subcommittee developed and distributed a survey questionnaire (*see Verification Audit Survey Tool attached to this report*) to the jurisdictions currently enrolled in the Retail Program Standards to gather information about verification audits.
   b. This part of the Program Standards Committee's final report outlines the disposition of issues worked on by the Issue 2014 II-005 Subcommittee and its recommendations to the Conference.
   c. *Charge 1: Identify areas where the Voluntary National Retail Food Regulatory Program Standards can be changed or improved to enhance enrollment and implementation;* **and** *Charge 3: Review the current verification audit requirement and: (a) Identify strengths of the current verification audit requirement; (b) Identify weaknesses of the current verification audit requirement, with emphasis on any barriers that may result from the current requirement; and (c) Determine whether there are potential changes to the requirement, or the administration of the requirement, that could maintain the credibility of the Retail Program Standards while reducing barriers to achievement that may result from the current verification audit requirement.*
      i. An excel spreadsheet identifying all enrolled jurisdictions, contact person and contact e-mail address was developed from data located in the Listing of Jurisdictions Enrolled in the Voluntary Retail Food Regulatory Program Standards on the FDA website at: http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/UCM434742.pdf. The Verification Audit Survey Tool was developed which contained both jurisdictional demographic information in addition to specific inquiries regarding the audit process, resources, and solicitation for improvements. Questions were based on the most current version of the Retail Program Standards (December 2013).

ii. 550 invitations to participate in the Verification Audit Survey were sent out, 53 were returned undeliverable, and 102 responses were received, combined and analyzed.

iii. The respondents were as follows: local (n=76); state (n=18); tribal (n=3); territory (n=1), and other (n=4).

iv. Verification Audit Survey Summary Related to Charge 1: *Identify areas where the Voluntary National Retail Food Regulatory Program Standards can be changed or improved to enhance enrollment and implementation*:

1. Regarding Retail Program Standard objectives being clearly outlined, respondents indicated that:
   a) Retail Program Standard requirements need to be simplified;
   b) Forms and procedures need to be simplified;
   c) Previous version of the FDA's verification audit guide for the Retail Program Standards was preferred due to increased thoroughness with step-by-step instructions and screenshots of audit tools; and
   d) Additional examples on how the individual Retail Program Standards can be met are desired.

v. Verification Audit Survey Summary Related to Charge 3: *Review the current verification audit requirement and*:

1. *Identify strengths of the current verification audit requirement*;
   a) 90% of respondents indicated that the audit requirements clearly outline the specific objective needed to meet a standard, and
   b) The FDA's self-assessment guide for the Retail Program Standards is helpful to prepare an enrollee for a successful verification audit.
2. *Identify weaknesses of the current verification audit requirement, with emphasis on any barriers that may result from the current requirement*;
   a) The lack of resources, both time and staffing, is a barrier to achieving the Retail Program Standards for the majority of the jurisdictions responding;
   b) Individuals do not feel comfortable conducting verification audits;
   c) Individuals feel that they do not meet the criteria to be a verification auditor;
   d) Enrolled jurisdictions do not know who they can contact to conduct a verification audit; and
   e) Additional funding is needed to assist jurisdictions in attaining the Retail Program Standards and for conducting a verification audit.
3. *Determine whether there are potential changes to the requirement, or the administration of the requirement, that could maintain the credibility of the Retail Program Standards while reducing barriers to achievement that may result from the current verification audit requirement*.
   a) Provide verification auditor training;
   b) Create a mentor program for verification auditors;
   c) Include information on the FDA website indicating if an enrolled jurisdiction is willing to conduct a verification audit of the Retail Program Standards for others,
   d) Provide funding to assist enrolled jurisdictions, and
   e) Allow for forms to be submitted electronically to auditor (*Note: Electronic submission is not specifically prohibited by the verification audit procedures.)*
4. Related specifically to "*maintaining the credibility of the Retail Program Standards*":
   a) Create a more clearly defined quality assurance step; and
   b) Establish criteria to become an "authorized" auditor.

vi. The FDA consultants requested that the Retail Program Standards Subcommittee brainstorm other models for who can conduct a verification audit. The subcommittee came up with four potential models for audits:

1. An enrolled jurisdiction conducts a verification audit of another jurisdiction;
2. FDA conducts the verification audits;
3. A third party auditor gets trained and conducts the verification audits; and,
4. No verification audit is required.

The Verification Audit Survey results indicated that agencies have limited staff time and financial resources in order to conduct audits for other jurisdictions. Additionally, several respondents indicated that they do not

feel qualified or comfortable conducting an audit of another agency. FDA resources are also limited. Potential third party auditors discussed were industry, students, and trade organizations or associations such as the National Environmental Health Association, Association of Food and Drug Officials, International Food Protection Training Institute, National Association of County and City Health Officials (NACCHO), Food Marketing Institute, and NSF International. These third party auditors would need additional training to be familiar with retail food and the Program Standards. **All of the subcommittee members felt strongly that the option to not require verification audits should not be considered.**

vii. The Retail Program Standards Subcommittee discussed with the FDA consultants the barriers related to the knowledge of a verification auditor and the need to remove those barriers by:
   1. Educating enrolled jurisdictions on the criteria for verification auditors;
   2. Providing auditor training courses to help create a pool of auditors and a support system for those conducting verification audits;
   3. Developing a mentorship program for verification auditors similar to the NACCHO Program Standards Mentorship Program; and
   4. Making jurisdictions and potential verification auditors aware of the FDA's 2011 Program Standards Self-Assessment & Audit resource disk that includes screenshots of the various worksheets and forms used to conduct a verification audit. *Note: This information can no longer be posted on the FDA's website due to the Americans with Disabilities Act accessibility requirements.*

d. *Charge 2. Work on a project to recognize levels of performance of enrollees that will demonstrate the progress of enrollees in a meaningful way and acknowledging the enrollees for taking the necessary incremental steps toward meeting the standards*. Subcommittee members felt that recognizing an enrolled jurisdiction for partial achievement of the Retail Program Standards would be beneficial and recommend continuation of this charge for the 2016 - 2018 Program Standards Committee. Work on this charge was limited to a brainstorming session resulting in the following discussion points:
   i. Ways that partial recognition is beneficial are:
      1. Shows decision makers that the jurisdiction is making strides to improve the program;
      2. Aids jurisdictions in obtaining additional resources in order to meet the Retail Program Standards;
      3. Shows that the Retail Program Standards may need to be revised if there is a Standard that is almost impossible to meet;
      4. Recognition of "the small wins" may be important to keep a jurisdiction moving forward in meeting the Retail Program Standards; and
      5. Recognition of partial achievement of a Retail Program Standard could be part of the supporting documentation for agencies striving for Public Health Accreditation through the Public Health Accreditation Board.
   ii. The committee discussed potential methods of recognition for partial achievement of a Standard and other issues related to partial achievement of a Standard. This cost/benefit analysis will depend on what the recognition is going to be. Options discussed were:
      1. Changing the FDA website to indicate/include partial achievement (cost)
      2. Verbal mention on enrollee achievements at regional conferences
      3. Letter from FDA recognizing partial achievement (cost)
   iii. Other issues to be considered related to developing an approach to recognize a partial achievement are:
      1. Will the recognition for partial achievement involve more audits? (cost)
      2. If an audit to recognize partial achievement of a standard is required, will the audit be a formal audit or will an informal audit be developed? (cost)
      3. Criteria will need to be developed for each standard so it is clear when partial achievement is attained, e.g., 25% of the elements in the standard have been met. (cost)
      4. Currently not all of the Standards are easily quantified for partial achievement. The Standards may need to be rewritten which may make them more complex. (cost)
      5. Imposes additional reporting requirements for enrolled jurisdictions. (cost)
      6. The criteria developed for determining partial achievement would need to be designed so that it can be applied consistently. (cost)

e. Recommendations from Issue 2014 II-005. Based on the work done by the Retail Program Standards Subcommittee, the Program Standards Committee has the following recommendations for consideration by Council (*See Issue PSC 3*):

i. To continue charges 1, 2 and 4 from Issue 2014 II-005 to the 2016 - 2018 Program Standards Committee as follows:

1. Identify areas where the Voluntary National Retail Food Regulatory Program Standards can be changed or improved to enhance enrollment and implementation; and
2. Work on a project to recognize levels of performance of Program Standards enrollees that will demonstrate the progress of enrollees in a meaningful way and acknowledging the enrollees for taking the necessary incremental steps toward meeting the Program Standards. As part of this project:
   a. Provide a Cost/Benefit Analysis for recognizing partial achievement of the Retail Program Standards;
   b. Identify different approaches that could be used to recognize partial achievement of the Retail Program Standards that would not require additional resources to perform or administer; and
   c. Examine whether there is an additional burden placed on enrollees or FDA (in time, money, or added complexity of the Standards) associated with development of a system to ensure that jurisdictions are uniformly recognized for partial achievement of the Standards.
4. Serve as a sounding board for FDA with respect to ideas generated during collaboration with the other entities such as NACCHO, PFP, AFDO.

ii. That a letter be sent to the FDA with the recommendations to encourage the FDA to:

a) Work on removing the barriers identified related to conducting a Retail Program Standard verification audit by: (1) providing auditor training; (2) creating a mentorship program for auditors; (3) including information on the online Listing of Enrolled Jurisdictions document indicating which enrollees are willing to serve as verification auditors for other enrollees; and (4) continuing to work to simplify the forms and procedures for the Program Standards in an effort to reduce the amount of time required to complete the required documentation.

b) Expand funding opportunities to help support and sustain the Retail Program Standards-related activities of enrollees.

c) Better publicize and promote the work that is being done by the FDA Clearinghouse Workgroup as an important resource for Retail Program Standards enrollees.

4. Additional progress on Issue 2014-005, *Charge 1: Identify areas where the Voluntary National Retail Food Regulatory Program Standards can be changed or improved to enhance enrollment and implementation.* The FDA requested work by the full Program Standards Committee on the Retail Program Standards as follows:

a. Review and provide feedback on proposed revisions to Standard 7. The committee members reviewed, deliberated, and supported the proposed revisions. The proposed revisions allow for electronic mechanisms, such as social media and web-based meetings or forums, to be used as a method to satisfy the Standard 7 requirement for two-way interaction between regulatory authorities and industry/community stakeholders. The committee will submit an issue to recommend that Council II accepts the proposed revisions to Standard 7 (*See Issue PSC 5*).

b. Review and provide feedback on the FDA's proposed response to the recommendations for Standard 4 submitted by the Certification of Food Safety Regulatory Professionals Committee in Issue 2012 II-025: Recommendations from Uniform Inspection Program Audit Pilot Project. The FDA consultants to the committee reviewed each of their proposed responses, including changes to Standard 4 and the CFP Field Training Manual. The committee members provided feedback with minor revisions to the proposed responses, including changes to Standard 4 language, and indicated no lack of support. The FDA will submit an issue to recommend that Council II accepts the proposed revisions to Standard 4.

c. Review and provide feedback on proposed revisions to Standard 9. The committee members reviewed, deliberated, and indicated no lack of support for the proposed revisions. The FDA will submit an issue to recommend that Council II accepts the proposed revisions to Standard 9.

5. Request from the Executive Board to plan and facilitate the Retail Program Standards Session to be held at the 2016 CFP biennial meeting. The purpose of the session is to provide a forum to share information about the Retail Program Standards, to gain insight from industry about the value of implementation of the Retail Program Standards by regulators, and to facilitate a discussion about success stories related to implementation of the Retail Program Standards. The Program Standards Committee has formed a planning team/workgroup consisting of industry and regulatory members to plan and facilitate the Retail Program Standards Session to be held on Tuesday, April 19, 2016.

6. Support for establishing workgroups within the Program Standards Committee to address charges previously assigned to the Certification of Food Safety Regulation Professionals Committee/Workgroup and the Interdisciplinary Foodborne Illness Training Committee.
   a. The members of the Program Standards Committee view the work of both the Certification of Food Safety Regulation Professionals Committee (CFSRP) and the Interdisciplinary Foodborne Illness Committee (IFIC) as being within the scope of the Retail Program Standards, respectively Standards 2 and 5.
   b. The Program Standards Committee encourages Council II to accept the recommendation in an issue submitted by the CFSRP to assign charges previously assigned to that committee to the 2016 - 2018 Program Standards Committee as follows:

      Issue 2014 II-002, Charge 1:

      Collaborate with the FDA Division of Human Resource Development, and the
      Partnership for Food Protection Training and Certification Workgroup (PFP TCWG) to:
      1. Continue review of all initiatives: existing, new or under development; involving the training, evaluation and/or certification of food safety inspection officers. This collaborative working relationship will ensure the sharing of information so as not to create any unnecessary redundancies in the creation of work product or assignment of tasks/responsibilities.
      2. Review the results of the partnership for food protection training and certification work group recommendations for the nationally recognized Retail Food Curriculum based on the
      Retail Food Job Task Analysis (JTA) to determine if changes are needed in the Standard 2 curriculum. Identify any gaps and recommendations for change and review the time frame for completion of Steps 1 through 4 for new hires or staff newly assigned to the regulatory retail food protection program.
      3. Review the results of the partnership of food protection training and certification work group recommendations to determine if the Conference for Food Protection Field Training Manual for Regulatory Retail Food Safety Inspection Officers and forms need to be revised.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Report – Program Standards Committee (PSC)
   a. Acknowledgement by Council II of the 2014-2016 Program Standards Committee Final report.
   b. Acknowledgement and thanks by Council II to the members of the committee. Acknowledgement of the work done by the co-leads of the two subcommittees for their diligence in facilitating work to address the charges.
2. PSC 2 – Recommendations from Issue 2014 II-003
   a. The Program Standards Committee is submitting recommendations with requests to the FDA regarding the Retail Program Standards.
3. PSC 3 – Recommendations from Issue 2014 II-005
   a. The Program Standards Committee is submitting recommendations with requests to the FDA regarding the Retail Program Standards and resources for the verification audit process.
4. PSC 4 – Posting of Retail Program Standards Infographic on CFP Website

   a. The Program Standards committee requests the posting of the infographic on the CFP website as a resource to exhibit the value to industry of regulators achieving Standards 2, 4 and 7 of the Retail Program Standards.
5. PSC 5 – Amend Retail Program Standard 7
   a. The committee recommends amendment of Standard 7 to allow electronic mechanisms, such as social media and web-based meetings for forums, to be used as a method to satisfy the requirement for two-way interaction between regulatory authorities and industry/community stakeholders.

Attachments:

Content Documents:
1. 2014 – 2016 Program Standards Committee Final Report
2. 2014 – 2016 Program Standards Committee Membership Roster
3. Retail Program Standards - Competency of Inspectors Infographic

Support Documents:
4. Verification Audit Survey Tool
5. Industry Support for Standards 2, 4 and 7 Survey Tool
6. Verification Audit Survey Results
7. Industry Support for Standards 2, 4 and 7 Survey Results (FMI Summary)
8. Industry Support for Standards 2, 4 and 7 Survey Results (NRA Summary)

COMMITTEE MEMBER ROSTER (attached):

Committee Name: 2014 - 2016 Program Standards Committee

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Lawrence	David	Chair	Regulatory - Local	Fairfax County Health Department	Fairfax	VA	(703) 246-8435	David.Lawrence@fairfaxcounty.gov
Friel	Caroline	Co Vice-Chair	Food Service Industry	Wawa, Inc.	Wawa	PA	(610) 322-6708	Caroline.Friel@wawa.com
Watts	Debbie	Co Vice-Chair	Regulatory - Local	Tulsa Health Department	Tulsa	OK	(918) 595-4305	dwatts@tulsa-health.org
Huang	Yao-wen	Member - Voting	Academia	University of Georgia	Athens	GA	(706) 542-1092	huang188@gmail.com
Grooters	Susan	Member - Voting	Consumer	Keep Antibiotics Working Coalition	Washington	DC	(802) 223-6303	susangrooters@gmail.com
Akin	Richard	Member - Voting	Regulatory - State	DBPR - Division of Hotels & Restaurants	Talahassee	FL	(850) 294-1404	Rick.Akin@myfloridalicense.com
Cyr	Angela	Member - Voting	Regulatory - State	Minnesota Department of Health	St. Paul	MN	(651) 201-4843	Angie.Cyr@state.mn.us
Helms	Dawn	Member - Voting	Regulatory - State	Wyoming Department of Agriculture	Cheyenne	WY	(307) 856-3326	Dawn.Helms@wyo.gov
Mers	Donald Todd	Member - Voting	Regulatory - State	Ohio Department of Agriculture	Reynoldsburg	OH	(614) 728-6250	tmers@agri.ohio.gov
Daniels	Amber	Member - Voting	Regulatory - Local	Mecklenburg County Health Department	Charlotte	NC	(704) 621-2291	Amber.Daniels@mecklenburgcountync.gov
Goode	Steven	Member - Voting	Regulatory - Local	Maricopa County Environmental Services Department	Phoenix	AZ	(602) 372-5599	Sgoode@mail.maricopa.gov
McNinch	David	Member - Voting	Regulatory - Local	Washoe County Health District	Reno	NV	(775) 328-2645	dmcninch@washoecounty.us
Theard	Joyce	Member - Voting	Regulatory - Local	St. Louis County Department of Health	Clayton	MO	(314) 615-6415	jtheard@stlouisco.com
Douglas	Amanda	Member - Voting	Food Service Industry	Wawa, Inc.	Wawa	PA	(267) 575-7881	Amanda.Douglas@wawa.com
Edelen	Jeff	Member - Voting	Retail Food Industry	The Kroger Co	Cincinnati	OH	(513) 762-1441	Jeff.Edelen@kroger.com
Gregg	Timothy	Member - Voting	Food Service Industry	Sodexo	Hugo	OK	(972) 465-0437	Timothy.Gregg@sodexo.com
Keener	Kathryn	Member - Voting	Food Industry Support	Compass Group	Charlotte	NC	(704) 328-5379	Kathryn.Keener@compass-usa.com
McDaniel	Jim	Member - Voting	Food Service Industry	CKE Restaurants Holding, Inc.	St. Louis	MO	(931) 337-4292	jmcdaniel@ckr.com

O'Donnell	James	Member - Voting	Food Industry Support	Hussmann Corporation	Bridgeton	MO	(314) 296-4778	James.Odonnell@hussmann.com
Whatley	Mike	Member - Voting	Food Industry Support	National Restaurant Association	Washington	DC	(202) 331-5917	mwhatley@restaurant.org
Arbizu	Thomas	Member - Elective	Regulatory - State	Texas Department of State Health Services	Austin	TX	(512) 834-6770	Tom.Arbizu@dshs.state.tx.us
MacLeod	Michael	**Member - Elective**	Retail Food Industry	Big Y Foods, Inc.	Springfield	MA	(413) 504-4453	mmacleod@bigy.com
Radke	Vince	Consultant	Regulatory - Federal	CDC	Atlanta	GA	770-488-4136	ver2@cdc.gov;
Hughes	Stephen	Consultant	Regulatory - Federal	FDA	College Park	MD	(240) 402-2833	Stephen.Hughes@fda.hhs.gov
Kennedy	Katey	Consultant	Regulatory - Federal	FDA	Beaverton	OR	(503) 671-9711 ext 16	Katey.Kennedy@fda.hhs.gov
Adan	Natalie	Member - "At Large"	Regulatory - State	Georgia Department of Agriculture	Atlanta	GA	(404) 754-1794	Natalie.Adan@agr.georgia.gov
Crabtree	Debbie	Member - "At Large"	Regulatory - Local	Fairfax County Health Department	Fairfax	VA	(703) 246-8431	Deborah.Crabtree@fairfaxcounty.gov
DeFrancesco	Joetta	Member - "At Large"	Regulatory - State	Florida Department of Agriculture and Consumer Services	Bonita Springs	FL	(850) 245-5520	Joetta.Defrancesco@freshfromflorida.com
Erwin	Robert	Member - "At Large"	Regulatory - Local	Fairfax County Health Department	Fairfax	VA	(703) 246-8430	Robert.Erwin@fairfaxcounty.gov
Finkenbinder	Dean	Member - "At Large"	Regulatory - State	Wyoming Department of Agriculture	Cheyenne	WY	(307) 777-6587	Dean.Finkenbinder@wyo.gov
Guzzle	Patrick	Member - "At Large"	Regulatory - State	Idaho Department of Health & Welfare	Boise	ID	(208) 334-5936	guzzlep@dhw.idaho.gov
Mickiewicz	Courtney	Member - "At Large"	Regulatory - State	Virginia Department of Agriculture & Consumer Services	Virginia Beach	VA	(757) 368-3905	Courtney.Mickiewicz@vdacs.virginia.gov
Read	David	Member - "At Large"	Emeritus	IFPTI	St. Paul	MN	(651) 485-8905	dread5668@gmail.com

RETAIL PROGRAM STANDARDS: A HOME RUN

	1	2	3	4	5	6	7	8	9	R
Industry	0	1	0	2	3					6
Regulatory	2	1	0	3	0					6

Standard 2...Standard 4...Standard 7...

40% of respondents were aware of the Retail Program Standards through local regulatory outreach/FDA website

92% of respondents found Program Standard 7, industry participation, to be very valuable

A committee was charged to identify the benefits to industry for regulatory authorities to achieve Standard 2, 4, and 7 of the Voluntary National Retail Food Retail Program Standards. A survey was designed to capture the benefits to industry as outlined in the Committee's charge and sent to participants in the National Restaurant Association (NRA) and Food Marketing Institute (FMI)

PROMOTING FOOD SAFETY THROUGH COLLABORATION

60% of respondents operate in 1 to 5 States.

60%

60% of respondents were aware of the Retail Program Standards prior to the survey

Training supports a consistent, credible approach to inspections

Training in Program Standard 2 allows more time for industry to focus on food safety rather than disputing improper citations

Most of the respondents were from larger organizations with many employees & operate in several states

True risks are measured and identified

Inspectors are better trained & the inspections are more consistent

Uniformity allows better allocation of resources

Added assurance that the inspector is adequately trained & reputable

Increased accuracy & confidence in results

Level Playing Field

Creates a level playing field for all operators and regulators which should lead to consistency

Apples to Apples comparison

Industry identified that Program Standard 2, properly trained staff, supports a consistent approach to inspections

90% of respondents found Program Standard 4, quality assurance, to be somewhat or very valuable

We all benefit from teamwork.

Prepared by the Conference for Food Protection Program Standards Committee 2014-2016

The Conference for Food Protection Program Standards Committee is asking for your input on the Voluntary National Retail Food Regulatory Program Standards and related verification audits. Your input is greatly appreciated and it will assist us in our work on the CFP Issue 2014-II-005.

Background Information:

The Program Standards Committee has the following charges related to Verification Audits:

1. Identify areas where the Voluntary National Retail Food Regulatory Program Standards can be changed or improved to enhance enrollment and implementation.
2. Review the current verification audit requirement and:
   - Identify strengths of the current verification audit requirement;
   - Identify weaknesses with the current verification audit requirement, with emphasis on any barriers that may result from the current requirement; and
   - Determine whether there are potential changes to the requirement, or the administration of the requirement, that could maintain the credibility of the Retail Program Standards while reducing barriers to achievement that may result from the current verification audit requirement.

Jurisdiction Type: [Local] [State] [Tribal] [Territory] [other_____]
Inspection Staff Size: _____
Number of Inspected Food Service Facilities in Inventory: _____
Population of Jursidiction:_____

What year did you enroll in the Retail Program Standards? [(year)_____] [don't know]

Please mark each item that applies to your jurisdiction:

1) Have you had a verification audit? [yes] [no]
   If yes, what standards have you had audited?
   [1] [2] [3] [4] [5] [6] [7] [8] [9]

2) When was/were the audits conducted?

Standard 1	[(year)_____]	[don't know]	[have never been audited]
Standard 2	[(year)_____]	[don't know]	[have never been audited]
Standard 3	[(year)_____]	[don't know]	[have never been audited]
Standard 4	[(year)_____]	[don't know]	[have never been audited]
Standard 5	[(year)_____]	[don't know]	[have never been audited]
Standard 6	[(year)_____]	[don't know]	[have never been audited]
Standard 7	[(year)_____]	[don't know]	[have never been audited]
Standard 8	[(year)_____]	[don't know]	[have never been audited]
Standard 9	[(year)_____]	[don't know]	[have never been audited]

3) What was the outcome of the Standards on which you have had a verification audit?

Standard 1 [Standard Met Criteria] [Standard Did Not Meet Criteria] [Have not been audited]
If Standard not met, why? _____
Standard 2 [Standard Met Criteria] [Standard Did Not Meet Criteria] [Have not been audited]
If Standard not met, why? _____
Standard 3 [Standard Met Criteria] [Standard Did Not Meet Criteria] [Have not been audited]
If Standard not met, why? _____
Standard 4 [Standard Met Criteria] [Standard Did Not Meet Criteria] [Have not been audited]
If Standard not met, why? _____
Standard 5 [Standard Met Criteria] [Standard Did Not Meet Criteria] [Have not been audited]
If Standard not met, why? _____
Standard 6 [Standard Met Criteria] [Standard Did Not Meet Criteria] [Have not been audited]
If Standard not met, why? _____
Standard 7 [Standard Met Criteria] [Standard Did Not Meet Criteria] [Have not been audited]
If Standard not met, why? _____
Standard 8 [Standard Met Criteria] [Standard Did Not Meet Criteria] [Have not been audited]
If Standard not met, why? _____
Standard 9 [Standard Met Criteria] [Standard Did Not Meet Criteria] [Have not been audited]
If Standard not met, why? _____

4) Have you conducted a verification audit for another agency? [Yes] [No]

5) On what standards have you conducted an audit for another agency?
[1] [2] [3] [4] [5] [6] [7] [8] [9] [not applicable]

6) What was/were the outcome(s) to the audits conducted for another agency?
[Agency met Standard Criteria]
[Agency did not meet Standard Criteria]
[Audit cancelled due to incomplete information to conduct]
[Other, please specify _____]
[Not applicable]

7) Why have you not conducted an audit for another agency?
[Have not been asked]
[Did not meet criteria to become an auditor]
[Do not feel comfortable conducting an audit]
[Other, please specify _____]

8) Would it be beneficial to have an available list of individuals that can conduct verification audits?
[yes] [no] [Don't know]

9) Would you be willing to be included on that list?
[yes] [no] [don't know]
If you don't know, please explain_____

The next several questions are about your agency and having an audit conducted to determine if a Standard has been met.

10) Do the audit requirements clearly outline the specific objectives needed to meet a Standard? [Yes] [No]
If no, please explain_____

11) What barriers have you had that have made you unable to conduct a verification audit on a Standard? *(Mark all that apply.)*
[Could not find an auditor to conduct verification audit]
[Requirements to conduct/complete a self-assessment leading to a verification audit not clear]
[Inadequate staff to conduct self-assessment that would lead to a verification audit]
[Inadequate time to conduct self-assessment and/or verification audit]
[No support of management to work on Program Standards]
[No barriers]
[Other – please list_____]

12) What resources were/are lacking to be able to complete a verification audit?
[Requirements identified to meet a specific Program Standard not clear or easy to follow]
[Inadequate knowledge to develop written internal policies to meet a Standard]
[Administrative Procedure documents (now a separate document, previously included under Standard 9) not easy to understand/not clear]
[No resources are currently lacking]
[Other – please identify _____]

13) What resources did you use to ensure a successful verification audit?
[Administrative procedure document (new in version 2013, previously in Standard 9]
[Self-assessment guide provided in the Program Standards]
[FDA Regional Retail Food Specialist]
[Contacts from other jurisdictions that are enrolled in the Standards]
[Participation in the NACCHO Mentorship Program]
[FDA Retail Program Standards Grant made available through a Cooperative Agreement with AFDO]
[No resources used]
[Other – please identify _____]

14) Would it be beneficial to your jurisdiction to be able to submit the Self-Assessment form, Verification Audit form, and any applicable documentation electronically to your auditor for review? [Yes] [No]
If no, please explain_____

15) What could increase the credibility of the audit process?
[A more clearly defined quality assurance step]
[Establish criteria to become an authorized auditor]
[Other – please list_____]

General information questions

16) Are you aware that a Clearinghouse Workgroup exists that can help clarify questions related to the Program Standards? [Yes] [No]

17) Do you have anything else you would like to share based on your experience?

18) If you would be willing to be contacted by the committee if they have any questions, please list your information below:
[Name]
[Agency]
[Role/Title]
[Address}
[City/Town]
[State]
[Zip]
[Email address]
[Phone number]

Thank you for your time in completing this survey. The information you provided will be of great assistance to the CFP Program Standards committee in accomplishing their charges as identified by the 2014 Conference.

Voluntary National Retail Food Regulatory Program Standards - 15 Minute Survey

This survey is completely anonymous; your candid feedback is appreciated.

This survey is designed to help the Conference for Food Protection Program Standards Committee identify benefits to industry for regulatory authorities to achieve Standard 2, Standard 4, and Standard 7 of the Voluntary National Retail Food Regulatory Program Standards. The Committee is due to report back at the 2016 Biennial Meeting on how the Conference can collaborate with industry to facilitate enrollment and achievement of the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards).

Retail Program Standards Overview

The Retail Program Standards are comprised of nine separate Standards, each focusing on a different aspect of a retail food regulatory program. Broadly speaking, the Standards:

- Serve as a guide to retail food regulatory program managers in the design and management of retail food regulatory programs;
- Are intended to help retail food regulatory programs enhance the services they provide to the public;
- Provide a foundation and system upon which all regulatory programs can build through a continuous improvement process;
- Encourage agencies to improve and build upon existing programs;
- Provide a framework designed to accommodate both traditional and emerging approaches to food safety; and reinforce proper sanitation (good retail practices)and operational and environmental prerequisite programs while encouraging regulatory agencies and industry to focus on the factors that cause and contribute to foodborne illness, with the ultimate goal of reducing the occurrence of those factors.

Standard 2 (Trained Regulatory Staff)
The regulatory retail food program inspection staff shall have the knowledge, skills, and ability to adequately perform their required duties.

Five step training process for retail food program inspection staff:
- Completion of initial course curriculum before conducting joint inspections.
- Completion of 25 joint inspections.
- Completion of 25 independent inspections, and completion of the remainder of the course curriculum.
- Completion of Standardization process (re-standardization occurs every three years).
- Completion of continuing education.

Standard 4 (Quality Assurance Program)

Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency, and uniformity among the regulatory staff.

Standard 7 (Industry/Community Outreach Activities)
This standard applies to industry and community outreach activities utilized by a regulatory program to solicit a broad spectrum input into a comprehensive regulatory food program, communicate sound public health food safety principles, and foster and recognize community initiatives focused on the reduction of foodborne disease risk factors.

1. Which of the following best describes your operation?

- [ ] Food Service Operation/Restaurant
- [ ] Retail Food Establishment
- [ ] Convenience Store
- [ ] Other Type of Operation (please specify)

2. How long has your company been in business?

- ○ 1 to 5 years
- ○ 6 to 25 years
- ○ 26 to 50 years
- ○ More than 50 years

3. How many employees work at your company?

- ○ 1 to 50 employees
- ○ 51 to 500 employees
- ○ 501 to 5,000 employees
- ○ More than 5,000 employees

4. How many States does your company operate in?

- ○ 1 to 5 states
- ○ 6 to 15 states
- ○ 16 to 30 states
- ○ More than 30 states

5. What is the approximate total revenue for your company?

- ○ $1K to $500K
- ○ $501K to $10 Million
- ○ $11 Million to $500 Million
- ○ More than $500 Million

6. Prior to receiving this survey, were you aware of the Retail Program Standards?

- ○ Yes
- ○ No

Voluntary National Retail Food Regulatory Program Standards - 15 Minute Survey (Small/New Businesses)

7. How did you become aware of the Retail Program Standards? Please select all options that apply.

- ☐ Industry peers
- ☐ Local Regulatory outreach/communication
- ☐ FDA website
- ☐ Peers/Coworkers
- ☐ Other (Please specify below in 'Other' box)

Other (please specify)

8. Would it be valuable to your company if all regulatory authority inspection staff responsible for conducting inspections at retail food establishments were trained to the Retail Program Standard 2 as outlined below?

Standard 2 (Trained Regulatory Staff)
The regulatory retail food program inspection staff shall have the knowledge, skills, and ability to adequately perform their required duties.

Five step training process for retail food program inspection staff:
- Completion of initial course curriculum before conducting joint inspections.
- Completion of 25 joint inspections.
- Completion of 25 independent inspections, and completion of the remainder of the course curriculum.
- Completion of Standardization process (re-standardization occurs every three years).
- Completion of continuing education.

- Very valuable
- Somewhat valuable
- Not very valuable
- Not at all valuable

Comments (Optional)

9. Would it be valuable to your company if all regulatory authorities implemented an ongoing Quality Assurance program as outlined in the Retail Program Standard 4, as outlined below?

Standard 4 (Quality Assurance Program)
Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency, and uniformity among the regulatory staff.

- Very valuable
- Somewhat valuable
- Not very valuable

Not at all valuable

Comments (Optional)

10. Would Industry find it beneficial if regulatory authorities invited industry to participate in food safety forums or to participate in food safety advisory boards to enhance food safety strategies or otherwise collaborate to improve food safety in the jurisdiction?

Very valuable

Somewhat valuable

Not very valuable

Not at all valuable

Comments (Optional)

11. What are the benefits to Industry when the regulatory authority invests in the Retail Program Standards by having trained regulatory staff (Standard 2), an ongoing Quality Assurance program (Standard 4) and Industry/Community outreach activities (Standard 7)? Please select all options that apply and add any additional benefits in the 'Other' box.

Confidence in retail food establishment assessment results by general public

Confidence in retail food establishment assessment results by Industry

Increased engagement with regulatory authority by Industry

Calibration of regulatory staff across the State/Jurisdiction

Other Benefits (please specify)

12. Please rate your identified benefits to Industry for regulatory authorites to invest in the Retail Program Standards by having trained regulatory staff, an ongoing Quality Assurance program and Industry/Community outreach activities?

	No Benefit	**Some Benefit**	**Greatest Benefit**	**N/A**
Confidence in retail food establishment	Confidence in	Confidence in	Confidence in	Confidence in

	No Benefit	Some Benefit	Greatest Benefit	N/A
assessment results by general public	retail food establishment assessment results by general public No Benefit	retail food establishment assessment results by general public Some Benefit	retail food establishment assessment results by general public Greatest Benefit	retail food establishment assessment results by general public N/A
Confidence in retail food establishment assessment results by Industry	Confidence in retail food establishment assessment results by Industry No Benefit	Confidence in retail food establishment assessment results by Industry Some Benefit	Confidence in retail food establishment assessment results by Industry Greatest Benefit	Confidence in retail food establishment assessment results by Industry N/A
Increased engagement with regulatory authority by Industry	Increased engagement with regulatory authority by Industry No Benefit	Increased engagement with regulatory authority by Industry Some Benefit	Increased engagement with regulatory authority by Industry Greatest Benefit	Increased engagement with regulatory authority by Industry N/A
Calibration of regulatory staff across the State/Jurisdiction	Calibration of regulatory staff across the State/Jurisdiction No Benefit	Calibration of regulatory staff across the State/Jurisdiction Some Benefit	Calibration of regulatory staff across the State/Jurisdiction Greatest Benefit	Calibration of regulatory staff across the State/Jurisdiction N/A

13. If you have multiple locations in different regulatory districts, can you identify benefits of working with a regulatory authority that is enrolled in the Retail Program Standards versus one that has is not enrolled in the Retail Program Standards?

- Not Applicable
- Yes
- No

Comments (please specify)

Conference for Food Protection Voluntary Retail Food Program Standards Subcommittee 5 – Verification Audit Summary

550 Total Invitations
18.5% responded (102)
1.1% opted out (6) – no reason given
9.6% bounced (53)
70.7% not responded (389)

550 total-53 bounced=**497** good email addresses

102 Total Responses
83.3% completed (85)
16.7% partial (17)

102 total responses/**497** good email addresses=**20.52%** response

---

Q1. Jurisdiction Type – 102 answered, 0 skipped

- Local (City &/or County) 74.51% (76)
- State 17.65% (18)
- Tribal 2.94% (3)
- Territory 0.98% (1)
- Other 3.92% (4)
    - University 1
    - Federal 2
    - Idaho 1

Q2. Number of Inspected Food Service Facilities in Inventory – 102 answered, 0 skipped

- ≤250 30
- 251-500 18
- 501-750 5
- 751-1000 7

- 1001-5000 27
- 5001-7500 4
- 7501-10000 3
- ≥10001 8

Q3. Inspection Staff Size – 102 answered, 0 skipped

≤5	56	(55%)
6-10	18	(18%)
11-25	17	(16.7%)
26-50	3	(2.9%)
51-75	4	(3.9%)
76-100	2	(1.9%)
≥101	2	(1.9%)

Q4. Population of Jurisdiction – 102 answered, 0 skipped

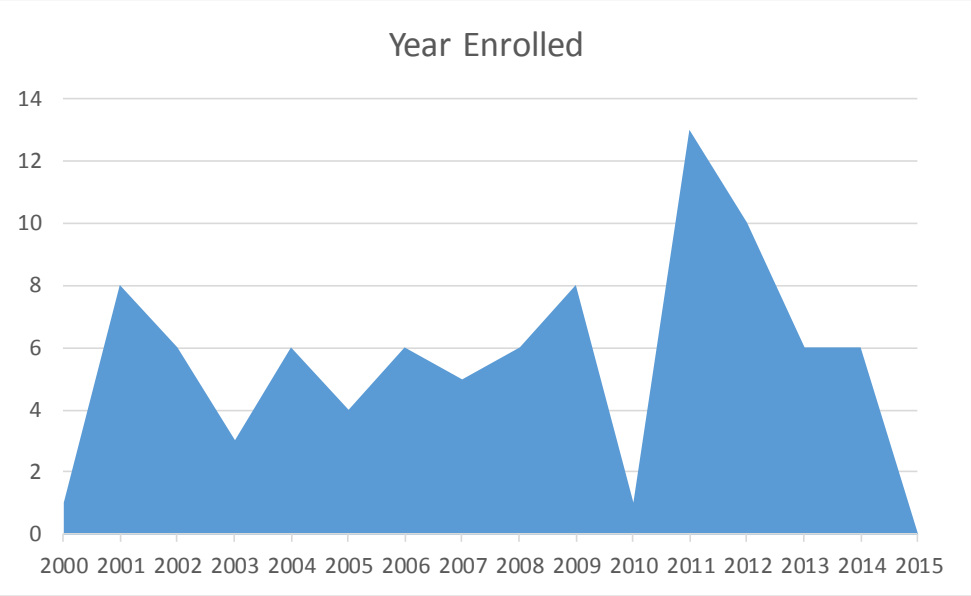
0 to 50,000	27	(26%)
50,001 to 100,000	13	(13%)
100,001 to 250,000	16	(16%)
250,001 to 500,000	11	(11%)
500,001 to 750,000	4	(4%)
750,001 to 999,999	3	(3%)
1M to 3M	13	(13%)
4M to 10M	7	(7%)
>10M	1	(1%)
Other	7	(67%)

- Retail food establishment such as restaurants, takeout, mobile units, catering, schools, correctional facilities, vending and senior citizen meals
- Resort casino
- Entire state of Nevada
- NA
- 27 tribes – don't know the actual population sizes
- Unknown
- Entire state – except local health jurisdictions

Q5. What year did you enroll in the Retail Program Standards? – 102 answered, 0 skipped

- Don't Know – 14 (13.73%)

- 2000 – 1
- 2001 – 8
- 2002 – 6
- 2003 – 3
- 2004 – 6
- 2005 – 4
- 2006 – 6
- 2007 – 5
- 2008 – 6
- 2009 – 8
- 2010 – 1
- 2011 – 13
- 2012 – 10
- 2013 – 6
- 2014 – 6
- 2015 – 0



Dates of Interest –

1999 – Pilot Test of Program Standards in each of the 5 FDA regions
2000 – Pilot Test results report to the Conference for Food Protection
2002 – 1st Version of the Program Standards, approved at the CF
2012 – 1st year of NACCHO Mentorship Program

Q6. Have you had a verification audit? – 102 answered, 0 skipped

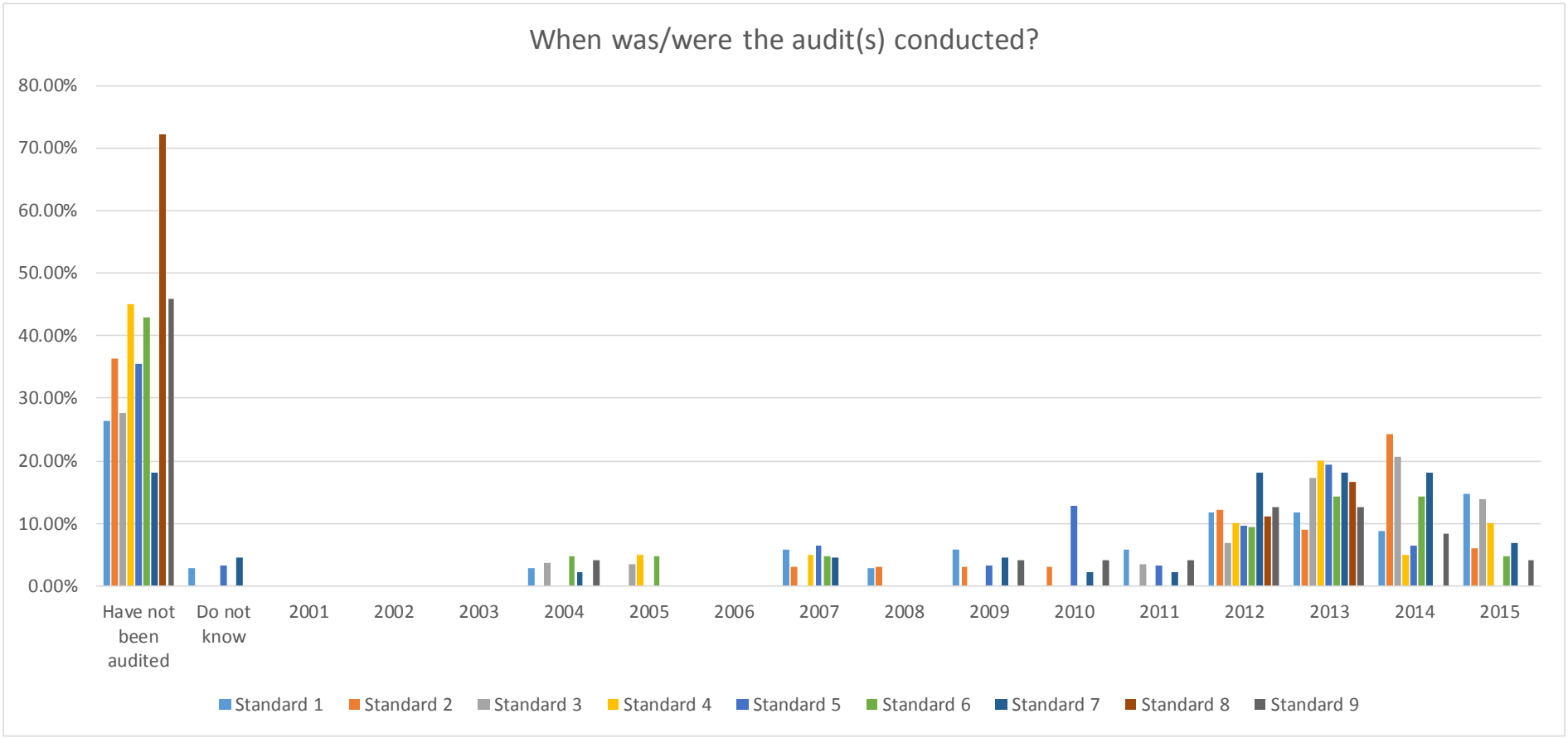
Yes	54.90%	56
No	45.10%	46

Q7. What Standards have you had audited? – 55 answered, 47 skipped

Standard 1	45.45%	25
Standard 2	36.36%	20
Standard 3	38.18%	21
Standard 4	20.00%	11
Standard 5	38.18%	21
Standard 6	21.82%	12
Standard 7	63.64%	35
Standard 8	9.09%	5
Standard 9	23.64%	13

Q8. When was/were the audit(s) conducted? – 59 answered, 43 skipped

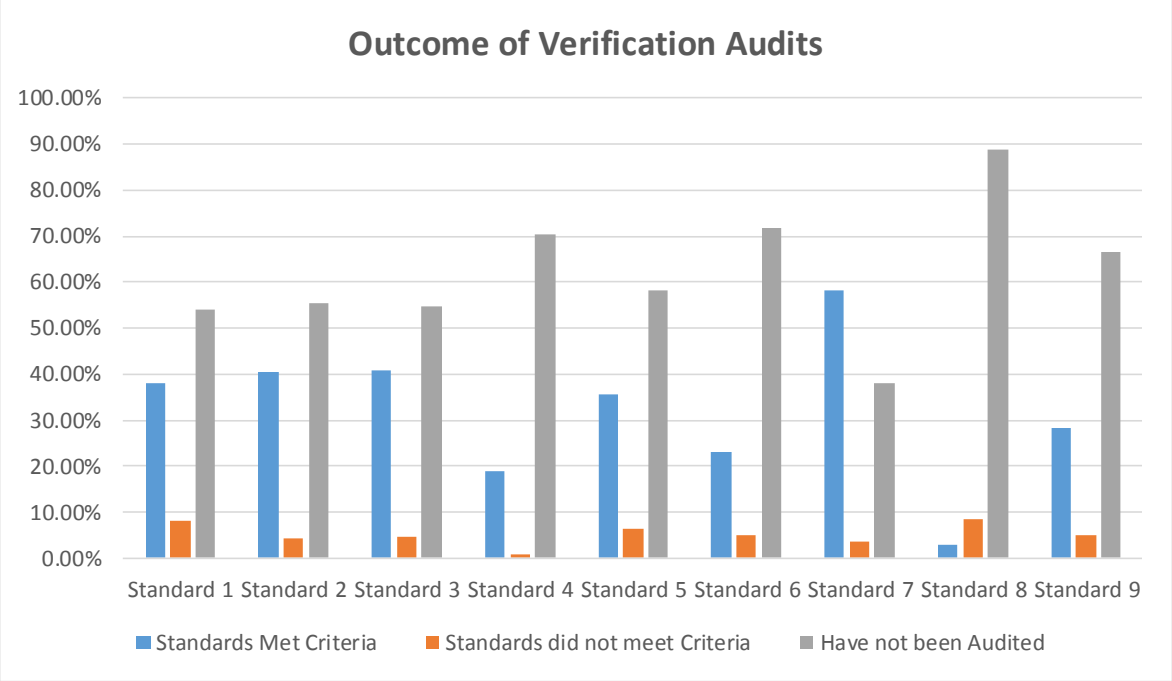
Year	Standard 1	Standard 2	Standard 3	Standard 4	Standard 5	Standard 6	Standard 7	Standard 8	Standard 9
Have not been audited	26.47%	36.36%	27.59%	45.00%	35.48%	42.86%	18.18%	72.22%	45.83%
Do not know	2.94%	0.00%	0.00%	0.00%	3.23%	0.00%	4.55%	0.00%	0.00%
2001	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
2002	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
2003	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
2004	2.94%	0.00%	3.60%	0.00%	0.00%	4.76%	2.27%	0.00%	4.17%
2005	0.00%	0.00%	3.45%	5.00%	0.00%	4.76%	0.00%	0.00%	0.00%
2006	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
2007	5.88%	3.03%	0.00%	5.00%	6.45%	4.76%	4.55%	0.00%	0.00%
2008	2.94%	3.03%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
2009	5.88%	3.03%	0.00%	0.00%	3.23%	0.00%	4.55%	0.00%	4.17%
2010	0.00%	3.03%	0.00%	0.00%	12.90%	0.00%	2.27%	0.00%	4.17%
2011	5.88%	0.00%	3.45%	0.00%	3.23%	0.00%	2.27%	0.00%	4.17%
2012	11.76%	12.12%	6.90%	10.00%	9.68%	9.52%	18.18%	11.11%	12.50%
2013	11.76%	9.09%	17.24%	20.00%	19.35%	14.29%	18.18%	16.67%	12.50%
2014	8.82%	24.24%	20.69%	5.00%	6.45%	14.29%	18.18%	0.00%	8.33%
2015	14.71%	6.06%	13.79%	10.00%	0.00%	4.76%	6.82%	0.00%	4.17%


When was/were the audit(s) conducted?
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
Have not been audited
Do not know
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
Standard 1
Standard 2
Standard 3
Standard 4
Standard 5
Standard 6
Standard 7
Standard 8
Standard 9

Q9. What was the outcome of the Standards on which you have had a verification audit?

67 answered, 35 skipped

	Standards Met Criteria	Standards did not meet Criteria	Have not been Audited	Total
Standard 1	38.00% (19)	8.00% (4)	54.00% (27)	20
Standard 2	40.43% (19)	4.26% (2)	55.32% (26)	47
Standard 3	40.91% (18)	4.55% (2)	54.55% (24)	44
Standard 4	18.92% (7)	10.81% (4)	70.27% (26)	37
Standard 5	35.42% (17)	6.25% (3)	58.33% (28)	48
Standard 6	23.08% (9)	5.13% (2)	71.79% (28)	39
Standard 7	58.18% (32)	3.64% (2)	38.18% (21)	55
Standard 8	2.78% (1)	8.33% (3)	88.89% (32)	36
Standard 9	28.21% (11)	5.13% (2)	66.67% (26)	39



Q10. Have you conducted a verification audit for another agency?
92 answered, 10 skipped

Yes	29	31.52%
No	63	68.48%

Q11. What Standards have you conducted an audit for another agency?
28 answered, 74 skipped

	# audit for standard	percentage
Standard 1	7	25.00%
Standard 2	11	39.29%
Standard 3	7	25.00%
Standard 4	4	14.29%
Standard 5	8	28.57%
Standard 6	4	1429%
Standard 7	17	60.71%
Standard 8	1	3.57%
Standard 8	3	10.71%

Q12. What was/were the outcome(s) to the audits conducted for another agency?
29 answered, 73 skipped

Agency met Standard Criteria	86.21%	25
Agency did not met Standard Criteria	13.79%	4
Audit cancelled due to incomplete information to conduct	6.90%	2

Q13. Why have you not conducted an audit for another agency?
74 answered, 28 skipped

Have not been asked	89.19%	66
Did not meet criteria to become an auditor	12.16%	9
Do not feel comfortable conducting an audit	24.32%	18

Q14. Would it be beneficial to have an available list of individuals that can conduct verification audits? – 91 answered, 11 skipped

Yes	79	85.71%
No	2	2.20%
Don't know	11	12.09%

Q15. Would you be willing to be included on that list? – 92 answered, 10 skipped

Yes	39	42.39%
No	29	31.52%
Don't know	24	26.09%

If respondent answered "no" or "don't know", they were asked to explain:

- Would need county approval
- Too busy with work requirements
- Time constraints is the issue (these things can be very time consuming)
- I am not sure if I would be qualified to fill this role
- Available time
- I will be retiring by the end of June 2015
- Within New Mexico, we know who in each agency can do a verification audit. I think this informal information network works well and ensures that we don't become overloaded. I don't know if the list you are proposing would go out to other states. This might get overwhelming.
- Our staff are not qualified yet
- No time
- Still working on our agency to be in conformance
- No time, very understaffed
- Don't understand it all that well
- My current job role would not allow me to do this
- Not sure I'm qualified to conduct audits
- Not sure we will continue effort due to costs
- Don't have time
- Currently have insufficient staffing to add another duty
- No time
- Time and resource issues
- Time constraints as I am trying to complete standardization for grant funding
- Agency representative instead of named individual
- Not certain of qualifications
- Do not have time
- Would be open to being an auditor, but additional information about how to conduct an audit would be helpful since our agency has not completed an audit.
- Extremely busy and understaffed, may not be approved
- Plan to retire soon

- Since we have not had a verification audit, I do not feel qualified to audit other LHDs
- Training needed, otherwise yes
- Do not qualify to become an auditor
- We have not had a lot of progress made in the program and staffing is limited
- No time to audit other regulatory agencies
- Too busy
- No time
- Staffing limitations

Q16. Do the audit requirements clearly outline the specific objective needed to meet a Standard? – 90 answered, 12 skipped

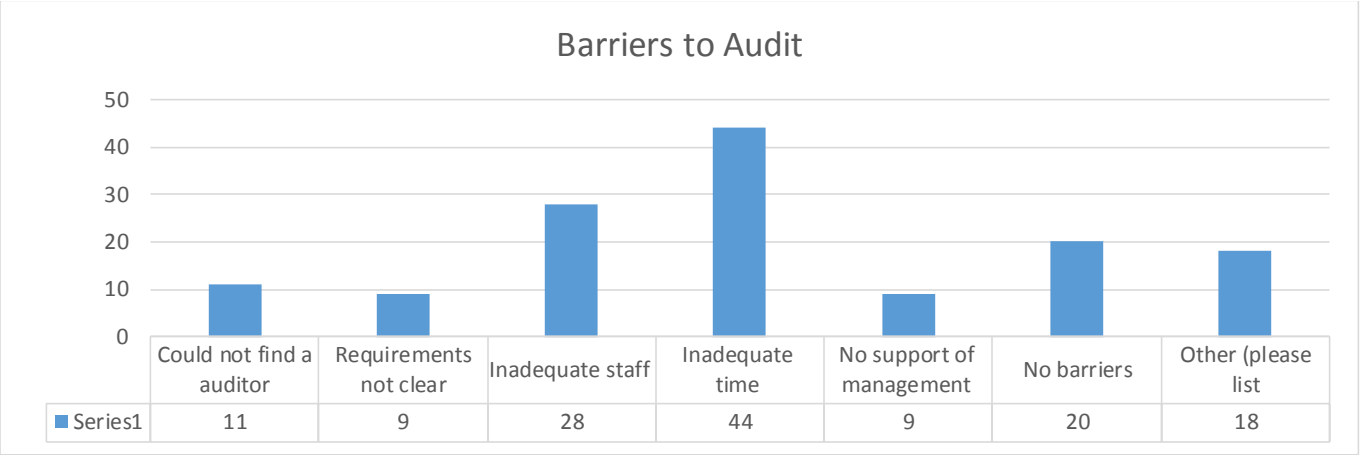
Yes	81	90.00%
No	9	10.00%

If respondent answered "no" they were asked to explain:

- Need to simplify
- No idea
- Forms and procedures need to be simplified
- The older version of the audit book was more thorough and had step by step instructions. The new versions of the book just gives an overall requirement. I prefer the older version
- Cumbersome
- There needs to be more examples of possible methods for meeting a standard. A FDA training for verification audits might be a god course to have better consistencies among those who do audits.
- Not clear
- No
- More is read into the requirements than is actually stated

Q17. What barriers have you had that have made you unable to conduct a verification audit on a Standard? – 84 answered, 18 skipped

Could not find an auditor to conduct verification audit	11	13.10%
Requirements to conduct/complete a self-assessment leading to a verification audit not clear	9	10.71%
Inadequate staff to conduct self-assessment that would lead to a verification audit	28	33.33%
Inadequate time to conduct self-assessment and/or verification audit	44	52.38%
No support of management to work on Program Standards	9	10.71%
No barriers	20	23.81%
Other (please list)	18	21.30%



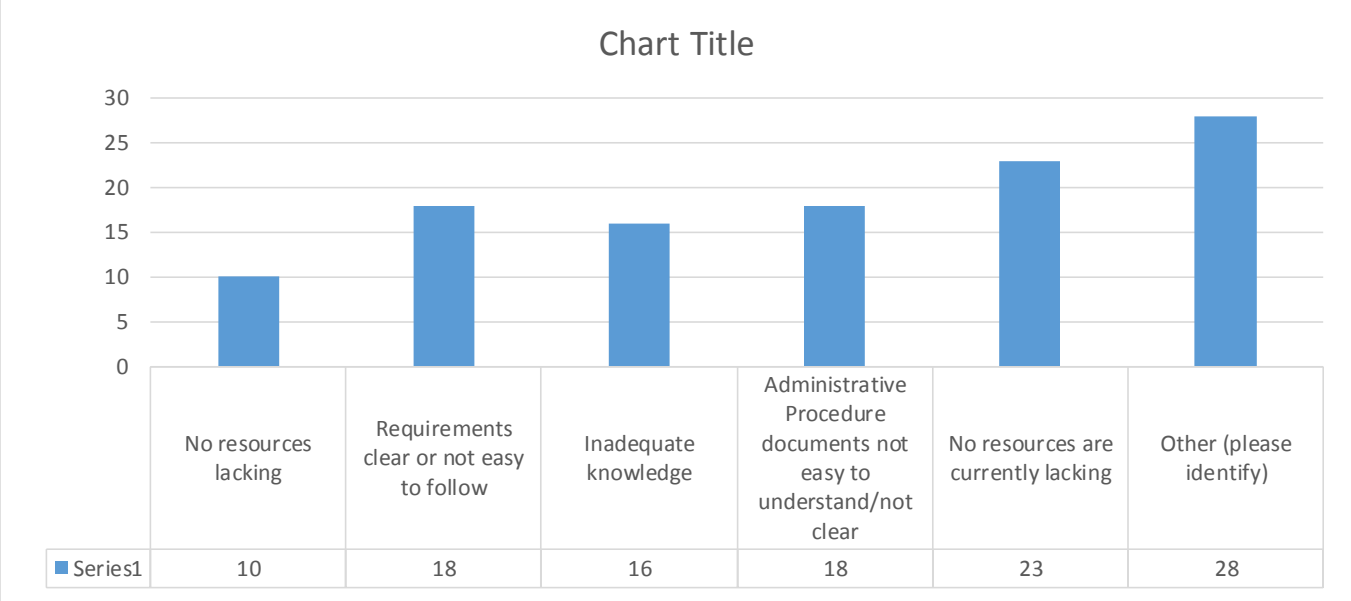
List of other responses provided:

- It was known that we did not meet the standards, so did not spend the time of the auditor
- IL, Dept. of Public Health – lack of support
- Self-assessment yields standard not met, so audit not needed
- Our self-assessment revealed that we don't meet the standards
- Availability of an agreed upon time that works for both agencies
- Lack of funding to support implementation of the retail standards
- Self-assessment done. Finding time for verification audit
- Unable to meet Standards 1, 3, 4, 6 due to inspection software
- First time jitters
- Not enough time to improve that self-assessments that did not meet the standards
- Program Standards is a very time intensive project
- We did the self-assessment, but not certain where to go for the audit
- Funding support
- No audit of the self-assessment was every conducted
- Dependence on state program
- Not clean
- Inadequate staff to conduct the work required to put processes/procedures in place to meet a standard
- Not trained to audit

Q18. What resources are lacking to be able to complete a verification audit?

84 answered, 18 skipped

No resources lacking	10	11.90%
Requirements identified to meet a specific Program Standard not clear or not easy to follow	18	21.43%
Inadequate knowledge to develop written internal policies needed to meet a Standard	16	19.05%
Administrative Procedure documents (now a separate document, previously included under Standard 9) not easy to understand/not clear	18	21.43%
No resources are currently lacking	23	27.38%
Other (please identify)	28	33.33%



List of other responses provided:

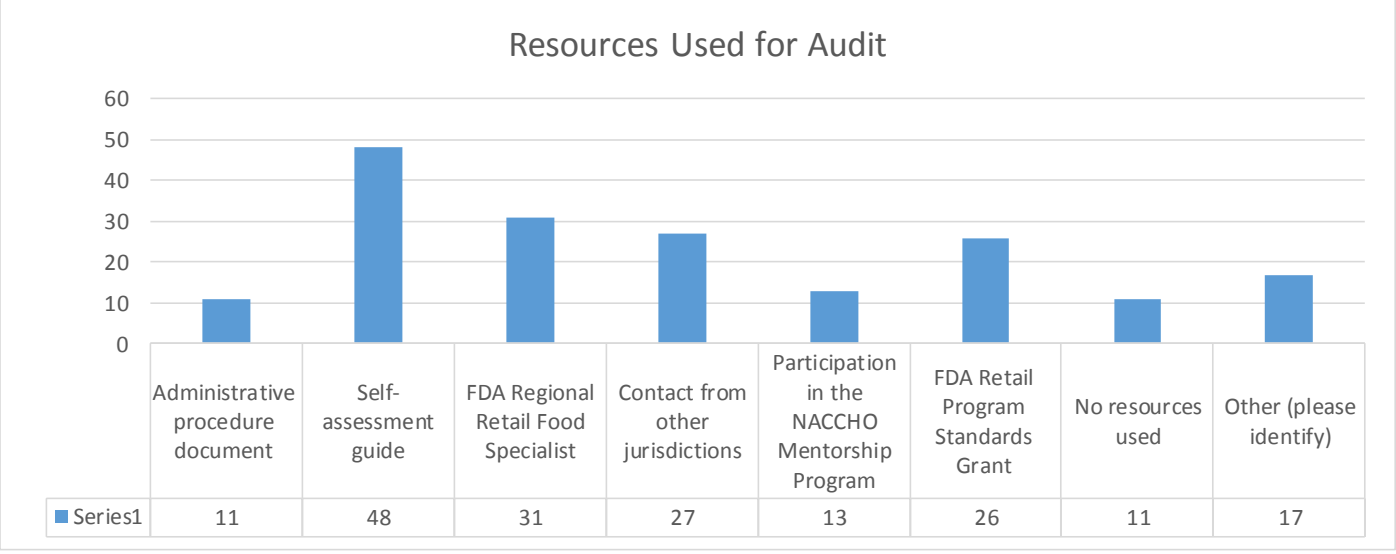
- Time
- Time and other priorities
- Change of staff, training issues
- Available time
- Time and people
- Finding the time to do it
- Time and staff; recently have spent time on inspection disclosure
- We are early in the process yet and have been focusing on training regulatory staff and hoping for the state to adopt the 2013 food code
- Time and staff
- More staff resources would be beneficial in implementing and audition standards
- Program requirements often changed without notification to participants
- I think these responses aren't clear: "no resources lacking" and "no resources are currently lacking" -??? We are currently lacking resources
- Lack of funding to support implementation of the retain standards
- Staff time, don't know who would be willing to audit locally

- Not enough time
- Lack resource
- Lacked resources to purchase new inspection software
- Not a clear understanding of the proper procedures
- Human resources and time
- Understaffed now, inspections delinquent, Standardization of staff is the priority
- Training, staffing
- Financial resources (other than ADFO Money) which is appreciated!
- Staff and time
- Time FTE's
- Time in standards coordinator work plan to accommodate the necessary work on a standard
- Time
- Never had an audit or performed one
- Staff limitations

Q19. What resources did you use to ensure a successful verification audit?

76 answered, 26 skipped

Administrative procedure document (new in Program Standards version 2013, previously located in Standard 9)	11	14.47%
Self-assessment guide provided in the Program Standards	48	63.16%
FDA Regional Retail Food Specialist	31	40.79%
Contact from other jurisdictions that are enrolled in the Standards	27	35.53%
Participation in the NACCHO Mentorship Program	13	17.11%
FDA Retail Program Standards Grant made available through a Cooperative Agreement with AFDO	26	34.21%
No resources used	11	14.47%
Other (please identify)	17	22.37%



List of other responses provided:

- Indiana State Dept. of Health Standards Workshop
- N/A
- Clearinghouse responses
- FDA Retail Program Standards Grant before AFDO
- We have not conducted an audit yet. Scheduled to be completed by September 2015
- Did not complete a verification audit
- Have no performed
- NACCHO is important
- Auditors list might be helpful in the long run
- FDA Self-assessment and Verification Audit Workshop materials
- Previous audits completed by our State Food program Manager, who has retired. Thus year plan to have Mark from Iowa audit.
- No audit was performed
- NA
- Nave not completed a verification audit
- NA
- Never had an audit or performed one.
- Have applied for the mentorship program but have not been accepted

Q20. Would it be beneficial to your jurisdiction to be able to submit the Self-Assessment form, Verification Audit form, and any applicable documentation electronically to your auditor for review? – 86 answered, 16 skipped

Yes	85	98.84%
No	1	1.16

If "no", please explain:

- Not sure – some documents are on a shared folder and it may be more time consuming to re-save those in a format that can be sent electronically and the files may be too large to send via e-mail
- No idea
- We scan and submit form electronically.
- There is way too much supporting documentation to submit everything electronically. This may work for some Standards, but not all.

Q21. What would increase the credibility of the audit process? – 72 answered, 30 skipped

A more clearly defined quality assurance step	40	55.56%
Establish criteria to become an authorized auditor	37	51.39%
Other (please list)	14	19.44%

List of other responses provided:

- Attending the Auditor's Course
- I don't know
- I think the reviews done currently are credible because each agency has a conscientious auditor. I think having authorized auditory would just add another layer of time commitment that many people would not be able to do.
- Some coaching from another auditor to make sure all steps and documentation is presented
- Resources available to see what other have submitted to meet the standard, and that are available for your organization to use and adapt to your environment.
- Compelling reason to participate
- Do not make it more complicate
- Simplify forms and procedures
- Provide auditor training
- Mock audit
- Auditor training in regions – grant to pay for training of auditors, make standards required for additional funding
- FDA staff to conduct Audits like MFRPS
- Don't know because never done the audit process
- Get the bureaucratic language out

Q22. Are you aware that a Clearinghouse Workgroup exists that can help clarify questions related to the Program Standards? – 88 answered, 16 skipped

Yes	51	59.30%
No	35	40.70%

Q23. Do you have anything else you would like to share based on your experience?
30 answered, 72 skipped

The answers in the clearinghouse are still not clear – would like more training in order to more clearly understand the requirements of each standard
In our particular organization, we do more than food inspections. Our licensing fees support our inspection process. License fees have not stayed current with costs associated to do inspections. The State Government has decided one again not to raise license fees. They have been increased only twice in the last approximately 35 years. The last time in 2007 or 2008…did not even bring it up to current costs then.
No
Being in Hawaii we find it very difficult to locate Auditor's and although we are in the internet age, it would be better if we could communicate with another jurisdiction on how they met a Standard. A face to face meeting is ideal vs. communication with email. Also because of the long distance and expense it is very difficult to participate in the mentor-mentee program.

I think the Program Standards are great and I'm glad our program enrolled. However, they are time consuming and it can be frustrating because you want to complete them but it seems there is never enough time. The FDA representative and clearinghouse have been very supportive.
A good idea, but frustration grows when Standards are not met and little time to improve. The focus is on making sure the inspections get done with the limited resources available. Staff is in the field with no staff assigned to any quality assurance and re-self-assessment.
The Regional FDA Specialist has been a great resource to us for pairing an auditor for our Standards.
We are a small health department and would not be able to work on conformance with the Standards if we didn't receive the grants from FDA, AFDO, and NACCHO.
We are very new to the standards and have not completed our first verification audit, so we were unable to answer several of the questions. Our audit is scheduled to be completed by September.
No
Our agency has been working towards the Retail Program Standards since enrollment in 2009. However, we are one of the few agencies active in the Retail Program Standards and as a result, have not been requested to complete an audit. We feel comfortable with the Standards, but would appreciate deeper understanding from an audit perspective. We are partnering/mentoring a recent enrolled agency and will most likely be requested to conduct an audit in the future.
No
Our health department get overwhelmed by the process and the amount of reading and instructions required. We are currently trying to break it up into smaller bits and assign standards to different inspectors to work on.
No
I am a one person department and have had challenges finding another agency nearby to assist. Many of the questions in the audit pertain to department with many staff members, and there are not options for small one-person departments.
No
If you want the VRFPS to be more accepted by locals, don't make it more complicated.
Again simplify the process and the forms.
I wish the annual FDA training traveling allowance is opened up for locals to attend. The only reason I cannot attend is I did not get the grant for travelling and our resources does not allow out of state travelling.
The audit of this jurisdiction has been delayed due to inadequate time and denied funding from FDA which was requested to complete the verification audit.
I would suggest that the standards be self-assessed and audited individually rather that all at once which in overwhelming to complete. Right or wrong that if how I have done this and that way each year we can work on one or two. We

have completed the second round of self-assessment and audit verifications on several Standards.
Could not have made progress on the Program Standards without participation in the NACCHO mentorship program and FDA grant support.
The self-assessment was completed, but no audit verification was ever completed by FDA
n/a
The number of inspectors listed in not FTE's for food inspections. They also have other duties. The number of facilities does not include any temp food events. We are also in a high tourist area which has increased out temp events, inspectors and the number of facilities as compared to our population.
We have not dedicated time to the program. Staffing constraints limit program development.
I don't understand why we need to complete the Self-Assessment info on the FDA Registry Form – when only submitting because an audit was performed. I also didn't realize the self-assessment must be done within 30 days of the audit. Sometimes a self-assessment is done way in advance to determine gaps that need to be filled. Marking these boxes can also be confused with the every 5 year self-assessment.
Should run Retail Standard like the Manufactured Food Standards. Have FDA Staff conduct audits. Other state and local jurisdictions don't have the time or resources to devote to auditing another agencies programs. Additionally our agency is hesitant to show another state agencies "how we do things".
The standard are too cumbersome for Deschutes County. We really believe in the standards but the amt of time it takes make it impossible to do all my other field work, supervisor duties, admin work, budget, etc.
It would be nice to get some kind of training when you sign up as a participant.

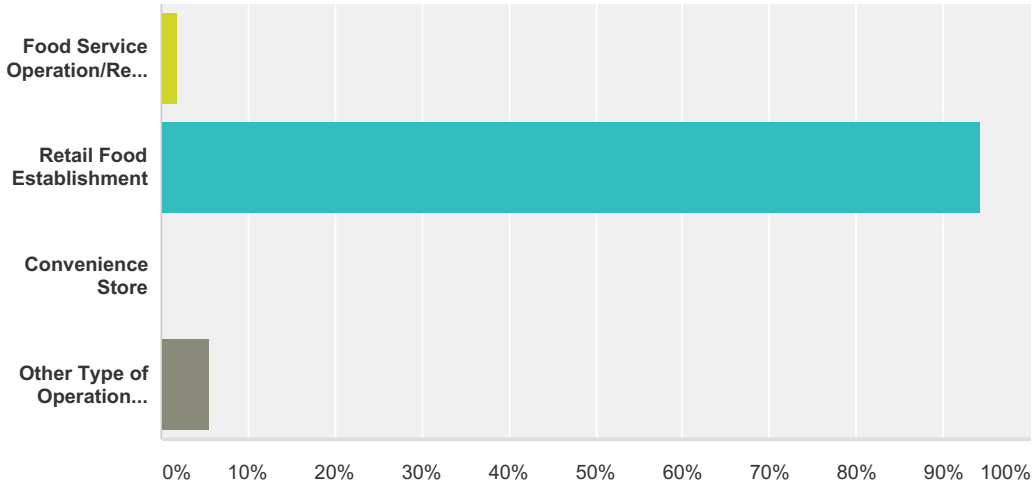
Q24. If you would be willing to be contacted by the committee if they have any questions, please list your information below. – 48 answered, 54 skipped

Respondents were asked to provide the following information if they were willing to be contacted:

Name
Agency
Role/Title
Address
City/Town
State
Zip
E-mail address
Phone number

Q1 Which of the following best describes your operation?

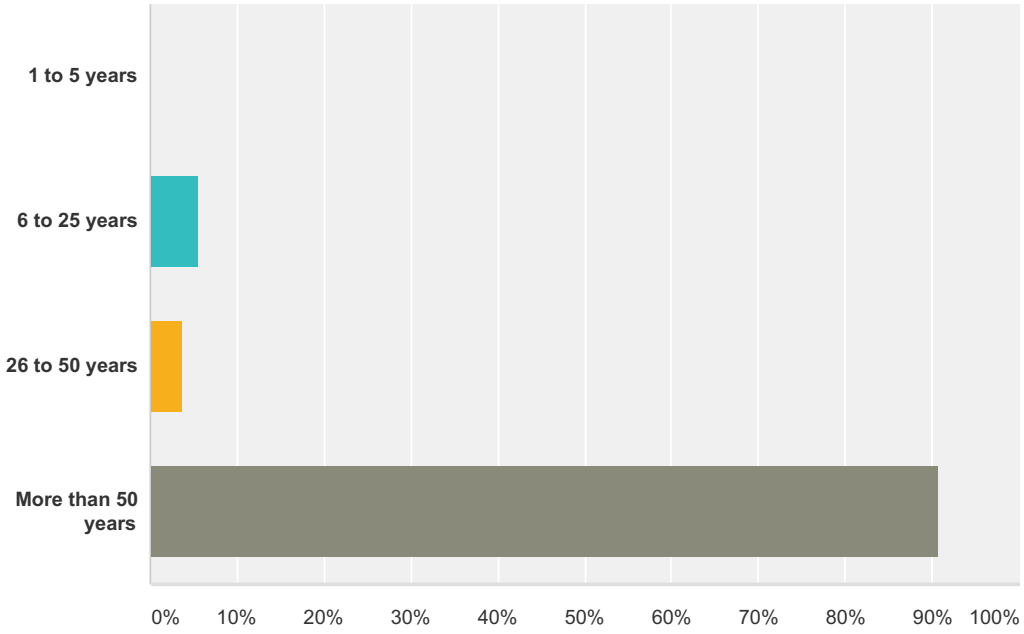
Answered: 54 Skipped: 0



Answer Choices	Responses	
Food Service Operation/Restaurant	**1.85%**	1
Retail Food Establishment	**94.44%**	51
Convenience Store	**0.00%**	0
Other Type of Operation (please specify)	**5.56%**	3
Total Respondents: 54		

Q2 How long has your company been in business?

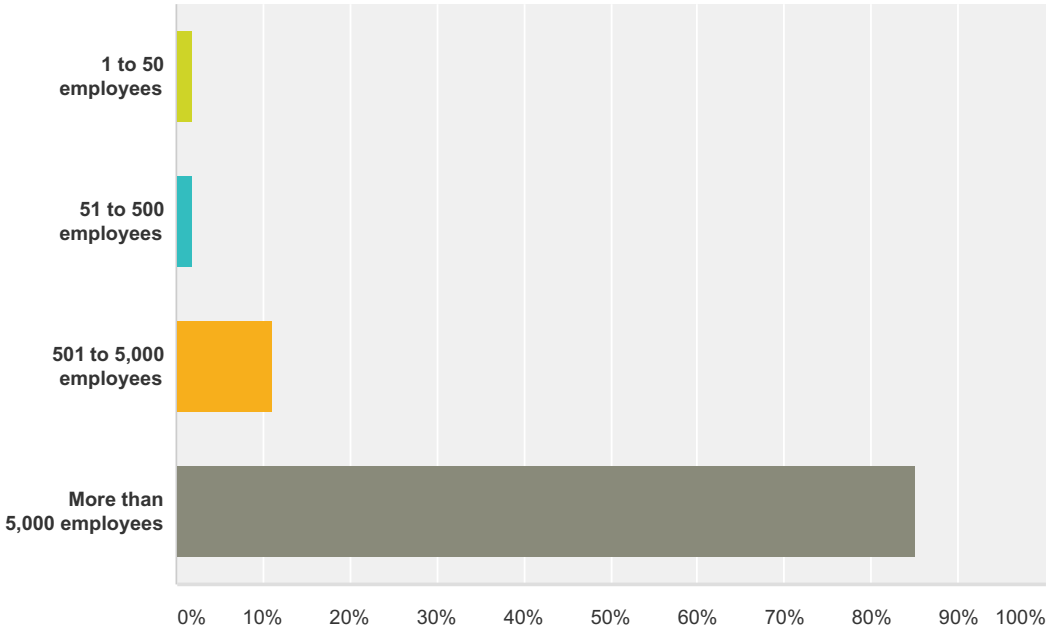
Answered: 54 Skipped: 0



Answer Choices	Responses	
1 to 5 years	**0.00%**	0
6 to 25 years	**5.56%**	3
26 to 50 years	**3.70%**	2
More than 50 years	**90.74%**	49
Total		**54**

Q3 How many employees work at your company?

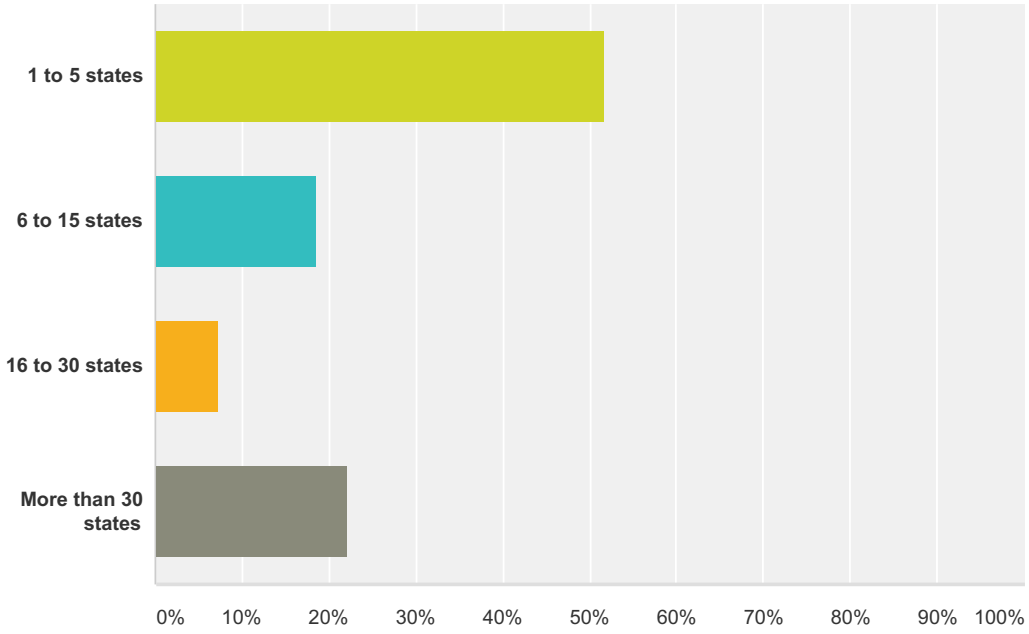
Answered: 54 Skipped: 0



Answer Choices	Responses	
1 to 50 employees	**1.85%**	1
51 to 500 employees	**1.85%**	1
501 to 5,000 employees	**11.11%**	6
More than 5,000 employees	**85.19%**	46
Total		**54**

Q4 How many States does your company operate in?

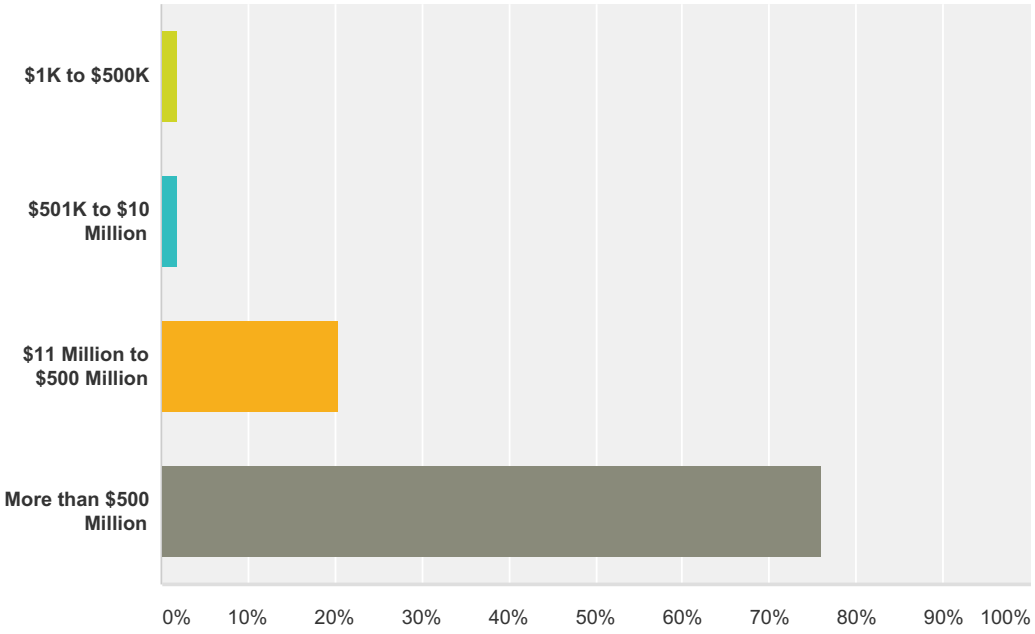
Answered: 54 Skipped: 0



Answer Choices	Responses	
1 to 5 states	**51.85%**	28
6 to 15 states	**18.52%**	10
16 to 30 states	**7.41%**	4
More than 30 states	**22.22%**	12
Total		**54**

Q5 What is the approximate total revenue for your company?

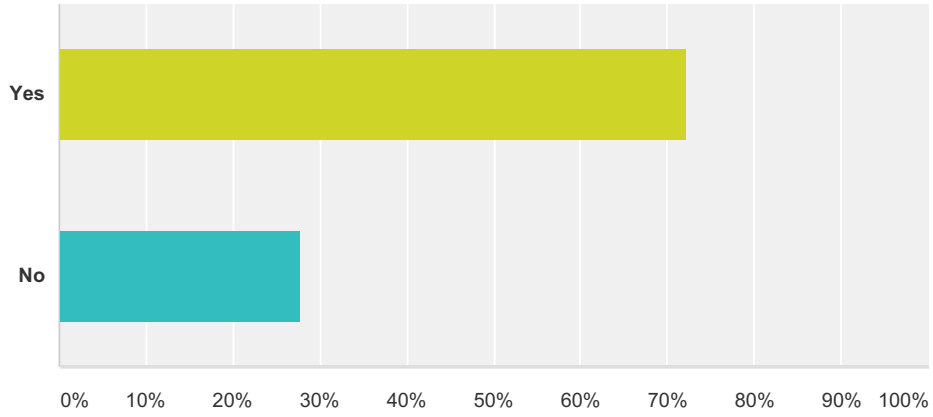
Answered: 54 Skipped: 0



Answer Choices	Responses	
$1K to $500K	**1.85%**	1
$501K to $10 Million	**1.85%**	1
$11 Million to $500 Million	**20.37%**	11
More than $500 Million	**75.93%**	41
Total		**54**

Q6 Prior to receiving this survey, were you aware of the Retail Program Standards?

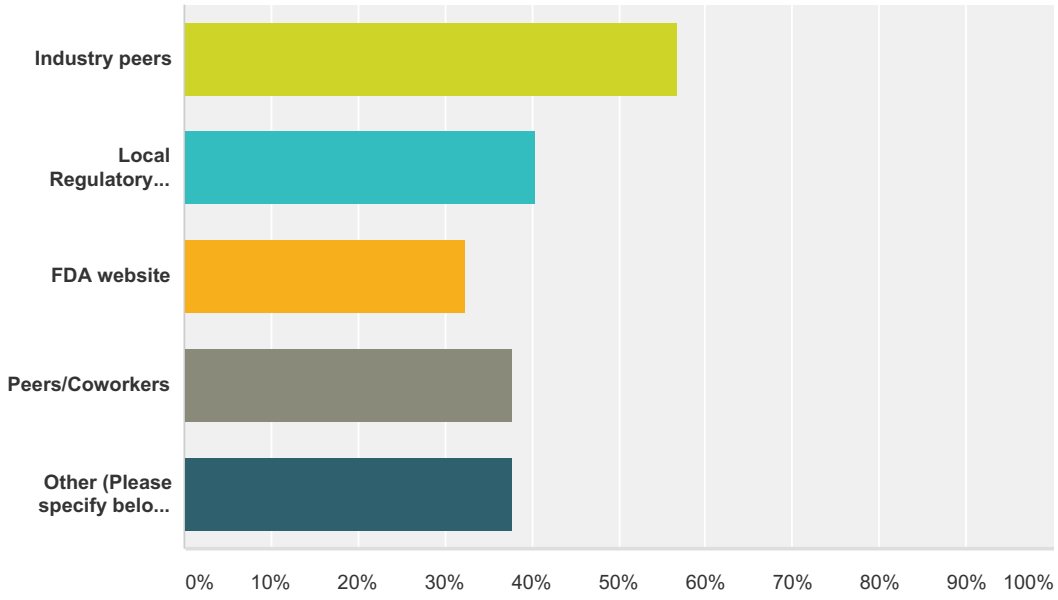
Answered: 54 Skipped: 0



Answer Choices	Responses	
Yes	**72.22%**	39
No	**27.78%**	15
Total		**54**

Q7 How did you become aware of the Retail Program Standards? Please select all options that apply.

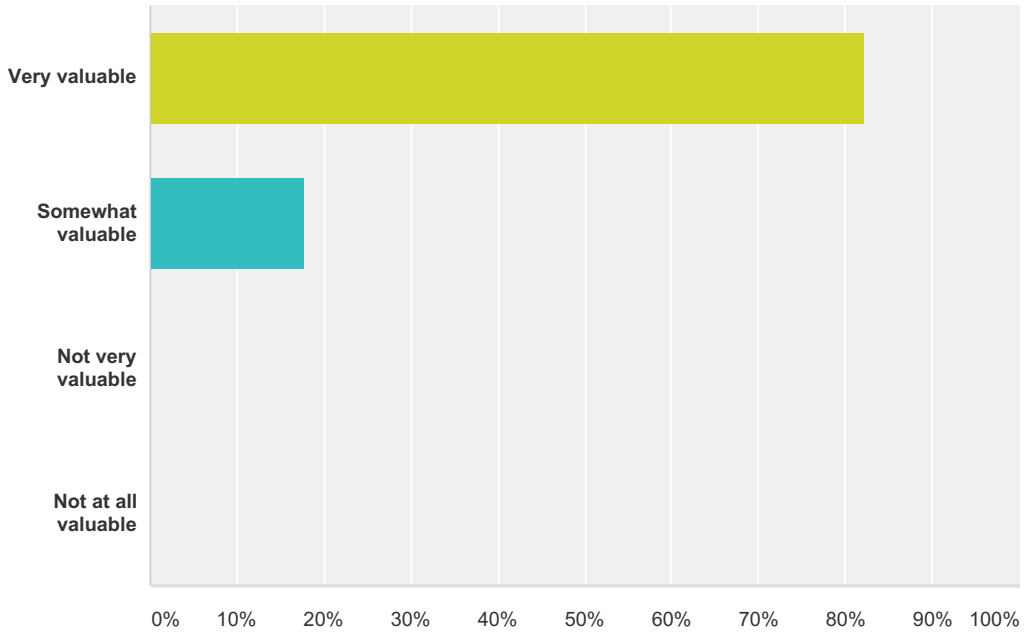
Answered: 37 Skipped: 17



Answer Choices	Responses	
Industry peers	**56.76%**	21
Local Regulatory outreach/communication	**40.54%**	15
FDA website	**32.43%**	12
Peers/Coworkers	**37.84%**	14
Other (Please specify below in 'Other' box)	**37.84%**	14
Total Respondents: 37		

Q8 Would it be valuable to your company if all regulatory authority inspection staff responsible for conducting inspections at retail food establishments were trained to the Retail Program Standard 2 as outlined below? Standard 2 (Trained Regulatory Staff)The regulatory retail food program inspection staff shall have the knowledge, skills, and ability to adequately perform their required duties.Five step training process for retail food program inspection staff:- Completion of initial course curriculum before conducting joint inspections. - Completion of 25 joint inspections.- Completion of 25 independent inspections, and completion of the remainder of the course curriculum. - Completion of Standardization process (re-standardization occurs every three years). - Completion of continuing education.

Answered: 51 Skipped: 3

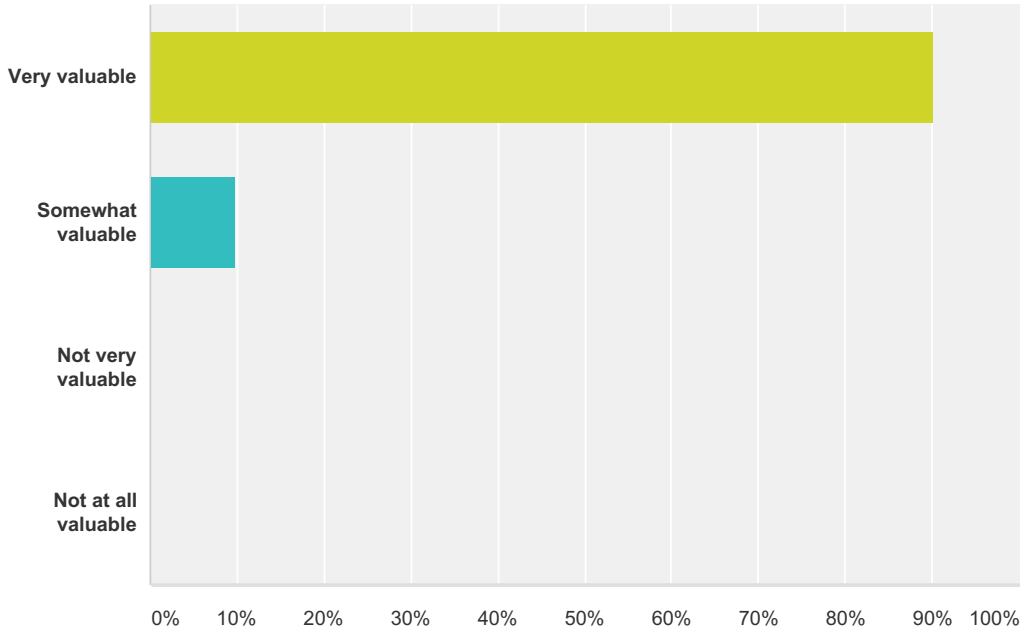


Answer Choices	Responses	
Very valuable	82.35%	42
Somewhat valuable	17.65%	9

Not very valuable	**0.00%**	0
Not at all valuable	**0.00%**	0
Total		**51**

Q9 Would it be valuable to your company if all regulatory authorities implemented an ongoing Quality Assurance program as outlined in the Retail Program Standard 4, as outlined below?Standard 4 (Quality Assurance Program)Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency, and uniformity among the regulatory staff.

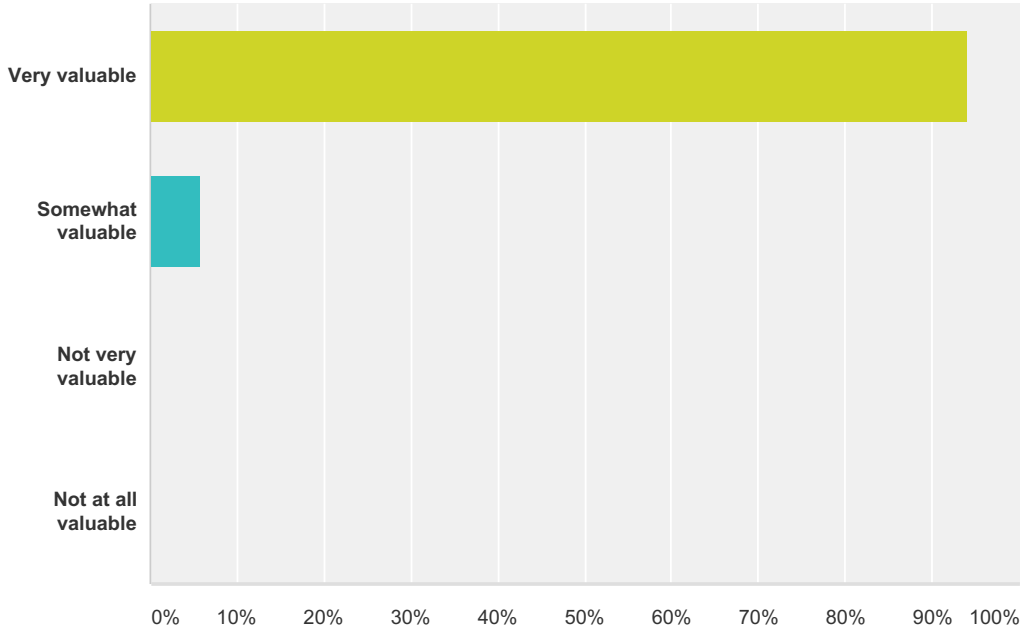
Answered: 51 Skipped: 3



Answer Choices	Responses	
Very valuable	**90.20%**	46
Somewhat valuable	**9.80%**	5
Not very valuable	**0.00%**	0
Not at all valuable	**0.00%**	0
Total		**51**

Q10 Would Industry find it beneficial if regulatory authorities invited industry to participate in food safety forums or to participate in food safety advisory boards to enhance food safety strategies or otherwise collaborate to improve food safety in the jurisdiction?

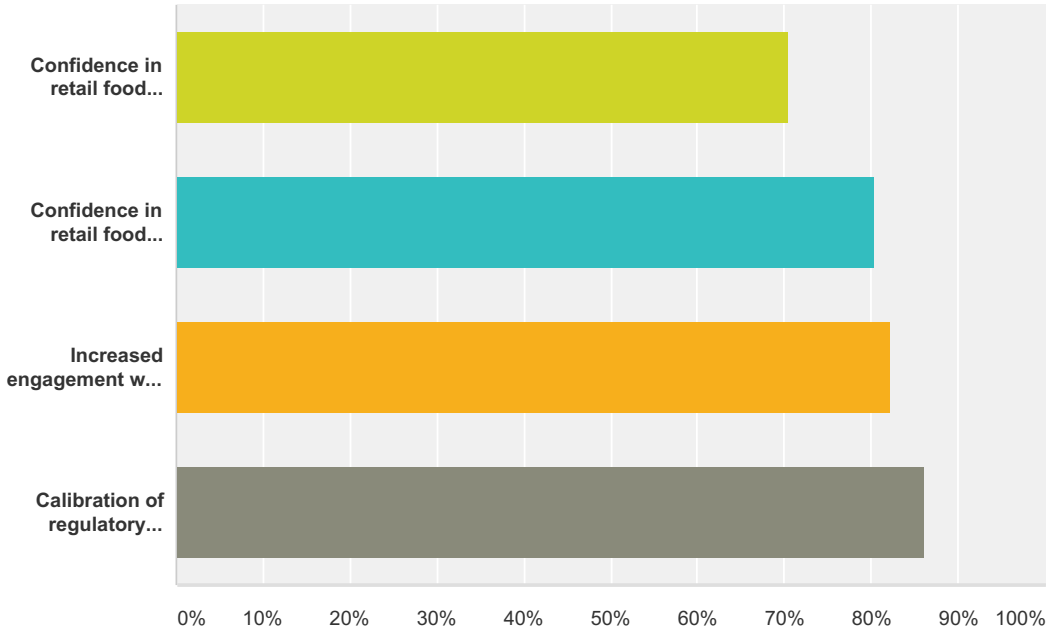
Answered: 51 Skipped: 3



Answer Choices	Responses	
Very valuable	**94.12%**	48
Somewhat valuable	**5.88%**	3
Not very valuable	**0.00%**	0
Not at all valuable	**0.00%**	0
Total		**51**

Q11 What are the benefits to Industry when the regulatory authority invests in the Retail Program Standards by having trained regulatory staff (Standard 2), an ongoing Quality Assurance program (Standard 4) and Industry/Community outreach activities (Standard 7)? Please select all options that apply and add any additional benefits in the 'Other' box.

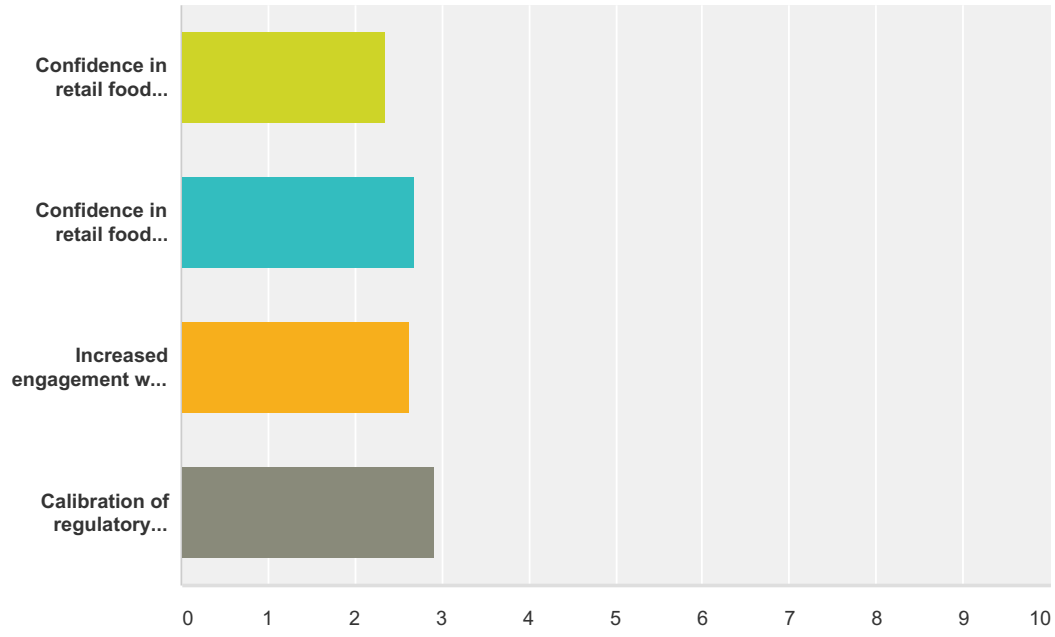
Answered: 51 Skipped: 3



Answer Choices	Responses	
Confidence in retail food establishment assessment results by general public	**70.59%**	36
Confidence in retail food establishment assessment results by Industry	**80.39%**	41
Increased engagement with regulatory authority by Industry	**82.35%**	42
Calibration of regulatory staff across the State/Jurisdiction	**86.27%**	44
Total Respondents: 51		

Q12 Please rate your identified benefits to Industry for regulatory authorites to invest in the Retail Program Standards by having trained regulatory staff, an ongoing Quality Assurance program and Industry/Community outreach activities?

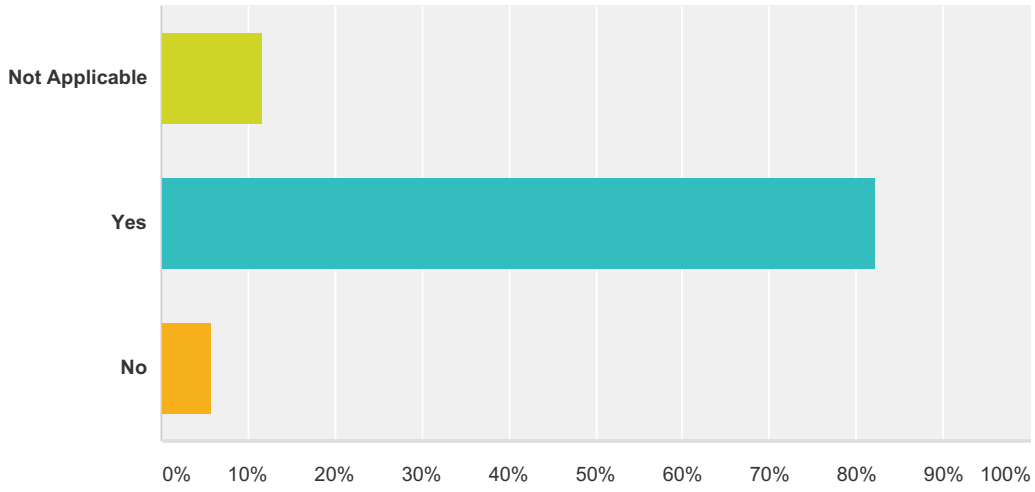
Answered: 51 Skipped: 3



	No Benefit	Some Benefit	Greatest Benefit	N/A	Total	Weighted Average
Confidence in retail food establishment assessment results by general public	**6.25%** 3	**52.08%** 25	**41.67%** 20	**0.00%** 0	48	2.35
Confidence in retail food establishment assessment results by Industry	**0.00%** 0	**30.00%** 15	**68.00%** 34	**2.00%** 1	50	2.69
Increased engagement with regulatory authority by Industry	**0.00%** 0	**37.25%** 19	**62.75%** 32	**0.00%** 0	51	2.63
Calibration of regulatory staff across the State/Jurisdiction	**0.00%** 0	**8.00%** 4	**92.00%** 46	**0.00%** 0	50	2.92

Q13 If you have multiple locations in different regulatory districts, can you identify benefits of working with a regulatory authority that is enrolled in the Retail Program Standards versus one that has is not enrolled in the Retail Program Standards?

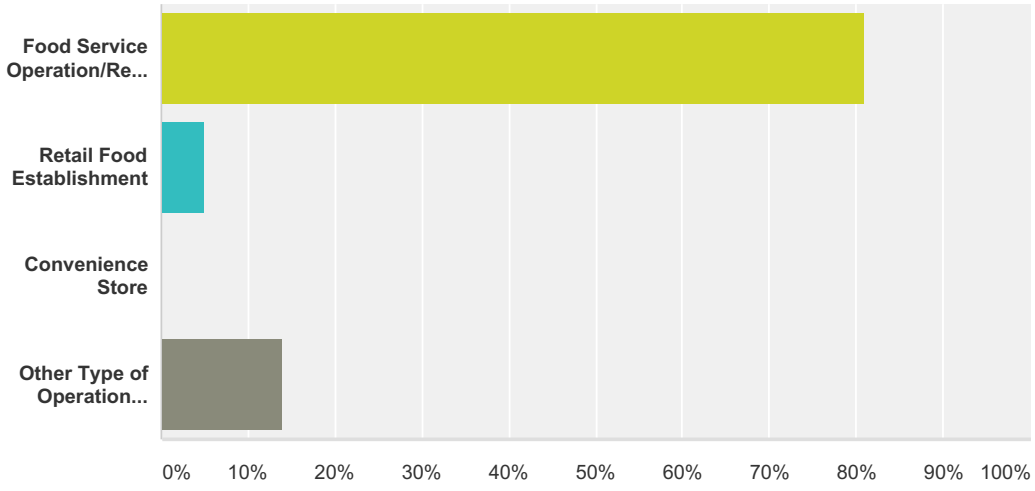
Answered: 51 Skipped: 3



Answer Choices	Responses	
Not Applicable	**11.76%**	6
Yes	**82.35%**	42
No	**5.88%**	3
Total		**51**

Q1 Which of the following best describes your operation?

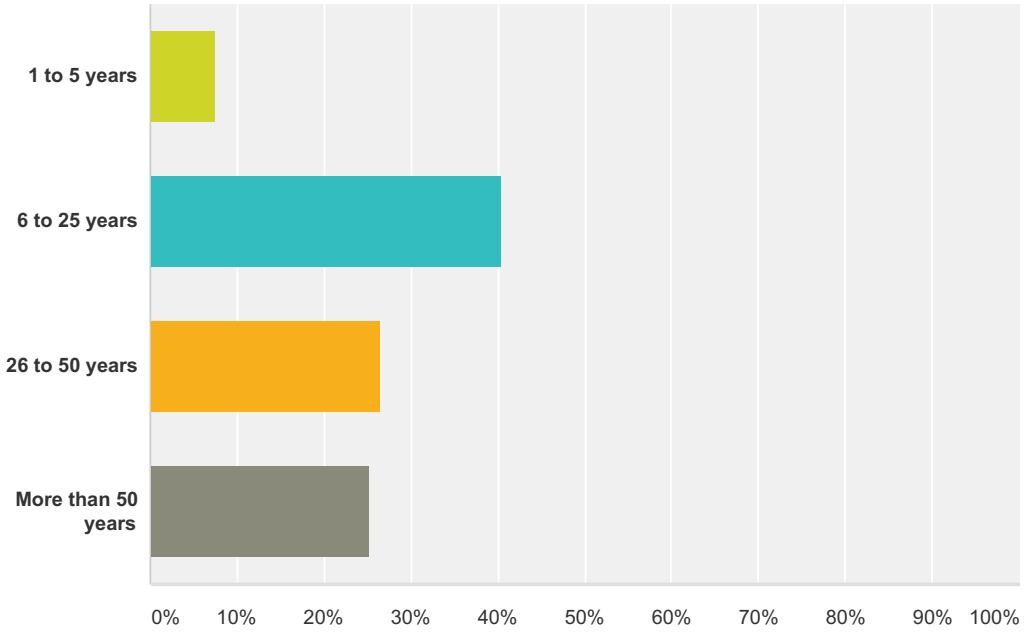
Answered: 79 Skipped: 0



Answer Choices	Responses	
Food Service Operation/Restaurant	**81.01%**	64
Retail Food Establishment	**5.06%**	4
Convenience Store	**0.00%**	0
Other Type of Operation (please specify)	**13.92%**	11
Total Respondents: 79		

Q2 How long has your company been in business?

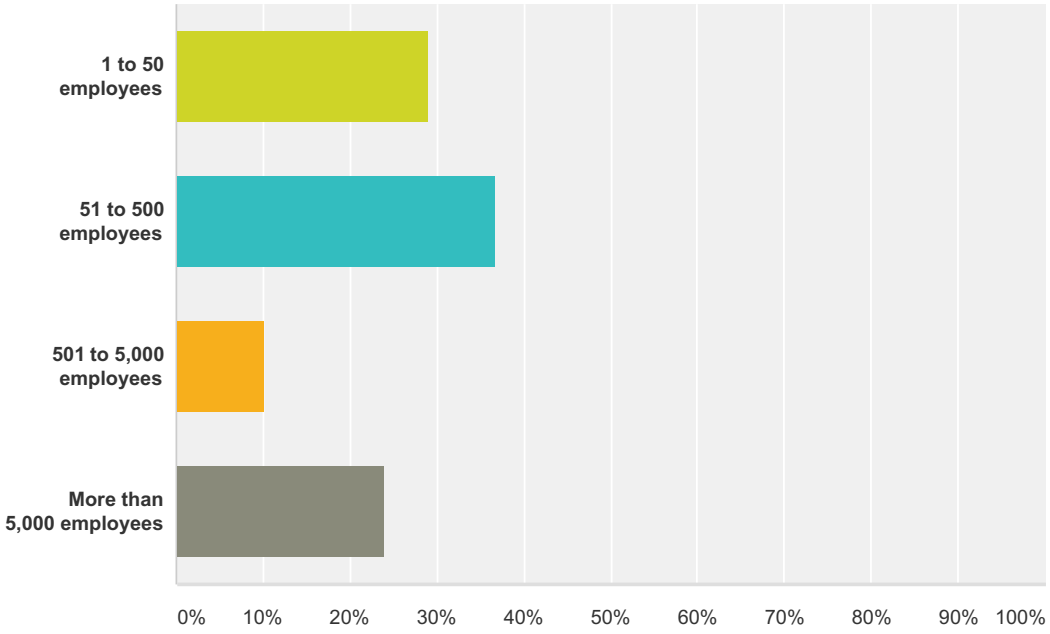
Answered: 79 Skipped: 0



Answer Choices	Responses	
1 to 5 years	**7.59%**	6
6 to 25 years	**40.51%**	32
26 to 50 years	**26.58%**	21
More than 50 years	**25.32%**	20
Total		**79**

Q3 How many employees work at your company?

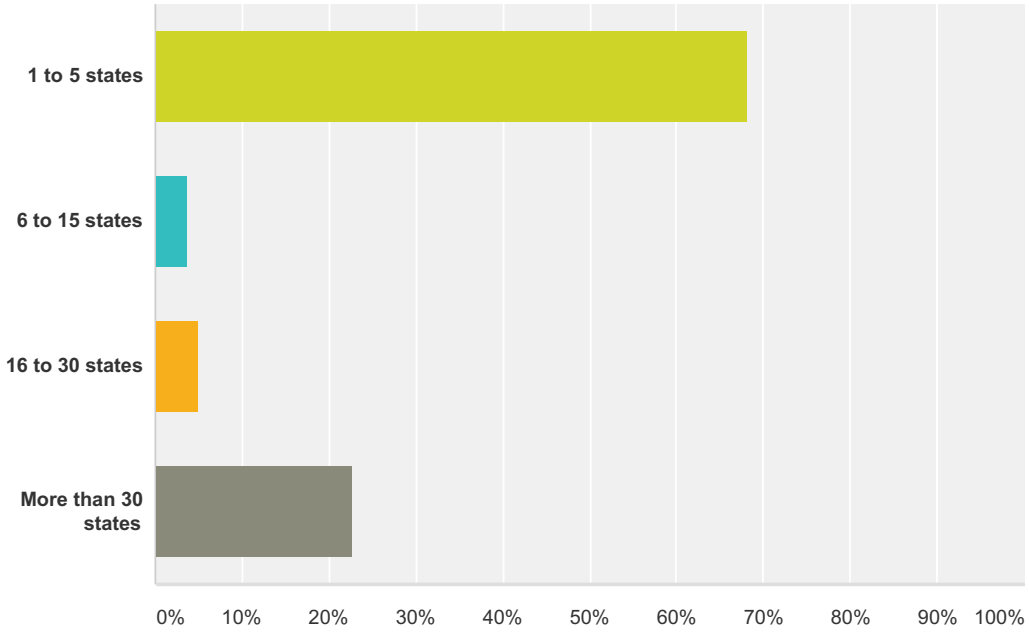
Answered: 79 Skipped: 0



Answer Choices	Responses	
1 to 50 employees	**29.11%**	23
51 to 500 employees	**36.71%**	29
501 to 5,000 employees	**10.13%**	8
More than 5,000 employees	**24.05%**	19
Total		**79**

Q4 How many States does your company operate in?

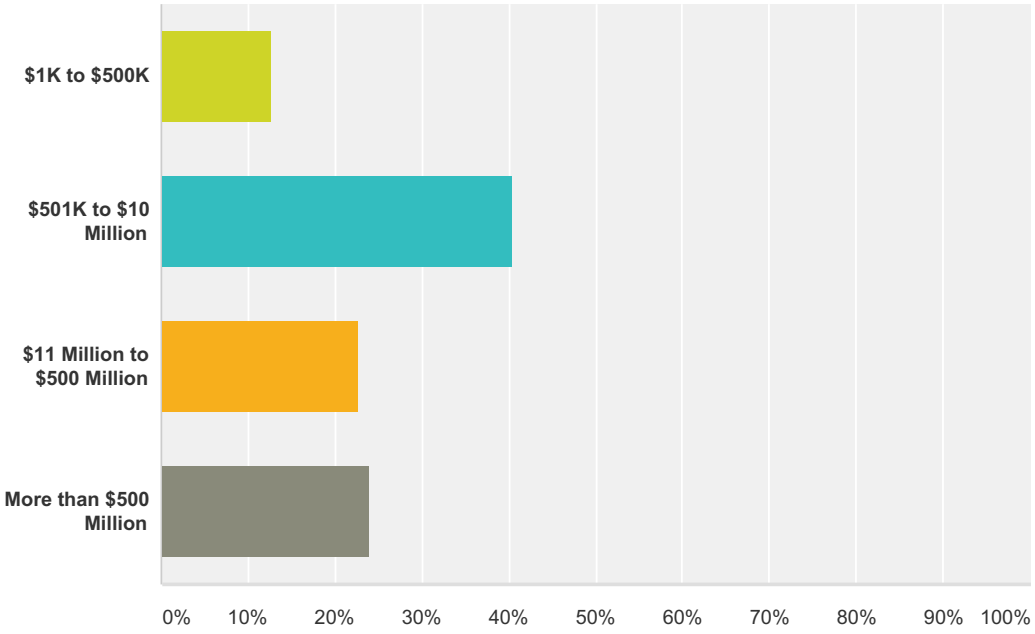
Answered: 79 Skipped: 0



Answer Choices	Responses	
1 to 5 states	**68.35%**	54
6 to 15 states	**3.80%**	3
16 to 30 states	**5.06%**	4
More than 30 states	**22.78%**	18
Total		**79**

Q5 What is the approximate total revenue for your company?

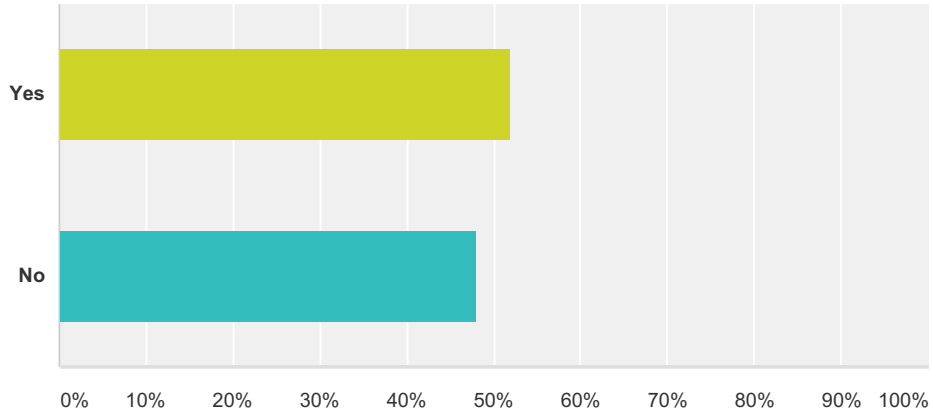
Answered: 79 Skipped: 0



Answer Choices	Responses	
$1K to $500K	**12.66%**	10
$501K to $10 Million	**40.51%**	32
$11 Million to $500 Million	**22.78%**	18
More than $500 Million	**24.05%**	19
Total		**79**

Q6 Prior to receiving this survey, were you aware of the Retail Program Standards?

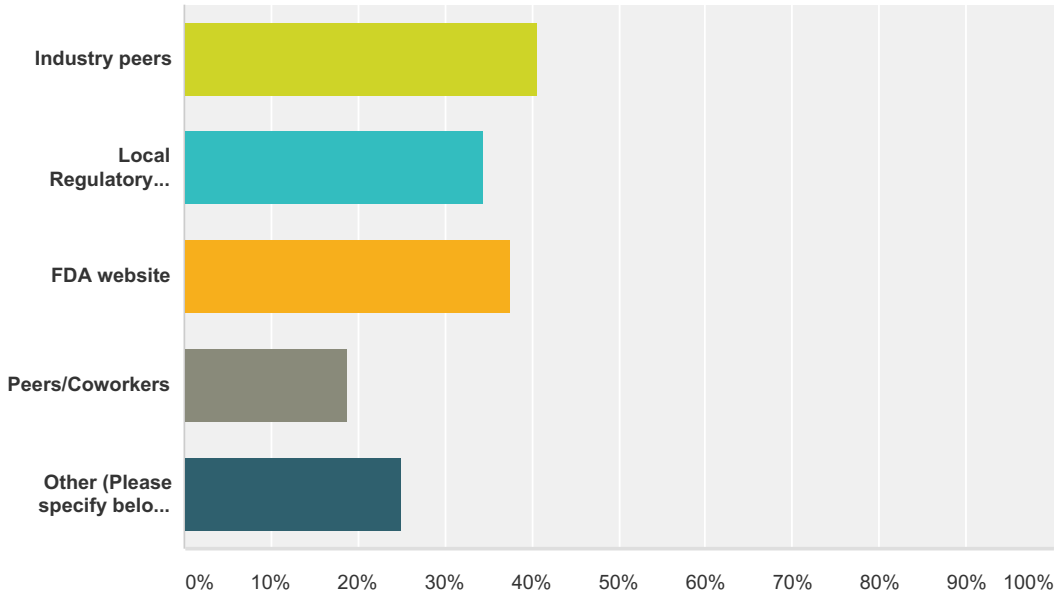
Answered: 79 Skipped: 0



Answer Choices	Responses	
Yes	**51.90%**	41
No	**48.10%**	38
Total		**79**

Q7 How did you become aware of the Retail Program Standards? Please select all options that apply.

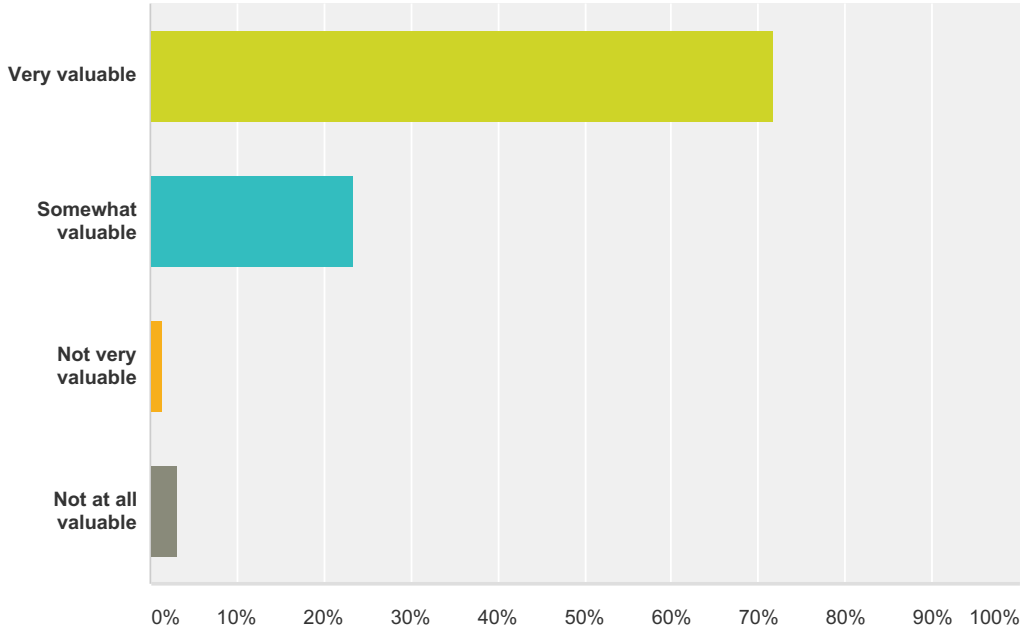
Answered: 32 Skipped: 47



Answer Choices	Responses	
Industry peers	**40.63%**	13
Local Regulatory outreach/communication	**34.38%**	11
FDA website	**37.50%**	12
Peers/Coworkers	**18.75%**	6
Other (Please specify below in 'Other' box)	**25.00%**	8
Total Respondents: 32		

Q8 Would it be valuable to your company if all regulatory authority inspection staff responsible for conducting inspections at retail food establishments were trained to the Retail Program Standard 2 as outlined below? Standard 2 (Trained Regulatory Staff)The regulatory retail food program inspection staff shall have the knowledge, skills, and ability to adequately perform their required duties.Five step training process for retail food program inspection staff:- Completion of initial course curriculum before conducting joint inspections. - Completion of 25 joint inspections.- Completion of 25 independent inspections, and completion of the remainder of the course curriculum. - Completion of Standardization process (re-standardization occurs every three years). - Completion of continuing education.

Answered: 64 Skipped: 15

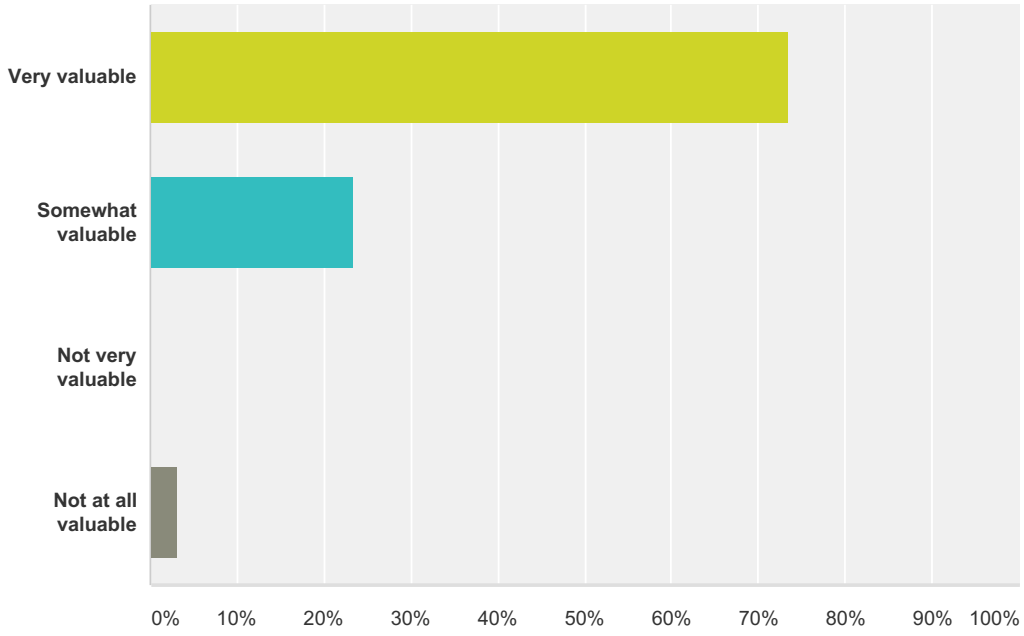


Answer Choices	Responses	
Very valuable	71.88%	46
Somewhat valuable	23.44%	15

Not very valuable	**1.56%**	1
Not at all valuable	**3.13%**	2
Total		**64**

Q9 Would it be valuable to your company if all regulatory authorities implemented an ongoing Quality Assurance program as outlined in the Retail Program Standard 4, as outlined below?Standard 4 (Quality Assurance Program)Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency, and uniformity among the regulatory staff.

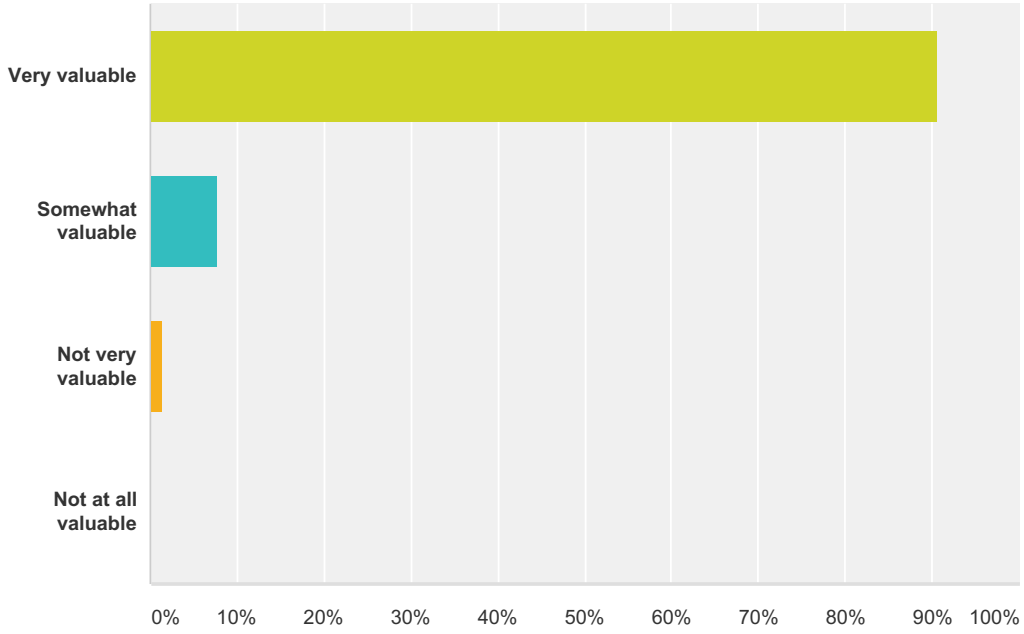
Answered: 64 Skipped: 15



Answer Choices	Responses	
Very valuable	73.44%	47
Somewhat valuable	23.44%	15
Not very valuable	0.00%	0
Not at all valuable	3.13%	2
Total		64

Q10 Would Industry find it beneficial if regulatory authorities invited industry to participate in food safety forums or to participate in food safety advisory boards to enhance food safety strategies or otherwise collaborate to improve food safety in the jurisdiction?

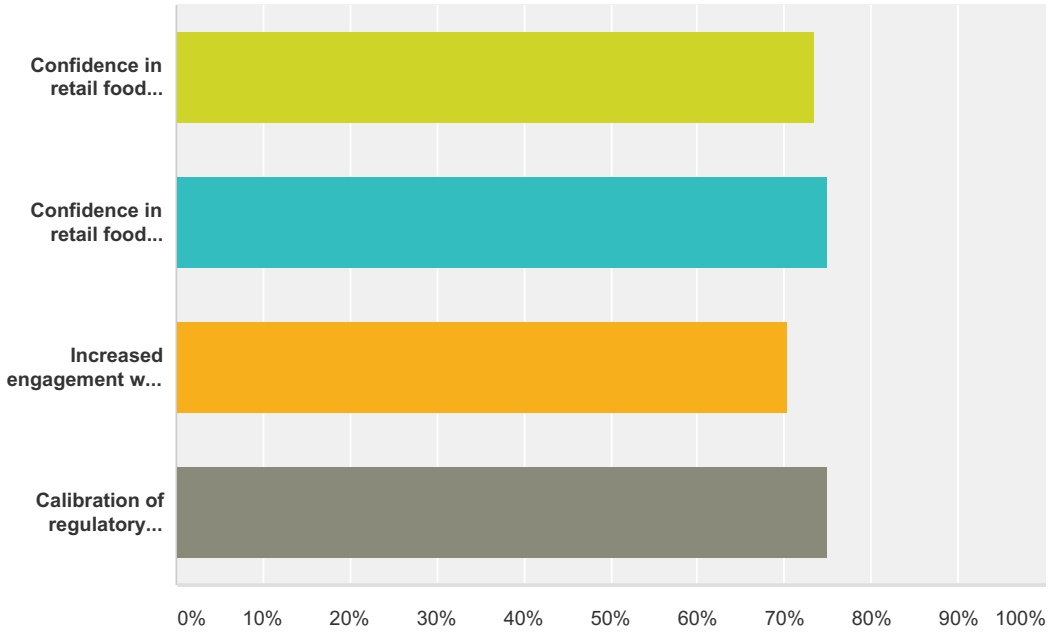
Answered: 64 Skipped: 15



Answer Choices	Responses	
Very valuable	**90.63%**	58
Somewhat valuable	**7.81%**	5
Not very valuable	**1.56%**	1
Not at all valuable	**0.00%**	0
Total		**64**

Q11 What are the benefits to Industry when the regulatory authority invests in the Retail Program Standards by having trained regulatory staff (Standard 2), an ongoing Quality Assurance program (Standard 4) and Industry/Community outreach activities (Standard 7)? Please select all options that apply and add any additional benefits in the 'Other' box.

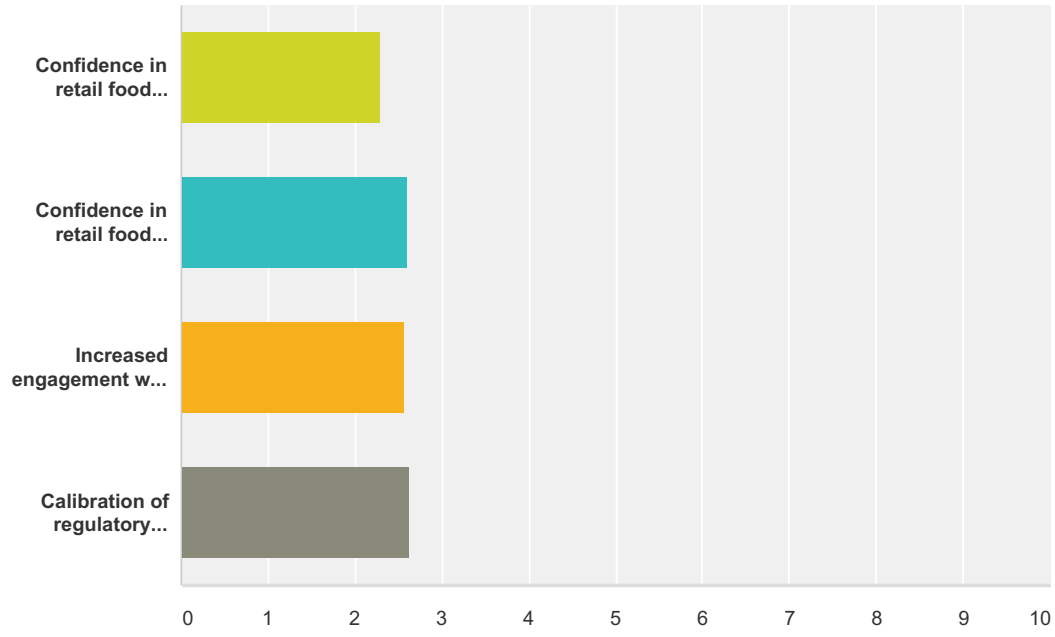
Answered: 64 Skipped: 15



Answer Choices	Responses	
Confidence in retail food establishment assessment results by general public	73.44%	47
Confidence in retail food establishment assessment results by Industry	75.00%	48
Increased engagement with regulatory authority by Industry	70.31%	45
Calibration of regulatory staff across the State/Jurisdiction	75.00%	48
Total Respondents: 64		

Q12 Please rate your identified benefits to Industry for regulatory authorites to invest in the Retail Program Standards by having trained regulatory staff, an ongoing Quality Assurance program and Industry/Community outreach activities?

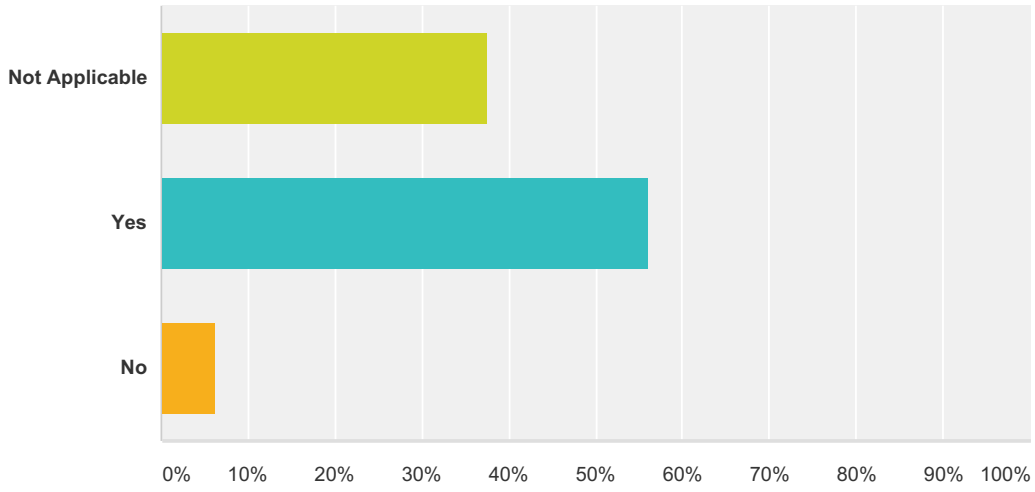
Answered: 64 Skipped: 15



	No Benefit	Some Benefit	Greatest Benefit	N/A	Total	Weighted Average
Confidence in retail food establishment assessment results by general public	**6.35%** 4	**57.14%** 36	**36.51%** 23	**0.00%** 0	63	2.30
Confidence in retail food establishment assessment results by Industry	**3.23%** 2	**33.87%** 21	**62.90%** 39	**0.00%** 0	62	2.60
Increased engagement with regulatory authority by Industry	**3.23%** 2	**35.48%** 22	**59.68%** 37	**1.61%** 1	62	2.57
Calibration of regulatory staff across the State/Jurisdiction	**1.56%** 1	**32.81%** 21	**65.63%** 42	**0.00%** 0	64	2.64

Q13 If you have multiple locations in different regulatory districts, can you identify benefits of working with a regulatory authority that is enrolled in the Retail Program Standards versus one that has is not enrolled in the Retail Program Standards?

Answered: 64 Skipped: 15



Answer Choices	Responses	
Not Applicable	**37.50%**	24
Yes	**56.25%**	36
No	**6.25%**	4
Total		**64**

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-007

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

PSC 2 - Recommendations from Issue 2014 II-003

Issue you would like the Conference to consider:

The Program Standards Committee has completed the charges outlined in Issue 2014 II-003 related to Retail Program Standards 2, 4 and 7. The Committee has proposed recommendations to be sent to the FDA.

Public Health Significance:

The Retail Program Standards offer a systematic approach to, through a continuous improvement process, enhance retail food regulatory programs. They define and provide a framework designed to accommodate both traditional and emerging approaches of a regulatory food safety system. To address Issue 2014 II-003 (*Charge 2: To solicit the support of industry to examine methods to support regulatory efforts to achieve Standard 2, Standard 4, and Standard 7 of the Voluntary National Retail Food Regulatory Program Standards*), a subcommittee interviewed regulatory agencies enrolled in the Retail Program Standards, mostly those who had achieved Standards 2, 4, and 7 and who conduct direct inspections, to examine and provide methods to support regulatory efforts to achieve Standard 2, Standard 4, and Standard 7.

Recommended Solution: The Conference recommends...:

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

1. Develop a Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) guide or template to help regulatory agencies to enroll in the Retail Program Standards, realize what they are getting involved in prior to enrollment, provide recommendations about where an enrollee should begin, and provide a roadmap to allow management to plan for proper staffing and resources to actually complete and sustain the activities associated with the Retail Program Standards;

2. Reward achievement of the Retail Program Standards by giving extra credit during the application review and scoring process for FDA grants;
3. Establish additional formal networks to complement the existing NACCHO Program Standards Mentorship Program (e.g., workgroups in each state or by FDA region with routinely scheduled webinars, conference calls, etc.) to assist regulatory agencies in their efforts with the Retail Program Standards;
4. Seek the expansion of existing forums (e.g., NACCHO sharing sessions, NEHA AEC Retail Program Standards Workshop, and cooperative agreements with NACCHO and AFDO, etc.) for enrollees to share their success stories with the Retail Program Standards;
5. Engage in a promotion of the FoodSHIELD Program Standards Resource Center when it goes live; and
6. Provide a means to ensure that each of the FDA Regional Retail Food Specialists has a minimum level of knowledge regarding implementation of the Retail Program Standards.

Submitter Information 1:

Name:	Todd Mers, Competency of Inspectors Subcommittee Co-Lead
Organization:	Program Standards Committee
Address:	Ohio Department of Agriculture8995 East Main Street
City/State/Zip:	Reynoldsburg, OH 43068
Telephone:	(614) 728-6250
E-mail:	tmers@agri.ohio.gov

Submitter Information 2:

Name:	Caroline Friel, Co Vice-Chair
Organization:	Program Standards Committee
Address:	Wawa, Inc.260 West Baltimore Pike
City/State/Zip:	Wawa, PA 19063
Telephone:	(610) 322-6708
E-mail:	caroline.friel@wawa.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-008

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

PSC 4 - Posting of Retail Program Standards Infographic on CFP Website

Issue you would like the Conference to consider:

The Program Standards Committee has completed the charges outlined in Issue 2014 II-003 related to Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) 2, 4 and 7. The committee has identified the benefits to industry for regulatory authorities to achieve Standard 2, Standard 4, and Standard 7. The committee developed an infographic poster that may serve as a resource for industry and other stakeholders to share those benefits.

Public Health Significance:

The 2011 Food Safety Modernization Act (FSMA) requires the FDA to partner with state and local food safety regulatory agencies to build a national Integrated Food Safety System (IFSS). The goal of a national IFSS is to develop a seamless partnership and operation of federal, state, and local food safety regulatory agencies to meet the public health mission of achieving a safer food supply. The benefits of having a regulatory authority meeting the Retail Program Standards contributes to an IFSS by improving the confidence in the food safety work being conducted by other agencies, focusing efforts on the reduction of risk factors known to contribute to foodborne illness, and encouraging retail food establishments to implement active managerial control over these risk factors.

Along with being a foundation and system upon which all retail food regulatory programs can build through a continuous improvement process, the Retail Program Standards provide a model of what a quality program should encompass. Standard 2 provides the essential elements of a training program for regulatory staff. Standard 4 pertains to implementing an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and consistency among the regulatory staff. Standard 7 concerns enhancing two-way communication with industry and consumers through forums designed to solicit input to improve the food safety program.

The Retail Program Standards Competency of Inspectors Infographic can be used by both industry, regulators, and other stakeholders to relate the benefits to industry for regulatory authorities to achieve Standards 2, 4 and 7 of the Retail Program Standards.

Recommended Solution: The Conference recommends...:

that the Retail Program Standards Competency of Inspectors Infographic be posted to the CFP website in PDF format as a Conference-developed guidance document.

Submitter Information 1:

Name:	David Lawrence, Chair
Organization:	Program Standards Committee
Address:	Fairfax County Health Department10777 Main Street, Suite 111
City/State/Zip:	Fairfax, VA 22030
Telephone:	(703) 246-8435
E-mail:	David.Lawrence@fairfaxcounty.gov

Submitter Information 2:

Name:	Todd Mers, Competency of Inspectors Subcommittee Co-Lead
Organization:	Program Standards Committee
Address:	Ohio Department of Agriculture8995 East Main Street
City/State/Zip:	Reynoldsburg, OH 43068
Telephone:	(614) 728-6250
E-mail:	tmers@agri.ohio.gov

Content Documents:

- "Retail Program Standards - Competency of Inspectors Infographic"

RETAIL PROGRAM STANDARDS: A HOME RUN

	1	2	3	4	5	6	7	8	9	R
Industry	0	1	0	2	3					6
Regulatory	2	1	0	3	0					6

Standard 2...Standard 4...Standard 7...

40% of respondents were aware of the Retail Program Standards through local regulatory outreach/FDA website

92% of respondents found Program Standard 7, industry participation, to be very valuable

A committee was charged to identify the benefits to industry for regulatory authorities to achieve Standard 2, 4, and 7 of the Voluntary National Retail Food Retail Program Standards. A survey was designed to capture the benefits to industry as outlined in the Committee's charge and sent to participants in the National Restaurant Association (NRA) and Food Marketing Institute (FMI)

PROMOTING FOOD SAFETY THROUGH COLLABORATION

60% of respondents operate in 1 to 5 States.

60%

60% of respondents were aware of the Retail Program Standards prior to the survey

Training supports a consistent, credible approach to inspections

Training in Program Standard 2 allows more time for industry to focus on food safety rather than disputing improper citations

Most of the respondents were from larger organizations with many employees & operate in several states

True risks are measured and identified

Inspectors are better trained & the inspections are more consistent

Uniformity allows better allocation of resources

Added assurance that the inspector is adequately trained & reputable

Increased accuracy & confidence in results

Level Playing Field

Creates a level playing field for all operators and regulators which should lead to consistency

Apples to Apples comparison

Industry identified that Program Standard 2, properly trained staff, supports a consistent approach to inspections

90% of respondents found Program Standard 4, quality assurance, to be somewhat or very valuable

We all benefit from teamwork.

Prepared by the Conference for Food Protection Program Standards Committee 2014-2016

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-009

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

PSC 3 - Recommendations from Issue 2014 II-005

Issue you would like the Conference to consider:

The Program Standards Committee has completed charge 3 of Issue 2014 II-005 to conduct an evaluation of the current verification audit requirement of the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards). The Committee has proposed recommendations to be sent to the FDA.

Public Health Significance:

The Program Standards Committee is a standing committee reporting to the CFP Executive Board. The Committee provides ongoing input to the FDA on issues that arise with the Retail Program Standards. The Committee serves the Conference by indirectly assisting Retail Program Standards enrollees in making progress towards meeting the Standards. Issue 2014 II-005 included the charge to *Review the current verification audit requirement and: (a) Identify strengths of the current verification audit requirement; (b) Identify weaknesses of the current verification audit requirement, with emphasis on any barriers that may result from the current requirement; and (c) Determine whether there are potential changes to the requirement, or the administration of the requirement, that could maintain the credibility of the Retail Program Standards while reducing barriers to achievement that may result from the current verification audit requirement.* To address the charge, a subcommittee developed and distributed a survey questionnaire (*see Verification Audit Survey Tool*) to the jurisdictions currently enrolled in the Retail Program Standards to gather information about verification audits.

Recommended Solution: The Conference recommends...:

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

1. Work on removing the barriers identified related to conducting a Voluntary National Retail Food Regulatory Program Standard verification audit by: (1) providing auditor training; (2) creating a mentorship program for auditors; (3) including information on

the online Listing of Enrolled Jurisdictions document indicating which enrollees are willing to serve as verification auditors for other enrollees; and (4) continuing to work to simplify the forms and procedures for the Retail Program Standards in an effort to reduce the amount of time required to complete the required documentation;

2. Expand funding opportunities to help support and sustain the Retail Program Standards-related activities of enrollees; and
3. Better publicize and promote the work that is being done by the FDA Clearinghouse Workgroup as an important resource for Retail Program Standards enrollees.

The Conference also recommends the continuation of charges 1, 2 and 4 from Issue 2014 II-005 to the 2016 - 2018 Program Standards Committee. Those charges are:

1. Identify areas where the Voluntary National Retail Food Regulatory Program Standards can be changed or improved to enhance enrollment and implementation; and

2. Work on a project to recognize levels of performance of Program Standards enrollees that will demonstrate the progress of enrollees in a meaningful way and acknowledging the enrollees for taking the necessary incremental steps toward meeting the Program Standards. As part of this project:

a. Provide a Cost/Benefit Analysis for recognizing partial achievement of the Retail Program Standards;

b. Identify different approaches that could be used to recognize partial achievement of the Retail Program Standards that would not require additional resources to perform or administer; and

c. Examine whether there is an additional burden placed on enrollees or FDA (in time, money, or added complexity of the Standards) associated with development of a system to ensure that jurisdictions are uniformly recognized for partial achievement of the Standards.

3. Serve as a sounding board for FDA with respect to ideas generated during collaboration with the other entities such as the National Association of County and City Health Officials (NACCHO), Partnership for Food Protection (PFP) and Association of Food and Drug Officials (AFDO).

Submitter Information 1:

Name:	Debbie C. Watts, MPH, Co Vice-Chair
Organization:	Program Standards Committee
Address:	Tulsa Health Department5051 South 129th East Avenue
City/State/Zip:	Tulsa, OK 74134
Telephone:	(918) 595-4305
E-mail:	dwatts@tulsa-health.org

Submitter Information 2:

Name:	Angie Cyr, Retail Program Standards Subcommittee Co-Lead
Organization:	Program Standards Committee
Address:	Minnesota Department of Health18 Wood Lake Drive SE
City/State/Zip:	Rochester, MN 55904
Telephone:	(507) 206-2744
E-mail:	Angie.Cyr@state.mn.us

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
2016 Issue Form

Issue: 2016 II-010

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

PSC 5 - Amend Retail Program Standard 7

Issue you would like the Conference to consider:

Amend Standard 7 of the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) to allow electronic mechanisms, such as social media and web-based meetings for forums, to be used as a method to satisfy the requirement for two-way interaction between regulatory authorities and industry/community stakeholders.

Public Health Significance:

Several jurisdictions have asked whether the use of social media sites such as twitter, blogs or food program websites with surveys or feedback buttons would meet the Retail Program Standard No. 7 requirements. In its current form, Standard 7 (written in 1997 before the modern internet) requires an annual 'meeting' with stakeholders with the intent to facilitate program feedback from industry and consumers in the community. The stated intent is to foster communication exchange between regulatory, industry and consumers. Web-based forums for communication have expanded since the late 90's and can provide an effective mechanism for feedback to the retail food regulatory program. These web-based forums offer two-way communication with not only the food industry but also for consumers, who have traditionally been difficult to include in formal, face-to-face meetings in a meaningful way.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending the following changes to Standard 7 of the Voluntary National Retail Food Regulatory Program Standards (new language is underlined; language to be deleted is in strikethrough format):

Standard 7

Industry and Community Relations

This standard applies to industry and community outreach activities ~~utilized~~ used by a retail food regulatory program to solicit a broad spectrum of input ~~into a comprehensive regulatory food program~~ about a retail food regulatory program's previous, current, and future activities, communicate sound public health food safety principles, and foster and recognize community initiatives focused on the reduction of foodborne ~~disease~~ illness risk factors.

Requirement Summary

The jurisdiction documents participation in forums that foster communication and information exchange among the regulators, industry and consumer representatives.

The jurisdiction documents outreach activities that provide educational information on food safety.

Description of Requirement

1. Industry and Consumer Interaction

The jurisdiction sponsors or actively participates in ~~meetings~~ forums with two-way communication such as food safety task force~~s~~ meetings, advisory boards, ~~or~~ advisory committees, customer surveys, web-based meetings or forums, or other mechanisms. These forums shall present information on food safety, food safety strategies and interventions to control risk factors. Offers of participation must be extended to industry and consumer representatives.

2. Educational Outreach

Outreach encompasses industry and consumer groups as well as media and elected officials. Outreach efforts may include industry recognition programs, websites, newsletters, Fight BAC™® campaigns, food safety month activities, food worker training, school-based activities, ~~customer surveys~~ use of oral culture learner materials, or other activities that increase awareness of the foodborne illness risk factors and control methods to prevent foodborne illness. Outreach activities may also include posting inspection information on a website or in the press.

Agency participation in at least one activity in each of the above categories annually is sufficient to meet this standard.

Outcome

The desired outcome of this standard is enhanced communication with industry and consumers through forums designed to solicit input to improve the retail food ~~safety~~ regulatory program. A further outcome is the reduction of foodborne illness risk factors through educational outreach and cooperative efforts with stakeholders.

Documentation

The ~~Q~~quality records needed for this standard ~~reflect activities over the most recent five-year period and~~ include:

1. Minutes, agendas or other records documenting that forums were conducted,
2. For formal, recurring meetings, documents such ~~documents~~ as by-laws, charters, membership criteria and lists, frequency of meetings, roles, etc.,
3. Surveys, web feedback links with associated follow-up materials and review documents,

4. Documentation of ~~performed actions or~~ activities designed with input from industry and consumers to improve the control of foodborne illness risk factors, or
5. Documentation of food safety educational efforts.

Statements of policies and procedures may suffice if activities are continuous, and documenting multiple incidents would be cumbersome~~, (~~e.g., recognition provided to establishments with exemplary records or an on-going website).

Submitter Information 1:

Name:	David Lawrence, Chair
Organization:	Program Standards Committee
Address:	Fairfax County Health Department10777 Main Street, Suite 111
City/State/Zip:	Fairfax, VA 22030
Telephone:	(703) 246-8435
E-mail:	David.Lawrence@fairfaxcounty.gov

Submitter Information 2:

Name:	Debbie C. Watts, MPH, Co Vice-Chair
Organization:	Program Standards Committee
Address:	Tulsa Health Department5051 South 129th East Avenue
City/State/Zip:	Tulsa, OK 74134
Telephone:	(918) 595-4305
E-mail:	dwatts@tulsa-health.org

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-011

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Amend VNRFRPS – Standard 4 – Uniform Inspection Program (Part 1)

Issue you would like the Conference to consider:

Amend Voluntary National Retail Food Regulatory Program Standard (VNRFRPS) No. 4 to reflect recommendations from the 2012 CFP Uniform Inspection Program Audit Pilot Project Report.

The Pilot Project Report is available with this Issue as a supporting attachment; it is also currently posted on the CFP website at: http://www.foodprotect.org/media/guide/uniform-inspection-program-audit-pilot-project-report.pdf

Public Health Significance:

The 2012 CFP Uniform Inspection Audit Pilot Project Report evaluated the Uniform Inspection Program process and audit worksheet as tools for conducting the quality assurance evaluations in Program Standard No. 4.

Implementing the following changes will address some of the recommendations provided in the Pilot Project Report, while also providing greater flexibility, improved program quality assessment, and greater consistency between Program Standard No. 2 and No. 4:

1. More closely align the ten Program Elements described in Program Standard No. 4 with the Performance Elements and Competencies contained in the Standard No. 2 - CFP Field Training Plan for new hires or staff newly assigned to the retail food protection program.
2. Provide a re-ordered listing of the Program Elements in Program Standard No. 4 to reflect the organized flow of the inspection process.
3. Increase the minimum number of required field assessments (joint inspections) to maintain consistency with the current statistical model upon which Standard 4 is based; this calculation is shown in "Attachment C - Update: Explanation of the Statistical Model for Program Standard No. 4."

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Program Standard No. 4 - Uniform Inspection Program, be amended to reflect the changes shown in "Attachment A - Proposed Amendments to Program Standard No. 4 - Uniform Inspection Program" (language to be added is underlined; language to be deleted is in strikethrough format).

Submitter Information:

Name:	Mary Cartagena
Organization:	Food and Drug Administration
Address:	5100 Paint Branch ParkwayHFS-320 Rm 3B038
City/State/Zip:	College Park, MD 20740
Telephone:	240-402-2937
E-mail:	mary.cartagena@fda.hhs.gov

Content Documents:

- "Attachment A- Program Standard No. 4 - Uniform Inspection Program"

Supporting Attachments:

- "Attachment B-Explanation of the Statistical Model for Program Standard No.4"
- "Attachment C-Updated Explanation of the Statistical Model for Prog. Std. 4"
- "Attachment D- Uniform Inspection Program - Audit Pilot Project Report"

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

STANDARD 4
UNIFORM INSPECTION PROGRAM

Table of Contents

STANDARD 4
UNIFORM INSPECTION PROGRAM

This standard applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance / enforcement procedures.

Requirement Summary

Program management has established a quality assurance program to ensure uniformity among regulatory staff in the interpretation and application of laws, regulations, policies, and procedures.

Description of Requirement

1) Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and uniformity among the regulatory staff. ~~The quality assurance program shall:~~

~~A. Be an on-going program.~~

~~B.~~ A. The quality assurance program shall ~~A~~assure that each inspector:

~~1. Determines and documents the compliance status of each risk factor and intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable is noted on the inspection form) through observation and investigation;~~
~~2. Completes an inspection report that is clear, legible, concise, and accurately records findings, observations and discussions with establishment management;~~
~~3. Interprets and applies laws, regulations, policies and procedures correctly;~~
~~4. Cites the proper local code provisions for CDC-identified risk factors and Food Code interventions;~~
~~5. Reviews past inspection findings and acts on repeated or unresolved violations;~~
~~6. Follows through with compliance and enforcement;~~
~~7. Obtains and documents on-site corrective action for out-of-control risk factors at the time of inspection as appropriate to the type of violation;~~
~~8. Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of control risk factor occurred on consecutive inspections. Options may include but are not limited to risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans;~~
~~9. Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met; and~~
~~10. Files reports and other documentation in a timely manner.~~
1. Has required equipment and forms to conduct the inspection.
2. Reviews the contents of the establishment file, including the previous inspection report, reported complaints on file, and, if applicable, required HACCP Plans or documents supporting the issuance of a variance.

3. Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met.
4. Provides identification as a regulatory official to the person in charge and states the purpose of the visit.
5. Interprets and applies the jurisdiction's laws, rules, policies, procedures, and regulations required for conducting retail food establishment inspections.
6. Uses a risk-based inspection methodology to conduct the inspection.
7. Accurately determines the compliance status of each risk factor and Food Code intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).
8. Obtains corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.
9. Discusses options for the long-term control of risk factors with establishment managers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.
10. Verifies correction of out-of-compliance observations identified during the previous inspection. In addition, follows through with compliance and enforcement in accordance with the jurisdiction's policies.
11. Conducts an exit interview that explains the out-of-compliance observations, corrective actions, and timeframes for correction, in accordance with the jurisdiction's policies.
12. Provides the inspection report and, when necessary, cross-referenced documents, to the person in charge or permit holder, in accordance with the jurisdiction's policies.
13. Demonstrates proper sanitary practices as expected from a food service employee.
14. Completes the inspection form per the jurisdiction's policies (i.e. observations, public health reasons, applicable code reference, compliance dates).
15. Documents the compliance status of each risk factor and intervention (IN, OUT, NA, NO).
16. Cites the proper code provisions for risk factors and Food Code interventions, in accordance with the jurisdiction's policies.
17. Documents corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.
18. Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.
19. Compliance or regulatory documents (i.e. exhibits, attachments, sample forms) are accurately completed, appropriately cross-referenced within the inspection report, and included with the inspection report, in accordance with the jurisdiction's policies.
20. Files reports and other documentation in a time manner, in accordance with the

jurisdiction's policies.

~~C.~~ B. The Quality Assurance Program shall ~~D~~describe the actions that will be implemented when the program analysis identifies deficiencies in quality or consistency in any program ~~aspect~~ element listed above in 1) ~~B.~~(A).

2) The quality assurance program must achieve an overall inspection program performance rating for each of the ~~ten~~ twenty measured ~~aspects~~ elements [Items1-~~10~~20] of at least 75% using the ~~following~~ self-assessment procedure and the appropriate ~~Table~~ table provided in the *Standard 4: Self-Assessment Instructions and Worksheet*.

An assessment review of each inspector's work shall be made during at least ~~two~~ three joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports of the same inspected establishments, during every self-assessment period.

[*NOTE: *Staff members who are within their initial 18 months of training and have not completed all prerequisite courses, 25 joint inspections and 25 independent inspections as required in Standard 2, are exempt from the joint on-site inspections and file reviews used in the performance measurement rating calculation in the Standard 4 Self-Assessment Worksheet.*]

Outcome

A quality assurance program exists that ensures uniform, high quality inspections.

Documentation

The quality records needed for this standard include:

1. A written procedure that describes the jurisdiction's quality assurance program that meets the criteria under the Description of Requirement section 1) ~~B~~(A)~~.~~, including corrective actions for deficiencies, and
2. Documentation that the program achieves a 75 percent performance rating on each ~~aspect~~ element using the self-assessment procedures described above.

EXPLANATION OF THE STATISTICAL MODEL for STANDARD 4

This is an explanation of the thinking that determined the statistical model relating to the criteria used for evaluating the inspectional performance of jurisdictions.

Evaluation of the performance of large jurisdictions

For large jurisdictions (jurisdictions with 10 or more inspectors), the evaluation is based on direct oversight of two inspections per inspector, with respect to 10 items of performance. If 10 or more inspectors are being evaluated in the program, then we will see 20 or more scores of satisfactory or unsatisfactory for each item. The standard for approval of the inspection performance is a passing score of 75% on each of the 10 items. An individual item receives a passing score if at least 75 percent of the instances of observation are completed in a satisfactory manner. For example, with 10 inspectors, we must have at least 15 (that is 75 percent of 20 inspections) completed correctly for item number 1. Similarly, for item number 2, we would need to see at least 15 inspections done correctly. In order for the program to pass the evaluation successfully with respect to inspection performance, all of the 10 items would be required to show satisfactory completion of at least 15 out of the 20 ratings. For those jurisdictions with more than 10 inspectors, we simply apply the 75 percent rule as we did for the jurisdiction with 10 inspectors. Using two overseen inspections for each inspector, record the observations for each item, figure the percent correct for each item, and round up to the next higher whole number when the percent is not a whole number.

The 75 percent per item rule was determined by the consensus of several highly experienced individuals working in the retail food safety team. We view the set of overseen inspections as a sample from a much larger set of total inspections performed. In this approach to program evaluation, the statistical measure does not evaluate any individual inspector. The emphasis is on the overall performance of the team, with respect to any item. Even if an inspection is observed in which one inspector fails all 10 items, the program would not necessarily fail.

The jurisdiction's quality assurance program, however, must address individual inspector's performance to ensure a standard of uniformity among the team. If each inspection were successful only 75 percent of the time for each item, the team as a whole would almost always fail. This is because they would almost always dip below 75 percent on at least one of the 10 items. For example, a team that scored 70, 70, 70, 75, 75, 75, 75, 80, 80, and 80 on each of the 10 items would be successful 75 percent of the time, but they would fail three times over since three items scored below 75. However, for a team with 10 inspectors exactly, if their chance of getting each item right improved to 88 percent at each inspection, then they would have a much better chance of keeping all 10 results at 75 percent or higher. Under the simple statistical assumption of independent sampling, a team achieving 88 percent at each inspection would pass the evaluation 75 percent of the time. Therefore, this 88 percent level of performance was used as a simple representation of a team that is good enough that we want them to have a

good chance of passing, but not so good that they would not find it advantageous to improve.

Evaluation of performance of small jurisdictions

A statistical issue was to determine a reasonable standard for those jurisdictions with less than 10 inspectors. When the sample gets this small, the relative error in the estimated fractions gets so large that the "each of 10 items rule" will fail good programs too frequently. Therefore, the 88 percent level of performance at each inspection was the feature of the standard that was kept constant in designing the sample sizes for the smaller jurisdictions

In jurisdictions with less than 10 inspectors, the statistical solution is to group all of the individual ratings, disregarding the individual items. For 5 inspectors we would review 5 x 2 = 10 inspections, with respect to all 10 items combined. This gives 100 observations. It is not possible to make a total observation test mimic exactly a 10 item test, but the minimum passing rates will be about as stringent as the 75 percent for each of 10 aspects test:

For 4 to 9 inspectors, conduct two joint inspections for each inspector. Chart 4-1 shows the lowest total passing score out of the complete set of combined items that would give at least a 75 percent chance of passing for a team with an 88 percent chance of getting any particular observation correct. For a team of three or less, it is recommended that extra oversight inspections be performed to produce a total of 8 inspections. This is an intuitive judgment call that any set smaller than 8 could randomly turn out to be odd enough to produce an unfair rating.

Chart 4-1
Method of Calculation for Jurisdictions with Less Than Ten Inspectors

# of inspectors	# inspections needed	# of items needed to be marked IN compliance in order to meet Standard 4 criteria
<4	8minimum	**65** (out of 80 possible Items)
4-9	2 per inspector	4 inspectors = **65** (out of 80 possible Items) 5 inspectors = **82** (out of 100 possible Items) 6 inspectors = **99** (out of 120 possible Items) 7 inspectors = **116** (out of 140 possible Items) 8 inspectors = **133** (out of 160 possible Items) 9 inspectors = **150** (out of 180 possible Items)

Update: EXPLANATION OF THE STATISTICAL MODEL for STANDARD 4

There is a proposal to change the number of performance elements used in Standard 4, resulting in the need to update the statistical model. Previously, in large jurisdictions (jurisdictions with 10 or more inspectors), the evaluation was based on direct oversight of two inspections per inspector, with respect to 10 performance elements. However, the proposal contains 20 performance elements instead of 10.

Using the previous statistical model and assumptions, a team achieving 88 percent at each inspection would pass the evaluation 75 percent of the time. Therefore, this 88 percent level of performance was used as a simple representation of a team that is good enough that we want them to have a good chance of passing, but not so good that they would not find it advantageous to improve. But now with 20 items instead of 10, a jurisdiction with 88 percent level of performance would pass only 59 percent of the time. This would fail too many high performing jurisdictions.

In order to rectify this, for large jurisdictions (jurisdictions with 10 or more inspectors), the evaluation must now be based on direct oversight of three inspections per inspector, with respect to 20 performance elements. With the additional inspections evaluated, the 88 percent performing jurisdiction will pass 75% of the time.

<u>Evaluation of performance of small jurisdictions</u>

A statistical issue was to determine a reasonable standard for those jurisdictions with less than 10 inspectors. When the sample gets this small, the relative error in the estimated fractions gets so large that the "each of 20 items rule" will fail good programs too frequently. Therefore, the 88 percent level of performance at each inspection was the feature of the standard that was kept constant in designing the sample sizes for the smaller jurisdictions

In jurisdictions with less than 10 inspectors, the statistical solution is to group all of the individual ratings, disregarding the individual items. For 5 inspectors we would review 5 x 3 = 15 inspections, with respect to all 20 items combined. This gives 300 observations. It is not possible to make a total observation test mimic exactly a 20 item test, but the minimum passing rates will be about as stringent as the 75 percent for the 20 item test:

For 4 to 9 inspectors, conduct three joint inspections for each inspector. Chart 4-1 shows the lowest total passing score out of the complete set of combined items that would give at least a 75 percent chance of passing for a team with an 88 percent chance of getting any particular observation correct. For a team of three or less, it is recommended that extra oversight inspections be performed to produce a total of 12 inspections. This is an intuitive judgment call that any set smaller than 12 could randomly turn out to be odd enough to produce an unfair rating.

Standard 4: Uniform Inspection Program Self-Assessment Worksheet

Chart 4-1: Method of Calculation for Jurisdictions with Less Than Ten Inspectors

# of inspectors	# inspections needed	# of items needed to be marked IN compliance in order to meet Standard 4 criteria
<4	12 minimum	200 (out of 240 possible Items)
4-9	3 per inspector	4 inspectors = 200 (out of 240 possible Items) 5 inspectors = 252 (out of 300 possible Items) 6 inspectors = 303 (out of 360 possible Items) 7 inspectors = 355 (out of 420 possible Items) 8 inspectors = 407 (out of 480 possible Items) 9 inspectors = 459 (out of 540 possible Items)

NOTE:

1. These minimum inspection program assessment criteria are comparable to the 75% IN Compliance rate for each of the ten inspection program areas for jurisdictions with 10 or more inspectors.

Example:

For 6 inspectors, there will be 3 field visits per inspector = 18 visits
18 visits X 20 Items per visit = 360 Total Possible Items

CONFERENCE FOR FOOD PROECTION

CERTIFICATION OF
FOOD SAFETY REGULATION PROFESSIONALS
WORK GROUP

UNIFORM INSPECTION PROGRAM AUDIT PILOT PROJECT REPORT

December 1, 2011

ACKNOWLEDGEMENTS

The following individuals and/or entities are to be recognized for their invaluable contributions to the development of this report and the implementation of the Uniform Inspection Program Audit Pilot Project

REGULATORY RETAIL FOOD PROTECTION PROGRAM – PILOT JURISDICTIONS

County of Santa Clara, Department of Environmental Health, Consumer Protection Division, CA

Florida Department of Agriculture, Food Safety Division, FL

City of Wichita, KS

Genesee County Health Department, MI

Minnesota Department of Agriculture, Dairy and Food Inspection Division, MN

Olmsted County Public Health Services, MN

St. Charles County, Department of Community Health and the Environment, MO

Taney County Health Department, MO

Yellowstone City-County Health Department dba RiverStone Health, MT

Lincoln-Lancaster County Health Department, NE

Oregon Department of Agriculture, OR

Texas Department of State Health Services, TX

Wisconsin Department of Agriculture, Trade, and Consumer Protection, WI

Wyoming Department of Agriculture, Consumer Health Services, WY

ACKNOWLEDGEMENTS

CONFERENCE FOR FOOD PROTECTION

CERTIFICATION OF FOOD SAFETY REGULATION PROFESSIONALS WORK GROUP

Rance Baker, National Environmental Health Association

Angela Benton, Jetro/Restaurant Depot

Martin Bucknavage, Penn State University

Lee M. Cornman, Florida Department of Agriculture, Food Safety Division

Catherine Cummins, Virginia Department of Health

Vicki Everly, Retired – Local Regulatory

Jim Fear, U.S. Food and Drug Administration

Michael Gentry, Alaska Department of Environmental Conservation

Ron Grimes, Co-Chair, NSF International

Joe Hainline, Jefferson County Health Department, MO

Cheryn Hargrave, United Supermarkets

Ruth N. Hendy, Texas Department of State Health Services

DeBrena Hilton, Tulsa Health Department, OK

Christina N. Johnson, Publix Super Markets, Inc.

Susan Kendrick, Co-Chair, Oregon Department of Agriculture

John Marcello, U.S. Food and Drug Administration

David McSwane, Indiana University

Stephanie Mohn, Marsh Supermarkets

Michelle Motsinger, Colorado Department of Public Health and Environment

Duane O'Donnell, Business Environmental Resource Center

Melvin Pascall, Ohio State University

Angela Paymard, N2N Global

David Read, Minnesota Department of Agriculture

Amy Roedl, National Restaurant Solutions

Michele Samarya-Timm, Somerset County Department of Health, NJ

Zia Siddiqi, Orkin Commercial Services

Joyce Thread, Saint Louis County Department of Health, MO

Uniform Inspection Program Audit
Pilot Project Report

Table of Contents

Page

Uniform Inspection Program Audit
Pilot Project Report

Appendices

Page

Executive Summary

The Certification of Food Safety Regulatory Profession (CFSRP) Work Group, originating with the 2004 Conference for Food Protection (CFP), has been working with representatives of the Food and Drug Administration to create a multi-tiered process for training and standardizing Food Safety Inspection Officers (FSIOs). The goal of this initiative is to develop a nationally recognized training and standardization process for FSIOs that can be used as a model by retail food regulatory programs to enhance the effectiveness of food establishment inspections and increase uniformity among regulatory professionals in their assessment of food safety practices in the retail food industry.

Over the past 5 years, the CFP CFSRP Work Group has used the criteria contained in the *FDA Voluntary National Retail Food Regulatory Program Standards (FDA Program Standards)*, Standard 2 – Trained Regulatory Staff to develop a comprehensive training model for regulatory retail Food Safety Inspection Officers. Jurisdictions using the CFP field training process and forms have indicated an overwhelmingly favorable experience.

Results from the follow-up interviews with jurisdictions using the Standard 2 criteria to train their retail food inspection staff indicated support for the development of an audit tool that mirrored the CFP field training process. The 2010 Conference charged the CFSRP Work Group with coordinating a pilot project to assess the appropriateness of using a customized version of the FDA Retail Food Level I Performance Audit process and forms with a limited number of jurisdictions enrolled in the FDA *Voluntary National Retail Food Regulatory Program Standards.*

The primary objective of the pilot project was to evaluate the *Uniform Inspection Program Audit* process and *Audit Worksheet* as tools for conducting the quality assurance evaluations included as part of Standard 4 – Uniform Inspection Program criteria. The Standard 4 criteria requires an assessment of each inspector's work during at least two joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports of the same inspected establishment. A model template for conducting this type of field assessment is not currently provided in Standard 4. One of the intended outcomes of the pilot project was to assess the feasibility for incorporating the *Uniform Inspection Program Audit* process and *Audit Worksheet* as model template contained in an Appendix to Standard 4.

A pilot application of the *Uniform Inspection Program Audit* process and *Audit Worksheet* was conducted by 14 retail food regulatory programs between July, 2010 and June, 2011. The type and number of jurisdictions that participated in the pilot project are: State (6), County (7), and City (1). The population living in the pilot jurisdictions ranged from 50,000 to more than 500,000. The total number of retail food and foodservice establishments under permit in the pilot jurisdictions ranged from 101 to over 6,000. The pilot jurisdictions were selected from regulatory agencies enrolled in the *FDA Voluntary National Retail Food Regulatory Program Standards* that had reported meeting the training requirements described in Steps 1 through 3 of Standard 2 – Trained Regulatory Staff.

A total of 76 FSIOs were assessed using the quality assurance inspection program criteria contained in Standard 4. A total of 42 FSIOs successfully performed all 10 Program Elements during the audit process. Seventy-one percent (71%) indicated that the uniform inspection program audit process is designed to facilitate a strengths-weaknesses assessment of a regulatory jurisdiction's retail food inspection program

More than seventy-eight percent (78.6%) of the pilot participants agreed that the Uniform Inspection Program audit process was a valuable use of their jurisdiction's resources. Most respondents were complimentary to the process and identified it as a "good start." These same respondents, however, submitted several recommendations for enhancing the effectiveness of the audit process and audit worksheet. Some of the recommendations were specific to re-evaluating the 10 Program Elements described in Standard 4 criteria.

Key recommendations for enhancing the effectiveness of the Standard 4 include, but are not limited to:

- Aligning the 10 Program Elements described in Standard 4 with the Performance Elements and Competencies contained in the Standard 2 – *CFP Field Training Plan* for new hires or staff newly assigned to the retail food protection program.
- Providing a linear listing of the Program Elements in Standard 4 to reflect an organized flow to the inspection process.
- Providing an assessment system that differentiates between the complexity and importance of the 10 Program Elements, particularly as they are assessed during the inspection review process.
- Clarifying the Standard 4 criteria as to what qualifications an individual charged with assessing the performance of field staff should have and what type of establishments should be selected for the file and field review.
- Re-evaluating the system currently in place for determining compliance with the Standard 4 criteria. The Standards are intended to apply to the operation and management of regulatory retail food programs NOT as assessments of practitioners in the field. The current system weighted on a practitioner's ability to demonstrate the 10 Program Elements during field inspections seems to be skewed more toward an assessment of the individual rather than an evaluation of the regulatory retail food inspection program.

The CFP CFSRP Work Group has prepared two issues related to the Uniform Inspection Program Audit Pilot Project for deliberation at the April 2012 Conference for Food Protection (CFP) in Indianapolis, IN. The issues include a recommendation for the Conference to send a letter to FDA requesting review of the recommendations outlined in this pilot project report including potential revisions to the Standard 4 criteria. The FDA review process is to illicit input and feedback from the CFP Program Standards Committee.

Introduction

Pilot Project

A pilot program began during the biennial CFP Conference in April 2010 when jurisdictions at all levels were solicited for their participation. During the conference, a fact sheet was distributed to prospective participants with basic information regarding the project. A gap analysis was conducted of the interested jurisdictions to determine if additional solicitation was needed to attain a demographically representative sample to reflect a national composition of regulatory retail food protection programs. In May of 2010, participant jurisdictions were selected and pilot project information packages were distributed.

In June of 2010, conference calls were held with the selected jurisdictions to provide them an overview of project objectives and information regarding the goals, methodology, data collection, and other pertinent issues. The pilot project was then launched in the summer of 2010 with a total enrollment of 14 State and Local jurisdictions. Additional conference calls were held as needed throughout the project and participating jurisdictions were able to correspond as needed with the Project Managers (Ms. Lee Cornman, Ms. Susan Kendrick, and Mr. John Marcello) for answers to their questions and problem resolution.

The pilot project was completed in July 2011 and this report represents the results.

Uniform Inspection Program Audit Pilot Project – Jurisdiction Feedback Form

To facilitate data collection on the project results and use of the Audit Worksheet, a survey instrument was designed for completion by the participant jurisdictions. The survey instrument titled, *Jurisdictions Feedback of the Audit Process and Forms*, (included as Appendix A), was designed to provide a structured process for collecting and analyzing feedback on the project. Results were then tabulated using statistical scoring software and narrative comments were tabulated and analyzed by Committee members.

For purposes of this report, the project results are presented in the same format as the actual Audit Process Feedback Form with each question appearing first followed by the tabulated results depicted in bold and within parenthesis after each response variable. Additionally, a summary of the analysis of the results is provided with tables and graphics where appropriate.

Pilot Project Objectives

The primary objectives of the pilot project focused on an assessment of the Uniform Inspection Program Audit Worksheet (included with this pilot project package) as a tool for the quality assurance evaluations conducted as part of Standard 4. Companion documents that included instructions and formats for using the Uniform Inspection Audit Worksheet were also included with this pilot project package.

Pilot project participants:

- Determined the strengths and weakness of the Uniform Inspection Audit Worksheet; instructions; and guidance documents.

- Provided feedback on the ease of use of the documents, including the instructions and format. Were jurisdictions able to use the documents independently without direct supervision or oversight?
- Determined the length of time required to use the documents and complete the audit process.
- Determined whether the audit process is an appropriate to assess the FSIO's knowledge, skills and ability when applying the competencies required during a field inspection.
- Reviewed the 10 inspection program areas and competencies that comprise the Uniform Inspection Program Audit Worksheet for omissions, additions, and items they deem to be not applicable.
- Determined whether the audit process is properly positioned as part of the Standard 4 criteria.

Uniform Inspection Program – *Audit Worksheet*

A significant component of the pilot project was the use of the Uniform Inspection Program – *Audit Worksheet*. This worksheet was developed during 2008 and 2009 after the CFP Certification for Food Safety Regulatory Professionals Work Group completed a comprehensive review of the field audit process used by FDA for their Consumer Safety Officers. The Uniform Inspection Program – *Audit Worksheet* was designed to be used by the jurisdictions as a quality assurance tool to measure the effectiveness of a jurisdiction's inspection program based on the performance elements and competencies identified in the Standard 2 – Trained Regulatory Staff, Field Training Plan. The use of the Uniform Inspection Program Audit provides a mechanism for regulatory jurisdictions to conduct quality assurance evaluations of their retail food protection programs while assessing the strengths and weakness within their training program for Food Safety Inspection Officers.

The data and feedback received from the pilot project jurisdictions on actual use of the Uniform Inspection Program – *Audit Worksheet* provide important insights on the strengths and weaknesses of using the Standard 4 criteria and assessment protocol as a quality assurance measurement. As a result of input received during the project, the CFP Certification for Food Safety Regulatory Professionals is submitting an issue to the 2012 Conference recommending that the Standard 4 criteria be reviewed, and revised were appropriate, to better reflect a comprehensive inspection program quality assurance protocol and measurement.

Terminology

For purposes of this report, the following terms and acronyms are defined:

Audit Worksheet – *Worksheet* used by jurisdictions during the two joint food safety inspections to assess FSIOs ability to demonstrate specific performance elements and competencies

FSIO – Food Safety Inspection Officer is an individual that has been newly hired or newly assigned to a regulatory retail food program

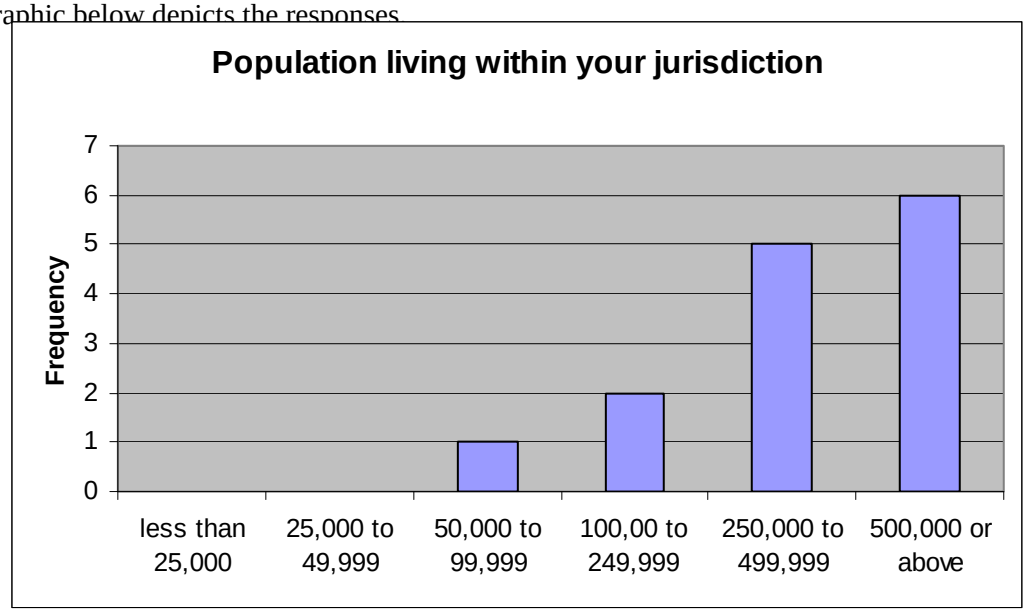
Uniform Inspection Program - Jurisdiction Audit Feedback Form – The survey instrument used during the pilot project to collect data and feedback from jurisdictions on the uniform inspection program audit process and forms. Terms in the narrative of the report pertaining to "survey"; "survey instrument"; and/or "survey questions" are direct references to the Jurisdiction Audit Feedback Form.

Section I - Demographics of Participant Jurisdictions

What is the population living within your Jurisdiction?

A. less than 25,000 **(0)**	**B.** 25,000 to 49,999 **(0)**	**C.** 50,000 to 99,999 **(1)**
D. 100,000 to 249,999 **(2)**	**E.** 250,000 to 499,999 **(5)**	**F.** 500,000 or above **(6)**

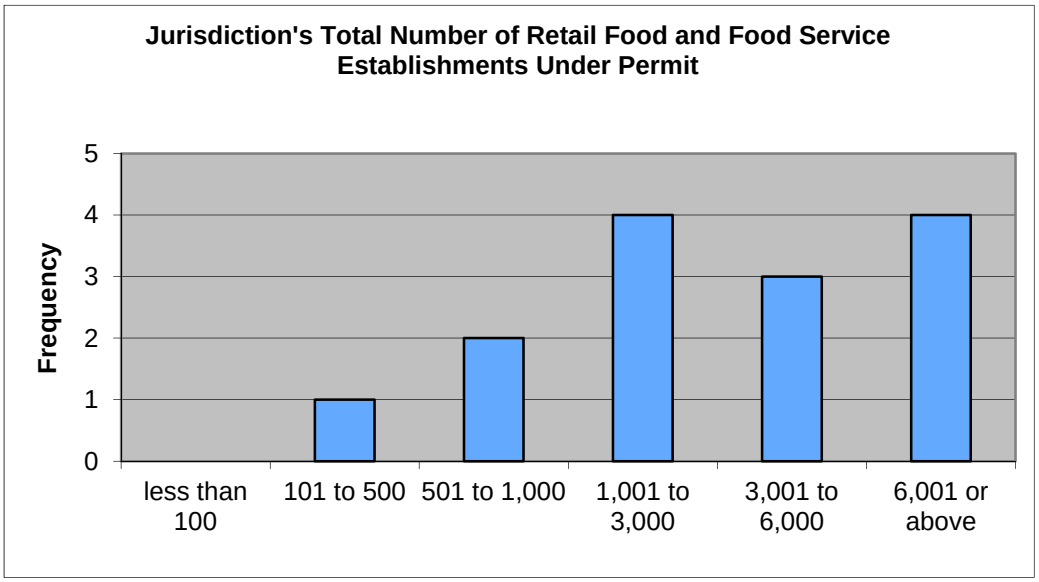
A total of 14 jurisdictions participated in the Audit Pilot Project. The population in these jurisdictions ranged from one jurisdiction with a population of 50,000 to 99,999 to 11 jurisdictions with populations of 250,000 or higher. Of the jurisdictions responding, 43% had population sizes of 500,000 or higher. The graphic below depicts the responses.



What is your Jurisdiction's total number of retail food and foodservice establishments under permit?

A. less than 100 **(0)**	**B.** 101 to 500 **(1)**	**C.** 501 to 1,000 **(2)**
D. 1,001 to 3,000 **(4)**	**E.** 3,001 to 6,000 **(3)**	**F.** 6,001 or above **(4)**

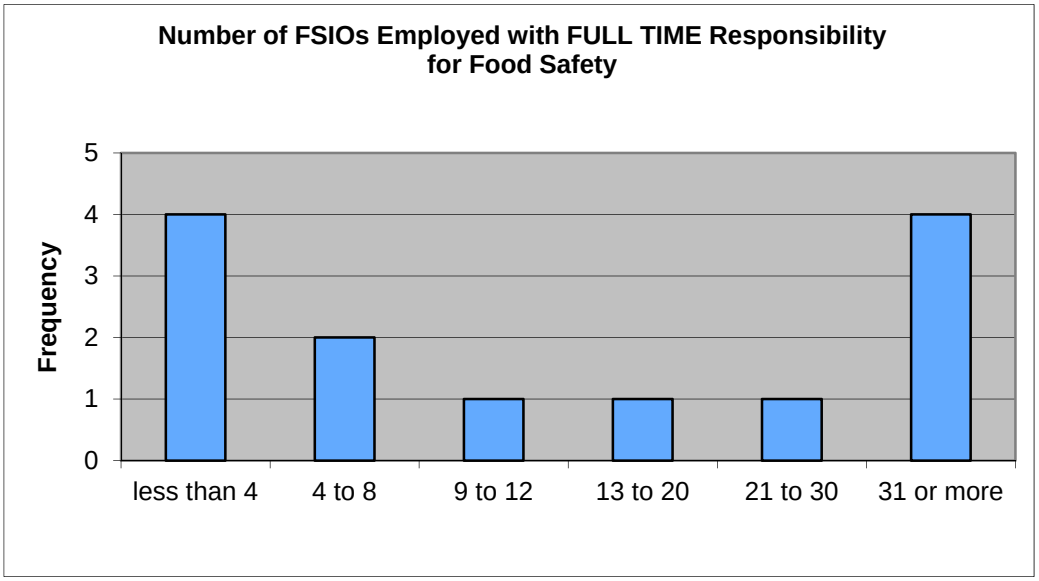
Of the 14 jurisdictions responding, no jurisdictions had less than 100 foodservice establishments under permit, while seven reported 3,001 or more such establishments. Fifty-nine percent (59%) of the jurisdictions reported having 3,001 or more establishments under permit. Twenty-nine percent (29%) of the jurisdiction reported having 6,001 or more establishment under permit. The graphic that appears at the top of the next page depicts the responses.



How many Food Safety Inspection Officers are employed by your Jurisdiction with FULL TIME (i.e., 100%) responsibility in the food safety program?

A. less than 4 **(4)** **B.** 4 to 8 **(2)** **C.** 9 to 12 **(1)**
D. 13 to 20 **(1)** **E.** 21 to 30 **(1)** **F.** 31 or more **(4)**
G. No Response **(1)**

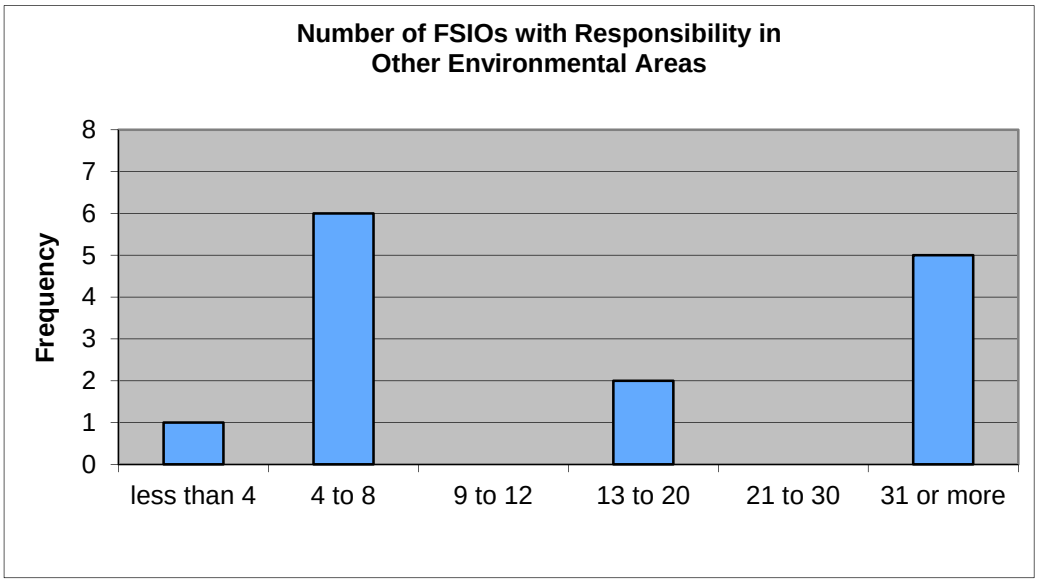
Of the 13 jurisdictions responding, four (31%) reported having less than 4 full-time FSIOs while four (31%) reported having 31 or more full-time FSIOs. The median number of responding jurisdictions was 9 to 12 full-time FSIOs. The chart below depicts the responses.



How many Food Safety Inspection Officers are employed by your Jurisdiction with responsibilities in other environmental health program areas in addition to their retail food protection duties?

A. less than 4 (1)	**B.** 4 to 8 (6)	**C.** 9 to 12 (0)
D. 13 to 20 (2)	**E.** 21 to 30 (0)	**F.** 31 or more (5)

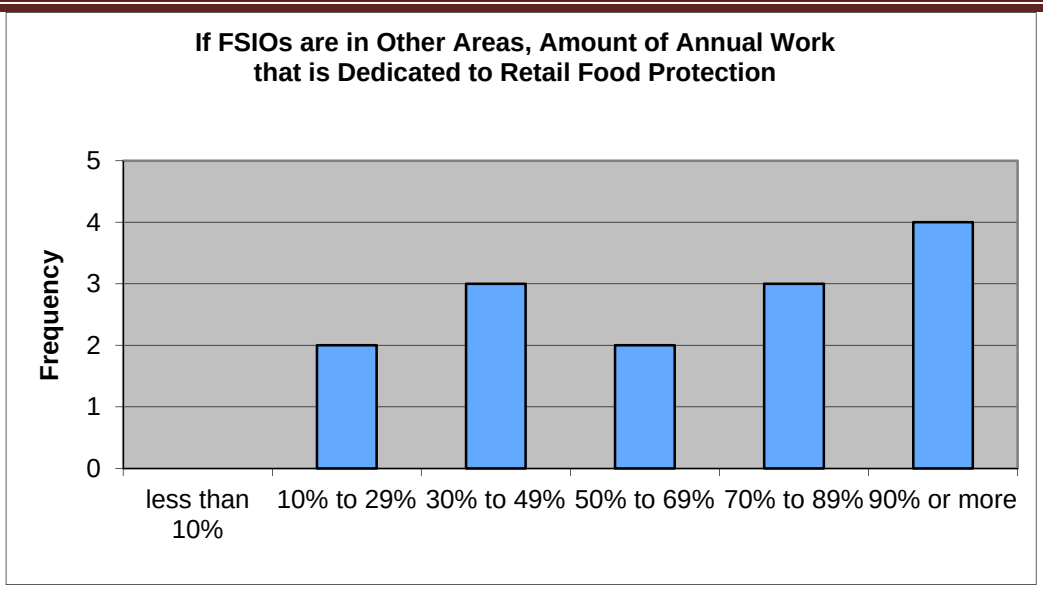
Of the 14 jurisdictions responding, the number of FSIOs with responsibilities in other environmental health program areas in addition to their retail food protection duties ranged from one jurisdiction with less than 4 FSIOs with alternate assignments to five jurisdictions (36%) having 31 or more FSIOS with alternate assignments. The graphic below depicts the responses.



If your Food Safety Inspection Officers have responsibilities in other environmental health program areas, on average, how much of their annual work plan is dedicated to the retail food protection program?

A. less than 10% **(0)**	**B.** 10% to 29% **(2)**	**C.** 30% to 49% **(3)**
D. 50% to 69% **(2)**	**E.** 70% to 89% **(3)**	**F.** 90% or more **(4)**

Of the 14 jurisdictions responding, two jurisdictions reported that their FSIOs dedicate, on the average, 10% to 29% of their annual work plan to the retail food program, while seven jurisdictions (50%) reported that their FSIOs dedicate 70% or more on their retail food program responsibilities. Twenty nine percent (29%) reported that their FSIOs dedicate 90% or more percent of their annual work plan to the retail food protection program. The following graphic appearing at the top of the next page depicts the response.



Is your Jurisdiction AWARE of the *FDA Draft Voluntary National Retail Food Regulatory Program Standards*?

Yes **(14)** No **(0)**

All 14 jurisdictions responding reported that their jurisdiction is aware of the *FDA Draft Voluntary National Retail Food Regulatory Program Standards.*

Is your Jurisdiction ENROLLED in the *FDA Draft Voluntary National Retail Food Regulatory Program Standards?*

Yes **(14)** No **(0)**

All 14 jurisdictions responding reported that their jurisdiction is enrolled in the *FDA Draft Voluntary National Retail Food Regulatory Program Standards.*

If enrolled in the *FDA Draft Voluntary National Retail Food Regulatory Program Standards*, has your jurisdiction MET all the Standard 2 – Trained Regulatory Staff criteria?

Yes **(14)** No **(0)**

All 14 jurisdictions responding reported that their jurisdiction meets the Standard 2 – Trained Regulatory Staff criteria contained in the *FDA Draft Voluntary National Retail Food Regulatory Program Standards.*

Does your Jurisdiction have a written field training plan that identifies the specific job performance elements and competencies a FSIO is expected to demonstrate during foodservice and retail food inspections?

Yes **(14)** No **(0)**

All 14 jurisdictions responding reported that their jurisdiction has a written field training plan that identified the specific performance elements and competencies a FSIO is expected to demonstrate during inspections of foodservice and retail food establishments.

If your answer to Question #9 above is YES, please identify the type of written FSIO field training plan that is in use within your jurisdiction.

Of the 14 jurisdictions responding, 12 jurisdictions (86%) indicated that they use a customized version of the CFP Field Training Plan included as an Appendix with Standard 2 – Trained Regulatory Staff.

A. The CFP Field Training Plan as presented in Appendix B-2, Standard #2 – Trained Regulatory Staff, *FDA Voluntary National Regulatory Retail Food Program Standards* **(0)**	**C.** A Field Training Plan developed in-house that meets the intent and scope of the CFP Field Training Plan **(1)**
B. A customized version of the CFP Field Training Plan, Appendix B-2, Standard #2 – Trained Regulatory Staff that is specific to our jurisdictions retail food inspection protocol **(12)**	**D.** Other **(1)**

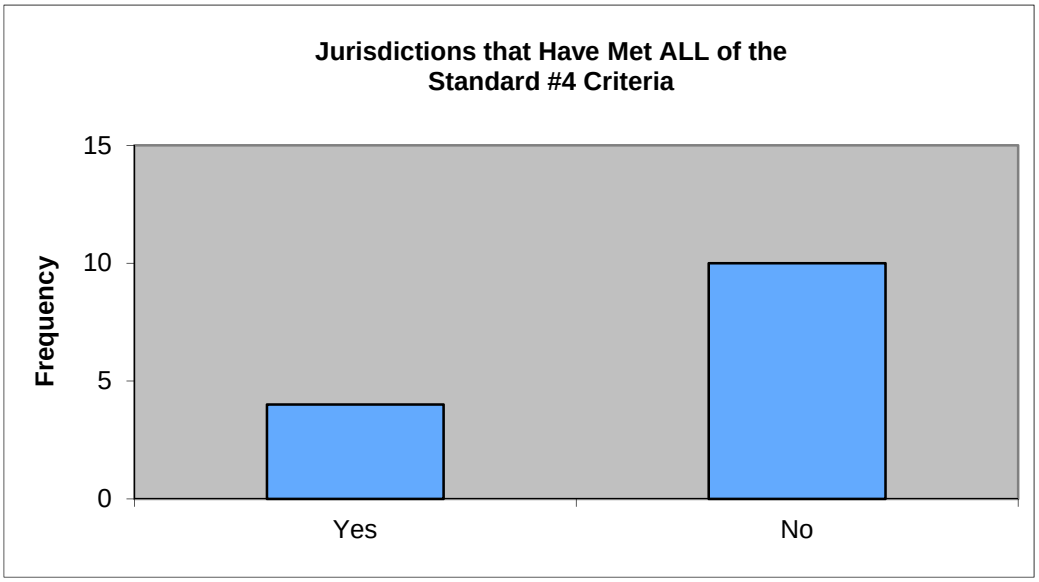
- We are moving from a Field Training Plan program developed in-house to a customized version of the CFP Field Training Plan. Mostly we are using a customized version.
- We have written policies and procedures for staff to follow while conducting inspections.

- We have specific protocols for inspections, training and enforcement that closely emulate federal standards and include state of Michigan accreditation standards.
- Our field training worksheet is almost identical to the one in Appendix B, except some sections are removed or slightly edited. For example, we don't use the section about sampling.
- Our agency has added the following to the CFP Field Training Plan: 1) the FSIO completes an open-book exercise on the content of the Texas Food Establishment Rules; 2) the FSIO must complete a citation exercise on the first 25 independent inspections.
- We have adopted the CFP Field Training Plan Appendix B-2 as presented and all FSIO's/Inspectors have completed the necessary training needs as specified by the Taney County Health Department, TCHD. The training involves mandatory state trainings and jurisdiction specific requirements as determined by the agency administrator.

If enrolled in the *FDA Voluntary National Retail Food Regulatory Program Standards,* has your Jurisdiction MET all the Standard #4 – Uniform Inspection Program criteria?

Yes **(4)** No **(10)**

While all 14 jurisdictions reported meeting the Standard 2 – Trained Regulatory Staff criteria contained in the *FDA Draft Voluntary National Retail Food Regulatory Program Standards,* only 4 (29%) indicated they met the Standard 4 – Uniform Inspection Program criteria. The graphic appearing at the top of the next page depicts the response.


Jurisdictions that Have Met ALL of the Standard #4 Criteria
Frequency
15
10
5
0
Yes
No

Section II - Guide to Uniform Inspection Program Audit - Content Evaluation

Were the instructions given in the *Guide to the Uniform Inspection Program Audit* sufficient for you to understand and implement the uniform inspection audit process in your jurisdiction?

Yes **(11)** No **(3)**

The majority of respondents (78.6%) indicated that the instructions given in the Guide were sufficient for understanding and implementation of the audit process.

Please put an "X" in the boxes below to identify any Section(s) of *the Guide to the Uniform Inspection Program Audit* you believe needs improvement. Please provide your recommendation(s) for improving the *Guide* in the space provided for each subject area. The page number from the *Guide* for each subject area is included in parentheses. If you have no recommended changes for a specific Section of the Guide, leave the corresponding box and comment area blank.

GUIDE TO THE UNIFORM INSPECTION PROGRAM AUDIT

***Preparing for Pilot Project Participation* (page 1)**

The write-in comments for this section are summarized below:

- Recommend clarifying that the review of the most recent three "inspection reports" are "regular" or "routine" inspections.
- The link to the Clearinghouse Q&A would not work.
- My overall comments on the document are that it's not helpful. We need a document similar to what was developed for Standard 2 that really explains the criteria for each component of the standard. This doesn't do it. We used it for about 4 staff members and found it to be too long and too cumbersome. We developed a one page summary that we used for the rest of our staff with whom we have done the joint inspections. The major item missing is the competencies, the criteria, for the ten elements--what is acceptable and what is not acceptable
- After the following statement:

  "After completing the training requirements in Steps 1 through 3, Standard 2, Trained Regulatory Staff,"

  List the steps 1 through 3. This gives the reader the needed information instead of having to look on another document to know what the 3 steps are. It may be helpful to describe/define "inspection quality" and the value of assessing quality via an audit process.

***Purpose of the Uniform Inspection Program Audit* (page 2)**

The write-in comments for this section are summarized below:

- Purpose of the UIP could have been expanded and explained a little better.
- The explanation of the purpose of the Uniform Inspection Program Audit was clear and understandable**.**

Selection of Establishments **(page 2)**

The write-in comments for this section are summarized below:

- How to select establishments was confusing. One question that was raised was how we could ensure establishments were not selected (or guard against) because of the amount of time an inspection would take (i.e. pick the "easy" ones).
- There should be additional clarification on determining what facilities should be selected as audit locations. Go back 3-5 years in the file to establish the firm has a history that needs follow-up, since many questions address issues from follow-up on previous violations and long term compliance. For example, pick complex establishments to make sure they are representative of all the components you need to evaluate.
- What are the standard 4 criteria that are to be followed in selecting establishments for the audit?
- The highest risk category establishments should always be included in the evaluation process even if the majority of the workload in the FSIO's jurisdiction is low risk.
- Selection of establishments should be from categories 3 and 4 from 2009 FDA Food Code Annex 5, Table 1 - Risk Categorization of Food Establishments,
- More guidance, education and direction to managers to ensure that they use strategies that involve randomization which will significantly help reduce potential for bias from a statistical standpoint. This will increase the reliability of the data collected.
- List the criteria from Standard 4. This gives the reader the needed information instead of requiring the reader to look on another document.

File Review – Selected Establishments **(page 2)**

The write-in comments for this section are summarized below:

- Include direction to compare what has changed at the store to the file history (name, operations, menu, etc.) so the need for changes in risk category or inspection frequency are identified.
- Must all 3 inspections in the file review have been completed by the inspector who is being audited? If so, how should newer inspectors be audited? For example, if a restaurant receives one inspection per year, it may be up to 4 years before an inspector can be audited.
- File review could be more clearly defined to include all auxiliary activities related to the establishment e. g. sampling, consumer complaints etc. that may not be included in the 3 most recent inspection reports.
- There needs to be more explanation for what items of the inspection report is to be reviewed during the file review.

FSIO's Role During Joint Field Inspections **(page 2)**

The write-in comments for this section are summarized below:

- To expect no communication between the FSIO and the auditor is unrealistic. There will be questions asked from both parties.
- The statement "The FSIO is responsible for independently conducting the inspection while being evaluated by the auditor." gives a mixed message, as the audit isn't about evaluating the FSIO. The audit's purpose is to identify strengths and weaknesses within the training program as one means of assessing quality.

***Uniform Inspection Auditor's Role During Joint Inspections* (page 2)**

The write-in comments for this section are summarized below:

- This is the hardest part of the audit program. When should the auditor step in if the FSIO is giving incorrect corrective actions or missed a potential imminent health hazard. It is very hard to watch the inspection and not give input. It really shows the value of standing back and observing what is going on in the facility as a whole and not jumping to details.
- There is no guidance included for auditor qualifications, only their role during the inspection. This can be difficult for some jurisdictions when there are union contracts, etc. There should be additional training requirements for the auditors specifically on the subject of auditing, since that will make a difference in how the audit protocol is applied and interpreted in the field.
- Please clarify whether or not the auditor should step in if the inspector misses a violation: a) during the inspection? b) at the end of the inspection, before leaving the facility, or c) not at all? Does this answer depend on the nature of the violation, e.g. a non-critical violation vs. a critical violation or a violation that involves adulteration (for example, an employee is about to serve a contaminated food item to a customer)?
- Needs to be expanded so this will not be a re-standardization. Also might list qualifications for the auditor. If the FSIO's are one's own employees then there might be a "halo effect."
- The auditor will have a role during the inspection. The auditor--that third person--will have an impact on the person in charge as well as the FSIO being audited. It needs to be acknowledged and recognized that the FSIO will think their manner of conducting an inspection is being assessed--as it is.
- Auditors need some more education in regard to their role during the inspection.
- Provide a systematic selection process for choosing establishments randomly with more specific criteria such as: establishments must have had an inspection within the last week/month/year; the establishment must be open for business for a set amount of time prior to the audit (such as 1-2 years); the inspector should have previously inspected the select establishments for a specified number of visits (for those jurisdictions with rotating work lists) prior to the audit; to name a few.
- One establishment selected for our audit had not been inspected for over one year and made it hard to track past inspection findings, compliance, and enforcement. Some other establishments selected for the audit were previously inspected by a different inspector which also made it hard to track. It seems that a lack of more specific selection criteria could possibly skew audit results.
- List the standard 4 criteria. This gives the reader the needed information instead of requiring the reader to look on another document.

***Pilot Project Steps – Uniform Inspection Program Audit – Step 1* (page 2)**

Only one generic comment for this section:

- This looks good

***Pilot Project Steps – Uniform Inspection Program Audit – Step 2* (page 3)**

Only one generic comment for this section:

- Step 2 This looks good

Pilot Project Steps – Uniform Inspection Program Audit – Step 3 **(page 3)**

The write-in comments for this section are summarized below:

- The guidance is confusing when it states "establishments used in the audit must be selected in accordance with the protocol outlined in Appendix D, Std 4". It should clearly state the "number of establishments that need to be selected" instead of just "establishments" since that appendix only addresses the statistical calculations and the number of establishments needed. The way it is currently written implies that protocol for the actual facility selection is found in Appendix D.
- The guide states that "Establishments used in the audit must be selected in accordance with the protocol outlined in Appendix D, Standard 4." This appendix does not specify how establishments should be selected. Establishments selected should be from categories 3 and 4 from 2009 FDA Food Code Annex 5, Table 1 - Risk Categorization of Food Establishments
- Step 3 looks good.

Pilot Project Steps – Uniform Inspection Program Audit – Step 4 **(page 3)**

The write-in comments for this section are summarized below:

- Again, the competencies for the 10 criteria are not outlined in this document, nor is the audit tool clearly defined.
- Found the Uniform Inspection Program Audit Reference Guide to be very helpful as an auditing tool for determining competencies to observe for each inspection program area. Would prefer using it not only in conjunction with this pilot project, but for future audits as well. The examples were helpful and kept the auditor on task
- Include the 10 inspection program areas listed in standard 4, so the reader doesn't have to refer to another document

Pilot Project Steps – Uniform Inspection Program Audit – Step 5 **(page 3)**

The write-in comments for this section are summarized below:

- Unclear on what is being looked at by the auditor during the file review. Make sure the FSIO acts on repeat violations or the establishment is acting upon their risk control plans?
- I think I understand, but not sure why the Guide says that the auditor should complete the "Audit Results Summary section of the Audit Results Summary and FSIO Training Plan Form." Why not just say that the auditor should complete the "Audit Results Summary and FSIO Training Plan Form"?
- The following sentence "The Audit Results Summary establishes a method for providing feedback to the FSIO and identifies any inspection program areas or competencies the FSIO needs additional training on." Is confusing. It gives the impression that the Audit and the Assessment of Training Needs processes have the same purpose. Because the 10 inspection program areas are broad (not linked to specific performance elements like the Assessment of Training Needs is) it may be inaccurate to identify an individual's specific training needs based upon 1 or 2 inspections where an auditor is present. The audit seems more suited to identifying areas where further policy development and/or training is needed for all (and where overall strengths are found).

Pilot Project Steps – Uniform Inspection Program Audit – Step 6 **(page 3)**

The write-in comments for this section are summarized below:

- It was not clear from the guide that for the pilot project this calculation was an optional step. Only a portion of our staff was audited to do this project, so this step was not possible. However, the step would be clear if the document was for guidance to evaluate the entire program and not just for the purpose of completing this pilot project.
- Attach the tables from Appendix D, Standard 4, so that the reader can access all needed information in one place.

Pilot Project Steps – Uniform Inspection Program Audit – Step 7 **(page 3)**

No comments were submitted for Step 7

Uniform Inspection Program Audit Pilot Project – Reference Documents **(page 4)**

Only one comment for this section:

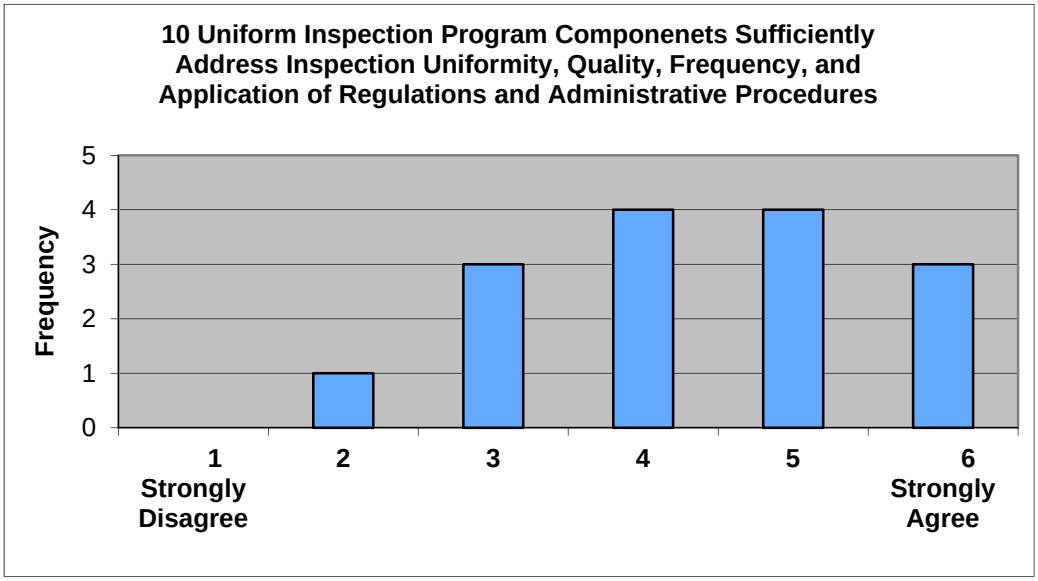
- Add 2009 FDA Food Code as a reference document

Section III
Audit Worksheet and Audit Reference Guide – Content Evaluation

The 10 Uniform Inspection Program Components included on the *Audit Worksheet* (and identified on page 1 of the *Audit Reference Guide*) sufficiently address inspection uniformity, inspection quality, inspection frequency, and uniform application of the regulatory jurisdictions retail food safety regulations and administrative procedures and are appropriate for all retail food program inspection staff. *(Please place an "X" in the box next to the rating that reflects the level of your agreement or disagreement with this statement).*

Strongly Disagree					**Strongly Agree**
1	**2 (1)**	**3 (3)**	**4 (3)**	**5 (4)**	**6 (3)**

Responses to this statement ranged from a low of 2 to a high of 6 with a mode (most frequently selected response) of 5. The mean (average) was 4.36 and the median (midpoint) was 4.5. Half of the jurisdictions (50.0%) selected 5 or higher, agreeing that the 10 performance elements sufficiently address the knowledge and skills a FSIO needs to effectively conduct independent inspections. The graphic below depicts the responses:



Please explain the reasons used to determine this rating.

Positive comments:

- Components made sense and had a lineal path.
- The audit guide explains the worksheet well. The program works well for local health depts. in Michigan that inspect retail food service establishments. Our state accreditation requirements are closely matched to the inspection components.
- All these components are the key to performing the job effectively because they cover all the knowledge, skills and abilities that FSIO's are expected to have to be successful.
- The audit reference guide was helpful in determining what performance elements should be considered for each section of the audit form.

Challenges:

- It was sometimes difficult to distinguish which category to debit some of the observations because they either blended together or required double debiting because of the nature of the observation.
- Some of the points are subjective and lead to individual interpretation.
- The Audit Worksheet is all subjective; there are no objective standards set for the competencies.

Recommendations for improvement:

- It could be broken down to be more detailed, to be a bit more specific to the needs.
- I believe item #1 can be best determined by creating a checklist, then based on a percentage, the auditor notes YES or NO.
- The identified categories are all there. However, the vagueness of the questions, the order in which the questions were organized, and the performance areas/competencies that are used as examples for each question in the guide do not seem logical for the purpose of conducting a field audit. Many times, the performance area/competency listed in the Reference Guide did not seem related to the question. Also, the weight of each question (i.e. the number of inspectional performance areas/competencies that each question was supposed to represent) did not seem equal for all questions. For example, questions 1 and 2 represented 5 or more competencies while question 10 represented only 1 competency. Additionally, for remotely located staff there can be some difficulty with establishing question 10 based on program policy (we typically mail all inspection and tracking documents in once a week, not per inspection, which is difficult for the auditor to determine while still completing the worksheet for one inspection and presenting findings in a timely manner to the auditee). There also seems to be overlap between question 2 and subsequent questions that discuss documentation in the Reference Guide. Proper documentation (whether a violation in routine inspection report as repeat occurrence or with additional regulatory documentation such as sanitary notice, embargo, etc.) seems to fall under both 2 and 6. There also appears to be overlap between 2 and 4 in regards to documentation in the inspection report for the code provisions (is it there vs. is it accurate?). The documentation for 7 could also be interpreted as being under 2 as well. Items 8-10 might also be better evaluated at a program level through management of resources and follow-up instead of at the individual inspection level. Whether or not the required frequency of inspection is being met could be based on many different factors and I don't think that is captured here (resources vs. improperly assigned risk category vs. management of facility inspection schedules based on risk). Number 8 is limited to long term corrections for continued out of compliance and could be better represented as long term corrections for all out of compliance findings (as opposed to just repeat violations).
- I wish there were a good way to include inspectors' demeanor as part of this audit. For example, focusing on educating the restaurant employees and fostering an atmosphere of change (when necessary), as opposed to focusing on the enforcement of violations through use of force or intimidation.
- Found competencies #1 and #4 to be similar when completing the audit worksheet. The 10 uniform component questions were vague and need to be more specific for the auditor to follow.
- The program components provide a means to sufficiently assess inspection frequency and uniformity (across the 10 components). The 10 components do not adequately address inspection quality. Uniformity does not always equal quality. In order to promote success in long-term control of foodborne illness risk factors, the program components should include an assessment of a food program's capacity for conducting effective risk-based inspections.

The required minimum of two retail food establishment file reviews and joint field inspections for each FSIO is the appropriate number for completing a uniform inspection program audit

Yes **(11)** No **(2)** Both **(1)**

The majority of jurisdictions 78.6% felt that the minimum of two retail food establishment file reviews and joint field inspections for each FSIO is the appropriate number for completing the inspection program audit.

Explanations provided for the responses to the question above.

YES – the minimum of two file reviews and joint inspections are appropriate

- Agreed. Was hard for us to meet this requirement due to the time it took from other tasks.
- The first joint inspection was done incorrectly by the auditor. This is mostly because the auditor did not know how to complete the audit worksheet. Had the audit been done correctly the first time, two inspections would be enough to complete the audit.

NO – the minimum of two file reviews and joint inspection are appropriate

- We feel that only two inspections do not give the training coordinator enough information to get an accurate feedback on what is lacking in the training program. How do you determine if the presence of the auditor is causing the FSIO to be nervous and making errors in the inspection? We are not sure as to how many, but enough to build up a comfort level with the auditor to remove the anxiety. This may be something that has to be developed at the beginning with a trainee and on through a mentor program or audit program with the supervisor.
- It depends on the number of FSIO's on staff. For instance, if we have only a few FSIO's, we need to do more than just two otherwise this can lead to major statistical analysis problems like; lack of internal consistency, unreliability of the data and the validity of the data can be questionable. Increasing the minimal number of file reviews and joint field inspections across the board can take care of these three major statistical analysis problems significantly. Also, encouraging the auditor's to select facilities to be inspected on a proven methodology like randomization thereby eliminating some forms of bias that might interfere with the credibility of the data.

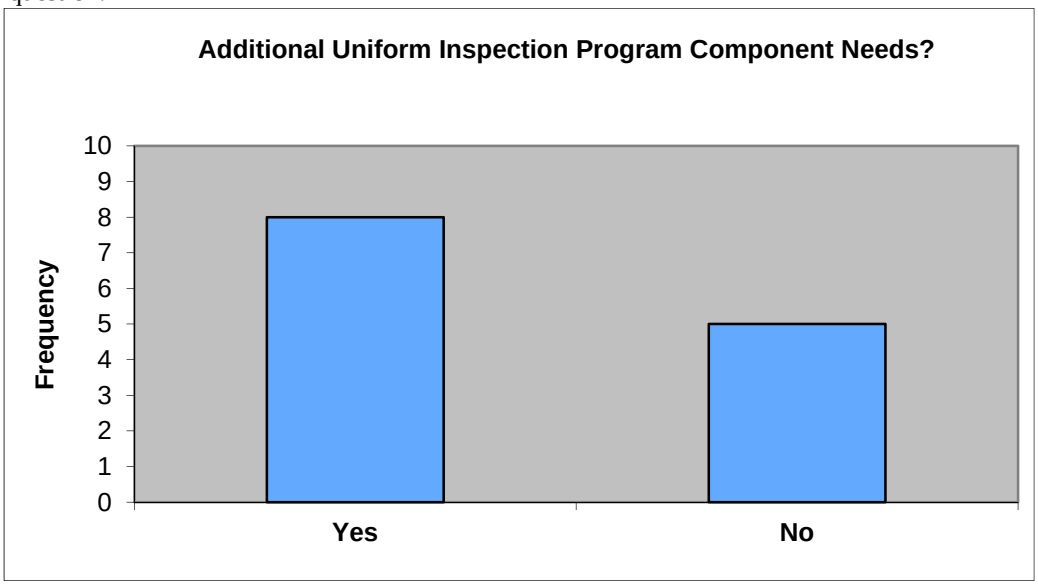
Both YES and NO – the minimum of two file reviews and joint inspection are appropriate

- It depends on how often an audit is conducted. I would think that 2 file reviews and inspections per FSIO every 6 months would be ideal. Less often (once per year) would be acceptable if other uniformity controls were in place, for example, requiring FSIOs to conduct joint inspections with each other every so often, so they can see their differences for themselves. We have found that this is a good way to discover questions you didn't know you even had.

Are there additional Program Components that you believe are necessary in order to effectively conduct a uniform inspection program audit but are MISSING from the current *Audit Worksheet*?

Yes **(8)** No **(5)** No Response **(1)**

Of the 13 jurisdictions responding, eight jurisdictions (61.5%) indicated that the current Audit Worksheet did not contain all the program components that are necessary to effectively conduct an inspection program audit. The graphic below depicts the response to this question.



Please identify and describe these missing components

YES– additional program components need to be added to effectively conduct a uniform inspection program audit

- Issues directly related to scoring an inspection. Feds/State do not score inspection. This can get "sticky" when doing an audit.
- Does the FSIO verify compliance with local requirements (i.e., is the establishment properly permitted based on the local/state permit requirements and meets the jurisdiction's requirements regarding food manager and employee food handler permit training requirements)? Perhaps this is to be included in #9.
- Some sort of weighting to make not meeting number 1 to be of greater import statistically than the other items like number 10. Maybe breaking the large section questions into multiple questions?
- The importance of determining risk factors is unquestionable. However good retail practice need to be represented in a distinct manner whether it be in a separate category or made clearer in the categories already developed.
- I was unable to find a good place to document items related to professionalism as exhibited by the FSIO. I was looking for something similar to the professionalism performance elements found in the CFP training guide.
- The program components should include an assessment of a food program's capacity for conducting effective risk-based inspections.

NO – additional program components need to be added to effectively conduct a uniform inspection program audit

(No specific comments provided on feedback form for the "NO" responses)

Were any of the 10 Program Components consistently difficult to assess during the uniform inspection program audit?

Yes **(8)** No **(4)** No Response **(2)**

Two-thirds (66.7%) of the 12 jurisdictions responding indicated that some of the 10 Program Components were consistently difficult to assess during the inspection program audit.

If you have identified DIFFICULT TO OBSERVE Program Component(s), what factors made them difficult to observe?

ITEMS 1, 3, 6

- Please refer to #1 of this section. Both are asking if the FSIO interpret enforcement procedures that are similar. For instance , 3 is looking at part to policies and procedures while 6 is looking at jurisdictions administrative procedures. One and the same, although the examples do give some differentiation.

ITEM 3

- Unclear – Explain what "Interpret" means or put into context.

ITEM 5

- This item could be addressed using a database and is harder when agency (local) depends on "Paper" review.
- The Audit Worksheet is vague and it is very hard to use as a standalone document. The questions do not clearly indicate or represent the performance areas/competencies that the Guide indicates. The 10 program components on the Audit Worksheet are not coordinated to flow with the normal inspection process itself. It also does not follow the same flow that the Abbreviated Field Inspection Training Worksheet has, which was used as a secondary reference when additional guidance was needed to connect observations from the audit with the proper program area/competency for documentation.
- It was difficult to assess review of past inspection findings when there were no violations present or when a different inspector previously inspected. Our files are mostly electronic.

ITEM 6

- File review may not have included any inspections that required follow up, or the previous inspections for the establishment may have been conducted by a different inspector. If the current joint inspection required a follow up, I would generally have completed my audit before the follow up inspection came due. (Perhaps I should have kept the audit "open" until after the follow up inspection, a month or so later?
- The Audit Reference Guide gives the following examples of competencies for Item 6
    - *FSIO follows the jurisdiction's compliance and enforcement policies and procedures regarding repeated and unresolved violations.*
    - *FSIO follows the jurisdiction's policy in regard to disclosure of confidential information.*

  There was never an opportunity to assess FSIO adherence to our policy regarding of confidential information during the audit process.

ITEMS 8 and 9

- We are still working on some of the components of the standards such as a uniform system for determining the risk category for a facility. We did not run across a situation where we had a long term control problem that could be addressed with the options listed in item 8 nor have we consistently used these options as a tool.

ITEM 9

- It's easy to observe licensed risk category but difficult to observe FSIO confirming the license process codes used in WI match the processes the establishment is engaged in.

ITEMS 8 and 10

- If you are only doing two joint inspections with the FSIO, documenting long term issues may be difficult to document. On item 10 our program does this but indirectly by receiving a report from our IT department when each inspector downloads their inspections.

Were there specific Program Components that FSIOs consistently experienced DIFFICULTY with?

Yes **(10)** No **(4)**

Please identify these by placing an "X" adjacent to the item number of the Performance Elements(s) FSIOs had DIFFICULTY with. The Item number below corresponds to the same item number on the Audit Worksheet.

Audit Worksheet

Item 1 **(4)**	Item 2 **(1)**	Item 3 **(1)**	Item 4 **(2)**	Item 5 **(5)**
Item 6 **(1)**	Item 7 **(1)**	Item 8 **(3)**	Item 9 **(1)**	Item 10

Based on the responses above, 10 jurisdictions (71.4%) indicated there were Program Components that FSIOs had consistent difficulty with. These pilot project results appear to indicate that there are several Program Components that should be reviewed for clarification or re-assessed to address the specific comments presented in the next section.

If you have identified Program Component(s) that FSIOs experienced DIFFICULTY with, what factors contributed to their challenges

ITEM 1

- How many of the Risk Factors would an FSIO be allowed to miss? Very few FSIOs inquire about health policies and perhaps missed a food cooling in the walk-in cooler.
- There was almost always some variation between the auditor and the FSIO. If the inspector misses just one violation, or forgets to ask about food source, or fails to take a temperature of an item that was cooked, then Item 1 is marked NO. So more often than not, our FSIOs did not meet item 1.
- Inspectors did not like the change of form from critical/non-critical to in/out/not observed/not applicable. Once the form was explained while looking at an inspection, they understood it better. It is also now used as a tool to educate operators to the overall picture of food safety in their establishment.

ITEM 2

- Legibility is in the eye of the beholder--handwriting that one person can easily read may not be easily read or understood by another person.

ITEM 3

- This program component was a catch all for not following our local jurisdictions policies and procedure. It is important that we capture the specific similar problems on the notes section to determine where the actual problem lies, especially for training purposes. There are too many variables in this program component that lead to non-compliance.

ITEM 4

- The FSIO did not always give the violation citation on the narrative. How many times does it take before the Auditor says that the FSIO gets a "did not meet the competency?"

ITEM 5

- Our agency does not have a computer system to track inspections. FSIOs do not have files in field and makes it hard to show facility staff past practices.
- What is meant by "act on repeated or unresolved violations"? We all know that there are those violations that will be noted as a repeat violation until such time the business is sold or burns down. Or are these only the High Risk areas?
- Historically, we have placed very little emphasis on reviewing past inspections (unless following up on a particular issue, short term). We are working on this weakness, but at this time, most inspectors were marked NO for item 5.
- Some of the FSIO's did not have a copy of the previous inspection with them. I feel you could present a case that is this really necessary? If the FSIO has been in this establishment sixteen times, is the previous inspection going to help?
- Not all FSIO's acted on repeated and unresolved violations and several of them did not file their reports on a timely manner as required.

ITEM 8

- Is there a difference between Item #5 and Item #8? Seems somewhat redundant. #5 and #8 should either be combined into one, or clarify the difference intended between the two.
- FSIO’s struggled with documentation of correction recommendations or long term corrective action plans for items identified as out of control either during current inspection or from consecutive inspections. WI training has not emphasized the successful use of risk control plans. Encouraging and assisting the PIC to create a risk control plan for items identified as out of control will become an opportunity for WI to eliminate this difficulty.

ITEMS 1, 4, 6, 7

- Our current database system is lacking and causes inconsistency between inspectors. This is because inspectors have the option of completing a report that assesses the risk factors and interventions. Some inspectors are good at assessing all the risk factors, some are good at assessing some of the risk factors, and one inspector does not assess them at all. Additionally, there is a lack of program policies/procedures to insure uniformity such as required inspection form completion, disclosure of confidential information, filing of reports, administrative policies, jurisdictional statutes, etc. With the lack of program policies comes the lack of requiring immediate corrective action for out-of-control risk factors and overall compliance. Our inspectors also need better training on the application of rules/regs for the manufacturing establishments.

ITEMS 8 and 9

- We are still working on some of the components of the standards such as a uniform system for determining the risk category for a facility. We did not run across a situation where we had a long term control problem that could be addressed with the options listed in item 8 nor have we consistently used these options as a tool except during standardization.

Do you think there are any Program Components that should be DELETED from the *Audit* Worksheet?

Yes **(5)** No **(8)** No Response **(1)**

The thirteen jurisdictional responses to this item were fairly evenly spread. Eight jurisdictions indicated that none of program component should be deleted. Those that indicated yes were asked to identify the program components that should be deleted from the audit process. Out of the 10 Program Components, only three, Items 8, 9, and 10 were identified as one that should be deleted or combined with other program components.

Please identify these by placing an "X" adjacent to the item number of the Performance Component(s) that should be DELETED. The Item number below corresponds to the same item number on the Audit Worksheet.

Audit Worksheet

Item 1	Item 2	Item 3	Item 4	Item 5
Item 6	Item 7	Item 8 **(2)**	Item 9 **(5)**	Item 10 **(1)**

If you have recommended that one or more Program Components be deleted, what rationale can you provide to support the recommendation?

ITEM 8

- I think it may be difficult to document what was discussed during an exit interview. I think this could be corrected by training and documenting procedures.
- I don't foresee us incorporating the risk control plans, etc. into our program in the immediate future. We are however actively working on a system to identify if a firm is in the proper risk category with the proper frequency of inspection so item 9 will be very helpful to us once our system is in place.

ITEM 9

- RISK characterization should be a separate process that is very objective (not connected to an inspection).
- Items #5 and #8 can be combined.
- These elements may not need to be deleted completely, but analyzed in a subsequent process outside of individual inspections. They do not seem of equal weight to questions 1 and 2. They might also be better analyzed on a program level as opposed to during an individual inspection, such as question 9 determining if the required inspection frequencies are being met based on risk (probably more reflective of a resource allocation issue or prioritization issue at the program level as opposed to an individual inspector choosing to review an individual facility for inspection). More pieces of the program come into play for these items so it is deserving of a review in a broader context than an individual inspection.
- I don't necessarily think Item 9 should be deleted, but it doesn't really apply to us as every establishment has the same inspection frequency (once per year). I do realize that ideally, we would base our inspection frequency on risk- but at this time, as directed by our contract with KS Dept of Agriculture, we do not consider risk.
- There is too much latitude in the current risk category worksheets that are in use.

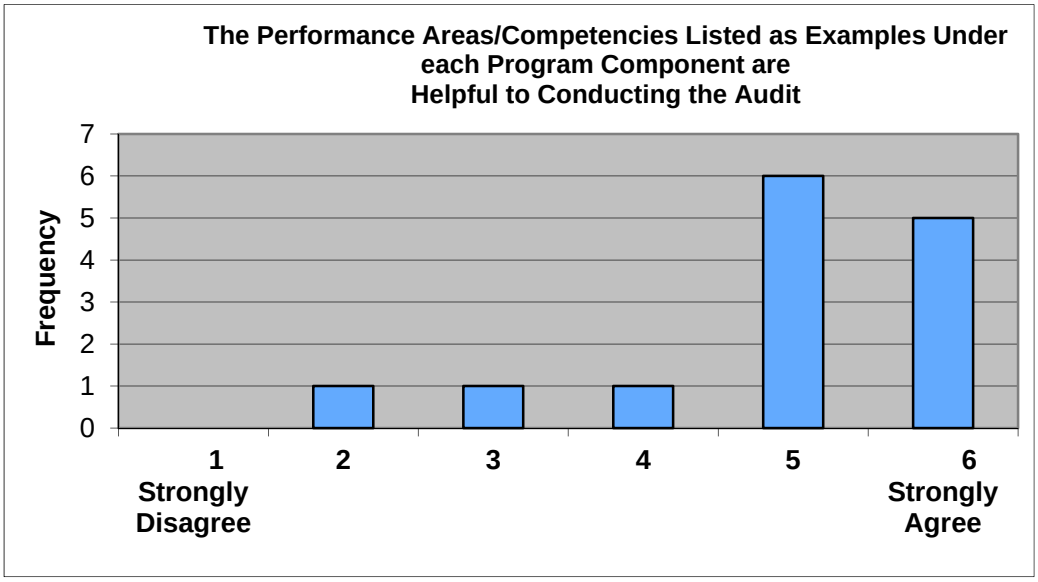
ITEM 10

- I don't feel this would help in the assessment of a program's effectiveness.

The performance areas/competencies listed as examples under each Program Component on pages 2 through 4 of the *Audit Reference Guide* are helpful to conducting the uniform inspection program audit. *(Please place an "X" in the box next to the rating that reflects the level of your agreement or disagreement with this statement).*

Strongly Disagree					**Strongly Agree**
1	**2 (1)**	**3 (1)**	**4 (1)**	**5 (6)**	**6 (5)**

Responses to this statement ranged from a low of 2 to a high of 6 with a mode (most frequently selected response) of 5. The mean (average) was 4.92 and the median (midpoint) was 5. Eleven jurisdictions (78.8%) responded with a 5 or above indicating agreement that the performance areas/competencies listed as examples, were for the most part helpful to conducting the inspection program audit.



Please provide an explanation for your response.

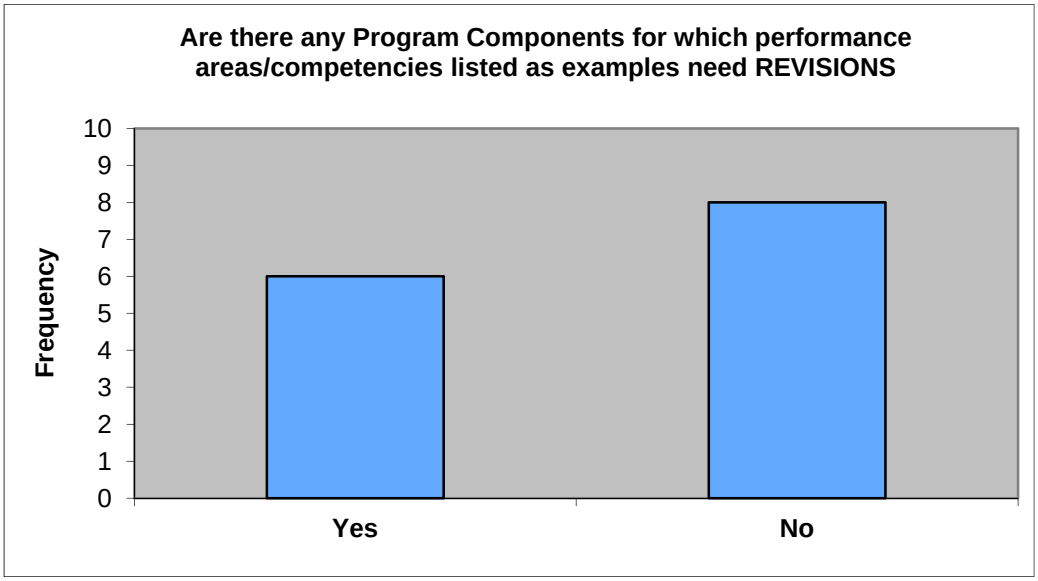
- We felt this guide was very useful in navigating through the program.
- Yes, we like the detailed examples given.
- Item #1 is the most difficult one to assess and rate for our department. We currently have 27 Risk Factors and 27 Good Retail Practices. If the FSIO consistently misses one of these does the Auditor mark NO on the Audit sheet for #1?
- The audit Reference Guide is too abbreviated. Pages 2-4 help a little, but it is just too abbreviated. The performance areas/competencies listed in the Reference Guide have their own guide of associated inspection observations in the Abbreviated Field Training Reference Document (pages 7-10 of the Abbreviated Field Training Worksheet). It was difficult to use the forms (Audit Worksheet, Audit Reference Guide, Abbreviated Field Training Worksheet references) during the audit inspection because you had to jump around between 3 forms that do not follow the same pattern. This meant that the Audit Worksheet could not be completed during the audit inspection, but was completed at a later time when paging through resources and cross referencing was possible using notes from the audit inspection. The Abbreviated Field Training Reference Guide was the most helpful and the easiest to use as a reference while completing the Audit Worksheet.
- The reference guide helped with details of each audit question.

- Some areas may need more or better examples to help clarify the component.
- The examples are very helpful, but some could use additional clarification.
    - Item 1: Is the list of regulations all-inclusive, or should other critical violations also be considered in Item 1 (presence of pests, toxic chemical violations, plumbing problems, etc.)? Also, should Item 1 be marked NO if only one performance area is out (for example, missed checking one cooler but did check all other coolers at an inspection)? Or should we mark YES if there is substantial competency shown?
    - Item 3: Does "other regulations… prevailing statutes, regulations and/or ordinances" refer to other critical violations from the Food Code (such as presence of pests, etc.), non-critical violations in the Food Code, or violations that are not even in the food code (which for us could include verifying that employees possess Food Handler Cards, or whether or not they are in compliance with their grease interceptor pumping)?
    - Item 9: the second example (HACCP Plans and Variance documentation) doesn't seem to go with the header for Item 9 (proper risk category and required inspection frequency). But maybe that is because the intention is to base risk category on presence or absence of HACCP plans and variances (this is not the case for us)?
- The listing was very helpful and I feel that it could be expanded by offering more examples.
- Need more examples or more objective examples of what competency of the criteria means.
- This is one way to help the auditor understand the different components of each item thus ensuring that they consider all the possible problems that might be associated with each item. From a statistical standpoint, this is a way that the CFP team can ensure that all the auditors understand the parameters that they are supposed to assess and provide them with the most accurate information so that they may be able to increase the accuracy of the information that they collect from the different jurisdictions in the country. Those examples increase the specificity of the data collected.
- Could not use the audit worksheet without referring back to the reference guide. Suggest combining the audit worksheet and reference guide as one document.
- The list of examples was essential to the process.
- The examples are very helpful. They help to further define the expectation of each area. Without them the audit process would include a much higher potential for subjectivity and inconsistency.

Are there any of the 10 Program Components for which the performance areas/competencies listed as examples on pages 2 through 4 of *the Audit Reference Guide* need REVISIONS (additions, deletions, changes)?

Yes **(6)** No **(8)**

The responses to this item were almost evenly split with 6 jurisdictions (42.9%) indicating there were Program Components in need of revisions and 8 jurisdictions (57.1%) indicating there were NOT any Program Components in need of revisions. The graphic at the top of the next page depicts these responses.



Please identify these by placing an "X" next to the item number of the Program Component(s) needing REVISIONS to the examples provided on pages 2 through 4 of the *Audit Reference Guide*.

Audit Reference Guide (pages 2-4)

Item 1 **(5)**	Item 2 **(2)**	Item 3 **(1)**	Item 4 **(1)**	Item 5 **(1)**
Item 6	Item 7 **(1)**	Item 8	Item 9 **(1)**	Item 10 **(1)**

Eight of the 10 Program Components were identified by at least one jurisdiction as an area needing revision. Six Program Components were identified only once as an area needing revision. Item 1 was identified by five jurisdictions (35.7%) as a Program Component in need of revision. The comments provided in the section below shed some light on potential challenges associated with the Program Components identified as ones needing revisions.

If you identified one or more Program Component(s) needing REVISIONS, what changes would you recommend to the performance areas/competencies listed as examples?

General Comments

- Perhaps a checklist for the auditor is needed and then a percentage is used to determine if the FSIO is meeting #1.
- The reference Guide and all supporting forms (Field Training Manual, etc.) lack a review of the planning and organizing component of an inspection. In some instances, an FSIO may overemphasize one component of the verification of risk based inspection methodology while missing another component entirely. This seems to be an issue that is not captured, especially if you are not seeing any violations in the one component that is being focused on. For example, the FSIO is observed taking numerous compliant temperatures in one display case while neglecting to make observations of a product cooling. There is no direction for how many of those performance areas/competencies listed in the guide for each question need to be deficient for the entire question to be answered "No". Is it one program area/competency, the majority of those that are listed, or would it be based on the severity of which ones are noted deficient (i.e. used risk based inspection methodology vs. correctly used inspection equipment from question 1) etc.? There also is no direction on how to document when an FSIO is neglecting to anticipate opportunities to make risk based observations (i.e. 10 items are observed being cooked during inspection and only 1 cooking temperature is verified by the FSIO).

ITEM 1

- For Item 1, if the intention is to identify all critical violations (risk factors), a line at the bottom of the list might read "any other critical (or priority or primary) risk factors." Also please identify where non-critical (supportive, secondary, core) risk factors are to be evaluated. Also there are so many components to item 1. I would prefer to break down Item 1 into separate sections.
- Item 1…Maybe a review of how many times a certain violation is marked by an FSIO?
- Example from Item 1.

  FSIO used a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food. When the risk factor and/or intervention was applicable and observable during the inspection, the FSIO verified.

  I recommend removing "and observable" from the last sentence. Lack of (active) managerial control of FBI risk factors can be identified via discussion even when the FSIO is unable to observe specific processes because they are not happening during the time of inspection.

  Recommend changing the word "verified" to "assessed" or "evaluated"

ITEMS 2 and 4

- The differences between Item 2 and Item 4 could be better defined as they both identify documenting code references

ITEMS 2 and 7

- The differences between Item 2 and Item 7 could be better defined as they both identify documenting corrective actions.

ITEM 3

- For Item 3, it would be helpful if examples of "other regulations" were included.
- Item 3…Might offer better examples to assist the accompanying supervisor.

ITEM 5

- Item 5 ..As stated above, does the previous inspection a good guide or a crutch?

ITEM 9

- Item 9…Maybe a better risk evaluation and maybe some jurisdictions are hindered by funding, staffing or legal guidelines.

ITEM 10

- Item 10…I wonder if this is necessary?

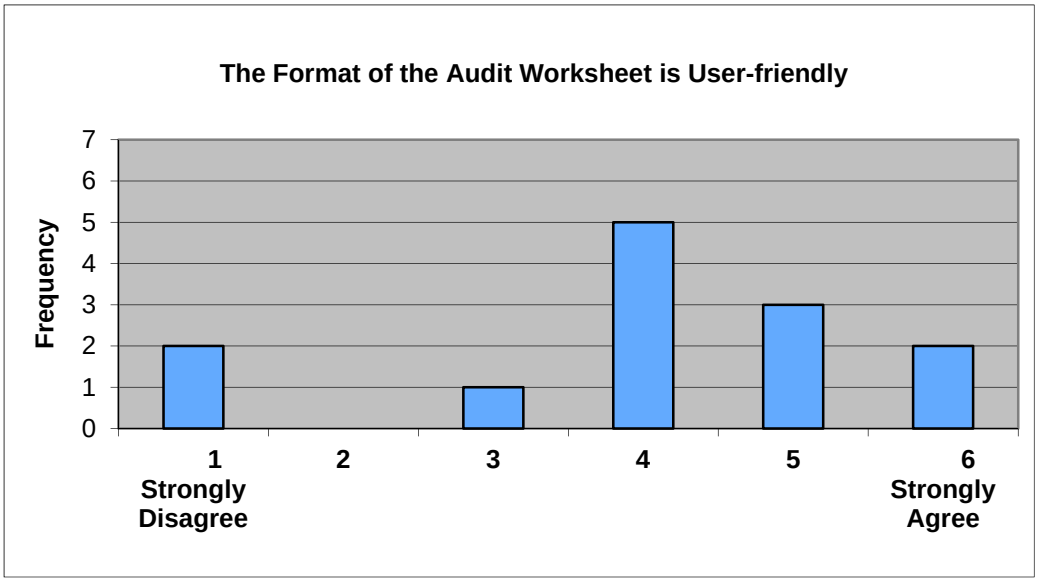
Section IV – Audit Worksheet – Format Evaluation

The format of the *Audit Worksheet* is user-friendly. *(Please place an "X" in the box next to the rating that reflects the level of your agreement or disagreement with this statement).*

Strongly Disagree					**Strongly Agree**
1 **(2)**	2	3 **(1)**	4 **(5)**	5 **(3)**	6 **(2)**

No Response **(1)**

Responses to this statement ranged from a low of 1 to a high of 6 with a mode (most frequently selected response) of 4. The mean (average) was 3.92 and the median (midpoint) was 4.0. The graphic below depicts the responses:



What improvements would you recommend?

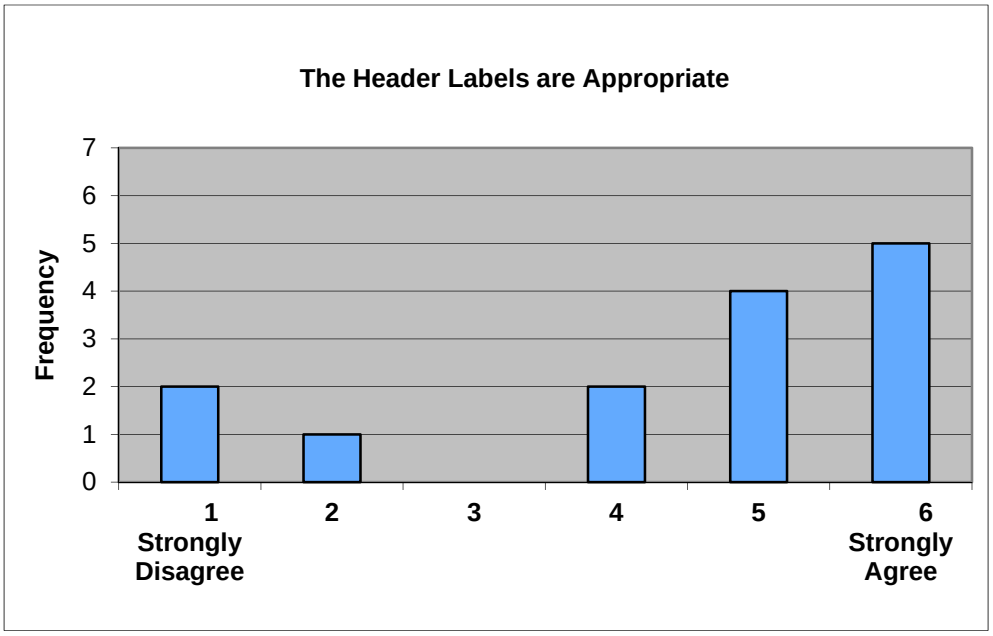
- Try to get complete audit worksheet on one page.
- The flow could be improved by having it match the workflow in the Field Training worksheet. For those program areas/competencies listed in the Audit Reference Guide that have additional reference observations in the Field Training Reference Document, just include the Field Training Reference Document observation list to eliminated the need for cross-referencing.
- Instead of just YES and NO being the only options for each of the 10 items, I would prefer to see some sort of a scale, for example "Always, Often, Sometimes, Rarely" or a numerical scale 1-5, so that I can indicate when something is very good but has room for improvement, or needs a lot of improvement. I want to be able to differentiate between a marginal FSIO and one who did everything great, but may have just missed one or two minor items
- The format was OK but had to adapt it so I could show percentages
- Response options should not be yes and no. Recommendation is to change yes and no to exceeds, meets, needs improvement and does not meet.
- Auditor instructions should indicate that all audit conclusions are supported in the comments section of the form.

- The audit worksheet jumps around rather than following the natural progression of an inspection e.g. reviewing the previous three reports would be one of the first thing to occur but is not referenced until Item 5. Item 9 references the confirmation of risk category and inspection frequency through file review which would come at the beginning of the process. Would conducting the risk category review during the inspection to confirm the establishment has not eliminated or added processes be a better fit for Item 9?
- We converted the 4 page worksheet to a one page worksheet.
- Combine the worksheet and reference guide. There needs to be examples for the auditor to follow.
- It would be nice to use one form to record the results of all of the audit inspections rather than having a separate form for each inspection.
- List the Performance Areas/Competencies under each Program Component

The header labels are appropriate.

Strongly Disagree					**Strongly Agree**
1 **(2)**	2 **(1)**	3	4 **(2)**	5 **(4)**	6 **(5)**

Responses to this statement ranged from a low of 1 to a high of 6 with a mode (most frequently selected response) of 6. The mean (average) was 4.43 and the median (midpoint) was 5.0. Nine jurisdictions 64.3% responded with a rating of 5 or above The graphic below depicts the responses:



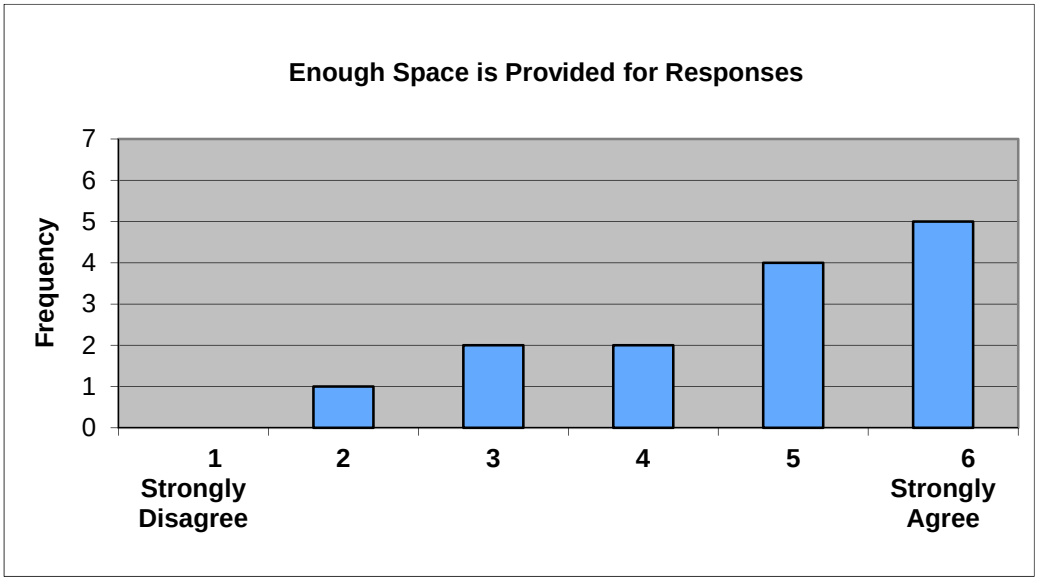
What improvements would you recommend?

- The audit form is too vague for questions 1 and 2 to represent the large number of program areas listed in the Audit Reference Guide and the questions are not really descriptive of those performance areas/competencies indicated in the Guide in many cases. The Audit Worksheet questions (which is what is assumed to be meant by "header labels") could be broken down to a larger number of questions or sub-questions (1a, 1b, 1c) to prevent false indications of program trends or deficiencies (for example, when question 1 may statistically indicate an overall program deficiency, when the deficiencies were actually spread in small numbers over multiple of the program areas/competencies that question 1 represents).
- I would suggest either removing the HACCP/ Variance component from item 9, or else rewording the title of #9 to clarify how this is relevant.
- Use newer Excel template.
- Rather than copying the header labels directly from Standard 4 they should be expanded to better incorporate the examples provided. During an audit we would not expect the auditor to have the examples memorized and flipping between the audit reference guide and the audit worksheet would be awkward.
- I didn't see header labels--just the competency.
- The first statement about the pre-requisite training courses could be separated more from the 10 questions - I put the information for question #1 in the wrong box the first time.

Enough space is provided for responses and comments.

Strongly Disagree					**Strongly Agree**
1	2 **(1)**	3 **(2)**	4 **(2)**	5 **(4)**	6 **(5)**

There was a large spread of responses on this item with the responses ranging from a low of 2 to a high of 6. The mode (most frequently selected response) was 6. The mean (average) was 4.71 and the median (midpoint) was 5. Sixty-four percent (64.3%) of the respondents selected 5 or higher indicating there was enough space provided for responses. The narrative comments in the next section provide additional information regarding this. The graphic below depicts the responses:



What improvements would you recommend?

- We thought there was too much room--as stated, we converted it to a one page table.
- More space would be better.
- Provide enough space to include the performance areas/competencies under each program area and room to make comments about the performance of the competency.

Is there any general information you believe is important that is MISSING?

Yes **(3)** No **(11)**

The majority of the jurisdictions (78.6%) indicted there was not any general information that was missing. Those that responded "yes" were asked to elaborate and a summary of their responses is provided below.

Please identify information that needs to be ADDED.

- Grade/Scoring space
- There should also be additional guidance on review of the individual Audit Worksheets for trends in the comments (if the overall answer for meeting the category is yes, b/c only one small section was not addressed but was documented in the comments, there should be a way to capture if that same small deficiency was noted among multiple audits). This would be for a competency such as risked based methodology, where 11 different elements are verified (demo of knowledge through consumer advisory). If 1-2 elements are consistently documented as being overlooked (such as cooling and food sources), the trend would still be identified if overall question 1 was answered as "yes" for all audits.
- I would like to see clarified in the general information, how this audit form is different (or how it is to be sued differently) from the field training worksheet, since so many of the components are exactly the same.

Is there any general information you believe should be DELETED?

Yes **(1)** No **(12)** No Response **(1)**

The majority of jurisdictions (92.3%) that responded felt there was NOT any general information that should be deleted. Those that responded "yes" were asked to elaborate and a summary of their responses is provided below.

Please identify information that should be DELETED.

- The question asking if the FSIO has successfully completed the pre-requisite training courses is not needed, because those FSIOs that have not completed the pre-requisites should not eligible for auditing because they are "still in training"

Did you modify the Audit Worksheet during the Uniform Inspection Program Pilot?

Yes **(4)** No **(10)**

The majority of the jurisdictions (71.4%) did not modify the *Audit Worksheet* during the pilot project.

Section V – Audit Results Summary and FSIO Training Plan (*optional form*)

The *Audit Results Summary and FSIO Training Plan* was included as an optional form a jurisdiction could use during the uniform inspection program audit pilot project. Did your jurisdiction decide to use the form?

Yes **(3)** No **(11)**

Of the 14 jurisdictions, 11 (78.6) did not choose to use the optional Audit Results Summary and FSIO Training Plan during the pilot project. The following section provides some insights as to the factors that impacted the jurisdictions decision not to use the form.

What factors influenced your decision?

- A little too much paperwork. Need to simplify.
- Summarizing in that format helped me tie together information from the audits. In the initial CFP Uniform Inspection Program, I was the sole auditor, this time around there were two of us, so at a quick glance and discussion, we were able to identify areas to develop in our training program.
- Our staff is regularly "Standardized". Any incompetencies observed on routine inspections can be addressed at that time. Staff meets the training requirements of Standard 2 before they are allowed to operate independently.
- The audit results were shared with the FSIO alone and they were allowed to seek additional training with their supervisor at their own discretion. Since this was a pilot project and not all FSIO staff was audited, it was deemed to be unfair to require follow-up with the supervisor on an individual basis when a significant number of staff was not audited. The auditors reviewed general audit findings as a group to determine if trends were present (which would then be identified as program trends for supervisors to address with the entire inspection staff). However, no clear trends were identified for reporting to supervisors in this project.
- We are using the State of Michigan Field Evaluation Form which is more detailed than the federal audit form. Items are broken down into more questions for the in/out/no/na answers. Michigan used the form from the Federal Voluntary Standards to create one for all jurisdictions to use.
- Standardization performed on a yearly basis (2-2-2=6) and a Supervisor's ongoing audit provide the necessary tools to evaluate individual performances.
- Time and resources to dedicate to this.
- A lot of these issues were already instituted and already in place.
- We did not use the document with the FSIO but decided it is important to go through the exercise to evaluate the usefulness of the too.
- We decided that it was too cumbersome. I would still like to see an audit tool that more completely describes what is needed to determine if competency for the program components has been met.
- Form was simple to use and very well structured.
- During the time of this audit, our department lost its' Director. Newly assigned staff to replace the Director was also an FSIO and was part of the audit process. Essentially, there was no supervisor available to address identified competencies in need of improvement.
- Feedback to the FSIO was handled verbally and only minor corrections were needed.
- The Audit Results Summary and Training plan puts the emphasis on individual performance. This should occur in the assessment of training needs and as part of overall performance management of an employee, so that auditing can focus on identifying overall program strengths and weaknesses and improving the program overall.

Responses from jurisdictions that used the optional Audit Results Summary and FSIO Training Plan

It should be noted that only a minority of jurisdictions that participated in the uniform inspection program audit pilot project opted to use the Audit Results Summary and FSIO Training Plan. The following items contained on the Uniform Inspection Program – Jurisdiction Audit Feedback Form pertain to the use of that form during the pilot project. Since a low number of jurisdictions used the form, the responses presented here should be used as informational references rather than used to draw any definitive conclusions.

The *Audit Result Summary and FSIO Training Plan* is a useful tool for documenting the audit process and ensuring that additional training is provided to the FSIO for Program Components noted as needing improvement during the establishment file reviews and joint field inspections. *(Please place an "X" in the box next to the rating that reflects the level of your agreement or disagreement with this statement).*

Strongly Disagree					**Strongly Agree**
1	2	3 **(2)**	4 **(1)**	5	6 **(3)**

No Response **(8)**

Six (42.8%) of the 14 jurisdictions responded this item. The responses ranged from a low of 3 to a high of 6 with a mode (most frequently selected response) of 6.

What improvements would you recommend?

- Maybe developing a spreadsheet so that you can see all the results summarized in one shot**.**
- More examples of good practices and maybe include more in depth instructions to the supervisor on how to "score" the audit sheet. I feel that Standard 4 should be re-worked and to get individual interpretations out of the process. Many of these same issues are covered in STD 2 and Std 9.
- None

The format of the *Audit Results Summary and FSIO Training Plan* is user-friendly

Strongly Disagree					**Strongly Agree**
1	2	3 **(1)**	4	5 **(3)**	6 **(2)**

No Response **(8)**

Six (42.8%) of the 14 jurisdictions responded this item. The responses ranged from a low of 3 to a high of 6 with a mode (most frequently selected response) of 5.

What improvements would you recommend?

(None of the pilot jurisdictions submitted comments for this item)

The header labels on the *Audit Results Summary and Training Plan* are appropriate.

Strongly Disagree					**Strongly Agree**
1	2	3 **(1)**	4	5 **(3)**	6 **(2)**

No Response **(8)**

Six (42.8%) of the 14 jurisdictions responded this item. The responses ranged from a low of 3 to a high of 6 with a mode (most frequently selected response) of 5.

What improvements would you recommend?

(None of the pilot jurisdictions submitted comments for this item)

Enough space is provided for responses and comments on the form.

Strongly Disagree					**Strongly Agree**
1	2	3 **(1)**	4	5 **(4)**	6 **(1)**

No Response **(8)**

Six (42.8%) of the 14 jurisdictions responded this item. The responses ranged from a low of 3 to a high of 6 with a mode (most frequently selected response) of 5.

What improvements would you recommend?

- When completed electronically the form adjusts and we would check mark 6 (Strongly Agree).
- When completed with pen to paper there is not sufficient room on the form and we would check mark this question 1 (Strongly disagree).
- More space will be needed because we had to use an extra sheet of paper.

Is there any general information that is missing?

Yes **(2)** No **(4)** No Response **(8)**

Please identify information that needs to be ADDED.

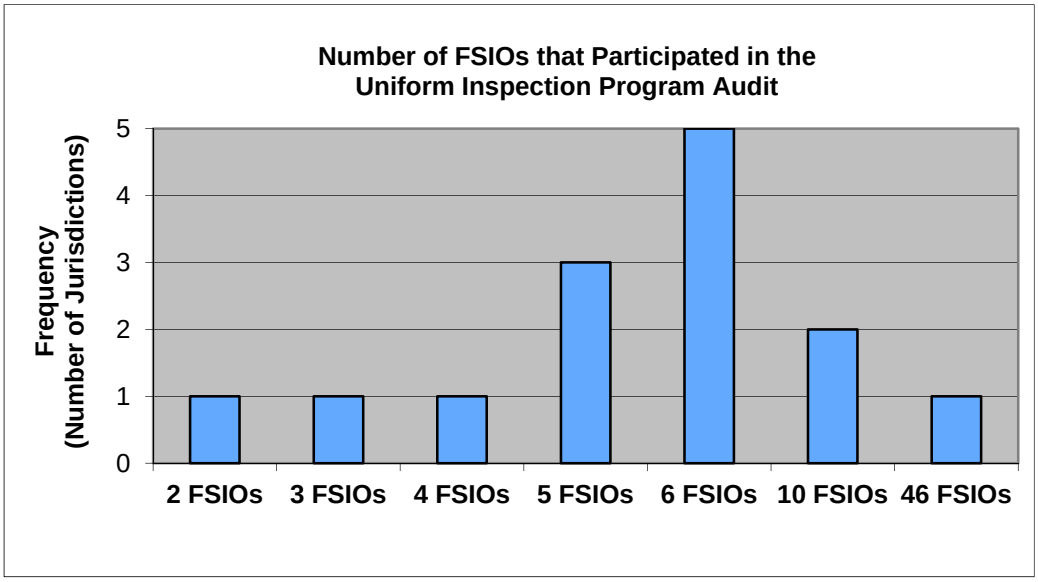
- A date should be established for completing the required re-training. When re-training has been completed a date should be designated for a follow-up audit.
- Adding a column with a timeframe on when the specific improvement will need to be completed.

Section VI – Uniform Inspection Program Audit Pilot Project Results

How many FSIOs were assessed as part of the jurisdiction's uniform inspection program audit?

2 - 1
3 - 1
4 - 1
5 - 3
6 - 5
10 - 2
46 - 1

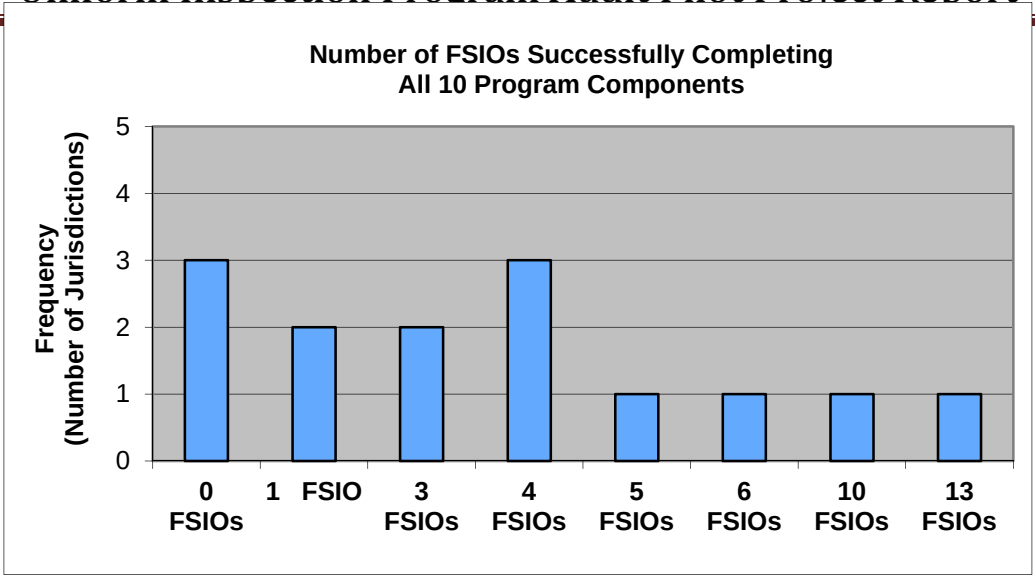
A total of 76 FSIOs participated in the Uniform Inspection Program Audit Pilot Project. The number of FSIO's from each individual jurisdiction ranged from one jurisdiction that had two FSIO participating to one jurisdiction that had 46 FSIOs participating. More jurisdictions (5) had six FSIOs participating 35.7% than any other number of FSIOs participating. The graphic below depicts the responses.



How many FSIOs successfully performed all 10 Program Components during the Audit Process?

0 - 3
1 - 2
3 - 2
4 - 3
5 - 1
6 - 1
10 - 1
13 - 1

A total of 42 FSIOs successfully performed all 10 Program Components during the audit pilot project. This represents 55.3% of the total number of FSIOs participating in the audit process The number of FSIO's successfully performing all 10 Program Components process ranged from zero (in 3 jurisdictions) to thirteen FSIOs in 1 jurisdiction. The graphic at the top of the next page depicts the responses.



Within your jurisdiction, who served as the "auditors" (individuals responsible for assessing FSIOs as part of the uniform inspection program audit)?*

A. Retail Food Program Managers **(2)**	**D.** Senior Food Safety Inspection Officers **(4)**
B. The Supervisors of the Food Safety Inspection Officer **(3)**	**E.** Quality Assurance/Quality Control Officers **(2)**
C. Training Officers **(2)**	**F.** Other – (Please described in the box provided below

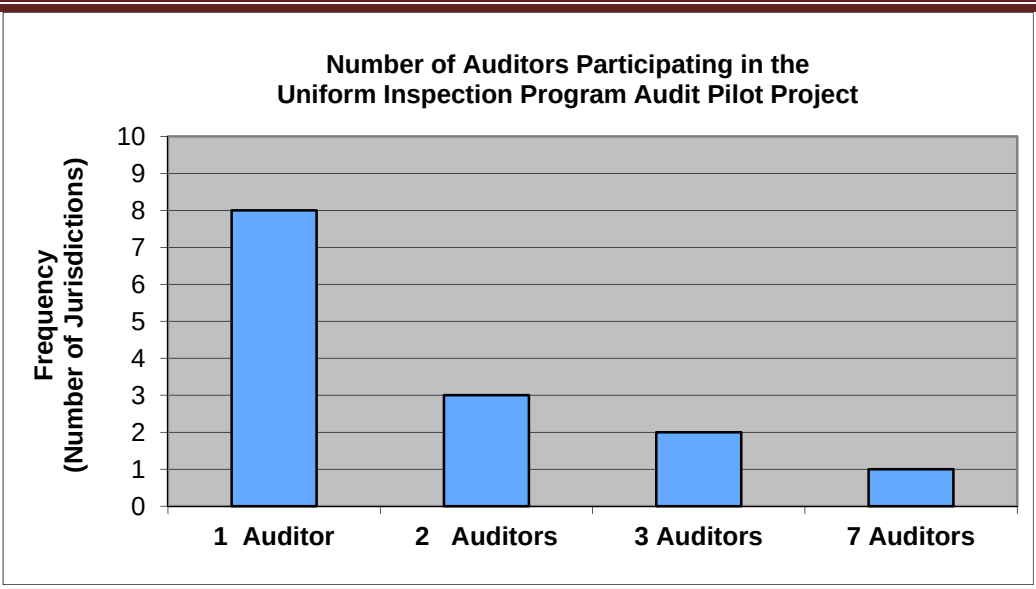
*** Total exceeds 14 because two jurisdictions listed more than one answer**

- The auditors are experience FSIOs, but not the most senior FSIOs on staff. These experienced FSIOs are also field inspection trainers as part of their job description (as are all FSIOs of that level in this program). They were chosen as auditors based on their ability to articulate their observations to the auditees. Only one auditor had completed formal auditor training designed specifically to impart skills on auditing field inspections.
- A, B, and C are all the same person (me) for our jurisdiction.
- The reason I put zero for completing all ten components was that the average was 80% and no one received a 100%
- FDA Certified Retail Standard and Evaluation Officer
- Registered Sanitarian knowledgeable with the audit process, but not manager of the program.

How many "auditors" (individuals responsible for assessing FSIOs as part of the uniform inspection program audit participated in the pilot project?

1 - 8
2 - 3
3 - 2
7 – 1

A total of 27 "auditors" participated in the Pilot Project. The number of auditors participating within each jurisdiction ranged from a low of one (57.1% reported using one auditor) to a high of seven. The graphic at the top of the next page depicts the responses.



Was there more than one auditor per Food Safety Inspection Officer?

Yes **(1)** No **(13)**

Only one (7%) of the 14 jurisdictions reported using more than one auditor per FSIO. In this one instance, FSIOs did not report any differences between the auditors (per the item below).

If you answered YES to the question above, did Food Safety Inspection Officers report any differences between the auditors related to how the audit was conducted?

Yes **(0)** No **(1)**

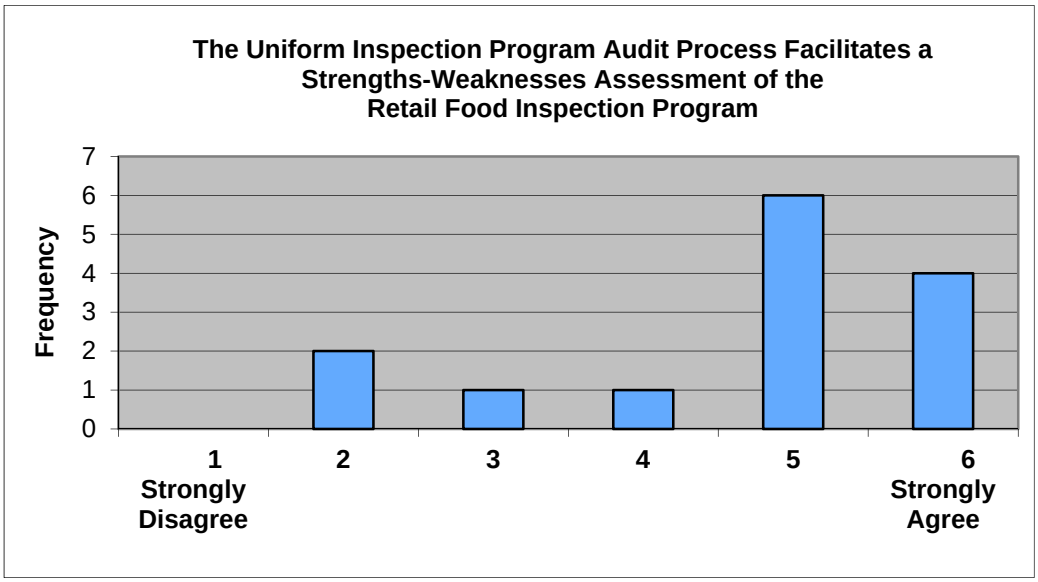
If differences were noted, provide specific examples?

(*None reported*)

The uniform inspection program audit process is designed in such a way as to facilitate a strengths-weaknesses assessment of our jurisdiction regulatory retail food protection inspection program. ***(Please place an "X" in the box next to the rating that reflects the level of your agreement or disagreement with this statement).***

Strongly Disagree					**Strongly Agree**
1	2 **(2)**	3 **(1)**	4 **(1)**	5 **(6)**	6 **(4)**

The responses ranged from a low of 2 to a high of 6 with a mode (most frequently selected response) of 5. The mean (average) was 4.64 and the median (midpoint) was 5. Seventy-one percent (71%) of the respondents selected 5 of higher agreeing that the Uniform Inspection Program audit process is designed in such a way as to facilitate a strengths-weaknesses assessment of a jurisdiction's regulatory retail food inspection program.. The graphic below depicts the responses.



What factors influenced your decision?

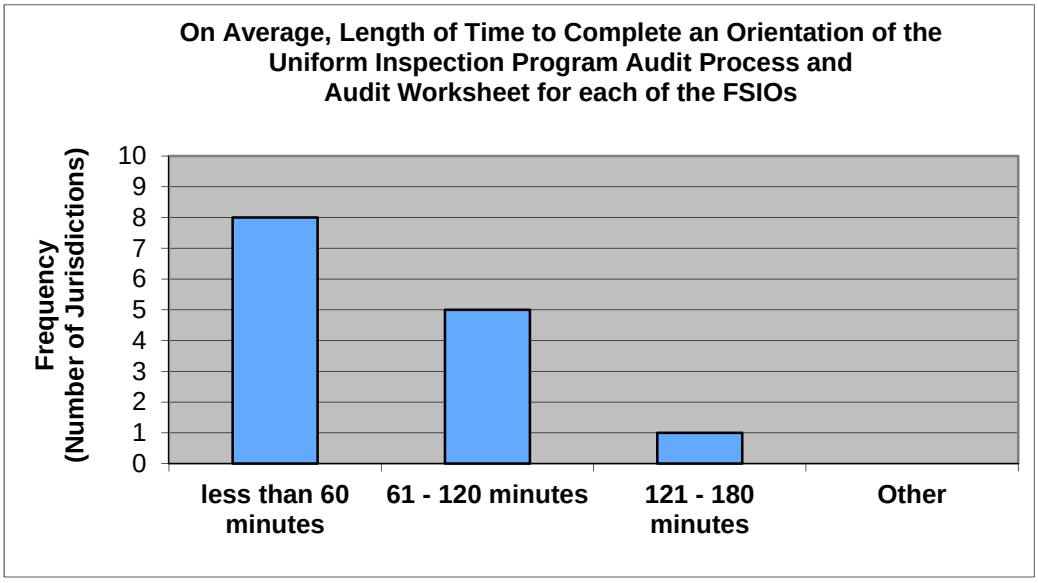
- Shorten length of all forms, if possible.
- It is a very useful tool. The area of concern for me, for one is doing enough audits to get representative samples to determine what change need to done. I feel that many FSIO feel that the ATN process is a pass or fail, even when they are repeatedly told it is not. Staff gets very nervous having someone evaluate them in the field. This may be an internal problem where there has not been any type of mentorship and/ audit program in the food inspection program. Also, how/when is it determined that it is the training program or an employee's lack to follow through with the training.
- Lincoln Lancaster County Health Department is evaluated by the NE Department of Agriculture, Bureau of Dairies and Foods every 5 years. Perhaps there can be a means to incorporate their evaluation of our program into Standard 4.
- The current design of the questions on the Audit Worksheet would result in a lot of individual interpretation during application in the field that would lead to inconsistent audit reporting and subsequently misleading program audit results. Specific areas resulting in individual interpretation are the potential overlap between audit questions and with other Voluntary Program Standards that is implied by the program areas/competencies listed in the Audit Reference Guide (see Section III question 1 for additional comment). The lack of auditor qualifications and marking instructions (such as when enough non-observations or deficiencies in individual program areas/competencies would warrant a "No" as opposed to a "Yes") would also lead to inconsistent application in the field and mis-representative program reporting.

- Clearly state where good retail practice variables should be addressed
- Standard 4 needs to be more distinctive because it is very much like a standardization. Standard 4 is supposed to be a program evaluation. Would an in depth study of how many times a violation is documented by various inspectors and a comparison between all inspectors by of more value?
- Give a definition of competency.
- Implement a training program for future auditors so that they will be comfortable and aware of the basic requirements of conducting effective audits.
- A breakdown of the risk factors would be helpful for the auditor.
- I would like to add performance elements associated with performance elements. Based on audit findings, we have made revisions to our new employee information packets to better inform them of our expectations.
- Removal of the emphasis on assessing individual performance.

On average, how long did it take to complete an orientation of the Uniform Inspection Program Audit process and *Audit Worksheet* for each of the Food Safety Inspection Officers?

A. less than 60 minutes **(8)** **B**. 61 – 120 minutes **(5)** **C.** 121 – 180 minutes **(1)**
D. Other. Please specify (0)

Eight of the jurisdictions (57.1%) indicated it took less than 60 minutes to complete an orientation of the Uniform Inspection Program Audit process and Audit Worksheet for each FSIO. Five jurisdictions (35.7%) indicated it took between 61 and 120 minutes and one jurisdiction indicated it took between 121 and 180 minutes. The graphic displayed below depicts the responses.



On average, how long did it take to complete an audit of the Pre-Inspection Establishment File Review?

Half of the participating jurisdictions indicated it took less than 30 minutes for the FSIO to conduct a Pre-Inspection Establishment File Review while the other indicated the review tool between 31 and 60 minutes. The table below summarized the responses to this question:

Average time it took a FSIO to conduct a Pre-Inspection Establishment File Review					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	less than 30 minutes	7	50.0	50.0	50.0
	31 - 60 minutes	7	50.0	50.0	100.0
	Other	0	0.0	0.0	100.0
	Total	14	100.0	100.0	

On average, how long did it take to complete the audit of a joint field inspection (SINGLE INSPECTION) using the Audit Worksheet (actual time in hours – including inspection, completion of the inspection report, and discussion of the inspection report with the person in charge)? Do NOT include travel time to & from the establishment.

As the table below indicates, the half of jurisdictions (n=7, 50%) indicated it took between 61 and 120 minutes (one to two hours) for an FSIO to complete a single on-site joint field inspection while using the Audit Worksheet. One jurisdiction reported it took four hours and one reported it tool 5 hours.

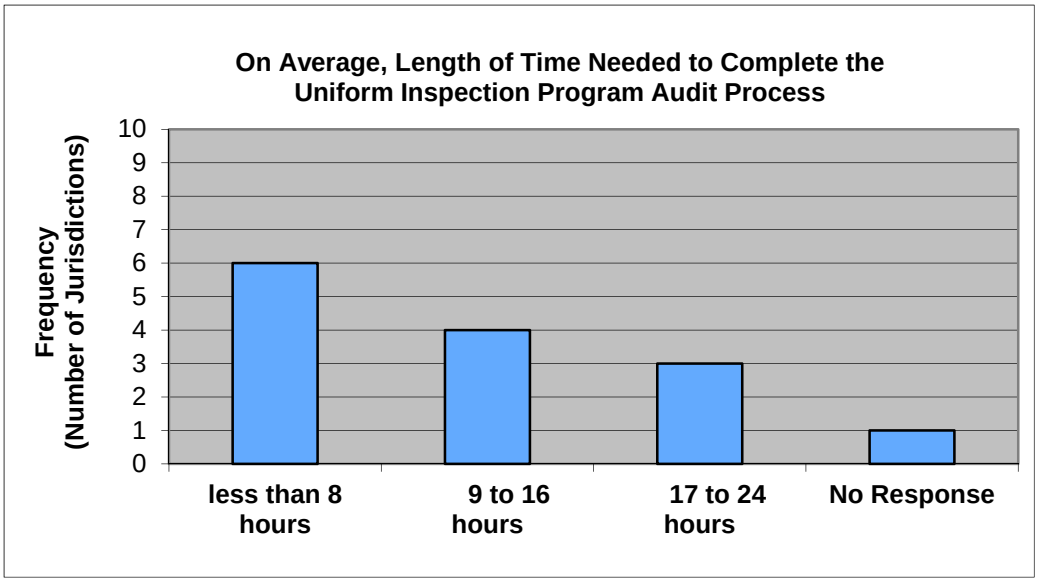
Average time it took to complete an on-site joint field-training inspection					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	less than 60 minutes	0	0.0	0.0	0.0
	61 - 120 minutes	5	35.7	35.7	35.7
	121 - 180 minutes	7	50.0	50.0	85.7
	Other (see below*)	2	14.3	14.3	100.0
	*4 hours – (1)				
	*5 hours – (1)				
	Total	14	100.0	100.0	

On average, how long did it take to complete the audit process for each individual FSIO? (Include the orientation process; establishment file reviews; actual inspection time; review of the audit reports with the FSIO; and completion of all inspection program audit documents/worksheets.)

The table below contains a frequency distribution of the responses regarding the average time for the FSIO to complete the audit process. The responses varied greatly from less than 8 hours to 17 - 24 hours. Ten (76.9%) of the 13 jurisdiction submitting responses indicated that the audit process was completed in less than 16 hours.

Average time for the FSIO to complete the Audit Process				
		Frequency	Percent	Cumulative Percent
Valid	less than 8 hours	6	42.9	42.9
	9 to 16 hours	4	28.6	71.5
	17 to 24 hours	3	21.4	92.9
	25 to 32 hours			
	33 to 40 hours			
	Other (see below*)			
	No Response	1	7.1	100.0
	Total	14	100.0	

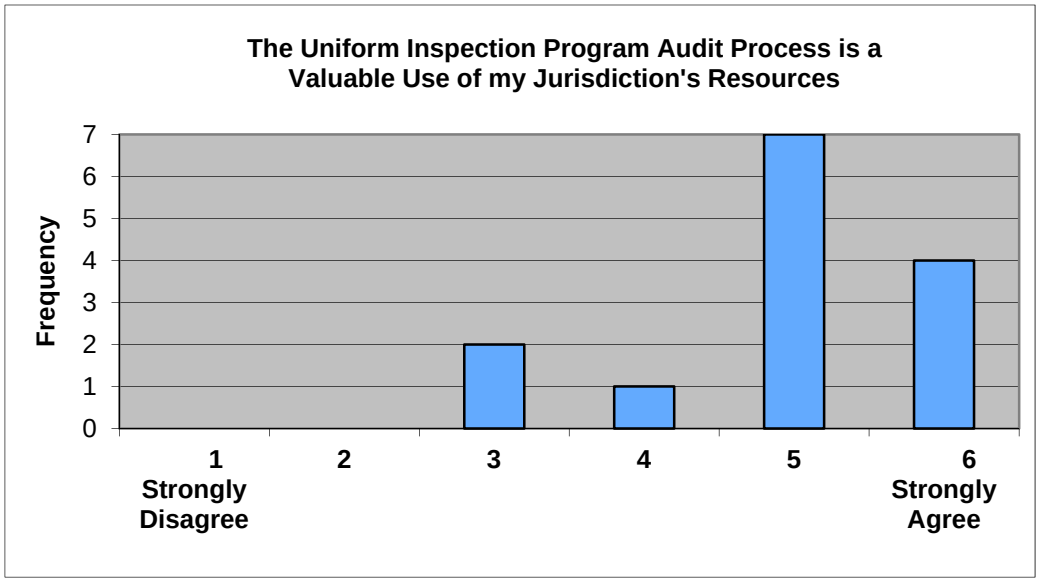
The graphic below depicts the response from the previous page pertaining to the average time needed to complete the audit process with FSIOs.



The uniform inspection program audit process is a valuable use of my Jurisdiction's resources (e.g., time; staff; finances).

Strongly Disagree					**Strongly Agree**
1	2	3 **(2)**	4 **(1)**	5 **(7)**	6 **(4)**

The responses ranged from a low of 3 to a high of 6. The mode (most frequently selected response) was 5. The mean (average) was 4.93 and the median (midpoint) was 5. A total of 11 (78.6%) jurisdictions selected either a 5 or 6 indicating agreement that the Uniform Inspection Program audit process was a valuable use of the Jurisdiction's resources. The graphic below depicts the results of this item.



Explain, why?

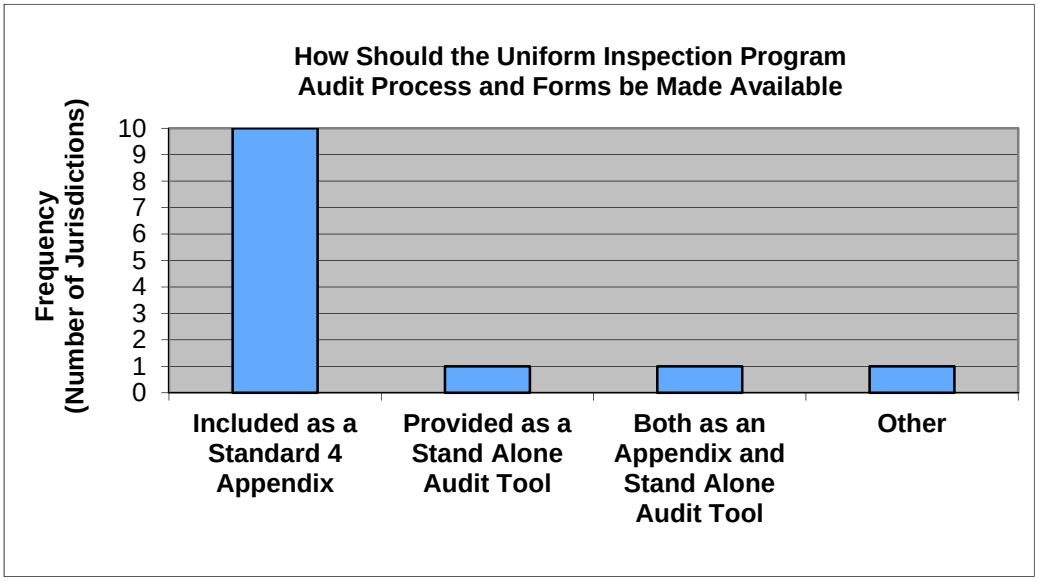
- Time consuming , but in the end gave us a very good understanding of the "big picture" of our program.
- The program is very useful. Even with the limited number of FSIO's audits we were able to find some areas in the inspection program that may need reviewed or beefed up in our training program.
- Lincoln Lancaster County Health Department is evaluated by the NE Department of Agriculture, Bureau of Dairies and Foods every 5 years. Perhaps there can be a means to incorporate their evaluation of our program into Standard 4.
- For our program, there is a limited set of resources for the evaluation of field inspections. The audit process would overlap with the standardization process, which is already a challenge to complete with current resources. It seems that there needs to be more clarification to the auditor and the auditee on the difference of the audit process from the standardization process to avoid getting bogged down in an exercise of evaluating very single observation (or lack thereof) from the audit inspection. Another option may be development of a tool to link portions of the current standardization process with the audit process to reduce the resources necessary since both the program audit and standardization are necessary. An example would be to have the audit conducted by the standard (for those programs that complete standardization within the agency) and the risk based inspection marking observations from the standardization documentation could be used as support for marking on questions 1 and 4 of the Audit Worksheet.
- We already complete audits/ reviews of staff to work on uniformity for Michigan accreditation so this uniform inspection program process was not anything new and different.
- Integrated nicely with our program and availability of Quality Assurance Specialist that are strategically placed around the State to handle this type of assessment as part of their responsibilities. Program evaluation is unique as another tool assessment for how the program is running collectively and has not put a strain on our resources. Our program initially started over 3 years ago and have benefited from the results in looking at our program collectively. We are in the process of addressing one of the deficiencies found during our first 3 year audit.
- Our program has a policy that each inspector is visited by their supervisor at least twice a year. Standard four can easily be interpreted as doing a standardization. I feel Std 4 should be more distinctive. Maybe a review of the data collected from FSIO's might be more meaningful.
- We modified it and will use our modification to help with the documentation for attainment of Standard 4.
- Because we have been able to develop a quality assurance program that has helped identify deficiencies or gaps within our division. As a result of this process, we have been able to implement a program to detect and deter problems noted during the audits and file reviews thus ensuring that we are using proactive rather that reactive management strategy. Having a division quality assurance for the first time has helped the manager and supervisor identify the training needs for different employees thus helping them to become better FSIO's.
- The process really helped our department to identify our programmatic weaknesses. While we were not able to fully improve upon FSIO competencies (due to loss of supervisor), the audit was useful for planning future program goals and objectives as we move forward with new leadership.
- We need a formalized process to evaluate our program after initial training has been completed.
- With the modifications that we made and the potential for ongoing improvements to the audit process as we continue to use and refine it.

If you indicated in Question #11 that the Uniform Inspection Program Audit process was a valuable use of your

Jurisdiction's resources, how should the audit documents and forms be made available to other regulatory retail food protection programs?

A. The Uniform Inspection Program Audit and Forms should be included as an example template in an Appendix to Standard 4 – Uniform Inspection Program, *FDA Voluntary National Retail Food Regulatory Program Standards* **(10)**	**B.** The Uniform Inspection Program Audit and Forms should be made available as a resource document on FDA's web site as a stand alone piece. The audit process and forms should not be included as part of the *FDA's Voluntary National Retail Food Regulatory Program Standards* **(1)**
C. Other – *Please describe in the box provided below* **(1)**	**D.** B and C **(1)**
No Response **(1)**	

Ten (76.9%) out of the 13 jurisdictions that responded indicated that the Uniform Inspection Program Audit and Forms should be includes as an example template in the Appendix to Standard 4 – Uniform Inspection Program, FDA Voluntary National Retail Food Regulatory Program Standards. The graphic below depicting these results is followed by specific comments related to this item.



- Much of the ability to audit is the fact that you are auditing against a set protocol and training regime. If the program does not also work to achieve std 2 and std 3, the feedback from this audit is not useful since the variation in results may be from many different sources (training development issues, training delivery issues, individual inspector implementations issues, supervisory/management issues, etc.), thereby limiting the ability to adequately identify and/or address the root cause of the trend noted in the program audit.
- Many states that do not have accreditation standards could benefit from the use of this tool.
- I believe the documents should be made available in both formats.
- They should be available as an appendix to standard 4 for jurisdictions enrolled in VRFRPS.
- The standalone document should be made user friendly for jurisdictions not enrolled in the VRFRPS e.g. eliminate the reference to standards 2 and 4.
- Consider creating a separate document/report that specifically speaks to Quality Standards for Food Protection Programs and include this as one tool that could be used to audit/assess quality.

Section VII – Uniform Inspection Program Audit Pilot – Additional Comments

General Comments

- Please remember that most retail inspection programs are local. Ensure audit program is very sensitive to local pressures, etc.
- Using these forms and completing inspections with staff show Michigan evaluation of staff is on target with federal standards
- The process has been presented in a very simplified manner and I would encourage other jurisdictions to participate in this audit process using the approach outlined by the CFP committee. Managers can use this audit process as a way of identifying the problems and devising strategies to deal with them effectively. In Taney County Health Department - Environmental Services Division, we have been able to implement a quality assurance program that utilizes the 10 inspection program areas. We anticipate on conducting the onsite inspections and file reviews biannually to ensure that our workforce is effective in delivery of services to the public.
- It would be very helpful if there were sample policies/procedures available for jurisdictions to utilize and build from rather than having to start from scratch. Sample inspection reports would also be helpful as we are looking at revising ours so that the risk factors will be more routinely addressed for each inspection.

Audit Worksheet

- I find the field inspection worksheet for standard 2 to be very helpful, more so than this form. I don't really understand how this is significantly different from the standard 2 worksheet. For the first several joint inspections, I actually thought I was supposed to be using the field inspection worksheet and didn't realize that there was a separate form for the "audit." Even after realizing I was using the wrong form initially, I preferred to continue using the standard 2 worksheet in addition to the pilot project audit worksheet, since the field training worksheet gives so much more information and breaks everything down.
- I would suggest some rearranging to make things flow better. Item 5 and Item 8 seem to be very closely related and should be next to each other or combined into one item. If I were setting this sheet up, I would arrange the 10 items as follows to reflect a more linear thought process as follows (item number as it appears on the Audit Worksheet is in parenthesis:

    - (1) compliance status
    - (3) interpret and apply laws
    - (5) review past inspections
    - (8) long term control
    - (7) corrective action
    - (6) compliance & enforcement
    - (9) risk category/ inspection frequency
    - (4) proper codes
    - (2) clear report
    - (10) file reports

- If I were setting this sheet up, I would arrange the 10 items as follows to reflect a more linear thought. The process has been presented in a very simplified manner and I would encourage other jurisdictions to participate in this audit process using the approach outlined by the CFP committee. Managers can use this audit process as a way of identifying the problems and devising strategies to deal with them effectively. In Taney County Health Department - Environmental Services Division, we have been able to implement a quality assurance program that utilizes the 10 inspection program areas. We anticipate conducting the onsite inspections and file reviews biannually to ensure that our workforce is effective in delivery of services to the public.

Audit Reference Guides

- The "Guide" is of little assistance on helping the auditor interpreting "Yes" or "No" on the Audit worksheet item #1. There are, in our case, too many Risk Factors (27) and Good Retail Practices (27) to consider and then determine if item #1 should be a YES or NO.
- "Revised" Audit Reference Guides that were used by auditors are attached. The numbers reference the sections of the Abbreviated Field Training Worksheet Reference Documents sections. One auditor completed the Abbreviated Field Training Worksheet and then used the cross reference numbers to cut and paste comments into corresponding Audit Worksheet sections (with use of the revised Audit Reference Guide).

Pilot Project Findings and Conclusions

The findings and conclusions for the pilot project will be presented in two parts:

Part I – Uniform Inspection Program Audit Process and *Guides*; and
Part II – *Audit Worksheet*

Part I – Uniform Inspection Program Audit Process and *Guides*

A solid majority (85.7%) of the pilot participants agreed that the *Uniform Inspection Program Audit* process was a valuable use of their jurisdiction's resources. Most respondents were complimentary to the process and identified it as a "good start." In a minority opinion, two jurisdictions identified the process as time consuming with too much paperwork and a potential drain on employee and monetary resources.

The majority of respondents (78.6%, n=11) indicated that the instructions given in the *Guide to the Uniform Inspection Audit Process* were sufficient for understanding and implementing the training process. However, some very good suggestions were made for clarifying and improving several sections of the *Guide*. For example, a significant number of jurisdictions noted that the *Guide* did not contain the level of detail and step-by-step instructions that is found in the Standard 2 – Field Training Manual. Some jurisdictions recommended revisions to the content to ensure the intended use is clear and terminology remained consistent.

In addition, the responses indicated support for a recommendation to more closely align the Standard 4 Program Elements with the Standard 2 Performance Elements. This appears to be one of the underlying factors for a majority of jurisdictions indicating that Program Components were "missing" (61.5%, n=8); difficult to assess (66.7%, n=8); or difficult for the FSIO to demonstrate (71.4%, n=10). The majority of these respondents (80%, n=10) agreed that the *Uniform Inspection Program Audit* process is designed to facilitate a strengths-weaknesses assessment of the jurisdiction's retail food protection program.

A majority (57.1%, n=8) of the pilot jurisdictions only used one auditor to conduct the all assessments of FSIOs during the two joint inspections. Of the jurisdictions that used multiple auditors, only one used more than one auditor to assess an individual Food Safety Inspection Officer's performance of the 10 Program Elements. The pilot jurisdictions reported selecting their auditors from a variety of positions within their retail food inspection program including: Senior Food Safety Inspection Officers (n=4); Supervisors of the Food Safety Inspection Officer (n=3); Training Officers (n=2); Retail Food Program Managers (n=2), and Quality Assurance/Quality Control Officers (n=2).

Eleven of the pilot jurisdictions (78.6%) agreed that a minimum of two retail food establishment file reviews and joint field inspections for each FSIO is the appropriate number for completing a uniform inspection program audit. Two jurisdictions indicated that a minimum of two file reviews and field inspections were not enough. One of the primary reason cited centered on a lack of sufficient information to conduct an assessment of root causes that may be associated with gaps in the administrative process and training program supporting the retail food inspection program. Slightly over fifty five percent (55.3%, n=42) of the FSIOs successfully performed all 10 Program Elements during the audit process.

When the pilot jurisdictions were asked how long it took for the FSIO to complete the Uniform Inspection Program Audit process, the responses varied from less than 8 hours to 24 hours. The majority of the respondents (76.9%, n=10) indicated the average time for the FSIO to complete the audit process was less than 16 hours.

Some pilot jurisdictions encouraged revision of the Standard 4 criteria so that the 10 Program Elements reflect a more linear process and can be directly associated with Performance Elements and competencies contained in the Standard 2 – FSIO Field Training Plan. In addition, a few jurisdictions noted that the audit process intended to assess inspection program strengths and weaknesses tends to focus too much on an assessment of the FSIO's individual performance. It was reported that inspection staff participating in the pilot project viewed the audit process as a mechanism to evaluate their own performance rather than a tool for determining program strengths-weaknesses. One jurisdiction recommended that process for determining compliance with the Standard 4 criteria be re-examined so that it more accurately reflects a quality assurance review of the inspection program rather than being solely based on the performance of staff during inspections.

Part II – *Audit Worksheet*

Only half the jurisdictions (50.0%, n=7) agreed that the 10 Program Elements sufficiently address inspection uniformity, inspection quality, inspection frequency, and uniform application of the regulatory jurisdiction's retail food safety regulations and administrative procedures. A majority of the jurisdictions (78.8%, n=11), however, indicated the competencies/criteria listed as examples under each program component were helpful to the audit process. Recommendations for improving the *Audit Worksheet* included:

- Developing a comprehensive instruction guide to accompany the reference sheet similar to that provided for the Standard 2, CFP Field Training Plan;
- Organizing the 10 Program Components in a linear format to better reflect the sequence encountered during the inspection process;
- Aligning the 10 Program Elements with the Performance Elements and competencies identified in the Standard 2, CFP Field Training Plan;
- Revising the 10 Program Elements to clarify the process for assessing a complex area such as observations of risk factors versus simpler areas such as the timely filing of inspection reports and other documentation;
- Reexamining the weighting of the 10 Program Elements based on their public health significance; and
- Expanding the quality assurance assessments to include a review of other Program Elements besides the field inspections, such as an analysis of the type and frequency of out of compliance observations.

Feedback related to format of the *Audit Worksheet* varied greatly. Suggestions for improving the format included:

- Providing a numerical scale assessment rather than an all or nothing Yes / No determination for each of the Program Elements.

- Providing a comment section to note specific observations made of the FSIO performance for each of the Program Elements;
- Combine and streamline the various Audit Guides / Reference documents that support the use of the Audit Worksheet; and
- Providing a linear presentation of the 10 Program Elements; and
- Providing enough space to include the competencies that pertain to each of the Program Elements.

Pilot Jurisdictions Recommendations to the Conference

Based on the findings and conclusions from the pilot project, the following summarizes recommendations received from participating jurisdictions for enhancing the effectiveness of the *Uniform Inspection Program Audit* process, *Audit Worksheet*, and *Audit Guides*.

1. Revise the *Guide to Conducting a Uniform Inspection Program Audit*. Some changes that should be considered include:

    - Developing a more comprehensive guidance document similar to the CFP Field Training Manual contained in Standard 2 that explains the criteria for each component of the audit process;
    - Clarifying the process for selecting the establishments that are to be used for the file and field review.
    - Clarifying the parameters for what is to be included as part of the establishment file review;
    - Providing expanded guidance on the auditor's qualifications, role, and responsibilities, and.

2. The 10 Program Elements contained in Standard 4 need to be aligned with the Performance Elements and competencies identified in the Standard 2 – CFP Field Training Plan. This alignment would necessitate revisions to the *Guide to Conducting a Uniform Inspection Program Audit, Audit Worksheet,* and Audit Reference Guide.

3. The presentation of the 10 Program Elements contained n the Standard 4 criteria, the *Guide to Conducting a Uniform Inspection Program Audit,* and *Audit Worksheet* need to be presented in a linear format to reflect a logical sequence to the inspection process.

4. The information contained in the *Audit Reference Guide* should be incorporated into the *Guide to Conducting a Uniform Inspection Audit* to eliminate the need for multiple documents.

5. The weighting/assessing of each of the 10 Program Elements is not consistent, Some Program Elements, such as the one that relates to assessing risk factors, are much more complex than others, such as the timely filing of reports and documents. A more equitable, objective assessment system should be established for the audit process.

6. The Standard 2 – CFP Field Training Plan builds in the flexibility for a jurisdiction to include performance elements / competencies that are important to their program. The Standard 4 criteria and associated audit worksheet and guides are more rigid in their format. The audit process and worksheet should be designed to allow jurisdictions the flexibility for assessing inspection Program Elements that are specific to their retail food protection program.

7. The field inspection assessment conducted as part of Standard 4 seems to take an all or nothing approach. Item 1 for examples pertains to an assessment of observations of risk factors and public health interventions – eleven different categories. If an inspector fails to make an observation of just one item in this category, this Program Element is not met. This level of performance is higher than what is used for FDA Food Code Standardizations. The assessment protocol for Performance

Elements needs to be re-evaluated and better guidance provided as to what constitutes an effective performance measurement.

8. Some of the Program Elements are very subjective in nature and do not contain definitive performance measurements, such as producing legible reports. The Program Elements contained in Standard 4 should have defined performance measurements that are quantifiable.

9. The *Audit Worksheet* should include a comment section so that a more detailed description can be provided as to the observations made of an inspector's performance of any one of the 10 Program Elements.

Next Steps

The CFP CFSRP Work Group conducted conference calls to discuss the data results and feedback from pilot project jurisdictions. Based on these conference calls, the Work Group reached consensus that the pilot project contained significant recommendation pertaining to the Standard 4 – Uniform Inspection Program criteria and should be forwarded to the U.S. Food and Drug Administration (FDA). FDA provides administrative oversight of the *Voluntary National Retail Food Regulatory Program Standards* and would be the lead entity for assessing any potential changes to the Standard 4 criteria.

The CFP CFSRP Work Group has prepared two issues related to the *Uniform Inspection Program Audit Pilot Project* for deliberation at the April 2012 Conference for Food Protection in Indianapolis, IN. The first issue recommends that the Conference accept this pilot project summary report and recognize the 14 State and local jurisdictions listed in the Acknowledgements section at the beginning of this report for their contributions to the success of the pilot project and recommendations for enhancing the quality assurance component contained within Standard 4.

The second issue recommends that the Conference send a letter to FDA requesting that they:

- Review for potential revisions to the Standard 4 – Uniform Inspection Program criteria and field inspection review process, the recommendations contained in this pilot project report.

- Obtain input and feedback from the CFP Program Standards Committee as part of FDA's review of the recommendations contained in this pilot project report.

Appendices

APPENDIX A – Jurisdiction Feedback Form on the Audit Process and Forms

APPENDIX B – CFP *Guide to the Uniform Inspection Program Audit*

APPENDIX C – CFP Uniform Inspection Program *Audit Worksheet*

APPENDIX D – CFP Uniform Inspection Program *Audit Reference Guide*

APPENDIX E – CFP Uniform Inspection Program *Audit Results Summary and FSIO Training Plan*

CONFERENCE FOR FOOD PROTECTION (CFP)

UNIFORM INSPECTION PROGRAM AUDIT PILOT PROJECT

JURISDICTION FEEDBACK ON THE AUDIT PROCESS AND FORMS

Name of Jurisdiction	**Type** *(place an "X" in the appropriate box)*			
	☐ **Federal** ☐ **State** ☐ **County**			
	☐ **District** ☐ **Tribal** ☐ **Other Specify** _____			
Jurisdiction Mailing Address:		**City**	**State**	**Zip**
Contact Person for the Jurisdiction	**Contact Phone #**	**Contact Fax #**	**Contact E-mail Address**	
Report Prepared By: *(if different from the Contact Person for the Jurisdiction)*	**Preparer Phone #**	**Preparer Fax #**	**Preparer E-mail Address**	

(Place an "X" in the space adjacent to the most appropriate response for each question)

SECTION I

JURISDICTION DEMOGRAPHICS

1. What is the population living within your Jurisdiction?

☐ **A.** less than 25,000 ☐ **B.** 25,000 to 49,999 ☐ **C.** 50,000 to 99,999
☐ **D.** 100,000 to 249,999 ☐ **E.** 250,000 to 499,999 ☐ **F.** 500,000 or above

2. What is your Jurisdiction's total number of retail food and foodservice establishments under permit?

☐ **A.** less than 100 ☐ **B.** 101 to 500 ☐ **C.** 501 to 1,000
☐ **D.** 1,001 to 3,000 ☐ **E.** 3,001 to 6,000 ☐ **F.** 6,001 or above

3. How many Food Safety Inspection Officers are employed by your Jurisdiction with FULL TIME (i.e., 100%) responsibility in the food safety program?

☐ **A.** less than 4 ☐ **B.** 4 to 8 ☐ **C.** 9 to 12
☐ **D.** 13 to 20 ☐ **E.** 21 to 30 ☐ **F.** 31 or more

4. How many Food Safety Inspection Officers are employed by your Jurisdiction with responsibilities in other environmental health program areas in addition to their retail food protection duties?

☐ **A.** less than 4 ☐ **B.** 4 to 8 ☐ **C.** 9 to 12
☐ **D.** 13 to 20 ☐ **E.** 21 to 30 ☐ **F.** 31 or more

(Section I – continues on the next page)

SECTION I

JURISDICTION DEMOGRAPHICS

(Section I – continued from the previous page)

5. If your Food Safety Inspection Officers have responsibilities in other environmental health program areas, on average, how much of their annual work plan is dedicated to the retail food protection program?

☐ **A.** less than 10% ☐ **B.** 10% to 29% ☐ **C.** 30% to 49%
☐ **D.** 50% to 69% ☐ **E.** 70% to 89% ☐ **F.** 90% or more

6. Is your Jurisdiction AWARE of the *FDA Voluntary National Retail Food Regulatory Program Standards*?

☐ **Yes** ☐ **No**

7. Is your Jurisdiction ENROLLED in the *FDA Voluntary National Retail Food Regulatory Program Standards?*

☐ **Yes** ☐ **No**

8. If enrolled in the *FDA Voluntary National Retail Food Regulatory Program Standards*, has your jurisdiction MET all the Standard #2 – Trained Regulatory Staff criteria?

☐ **Yes** ☐ **No**

9. Does your Jurisdiction have a written field training plan that identifies the specific job performance elements and competencies a FSIO is expected to demonstrate during foodservice and retail food inspections?

☐ **Yes** ☐ **No**

10. If your answer to Question #9 above is YES, please identify the type of written FSIO field training plan that is in use within your jurisdiction.

☐ **A.** The CFP Field Training Plan as presented in Appendix B-2, Standard #2 – Trained Regulatory Staff, *FDA Voluntary National Regulatory Retail Food Program Standards*

☐ **B.** A customized version of the CFP Field Training Plan, Appendix B-2, Standard #2 – Trained Regulatory Staff that is specific to our jurisdictions retail food inspection protocol

☐ **C.** A Field Training Plan developed in-house that meets the intent and scope of the CFP Field Training Plan

☐ **D.** Other – Please describe in box provided below

11. If enrolled in the *FDA Voluntary National Retail Food Regulatory Program Standards*, has your Jurisdiction MET all the Standard #4 – Uniform Inspection Program criteria?

☐ **Yes** ☐ **No**

SECTION II

GUIDE TO THE UNIFORM INSPECTION PROGRM AUDIT EVALUATION OF CONTENT

(Please refer to the "Guide to the Uniform Inspection Program Audit" document when responding to the following questions)

1. Were the instructions given in the *Guide to the Uniform Inspection Program Audit* sufficient for you to understand and implement the uniform inspection audit process in your jurisdiction?

☐ **Yes** ☐ **No**

2. Please put an "X" in the boxes below to identify any Section(s) of *the Guide to the Uniform Inspection Program Audit* you believe needs improvement. Please provide your recommendation(s) for improving the *Guide* in the space provided for each subject area. The page number from the *Guide* for each subject area is included in parentheses. If you have no recommended changes for a specific Section of the Guide, leave the corresponding box and comment area blank.

☐	**Preparing for Pilot Project Participation (page 1)**

☐	**Purpose of the Uniform Inspection Program Audit (page 2)**

The Uniform Inspection Program Audit Process

☐	**Selection of Establishments (page 2)**

☐	**File Review – Selected Establishments (page 2)**

(Section II – continues on the next page)

SECTION II

GUIDE TO THE UNIFORM INSPECTION PROGRAM AUDIT
EVALUATION OF CONTENT

(Section II – continued from the previous page.
Please refer to the "Guide to the Uniform Inspection Program Audit" document when responding to the following questions)

The Uniform Inspection Program Audit Process (continued)

☐	**FSIO's Role During Joint Field Inspections (page 2)**

☐	**Uniform Inspection Auditor's Role During Joint Inspections (page 2)**

Pilot Project Steps – Uniform Inspection Program Audit

☐	**Step 1 (page 2)**

☐	**Step 2 (page 3)**

☐	**Step 3 (page 3)**

(Section II – continues on the next page)

SECTION II
GUIDE TO THE UNIFORM INSPECTION PROGRAM AUDIT
EVALUATION OF CONTENT

(Section II – continued from the previous page.
Please refer to the "Guide to the Uniform Inspection Program Audit" document when responding to the following questions)

Pilot Project Steps – Uniform Inspection Program Audit (continued)

☐	**Step 4 (page 3)**

☐	**Step 5 (page 3)**

☐	**Step 6 (page 3)**

☐	**Step 7 (page 3)**

☐	**Uniform Inspection Program Audit Pilot Project – Reference Documents (page 4)**

(Section III – Starts on the next page)

SECTION III

UNIFORM INSPECTION PROGRM AUDIT PILOT PROJECT
AUDIT WORKSHEET AND AUDIT REFERENCE GUIDE
EVALUATION OF CONTENT

(Please refer to the Uniform Inspection Program Audit Worksheet and Audit Reference Guide when responding to the following questions)

1. **The 10 uniform inspection Program Components included on the *Audit Worksheet* (and identified on page 1 of the *Audit Reference Guide*) sufficiently address inspection uniformity, inspection quality, inspection frequency, and uniform application of the regulatory jurisdictions retail food safety regulations and administrative procedures and are appropriate for all retail food program inspection staff. *(Please place an "X" in the box next to the rating that reflects the level of your agreement or disagreement with this statement).***

Strongly Disagree **Strongly Agree**

☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6**

Please explain the reasons used to determine this rating.

2. **The required minimum of two retail food establishment file reviews and joint field inspections for each FSIO is the appropriate number for completing a uniform inspection program audit?**

☐ **Yes** ☐ **No**

If you answered No, how many retail food establishment file reviews and joint field inspections do you believe should be conducted with each FSIO as part of the audit process? Please explain the reason for your answer.

3. **Are there additional Program Components that you believe are necessary in order to effectively conduct a uniform inspection program audit but are MISSING from the current *Audit Worksheet*?**

☐ **Yes** ☐ **No**

Please identify and describe these MISSING Program Components.

(Section III – continues on the next page)

SECTION III

UNIFORM INSPECTION PROGRM AUDIT PILOT PROJECT
AUDIT WORKSHEET AND AUDIT REFERENCE GUIDE
EVALUATION OF CONTENT

(Section III – continued from the previous page.
Please refer to the Uniform Inspection Program Audit Worksheet and Audit Reference Guide when responding to the following questions)

4. Were any of the 10 Program Components consistently difficult to assess during the uniform inspection program audit?

☐ **Yes** ☐ **No**

Please identify these by placing an "X" adjacent to the item number that identifies any Program Component(s) that were DIFFICULT TO OBSERVE. The Item number below corresponds to the same item number on the Audit Worksheet.

Audit Worksheet

☐ Item 1	☐ Item 3	☐ Item 5	☐ Item 7	☐ Item 9
☐ Item 2	☐ Item 4	☐ Item 6	☐ Item 8	☐ Item 10

5. If you have identified DIFFICULT TO OBSERVE Program Component(s), what factors made them difficult to observe?

6. Were there specific Program Components that FSIOs consistently experienced DIFFICULTY?

☐ **Yes** ☐ **No**

Please identify these by placing an "X" adjacent to the item number of the Performance Elements(s) FSIOs had DIFFICULTY with. The Item number below corresponds to the same item number on the Audit Worksheet.

Audit Worksheet

☐ Item 1	☐ Item 3	☐ Item 5	☐ Item 7	☐ Item 9
☐ Item 2	☐ Item 4	☐ Item 6	☐ Item 8	☐ Item 10

7. If you have identified Program Component(s) that FSIOs experienced DIFFICULTY with, what factors contributed to their challenges?

(*Section III – continues on the next page)*

SECTION III

UNIFORM INSPECTION PROGRM AUDIT PILOT PROJECT
AUDIT WORKSHEET AND AUDIT REFERENCE GUIDE
EVALUATION OF CONTENT

(Section III – continued from the previous page.
Please refer to the Uniform Inspection Program Audit Worksheet and Audit Reference Guide when responding to the following questions)

8. Do you think there are any Program Components that should be DELETED from the *Audit Worksheet*?

☐ **Yes** ☐ **No**

Please identify these by placing an "X" next to the item number of the Program Component(s) that should be DELETED. The Item number below corresponds to the same item number on the Audit Worksheet.

Audit Worksheet

☐ Item 1	☐ Item 3	☐ Item 5	☐ Item 7	☐ Item 9
☐ Item 2	☐ Item 4	☐ Item 6	☐ Item 8	☐ Item 10

9. If you recommended that one or more Program Components be deleted in Question #8, what rationale can you provide to support your recommendation?

10. The performance areas/competencies listed as examples under each Program Component on pages 2 through 4 of the *Audit Reference Guide* are helpful to conducting the uniform inspection program audit. ***(Please place an "X" in the box next to the rating that reflects the level of your agreement or disagreement with this statement).***

Strongly Disagree					**Strongly Agree**
☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**	☐ **6**

Please provide an explanation for your response.

(Section III – continues on the next page)

SECTION III

UNIFORM INSPECTION PROGRM AUDIT PILOT PROJECT
AUDIT WORKSHEET AND AUDIT REFERENCE GUIDE
EVALUATION OF CONTENT

(Section III – continued from the previous page.
Please refer to the Uniform Inspection Program Audit Worksheet and Audit Reference Guide when responding to the following questions)

11. Are there any of the 10 Program Components for which the performance areas/competencies listed as examples on pages 2 through 4 of *the Audit Reference Guide* need REVISIONS (additions, deletions, changes)?

☐ **Yes** ☐ **No**

Please identify these by placing an "X" next to the item number of the Program Component(s) needing REVISIONS to the examples provided on pages 2 through 4 of the *Audit Reference Guide*.

Audit Reference Guide (pages 2-4)

☐ Item 1	☐ Item 3	☐ Item 5	☐ Item 7	☐ Item 9
☐ Item 2	☐ Item 4	☐ Item 6	☐ Item 8	☐ Item 10

12. If you identified one or more Program Component(s) needing REVISIONS, what changes would you recommend to the performance areas/competencies listed as examples?

(Section IV – Starts on the next page)

SECTION IV

UNIFORM INSPECTION PROGRM AUDIT PILOT PROJECT
AUDIT WORKSHEET
EVALUATION OF THE WORKSHEET FORMAT

(Please refer to the Uniform Inspection Program Audit Worksheet when responding to the following questions)

1. The format of the *Audit Worksheet* is user-friendly. *(Please place an "X" in the box next to the rating that reflects the level of your agreement or disagreement with this statement).*

Strongly Disagree **Strongly Agree**

☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6**

What improvements would you recommend?

2. The header labels are appropriate.

Strongly Disagree **Strongly Agree**

☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6**

What improvements would you recommend?

3. Enough space is provided for responses and comments.

Strongly Disagree **Strongly Agree**

☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6**

What improvements would you recommend?

4. Is there any general information you believe is important that is MISSING?

☐ **Yes** ☐ **No**

Please identify information that needs to be ADDED.

(Section IV – continues on the next page)

SECTION IV

UNIFORM INSPECTION PROGRM AUDIT PILOT PROJECT
AUDIT WORKSHEET
EVALUATION OF THE WORKSHEET FORMAT

(Section IV – continued from the previous page.
Please refer to the Uniform Inspection Program Audit Worksheet when responding to the following questions)

5. Is there any general information that should be DELETED?

☐ **Yes** ☐ **No**

Please identify information that should be DELETED.

6. Did you modify the *Audit Worksheet* during the Uniform Inspection Program Pilot Project?

☐ **Yes** ☐ **No**

If Yes, please attach a copy of your modified *Audit Worksheet*.

(Section V – Starts on the next page)

SECTION V

UNIFORM INSPECTION PROGRAM AUDIT PILOT PROJECT (OPTIONAL FORM) AUDIT RESULTS SUMMARY AND FSIO TRAINING PLAN

(Please refer to the Audit Results Summary and FSIO Training Plan to respond to the following questions)

1. **The *Audit Results Summary and FSIO Training Plan* was included as an optional form a jurisdiction could use during the uniform inspection program audit pilot project. Did your jurisdiction decide to use the form?**

☐ **Yes** ☐ **No**

What factors influenced your decision?

IF YOUR JURISDICTION USED THE OPTIONAL AUDIT RESULTS SUMMARY AND TRAINING PLAN – PLEASE RESPOND TO QUESTIONS 2-6. IF YOU DID NOT USE THE OPTIONAL AUDIT RESULTS AND TRAINING PLAN PROCEED TO SECTION VI

2. **The *Audit Result Summary and FSIO Training Plan* is a useful tool for documenting the audit process and ensuring that additional training is provided to the FSIO for Program Components noted as needing improvement during the establishment file reviews and joint field inspections. *(Please place an "X" in the box next to the rating that reflects the level of your agreement or disagreement with this statement).***

Strongly Disagree **Strongly Agree**

☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6**

What improvements would you recommend?

3. **The format of the *Audit Results Summary and FSIO Training Plan* is user-friendly**

Strongly Disagree **Strongly Agree**

☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6**

What improvements would you recommend?

(Section V – continues on the next page)

SECTION V

UNIFORM INSPECTION PROGRAM AUDIT PILOT PROJECT (OPTIONAL FORM) AUDIT RESULTS SUMMARY AND FSIO TRAINING PLAN

(Section V – continued from the previous page.
(Please refer to the Audit Results Summary and FSIO Training Plan to respond to the following questions)

4. The header labels on the *Audit Results Summary and Training Plan* are appropriate.

Strongly Disagree **Strongly Agree**

☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6**

What improvements would you recommend?

5. Enough space is provided for responses and comments on the form.

Strongly Disagree **Strongly Agree**

☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6**

What improvements would you recommend?

6. Is there any general information that is missing?

☐ **Yes** ☐ **No**

Please identify information that needs to be ADDED.

(Section VI – Starts on the next page)

SECTION VI

UNIFORM INSPECTION PROGRAM AUDIT PILOT PROJECT RESULTS SUMMARY

1. How many FSIOs were assessed as part of the jurisdiction's uniform inspection program audit? _____

2. How many FSIOs successfully performed all 10 Program Components during the Audit Process? _____

3. Within your jurisdiction, who served as the "auditors" (individuals responsible for assessing FSIOs as part of the uniform inspection program audit)?

☐ **A.** Retail Food Program Managers
☐ **B.** The Supervisors of the FSIOs
☐ **C.** Training Officers
☐ **D.** Senior FSIOs
☐ **E.** Quality Assurance/Quality Control Officers
☐ **F.** Other – Please describe in box provided below

3. How many "auditors" (individuals responsible for assessing FSIOs as part of the uniform inspection program audit) participated in the Pilot Project? _____

4. Was there more than one auditor per FSIO?

☐ **Yes** ☐ **No**

5. If you answered YES to Question #4 , did FSIOs report any differences between the auditors related to how the audit was conducted?

☐ **Yes** ☐ **No**

If differences were noted, provide specific examples?

(Section VI – continues on the next page)

SECTION VI

UNIFORM INSPECTION PROGRAM AUDIT PILOT PROJECT RESULTS SUMMARY

(Section VI – continued from the previous page).

6. The uniform inspection program audit process is designed in such a way as to facilitate a strengths-weaknesses assessment of our jurisdiction regulatory retail food protection inspection program. ***(Please place an "X" in the box next to the rating that reflects the level of your agreement or disagreement with this statement).***

Strongly Disagree **Strongly Agree**

☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6**

What changes would you recommend to enhance the inspection program audit process?

7. On average, how long did it take to complete an orientation of the Uniform Inspection Program Audit process and *Audit Worksheet* for each of the FSIOs?

☐ **A.** less than 60 minutes ☐ **B.** 61 – 120 minutes ☐ **C.** 121 – 180 minutes
☐ **D.** Other. Please Specify

8. On average, how long did it take to complete an audit of the Pre-Inspection Establishment File Review?

☐ **A.** less than 30 minutes ☐ **B.** 31 – 60 minutes ☐ **C.** Other. Please Specify

9. On average, how long did it take to complete the audit of a joint field inspection (SINGLE INSPECTION) using the Audit Worksheet (actual time in hours – including inspection, completion of the inspection report, and discussion of the inspection report with the person in charge)? Do NOT include travel time to & from the establishment.

☐ **A.** less than 60 minutes ☐ **B.** 61 – 120 minutes ☐ **C.** 121 – 180 minutes
☐ **D.** Other. Please Specify

10. On average, how long did it take to complete the audit process for each individual FSIO? (Include the orientation process; establishment file reviews; actual inspection time; review of the audit reports with the FSIO; and completion of all inspection program audit documents/worksheets.)

☐ **A.** less than 8 hours ☐ **B.** 9 – 16 hours ☐ **C.** 17 – 24 hours
☐ **D.** 25 – 32 hours ☐ **E.** 33 – 40 hours ☐ **F.** Other. Please Specify:

(Section VI – continues on the next page)

SECTION VI

UNIFORM INSPECTION PROGRAM AUDIT PILOT PROJECT RESULTS SUMMARY

(Section VI – continued from the previous page).

11. The uniform inspection program audit process is a valuable use of my Jurisdiction's resources (e.g., time; staff; finances).

Strongly Disagree					**Strongly Agree**
☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**	☐ **6**

Explain, why?

12. If you indicated in Question #11 that the Uniform Inspection Program Audit process was a valuable use of your Jurisdiction's resources, how should the audit documents and forms be made available to other regulatory retail food protection programs?

☐ **A.** The Uniform Inspection Program Audit and Forms should be included as an example template in an Appendix to Standard 4 – Uniform Inspection Program, *FDA Voluntary National Retail Food Regulatory Program Standards.*

☐ **B.** The Uniform Inspection Program Audit and Forms should be made available as a resource document on FDA's web site as a stand alone piece. The audit process and forms should not be included as part of the *FDA Voluntary National Retail Food Regulatory Program Standards*

☐ **C.** Other – Please describe in box provided below

(Section VII – Starts on the next page)

SECTION VII

UNIFORM INSPECTION PROGRAM AUDIT
ADDITIONAL COMMENTS SECTIONS

(Provide any additional comments on any aspect of the Uniform Inspection Program Audit process or forms)

GUIDE TO THE UNIFORM INSPECTION PROGRAM AUDIT

Conference for Food Protection
Uniform Inspection Program Audit Pilot Project

The Guide to the Uniform Inspection Program Audit:

- Provides the background leading up to the development of the Conference for Food Protection (CFP) Uniform Inspection Program Audit Pilot Project;
- Describes the purpose of the audit;
- Defines Food Safety Inspection Officer's (FSIO) role;
- Clarifies the auditor's role;
- Discusses food establishment selection criteria, and
- Outlines the implementation steps for the project.

Preparing for Pilot Project Participation

A work group originally assembled by the 2004 Conference has been working with representatives of the Food and Drug Administration (FDA) to create a multi-tiered process for training and standardizing FSIOs. Over the past 5 years, the work group has used the criteria contained in the *FDA Voluntary National Retail Food Regulatory Program Standards (FDA Program Standards),* Standard 2 – Trained Regulatory Staff to develop a comprehensive training model for regulatory retail food safety inspection officers.

Jurisdiction's participating in the pilot project must implement the training criteria in Standard #2 for FSIOs newly hired or assigned to the retail food protection program. A copy of the Standard 2 criteria, including the CFP Field Training Plan is included with the CFP Pilot Project Package

After completing the training requirements in Steps 1 through 3, Standard 2, Trained Regulatory Staff, the FSIO is now eligible as a candidate for the Uniform Inspection Program Audit that is to be used in conjunction with the quality assurance criteria contained in Standard 4. Standard 4 applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies, and compliance/enforcement procedures. It requires that an assessment review of each inspector's work be made during at least two joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports. The quality assurance assessment must include a review of 10 program components that comprise the Uniform Inspection Program Audit Worksheet used to evaluate inspection uniformity, inspection quality, inspection frequency, and uniform application of the regulatory jurisdictions retail food safety regulations and administrative procedures by all inspection staff.

Jurisdiction's participating in the pilot project must follow the criteria in Standard#4 and commit to conducting at least two file reviews and joint field inspections of selected retail food

establishments with eligible FSIOs. A copy of the Standard 4 criteria is included with the CFP Pilot Project Package.

Purpose of the Uniform Inspection Program Audit

The use of the Uniform Inspection Program Audit provides a mechanism for regulatory jurisdictions to conduct quality assurance evaluations of their retail food protection programs while assessing the strengths and weakness within their training program for FSIOs.

The Uniform Inspection Program Audit Process

Selection of Establishments

Management should select the two establishments to be used for the uniform inspection program audit following the Standard 4 criteria. In all cases, the food establishments selected should reflect the work covered during the FSIO's training and provide an opportunity to assess all 10 program components identified in the Standard 4 criteria.

File Review – Selected Establishments

A file review of each of the selected establishments is to be conducted as part of the audit process in order to assess the inspection program areas and competencies that may not be observable on-site at the facility. For example, repeat violations, follow-up compliance and enforcement, and discussion and documentation of long-term corrective options may be difficult or impossible to assess without an establishment file review.

FSIO's Role During Joint Field Inspections

The FSIO is responsible for independently conducting the inspection while being evaluated by the auditor. The FSIO should refrain from asking the auditor questions pertinent to the inspection (e.g. advice, assistance), but should feel free to explain his/her actions to the auditor before and during the audit. These explanations help the auditor understand the FSIO's approach to the inspection and reduce the risk of the auditor drawing inaccurate conclusions about the FSIO's actions. If unique or unexpected circumstances are encountered during the audit, the FSIO may seek appropriate guidance from his/her supervisor (or designee) while keeping the auditor informed of these contacts.

Uniform Inspection Auditor's Role During Joint Inspections

The uniform inspection program auditor assesses the FSIO's ability to conduct an inspection using the Standard 4 criteria and plays no role in conducting the inspection. The FSIO should conduct the inspection as if the auditor were not present. The auditor needs to be as unobtrusive as possible. The auditor may ask questions of the FSIO to better understand or clarify the rationale for the candidate's actions.

Pilot Project Steps – Uniform Inspection Program Audit

NOTE: Overall responsibility for the implementation of this pilot project within each jurisdiction rests with the (State, Local, Tribal) retail food protection program management. Management may want to delegate audit responsibilities to first line

supervisors (i.e. establishment selection, audit scheduling, and completion of uniform inspection program tables contained in Appendix D, Standard 4).

Step 1 – The FSIO works with his/her first line supervisor (or designee) to complete all requirements listed in Steps 1 through 3, Standard 2 – Trained Regulatory Staff.

Step 2 – The supervisor confirms that the FSIO has completed the required Standard 2 training outlined in Step 1 above.

Step 3 – The Department Director (or designee) selects the individual(s) to conduct the uniform inspection program audits. At least two retail food establishment file reviews and joint field inspections must be completed for each eligible FSIO. Establishments used in the audit must be selected in accordance with the protocol outlined in Appendix D, Standard 4 – Uniform Inspection Program.

> **NOTE:** Jurisdictions having less than four FSIOs will need to conduct extra inspections with each inspector in order to reach a minimum total of 8 inspections. This is necessary in order to have a sample of inspection large enough to statistically measure the uniformity of the inspection program fairly (Standard 4, Appendix D).

Step 4 – Each eligible FSIO performs a file review and field inspection with the jurisdiction's designated auditor. During these quality assurance assessments, the jurisdiction's designated auditor will verify that FSIO successfully demonstrates each of the desired activities and competencies for the 10 inspection program areas listed in the Standard 4 criteria. The CFP Uniform Inspection Program Audit Worksheet is completed by the auditor for each of the selected establishments. For this CFP pilot project, the Uniform Inspection Program Audit Reference Guide has been developed as an auditing tool for determining the competencies to observe for each inspection program area.

Step 5 – Upon completion of the file reviews and joint field training inspections for the selected establishments, the jurisdiction's designated auditor completes the Audit Results Summary section of the Audit Results Summary and FSIO Training Plan Form. The Audit Results Summary establishes a method for providing feedback to the FSIO and identifies any inspection program areas or competencies the FSIO needs additional training on. The jurisdiction has the flexibility to address these additional training areas using their internal procedures and training programs. A FSIO Training Plan template is included as a tool for jurisdiction to develop a structured approach for addressing each competency the FSIO did not perform successfully during the audit process.

Step 6 – The FSIO performance results from all Uniform Inspection Audit Worksheets are used to complete the Standard 4 quality assurance assessment of the retail food protection inspection program. The jurisdiction uses the tables in Appendix D, Standard 4, to determine conformance with the uniform inspection program criteria.

- Jurisdictions with less than 10 FSIOs are to use Table D-1
- Jurisdictions with more then 10 FSIOs are to use Table D-2

Appendix D, Standard 4 provides instructions for how to use each of the tables described above.

Step 7 – The jurisdiction uses the results from the Standard 4 – Uniform Inspection Audit as one of the tools for determining the strengths and gaps within their Food Safety Inspection Officer training program. If any of the 10 uniform inspection program areas are not met, the jurisdiction may need to re-assess the training materials/methods used to prepare FSIOs for performing these inspection program competencies.

Uniform Inspection Program Audit Pilot Project - Reference Documents

- FDA Voluntary National Retail Food Regulatory Program Standards (April 2009):
  - Standard 2, Trained Regulatory Staff
  - Appendix B – Supplement to Standard 2 – Trained Regulatory Staff
  - Standard 4, Uniform Inspection Program
  - Appendix D – Supplement to Standard 4 – Uniform Inspection Program
- Guide to the Uniform Inspection Program Audit
- Uniform Inspection Program Pilot Project – Audit Worksheet
- Uniform Inspection Program Pilot Project – Audit Reference Guide
- Uniform Inspection Program Pilot Project – Audit Results Summary and FSIO Training Plan

Audit Worksheet

Conference for Food Protection
Uniform Inspection Program Audit Pilot Project

Food Safety Inspection Officer:	
Date of Audit Start:	**Date of Audit End:**
Jurisdiction's Auditor:	
Selected Establishment:	**Permit Number:**
Establishment Address:	

Uniform Inspection Program Audit Worksheet

(To be used for the two joint field inspections and file reviews conducted as part of the Standard 4 – Uniform Inspection Program quality assurance assessment)

Food Safety Inspection Officer (FSIO) has successfully completed pre-requisite training courses as specified in the *FDA Voluntary National Retail Food Regulatory Program Standards*, Standard 2 – Trained Regulatory Staff.

☐ YES ☐ NO

COMMENTS

1. Did the Food Safety Inspection Officer (FSIO) determine and document the compliance status of each risk factor and intervention (i.e., IN compliance, OUT of Compliance, Not Observed, or Not Applicable) through observation and investigation?

☐ YES ☐ NO

COMMENTS

2. Did the FSIO complete an inspection report that is clear, legible, concise, and accurately records findings, observations and discussion with establishment management?

☐ YES ☐ NO

COMMENTS

3. Did the FSIO interpret and apply laws, regulations, policies and procedures correctly?

☐ YES ☐ NO

COMMENTS

4. Did the FSIO cite the proper code provisions for CDC-identified risk factors and Food Code interventions?

☐ YES ☐ NO

COMMENTS

5. Did the FSIO review past inspection findings and act on repeated or unresolved violations?

☐ YES ☐ NO

COMMENTS

6. Did the FSIO follow through with compliance and enforcement procedures in accordance with the jurisdiction's administrative procedures?

☐ YES ☐ NO

COMMENTS

7. Did the FSIO obtain and document on-site corrective action for out-of-control risk factors at the time of inspection as appropriate to the type of violation?

☐ YES ☐ NO

COMMENTS

8. Did the FSIO document that options for the long term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurred on consecutive inspections? Options may include but are not limited to risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.

☐ YES ☐ NO

COMMENTS

9. Did the FSIO verify that the establishment is in the proper risk category and that the required inspection frequency is being met?

☐ YES ☐ NO

COMMENTS

10. Does the FSIO file reports and other documents in a timely manner?

☐ YES ☐ NO

COMMENTS

AUDIT REFERENCE GUIDE

Conference for Food Protection
Uniform Inspection Program Audit Pilot Project

Standard 4 applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies, and compliance/enforcement procedures. It requires that an assessment review of each inspector's work be made during at least two joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports. The quality assurance assessment must include a review of 10 program components that evaluate inspection uniformity, inspection quality, inspection frequency, and uniform application of the regulatory jurisdictions retail food safety regulations and administrative procedures by all inspection staff. The quality assurance assessment is intended to assure that each inspector:

1. Determines and documents the compliance status of each risk factor and intervention (i.e., IN compliance, OUT of Compliance, Not Observed, or Not Applicable) through observation and investigation;
2. Completes an inspection report that is clear, legible, concise, and accurately records findings, observations and discussion with establishment management;
3. Interprets and applies laws, regulations, policies and procedures correctly;
4. Cites the proper code provisions for CDC-identified risk factors and Food Code interventions;
5. Reviews past inspection findings and acts on repeated or unresolved violations;
6. Follows through with compliance and enforcement;
7. Obtains and documents on-site corrective action for out-of-control risk factors at the time of inspection as appropriate to the type of violation;
8. Documents that options for the long term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurred on consecutive inspections. Options may include but are not limited to risk control plans, standard operating
   procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans;
9. Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met; and
10. Files report and other documents in a timely manner

Standard 4 requires that an assessment of each inspector's work, using the above 10 inspection program areas, be made during a least two joint on-site inspections, with a corresponding file review of the three most recent inspection reports. Retail food program inspection staff must demonstrate competency for each of the 10 Standard 4 inspection program areas. The Audit Reference Guide is designed to help clarify the competencies that correspond to each of the 10 inspection program areas identified in the Standard 4 criteria and included as part of the Uniform Inspection Program Audit Worksheet.

For each inspection program area, examples of applicable competencies from the CFP Field Training Plan are included as part of the Audit Reference Guide. The list of competencies under each inspection program area, are examples and **not** intended to be all inclusive. Should further guidance be needed, the CFP Field Training Plan contains a comprehensive listing of competencies that can be used to determine that a FSIO has successfully demonstrated the required inspection program area.

UNIFORM INSPECTION PROGRAM AREAS

11. **Did the Food Safety Inspection Officer (FSIO) determine and document the compliance status of each risk factor and intervention (i.e., IN compliance, OUT of Compliance, Not Observed, or Not Applicable) through observation and investigation?**

Examples of Performance Areas/Competencies from the Standard 2 CFP Field Training Plan:

- FSIO correctly used inspection equipment during joint inspections.
- FSIO asked questions and engages in a dialogue with person in charge/employees to obtain information relevant to inspection.
- FSIO used available means (e.g., interpreter, drawings, demonstrations, diagrams, international food safety icons) to overcome language or communication barriers.
- FSIO demonstrated proper sanitary practices as expected from a food service employee.
- FSIO used a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food. When the risk factor and/or intervention was applicable and observable during the inspection, the FSIO verified:
    i. Demonstration of Knowledge of the person in charge
    ii. Approved food sources
    iii. Food safety practices for preventing cross-contamination of ready-to-eat foods
    iv. Food contact surfaces are cleaned and sanitized
    v. Restriction and exclusion of ill employees
    vi. Employee handwashing
    vii. Cooking temperatures to destroy bacteria and parasites
    viii. Cold holding, hot holding, cooling and reheating temperatures of foods requiring time/temperature control for safety (TCS)
    ix. Procedures are in place when time alone is used as a microbial growth barrier
    x. Date marking of ready-to-eat, TCS food held for more than 24 hours
    xi. Availability of a consumer advisory for foods of animal origin served raw or undercooked

12. Did the FSIO complete an inspection report that is clear, legible, concise, and accurately records findings, observations and discussion with establishment management?

Examples of Performance Areas/Competencies from the Standard 2 CFP Field Training Plan:

- FSIO completed inspection form per jurisdiction's administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).
- FSIO included with inspection report any compliance or regulatory documents identified or cross-referenced in written statements (e.g., exhibits, attachments, sample forms, embargo forms, destruction forms, suspension notices).
- FSIO presented inspection report, and when necessary cross-referenced documents, to person in charge.
- FSIO conducted an exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.
- FSIO only reported substantiated findings as violations.
- FSIO used effective communication and conflict resolution techniques to overcome inspection barriers

13. Did the FSIO interpret and apply laws, regulations, policies and procedures correctly?

Examples of Performance Areas/competencies from the Standard 2 CFP Field Training Plan:

- FSIO correctly assessed the compliance status of other regulations (not included in Item 1 above) that are included in jurisdiction's prevailing statutes, regulations and/or ordinances.
- FSIO provided the person in charge/employees with accurate answers to inspection-related questions.

14. Did the FSIO cite the proper code provisions for CDC-identified risk factors and Food Code interventions?

Examples of Performance Areas/Competencies from the Standard 2 CFP Field Training Plan:

- FSIO has knowledge of jurisdiction's laws, rules, and regulations required for conducting retail food/foodservice inspections.
- FSIO cited the proper code provision for CDC-identified risk factors and Food Code interventions on the written inspection report.

15. Did the FSIO review past inspection findings and act on repeated or unresolved violations?

Examples of Performance Areas/Competencies from the Standard 2 CFP Field Training Plan:

- FSIO reviewed establishment file for previous inspection reports noting documented out of compliance observations.
- FSIO reviewed establishment complaints on file.
- FSIO verified correction of out of compliance observations identified during previous inspections.

16. Did the FSIO follow through with compliance and enforcement procedures in accordance with the jurisdiction's administrative procedures?

Examples of Performance Areas/Competencies from the Standard 2 CFP Field Training Plan:

- FSIO follows the jurisdiction's compliance and enforcement polices and procedures regarding repeated and unresolved violations.
- FSIO follows the jurisdiction's policy in regard to disclosure of confidential information.

17. Did the FSIO obtain and document on-site corrective action for out-of-control risk factors at the time of inspection as appropriate to the type of violation?

Examples of Performance Areas/Competencies from the Standard 2 CFP Field Training Plan:

- FSIO obtained immediate corrective action for out of compliance employee practices and management procedures essential to the safe storage, preparation, and service of food.
- FSIO documented on the written inspection report the immediate corrective action that was taken for each out-of-control risk factor.

18. Did the FSIO document that options for the long term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurred on consecutive inspections? Options may include but are not limited to risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.

Examples of Performance Areas/Competencies:

- FSIO discussed options, included in the jurisdiction's administrative policies, for long term control of risk factors with the person in charge in case where the out-of-control risk factor occurred on consecutive inspections.
- FSIO documented on the inspection report the long term control option agreed to by the person in charge for the identified out-of-control risk factor.

19. Did the FSIO verify that the establishment is in the proper risk category and that the required inspection frequency is being met?

Examples of Performance Areas/Competencies from the Standard 2 CFP Field Training Plan:

- FSIO reviewed establishment file to determine proper risk category and that the required inspections have been completed
- If applicable, FSIO reviewed establishment files for required HACCP Plans or documents supporting the issuance of a variance.

20. Does the FSIO file reports and other documents in a timely manner?

Examples of Performance Areas/Competencies:

- A review of the records within the establishment file indicates that the FSIO has followed the jurisdiction's administrative procedures pertaining to the filing of inspection reports and support documents.

Audit Results Summary and FSIO Training Plan

Conference for Food Protection
Uniform Inspection Program Audit Pilot Project

Use of the Audit Results Summary and FSIO Training Plan

The *FDA Voluntary National Retail Food Regulatory Program Standards* (Program Standards) provide a foundation upon which a regulatory retail food protection program can build through a continuous improvement process. The CFP Uniform Inspection Program Audit Pilot Project provides a quality assurance assessment of the jurisdiction's inspection program and identifies training priorities for each Food Safety Inspection Officer (FSIO). The Audit Results Summary and FSIO Training Plan provides a method for addressing additional inspection program training needs identified during the uniform inspection program audit process.

As the title implies, the Audit Results Summary and FSIO Training Plan consists of two parts:

- PART I – Audit Results Summary
- PART II – FSIO Training Plan

Completion of each part of the form establishes a structure for ensuring that FSIOs are provided the necessary program support to address any of the competencies noted during the inspection program audit process as ones where additional training is needed.

PART I – Audit Results Summary

The jurisdiction's designated auditor completes the audit results summary, including the header information. In the header section, the auditor will indicate if the FSIO requires additional training for one or more competencies observed during the audit process.

A. No Additional Training Needs Identified During the Audit
If "NO" additional training needs have been identified, then the auditor, FSIO, and the FSIO's Supervisor sign the bottom of the summary section confirming the audit results. The original should be placed in the FSIO's Training file. The FSIO should make a copy for their records.

B. Additional Training Needs Identified During the Audit
If additional training needs were identified during the uniform inspection program audit process, the auditor checks the "YES" box in the header section. In the table below the header section, the auditor identifies the competencies from the Audit Worksheet for which the FSIO requires additional training. The auditor reviews these items with the FSIO and the FSIO's Supervisor to ensure understanding of the specific competency that is to be addressed through training. The auditor, FSIO, and the FSIO's Supervisor all sign the form at the bottom of the page confirming the audit results.

PART II – FSIO Training Plan

(**NOTE:** Part II is not completed unless the auditor has identified FSIO competencies (in Part I) that require additional training)

The FSIO's Supervisor meets with the FSIO to set up an appropriate training plan to address competencies in need of improvement. The jurisdiction's inspection program policies and procedures should address appropriate types of training and methods. Training could range from simply a demonstration or discussion of the proper procedures to a structured training workshop. The selected training method should provide the FSIO the knowledge, skill, and ability to perform each of the competencies the auditor earmarked for improvement. In PART II, the FSIO's Supervisor documents the agreed upon training plan. The FSIO and the FSIO's Supervisor sign indicating full understanding and commitment to the training.

The FSIO supervisor follows up to ensure that the training plan is completed per the jurisdiction's administrative procedures and time frames. The supervisor documents when the FSIO has successfully demonstrated the competencies identified in the training plan. If additional training is needed, the supervisor documents the new plan. Upon successful completion of the training plan, the FSIO, FSIO's Supervisor, and Food Program Manager sign the bottom of training plan. The original is placed in the FSIO's Training file. The FSIO retains a copy for their records.

Audit Results Summary and FSIO Training Plan

Conference for Food Protection
Uniform Inspection Program Audit Pilot Project

Date:
Food Safety Inspection Officers Name:
Jurisdiction's Auditor Name:
Date Uniform Inspection Audit Completed:
Uniform Inspection Program Audits Results indicate additional FSIO training needs: ☐ **YES** ☐ **NO**

If Audit Results indicate additional FSIO training is needed, complete the following table:

PART I – AUDIT RESULTS SUMMARY	
Identify the specific competencies needing improvement from the Uniform Inspection Program Audit Worksheet and describe the specific performance required.	
Competency:	
Specific Improvement Required:	
Competency:	
Specific Improvement Required:	
Competency:	
Specific Improvement Required:	
Competency:	
Specific Improvement Required:	
Competency:	
Specific Improvement Required:	

Confirmation of Audit Results Signatures	
Jurisdiction's Auditor:	Date:
FSIO:	Date:
FSIO's Supervisor:	Date:

PART II – FSIO Training Plan

Describe the training methods and instruction for addressing each competency identified in the table above.

Training Plan Agreement Signatures	
FSIO:	Date:
FSIO's Supervisor:	Date:

Follow-Up on FSIO Training Plan

Follow-up Training Completion Date(s):			

☐ *FSIO has successfully demonstrated the competencies identified in the training plan*

☐ *FSIO has not successfully demonstrated the competencies identified – additional training is needed*

The competencies where additional training is needed include:

Follow-up Review Signatures	
FSIO:	Date:
FSIO's Supervisor:	Date:
Food Program Manager:	Date:

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-012

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Amend VNRFRPS – Standard 4 – Uniform Inspection Program (Part 2)

Issue you would like the Conference to consider:

Amend the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) No. 4 - Uniform Inspection Program to reflect recommendations from the 2012 CFP Uniform Inspection Program Audit Pilot Project Report.

The Pilot Project Report is attached to the "Part 1" Issue on this topic; Issue titled: Amend VNRFRPS - Standard 4 - Uniform Inspection Program (Part 1)

The report is also currently posted on the CFP website at: http://www.foodprotect.org/media/guide/uniform-inspection-program-audit-pilot-project-report.pdf

Public Health Significance:

The 2012 CFP Uniform Inspection Audit Pilot Project Report evaluated the Uniform Inspection Program process and audit worksheet as tools for conducting the quality assurance evaluations in Program Standard No. 4.

Implementing the following changes will address some of the recommendations provided in the Pilot Project Report, while also providing greater flexibility, improved program quality assessment, and greater consistency between Program Standards No. 2 and No. 4:

1. Clarify that jurisdictions may assess additional performance elements as part of their field assessment process. However, for the purposes of achieving conformance with the Standard, only the performance elements specified in the Standard will be used to assess conformance with the Standard.
2. Clarify that the assessment of the performance elements is not an all-or-nothing approach. (For instance, someone that misses one risk factor out of 10 risk factors during a field assessment may still achieve an acceptable level of performance/uniformity on a particular performance element.)

3. Clarify that enrolled jurisdictions may wish to create a field assessment tool that includes specific comments and feedback for the individual food safety inspection officer.
4. Clarify how establishments should be selected for the field assessment process.
5. Provide specific guidance about the file review process.
6. Clarify who should conduct the field assessment and associated file review.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Program Standard No. 4 - Self-Assessment Instructions and Worksheet, be amended to reflect the changes shown in "Attachment A - Instructions and Worksheet for Conducting a Self-Assessment" (language to be added is underlined; language to be deleted is in strikethrough format).

Submitter Information:

Name:	Mary Cartagena
Organization:	Food and Drug Administration
Address:	5100 Paint Branch ParkwayHFS-320 Rm 3B038
City/State/Zip:	College Park, MD 20740
Telephone:	240-402-2937
E-mail:	mary.cartagena@fda.hhs.gov

Content Documents:

- "Attachment A-Proposed Amendments for PS No.4-SelfAssessmentInstr.Worksheet"

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.

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

STANDARD 4 – TRAINED REGULATORY STAFF

Using the Standard 4 Self-Assessment Worksheet
Criterion three on the *Standard 4: Self-Assessment and Verification Audit Form* requires a statistical measure of the program's effectiveness. Tables 4-1 and 4-2 on the *Standard 4: Self-Assessment Worksheet*, included at the end of these instructions, are designed to assist the jurisdiction in determining by statistical method the effectiveness of its Uniform Inspection Program and in documenting its findings. The jurisdictions are not obligated to use the worksheet. Equivalent forms or processes are acceptable provided that the statistical process and result is available for review.

Step 1 – Conduct three field reviews for each employee performing food service or retail food inspection work during the five-year self-assessment period.
The jurisdiction must conduct three field reviews with each employee performing food service or retail food inspection work during the five-year self-assessment period. Staff members who are within their initial 18 months of training and have not completed all prerequisite courses, 25 joint inspections and 25 independent inspections as required in Standard 2, are exempt from the field reviews and file reviews used in the performance measurement rating calculation in the Standard 4 Self-Assessment Worksheet.

Field reviews must be conducted by someone who has competed Steps 1-3 in Standard 2, and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.

Some of the performance elements can only be assessed after thorough a review of the establishment file. Therefore, each field review must be accompanied by a review of the establishment file. Information from the file review will help the field assessor determine if the FSIO:

- Obtained corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies;
- Discussed options for the long-term control of risk factors with establishment managers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies; and
- Verified correction of out-of-compliance observations identified during the previous inspection. In addition, follows through with compliance and enforcement in accordance with the jurisdiction's administrative procedures.

The field reviews must be conducted at establishment types representative of the employee's case load. The jurisdiction should determine a method for selecting appropriate facilities for the field review process, and use that method consistently for all employees.

The field review process (and the accompanying file review) is intended to evaluate the quality and consistency of the program for each performance element. The following should be taken into consideration when implementing the field review process:

- This Standard is intended to ensure that inspections are of a satisfactory quality and uniformity across the entire program.
- When assessing a staff member's performance during the field review process, perfection is not required to demonstrate successful achievement of a performance element.
- Table 4-2 is intended to document the results of the field review process for the purpose of determining if a jurisdiction has achieved conformance with Standard 4. Table 4-2 is not intended as a mechanism for providing feedback to staff on their performance during the field review process. Therefore, jurisdictions are encouraged to incorporate the performance elements from Standard 4 into a field review tool so that staff can be provided with meaningful feedback that improves the quality and uniformity of their inspections.
- Jurisdictions may assess additional jurisdiction-specific performance elements during the field review process. However, for the purposes of determining conformance with Standard 4, additional jurisdiction-specific performance elements may not be included in the calculation used for Table 4-1 or 4-2.

Step ~~1~~2 – Confirm that ~~Two~~ three field reviews have been conducted for each employee performing foodservice or retail food inspection work during the five-year self-assessment period.

Table 4-2 of the *Standard 4: Self-Assessment Worksheet* is used to document the field inspections and to analyze statistically the program's overall effectiveness. The jurisdiction conducts at least ~~two~~ three field inspections with each inspector who conducts food service or retail food inspections during each five-year self-assessment period.

Table 4-2 must be completed with at least ~~eight~~ twelve field inspections. Jurisdictions with less than four inspectors must complete additional field inspections with each inspector in order to reach a total of ~~eight~~ twelve inspections. For example, a jurisdiction with three inspectors would need to:

- Complete ~~three~~ four inspections ~~with two of the~~ each inspector~~s.~~; ~~and~~
- ~~Complete two inspections with one inspector.~~

Step ~~3~~2 – Use Table 4-2 to enter the results from the two field reviews for each Food Safety Inspection Officer (FSIO)

- In the first column of Table 4-2, identify each FSIO by name or by a code.
- In the Establishment ID column, identify the two establishments included in the field reviews for each FSIO.
- In the "DATE" column, record the dates of the field visit and file review.
- Items 1 through 20~~10~~, ~~summarized below, list~~ are the Standard 4 criteria related to the FSIOs competencies.

~~1. The jurisdiction's quality assurance program assures that each inspector documents the compliance status of each foodborne illness risk factor and intervention through observation and investigation. (i.e. proper and consistent marking of the inspection form using the IN, OUT, NA, and NO conventions appropriately.)~~

2. ~~The jurisdiction's quality assurance program assures that each inspector completes an inspection report that is clear, legible, concise, and accurately records findings, observations and discussion with establishment management.~~
3. ~~The jurisdiction's quality assurance program assures that each inspector interprets and applies laws, regulations, policies and procedures correctly.~~
4. ~~The jurisdiction's quality assurance program assures that each inspector cites the proper local code provisions for the CDC-identified risk factors and *Food Code* interventions.~~
5. ~~The jurisdiction's quality assurance program assures that each inspector reviews past inspection findings and acts on repeated or unresolved violations.~~
6. ~~The jurisdiction's quality assurance program assures that each inspector follows through with compliance and enforcement in accordance with the agency's policies and procedures.~~
7. ~~The jurisdiction's quality assurance program assures that each inspector obtains and documents on-site corrective action for out-of-control risk factors at the time of the inspection as appropriate to the violation.~~
8. ~~The jurisdiction's quality assurance program assures that each inspector documents that options for the long-term control of risk factors were discussed with managers when the same out-of-control risk factor occurred on consecutive inspections.~~
9. ~~The jurisdiction's quality assurance program assures that each inspector verifies that the establishment is in the proper risk category and that the required inspection frequency is being met.~~
10. ~~The jurisdiction's quality assurance program assures that each inspector files reports and other documents in a timely manner.~~

~~**NOTE:** Some items (such as 5, 6, 8, and 9) cannot be verified without a review of the file for the establishment visited.~~

The self-assessor must place a check mark in the corresponding column of Table 4-2 when the activity or competency is verified.

Step ~~3~~4 – Conduct calculations to Determine Program Effectiveness

JURISDICTIONS WITH TEN OR MORE INSPECTORS

For jurisdictions with ten or more inspectors conducting foodservice or retail food inspections, the self-assessor must:

1. Add the number of check marks in the column titled "Item 1";
2. Divide the total number of checks marks from Step 1 by the total number of field inspections documented in Table 4-2;
3. Multiply the number in Step 2 by 100; and
4. Repeat this process for Item 1 through Item ~~10~~ 20.

This results in a percent achievement for each of the ~~ten~~ twenty quality elements. Each of the twenty ~~ten~~ columns must show at least a 75% achievement rate in order for the program to meet the effectiveness measure. Perform and review the calculations for each of the ~~ten~~ twenty columns.

JURISDICTIONS WITH LESS THAN TEN INSPECTORS

For jurisdictions with less than ten inspectors conducting foodservice or retail food inspections, an adjustment must be made in the statistical method to compensate for the small sample size. The self-assessor must:

1. Add the total number of check marks for Item 1 through Item ~~10~~ 20;
2. Refer to Chart 4-1. Column three of Chart 4-1 shows the minimum number of items that must be marked "IN Compliance" to meet the effectiveness measure for Standard 4.
3. Complete Table 4-1 to determine if the jurisdiction achieves conformance with the effectiveness measure in Standard 4.

Step 5~~4~~ – Document Results of the Uniform Program Assessment

Use the worksheet results to mark "YES" or "NO" for criteria list under "*3 – Demonstration of Program Effectiveness Using the Statistical Method in Standard 4 Self-Assessment Worksheet*" on the *Standard 4: Self-Assessment and Verification Audit Form*.

Standard 4: Uniform Inspection Program
Self-Assessment Worksheet

Chart 4-1
Method of Calculation for Jurisdictions with Less Than Ten Inspectors

# of inspectors	# inspections needed	# of items needed to be marked IN compliance in order to meet Standard 4 criteria
<4	8 12 minimum	**~~65~~200** (out of 240~~80~~ possible Items)
4-9	~~2~~ 3 per inspector	4 inspectors = **200~~65~~** (out of ~~80~~240 possible Items) 5 inspectors = **252~~82~~** (out of 300~~100~~ possible Items) 6 inspectors = **303~~99~~** (out of 360~~120~~ possible Items) 7 inspectors = **355~~116~~** (out of 420~~140~~ possible Items) 8 inspectors = **407~~133~~** (out of 480~~160~~ possible Items) 9 inspectors = **459~~150~~** (out of 540~~180~~ possible Items)

NOTE:

1. These minimum inspection program assessment criteria are comparable to the 75% IN Compliance rate for each of the ten inspection program areas for jurisdictions with 10 or more inspectors.

Example: For 6 inspectors, there will be 3~~2~~ field visits per inspector = ~~12~~18 visits ~~12~~18 visits X ~~10~~20 Items per visit = ~~120~~360 Total Possible Items

Table 4-1
Calculation of Uniformity for Jurisdictions with Less Than Ten Inspectors

Period from ___ _____ to _____ _____

1. Number of inspectors in the jurisdiction	
2. Number of inspections used in the calculation (minimum of ~~8~~12)	
3. Total number of items marked as correct during joint field visits and corresponding file reviews and recorded on Table 4-2.	
4. Total number of possible items based on the number of inspections (~~10~~20 items times the # of inspections – see Chart 4-1, column 3)	

Determine conformance (YES or NO) using Chart 4-1, column 3	

Standard 4: Uniform Inspection Program
Self-Assessment Worksheet

Table 4-2: Calculation of Uniformity for Jurisdictions with Ten or More Inspectors

No.	Inspector ID	Establishment ID	Date	Item (1)	Item (2)	Item (3)	Item (4)	Item (5)	Item (6)	Item (7)	Item (8)	Item (9)	Item (10)	Item (11)	Item (12)	Item (13)	Item (14)	Item (15)	Item (16)	Item (17)	Item (18)	Item (19)	Item (20)
1				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
4				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
5				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
7				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
8				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
9				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
10				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
11				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
12				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
13				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
14				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
15				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
16				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
17				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
18				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
19				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
20				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOTE:

1. A check mark indicates the inspector complies with the item.

Standard 4: Uniform Inspection Program
Self-Assessment Worksheet

Table 4-3: Calculation of Uniformity for Jurisdictions with Ten or More Inspectors

	Item (1)	Item (2)	Item (3)	Item (4)	Item (5)	Item (6)	Item (7)	Item (8)	Item (9)	Item (10)	Item (11)	Item (12)	Item (13)	Item (14)	Item (15)	Item (16)	Item (17)	Item (18)	Item (19)	Item (20)
1. Number of Check Marks From Table 4-2																				
2. Number of Inspections Reviewed in Table 4-2																				
3. % IN Compliance (Row 1 ÷ Row 2)	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-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:

Amend FDA VNRFRPS Standard 9 – Program Assessment

Issue you would like the Conference to consider:

Amend Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard No. 9 to adjust the required facility types for a Risk Factor Study, such that nine separate facility type assessments would no longer be a requirement. This would be consistent with FDA's approach to the current Risk Factor Study which no longer includes nine separate facility types.

Public Health Significance:

In order to achieve conformance with Program Standard No. 9, a jurisdiction must collect risk factor data every 60 months, write a report and analyze the data, and implement an intervention strategy based on the data collected in the risk factor study. Jurisdictions may collect risk factor data through a risk factor study, or through routine inspectional data. However, jurisdictions must collect data for each facility type identified in Program Standard No. 9, if the facility type is regulated by the jurisdiction. Program Standard No. 9 currently identifies nine (9) specific facility types:

- Institutions
    - Hospitals;
    - Nursing Homes;
    - Elementary Schools (kindergarten through grade 5)
- Restaurants
    - Full Service
    - Fast Food
- Retail Food Stores
    - Delis;

- Meat Departments;
- Seafood Departments;
- Produce Departments

After the completion of FDA's third Risk Factor Study and subsequent Trend Analysis Report, FDA embarked on a revised Risk Factor Study design that incorporates lessons learned from the first ten year study. One substantial modification to the current risk factor study design involves the facility types chosen for the data collection. Rather than collect data for each of the nine facility types, FDA modified its approach by adjusting the facility types within certain facility categories used for data collection. This new design allows for greater flexibility to collect meaningful data and identify trends.

FDA would like enrolled jurisdictions to use this new model, including the changes to the facility type categories, and have the changes incorporated into Program Standard No. 9 as described below. Jurisdictions would continue to be required to collect and analyze data from all facility categories under their regulation, but would incorporate the following new options;

1. Rather than specify the nine (9) facility types that must be included, Program Standard No. 9 would specify four (4) broad facility categories:
   (1) Health Care;
   (2) Schools (kindergarten through grade 12);
   (3) Restaurants;
   (4) Retail Food Stores.
2. In order to meet Standard 9, jurisdictions would be required to collect and analyze data for each facility category under regulation.
3. Jurisdictions would have flexibility to evaluate patterns and subcategories within each facility category. For instance, a jurisdiction could separate the restaurant category into the traditional 'full service' and 'fast food' type operations, or all restaurants could be evaluated together.

The proposed changes will provide greater efficiency and flexibility, and enable a risk-based approach when measuring the success of a program to reduce the occurrence of foodborne illness risk factors.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Standard Number 9 - Program Assessment, be amended to reflect the changes shown in *"Attachment A - Proposed Amendments to Program Standard No. 9 - Program Assessment."*

Those areas of the Standard with proposed changes are noted below (underline indicates language to be added; strikethrough format used to indicate language to be deleted)

STANDARD 9

PROGRAM ASSESSMENT

This Standard applies to the process used to measure the success of a jurisdiction's program in reducing the occurrence of foodborne illness risk factors to enhance food safety and public health in the community.

Requirement Summary

Program management must ensure that:

1. A risk factor study on the occurrence of the five foodborne illness risk factors is conducted and repeated at least once every 60 months to measure trends in the occurrence of the risk factors;

2. An analysis is made of the data collected and a report on the outcomes and conclusions of the risk factor study is written; and

3. A targeted intervention strategy designed to address the occurrence of the risk factors(s) identified in their risk factor study is implemented and the effectiveness of such strategy is evaluated by subsequent risk factor studies or other similar tools.

Description of Requirement

To achieve the criteria of Standard 9, a jurisdiction must ensure that:

A. A risk factor study and report on the occurrence of the five (5) foodborne illness risk factors must be completed. A risk factor study serves two purposes:

1. To identify risk factors most in need of priority attention in order to develop strategies to reduce their occurrence.
2. To evaluate trends over time to determine whether progress is being made toward reducing the occurrence of foodborne illness risk factors. Studies designed to measure trends require analysis of data over a period of time, and no single point in time can be used to derive trend conclusions.

B. The risk factor study includes all facility ~~types~~ categories under regulation by the jurisdiction.

It is recommended that a jurisdiction's first risk factor study be conducted as soon as possible following its first self-assessment, before programmatic changes are made. There is value in using the first study to establish a "baseline" against which future performance can be measured. Program improvements and changes may then be reflected in subsequent studies.

C. The risk factor study information is to be updated at least once every 60 months to measure trends specific to the occurrence of the five (5) foodborne illness risk factors.

The data collection and analysis ~~for the various facility types under regulation by the jurisdiction~~ may occur at various times over the 60-month period, as long as all facility ~~types~~ categories under regulation are included in the 60-month cycle. The 60-month study update is required to maintain achievement of Standard 9. The subsequent studies and reports will ~~determine whether or not~~ indicate if there has been a net change in the occurrence of the risk factors.

The ~~nine (9)~~ four (4) facility categories ~~types~~ are:

- ~~Institutions~~
    - ~~Hospitals;~~

- ~~Nursing Homes;~~
- ~~Elementary Schools (K-5)~~

- ~~Restaurants~~
  - ~~Full Service~~
  - ~~Fast Food~~
- ~~Retail Food Stores~~
  - ~~Delis;~~
  - ~~Meat Departments;~~
  - ~~Seafood Departments;~~
  - ~~Produce Departments~~

1. Health Care;
2. Schools (K-12);
3. Restaurants;
4. Retail Food Stores.

D. A jurisdiction may use routine inspection data or may conduct a separate data collection in completing a risk factor study. A data collection instrument similar to the FDA Model Data Collection Form using the IN, OUT, NA, and NO convention, is required.

Failure to use this convention skews the data toward either IN compliance or OUT of compliance. The FDA data collection instrument is not intended as an inspection form. However, jurisdictions that have developed an inspection form using the IN, OUT, NA and NO convention may use that inspection form as a survey instrument.

If the jurisdiction uses a different form, the data may be difficult to compare with the data from the *FDA National Foodborne Illness Risk Factor Studies* or with data from other jurisdictions.

E. A jurisdiction must ensure that a targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their Risk Factor Study is implemented and the effectiveness is evaluated by subsequent Risk Factor Studies or other similar tools. Jurisdictions are encouraged to incorporate various types of interventions such as code changes, educational and training activities, enforcement and compliance strategies, etc. The purpose of the intervention strategy is to attempt to affect improvement in reducing priority risk factor(s) occurrence rates between measurement intervals and assess their effectiveness.

Outcome

The desired outcome of this Standard is to enable managers to measure their program against national criteria and to demonstrate improvement in food safety. The process identifies program elements that may require improvement or be deserving of recognition.

Documentation

The quality records required for this standard include:

1. Survey reports on the occurrence of risk factors and *FDA Food Code* interventions,

2. Survey collection tools or inspection sheets used for the data collection,
3. Documentation that each facility category ~~type under~~ regulation~~ed~~ is surveyed during the 60-month survey cycle,
4. Documentation of performed interventions, actions or activities designed to improve the control of risk factors,
5. Documentation that the effectiveness of performed interventions is evaluated.

.

Submitter Information:

Name:	Mary Cartagena
Organization:	Food and Drug Administration
Address:	5100 Paint Branch ParkwayHFS-320 Rm 3B038
City/State/Zip:	College Park, MD 20740
Telephone:	240-402-2937
E-mail:	mary.cartagena@fda.hhs.gov

Content Documents:

- "Attachment A-Proposed Amendments to Program Standard No. 9 - Program Assess"

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

STANDARD 9
PROGRAM ASSESSMENT

Table of Contents

STANDARD 9
PROGRAM ASSESSMENT

This Standard applies to the process used to measure the success of a jurisdiction's program in reducing the occurrence of foodborne illness risk factors to enhance food safety and public health in the community.

Requirement Summary

Program management must ensure that:

1. A RISK FACTOR STUDY on the occurrence of the five foodborne illness risk factors is conducted and repeated at least once every 60 months to measure trends in the occurrence of the risk factors;

2. An analysis is made of the data collected and a report on the outcomes and conclusions of the RISK FACTOR STUDY is written; and

3. A targeted intervention strategy designed to address the occurrence of the risk factors(s) identified in their RISK FACTOR STUDY is implemented and the effectiveness of such strategy is evaluated by subsequent RISK FACTOR STUDIES or other similar tools.

Description of Requirement

To achieve the criteria of Standard 9, a jurisdiction must ensure that:

A. A RISK FACTOR STUDY and report on the occurrence of the five (5) foodborne illness risk factors must be completed. A RISK FACTOR STUDY serves two purposes:

   1. To identify risk factors most in need of priority attention in order to develop strategies to reduce their occurrence.

   2. To evaluate trends over time to determine whether progress is being made toward reducing the occurrence of foodborne illness risk factors. Studies designed to measure trends require analysis of data over a period of time, and no single point in time can be used to derive trend conclusions.

B. The RISK FACTOR STUDY includes all facility ~~types~~ categories under regulation by the jurisdiction.

   It is recommended that a jurisdiction's first RISK FACTOR STUDY be conducted as soon as possible following its first SELF-ASSESSMENT, before programmatic changes are made.

There is value in using the first study to establish a "baseline" against which future performance can be measured. Program improvements and changes may then be reflected in subsequent studies.

C. The RISK FACTOR STUDY information is to be updated at least once every 60 months to measure trends specific to the occurrence of the five (5) foodborne illness risk factors.

The data collection and analysis ~~for the various facility types under regulation by the jurisdiction~~ may occur at various times over the 60-month period, as long as all facility ~~types~~ categories under regulation are included in the 60-month cycle. The 60-month study update is required to maintain achievement of Standard 9. The subsequent studies and reports will ~~determine whether or not~~ indicate if there has been a net change in the occurrence of the risk factors.

The ~~nine (9)~~ four (4) facility categories ~~types~~ are:

- ~~**Institutions**~~
  - ~~Hospitals;~~
  - ~~Nursing Homes;~~
  - ~~Elementary Schools (K-5)~~
- ~~**Restaurants**~~
  - ~~Full Service~~
  - ~~Fast Food~~
- ~~**Retail Food Stores**~~
  - ~~**D**elis;~~
  - ~~Meat Departments;~~
  - ~~Seafood Departments;~~
  - ~~Produce Departments~~

1. Health Care;
2. Schools (K-12);
3. Restaurants;
4. Retail Food Stores.

D. A jurisdiction may use routine inspection data or may conduct a separate data collection in completing a RISK FACTOR STUDY. A data collection instrument similar to the FDA Model Data Collection Form using the IN, OUT, NA, and NO convention, is required.

Failure to use this convention skews the data toward either IN compliance or OUT of compliance. The FDA data collection instrument is not intended as an inspection form. However, jurisdictions that have developed an inspection form using the IN, OUT, NA and NO convention may use that inspection form as a survey instrument.

If the jurisdiction uses a different form, the data may be difficult to compare with the data

from the *FDA National Foodborne Illness Risk Factor Studies* or with data from other jurisdictions.

E. A jurisdiction must ensure that a targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their Risk Factor Study is implemented and the effectiveness is evaluated by subsequent Risk Factor Studies or other similar tools. Jurisdictions are encouraged to incorporate various types of interventions such as code changes, educational and training activities, enforcement and compliance strategies, etc. The purpose of the intervention strategy is to attempt to affect improvement in reducing priority risk factor(s) occurrence rates between measurement intervals and assess their effectiveness.

Outcome

The desired outcome of this Standard is to enable managers to measure their program against national criteria and to demonstrate improvement in food safety. The process identifies program elements that may require improvement or be deserving of recognition.

Documentation

The quality records required for this standard include:

1. Survey reports on the occurrence of risk factors and *FDA Food Code* interventions,
2. Survey collection tools or inspection sheets used for the data collection,
3. Documentation that each facility category ~~type under~~ regulation~~ed~~ is surveyed during the 60-month survey cycle,
4. Documentation of performed interventions, actions or activities designed to improve the control of risk factors,
5. Documentation that the effectiveness of performed interventions is evaluated.

.

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-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:

Report - Certification of Food Safety Regulation Professionals (CFSRP)

Issue you would like the Conference to consider:

The 2014-2016 CFSRP Workgroup seeks Council's acknowledgement of its final report.

Public Health Significance:

A national model that addresses training and the professional development of regulatory retail food safety professionals is essential to enhancing the effectiveness of the nation's retail food protection system. The Voluntary National Retail Food Regulatory Program Standards, Standard 2 training and standardization model should be viewed as a working document that will need to be updated and revised to meet the ever-changing retail food safety environment. The Conference for Food Protection provides the mechanism to:

1. Maintain and update this national training model;

2. Explore additional training and/or assessment needs for regulatory retail food programs; and

3. Build consensus among all retail food safety stakeholders.

Recommended Solution: The Conference recommends...:

1. Acknowledgment of the 2014-2016 Certification of Food Safety Regulation Professionals (CFSRP) final report, and
2. Extending thanks to all the 2014-2016 CFSRP members for their work and dedication and to those organizations/agencies that they represent for supporting the Conference for Food Protection process.

Submitter Information 1:

Name: DeBrena Hilton
Organization: CFSRP Workgroup Co-Chair

Address: Tulsa Health Department5051 S. 129th E. Avenue
City/State/Zip: Tulsa, OK 74134
Telephone: 918-595-4302
E-mail: dhilton@tulsa-health.org

Submitter Information 2:

Name: Angela Benton
Organization: CFSRP Workgroup Co-Chair
Address: Jetro/Restaurant Depot133-11 20th Avenue
City/State/Zip: College Point, NY 11356
Telephone: 718-939-6400 ext.601
E-mail: Abenton@jetrord.com

Content Documents:

- "Certification of Food Safety Regulation Professionals (CFSRP) Roster"
- "Final Report - Certification of Food Safety Regulation Professionals"

Supporting Attachments:

- "CFSRP Conference Call Minutes"

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

Committee Name: Certification of Food Safety Regulation Professionals Workgroup

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Hilton	DeBrena	Chair	Local Regulatory	Tulsa City-County Health Department	Tulsa	OK	918-595-4302	dhilton@tulsa-health.org
Benton	Angela	Vice-Chair	Food Industry	Jetro Restaurant Depot	College Point	NY	(718) 939-6400	ABenton@jetrord.com
Albrecht	Julie	Member	Academia	University of Nebraska/Lincoln	Lincoln	NE	(402) 472-8884	jalbrecht1@unl.edu
Kender	Linda	Member	Academia	Johnson & Wales University CCA	Providence	RI	(401) 598-1278	Linda.Kender@jwu.edu
Grooters	Susan Vaughn	Member	Consumer	KAW Coalition	Washington	DC	(802) 223-6303	susangrooters@gmail.com
Baker	Rance	Member	Food Industry Support	National Environmental Health Association	Denver	CO	(303) 756-9090	RBaker@neha.org
Chapman	Bryan	Member	Food Industry Support	StateFoodSafety.com	Orem	UT	(801) 805-1872	bchapman@abovetraining.com
Buck	Francie	Member	Food Industry Support	Sealedair (Diversey)	Racine	WI	(505) 610-3818	francie.buck@sealedair.com
Hussein	Sima	Member	Food Industry Support	Ecolab	Greensboro	NC	(336) 312-1285	Sima.Hussein@ecolab.com
Maeson	Jordan	Member	Food Industry Support	Safer Dining LLC	St. Petersburg	FL	(727) 422-7392	Jordan@SaferDining.com
Weichelt	William	Member	Food Industry Support	National Restaurant Association	Chicago	IL	(312) 715-5388	wweichelt@restaurant.org
Wilmsmeyer	Doug	Member	Food Industry Support	Alchemy Systems	Austin	TX	(512) 637-5100	doug.wilmsmeyer@alchemysystems.com
Cranford	Vanessa	Member	Processing Food Industry	Taylor Farms Florida	Orlando	FL	(407) 495-7333	vcranford@taylorfarms.com
MacLeod	Michael	Member	Retail Food Industry	Big Y Foods Inc.	Springfield	MA	(413) 504-4453	mmacleod@bigy.com
Dickhans	Carrie	Member	Local Regulator	St. Louis County Department of Health	Berkely	MO	(314) 615-8925	cdickhans@stlouisco.com
Hults	Julie	Member	Local Regulatory	City of Milwaukee	Milwaukee	WI	(414) 286-5746	JHULTS@milwaukee.gov

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Sylvis	Christine	Member	Local Regulatory	Southern Nevada Health District	Las Vegas	NV	(702) 759-1251	sylvis@snhdmail.org
Atkins	Hugh	Member	State Regulatory	Tennessee Department of Health	Nashville	TN	(615) 741-8535	Hugh.Atkins@tn.gov
DeFrancesco	Joetta	Member	State Regulatory	Florida Department of Ag. & Consumer Services	Bonita Springs	FL	(850) 245-5520	Joetta.Defrancesco@freshfromflorida.com
Fenn	Phyllis	Member	State Regulatory	Alabama Department of Public Health	Montgomery	AL	(334) 206-5375	Phyllis.Fenn@adph.state.al.us
Kendrick	Susan	Member	State Regulatory	Oregon Deparment of Agriculture	Salem	OR	(503) 986-4720	skendrick@oda.state.or.us
Cyr	Angela	Member	State Regulatory	Minnesota Department of Health	St Paul	MN	(651) 201-4843	angie.cyr@state.mn.us
Owens	Jacqueline	Member	State Regulatory	WI Dept of Agriculture - Division of Food Safety	Madison	WI	(608) 224-4734	Jacqueline.Owens@wisconsin.gov
Samarya-Timm	Michéle	Non-voting member*	Food Industry Support	Somerset County Department of Health	Somerville	NJ	(908)541-5749	SamaryaTimm@co.somerset.nj.us
Hazan	Stan	Non-voting member*	Food Industry Support	NSF International	Ann Arbor	MI	(734) 769-5105	Hazan@nsf.org
Read	David	Non-voting member*	Programs and Policy Support	IFPTI				dread5668@gmail.com
Carotenuto	Anthony	Non-voting member*	Programs and Policy Support	Navy and Marine Corps Public Health Center			(757)953-0712	Anthony.Carotenuto@med.navy.mil
Tart	Alan	Non-voting member*	Support	FDA			404-253-1267	alan.tart@fda.hhs.gov
Williams	Laurie	Non-voting member*	Support	FDA			240-402-2938	laurie.williams@fda.hhs.gov
Radke	Vincent	Non-voting member*	Support	CDC			770-488-7065	vradke@cdc.gov

* At-Large

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: Certification of Food Safety Regulation Professionals (CFSRP) Workgroup

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council II

DATE OF REPORT: December 3, 2015 (Revised February 4, 2016)

SUBMITTED BY: DeBrena Hilton and Angela Benton

COMMITTEE CHARGE(s): From **Issue: 2014 II-002**

Charge 1: Collaborate with the FDA Division of Human Resource Development, and the Partnership for Food Protection Training and Certification Workgroup (PFP TCWG) to:

1. Continue review of all initiatives: existing, new or under development; involving the training, evaluation and/or certification of food safety inspection officers. This collaborative working relationship will ensure the sharing of information so as not to create any unnecessary redundancies in the creation of work product or assignment of tasks/responsibilities.

2. Review the results of the partnership for food protection training and certification work group recommendations for the nationally recognized Retail Food Curriculum based on the Retail Food Job Task Analysis (JTA) to determine if changes are needed in the Standard 2 curriculum. Identify any gaps and recommendations for change and review the time frame for completion of Steps 1 through 4 for new hires or staff newly assigned to the regulatory retail food protection program.

3. Review the results of the partnership of food protection training and certification work group recommendations to determine if the Conference for Food Protection Field Training Manual for Regulatory Retail Food Safety Inspection Officers and forms need to be revised.

Charge 2: Work in collaboration with the CFP Program Standards Committee to:

1. Provide technical assistance with questions regarding the comments contained in the 2012 CFP CFSRP's Workgroup's uniform inspection program audit pilot project report on the CFP website that might trigger revisions of the VNRFRPS, Standard 4 Uniform Inspection Program.

2. Assess if any changes will be needed in Standard 2-Trained Regulatory Staff based on the current standard for review referenced in (1) above to provide better alignment with Standard 4 of the VNRFRPS.

Charge 3: Report back the Workgroup's findings and outcomes to the 2016 Biennial Meeting of the Conference for Food Protection.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

   a. Executive Background Summary

   i. Due to the large amount of work that came out of the CFSRP Workgroup revised Standard 2 process; well-defined curriculum with specific course references; field training manual and forms for regulatory retail food safety professionals, etc., the work group evolved into a separate conference "committee."
   ii. The 2014-2016 CFSRP Workgroup membership is comprised of twenty-three members from each of the Conference for Food Protection (CFP) regions. Per

the Constitution and Bylaws, a balanced ratio of regulatory to industry members was maintained; ten (10) regulatory, ten (10) food industry, two (2) academia, and one (1) consumer members. The remainder of the workgroup roster is made up of non-voting members that have been included in Workgroup activities.

iii. The CFSRP Workgroup Chair participated on Program Standards Committee conference calls to stay abreast of information related to the 2014-2016 CFSRP charges.

b. Outcome/disposition of charges - During the 2014-2016 biennium, the CFSRP Workgroup met three times via conference call (October 17, 2014; December 16, 2014; May 27, 2015).

i. Charge 1:

1. The FDA Division of Human Resource Development (DHRD), and the PFP TCWG have made substantial progress in developing a nationally recognized training framework for regulatory food safety professionals. However, the process for developing a nationally recognized Retail Food Curriculum prevented the CFSRP Workgroup from being able to move forward in determining whether the Conference for Food Protection Field Training Manual for Regulatory Retail Food Safety Inspection Officers and forms need to be revised.
2. Issue: 2014 II-002 was not completed during the 2014-2016 biennium due to forthcoming training developments and potential changes to the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS).
    a. The CFSRP Workgroup is submitting an issue titled “CFSRP 2– Reassign charges to the Program Standards Committee (PSC)” so that the PSC can continue to make recommendations concerning any forthcoming regulatory retail food protection program training initiatives.

ii. Charge 2:

1. The CFSRP Workgroup chair worked in collaboration with the CFP Program Standards Committee during their review of the 2012 CFP CFSRP’s Workgroup's uniform inspection program audit pilot project report along with FDA DHRD and the PFP TCWG to assess whether revisions of the VNRFRPS, Standard 4 Uniform Inspection Program would be necessary. The PSC FDA consultants reviewed and proposed responses, including recommended changes to Standard 4 and the CFP Field Training Manual (part of Standard 2). The PSC members provided feedback with minor revisions to the proposed responses and indicated their support. The FDA will submit an Issue to recommend that Council II accepts the proposed responses and changes related to Standard 4 at the 2016 CFP.
2. The CFP Program Standards Committee will continue to assess whether any changes will be needed in VNRFRPS Standard 2-Trained Regulatory Staff based on any revisions made to VNRFRPS, Standard 4.

2. Recommendations for consideration by Council:

   a. FUTURE OF THE COMMITTEE: The CFSRP Workgroup recommends that it be dissolved as a standalone workgroup and that subsequent issues related to the certification of food safety regulation professionals be managed within the scope of the Program Standards Committee in order to ensure a consistent and uniform approach when addressing the Voluntary National Retail Food Regulatory Program Standards. Dissolving the CFSRP workgroup will eliminate any potential confusion among CFP stakeholders concerning the entity that is responsible for addressing issues related to the Program Standards and will also eliminate the potential for redundancy of work.

      i. The results of an email vote sent out on October 10, 2015 were four (4) abstentions and nineteen (19) members **FOR** dissolving the CFSRP as a standalone workgroup in order to minimize any potential confusion or redundancy of work.

      ii. The CFSRP Workgroup recommends the transfer of the following charges to the Program Standards Committee:

         1. Collaborate with the FDA Division of Human Resource Development, and the Partnership for Food Protection Training and Certification Workgroup (PFP TCWG) to:

            a. Continue review of all initiatives: existing, new or under development; involving the training, evaluation and/or certification of food safety inspection officers. This collaborative working relationship will ensure the sharing of information so as not to create any unnecessary redundancies in the creation of work product or assignment of tasks/responsibilities.

            b. Review the results of the partnership for food protection training and certification work group recommendations for the nationally recognized Retail Food Curriculum based on the Retail Food Job Task Analysis (JTA) to determine if changes are needed in the Standard 2 curriculum. Identify any gaps and recommendations for change and review the time frame for completion of Steps 1 through 4 for new hires or staff newly assigned to the regulatory retail food protection program.

            c. Continue to assess if any changes will be needed in Standard 2-Trained Regulatory Staff based on the current standard for review referenced in (1) above to provide better alignment with Standard 4 of the VNRFRPS.

            d. Report back their findings and recommendations to the 2018 Biennial Meeting of the Conference for Food Protection.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

The Committee Chair and Co-Chair are submitting two (2) issues with supporting attachments on behalf of the CFSRP Workgroup.

1. Report - Certification of Food Safety Regulation Professionals (CFSRP) Workgroup
2. CFSRP 2 – Reassign charges to Program Standards Committee

List of Attachments –

Content Documents: Committee Report

Supporting Attachments: Conference Call Minutes from October 17, 2014; December 16, 2014; and May 27, 2015.

COMMITTEE MEMBER ROSTER (attached): Certification of Food Safety Regulation Professionals (CFSRP)

Conference for Food Protection
Certification of Food Safety Regulation Professionals (CFSRP)
Conference Call Minutes
Friday, October 17th - 2014 @ 10:30am CST

Work Group Members Participating on the Call: DeBrena Hilton (Chair), Mhati Elluru (for Angela Benton – scribe), Linda Kender, Susan Grooters, Rance Baker, Sima Hussein, Jordan Maeson, William Weichelt, Michael MacLeod, Julie Hults, Christine Sylvis, Hugh Atkins, Phyllis Fenn, Susan Kendrick, Jacqueline Owens, Laurie Williams, Alan Tart, Angela Cyr, Francie Buck, Vanessa Cranford and Doug Wilmsmeyer

Work Group Members Unable to Participate: Angela Benton (co-chair), Bryan Chapman, Carrie Dickhauns, Joetta DeFrancesco, David Read, Stan Hazan, Anthony Carotenuto, and Michelle Samarya-Timm

Agenda-

1) Welcome: 10:30 AM – 10:31 AM – Welcome notes by DeBrena
2) Roll Call: 10:31 AM – 10:35 AM

   10:35 AM – 10:36 AM – DeBrena thanked everyone for attending the call
3) Review Antitrust Statement: 10:36 AM – 10:38 AM (attached)
4) 10:38 AM – 10:41 AM: Responsibilities of committee members, voting and non-voting, as provided in the Part VIII of the CFP Biennial Meeting/Conference Procedures 2014 (CFP Bylaws)
   a) Committee Roster
      i) As far as committees go, when DeBrena reached out to all initially to thank for being a part of the committee, she provided insight on the committee size which is limited to 23 voting members (permitted on a council committee)
      ii) Members not selected for a voting position were offered an 'At-Large' or non-voting position on this committee
      iii) At-Large members will be included and allowed to participate in all committee functions including but not limited to meetings, conference calls, emails, deliberations, research activities, but will not have an individual vote on committee actions
      iv) All voting members and At-Large non-voting members shall be identified on the committee roster **{ACTION} – send roster out to members**
      v) In the event that a council committee voting member leaves the committee during the biennial cycle, an At-Large member of the same constituency as the departing member shall be selected by the Chair to fill the vacancy
      vi) There are 2 openings on the committee for Food Industry representatives. At the end of this call, anyone representative of the food industry constituency that is interested in being listed as a voting member should email DeBrena for consideration. **{ACTION} DeBrena will reach out individually to fill in the 2 spots.**
5) 8:41 AM – 8:48 AM: Overview of charges and background information

a) See Issue #2 at http://www.foodprotect.org/media/meeting/Council%20II%20Recommendations%20Final%20Version.pdf

b) For the new committee members, DeBrena provided background on the Voluntary National Retail Food Regulatory Program Standards(VNRFRPS) 4, Uniform Inspection Program http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/UCM372499.pdf

* Standard 4 of the VNRFRPS applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance / enforcement procedures.
* Program Standard 2 of the VNRFRPS applies to the essential elements of a training program for regulatory staff and provides a curriculum for retail food safety inspection officers, with some pre-requisite curriculum courses available online via FDA ORA U website and some post curriculum courses that are recommended to be completed within 18 months of hire.

http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/UCM372482.pdf

The VNRFRPS are voluntary, developed through the CFP process, offered by the FDA for continuous improvement and uniformity among regulatory retail food protection program.

Discussion 8:48 AM – 8:53 AM – Question by Alan Tart, FDA (for clarification of Charge 2) – Speakers: Alan Tart, DeBrena, Susan Kendrick

* Alan's Question — clarification of Charge 2 ---review the uniform inspection program audit pilot and determine if changes are need to Standard 2. In other words, see if there are any changes that would be needed for Standard 2 curriculum based on Standard 4 pilot to provide a better alignment on Standard 4.

* Alan Tart is a part of an internal FDA work group that is looking at incorporating the recommendations from that pilot into changing standard 4
* Looking at the recommendations from that pilot, found on page 49 and 50 of that report, he did not see any recommendations from that pilot about changing standard 2; it is all about making Standard 4 more in line with Standard 2.
* Alan Tart requested clarification of what that pilot had to do with Standard 2
* Susan Kendrick responded and explained this committee was in charge of running that pilot at the request of Jim Fear because there was a Pilot for Std. 4
* Susan said - In the conclusions of the report, it says that is should be more aligned with Standard 2
* Susan's understanding is that the Charge is to look at whatever the program standards committee comes up with and see if anything comes out of that committee that would require

change of standard 2 —— we don't necessarily anticipate any changes in standard 2, but just to evaluate that.

* Alan said that there is an FDA group is actively working on taking recommendations from the pilot and coming up with recommended changes to standard 4; the group is working internally right now; FDA plans to directly go to CFP Program Standards Committee and work with them on the recommended changes
* Susan asked Alan if FDA has a timeframe for when the recommendations will be ready
* Alan Tart responded — internal Program Standards work group has finished what they need to; they need an instruction sheet to go along with what they've developed, which is a modified performance audit form and a rubric to go along with it. Developing clear instructions for that.
* After the instructions are created, it will go to internal steering committee
* After steering committee approval it will go to the CFP Program Standards committee —— all of this is expected to happen within the next few months

6) 8:53 AM – 8:56 AM: Any members working with Partnership for Food Protection Training and Certification Workgroup or CFP Program Standards Committee? Speakers: DeBrena, Alan Tart, Susan Quam, Angie Cyr.

* Linder Kinder asked if there was a conflict of interest with being a part of the CFRSP committee and Food Protection Manager Certification Committee. Susan Quam (Council II Chair) answered that there is no conflict of interest for members that are a part of this committee and the Food Protection Manager Certification Committee; both committees run independently of each other. Susan Kendrick is also on that committee –our primary charge for the CFRSP committee is to keep surveillance on all the other training issues that are going on so that if anything comes up that addresses Standard 2, we can address it.
* Alan Tart confirmed he is on the Partnership for Food Protection Training and Certification work group.
* Angie Cyr confirmed she is on the CFP Program Standards Committee Workgroup.
* DeBrena to Angie— did you have any opportunity to meet? Any timeframes on the work that that committee has been charged with?
* Angie – Program Standards Committee had a couple of conference calls, working on 2 different CFP issues. 2 subcommittees have started working on that.

7) 8:56 AM – 8:57 AM: Future assignments
   a) In the past, sub-committees were used to address the charges to review proposed initiatives involving training, evaluation and/or certification of food safety inspection officers. Sub-committees were used to help address charges to ensure all work is completed in a timely manner
      i) Francie Buck offered to lead a sub-group if needed.

8:57 AM – 8:59 AM – DeBrena to Susan —— to provide any background information concerning charges or previous work done by the committee – Speakers: DeBrena, Susan Kendrick

* One of the biggest pieces of Standard 2 that this committee worked on several years ago is the Field Training Plan **{ACTION – look over Field Training Plan}**
* If members have not had a chance to look at that over, that was a really important piece where a lot of work went into development of this committee
* Sub-committees work very well when there are a lot of things that needed to be researched and worked on the side
* Susan expressed that work might best be done as an entire group since we are just getting updates on where committees are at until we can move forward

8:59 AM – 9:03 AM – DeBrena checked for questions or comments about the charges/work groups – Speakers: DeBrena, Susan Kendrick, Alan Tart, Rance Baker

* The charges are pretty much to review work done by other committees and work groups; provide assistance with answering questions
* Until DeBrena receives information from the people/groups that are doing that work we will be on hold. Hopefully we will have something to go on in the next couple of months, as the Partnership for Food Protection (PFP) finalizes some things.
* Rance Baker — a lot of work has already been done with Charge 1. The Division of Human Resources Development (DHRD) created a group that maps the JTA (Job Task Analysis) for the retail group food specialists position over to their current instructor-led curriculum; developed a new map of that curriculum based off of the JTA for the food safety specialist and the FDA curriculum; he believes that it is a part of the charge for the CFP committee to take that material and once again map it over to VNRFRPS and Standard 2 to see if there are any gaps between those two standards ; and what has already been mapped over for curriculum for the retail food specialist. A lot of work has been done on that and the information may be available through DHRD.

Alan – will provide update from Jim Fear (in writing) on PFP activities and expected time frames.

* DeBrena requested members to send documents/links of work that is already being done; she will review and disseminate the information back out to CFRSP committee members
* Susan Kendrick — also attended JTA analysis with Rance Baker last November. Janet Williams was the point person on that, is she still the point of contact?
* Alan confirmed that now he will be the liaison for the group and provided a brief update from that meeting. **ACTION – Alan will provide update in writing.** Little premature right now per Jim Fear.
* It is in early phases — they have taken the 8 job task analysis reports that were provided, with the PFP activities they are developing curriculums for all of the integrated food safety system inspector positions to include retail, milk, shellfish, feed, manufactured foods, etc.
* They have taken all of those and looked at the common competencies across of all of those 8 JTAs; then they are going to whittle it down into retail food, manufactured food, milk, etc. and then whittle it down further starting in November. At the point that we can use what they are coming up with that's what is in question. Alan will find out, it's a little too early right now – not far off.

8) 9:03 AM – 9:05 AM: Next meeting – November? December? Doodle poll survey

* Tentative date: Mid Dec, just before the holidays – to get additional information from other committees.
* DeBrena to send out doodle poll survey/meeting request.

Jordon Mason – volunteered to also work with on subcommittee if needed with Francie Buck.

9:05 AM — DeBrena's Thank you notes and request for updates from other committees.

END OF CALL

Certification of Food Safety Regulation Professionals (CFSRP)
Conference Call Minutes – 12/16/2014
Call recording lost – brief summary provided below

1. Roll Call – start 11:04am
2. Approval of minutes – no corrections
3. Anti-trust Statement
4. Committee Roster – send any updates to dhilton@tulsa-health.org
5. Charges reviewed
6. Updates:
   FDA DHRD – JTA: ongoing work, on hold. CFP Standards Program reviewing Standard 4 pilot changes to determine whether any changes are needed.

   Program Standards – looking at recommendations provided from workgroup

   IFPTI Curriculum available on website – content areas – competencies. Long process to develop.

End call 11:20am

Conference for Food Protection
Certification of Food Safety Regulation Professionals (CFSRP)
Conference Call Minutes
Wednesday, May 27th – 2015 @ 9:00am CST

Work Group Members Participating on the Call: DeBrena Hilton (Chair), Angela Benton (co-chair), Francie Buck, Doug Wilmsmeyer, Carrie Dickhans, Julie Hults, Christine Sylvis, Joetta DeFrancesco, Phyllis Fenn, Susan Kendrick, Michéle Samarya-Timm, David Read, Anthony Carotenuto, Alan Tart, Laurie Williams, and Vince Radke

Work Group Members Unable to Participate: Julie Albrecht, Linda Kender, Susan Grooters, Rance Baker, Bryan Chapman, Sima Hussein, Jordan Maeson, William Weichelt, Vanessa Cranford, Michael MacLeod, Hugh Atkins, Jacqueline Owens, Angela Cyr and Stan Hazan

Agenda-

9) Welcome:

10) Roll Call: notes from last call on December 16, 2014 will be incorporated following the minutes from 5/27/2015

11) Newest member – Vince Radke CDC replacing Kristin Delea

12) Review Charges –

Charge 1: Collaborate with the FDA DHRD, and the Partnership for Food Protection Training and Certification Workgroup (PFP TCWG) to:

i) Continue review of all initiatives existing, new or under development involving the training, evaluation and/or certification of food safety inspection officers.
ii) Review the results of the PFP training and certification work group recommendations for the nationally recognized Retail Food Curriculum based on the Retail Food Job Task Analysis (JTA) to determine if changes are needed in the Standard 2 curriculum.
    - Identify any gaps and recommendations for change and review the time frame for completion of Steps 1 through 4 for new hires or staff newly assigned to the regulatory retail food protection program.
iii) Review the results of the partnership of food protection training and certification work group recommendations to determine if the Conference for Food Protection Field Training Manual for Regulatory Retail Food Safety Inspection Officers and forms need to be revised.

Charge 2: Work in collaboration with the CFP program standards committee to:

i. Provide technical assistance with questions regarding the comments contained in the 2012 CFP CFSRP's Workgroup's uniform inspection program audit pilot project report on the CFP website that might trigger revisions of the VNRFRPS, Standard 4 Uniform Inspection Program.

ii. Assess if any changes will be needed in Standard 2-Trained Regulatory Staff based on the current standard for review referenced in (1.) above to provide better alignment with Standard 4 of the VNRFRPS.

Charge 3: Report back the Workgroup's findings and outcomes to the 2016 Biennial Meeting of the Conference for Food Protection.

Charge 1 update:

Alan Tart –Training and Certification Workgroup. Various inspector roles general education curriculum development underway. 25 content areas. Retail will be covered broadly. All inspectors – specialty areas will be included. Competency statements almost done. DHRD will rely on cooperative agreements with others to put courses online. Retail Meeting June 15th in Denver to begin Retail competency statements. After general education and retail courses have been developed, gap analysis will be formed to determine current training and training needs. Recommendations for new courses or course development. Anticipated completion for retail will be next year. Changes to Standard 2 – on hold. Doesn't appear that our committee will be prepared to present issues regarding this charge to the 2016 CFP Conference.

Dave Read – PFP/IFPTI: a lot of work underway now. Example of training framework available at www.ifpti.org

FDA, CFP and IFPTI have been working for past 2 years on training concepts. Multi-colored diagram that covers Basic/Advanced/Journey/Leadership Areas – Food Safety Professional Competencies required for each content area on framework. Worked through general education courses. Working on Basic Level Framework – June Meeting will be to develop basic level framework for Retail Food. Content area reviewed to determine elements to go into training framework. Subject matter experts look at to determine elements that should go into each content area (Learning events, on the job training, etc…).

Substantial progress has been made over past few years but more work needs to be done.

Note to committee: CFP Master Calendar – December 4, 2015 final committee reports due from Committee Chairs and Committee Issues to Council Chairs for preliminary review.

After June Meeting, CFSRP committee will determine whether we will be able to meet issue deadline – recommendation made to draft issue to continue the work. Looking for results of initial survey sent out to stakeholders by July. After June meeting will also need to send out to stakeholders for review. Unlikely that CFSRP committee will have any information needed to move forward with Charge 1.

Charge 2:

Reviewed information from Standard's Committee – Recommendations from CFP's Uniform Inspection Program Audit Pilot Project Report that are incorporated into proposed language (see attached). Please review and respond with questions or suggestions to table recommendations.

Alan provided clarification that CFSRP Committee work is pending the Standards Committee Charges as it relates to Standard 4. Any changes made to Standard 4 would then be reviewed to determine any related effects on Standard 2.

****

CFSRP committee on hold pending additional information regarding Charge 1 and Charge 2.

Charge 3 – more than likely the issues charged to CFSRP will be resubmitted to the 2016 Biennial Meeting of the Conference for Food Protection.

Next meeting – tentative July 2015

Reminder: Council Application Period Open – Closes June 19th.

October 10, 2015 - CFSRP Conference Call Tally Vote to Dissolve Workgroup

Last Name	First Name	Position (Chair/Member)	Constituency	Vote
Hilton	DeBrena	Chair	Local Regulatory	**For**
Benton	Angela	Vice-Chair	Food Industry	**For**
Albrecht	Julie	Member	Academia	**For**
Kender	Linda	Member	Academia	**For**
Grooters	Susan Vaughn	Member	Consumer	Abstention
Baker	Rance	Member	Food Industry Support	**For**
Chapman	Bryan	Member	Food Industry Support	**For**
Buck	Francie	Member	Food Industry Support	**For**
Hussein	Sima	Member	Food Industry Support	**For**
Maeson	Jordan	Member	Food Industry Support	**For**
Weichelt	William	Member	Food Industry Support	**For**
Wilmsmeyer	Doug	Member	Food Industry Support	**For**
Cranford	Vanessa	Member	Processing Food Industry	Abstention
MacLeod	Michael	Member	Retail Food Industry	**For**
Dickhans	Carrie	Member	Local Regulator	**For**
Hults	Julie	Member	Local Regulatory	**For**
Sylvis	Christine	Member	Local Regulatory	**For**
Atkins	Hugh	Member	State Regulatory	**For**
DeFrancesco	Joetta	Member	State Regulatory	**For**
Fenn	Phyllis	Member	State Regulatory	Abstention
Kendrick	Susan	Member	State Regulatory	**For**
Owens	Jacqueline	Member	State Regulatory	Abstention
Cyr	Angela	Member	State Regulatory	**For**
Samarya-Timm	Michéle	Non-voting member*	Food Industry Support	At-Large Member
Hazan	Stan	Non-voting member*	Food Industry Support	At-Large Member
Read	David	Non-voting member*	Food Industry Support	At-Large Member
Carotenuto	Anthony	Non-voting member*	Programs and Policy Support	At-Large Member
Tart	Alan	Non-voting member*	Support	At-Large Member
Williams	Laurie	Non-voting member*	Support	At-Large Member
Radke	Vince	Non-voting member*	Support	At-Large Member

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-015

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:

CFSRP 2– Reassign Charges to the Program Standards Committee

Issue you would like the Conference to consider:

The CFSRP Workgroup recommends that it be dissolved as a standalone workgroup and that future issues dealing with the certification of food safety regulation professionals be assigned to the Program Standards Committee in order to ensure a consistent and uniform approach to addressing the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS).

Public Health Significance:

The management of issues relating to the certification of food safety regulation professionals by the Program Standards Committee will eliminate any potential confusion among CFP stakeholders concerning the entity that is responsible for addressing issues related to the VNRFRPS and will also eliminate the potential for redundancy of work related to the VNRFRPS.

Recommended Solution: The Conference recommends...:

that the Certification of Food Safety Regulation Professionals (CFSRP) Workgroup be dissolved as a standalone workgroup, and that the remaining subcharges from Issue 2014 II-002, Charge 1 be reassigned to the 2016 - 2018 Program Standards Committee as follows:

Collaborate with the FDA Division of Human Resource Development, and the Partnership for Food Protection Training and Certification Workgroup (PFP TCWG) to:

1. Continue review of all initiatives: existing, new or under development; involving the training, evaluation and/or certification of food safety inspection officers. This collaborative working relationship will ensure the sharing of information so as not to create any unnecessary redundancies in the creation of work product or assignment of tasks/responsibilities.

2. Review the results of the partnership for food protection training and certification work group recommendations for the nationally recognized Retail Food Curriculum based on the Retail Food Job Task Analysis (JTA) to determine if changes are needed in the Standard 2 curriculum. Identify any gaps and recommendations for change and review the time frame for completion of Standard 2 Steps 1 through 4 for new hires or staff newly assigned to the regulatory retail food protection program.

3. Continue to assess if any changes will be needed in Standard 2-Trained Regulatory Staff based on the current standard for review referenced in (1) above to provide better alignment with Standard 4 of the VNRFRPS.

4. Report back their findings and recommendations to the 2018 Biennial Meeting of the Conference for Food Protection.

Submitter Information 1:

Name:	DeBrena Hilton
Organization:	CFSRP Workgroup Co-Chair
Address:	Tulsa Health Department5051 S. 129th E. Avenue
City/State/Zip:	Tulsa, OK 74134
Telephone:	918-595-4302
E-mail:	dhilton@tulsa-health.org

Submitter Information 2:

Name:	Angela Benton
Organization:	CFSRP Workgroup Co-Chair
Address:	Jetro/Restaurant Depot133-11 20th Avenue
City/State/Zip:	College Point, NY 11356
Telephone:	718-939-6400 ext.601
E-mail:	Abenton@jetrord.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-016

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: Interdisciplinary Foodborne Illness Training Committee (IFITC)

Issue you would like the Conference to consider:

The 2014-2016 Interdisciplinary Foodborne Illness Training Committee (IFITC) seeks the Council's acknowledgement of its report.

Public Health Significance:

The Interdisciplinary Foodborne Illness Training Committee has been tasked with:

1. Use the Crosswalk submitted in the 2012-2014 Committee report to identify current gaps in the training for Program Standard #5 as established by Council to Improve Foodborne Outbreak Response (CIFOR) and the Partnership for Food Protection as best practices for foodborne illness investigation.
2. Identify new training programs as they relate to the Crosswalk and Standard 5.
3. Work within the Conference process to post the Crosswalk document from the 2012-2014 Committee to the CFP Website.
4. Report back to the 2016 biennial meeting a revised Crosswalk document for foodborne illness investigation.

The Committee believes that it has completed the assigned charges set by the Conference.

It is our belief that the need for foodborne illness training is important, and given that different jurisdictions do not use a consistent approach to foodborne illness investigations, the gathering and sharing of this information will make it possible for health agencies, universities, industry and other non-governmental organizations to determine if the training materials they are using matches the requirements of Standard 5.

The Committee does believe that improved training opportunities should increase awareness as well as promote the importance of Foodborne Illness Investigations.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the report of the Interdisciplinary Foodborne Illness Training Committee.

2. Thanking the Committee members for their work and dedication for completing the charges.

Submitter Information:

Name:	James Steele
Organization:	IFITC
Address:	Walt Disney WorldPO Box 10,000
City/State/Zip:	Lake Buena Vista, FL 32830
Telephone:	321-395-1665
E-mail:	james.steele@disney.com

Content Documents:

- "Report: Interdisciplinary Foodborne Illness Training Committee (IFITC)"
- "Crosswalk - Requirements For Foodborne Illness Training Programs"
- "CFP Committee Roster Interdisciplinary FBI Training Committee 11302015"

Supporting Attachments:

- "Minutes - 2016 Interdisciplinary Foodborne Illness Training Committee"

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: Interdisciplinary Foodborne Illness Training (IFITC)

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council II

DATE OF REPORT: December 3, 2015 (revised 1-11-16)

SUBMITTED BY: Committee Co-Chairs James Steele and Patricia Welch
Vice-Chair – Tim Mitchell

COMMITTEE CHARGE(s):

1. Use the Crosswalk submitted in the 2012-2014 Committee report to identify current gaps in the training for Program Standard 5 as established by Council to Improve Foodborne Outbreak Response (CIFOR) and the Partnership for Food Protection as best practices for foodborne illness investigation.
2. Identify new training programs as they relate to the Crosswalk and Standard 5.
3. Work within the Conference process to post the Crosswalk document from the 2012-2014 Committee to the CFP Website.
4. Report back to the 2016 biennial meeting a revised Crosswalk document for foodborne illness investigation.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:
   a. Committee meetings: The committee met regularly via conference call to work on charges. The first conference call was held on October 20, 2014. During the initial meetings, time was allocated to introduce new members to the historical perspective of the committee and to review committee membership expectations. All members were asked to review the existing Crosswalk and committee charges and come with recommendations for the next meeting. The second conference call was held on 12/15/14. The committee decided to have two subcommittees to work on the charges. Subcommittee 1 worked on Charge 1 to identify current gaps in training for Standard 5. Subcommittee 2 worked on Charge 2 to identify new training programs as they relate to the Crosswalk and

Standard 5. The full committee held a conference call on 6/11/15 to identify progress being made by the subcommittees. A final conference call and email voting was taken in November 2015 on recommendations to CFP and on dissolving this committee.

b. Progress Addressing each Assigned Committee Charge

i. Charge 1 - Use the Crosswalk submitted in the 2012-2014 Committee report to identify current gaps in the training for Program Standard 5 as established by Council to Improve Foodborne Outbreak Response (CIFOR) and the Partnership for Food Protection as best practices for foodborne illness investigation.

1. The committee reviewed the Voluntary National Retail Food Regulatory Program Standard 5 and created a Crosswalk document with the training programs submitted in the 2012-2014 Committee report. This was to identify any gaps or requirements in the training programs as it relates to Standard 5.

2. The Committee also amended the Crosswalk with additional training programs that were identified by our subcommittee that was working on Charge 2.

3. The Committee also recognized that in the process of determining gaps the Crosswalk could now have an expanded purpose of (1) identifying available resources related to Foodborne Illness Training; (2) setting a content baseline for the development of Foodborne Illness Training Programs; (3) establishing some consistency for training programs as a whole. As a result, the Crosswalk was titled Crosswalk –Requirements For Foodborne Illness Training Programs Based on Standard 5

4. The Committee did discuss the best practices aspect of Charge #1 but recognized, as it did in point #3, that a better and more powerful interpretation of the Charge is for the Crosswalk to be used as a resource as well as a document that would guide an agency to include the appropriate sections/content when developing a training program.

ii. Charge 2 - Identify new training programs as they relate to the Crosswalk and Standard 5 of the Voluntary National Retail Food Regulatory Program Standards.

1. The following training programs were in the 2012-2014 Committee report:
   a. Food and Drug Administration (FDA) Office of Partnerships (OP) Rapid Response Team (RRT) Program Chapter 5. Food Emergency Response Plan
   b. Council to Improve Foodborne Outbreak Response (CIFOR)

c. FDA - Manufactured Food Regulatory Program Standard No. 5 Food-related Illness and Outbreaks and Response
d. CDC e-learning course “Environmental Assessment of Foodborne Illness Outbreaks”.
e. National Association State Departments of Agriculture (NASDA), Version 4.0, August 2011
f. International Association for Food Protection (IAFP), “Procedures to Investigate Foodborne Illness”, Sixth Edition

2. The following trainings programs were identified by the 2014-2016 committee to review:
   a. National Environmental Health Association (NEHA) course “I-FITT-RR” provides training in many of the identified crosswalk areas. This program is the Industry-Foodborne Illness Investigation Training and Recall Response
   b. National Environmental Health Association (NEHA) Epi-Ready – Foodborne Illness Response Strategies, June 2006

iii. Charge 3 - Work within the Conference process to post the Crosswalk document from the 2012-2014 Committee to the CFP Website.

1. The committee sent the Crosswalk document to CFP, Executive Assistant to be posted on the CFP website in October 2014.

2. A short description was requested on what the Crosswalk is or represents and this was submitted in October 2014. The CIFOR/RRT/MFRPS/VRFRPS Crosswalk is a document that combines the Core Components required for the implementation of a Foodborne Disease response with the Phases of a Food Incident Response. By combining these, the baseline is set for the development of Foodborne Illness training programs be it in an academic, agency or private industry setting. As we know, unless there is proper collaboration, precise and accurate communication, and use of policies and procedures that are consistent between groups, there could be a response that is muddled at best. By using the Crosswalk, training requirements can be identified that would be used to create robust foodborne illness training programs with similar content.

iv. Charge 4 - Report back to the 2016 biennial meeting a revised Crosswalk document for foodborne Illness investigation.

1. The committee developed a document: Crosswalk – Requirements For Foodborne Illness Training Programs Based on Standard 5. This document will be useful when determining which part of Standard 5 is

covered by the programs reviewed and potentially where future training needs to be developed.

2. The committee recommends this revised Crosswalk document be posted on the CFP website.

2. Recommendations for consideration by Council:

   a. The Interdisciplinary Foodborne Illness Training Committee recommends that the Crosswalk – Identified Gaps in Foodborne Illness Training Programs Based on Standard 5 created by the committee be posted on the CFP website in Word and PDF formats and that the committee be dissolved as it has completed the charges from the 2014 CFP Biennial Meeting.
   b. The Interdisciplinary Foodborne Illness Training Committee also recognizes the importance of training on foodborne illness and recommends that Council II consider that any future work on training resources, including updating the Crosswalk, for foodborne illness response and investigation be coordinated under the Program Standards Committee. The Specific charge is as follows: The Program Standards Committee will review and update the Crosswalk - Identified Gaps in Foodborne Illness Training Programs Based on Standard 5 based on any newly developed courses or training programs
   c. The Interdisciplinary Foodborne Illness Training Committee recommends that Council II acknowledge this final report.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

The Interdisciplinary Foodborne Illness Training will submit three (3) Issues at the 2016 biennial meeting based on the recommendations of the committee. The Issues are:

1. Report – Interdisciplinary Foodborne Illness Training Committee – The first Issue is to request the Conference to acknowledge the 2014-2016 Interdisciplinary Foodborne Illness Training Committee final report and thank the committee members for their work.
2. IFITC 2 – The second Issue is to recommend that the Conference approves the Crosswalk –Requirements For Foodborne Illness Training Programs Based on Standard 5 and the posting of this document on the CFP website. Based on Charge 1, the Interdisciplinary Foodborne Illness Training Committee developed a Crosswalk –Requirements For Foodborne Illness Training Programs Based on Standard 5 which identified areas that were not covered in Standard 5. It was agreed that the Crosswalk could be used to identify areas that should be in a Foodborne Illness Training Program. Further, the Crosswalk can be used to identify the resources available when developing a training program for Standard 5. With that in mind, the numbered pages shown in the columns and rows of the Crosswalk are the areas that are consistent with areas in the Standard 5. The Committee also agreed that the Conference should be asked to post this on the CFP website.

3. IFITC 3 – The third Issue we would like the Conference to consider is as follows: Dissolve the IFITC and transfer specific charges to the Program Standards Committee. In particular IFITC would word the Charges accordingly:

   The Conference further recommends assigning the Program Standards Committee with the following standing charges:

   1. Identify available resources related to foodborne illness training.
   2. Assess any newly developed foodborne illness training courses or programs.
   3. Maintain the document titled *Crosswalk - Requirements For Foodborne Illness Training Programs Based on Standard 5* as a resource and content baseline for foodborne illness training.
   4. Report back any findings and recommendations to future biennial meetings of the Conference for Food Protection.

List of Attachments:

Content Document:

Crosswalk - Identified Requirements in Foodborne Illness Training Programs Based on Standard 5

Supporting Attachments:

2014-2016 Interdisciplinary Foodborne Illness Training Minutes

Committee Member Roster:

2014-2016 Interdisciplinary Foodborne Illness Training Committee Membership Roster

Crosswalk - Requirements For Foodborne Illness Training Programs Based on Standard 5

Introduction:
The 2012 – 2014 Interdisciplinary Foodborne Illness Training Committee (IFITC) obtained the FSMA 205 C(1) Phases of a Food Incident Response (CIFOR/RRT/MFRPS/VNRFRPS Crosswalk) and used this Crosswalk as the response to the Charge to identify essential education content of foodborne disease outbreak training programs.
The 2014 – 2016 Interdisciplinary Foodborne Illness Training Committee (IFITC) was now charged with developing a Crosswalk that would identify areas where training programs could be compared to Standard 5 of the Voluntary National Retail Food Regulatory Program Standards. Using the CIFOR/RRT/MFRPS/VNRFRPS Crosswalk as a base, the Committee revised the Crosswalk to compare additional training programs that were identified. In addition to the training programs identified in the CIFOR/RRT/MFRPS/VNRFRPS Crosswalk, the IFITC also reviewed:

1. National Environmental Health Association (NEHA) course "I-FITT-RR"
2. National Environmental Health Association (NEHA) Epi-Ready – Foodborne Illness Response Strategies, June 2006

The resulting Crosswalk now identified the content of all the training programs and indicated, using a table format, how these compared to Standard 5. This Crosswalk is called Crosswalk – Requirements for Foodborne Illness Training Programs Based on Standard 5.
The Committee also recognized that in the process of determining gaps the Crosswalk could now have an expanded purpose of (1) identifying available resources related to Foodborne Illness Training; (2) setting a content baseline for the development of Foodborne Illness Training Programs; (3) establishing some consistency for training programs as a whole. The Committee considered this a more powerful interpretation of the first Charge and as such did not include any references to best practices.
The Committee also agreed that the this document will be useful to regulators, academics and NGO's when new training programs are being considered especially as it would introduce consistency, a much needed component in Foodborne Illness Training Programs.

Acronyms Used:

RRT: Rapid Response Team
CIFOR: Council to Improve Foodborne Outbreak Response
MFRPS: Manufactured Food Regulatory Program Standards
IAFP: International Association of Food Protection

NASDA: National Association of State Departments of Agriculture – Food Emergency Response Plan Template
http://www.nasda.org/File.aspx?id=4065
NEHA Epi-Ready: National Environmental Health Association
NEHA I-FITT-RR: Industry-Foodborne Illness Investigation Training and Recall Response
CDC – Center for Disease Control
VNRFPS: Voluntary National Retail Food Regulatory Program Standards – Standard 5

STANDARD 5 - Voluntary National Retail Food Regulatory Program Standards								
1. Investigative procedures.								
Standard 5	RRT	CIFOR	MFRPS	IAFP Procedures To Investigate Foodborne Illness Sixth ed.	NASDA Version 4.0. August 2011	NEHA Epi-Ready. Foodborne Illness Response Strategies. June 2006	NEHA I-FITT-RR	CDC Foodborne Illness Outbreak Environmental Assessments
a. The program has written operating procedures for responding to and /or	II. A. Chapter 1	3.1	5.3	Page 3-4	IV, V, VI, IX, XII	Modules 1,2,3,4, 5,6	Module 1	

conducting investigations of foodborne illness and food-related injury*. The procedures clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.								
Standard 5	RRT	CIFOR	MFRPS	IAFP Procedures To Investigate Foodborne Illness Sixth ed.	NASDA Version 4.0. August 2011	NEHA Epi-Ready. Foodborne Illness Response Strategies. June 2006	NEHA I-FITT-RR	CDC Foodborne Illness Outbreak Environmental Assessments

b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury* or contamination of food.	II.B. Chapters 2&3.	3.6	5.3 c	Page3-4	III, V, VI		Module 1	
c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties and responsibilities of each party.	II.A. Chapter 1.	3.1	5.3 a		V, VI, IX, XIII		Module 1	

Standard 5	RRT	CIFOR	MFRPS	IAFP Procedures To Investigate Foodborne Illness Sixth ed.	NASDA Version 4.0. August 2011	NEHA Epi-Ready. Foodborne Illness Response Strategies. June 2006	NEHA I-FITT-RR	CDC Foodborne Illness Outbreak Environmental Assessments
d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury* or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.	II. E. Chapter 11	3.5	5.5	Page 2,3,4	V, VI, X	Module 1	Module 2	
e. Program procedures describe the disposition, action or follow-up and reporting	Chapter 9,10,11 & 13	Chapter 4, 4.3, Chapter 5	5.5	Page3-11		Module 1, 6	Module 2	

required for each type of complaint or referral report.								
f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.	Chapters 9, 10, 11 & 13 (pg.212?) Subsection D	Chapter 4,5	5.5		IX	Module 1	Module 2	
Standard 5	RRT	CIFOR	MFRPS	IAFP Procedures To Investigate Foodborne Illness Sixth ed.	NASDA Version 4.0. August 2011	NEHA Epi-Ready. Foodborne Illness Response Strategies. June 2006	NEHA I-FITT-RR	CDC Foodborne Illness Outbreak Environmental Assessments
g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, food-related injury*, or	Chapters 9,10, 11 & 13 Page 212? Subsection D	Chapter 4, 5	5.5	Pages 41-45	VI	Module 3,5	Module 2	Lesson 5

outbreak investigations.								
h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.	Chapter 6, 10	3.1, 3.10, 6.3	5.5	Pages 99-103	IV, VI, IX, XI	Modules 1,6	Module 8	
i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.	Chapter 6, 10	3.1, 3.10, 7.3	5.3	Pages 6-7	IV, VI, IX, XII	Modules 1,6, Appendix 2	Module 2	Lesson 7
2. Reporting Procedures								
Standard 5	RRT	CIFOR	MFRPS	IAFP Procedures To Investigate Foodborne Illness Sixth ed.	NASDA Version 4.0. August 2011	NEHA Epi-Ready. Foodborne Illness Response Strategies. June	NEHA I-FITT-RR	CDC Foodborne Illness Outbreak Environmental Assessments

						2006		
a. Possible contributing factors to the food-related illness, food-related injury* or intentional food contamination are identified in each on-site investigation report.	Chapters 9, 10, 11	5.2	5.3	Pages 34-41	VI	Module 3,6	Module 3	Lesson 2
b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks* with CDC.	Chapter 3, 6, 13	4.2, 4.3, 4.4, 7.5, 9.1	5.5	Page 75	VI	Module 1,6 Appendix 6	Module 4	
3. Laboratory Support Documentation								
a. The program has a letter of understanding, written procedures, contract or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation		4.2, 4.3, 4.4, 9.1,	5.5		VI			

describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.								
b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific		4.2, 4.3, 4.4, 9.1	5.5		VI			

analysis that cannot be performed by the jurisdiction's primary laboratory(s).								
4. Trace-back Procedures								
Standard 5	RRT	CIFOR	MFRPS	IAFP Procedures To Investigate Foodborne Illness Sixth ed.	NASDA Version 4.0. August 2011	NEHA Epi-Ready. Foodborne Illness Response Strategies. June 2006	NEHA I-FITT-RR	CDC Foodborne Illness Outbreak Environmental Assessments
a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a	Chapter 9	5.2	5.3	Forms J 1, 2 & 3	V			Lesson 7

coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.								
5. Recalls								
a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.	Chapter 12	5.2	5.3		V, IX		Module 8	
b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.	Chapter 12	5.2			VI, IX		Module 8	
Standard 5	RRT	CIFOR	MFRPS	IAFP Procedures To Investigate Foodborne Illness Sixth ed.	NASDA Version 4.0. August 2011	NEHA Epi-Ready. Foodborne Illness Response Strategies. June 2006	NEHA I-FITT-RR	CDC Foodborne Illness Outbreak Environmental Assessments

c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.	Chapter 12	5.2			VI			
6. Media Management								
a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.	Chapter 3, 6	3.6	5.5	Page 73 and 105	V, VI, XI, XII	Module 6 Appendix 2	Module 8	
7. Data Review and Analysis								
Standard 5	RRT	CIFOR	MFRPS	IAFP Procedures To Investigate	NASDA Version 4.0. August 2011	NEHA Epi-Ready. Foodbor	NEHA I-FITT-RR	CDC Foodborne Illness Outbreak Environmental

				Foodborne Illness Sixth ed.		ne Illness Respons e Strategie s. June 2006		Assessments
a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.	Chapter 13, 14	4.3, Chapter 8		2&3				
b. The review is conducted with prevention in mind and focuses on, but is not	Chapter 13, 14	4.3, Chapter 8						

limited to, the following: 1) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* in a single establishment; 2) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Disease Outbreaks* in the same establishment type; 3) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* implicating the same food; 4) Foodborne Disease outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* associated with similar food								

preparation processes; 5) Number of confirmed foodborne disease outbreaks*; 6) Number of foodborne disease outbreaks* and suspect foodborne disease outbreaks*; 7) Contributing factors most often identified; 8) Number of complaints involving real and alleged threats of intentional food contamination; and 9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.								
c. In the event that there have been no food-related illness or food-related injury* outbreak investigations conducted during the	Chapter 8							

twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne disease outbreak* and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak* investigations occur.								

Committee Name: Interdisciplinary Foodborne Illness Training Committee (IFITC)

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Algeo	Susan	Member	Food Industry Support	Paster Training, Inc.	Gilbertsville	PA	610-970-1776	susan.algeo@pastertraining.com
Belmont	Jeffrey	Member	Food Industry Support	NRFSP	Orlando	FL	407-226-3500	jbelmont@nrfsp.com
Catalan	Linda	Member	Retail Food Industry	Brinker International	Dallas	TX	972-770-8746	linda.catalan@brinker.com
Chapman	Bryan	Member	Food Industry Support	State Food Safety	Orem	UT	801-494-1879	bchapman@statefoodsafety.com
Cooper	Ivory Gene	Member	Local Regulator	Dist. Of Columbia	Washington	DC	202-535-2180	ivory.cooper@dc.gov
Fabian	Sandra	Member	Food Service Industry	Wawa, Inc.	Media	PA	610-358-8779	sandra.fabian@wawa.com
Follett	Emilee	Member	Food Industry Support	State Food Safety	Orem	UT	801-805-4679	efollett@statefoodsafety.com
Jenkins	Matthew	Member	Food Service Industry	Sodexo	Chicago	IL	630-390-4020	matthew.jenkins@sodexo.com
Markulin	Kris	Member	Retail Food Industry	Delhaize America	Reston	VA	703-347-2072	kris.markulin@delhaize.com
Mitchell	Tim	Vice-Chair	Retail Food Industry	Publix Super Markets	Lakeland	FL	863-688-1188	tim.mitchell@publix.com
Okenu	Dan	Member	Food Service Industry	TransGlobal Consults, LLC	Snellville	GA	404-805-2221	dan.okenu@transglobalconsults.com
Sheehan	Pieter	Member	Local Regulator	Fairfax County Health Dept.	Fairfax	VA	703-246-8470	Pieter.sheehan@fairfaxcounty.gov
Steele	James	Chair	Food Service Industry	Walt Disney World	Lake Buena Vista	FL	407-560-4724	james.steele@disney.com
Welch	Patricia	Chair	State Regulator	IL Dept. of Public Health	Springfield	IL	217-785-2439	patricia.welch@illinois.gov
Williams	Janet	Member	Federal Regulator	FDA/ORA/DHRD	Rockville	MD		janet.williams@fda.hhs.gov

2016 Interdisciplinary Foodborne Illness Training Committee

Minutes

10/20/2014

1. Susan Algeo
2. Jeff Belmont
3. Sandy Fabian
4. Emilee Follet
5. Matt Jenkins
6. Kris Markulin
7. Jackie Owens
8. Pieter Sheehan
9. Pat Welch
10. Janet Williams
11. Tim Mitchell
12. Dan Okenu

- One committee member announced she is going on maternity leave so she will not be on the next one or two calls. I believe it was Emilee Follet (sorry, did not hear her name well)

- Reviewed Part VII Committee Membership Expectations
- Pat gave a brief history of the committee and the crosswalk
- Tim sent the crosswalk and the charges out to the committee because some folks either did not receive or lost them
- Reviewed the charges to the committee
- Pat will look into setting up Food Shield for the group to work collaboratively on the crosswalk document
- Janet will try to get a copy of the RRT training to share with the team
- All members asked to review the crosswalk and charges and come with recommendations for the next meeting
- Next meeting on 11/17/14 1:00 pm EST

Thank you,

Tim Mitchell RS, CP-FS

2016 Interdisciplinary Foodborne Illness Training Committee

Minutes

12/15/2014

- David Lawrence
- Susan Quam
- Susan Algeo
- Jeff Belmont
- Matt Jenkins
- Kris Markulin
- Tim Mitchell
- Roger Mozingo
- Pat Welch

Pat reviewed Food Shield, sounds like everyone is getting registered. Some folks already have access.

Matt Jenkins and Pat Welch, Roger, Jeff Agreed to examine for gaps. (Charge 1/Subcommittee 1)

Tim will look at number 2 with Susan Algeo and Dan and Kris. (Charge 2/Subcommittee 2)

The group will work with the conference to get the current crosswalk posted. (Charge 3)

Next group meeting will be 2/17/15 at 12 CST. (Pat to set Up)

Sub committees will meet before 2/17/15 #1 will be 1/13/15 and Number 2 will be 1/23/15.

Thank you,

Tim Mitchell
Vice Chair

2016 Interdisciplinary Foodborne Illness Training Committee

Minutes

3/3/2015

1. Susan Algeo
2. Jeff Belmont
3. Sandy Fabian
4. Matt Jenkins
5. Kris Markulin
6. Roger Mozingo
7. Jackie Owens
8. Gale Prince
9. Pat Welch
10. Tim Mitchell
11. Dan Okenu
12. James Steele

- Reviewed the progress of the two subcommittees and determined that the subcommittees were on the right track.
- The subcommittees with continue to meet before the next full committee meeting scheduled for 5/21/15.

2016 Interdisciplinary Foodborne Illness Training Committee

Minutes

6/11/2015

Present on conference call:
Susan Algeo
Jeff Belmont
Matthew Jenkins
Kris Markulin
Tim Mitchell
Roger Mozingo
Dan Okenu
Pat Welch

- Reviewed the progress of the two subcommittees and determined that the subcommittees were on the right track.

  Workgroup 1 reported that they completed an assessment of the following programs:
  - RRT
  - CIFOR
  - MFRPS
  - IAFP Procedures to Investigate Foodborne Illness
  - NASDA version 4.0
  - NEHA Epi-Ready

  Workgroup 2 reported that they assessed the following new programs that were not in the original crosswalk document:
  - NEHA I-FITT-RR
  - CDC Foodborne Illinois Outbreak Environmental Assessments

  Further work to accomplish – Summary of recommendations

  Discussed that the final committee report is due December 4, 2015 and that we needed to think about what are recommendations from the committee will be to CFP.
  We also need to decide whether our committee wishes to be reformed to continue its work to complete current/new charges for the 2016-2018 biennium or if it will have run its course and can be retired.

  These will be discussed on our 8/20/15 call.

- The subcommittees with continue to meet before the next full committee meeting scheduled for 08/20/15.

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-017

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

IFITC 2 – Approval and Posting of the Crosswalk

Issue you would like the Conference to consider:

That the Conference considers that new and updated foodborne disease outbreak training programs will continue to occur and that all target agencies could benefit from a process that updates the list of training program and reviews the programs. Posting the Crosswalk will provide a tool that will facilitate the development of robust foodborne illness training programs.

Public Health Significance:

Delays in reporting or investigating a possible foodborne disease outbreak can prolong an outbreak event, potentially resulting in further illness or economic disruption. Effective training of public health professionals, health agencies, universities and industry in outbreak response can mitigate the negative impact of any outbreak. However, these entities may not be aware of the foodborne disease outbreak trainings that are currently in existence.

The Interdisciplinary Foodborne Illness Training Committee believes that these opportunities provide the chance for the Conference for Food Protection to continue to influence the food and beverage community, health agencies, universities, in the minimum, to review their Foodborne Illness Training to determine if their program is complete as outlined in Standard 5. The Interdisciplinary Foodborne Illness Training Committee created a Crosswalk titled Crosswalk - Requirements for Foodborne Illness Training Programs Based on Standard 5 that we recommend is posted to the CFP website.

Recommended Solution: The Conference recommends...:

1) approving the document titled *"Crosswalk - Requirements for Foodborne Illness Training Programs Based on Standard 5"* created by the Interdisciplinary Foodborne Illness Training Committee (document is attached to the Issue titled: Report - Interdisciplinary Foodborne Illness Training Committee).

2) posting the final document on the CFP website in MS Word and PDF.

Submitter Information:

Name:	James Steele
Organization:	IFITC
Address:	Walt Disney WorldPO Box 10,000
City/State/Zip:	Lake Buena Vista, FL 32830
Telephone:	321-395-1665
E-mail:	james.steele@disney.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-018

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

IFITC 3 - Reassign Charges to Program Standards Committee

Issue you would like the Conference to consider:

That the Conference considers that new and updated foodborne disease outbreak training programs will continue to occur and that all target agencies could benefit from a process that updates the list of training programs and reviews the programs. The IFITC firmly believes that the better avenue to continue this work will be under the Programs Standards Committee, a standing committee of the Conference for Food Protection.

Public Health Significance:

Delays in reporting or investigating a possible foodborne disease outbreak can prolong an outbreak event, potentially resulting in further illness or economic disruption. Effective training of public health professionals, health agencies, universities and industry in outbreak response can mitigate the negative impact of any outbreak. However, these entities may not be aware of the foodborne disease outbreak trainings that are currently in existence.

The Interdisciplinary Foodborne Illness Training Committee believes that these opportunities provide the chance for the Conference for Food Protection to continue to influence the food and beverage community, health agencies, universities, in the minimum, to review their Foodborne Illness Training to determine if their program is complete as outlined in Standard 5.

Recommended Solution: The Conference recommends...:

dissolving the Interdisciplinary Foodborne Illness Training Committee.

The Conference further recommends assigning the Program Standards Committee with the following standing charges:

1. Identify available resources related to foodborne illness training.
2. Assess any newly developed foodborne illness training courses or programs.

3. Maintain the document titled *Crosswalk - Requirements For Foodborne Illness Training Programs Based on Standard 5* as a resource and content baseline for foodborne illness training.
4. Report back any findings and recommendations to each biennial meeting of the Conference for Food Protection.

Submitter Information:

Name:	James Steele
Organization:	IFITC, Co-Chair
Address:	Walt Disney WorldPO Box10,000
City/State/Zip:	Lake Buena Vista, FL 32830
Telephone:	321-395-1665
E-mail:	james.steele@disney.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-019

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Clarification for Re-standardization in VNRFRPS Standard 2

Issue you would like the Conference to consider:

The Voluntary National Retail Food Regulatory Program Standards (Program Standards) establish best practices for regulatory programs that license and inspect foodservice and retail food establishments; when applied, the Program Standards are intended to enhance uniformity within and between regulatory agencies.

A major requirement in Standard 2 (Trained Regulatory Staff) is the standardization of at least 90% of the regulatory inspection staff. Standard 2 is specific in stating that continuing standardization (re-standardization) *"shall be maintained by performing four joint inspections with the 'training standard' every three years,"* but lacks specific requirements related to the protocol or process to be used when conducting these joint inspections. The common assumption is that the process used for initial standardization shall also be used for re-standardization... but this is not stated in Standard 2.

In addition, the Program Standards Definition for a "training standard" lacks requirements for both continuing education and re-standardization. Again, the common assumption is that re-standardization of a "training standard" is required every three (3) years, with the same continuing education requirements as for regulatory inspection staff, and using the same process as that used for initial standardization of the "training standard"... but none of this is stated in the Definitions or in Standard 2.

Public Health Significance:

Non-specific language regarding continuing standardization in the Definitions and in Standard 2 requires every program manager who has achieved conformance with Standard 2 to make assumptions about how to effectively achieve re-standardization in his/her jurisdiction. In addition, a lack of stated requirements forces an auditor to also make assumptions about the requirements during a verification audit. Differing interpretations... and differing expectations... could result in a non-confirming audit. Moreover, specific

requirements that might be acceptable by one auditor... could be rejected in a subsequent audit by a different auditor.

The absence of specific language regarding continuing standardization (re-standardization)... and the need to rely on unstated (and potentially differing) assumptions... could easily result in regulatory agencies being held to vastly different requirements in order to successfully pass a second (and subsequent) verification audit of Standard 2.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending:

1) Clarification of continuing standardization (re-standardization) requirements in the *Voluntary National Retail Food Regulatory Program Standards-January 2015* by insertion/deletion of the following language in the DEFINITIONS and in STANDARD 2 *(only those paragraphs impacted are included below; language to be inserted is in underline format and language to be removed is in strikethrough format. Full text of Standard 2 and suggested edits is available in the attached content document titled:* ***VNRFRPS Standard 2 Revision - full text****)*:

a) DEFINITIONS - Definition #29

Training Standard - An individual who has successfully completed the following training elements AND standardization elements in Standard 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees. The training and standardization elements include:

1. Satisfactory completion of the prerequisite curriculum;

2. Completion of a field training process similar to that contained in Appendix B-2;

3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum; ~~and~~

4. Successful completion of a standardization process based on a minimum of eight inspections that includes development of HACCP flow charts, completion of a risk control plan, and verification of a HACCP plan, similar to the FDA standardization procedures~~.~~;

5. Completion of a minimum of 20 contact hours of continuing education in food safety every three (3) years as outlined in Standard 2; and

6. Successful standardization renewal every three (3) years based on the same protocol and field inspection process as that used to achieve initial standardization.

b) STANDARD 2, Trained Regulatory Staff (see attached content document titled: ***VNRFRPS Standard 2 Revision - full text)***

Requirement Summary, STEP 4: Food Safety Inspection Officer - Field Standardization

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years; joint inspections shall be conducted using the same protocol, include the same field exercises, and apply the same scoring and assessment criteria used during initial standardization.

Note: *If a jurisdiction updates their standardization protocol, or their scoring and assessment tools, the most recent version shall be used during re-standardization.*

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 18 month time frame, or should a jurisdiction fail to meet all re-standardization requirements every three years, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);
2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. NOTE: The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization and/or re-standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

2) Updating of any support material or documents related to Standard 2 and the Definitions of the *Voluntary National Retail Food Regulatory Program Standards-January 2015* to reflect any language change.

Submitter Information 1:

Name:	Manuel Ramirez
Organization:	City of Berkeley, Division of Environmental Health
Address:	2180 Milvia Street, 2nd Floor
City/State/Zip:	Berkeley, CA 94704
Telephone:	510-981-5261
E-mail:	mramirez@cityofberkeley.info

Submitter Information 2:

Name:	Vicki Everly
Organization:	City of Berkeley, Division of Environmental Health
Address:	2180 Milvia Street, 2nd Floor
City/State/Zip:	Berkeley, CA 94704
Telephone:	510-501-0417

E-mail: veverly@cityofberkeley.info

Supporting Attachments:

- "• VNRFRPS Standard 2 Revision - full text"

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

STANDARD 2
TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual.*

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 18 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 18 months of training.

Step 1: Pre-Inspection Curriculum
Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre-requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm

Note: *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*

- *Logs/records that are completed based on sign-in sheets; or*
- *Information validated from the certificate at the time-of-issuance; or*
- *A college transcript with a passing grade or other indication of successful completion of the course; or*
- *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
- *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORA U courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant and institutional

foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

> **Note:** *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*
>
> - *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
> - *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

> **Note:** *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*
>
> - *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
> - *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 18 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following six curricula areas, must be completed within this 18 month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 18 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

Note: *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm

Step 4: Food Safety Inspection Officer – Field Standardization

Within 18 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Note: *The field standardization criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using*

standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors, and communicates vital information about the inspection in a way that can be received, understood and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years; joint inspections shall be conducted using the same protocol, include the same field exercises, and apply the same scoring and assessment criteria used during initial standardization.

> ***Note:*** *If a jurisdiction updates their standardization protocol, or their scoring and assessment tools, the most recent version shall be used during re-standardization.*

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 18 month time frame, or should a jurisdiction fail to meet all re-standardization requirements every three years, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan

outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (18 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

6. Delivering presentations at professional conferences;
7. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
8. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period.

> **Note:** *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

9. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE

credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);
2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization and/or re-standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-020

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Reevaluation of FDA VNRFRP Standard 8

Issue you would like the Conference to consider:

The FDA *Voluntary National Retail Food Regulatory Program Standards* (VNRFRPS) provides an excellent framework for measure of conformity and serves as a benchmark for local health departments. It is our opinion that Standard 8 should be reevaluated to promote more feasible, sensible, and realistic criteria that can be obtained by health departments without reducing the overall objective of Standard 8.

Public Health Significance:

Standard 8 of the VNRFRPS creates an unattainable standard that prohibits local health departments (LHDs) from achieving this level of model operation.

Very few LHDs have met this Standard. Of this small number, many were one person jurisdictions that do not operate on the same capacity of the majority of LHDs. From the FDA VNRFRP website, of the 671 LHDs that are enrolled, only 27 have met Standard 8 thru self-assessment, 14 of those conducted their assessments over 5 years ago, and only 2 of the 27 were actually verified via an audit.

While the Standard surely should exist, the logic model doesn't seem sound when it is unattainable or impractical to efficient operations of LHDs. Standard 8 should be reevaluated, not to reduce the quality of the benchmark, but to review the criteria to be sure it is accurate and reasonable, as well as being an attainable standard of measure for LHDs to strive to attain.

Recommended Solution: The Conference recommends...:

that the CFP Program Standards Committee be charged to evaluate Standard 8 of the FDA Voluntary National Retail Food Regulatory Program Standards, as follows:

1. review the "Description of Requirements" for "Staffing Level" to ensure they are accurate, reasonable, and attainable for jurisdictions of all sizes,

2. report back their findings and recommendations to the 2018 Biennial Meeting of the Conference for Food Protection.

Submitter Information 1:

Name:	Michael Schaffer
Organization:	Harris County Public Health & Environmental Services
Address:	2223 W. Loop S.
City/State/Zip:	Houston, TX 77027
Telephone:	713-274-6400
E-mail:	mschaffer@hcphes.org

Submitter Information 2:

Name:	Deanna Copeland
Organization:	Harris County Public Health & Environmental Services
Address:	101 S. Richey, Ste. G
City/State/Zip:	Pasadena, TX 77506
Telephone:	713-274-6443
E-mail:	dcopeland@hcphes.org

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-021

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Recommended Food Code adoption process

Issue you would like the Conference to consider:

This Issue makes it easy for all stakeholders to quickly identify differences between a jurisdiction's food code and the FDA Food Code.

Adoption of the FDA Food Code by States, Territories and Local jurisdictions can be a laborious process. Besides taking a long time and extensive resources of regulatory authorities, it is often difficult to determine which sections of a jurisdiction's food code are different from the FDA Food Code. This issue asks the conference to consider providing in Standard 1 of the Voluntary National Retail Food Regulatory Program Standards (or anywhere else FDA feels appropriate) a suggested method for FDA Food Code adoption.

This issue recommends adoption via an exception process. A number of states have utilized this process successfully, Iowa, New Mexico, North Carolina and West Virginia for example. As the jurisdiction reviews the latest FDA Food Code for adoption, it creates a statute or administrative rule which:

1. First adopts the current version of the FDA Food Code;
2. Secondly creates paragraphs within their statute/rule which adopt jurisdiction specific requirements which replace or amend the referenced sections of the FDA Food Code.

Public Health Significance:

This process does not compromise food safety in any manner and would simplify the Food code adoption process. Since many multi-jurisdictional companies utilize the current version of the FDA Food Code as their standard for Food Safety, it would allow them to easily identify Food Code sections that differ from the FDA Food Code. A few of the advantages of this type of adoption process include:

1. Less chance of transcription errors-missing words, misspelled words, etc.
2. Less chance of missing relevant Food Code citations or cross references.

3. Changes from the FDA Food code are easy to pick out since they will be incorporated into a much briefer rule. No need to search the whole food code of a jurisdiction to see what is different.
4. Less chance of industry being out of compliance with a jurisdictions food code since they did not know that a jurisdiction's food code differed from the FDA Food Code in any given section.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending that Standard 1 of the Voluntary National Retail Food Regulatory Program Standards include a process for adopting the FDA Food Code with exceptions. The following is sample language:

When adopting the FDA Food Code, the following is a recommended process:

1. Adopt Chapters 1-7 or 8 (if it's compatible with the jurisdiction's administrative procedures) if allowed by the jurisdiction's rulemaking process and by stakeholders.
2. Any changes should then be incorporated into this administrative rule citing which specific sections of the FDA Food code are not being adopted or are being modified. List specific wording changes that are replacing the exempted FDA sections, including a reference to the specific FDA section being changed.
3. Additional jurisdiction specific chapters may be added and may include items such as mobile units, temporary events, cottage foods, etc.
4. When adding additional chapters, consider reviewing available guidance documents on the CFP and Association of Food and Drug Officials (AFDO) websites for model codes that can be used in creating additional content.
5. An 'unofficial' inspectors copy of the final adopted code be created which includes full text of the Food Code including changes so inspectors do not need to cross reference back and forth between the FDA Food Code and the jurisdiction's adopted rule.

Submitter Information:

Name:	Christopher Melchert
Organization:	National Restaurant Association
Address:	2055 L Street NWSuite 700
City/State/Zip:	Washington, DC 20036
Telephone:	202-973-3960
E-mail:	cmelchert@restaurant.org

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-022

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

All information above the line is for conference use only.

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014, III-017; the recommended solution has been revised.

Title:

Complimenting Unannounced with Scheduled Inspections

Issue you would like the Conference to consider:

30,000+ health inspectors/assessors have an opportunity to be more focused on prevention in keeping with the principles of Active Managerial Control (AMC) and in the spirit of the Food Safety Modernization Act (FSMA).

A condition for improved learning for food handlers and their managers can be achieved by scheduling inspections rather than trying to learn during routine, unannounced inspections, especially when key managers are missing.

Local initiatives show that a scheduled assessment format is capable of culture change and the building of mutual respect between inspector and operator. Once a program of scheduled inspections is implemented neither party wants to return to former practices.

Discussions with the person-in-charge (PIC) and senior facility management, focused on prioritized risks, uncover many risks that cannot be discovered by observation alone. This point is crystallized in this quote from an operator during an outbreak investigation. "Why didn't you point out all these risks? Why did you wait until we had an outbreak?" http://handwashingforlife.com/blog/mike-mann/scheduled-restaurant-inspections

Public Health Significance:

Better-utilized health inspector time can protect the public by minimizing foodborne outbreaks.

Minimally trained foodservice managers and staff threaten public health. Without knowledge of clear risk-based objectives, managers are themselves barriers to effective and sustainable staff training as they set priorities and control budgets. It is the onsite manager education that has been the missing link, and high industry turnover rates exacerbate the issue.

There are approximately 30,000 inspector/trainers in the U.S. who conduct an estimated 20 million retail food inspections per year. Encouraging unannounced inspections will improve public health by focusing some of these inspections on communication and a training partnership between industry and regulators.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending that the 2013 Food Code Annexes be amended to encourage complimenting unscheduled with scheduled inspection programs by regulatory agencies.

Submitter Information:

Name:	Jim Mann
Organization:	Handwashing For Life
Address:	1216 Flamingo Parkway
City/State/Zip:	Libertyville, IL 60048
Telephone:	847-918-0254
E-mail:	jmann@handwashingforlife.com

Supporting Attachments:

- "Olmsted County Receives "Model Practice Award""
- "Olmsted County Crumbine Award Package"
- "Olmsted County - Risk Factor Identification"

Public Health Services
2100 Campus Drive SE
Rochester, MN 55904-4722
507/285-8370
FAX: 507/287-1492
www.olmstedcounty.com

MEDIA RELEASE

CONTACT: Pete Giesen, 285-8346

FOR IMMEDIATE USE
DATE: 7-13-05

Olmsted County Public Health Services Receives "Model Practice Award"

The National Association of County and City Health Officials (NACCHO) honors Olmsted County Public Health Services' on July 13, 2005 at the NACCHO annual conference in Boston for "excellence and continual improvement" in the County's food protection program. Olmsted County joins a special group of public health agencies that exemplify the forward thinking, proactive attitude of our nation's public health system," said NACCHO President Michael Caldwell, MD, MPH. "NACCHO congratulates Olmsted County Public Health Services on this important recognition."

Olmsted County's food protection program entry, titled "Discovering Previously Unidentified Foodborne Illness Risks Through Discussion," summarizes the County's process of assisting food establishment mangers develop their policies and systems that address conditions most often associated with food-borne illness. This approach typically results in longer lasting food safety improvements and it identifies about 50% more risk conditions associated with employee health, hand-washing, cooking, and cooling than traditional facility inspection models.

The methods, initiated in the late 1990's, are under continued development with assistance by a local Food Safety Advisory Task Force that includes local food service establishment, Olmsted County Environmental Commission, and County Public Health representatives. Environmental Health Director and food program manager, Rich Peter, attributes the program's success to "the community's commitment to continual improvement that is shared by our local food service industry and State & local public health for protecting the public's health."

NACCHO's Model Practice Awards program honors 39 initiatives in 2005, that demonstrate how local public health agencies and their community partners can effectively collaborate to address local public health concerns. A committee of peers selected Olmsted County from 106 local public health agency applicants. All award winning programs will become part of a NACCHO online, searchable database of successful public health practices including immunization, infectious disease, emergency preparedness, and maternal and child health.

- OCPHS -

Samuel J. Crumbine Consumer Protection Award

2000 Award Application By:

Olmsted County Public Health Services
Environmental Health Division
1650 4th Street Southeast
Rochester, Minnesota 55904
Phone: (507) 285-8342
FAX: (507) 287-1492

Executive Summary

This is the Information Age where change is a constant, and we know that well in Olmsted County, Minnesota. Many people here make their living as innovators, at places like the Mayo Clinic and the IBM AS400 facility. In this progressive environment, we in the Environmental Health division began to question the purpose to our assigned work. We concluded that preventing foodborne illness is a job for the people who work with the food. Our job is to assist them in this prevention work.

Before it was common for local public health agencies to do so, this division developed the capability to investigate outbreaks of foodborne illness. But reacting to an outbreak is like a fire department arriving on the scene after the house has burned down. Like a fire department, we needed to focus on prevention, and we needed a way to do this practically.

This method would have to zero in on health risks--those conditions and practices that are known, through epidemiology, to cause foodborne illness. This was difficult to do during a traditional, unannounced inspection geared toward code compliance and enforcement. Too much time was spent on low risk conditions, adversarial relationships tended to develop, and communication was poor. Food service operators didn't listen to us--our message was of little value to them.

But when the message was focused on risk reduction, restaurant operators were willing to listen, and when they continued to hear us talking about food safety, they began to see us as allies. And then we could begin working with them to prevent foodborne illness in their establishments.

A pilot project to build these lessons into a risk-based inspection format was proposed, and was supported by the Minnesota Department of Health, with funding assistance from the University of Minnesota, Food Science Department. Other local agencies joined us in a week-long training exercise led by D.J. Inman.

After the training, the pilot was expanded to more food service sites, and we developed a practical and systematic method for assessing health risk. It is called Food Safety Systems Review, or System Review for short. It is a HACCP-based screening tool that doesn't need plans or manuals to be put into use. With the cooperation of the operator the practices that increase the risk of illness are identified, and with the sanitarian's assistance, safer procedures are developed. The operator is left to put these changes into practice, and our experience tells us that these changes are taking place.

An ongoing challenge is to quantify our results to track this progress over time, and ironically, return to unannounced inspections; this time as a partner, not an adversary.

We didn't do this alone...

We would like to express our appreciation for the permission, help, and encouragement we received from the people of: the 6 restaurants that agreed to participate with us in our training and pilot project; the Olmsted County Environmental Commission; the Olmsted County Board; Joellen Feirtag, PhD, at the University of Minnesota; the public health agencies of Brown-Nicollet, Waseca, and Winona Counties; the Minnesota Department of Health, especially Mary Sheehan; the US Food and Drug Administration; and people working outside of government, especially D.J. Inman.

But most of all we would like to thank the food service operators of Olmsted County. They were generous enough to take the hand we extended to them and join us in a partnership dedicated to preventing foodborne illness. They have told us we can accomplish this work *together*.

Table of Contents

Part I: Who We Are

Our Community

Olmsted County is located in southeast Minnesota, a mainly rural, agricultural area. Its population is a study in contrasts: here are people from all over the world who have recently made a new home, as well as people who have farmed the same land for generations. Its population is concentrated in the largest city, Rochester, with 70% of the county's approximately 115,000 people.

Rochester is the home of the Mayo Clinic, which gives it the distinction of having the greatest per capita concentration of physicians in the world. IBM and its AS400 computer assembly facility is the second leading employer. Together, with a strong Convention Bureau, they annually attract over 1 million visitors to Rochester from all over the world. Rochester's leaders and citizens are also proud of being named the "Best Place to Live in America" by *Money Magazine*.

As well as attracting visitors, Olmsted County and Rochester have become a new home for thousands of immigrants and refugees. This influx began in the 1970's with arrivals from Cambodia, Laos, and Vietnam. More recently, Hispanic migrant workers, and people from Ethiopia, China, Bosnia, Russia, Somalia, Sudan, and Zaire have settled here. As a result, the unique cuisine of these cultures has become a part of the 300+ food establishments in our community.

Olmsted County is also host to over 30 community celebrations and special events annually. Most notable are Rochesterfest, the Olmsted County Fair, Gold Rush Antique Flea Markets, and the Viola Gopher Count. These events attract several hundred thousand people annually.

Our Public Health Challenges

At OCPHS we feel we are carrying on the work of our department's founder and first health officer, Dr. William Mayo. Of special concern is the large number of Mayo Clinic patients who come to our community for treatment. Many suffer from illnesses that make them more susceptible to foodborne illness. Some of these people are here for months at a time, staying in and eating at licensed facilities.

Our Resources

A strength of our division is the diversity of our staff: 3 ½ Sanitarians, 2 Senior Sanitarians, 1 Health Educator, 3 Technicians, 1 Secretary, 1 Environmental Health Services Coordinator, and 1 Director. The Sanitarians, Coordinator and Director, all registered sanitarians, obtain an average of 15 continuing education units each year, enhancing not only their food safety knowledge, but also communication and presentation skills, and even a "Thinking Outside the Lines" seminar. We regularly participate in external committees and project work, including state committees and presentations (see Appendix for staff CEUs and presentations). The addition of an epidemiologist to the department staff in 1991 enhanced disease surveillance, improved communication with the medical community, and helped uncover many local, statewide, and even national outbreaks. In addition to the conventional inspection equipment, staff now carry, or have access to, thermocouples, infrared thermometers, a computerized data-logging thermometer, and pH meter. Each sanitarian also has a personal computer with e-mail and access to the Internet.

Part II: Our Story

We are a group of food safety professionals, united in the belief that we have an important job to do. We used to think it was our job to prevent foodborne illness. By trial and error we discovered that we cannot prevent foodborne illness--at least, not by ourselves. What we can do is to work with the people who work with the food. They can prevent foodborne illness.

We started out doing traditional inspections: walk in unannounced, see what there is to see at that point in time, write up correction orders, and briefly discuss the results with the operator (if they were there). Over nearly 10 years we evolved, trying to sharpen the focus on disease risks and communicate effectively with food service operators. The change process intensified during the last 3 years, resulting in an inspection approach that has reached new levels of risk assessment and communication. What follows is the story of our journey - a journey through three main issues and challenges: focusing on risk, improving communication, and measuring outcomes (these issues and challenges are discussed in more detail in Part III).

The Early Years - Consistency and Education

In the early 1990s, we made a major effort to improve consistency between inspectors by doing "standardization" inspections, where every observable violation was cited. Crumbs in a corner became a dirty floor, and one dirty spoon was written up as soiled utensils. We felt that if the operator knew all of the code provisions (through our thorough, standardized inspections) at the same time we de-emphasized the inspection scores (because many restaurants had lower scores as an outcome of this approach), in the long run, we should see safer food establishments.

To achieve consistency in reporting and to avoid illegible handwritten reports, we used pre-written standard orders that were stored in a computer database. There were several hundred orders, which attempted to cover every situation likely to be encountered. We added the public health reason to each of the corrections in an attempt to persuade operators we had the highest motives in asking them to make all the changes. Unfortunately, the educational content of the reasons was lost in reports that often ran to twenty pages. Also lost in the bulky reports was the first attempt to emphasize the high risk items, which had their own section at the beginning.

But because of our standardization style, many low risk items were left uncorrected. The method for dealing with these was to ask the operator to draw up a Plan of Action, which was a description of how and when the owner was going to fix or correct them. Follow-through was inconsistent, both by operators and sanitarians. Again, we hoped a long-term written plan would lead to improvement.

We thought long-term compliance would improve if we increased the rate of scheduled reinspections. High risk items and "Repeat" items were given priority. We did get better compliance from operators, however, we often saw the same or similar problems at the next inspection. We started asking ourselves, "Are we preventing disease"? "Are we reducing the risk?" "Are we confident that the minute our inspection is over the food served in that restaurant is safe, or at least safer?" **We concluded that this system of inspection encouraged operators to correct items temporarily to satisfy the inspector, instead of incorporating the corrections as changes in their day-to-day operations.**

The Mid 1990s – Customer Service and Reorganization

We received a boost of energy from our county management when they adopted Total Quality Management principles. They asked us to work as teams, and view both our fellow employees and outside contacts as customers. This encouraged us to try to see things from the operator's point of view. We decided to tailor our inspections to fit their needs. We wanted them to see the inspection process as a "valuable product," so they would improve their compliance.

These county directives fueled a reorganization. We got training in teambuilding. We split the county into three districts and assigned a team of two sanitarians to each. We set a goal of inspecting all our establishments at least once per year, stored inspection dates in newly available computer software, and tracked our progress with graphs. We set a regular schedule to replace our previously occasional and casual staff meetings, and worked from an agenda prepared in advance.

We also decided to overhaul the standard orders before putting them in a new database, and worked on this project as a team. The number of orders was cut in half and rewritten to cover situations generally instead of specifically. The emphasis became high risk items, now called "Critical Conditions." We spent great care on the wording--another attempt to persuade operators to complete their corrections. Unfortunately, the new orders were no more successful than the old ones.

Throughout the '80s and '90s – The Foodborne Outbreak Inspection

Unlike traditional inspections, the approach used over the last 15 years during foodborne illness investigations has proved successful. Outbreaks are usually threatening to food service operators--a restaurant's future can hang in the balance. From the onset, the

investigation team immediately tries to establish an honest and trusting relationship with management. Our premise is that their undivided attention, cooperation, and honesty are essential in finding the cause of the outbreak.

Not only was our communication style different from a routine inspection, so was the information we were interested in and the way we went about getting it. Our attention was totally focused on health risk. We talked to both employees and management. We asked all food employees questions about their illness history and work duties, and then we listened carefully to their responses to identify suspect preparation procedures or other causes. We helped the manager and the staff identify not just what they were doing wrong, but also what corrections to make, and how to monitor those corrections to prevent future outbreaks. Managers started to ask why this type of focused inspection wasn't being done before an outbreak. Could we switch to an illness prevention program focused on health risk? And even if we could, how could we do it practically? We couldn't go into every restaurant and analyze the preparation of every food.

The Mid 1990s Again – The Change Process Accelerates

Inspired by a food safety plan drafted by the Minnesota Department of Health, our Director developed a tool titled "Food Safety Systems Review." This "tool" captured the important food safety systems and practices that should be assessed during an inspection. In late 1996 we were making plans to use this hazard analysis-based method (described in more detail in Issue #1), but realized it required a lot of information gathering, which still made it impractical to use during a standard, unannounced inspection. We put this tool on the shelf.

At the same time, we were hearing new ideas from food safety innovators across the country who advocated using hazard analysis and re-tooling the standard inspection format.

As the epidemiology continued to point to more specific food preparation and hygiene errors as causes of disease outbreaks (the foodborne illness – FBI – factors), we concluded that it was important to use hazard analysis to identify the FBI factors in an establishment. But identifying the hazards was not enough. In order to make a significant reduction in the incidence of foodborne illness it was necessary to get food preparers to change their behavior. Once we recognized this, we realized the way we did inspections was one of the barriers to change. We had already been trying to persuade people to change with our carefully crafted standard orders. And people did change, but only until we walked out the door after their reinspection. We needed help to move beyond the regulatory-only "box" in order to impact behavior.

In February of 1997, Mary Sheehan of MDH had the vision to bring the FDA Food Leadership Workshop to Minnesota. There, our Coordinator Pete Giesen, and Director, Rich Peter met D.J. Inman. Just as a chemical catalyst helps drive a reaction to completion, the influence and energy of D.J. helped us to put together the food safety puzzle pieces we had collected: focusing on health risk, improving communication with operators, and giving them a reason to cooperate with us. D.J. is a former FDA food safety specialist and a current food safety consultant. He advocates forming partnerships and building relationships with operators to achieve the common goal of preventing foodborne illness. He promotes a respectful, consultative method where sanitarians ask questions in order to become familiar with the operation and its food preparation methods, especially for high risk foods. Problems will then "float to the top," and safer methods for food preparation can be discussed. This fit in well with our realization that a code-based inspection is not effective in identifying the real

food safety problems nor at persuading most people to permanently change their practices or behavior.

1997 Through Today - The Pilot Project

We decided we wanted to try this new way of inspecting. Other nearby local agencies were also interested in the approach. With approval from the Minnesota Department of Health (MDH) and our County Environmental Commission, we embarked on a pilot project with six local restaurateurs. Funding from the University of Minnesota Food Science Department helped us to bring D.J. back to Minnesota to put on a training workshop. Sanitarians from Brown-Nicollet, Olmsted, Waseca, and Winona Counties, and MDH participated.

After the week-long training, the response from both the operators and participating sanitarians was so overwhelmingly positive that a decision was made to expand the number of restaurants involved. But as more staff members joined in, it became apparent that there was not enough structure in the inspection format to satisfy our diverse group, to document our activities, and to have measurable outcomes for assessment.

This is when the Systems Review form was pulled off the shelf. The review is based on Hazard Analysis Critical Control Points (HACCP). HACCP is basically a vertical approach and the Systems Review is a horizontal approach. Think of it this way. Visualize a flow chart of a process or recipe. It starts at the top of the page with ingredients, and ends at the bottom with finished product. Now visualize several flow charts placed side by side. If you go across the pages from side to side, there will be some alignment of common elements. These are food preparation processes such as cooling, cooking, and reheating. When using this method it is not important whether a given process is a critical control point in a given

recipe--all the "systems" are treated as being critical. For example: always use rapid cooling methods, always wash hands before touching food, always avoid cross-contamination, etc. The systems review process (which is further described in the Issues/Challenges section) is the cornerstone of today's program.

Forming partnerships with the "other side" can be a tough concept for enforcement-oriented people to accept. Our experience confirms that operators are not trying to get away with things when it comes to safe food; they're not the "other side". They take pride in their business and are very aware that a foodborne outbreak could cost them their reputation, or their livelihood. They also have strong feelings of loyalty to their base of regular customers, and know that the relationship might not survive our "common enemy"--foodborne illness.

Part III: Our Issues and Challenges

As we journeyed through the last 8 to 10 years, we would like to say our program's improvements proceeded smoothly from point A to point B, guided by a clear list of goals, objectives, and methods, all tagged with staff assignments and completion dates – but it didn't happen that way. We seemed to know where we wanted to go but we didn't know how to get there.

Our Community Health Services (CHS) Assessment and Plan helped. This process, required by Minnesota Statutes, is for communities to help local health agencies to identify and prioritize health problems, and develop goals, objectives, and methods for solving them (see the Appendix for excerpts from our 1996 and 2000 plans). This four-year planning cycle greatly influenced how we approach our work. We started talking about health

problems, not just *programs*. As early as 1992, we started to recognize some of the barriers to improving health outcomes with a goal to:

> *"Improve communications with businesses and other organizations to improve efficiency and effectiveness of education, consultation and regulatory services authorized by the State of Minnesota and Olmsted County."* (1992 CHS Plan).

But focusing on the health problems within a regulatory framework was a huge challenge (we could no longer say, "By enforcing the code, we will prevent foodborne illness"). We had to come up with solutions to actually impact the problem. In retrospect, this conflict between the regulatory paradigm and health-outcomes paradigm is why it was difficult to "plan" for the change we went (and are going) through.

However, of the many challenging issues we faced during our journey, three stand out: 1) focusing on risk, 2) improving communication, and 3) measuring outcomes. If we thoroughly assess the foodborne disease risks (1st priority), and effectively communicate them with the food service operator (2nd priority), the public's health will be better protected and the resulting outcomes can be measured (3rd priority). Any other order has a diminished effect.

Issue/Challenge 1: Focusing on Risk

Traditional food service inspections were not focused on health risks--they were driven by a code-based system whose good intentions became an obstacle to preventing foodborne illness.

OUTCOME: We have instituted a risk-based inspection system that is similar to the investigation of a foodborne illness.

No one can deny that the primary purpose of food service inspections is to reduce the risk of foodborne illness. But it can be argued that the "letter" of the food code often overshadows the "spirit" of the code. This, combined with our early tradition of being the "sanitary police," has created an image of us as regulators - not educators or consultants.

Add to this a changing epidemiology of foodborne disease that doesn't follow the rules or wait for the next code update, and you have a food inspection program that's soon out-of-date.

Unfortunately, this combination creates many problems: uncertainty among food safety professionals, adversarial relations with operators during inspections, and most importantly, the belief that strict enforcement of the food code is the only effective way to reduce risk. Our focus on risk is our attempt to balance these forces. Our journey continues.

How did we reach our outcome?

Our Early Efforts to Focus on Risk – A Lesson from a Water Contamination Incident

We started to learn about and appreciate the meaning of a risk-based approach back in 1990. At the Olmsted County Fair, a temporary water distribution system became contaminated (JEH - March, 1996). We thought we'd been doing a good job at the fair because we inspected all the food stands, but we weren't seeing the fair as a community with the same public health risks faced by any large community. We suddenly realized that it wasn't enough to react to problems--we had to anticipate them by looking at all the potential problems and their risks. In this case, a week-long event with 200,000 visitors, animals and their manure, food stands, water distribution systems, waste disposal facilities, and campground on a 50-acre site.

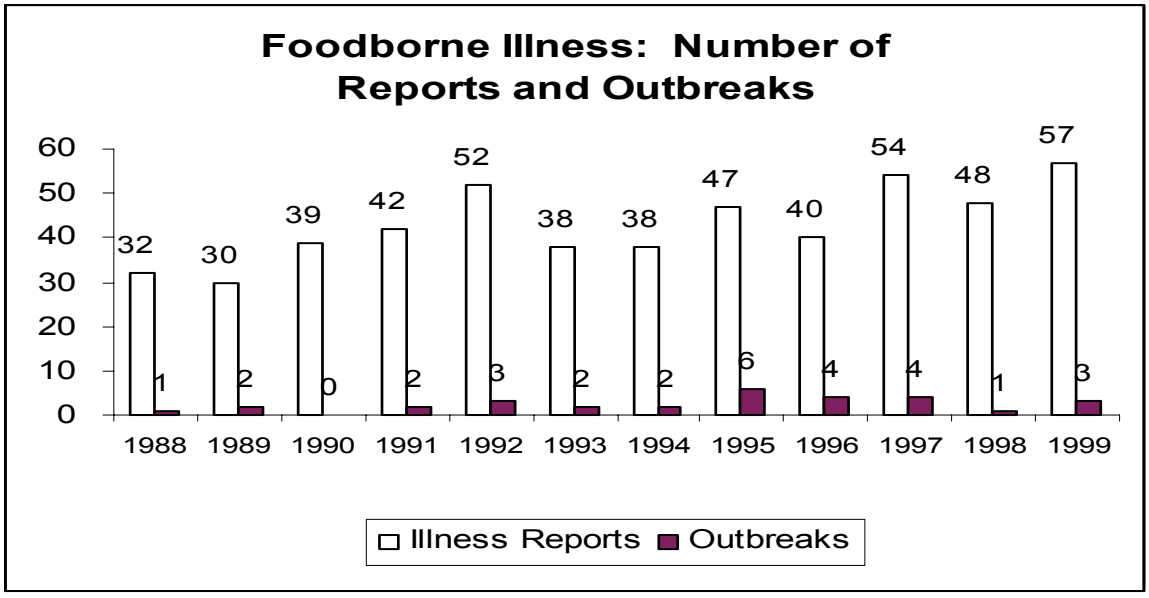
Since then, we work each year with the organizers of over 30 special events to discuss their set-up plans well before the event. We troubleshoot issues during the event, and follow-up afterward to better prepare for the following year. The outcomes of this consultative work have been significant: volunteer organizers have coordinated the design and installation of properly sized water distribution systems; handwashing stations were placed adjacent to portable restrooms and animal handling areas; storm sewer inlets were stenciled with

educational messages about environmentally-safe wastewater disposal; and food vendors were licensed well in advance of events, and were required to describe their menus, equipment, and food preparation procedures. We looked for opportunities to apply this risk-based, consultative approach to other areas of our work.

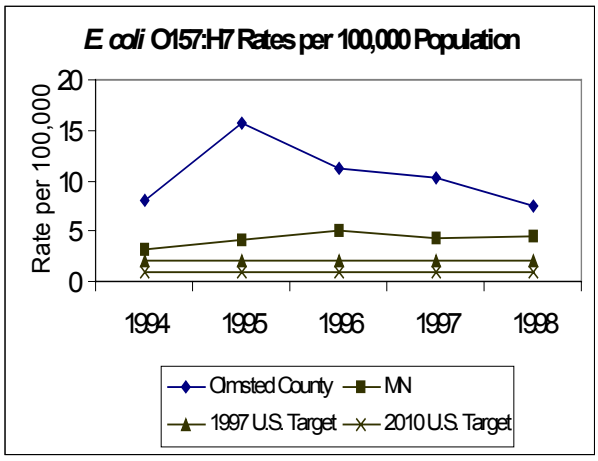
The Foodborne Outbreak Inspection – a Natural Focus on Risk

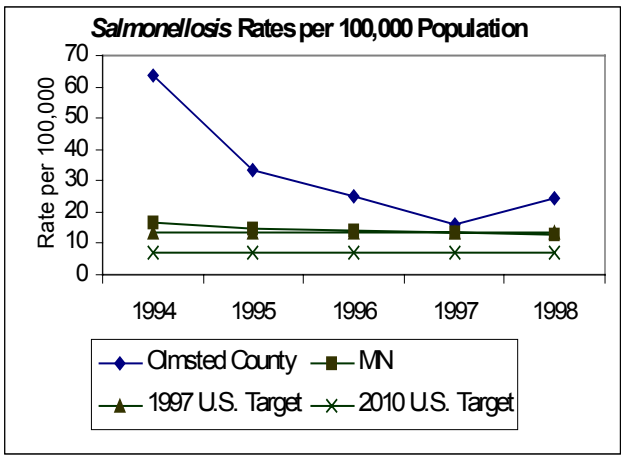
As mentioned previously, foodborne outbreak inspections also focused us on risk. Since 1984, OCPHS, in cooperation with the MDH Acute Disease Epidemiology Section, has investigated over 35 food and waterborne outbreaks in Olmsted County (see Appendix for summary of procedures and list). Outbreaks that may have gone undetected elsewhere were uncovered through strong statewide disease surveillance (currently Minnesota is a FoodNet site), and ongoing communication between OCPHS, the Mayo Clinic, and Olmsted Medical Center. For example, our epidemiologist was instrumental in identifying an increase in the number of *Salmonella* cases at the local level which was the tip of the iceberg of a nationwide outbreak of *Salmonella Enteritidus* associated with Schwan's Ice Cream.

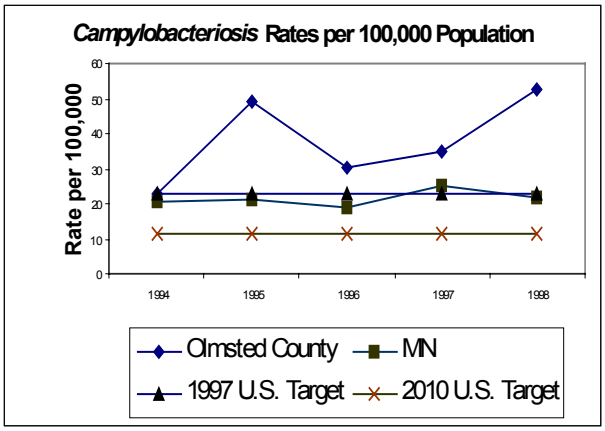
Both the number of outbreaks and the number of reports of illness have been increasing in Olmsted County and Minnesota (see graphs below).

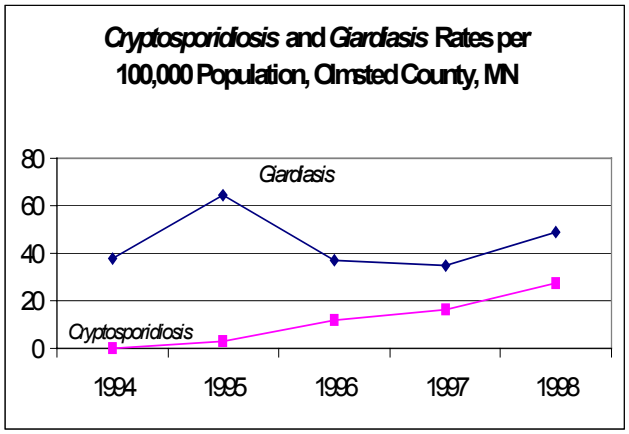


Pathogen-specific rates are also higher than Minnesota rates and National goals. We suspect that for most pathogens (but possibly, not all) this is not due to a bigger problem in Olmsted County, but that better diagnosis, improved lab procedures, and increased reporting by physicians and the public has uncovered a larger part of the foodborne illness iceberg.









While these rates are not sensitive enough to measure the impact of our program, they do provide a benchmark for the community.

With each outbreak, and a better understanding of the epidemiology of each of the pathogens, it reinforces the foodborne disease risk factors in Olmsted County:

- Food contamination by workers(ill employees/lapses in handwashing)
- Food time/temperature problems, and
- Cross contamination

What are the underlying root causes of these factors? Although each outbreak is different, and in some outbreaks the risk factor is not known, in many they are behaviors or practices. These behaviors and practices are difficult to thoroughly assess during a traditional inspection. If identified, it's likely a very small piece of a bigger problem. Issuing an "order to correct a violation" will not likely change the condition in the long term. For example, root causes of risk factors may be:

- "Bad habits" formed over many years (e.g. not washing hands),
- Ingrained in how the business is run and common across the entire industry (e.g. hand cross contamination between raw meats and ready to eat foods at a busy cookline),
- Influenced by outside forces (e.g. I have to work to get paid, even though I'm ill),
- Due to lack of information (e.g. I never knew I should cool the food quickly)

This ongoing challenge to keep pace with the changing epidemiology of foodborne disease and the underlying root causes has set the stage for the paradigm shift in the inspection process.

The Outcome of Our Focus on Risk: The Systems Review Inspection

A product of our pilot project training was the systems review inspection. This process starts with scheduling the inspection, an important first step in building a relationship with the operator. The call includes a brief explanation of the approach, and a request for an appointment at a time convenient for the operator. Instant rapport can be established simply by saying, "I would like to sit down with you and talk about food safety."

Once at the food service, we meet the owner and/or manager(s) and re-introduce the systems review inspection. We share with them the reason for the change, emphasizing local outbreaks. Non-traditional techniques are crucial in this initial dialogue, such as sitting down with the operator, sharing what's being written on the forms, listening for subtle messages on important issues, and using non-technical language. After this introduction, we conduct the systems review inspection this way:

1. **Build a Profile of the Business**. What are your days and hours of operation? How many meals are served per day? When is food prepared for banquets, parties or happy hours? How many employees do you have? What days of the week are foods delivered? (see Appendix for form used). These and other questions help us learn more about the business and its potential risks.
2. **Discuss the Food Safety Systems**. The Systems Review is the second step, the sitting down and talking. The sanitarian asks open-ended questions about each system, including ill employee policies, cooling procedures, and cross contamination prevention (see Appendix for the listing of systems on the form used). Then we listen, and listen some more.

Most operators realize this is an opportunity to improve their operation. They are actually interested in what we have to say. They are also more likely to make needed changes if we discuss various options for improvements with them so they can pick the one they think will work best for their situation. Our goal is to effectively describe the potential problem and "lead the operator down the path to self discovery" (Inman). That is, the operator solves the problem without us! This makes a permanent change in the practice much more likely.

3. **Evaluate the Preparation of a Food**. From the systems review discussion, a food (or foods) "floats to the top" as a potential problem. Example: When discussing their system for cooling food, we may be told that the vegetable beef soup is cooled in 5 gallon buckets. That's not only noted on our systems form, but also mentally so we can come back to this system and evaluate the prep in more detail. We'll discuss and chart the process, from ingredients to service, looking for other possible hazards: reheating temperatures, how many cooling/reheating cycles the food goes through, etc. (see Appendix for form used and an example).
4. **Walk-Through of the Facility.** While going through the facility with the manager, we focus on critical areas: food temperatures, food prep areas, and cooking areas. We'll see where and how the evaluated food is actually prepped, piecing together what we learned in the discussion with what we see. Our experience has been that people do not alter their work habits just because we are there. And if they're not cutting up the raw chicken when we happen to be there, we can still discuss it. Depending on what is seen, we may come back to see them prep the chicken in no

more time than would have been spent on a reinspection. We'll also note significant non-criticals observed during the walk-thru.

Along with the manager, we also engage employees in discussion and take advantage of the "teachable moment." If it becomes apparent someone is not well versed in a particular aspect of food safety, we have simple educational information sheets in a 3-ring binder that list the essential information for that system (see Appendix for Info Sheet examples). The 3-ring binder is given to each food service manager to serve as a reference and employee training manual. It's also the time to offer to return and teach an organized class or run a handwashing training session.

5. **Report the Results**. Ironically, we are returning more to handwritten reports (see Issue # 2 and Appendix for forms used) that are left with the operator before we leave. At their request, the report form serves mainly as a quick reference "to-do" list because of the one-on-one education focus of the inspection. The educational sheets discussed during the inspection are also referenced on the inspection form, serving as documentation (if enforcement is needed) that education was provided and the public health reasons were shared. The report form documents the critical system problems and actions taken which will be entered into our database.

Learning from a previous Crumbine Award winner, DuPage County, Illinois, we have consolidated this process for chain restaurants since the systems are the same (or should be) for the entire chain. We meet once with the owner, district managers, and store managers to discuss their systems and then follow-up with shorter onsite visits at each store. It has improved both efficiency and effectiveness. We quickly learned that the food safety commitment is established above the store manager level. Working with regional managers

and/or corporate headquarters on a routine basis (rather than only when there is a crisis) gets better results.

Once we established this process and became trained in the techniques, the entire process takes only slightly longer than a traditional inspection and reinspection of any "High Risk" category facility. We anticipate even less time will be needed per "routine" visit as communication with operators are enhanced, and we better understand the business and the systems in place. A shorter unannounced visit to directly observe food preparation during busy times can determine if the food safety systems are in place. We even anticipate a return to unannounced visits based on the day of the week or time of day food is being prepared. This time we will be welcome partners and not intruders.

Emergence of a Risk-Based Enforcement Process

Throughout the '70s and '80s, considerable time and training was spent on enforcement activities, such as violation notices, administrative hearings, board reviews and license suspensions. We saw enforcement as our primary role and considered it so important that each sanitarian was officially deputized by the sheriff, and given a badge and citation book. We narrowly viewed every inspection only as the first step of a potential enforcement action.

But we began to question the effectiveness of this approach. A time study revealed that for the amount of time spent on one enforcement case, almost 10 routine inspections could have been done. Another concern was that enforcement cases often dealt mainly with non-critical conditions. We knew there must be a "smarter" approach.

It wasn't until our experience with scheduled system inspections that it became clearer how to improve our enforcement procedures. We could finally appreciate the

approach described by Sanford M. Brown (Journal of Environmental Health, 1988). He places enforcement within the context of prevention, describing it as:

> *"a results-oriented style that is flexible, that emphasizes responsiveness, forbearance, and the communication of information. Conciliatory health professionals utilize discretion in the process of education, consultation, and negotiation to obtain compliance from violators and potential violators."*

We've embraced this philosophy. We believe no food service operator wants to make customers sick. Given information instead of orders, most operators (the "90+%") will improve their food handling procedures. Traditional enforcement is then left for those who can't or won't change, or when an imminent health risk is present.

In 1999, we formed an enforcement committee consisting of the Director and senior staff to: review our techniques, update our procedures, and review potential cases. Our procedures include fees for 2nd reinspections, administrative reviews, and referrals to the Board or County Attorney for action. The most significant addition has been adding an unannounced reinspection for establishments that have not demonstrated improvements in their systems. The reinspection is done at a time when major food prep is occurring (see Appendix for enforcement worksheet and flow chart). This approach has allowed us to evaluate the extent to which improvements in food safety systems are actually implemented.

Our documentation for enforcement cases still begins with the inspection, but the prevention focus of the approach provides many more tools to achieve compliance than just "orders to correct violations". As an enforcement case is pursued, communications with the licensee continue to emphasize the public health concern of the conditions, but also the licensee's legal responsibilities, and the enforcement options that may be pursued - each step building a stronger case.

We think that placing enforcement within this context of prevention, increases the likelihood that long-term improvements in food safety will take place (for the "90+%"), while reserving enforcement for when it's truly warranted.

Issue/Challenge 2: Improving Communication

Communication was not an important part of our regulatory model. This may have led food service operators to believe we had nothing of value to communicate to them.

OUTCOME: Communication has become the most important part of our work in education and in building partnerships. The content of our communication focuses on practices and procedures that increase foodborne illness risk. We use a non-authoritarian, non-threatening approach that emphasizes consultation, collaboration, and education to achieve long-term changes.

How did we reach our outcome?

We focused on two areas: 1) improving the communication with operators so they value our service and recognize their food safety responsibilities, and 2) enhancing our educational communication and outreach.

1. Improving Communication with Operators

Before our communication with industry was risk based, it focused on compliance with the food code. Communication was basically a one way street. Sanitarians inspected and issued orders for correction, and operators were expected to comply. The unannounced inspection was the only tool available to verify compliance with the code, instilling the "catch-'em-doing-things-wrong" attitude. This inspection style immediately created barriers between the operator and inspector (even if not intentionally). The operator was in an inferior position, and was "forced" to postpone whatever they were doing, no matter how important. Because inspections focused on what was visible at the time of the inspection, the communication that did take place was limited to the immediately observable conditions.

Little information was obtained about their operation or food preparation procedures. Using this communication style it was impossible to develop trust, much less develop a partnership.

We made several attempts to improve communication with operators over the years:

A. <u>Through Partnerships</u>:

From the following experiences, we began to realize partnerships can't be one-way or forced. They are built one-on-one with each operator beginning at the inspection. If you have a service that is of value, and treat operators with respect, partnership begins to build.

- **<u>Quality Assurance Council.</u>**. As early as 1988, Environmental Health partnered with a food safety consultant and area restaurants to form a Quality Assurance Council. The Council's charge was to improve the inspection process by making it more risk-based. However, improvement did not happen and the Council faded. Code compliance inspections failed to support the experiment. The Council was onto something, but the follow through wasn't there.
- **<u>Round Table Meetings</u>**. At these "round table" meetings we invited operators to ask questions and discuss their concerns about the food program. Although insightful for us, and hopefully informative for attendees, turnout was poor. The only time more than five people attended was when the agenda hinted at a proposed large increase in their license fees. We wanted to be seen as a resource, but most operators didn't see our "product" as having value.
- **<u>Rochester Lodging and Hospitality Association (RLHA)</u>**. In 1995, the RLHA asked our department to provide the following: 1) limit of one inspector to conduct inspections for any lodging, pool, and food service located in the same building, 2)

streamline the inspection reports, and 3) re-organize the inspection reports relative to risk. As we worked to address these requests, we became more aware of the operator's needs as a primary customer.

B. Through the Inspection Process:

- **The Systems Review Process** The scheduled, systems review inspection was the key to removing communication barriers built over many years. When asked in our 1998-99 operator survey: "What part of the scheduled inspection was the most helpful to you and why?," one operator reported:

> *"All parts were helpful. My kitchen staff learned more from our last scheduled inspection than all other inspections combined! The sit down portion allows me to understand reasons for things and the ability to ask questions. During the staff portion of the visit my employees were able to do the same. After the visit they all said "wow" that was sure informative!"*

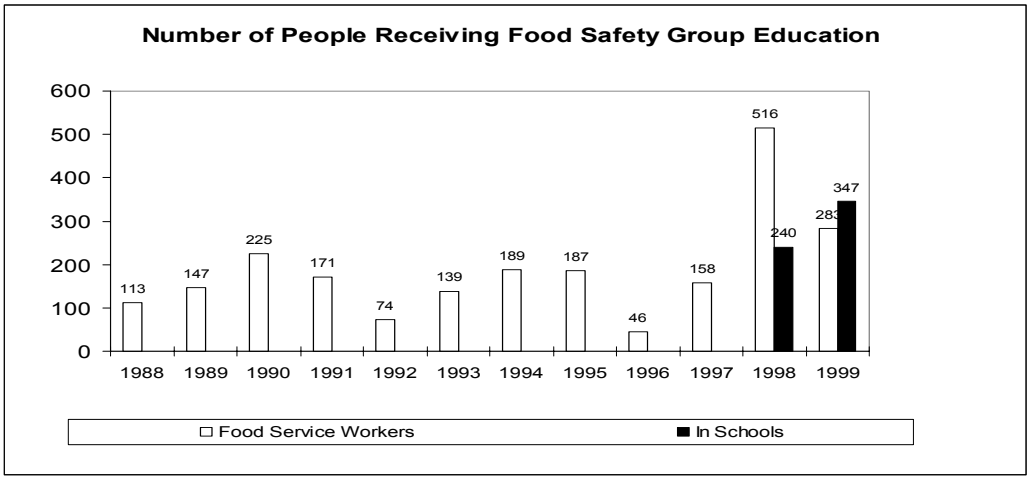
(The overwhelming majority of respondents also made similar responses - see Appendix for complete 1998-99 operator survey responses, and 1999 "success stories").

In the systems review inspection our principal form of communication is verbal, which is the opportunity to develop a mutual understanding. This is supplemented with printed educational materials, given to the manager in a 3-ring binder, which are also referenced on our report form (see appendix).

- **Onsite Training as Part of the Inspection**

Another outcome of improved communication has been an increase in onsite employee training services. Even certified food managers have told us they need reinforcement in training their employees because of high employee turnover. As a result, each systems review inspection includes on-site employee training or a

separate training session is scheduled (see Appendix for list of educational materials/resources). There is no charge for this training and we have received a tremendous response (see graph below).



Training focuses on the foodborne disease factors specific to the operation and usually includes a "Glo Germ" handwashing demonstration. Training in their facility is more convenient and is scheduled during staff meetings, evenings, and weekends.

2. Enhancing our Educational Communications Through:

A. Food Safety Classes: OCPHS has a long tradition of providing food safety education. Starting in the late 1970s, we taught two, 2-day food manager certification courses each year which focused on HACCP principles. In these voluntary courses, we reviewed recipes during class and encouraged participants to write a procedures manual incorporating what they learned, including food times and temperatures at each step in their recipes. License fee discounts were offered to those who successfully completed the course ($25 discount) and completed their policy and procedure manual (additional $25 discount). Unfortunately, we didn't have an

inspection system that reinforced what they learned. Reviewing and discussing their procedures wasn't part of the inspection process!

Now all food manager certification courses are provided to operators by the private sector. We encourage and promote these private efforts by offering our mailing list/labels to the course organizer and advertise the course in our newsletter and during inspections.

B. Newsletters and News Releases:

Since 1989, the newsletter "**Food Talk,**" complete with our own inserts of local food safety-related events has been sent to all our licensed food services on a quarterly basis. We've expanded our mailing to include grocery stores, nursing homes, hospitals, group homes, and other food facilities we don't license. Operators tell us they do read the newsletter and find it a valuable resource (See Appendix).

Other time sensitive notices are mailed to all licensed food service operations alerting them to the increased risk posed by foodborne diseases such as hepatitis A and Norwalk-like viruses that appear to be "moving through" the community. Media news releases are issued as needed (see Appendix).

C. Community Outreach:

In September 1997, we started participating annually in National Food Safety Education Month. Annually since then, a news release is issued promoting food safety in the community. With the help of a committee composed of one of our Sanitarians, a University Extension Specialist, Public Health Nurses and a Health Educator, we developed food safety information that was:

- printed in weekly feature articles in the Rochester Post Bulletin newspaper;

- the focus of an article for the Advocate, a community action newsletter;
- broadcast on local radio stations through staff interviews and "Fight Bac" public service announcements;
- displayed at area grocery stores; and
- presented to groups and high school Family and Consumer Science students.

In addition, we also regularly teach Community Education courses which are targeted at day care providers, special event organizers, and restaurant employees, as well as people who cook at home.

Issue/Challenge 3: Measuring Outcomes

We collected data that measured what we did, not what impact our work had on food safety. It was limited to the number of inspections completed and scores based on the 44 item inspection sheet.

OUTCOME: The Systems Review inspection process allows for a better assessment of the risk factors. This created an opportunity to develop our forms, procedures and database to measure the frequency of each of the foodborne disease factors over time. Quantitative data show an increase in the number of risk factors identified, which is a more accurate reflection of what's taking place. Qualitative data from 2 separate industry surveys reflect changes in food safety practices and a positive response to the system inspection approach.

How did we reach our outcome?

Our first attempt to improve our program measurement was to discontinue issuing inspection scores and begin categorizing and counting the number of "Critical" and "Non-critical" conditions observed during inspections. However, counts of critical items didn't tell us which of the foodborne disease factors were the problem. Our challenge was to convert a tracking system based on a "snapshot" of observations to a big picture assessment based on discussions and observations. Because we were asking many more questions, in a non-threatening way, we were being told about many more "systems out of control" than we ever

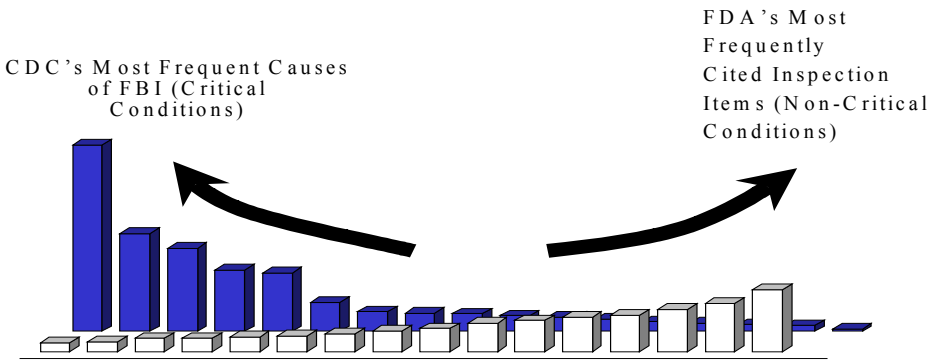
would have suspected or observed. In addition, Minnesota adopted a new food code in September, 1998 based on the FDA model code. This added additional specific critical conditions within each system that needed to be tracked.

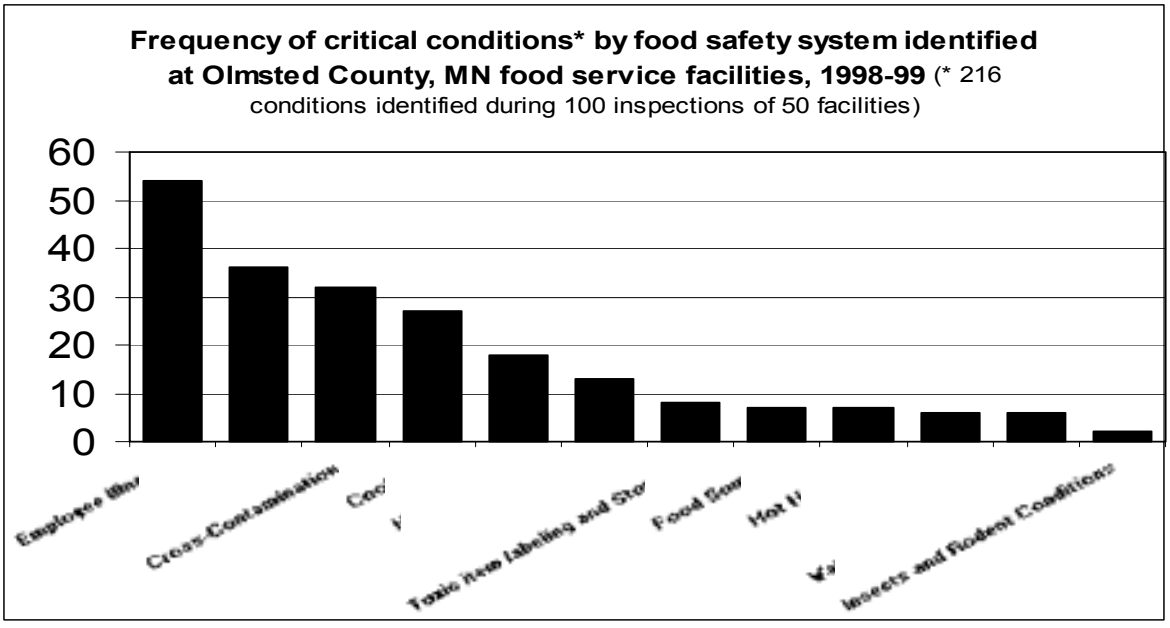
To help manage our ever-changing data needs, we applied for, and received an Olmsted County Research and Development grant in 1999 to build a new database called EHDOC (phase 1 to be completed in April, 2000). Coordinated through the Minnesota Counties Computer Consortium (MCCC), this database will provide flexibility to measure trends both at the systems level and for specific risk factors (see Appendix for more information on EHDOC).

Results To Date from Systems Review Inspections

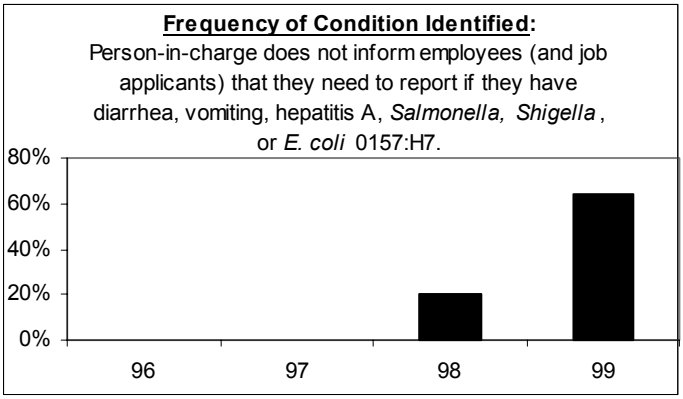
Quantitative: Because our approach focuses on learning the business' food safety systems, we are uncovering more of the disease risk factor "iceberg." A statistically random sample of inspection data from high risk facilities support the shift from non-criticals to a more thorough assessment of the known foodborne disease risk factors (the food safety systems).

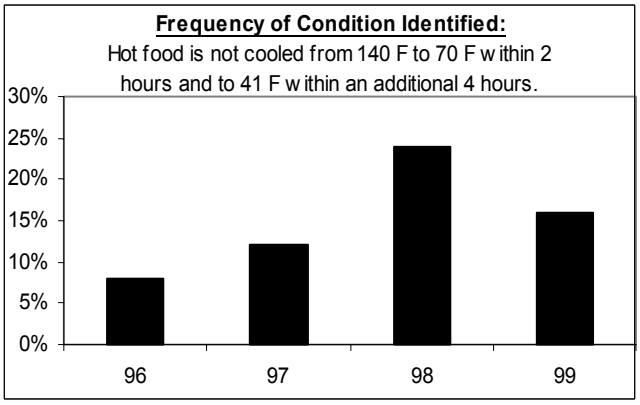
A Comparison of the Most Frequent Causes of Foodborne Illness (FBI) vs. Most Frequently Cited Conditions During Inspections

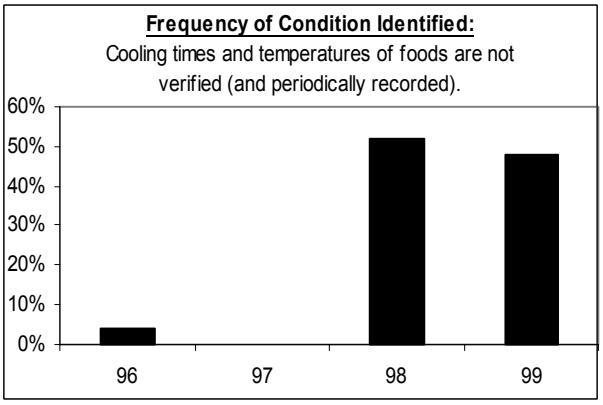


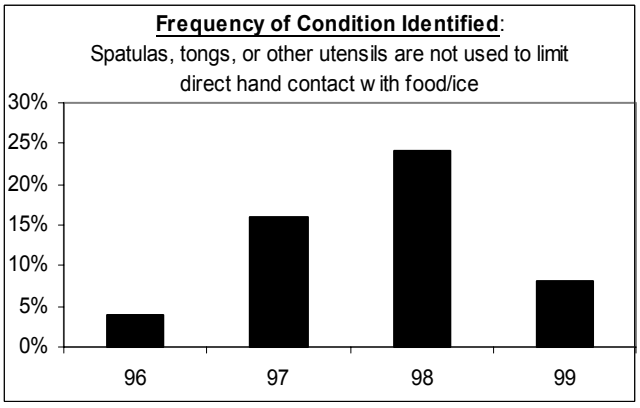


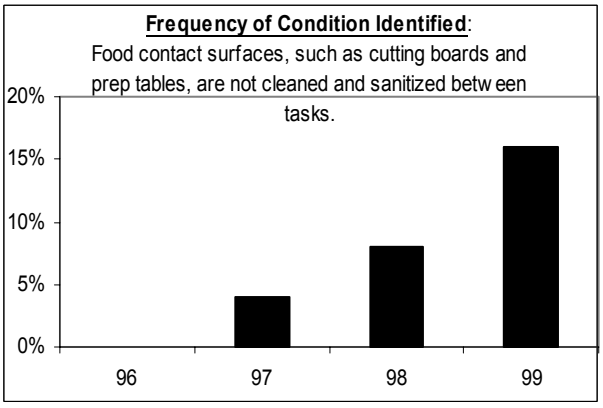
This more sensitive approach provides an opportunity to track outcomes at both the system level (above) and within each system. The graphs below are specific risk factors within several food safety systems. They further highlight the shift in focus and provide a baseline for future trend comparisons.



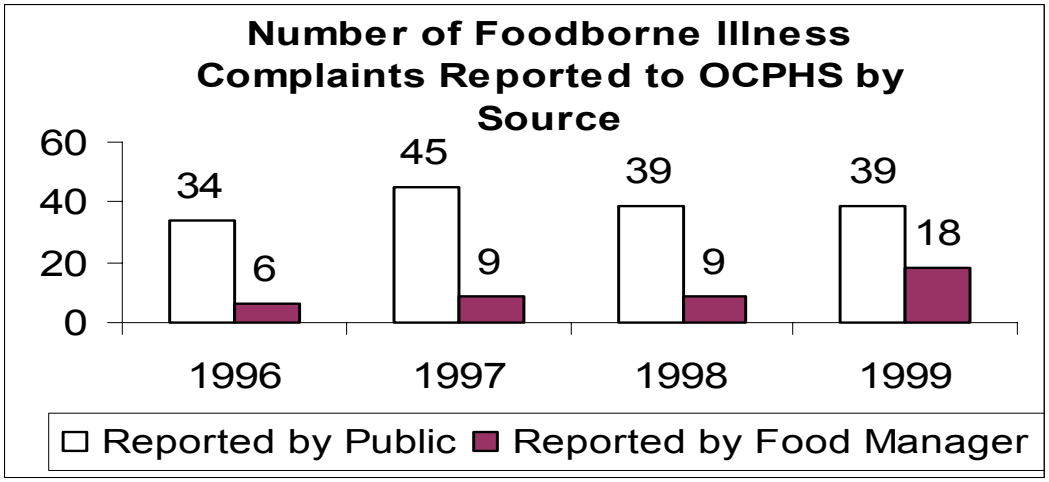








In addition, we have seen an increase in the number of operators who call us when they receive a complaint of illness.



Qualitative: The qualitative data gathered within the past three years, from 2 separate operator surveys, has been extremely valuable to help us assess our effectiveness (see Appendix for sample surveys and compilation of results). Have we seen changes in food handling practices as a result of this approach? Here is a sample of specific changes (that loose some of their significance when quantified) made by operators in how they prepare food (also see the comments made on the 1998-99 operator survey in Appendix),:

- Using tongs instead of hands for handling raw chicken at the cookline,
- Cooking soup for the day and then discarding, rather than advance prepping for several days (we were told it actually cost less to do it this way too),
- Dedicating an area of a room for raw chicken prep instead of prepping the chicken in several areas,
- Cooking chicken to 165ºF instead of the 140ºF the chef thought was sufficient,

- *"We started the use of the food meat thermometer, started the procedure of keeping temperature logs and food flow charts. This will help make staff more aware of food temps/proper cooking."* (1998-99 Operator Survey),

Our most recent survey shows operators are overwhelmingly positive about the change. They are not only requesting the scheduled inspections to continue, but in several cases explained in length why and what they've learned. We're planning to update the survey this year to focus our questions on ways to further improve our service and eventually to gain further insight into overcoming the barriers to long-term behavior change – ultimately for better public health protection.

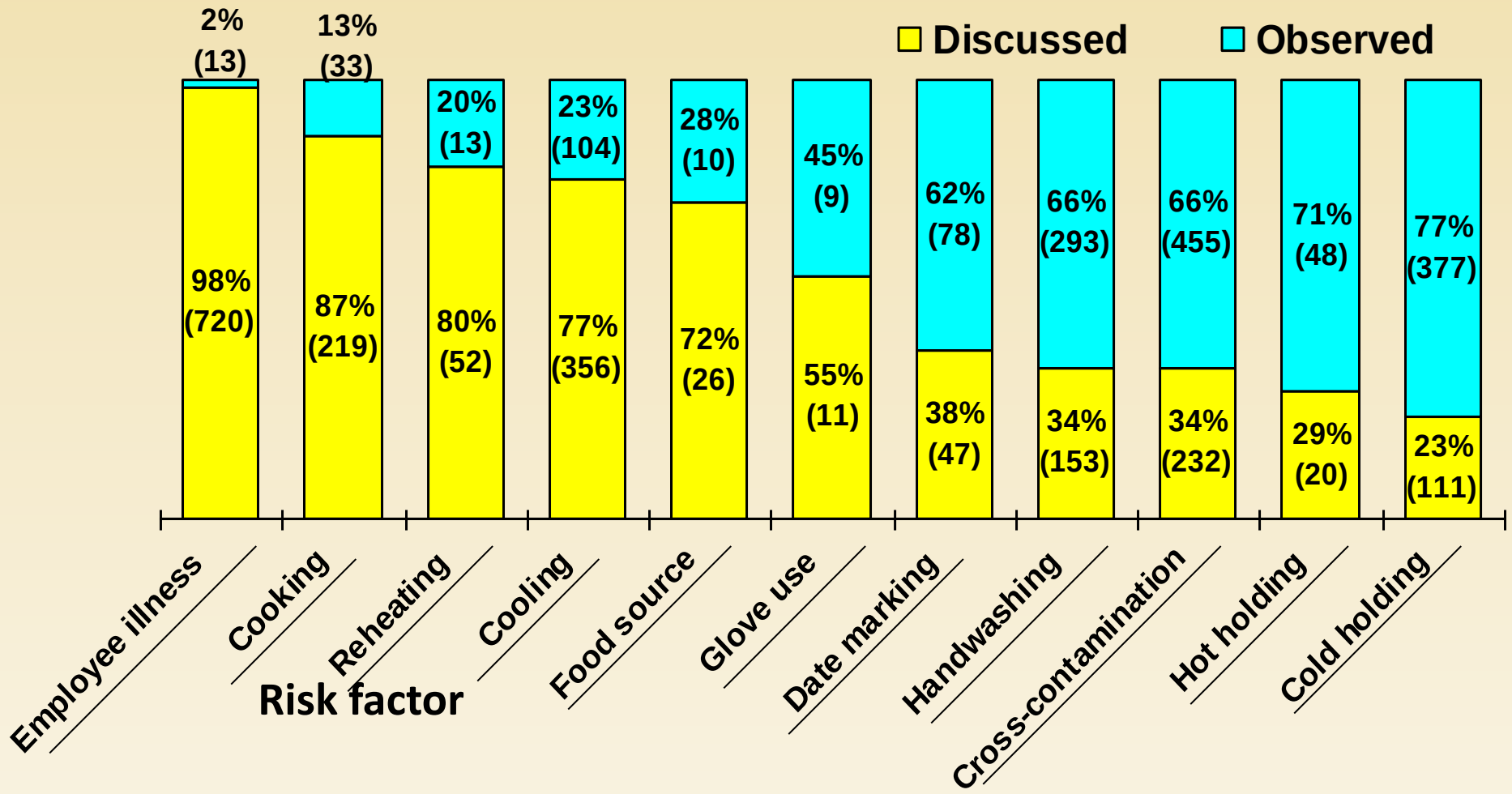
Part IV: Conclusion (or 2000 and Beyond)

With the help of many partners, we feel we have merged the epidemiology of foodborne disease with a common-sense inspection approach. Where the traditional inspection put operators on the defensive, this new approach invites informed cooperation with clearly defined goals and avenues for positive change.

Industry graciously invited us to use their businesses as a "laboratory" during the development process. They were patient with us as we experimented with teaching styles and inspection reports. We've learned a lot from them and look forward to it continuing.

With renewed enthusiasm and a greater appreciation of our customer's needs, we will continue to search outside the "box" to improve food safety in Olmsted County. Completion of our database, developing a Food Safety Advisory Council, expanding the systems review concepts and training into the plan review process and other environmental health programs – are all goals for 2000 and beyond. This transition we're going through is a process of continuous improvements; we're on a "path to self discovery."

Percentage of Risk Factors Identified by Discussion vs. Observation 2001-2004 Olmsted County (N=1142 assessments)



Conference for Food Protection
2016 Issue Form

Issue: 2016 II-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:

Report - Food Protection Manager Certification Committee (FPMCC)

Issue you would like the Conference to consider:

Please acknowledge the final report and thank the 2014-2016 Food Protection Manager Certification Committee (FPMCC) members for their effort in addressing the charges from the 2014 Biennial Meeting of the Conference for Food Protection.

Public Health Significance:

Food establishments have fewer critical risk factors according to the CDC as stated in the endorsement letter to the Conference for Food Protection (dated April 5, 2006, and referenced on the Conference website) when food establishments employ managers who have a Food Protection Manager Certification in accordance with the Conference for Food Protection's Standards.

Recommended Solution: The Conference recommends...:

acknowledging the Food Protection Manager Certification Committee (FPMCC) final report with attachments, and extending thanks to the Committee members for their work.

The Conference further recommends that the FPMCC continue its work on unfinished Issues from the 2014 Biennial Meeting, including:

1. Issue II-012 - Continue work with the CFP Executive Board and the American National Standards Institute (ANSI)-CFP Accreditation Committee (ACAC) to maintain the Standards for Accreditation of Food Protection Manager Certification Programs in an up-to-date format; including, but not limited to, recommending language for items that could be made less prescriptive without a negative effect on security.

2. Issue II-015 - Determining the process and requirements for potential acceptance of the International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) 17024-2012 for food protection manager certification as an additional option to and without impact on the existing CFP Standards for Accreditation of Food Protection

Manger Certification Programs, with the input of standards development expertise from American National Standards Institute (ANSI).

3. Report back its findings and recommendations to the Executive Board and the 2018 Biennial Meeting of the Conference for Food Protection.

Submitter Information:

Name:	Jeff Hawley, Chair
Organization:	Food Protection Manager Certification Committee
Address:	Harris Teeter, LLC701 Crestdale Rd
City/State/Zip:	Matthews, NC 28105
Telephone:	704-844-3098
E-mail:	jhawley@harristeeter.com

Content Documents:

- "Food Protection Manager Certification Committee (FPMCC) Roster"
- "Report: Food Protection Manager Certification Committee"
- "Standards for Accreditation of Food Protection Mgr Certification Programs"

Supporting Attachments:

- "Security Evaluation Workgroup Baseline & Summative Self-Report Findings"
- "CFP-ISO Standards Comparison Equivalency Report"

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

Committee Name: Food Protection Manager Certification Committee

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Anderson	Hugh	Alternate	Certification Provider	Prometric	Baltimore	MD	(443) 455-6011	hugh.anderson@prometric.com
Bagwell	Cynthia	Voting Member	Food Service Industry	Taco Bell Corp/Yum Brands	Irvine	CA	(949) 863-3834	cbagwell@tacobell.com
Brainerd, Jr	Dana	Voting Member	Retail Food Industry	CVS/Caremark	Cumberland	RI	(401) 770-6194	dana.brainerd@cvscaremark.com
Carotenuto	Tony	Voting Member	Federal Regulator	Navy and Marine Corps Public Health Center	Portsmouth	VA	(757) 953-0712	anthony.carotenuto@med.navy.mil
Chapman	Bryan	Voting Member	Food Industry Support-Training	StateFoodSafety.com	Orem	UT	(801) 805-1872	bchapman@abovetraining.com
Chong	Korey	Alternate	Food Industry Support-Training	Premier Food Safety	Fullerton	CA	(714) 451-0075	korey@premierfoodsafety.com
Coleman	Gary	Voting Member	Food Industry Support	Consultant (UL-Retired)	Holden Beach	NC	(619) 627-5322	garycoleman@nc.rr.com
Connell	Kevin	Alternate	Retail Food Industry	Wawa	Wawa	PA	(610) 505-4964	kevin.c.connell@wawa.com
Corchado	Liz	Alternate	Certification Provider	Environmental Health Testing (National Registry)	Orlando	FL	(800) 446-0257	lcorchado@nrfsp.com
Crownover	David	Alternate	Certification Provider	National Restaurant Association Solutions	Chicago	IL	(312) 715-5396	dcrownover@restaurant.org
Douglas	Craig	Voting Member	Certification Provider	360training.com dba Learn2Serve.com	Austin	TX	(512) 539-2754	craig.douglas@360training.com
Dunleavy	Sean	Voting Member	State Regulator	Michigan Department of Agriculture	Lansing	MI	(517) 243-8895	dunleavys@michigan.gov
Gaither	Marlene	Voting Member	Local Regulator	Coconino County (AZ) Health Department	Flagstaff	AZ	(928) 679-8761	mgaither@coconino.az.gov
Guzzle	Patrick	Voting Member	State Regulator	Idaho Department of Health and Welfare	Boise	ID	(208) 334-5936	plguzzle@gmail.com
Halbrook	Courtney	Voting Member	Food Service Industry	Brinker International	Dallas	TX	(972) 770-1291	courtney.halbrook@brinker.com
Hancock	Roger	ACAC Representative	ACAC	Recallinfolink	Boise	ID	(208) 284-1508	roger.hancock@recallinfolink.com

Committee Name: Food Protection Manager Certification Committee

Hawley	Jeff	Chair	Retail Food Industry	Harris Teeter, LLC	Matthews	NC	(704)-844-3098	jhawley@harristeeter.com
Hollenbeck	Christine	Vice Chair	Regulatory	National Environmental Health Association	Denver	CO	(303) 756-9090	chollenbeck@ymail.com
Jackson	Keith	Voting Member	Vending and Distribution Food Industry	Performance Food Group	Richmond	VA	(804) 484-7975	keithjackson@pfgc.com
Jensen	Joyce	ACAC Representative	ACAC	Lincoln-Lancaster Co. Health Dept	Lincoln	NE	(402) 441-8033	jjensen@lincoln.ne.gov
Kender	Linda	Voting Member	Academia	Johnson & Wales University CCA	Providence	RI	(401) 598-1278	lkender@jwu.edu
Krishna	Vijay	ANSI Representative	ANSI	American National Standards Institute	Washington	DC	(202) 331-3614	vkrishna@ansi.org
Lang	Jeff	Voting Member	Local Regulator	Lane County Environmental Health	Eugene	OR	(541) 682-3636	jeffrey.lang@co.lane.or.us
Louden	Kathy	Voting Member	Local Regulator	City of Minneapolis Environmental Health	Minneapolis	MN	(612) 673-3869	kathy.louden@minneapolismn.gov
Luebkemann	Geoff	Voting Member	Food Service Industry	Florida Restaurant and Lodging Associaton	Tallahassee	FL	(850) 224-2250	gluebkemann@frla.org
Lynch	Lawrence J.	Voting Member	Certification Provider	National Registry of Food Safety Professionals	Orlando	FL	(800) 446-0257	llynch@nrfsp.com
McMillion	Ryan	Voting Member	Certification Provider	Prometric	Baltimore	MD	(443) 455-6244	ryan.mcmillion@prometric.com
Neal	Jay	Voting Member	Academia	University of Houston	Houston	TX	(713) 743-2496	jneal@central.uh.edu
Paster	Tara	Voting Member	Food Industry Support-Training	Paster Training, Inc.	Gilbertsville	PA	(610) 970-1776	tara.paster@pastertraining.com
Piche	Kathleen	Voting Member	Certification Provider	National Restaurant Association	Chicago	IL	(312) 261-5348	kpiche@restaurant.org
Pilonetti	Therese	Voting Member	State Regulator	Colorado Dept of Public Health & Environment	Denver	CO	(303) 902-4372	therese.pilonetti@state.co.us
Prouse	Julie	Alternate	Academia	Texas AgriLife Extension Service	College Station	TX	(979) 458-2025	jprouse@tamu.edu

Committee Name: Food Protection Manager Certification Committee

Quam	Susan	Voting Member	Food Service Industry	Wisconsin Restaurant Association	Madison	WI	(608) 270-9950	squam@wirestaurant.org
Radke	Vince	Advisor/Consultant	CDC	Centers for Disease Control	Atlanta	GA	(770) 488-4136	vradke@cdc.gov
Roughan	George	Voting Member	Food Industry Support-Training	TAP Series LLC	Thousand Oaks	CA	(805) 217-8605	gr@tapseries.com
Sarrocco-Smith	Davene	Voting Member	Local Regulator	Lake County General Health District	Painesville	OH	(440) 350-2543	dsarroccosmith@lcghd.org
Scott	Ken	Voting Member	Food Service Industry	Bojangles' Restaurants, Inc.	Charlotte	NC	(704) 527-2675	kscott@bojangles.com
Solter	Mike	Alternate	State Regulator	Alaska Dept of Environmental Conservation	Anchorage	AK	(907) 269-7629	michael.solter@alaska.gov
Steck	David	Alternate	Food Industry Support-Training	Serve It Up Safe!	Tampa	FL	(813) 781-8884	dave@serveitupsafe.com
Trevino	Tom	Alternate	Local Regulator	Salt Lake County Health Department	Murray	UT	(385) 468-3821	TTrevino@slco.org
Tryba	Casimir M.	Voting Member	Retail Food Industry	Big Y Foods, Inc.	Springfield	MA	(413) 504-4450	tryba@bigy.com
Williams	Laurie	Advisor/Consultant	FDA/CFSAN	FDA/CFSAN Office of Food Safety	College Park	MD	(240) 402-2938	Laurie.Williams@fda.hhs.gov
Wood	Sharon	Voting Member	Retail Food Industry	HEB Grocery Company	San Antonio	TX	(210) 938-6511	wood.sharon@heb.com

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: Food Protection Manager Certification Committee (FPMCC)

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Executive Board

DATE OF REPORT: January 30, 2016

SUBMITTED BY: Jeff Hawley, Chair

COMMITTEE CHARGE(s):

Issue: 2014 II-012

1. Continue working with the CFP Executive Board and the American National Standards Institute (ANSI)-CFP Accreditation Committee (ACAC) to maintain the *Standards for Accreditation of Food Protection Manager Certification Programs* in an up-to-date format.

2. Evaluate the results of the exam security evaluation process and Standards revisions approved by the 2012 CFP Biennial Meeting to ensure that they are resulting in substantial improvement of exam security.

3. Report back to the Executive Board and the 2016 Biennial Meeting of the Conference for Food Protection.

Issue: 2014 II-015

The Food Protection Manager Certification Committee (FPMCC) determine the process and requirements for potential acceptance of the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17024-2012 for food protection manager certification as an additional option to and without impact on the existing CFP Standards for Accreditation of Food Protection Manger Certification Programs and report back its findings at the 2016 Biennial Meeting.

Constitutional Charge: Article XV, Section 6

The Food Protection Manager Certification Committee shall report to the Board. The Food Protection Manager Certification Committee shall work with the accreditation organization for food protection manager certification programs to:

- ***Subsection 1.*** Establish and refine policies and standards to which certifiers must conform in order for them to be accredited;
- ***Subsection 2.*** Provide Conference input into the development of accreditation standards for certifying organizations specific to food protection manager certification programs;
- ***Subsection 3.*** Develop strategies for enhancing equivalence among food protection manager certificates issued by certifiers; and
- ***Subsection 4.*** Promote universal acceptance of certificates issued by accredited certifiers.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. **Progress on Overall Committee Activities:**

A. The Food Protection Manager Certification Committee (FPMCC) had face-to-face meetings October 15-16, 2014 in Kansas City, KS; April 1-2, 2015 in Milwaukee, WS; and October 21-22, 2015 in Dallas, TX. In addition, the Committee plans to meet April 15, 2016, prior to the 2016 biennial meeting. The Committee and workgroups had additional conference calls throughout the 2-year period.

B. The FPMCC formed 6 workgroups to address charges from the 2014 biennial meeting and conduct business of the Committee. These are the workgroups and their chairs:

1. Standards – Kate Piche (Certification Provider)
2. Standards Comparison – Christine Hollenbeck (Regulatory)
3. Bylaws – Sharon Wood (Retail Industry)
4. Logistics – Geoff Luebkemann (Food Service Industry)
5. Communications – George Roughan (Training Provider)
6. Security Evaluation – Bryan Chapman (Training Provider)

C. Progress on Issue #: 2014 II-012(1): Continue working with the CFP Executive Board and the American National Standards Institute (ANSI)-CFP Accreditation Committee (ACAC) to maintain the Standards for Accreditation of Food Protection Manager Certification Programs in an up-to-date format.

The FPMCC Standards Workgroup is chaired by Kate Piche. This workgroup recommended editorial revisions to the CFP Standards. This included punctuation, italics, capitalization, and other non-substantive changes (See Content Attachment 1).

The Standards Workgroup was asked by Chair, Jeff Hawley and the Committee to review the Standards, and identify sections that can be made less prescriptive, and determine the security impact (positive, negative, or unknown) for each. The workgroup considered a lengthy list of items that could be considered as too specific, prescriptive, or otherwise lacking utility for effectiveness of the CFP Standards. The workgroup has developed a list of such items, and will continue this work during the next biennium.

D. Progress on Issue #: 2014 II-012(2): Evaluate the results of the exam security evaluation process and Standards revisions approved by the 2012 CFP Biennial Meeting to ensure that they are resulting in substantial improvement of exam security.

To evaluate the data and determine if the new security standards are effective, Dr. Donald Ford (ANSI) compared security data provided by certification providers before the new standards were in place, and data after the new security standards were implemented following the 2012 Biennial Meeting. Security data from July 1, 2009-June 30, 2010 was compared to data from July 1, 2013-June 30, 2014 (See Supporting Attachment 1). This is a summary of Dr. Ford's findings:

Goal 1: Enforce Proctor/Administrator Disciplinary Actions.
The percentage of test administrators/proctors who committed violations decreased from 2009-10 to 2013-14 from 5.72% to 4.4%. The most probable reason for

reduction in violations was that all test administrators/proctors were retrained by the certification providers. Violations included:

a. Failure to return exams/answer sheets on time
b. Failure to return all materials, or to sign/seal return envelopes
c. Failure to use a traceable shipping carrier
d. Failure to follow proctor guidelines, including not being present the entire time or allowing test-takers to self-proctor
e. Suspected/confirmed cheating or colluding with test takers

Goal 2: Reduce Exam Packaging and Shipping Irregularities (lost exams/answer sheets).
There was an increase in reported lost materials from 2009 to 2013: 0.01% to 0.02%. Percentage of lost exams/answer sheets has remained steady at 0.02% over the last 2 years.
Note: We may have reached a theoretical limit in preventing lost exams/answer sheets. Current safeguards are effective in the majority of cases, but zero losses appear to be unattainable under the current system of testing.

Goal 3: Reduce Test Site Irregularities.
Test Administration problems show a big increase: less than 0.5% to 3.19%, while test site problems remain small at 0.01%. The increase in test administration irregularities was probably due to better detection and reporting rather than an actual increase in incidents. Greater focus on test administration and test site irregularities is helping to uncover previously unreported problems.

Most Frequent Reasons for Test Site Irregularities in 2014

a. Candidate demographic changes (wrong name or other personal information at registration)
b. Exam was given in a restaurant during service or otherwise interrupted by outside noise
c. Examinees were allowed to sit too close together
d. Technical issue with online testing site hardware

Most Frequent Reasons for Test Administration Irregularities

a. Failure to follow shipping policies for returning materials on time
b. Failure to properly return all materials via traceable carrier
c. Failure to follow policies and procedures for proctoring – partially unproctored or self-proctored exams
d. Cheating or collusion: candidates were allowed to talk in a foreign language during the exam, proctor colluded in cheating, candidates shared notes during exam

Goal 4: Reduce Cheating and Test Administration Irregularities.
Confirmed/suspected cases of cheating went from 10 in 2009-10, to 16 in 2012-13, to 13 in 2013-14. Better detection, reporting and enforcement resulted in more confirmed cases initially. Percentage of test administration violations decreased from 0.24% in 2009-10 to 0.14% in 2013-14. This decrease is a result of better detection and enforcement.

Most Frequent Corrective Actions Taken To Combat Cheating

a. Use multiple versions of the exam at each administration
b. Revoke proctor privileges for collusion
c. Enforce spacing and other environmental guidelines
d. Use biometrics to verify examinee identity
e. Require examinees to retest when cheating is suspected
f. Adopt better exam forensic analysis methods
g. Increase exam session audits

Goal 5: Improve Test Quality Assurance (QA)

2009-10: Only 1 of 3 providers had a QA system installed, and it was incomplete.
2012-13: All 4 providers had QA system in place, but still implementing some features.
2013-14: QA system fully functional for all providers.

QA elements include:

a. Document control
b. Internal audit
c. Management review
d. Exam security plan
e. External audit/certification

E. **Progress on Security Improvements.** After implementing the security measures from the Standards adopted in 2012, security of the test administration process has improved, and the number of breaches has dramatically decreased. Much progress has been made, but there is still room for improvement. More can be done to standardize test administration and minimum standards for test sites. Recommendations for best practices by certification providers have been implemented, and have led to measurable improvements in test administration security. Certification providers will continue with their efforts to make improvements in the following areas:

1) Proctors/Administrators:
   a) Increase screening, selection and training standards
   b) Continue to vigorously apply disciplinary actions against offenders

2) Shipping Irregularities:
   a) Use traceable carriers only, especially those with high reputation for security and reliability
   b) Continue to enforce rules for shipping

3) Test Sites/Administration:
   a) Standardize test site requirements across all providers
   b) Share best practices for administration

4) Test Cheating:
   a) Share best practices for data forensics and cheating detection
   b) Encourage test-takers to report cheating (whistleblower hotline)

5) QA System:

a) Fully implement all features for all providers
b) Use it as preventive mechanism and early warning system

F. Issue #: 2014 II-015: The Food Protection Manager Certification Committee (FPMCC) determine the process and requirements for potential acceptance of the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17024-2012 for food protection manager certification as an additional option to and without impact on the existing CFP Standards for Accreditation of Food Protection Manger Certification Programs and report back its findings at the 2016 Biennial Meeting.

The Standards Comparison Workgroup did a line by line comparison of the CFP Standards and ISO 17024 to determine areas of "equivalencies", and also identified items that would need further review to determine equivalency of the two standards (See Supporting Attachment 2). There was much discussion concerning unintended consequences, such as operational impacts and additional costs of implementation that must be considered in the comparison of CFP Standards and ISO 17024.

After much discussion consensus could not be reached, and the Committee made the decision to request a continuation of Charge #: 2014 II-015 to the next biennium. The Committee also realized that additional expertise in standards review and evaluation was necessary to help create a foundation for understanding and comparing CFP Standards and ISO 17024. Dr. Vijay Krishna (ANSI) offered to conduct a workshop on standards writing methodology and verifiability at the first meeting of the FPMCC in the 2016-18 biennium.

The FPMCC reports it has conducted an extensive but incomplete study comparing current CFP Manager Certification Standards and ISO 17024, and therefore recommends that Charge 2014 II-015 be continued for the 2016-18 biennium to permit completion of the comparison with the input of standards development expertise from ANSI, as such expertise will better enable the FPMCC to both resolve the comparison and provide support in ongoing improvement of the CFP Manager Certification Standards while completing work on Charge 2014 II-015.

Acknowledgements

The FPMCC would like to thank Big Y World Class Market, Florida Restaurant and Lodging Association, National Registry of Food Safety Professionals, National Restaurant Association, Performance Food Group, State Food Safety, and Wisconsin Restaurant Association for their sponsorship of our meetings.

The Chair would also like to recognize and thank Vice-Chair Christine Hollenbeck, and workgroup chairs Kate Piche, Sharon Wood, George Roughan, Christine Hollenbeck, Bryan Chapman and Geoff Luebkemann. They have been very diligent in fulfilling their responsibilities, and have enabled the committee to complete our assigned charges successfully.

And lastly, the Chair would like to recognize and thank the 2014-2016 FPMCC members, and the organizations/agencies they represent, which allowed them to participate on the Committee.

Without the commitment and support of individuals and their organizations/agencies we would not have been able to complete our assigned charges.

2. **Recommendations for consideration by Council:**

A. Thank the members of the 2014-2016 Food Protection Manager Certification Committee (FPMCC) for their hard work, and acknowledgement of this report.

B. Approve revisions to the Standards for Accreditation of Food Protection Manager Certification Programs (see Content Attachment 1)

C. That the following charges assigned to the Food Protection Manager Certification Committee (FPMCC) be continued for the 2016-18 biennium:
   a. Issue 2014 II-012: working with the CFP Executive Board and the American National Standards Institute (ANSI)-CFP Accreditation Committee (ACAC) to maintain the Standard for Accreditation of Food Protection Manager Certification Programs in an up-to-date format; including, but not limited to, recommending language for items that could be made less prescriptive without a negative effect on security.
   b. Charge 2014 II-015: to permit completion of the comparison of ISO/IEC 17024-2012 to CFP Standards for Accreditation of Food Protection Manger Certification Programs, with the input of standards development expertise from American National Standards Institute (ANSI). ANSI expertise will better enable the FPMCC to both resolve the comparison, and provide support in ongoing improvement of the CFP Manager Certification Standards, while completing work on Charge 2014 II-015.
   c. Report back findings and recommendations to the 2018 Biennial Meeting of the Conference for Food Protection.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

The FPMCC is submitting the following two Issues:

1. Report: Food Protection Manager Certification Committee (FPMCC)

2. FPMCC 2: Standards for Accreditation of Food Protection Manager Certification Programs - Revisions

Content Attachments:

1. Standards for Accreditation of Food Protection Manager Certification Programs (draft May 2015)

Supporting Attachments:

(Note: supporting attachments may not represent the views of the Conference for Food Protection)

1. Security Evaluation Workgroup Baseline & Summative Self-Report Findings 2013-14

2. CFP-ISO Standards Comparison Equivalency Report

COMMITTEE MEMBER ROSTER (attached):

Food Protection Manager Certification Committee Roster 2014-2016

Conference for Food Protection

Standards for Accreditation of Food Protection Manager Certification Programs

As Amended at the 2014 Biennial Meeting of the Conference for Food Protection

Preamble

The Conference for Food Protection, hereinafter referred to as the CFP, is an independent voluntary organization that has identified the essential components of a nationally recognized Food Protection Manager *Certification* Program and established a mechanism to determine if *certification organizations* meet these ~~standards~~ Standards. The CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs is intended for all *legal entities* that provide *certification* for this profession. The ~~standards~~ Standards have been developed after years of CFP's research into, and discussion about, Food Protection Manager *Certification* Programs.

All *certification organizations* attesting to the *competency* of Food Protection Managers, including *regulatory authorities* that administer and/or deliver *certification* programs, have a responsibility to the individuals desiring *certification*, to the employers of those individuals, and to the public. *Certification organizations* have as a primary purpose the evaluation of those individuals who wish to secure or maintain Food Protection Manager *Certification* in accordance with the criteria and ~~standards~~ Standards established through the CFP. *Certification organizations* issue *certificates* to individuals who meet the required level of *competency*.

The professionals involved in the credentialing process for *Certified Food Protection Managers* shall recognize that the justification for regulating entrance to the occupation of *Certified Food Protection Manager* is to:

- protect and promote food safety for the welfare of the public;
- ensure that the responsibility and liability for overseeing the protection of safety and welfare of the public lies with those governmental jurisdictions at the Federal, state and local levels having the power to set forth laws regulating entrance to and performance in this occupation;
- ensure that the rights of the public at large and of those members of the public who wish to enter this occupation shall be balanced in terms of fairness and due process in the form of a credentialing process for admitting qualified persons to perform in that occupation; and
- ensure that the *validity* of the credentialing process for *Certified Food Protection Manager* is dependent on unbiased application of all aspects of that process, requiring

careful determination of the competencies necessary to prevent foodborne illness, unbiased education and training for acquisition of those competencies, and fair assessment practices to ensure that individuals have achieved mastery of the competencies.

Therefore, professionals involved in the credentialing process for *Certified Food Protection Manager* accept responsibilities based on these considerations.

The CFP ~~standards~~ Standards are based on nationally recognized principles used by a variety of organizations providing *certification* programs for diverse professions and occupations. *Accreditation*, through the process recognized by CFP, indicates that the *certification organization* has been evaluated by a third party *accrediting organization* and found to meet or exceed all of the CFP's established ~~standards~~ Standards.

To earn *accreditation*, the *certification organization* shall meet the following CFP ~~standards~~ Standards and provide evidence of compliance through the documentation requested in the application. In addition, the *certification organization* shall agree to abide by *certification* policies and procedures which are specified by the CFP Food Protection Manager ~~Certification~~ *Certification* Committee, hereinafter referred to as the FPMC Committee, approved by the CFP, and implemented by the *accrediting organization*.

The *accrediting organization* shall verify and monitor continuing compliance with the CFP ~~standards~~ Standards through the entire *accreditation* period. The CFP FPMC Committee will work directly with the *accreditation organization* to enhance and maintain *certification* policies and procedures that meet the specific needs of Food Protection Managers while ensuring a valid, reliable and *legally defensible* evaluation of *certification* programs.

The American National Standards Institute (ANSI) was selected as the *accrediting organization* for the CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs and assumed its duties in January, 2003. The CFP FPMC Committee continues to work within the Conference structure to monitor the criteria and selection process for the organization serving as the accrediting body for Food Protection Manager *Certification* Programs.

The CFP strongly encourages regulatory authorities and other entities evaluating credentials for Food Protection Managers to recognize and endorse these ~~standards~~ Standards and the ~~accreditation~~ *accreditation* process. The CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs provides the framework for universal acceptance of individuals who have obtained their credentials from an *accredited certification program*. In the U.S Food and Drug Administration's Food Code, hereinafter referred to as the

FDA Food Code, Section 2-102.20 recognizes Food Protection Manager *certificate*s issued by an *accredited certification program* as one means of meeting the FDA Food Code's "Demonstration of Knowledge" requirement in Section 2-102.11.

Please note that words that appear in italics are defined terms.

Modifications and Improvements

The FPMC Committee followed the Conference directive to use the 1996 conference working document, Standards for Training, Testing and *Certification* of Food Protection Managers, in the development of ~~accreditation~~ accreditation standards. Extensive revision of this document was presented to CFP's 2012 Biennial Meeting of the Conference~~s~~ for Food Protection under the title, Standards for *Accreditation* of Food Protection Manager *Certification* Programs.

The charge to the FPMC Committee from the 2010 Biennial Meeting of the Conference for Food Protection resulted in revisions to the ~~*Standards*~~ Standards to enhance the integrity of the entire examination process, which included identification and analysis of root causes of security violations and implementation of solutions.

The revision and reformatting of the document were made after a comprehensive FPMC Committee review of each section. This revision of the ~~*Standards for*~~ Standards for *Accreditation* ~~*of Food Protection Manager*~~ of Food Protection Manager *Certification* ~~*Programs*~~ Programs:

1. adds and improves definitions that are more precise and more consistent with terminology and definitions used in the *psychometric* community and by ~~accreditation~~ *accreditation* organizations;
2. reorganizes ~~*Standards*~~ Standards to eliminate duplication and align with purpose;
3. modifies or creates ~~*Standards*~~ Standards to better address professional credibility and training of *test administrators/proctors*; handling of examination packages; shipping irregularities; location (site) irregularities; and breach of the *certification organization's test administrators/proctors* protocols and requirements;
4. uses "*test administrator/proctor*" in the ~~*Standards*~~ Standards to indicate duties for both "*test administrator*" and "*proctor;*" and
5. adds a standard for management systems.

Annex

The annex located at the back of the document is NOT part of the ~~standards~~ Standards, but provide~~s~~ information to guide those responsible for implementing or reviewing Food Protection Manager *Certification* Programs. The annex provides guidelines for specific responsibilities that ~~impact~~ affect the effective implementation of the Conference Standards for *Accreditation* of Food Protection Manager *Certification* Programs.

Annex A provides guidance to regulatory authorities that incorporate Food Protection Manager *Certification* as part of their requirements to obtain or retain a permit to operate. The CFP ~~*Standards for*~~ Standards for *Accreditation* ~~*of Food Protection Manager*~~ of Food Protection Manager *Certification* ~~*Programs*~~ Programs is designed to be a set of voluntary unifying national standards providing a mechanism for the universal acceptance of food protection managers who obtain their *certificate*s from an *accredited certification program*.

Over the past ~~25~~ twenty-five years, many regulatory authorities have developed their own Food Protection Manager *Certification* Programs. This has resulted in a variety of ~~standards~~ Standards for *certification* programs. The CFP national ~~standards~~ Standards for universal acceptance of

*Certified Food Protection Manager*s provide regulatory authorities reliable and *legally defensible* criteria for evaluating *certification* programs. In addition, they eliminate duplication of testing and additional cost for the industry.

Regulatory authorities that may not be in a position to eliminate their existing programs are encouraged to recognize food protection managers certified in accordance with these ~~standards~~ Standards as fulfilling their program requirements. Annex A provides additional guidance, developed through the CFP, for the implementation of these regulatory *certification* programs.

TABLE OF CONTENTS

TABLE OF CONTENTS (continued)

SECTION 1.0 - DEFINITIONS

1.0 Definitions.

1.1 **Accreditation** means that an *accrediting organization* has reviewed a Food Protection Manager *Certification* Program and has verified that it meets ~~standards~~ Standards set by the CFP (a review of a *certification organization* by an independent organization using specific criteria, to verify compliance with the Food Protection Management *Certification* Program Standards).

1.2 **Accrediting organization** means an independent organization that determines whether a Food Protection Manager *Certification* Program meets the ~~standards~~ Standards set by the CFP.

1.3 **Accredited certification program** means a Food Protection Manager *Certification* Program that has been evaluated and listed by an *accrediting organization* accepted by the CFP and has met the CFP ~~standards~~ Standards for such programs.

A. refers to the *certification* process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, *continued proficiency*, discipline, and grievance procedures; and examination development and administration.

B. does not refer to training functions or educational programs.

1.4 **Algorithm** means a set of procedures or rules pertaining to the selection of questions on an examination.

1.5 **Certificate** means documentation issued by a *certification organization*, verifying that an individual has complied with the requirements of an *accredited certification program*.

1.6 **Certification** means the process wherein a *certificate* is issued.

1.7 **Certification organization** means an organization that provides a *certification* program and issues the *certificate*.

1.8 **Certified Food Protection Manager** means a person who has demonstrated by means of a *food safety certification examination* to a *certification organization* that he/she has the ~~knowledge, skills and abilities~~ *knowledge, skills and abilities (KSA's)* required to protect the public from foodborne illness. Duties of such persons include but are not necessarily limited to:

A. responsibility for identifying hazards in the day-to-day operation of a *food establishment* that provides food for human consumption;

B. development or implementation of specific policies, procedures or standards aimed at preventing foodborne illness;

C. coordination of training, supervision or direction of food preparation activities, and responsibility for taking corrective action as needed to protect the health of the consumer; and

D. responsibility for completion of in-house self-inspection of daily operations on a periodic basis to see that policies and procedures concerning food safety are being followed.

1.9 **Competency** means a defined combination of ~~knowledge, skills, and abilities~~ *knowledge, skills and abilities (KSA's)* required in the satisfactory performance of a job.

1.10 **Competency examination** means an instrument that assesses whether an individual has attained at least a minimum level of *competency* that has been determined to be necessary to perform effectively and safely in a particular occupation or job. It shall be based on a thorough analysis of requirements for safe and effective performance.

1.11 **Computer-adaptive testing** means a method of *computer-based testing* that uses *algorithm*s based on the statistics of the examination questions to determine the *examinee's* proficiency by selecting *item*s at various difficulty levels.

1.12 **Computer-based testing** means an examination administered on a computer.

1.13 **Continued proficiency** means a *certification organization's* process or program designed to assess continued *competence* and/or enhance the *competencies* of *Certified Food Protection Managers*.

1.14 **Demographic data** means the statistical data of a population, especially the data concerning age, gender, ethnic distribution, geographic distribution, education, or other information that will describe the characteristics of the referenced group.

1.15 **Educator,** in this instance, means a teacher in a secondary or post-secondary program leading to a degree or *certificate* in a course of study that includes *competencies* in prevention of foodborne illness.

1.16 **Entry level performance** means carrying out job duties and tasks effectively at a level that does not pose a threat to public safety but not necessarily beyond that level. It requires safe performance of tasks expected of a worker who has had at least the minimal training (either in a formal school ~~setting~~ or on-the-job setting), but not long experience.

1.17 **Equivalency** (in "equivalent examinations") means that there is specific *psychometric* evidence that various forms of an examination cover the same content and their respective passing scores represent the same degree of competence.

1.18 Examination Booklet means the paper version of the *food safety certification examination*.

1.19 Examination Developers means the individuals involved in the process of creating the Food Safety ~~Certification~~ *Certification* Examination.

1.20 Examination forms means alternate sets of examination questions (with at least 25% alternate questions) to assess the same *competencies*, conforming to the same *examination specifications*.

1.21 Examination specifications means the description of the specific content areas of an examination, stipulating the number or proportion of *item*s for each area of *competency* and the level of complexity of those *item*s. The specifications are based on the *job analysis* and its verification.

1.22 Examination version means an examination in which the exact set of *item*s in an *examination form* is presented in another order, language, manner or medium.

1.23 Examinee means a person who takes an examination.

1.24 Exposure Plan means the policies and procedures in place to ensure that examination *item*s are not exposed to *examinees* or other people that may result in an examination *item* being memorized and/or shared.-

1.25 Food establishment

A. Food establishment means an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption:
   1) such as a restaurant, satellite or catered feeding location, catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people, market, vending location, conveyance used to transport people, institution, or food bank; and
   2) that relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

B. including:
   1) an element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the *regulatory authority*; and
   2) an operation that is conducted in a mobile, stationary, temporary or permanent facility or location; where consumption is on or off the premises; and regardless of whether there is a charge for the food.

C. not including:

1) an establishment that offers only prepackaged foods that are not potentially hazardous;
2) a produce stand that only offers whole, uncut fresh fruits and vegetables;
3) a food processing plant;
4) a kitchen in a private home if only food that is not potentially hazardous is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by law and if the consumer is informed by a clearly visible placard at sales or service locations ~~that~~ where the food is prepared in a kitchen that is not subject to regulation and inspection by the *regulatory authority*;
5) an area where food that is prepared as specified in Subparagraph ~~(c) (iv)~~ (C) of this definition is sold or offered for human consumption;
6) a kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers food to guests if the home is occupied, the number of available guest bedrooms does not exceed ~~6~~ six, breakfast is the only meal offered, the number of guests served does not exceed ~~18~~ eighteen, and the consumer is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration areas ~~that~~ where the food is prepared in a kitchen that is not regulated and inspected by the *regulatory authority*; or
7) a private home that receives catered or home-delivered food.

1.26 Food safety certification examination means an examination in food safety approved in accordance with the provisions of this program.

1.27 Instructor means an individual who teaches a course that includes *competencies* in prevention of foodborne illness.

1.28 Item means an examination question.

1.29 Item bank means all of the *item*s that have been developed for the several forms of an examination. It includes all of the *item*s available to create *examination forms*.

1.30 Item sequence means the presentation order of examination *item*s in an examination.

1.31 Job analysis means the description of functions or tasks required for an individual to perform to entry level standards in a specific job or occupation, including information about the attributes required for that performance. It defines the performance dimension of a job and includes ~~knowledge, skills, and abilities~~ *knowledge, skills and abilities (KSA's)*necessary to carry out the tasks.

A **Tasks** are the individual functions, whether mental or physical, necessary to carry out an aspect of a specific job.

B. **Knowledge, skills, and abilities (KSAs)** include the information and other

attributes that the worker shall possess in order to perform effectively and safely. They include information and understanding as well as learned behaviors and natural attributes.

1.32 **Legal entity** means an organization structured in a manner that allows it to function legally and be recognized as a responsible party within the legal system.

1.33 **Legally defensible** means the ability to withstand a legal challenge to the appropriateness of the examination for the purpose for which it is used. The challenge may be made by actual or *potential examinees* or on behalf of the public. *Examinees'* challenges may pertain to perceived bias of the examination or inappropriately chosen content. Challenges on behalf of the public may claim that the examination does not provide adequate measures of an *examinee's* ~~knowledge, skills, and abilities~~ *knowledge, skills and abilities (KSA's)*required to protect the consumer from foodborne illness.

1.34 **Overexposure** means the relative frequency in which an examination *item* which is presented across all computerized tests has undermined the integrity of the examinations. Whether a test *item* is overexposed or not is based upon the type of examination test *item* (pictorial vs. written) and its frequency of use.

1.35 **Potential examinee** means a person capable of taking an examination.

1.36 **Proctor** means a person under the supervision of a *test administrator*, ~~assisting~~ who assists by assuring that all aspects of an examination administration are being carried out with precision, with full attention to security and to the fair treatment of ~~examinees~~ *examinees*. *Proctors* have the responsibility and shall have the ability to observe *examinee* behaviors, accurately distribute and collect examination materials, and assist the *test administrator* as assigned. They shall have training or documented successful experience in monitoring procedures and shall affirm in writing an agreement to maintain examination security and to ensure that they have no conflict of interest. There must be at least one *proctor* for every 35 ~~examinees~~ *examinees*~~-~~. The *proctor* can also be a *test administrator*.

1.37 **Psychometric** means scientific measurement or quantification of human qualities**,** traits, or behaviors.

1.38 **Psychometrician** means a professional with specific education and training in development and analysis of examinations and other assessment techniques and in statistical methods. Qualifications may vary but usually include at least a bachelor's degree and a minimum of two formal courses in examination development and a minimum of two in statistical methods.

1.39 **Regulatory authority** means a government agency that has been duly formed under the laws of that jurisdiction to administer and enforce the law.

1.40 **Reliability** means the degree of consistency with which an examination measures the attributes, characteristics or behaviors that it was designed to measure.

1.41 **Retail food industry** means those sectors of commerce that operate *food establishments*.

1.42 **Test administrator** means the individual at the test site who has the ultimate responsibility for conducting a *food safety certification examination*. The *test administrator* can also be a *proctor*.

1.43 **Test encryption and decoding** means the security aspects of a computer examination to prevent the examination from being read by unauthorized persons if downloaded or otherwise accessed without authorization. Encryption refers to how a computer examination is coded. Decoding refers to how the computer examination is translated back from the code.

1.44 **Trainer,** in this instance, means a professional with appropriate expertise who conducts a course in food safety for *potential examinees* for *certification* as Food Protection Managers.

1.45 **Validity** means the extent to which an examination score or other type of assessment measures the attributes that it was designed to measure. In this instance, does the examination produce scores that can help determine if *examinees* are competent to protect the public from foodborne illness in a *food establishment*.

SECTION 2.0 – PURPOSE OF CERTIFICATION ORGANIZATIONS

2.0 Purpose of *Certification Organizations.*

2.1 The *certification organization* shall have as a purpose the evaluation of those individuals who wish to secure or maintain Food Protection Manager *Certification* in accordance with the criteria and ~~standards~~ Standards established through the CFP, and the issuance of *certificates* to individuals who meet the required level of *competency*.

2.2 A *certification organization* responsible for attesting to the *competency* of Food Protection Managers has a responsibility to the individuals desiring *certification*, to the employers of those individuals, and to the public.

2.3 A *certification organization* for Food Protection Manager *Certification* Programs shall not be the *accrediting organization* nor ~~may~~ shall the *certification organization* have any conflict of interest with said *accrediting organization.*

SECTION 3.0 – STRUCTURE AND RESOURCES OF CERTIFICATION ORGANIZATIONS

3.0 Structure and Resources of *Certification Organizations.*

3.1 **Structure of *certification organizations*.** The *certification organization* shall be incorporated as a *legal entity* (applies to the parent organization if the *certification organization* is a subsidiary of another organization).

3.2 A *certification organization* shall conform to all CFP ~~standards~~ Standards for *accreditation* and demonstrate that the relationship between the *certification organization* and any related association, organization or agency ensures the independence of the *certification* program and its related functions.

3.3 If a *certification organization* provides both education and *certification*, the *certification organization* shall administratively and financially separate any education and *certification* functions that are specific to Food Protection Manager *Certification* to ensure that the *certification* program is not compromised. This may be satisfied if the governing structure documents to the *accrediting organization* the distinct separation of the two functions, confirming that no undue influence is exercised over either the education or the *certification* process by virtue of the structure within the association, organization, agency or another entity.

3.4 **Resources of *Certification Organizations*.** A *certification organization* shall conform to all CFP ~~standards~~ Standards for *accreditation* and demonstrate

A. the availability of financial resources to effectively and thoroughly conduct regular and ongoing *certification* program activities.

B. that staff possesses the knowledge and skills necessary to conduct the *certification* program or has available and makes use of non-staff consultants and professionals to sufficiently supplement staff knowledge and skills.

SECTION 4.0 – FOOD SAFETY CERTIFICATION EXAMINATION DEVELOPMENT

4.0 ***Food Safety Certification Examination*** **Development.**

4.1 *Food safety certification examinations* administered by *accredited certification organizations* shall comply fully with all criteria set by the CFP and shall meet explicit and implicit ~~standards~~ Standards to protect the public from foodborne illness. The *accredited certification organization* shall provide a *food safety certification examination* that:

A. conforms to all CFP Standards for ~~Accreditation~~ *Accreditation* of Food Protection Manager ~~Certification~~ *Certification* Programs;

B. has been developed from an *item bank* of at least ~~1000~~ one thousand questions; and

C. on a quarterly basis is provided in at least two new *examination forms* in the English language.

4.2 Each *certification organization* shall provide evidence that it meets the following professional requirements:

A. ability to conduct or otherwise use a *legally defensible* and psychometrically valid *job analysis*;

B. demonstrated experience in the development of psychometrically valid *competency examinations*;

C. demonstrated capability to develop and implement thorough procedures for security of the *item bank,* printed, taped or computerized examinations, examination answer sheets, and *examinee* scores;

D. data handling capabilities commensurate with the requirements for effective processing, reporting, and archiving of *examinee food safety certification examination* scores; and

E. demonstrated evidence of an understanding of and willingness to abide by the principles of fairness and due process.

4.3 The *certification organization* shall provide complete information about the *food safety certification examination*, including ~~that~~ information related to procedures and personnel involved in all aspects of the examination development and analysis. The information required for *accreditation* will include but is not necessarily limited to:

A complete description of the scope and usage of the examination;
B. *job analysis* task list, with ~~knowledge, skills, and abilities (KSAs~~*)* *knowledge, skills, and abilities (KSAs);*
C. *examination specifications*;

D. the number of unduplicated *item*s in the *item bank*;
E. statistical performance of each *item* in the bank;
F. number of *examination forms* and evidence of their *equivalence* to each other;
G. description of method used to set passing score;
H. copies of all logs, diaries, and personnel lists and descriptions kept as
f required in the development process;
I. summary statistics for each *examination form*; and
J. names, credentials, and *demographic* information for all persons involved in the *job analysis*, *item* writing and review, and setting the passing score.

4.4 ***Job Analysis.*** The content *validity* of a *food safety certification examination* shall be based on a psychometrically valid *job analysis* developed by *psychometricians* and a demographically and technically representative group of individuals with significant experience in food safety. The representative group shall include but not necessarily be limited to persons with experience in the various commercial aspects of the *retail food industry*, persons with local, state or national regulatory experience in retail food safety, and persons with knowledge of the microbiology and epidemiology of foodborne illness, and shall be sufficiently diverse as to avoid cultural bias and ensure fairness in content according to all ~~federal~~ Federal requirements.

4.5 The *job analysis* shall provide a complete description of the ~~knowledge, skills, and abilities (KSAs)~~ *knowledge, skills, and abilities (KSAs)* required to function competently in the occupation of *Certified Food Protection Manager*, with emphasis on those tasks most directly related to the *Certified Food Protection Manager's* role in the prevention of foodborne illness.

4.6 Detailed *food safety certification examination* specifications shall be derived from a valid study of the *job analysis* tasks and their accompanying ~~knowledge, skills, and abilities (KSAs)~~ *knowledge, skills, and abilities (KSAs)* and shall be appropriate to all aspects of the *retail food industry*. The *job analysis* shall include consideration of scientific data concerning factors contributing to foodborne illness and its epidemiology. The *examination specifications*, consisting of percentage weights or number of *item*s devoted to each content area, shall be available to *examinees* and to the public.

4.7 The *certification organization* or its contracted examination provider shall maintain a log and diary of the procedures and a list of the qualifications, identities, and *demographic data* of the persons who participated in development of the *job analysis* and of the *food safety certification examination specifications*. Those materials shall be provided to the *accrediting organization* on demand.

4.8 The *certification organization* is required to systematically evaluate practices in the *retail food industry* to ensure that the *job analysis* on which an examination is based remains appropriate for the development of *food safety certification examinations* on which the universal credential is awarded. The maximum length of use for any *job analysis* is five years from the date of validation.

4.9 ***Psychometric*** **Standards**. *Food safety certification examination* development, including setting the passing score, shall be based on the most recent edition of ~~*Standards for Educational and Psychological Testing*~~ Standards for Educational and Psychological Testing, developed jointly by the American Psychological Association, American Educational Research Association and National Council for Measurement in Education, and on all appropriate ~~federal~~ Federal requirements (for example, Americans with Disabilities Act). *Food safety certification examinations* shall be revised as needed to be in compliance with changes in the ~~*Standards for Educational and Psychological Testing*~~ Standards for Educational and Psychological Testing or in any of the ~~federal~~ Federal requirements.

4.10 The *food safety certification examination* development procedures shall ensure that the *competencies* assessed in the *accredited certification program* are those required for *competent entry level performance* in the role of *Certified Food Protection Manager*, as defined by law and industry standards, and that they focus on factors related to the prevention of foodborne illness in the *retail food industry*.

4.11 The *food safety certification examination* shall be based on psychometrically valid procedures to ensure the relative equivalence of scores from various *examination forms*. The *certification organization* shall provide evidence of such equivalence as public information.

4.12 The *food safety certification examination* shall be developed to be free from bias due to characteristics that have no bearing on the competencies being measured. Such characteristics as gender, ethnicity, race, socioeconomic status, age, and any other concerns unrelated to ability to apply the required competencies will not be allowed to create differences in *examinee* scores.

4.13 When the *food safety certification examination* is administered in a medium other than the common pencil-and-paper format, evidence shall be provided to ensure that all *competencies* are assessed in a reliable manner and that the *validity* of the examination is preserved. Evidence of comparability with other *examination forms* shall be provided.

4.14 When any form and/or *item bank* of the *food safety certification examination* is translated into a language other than that in which it is originally developed and validated, the developer of the examination shall provide evidence of content *equivalency* of the translated version with the original *examination form* and/or *item bank*. The developer shall provide a detailed description of the translation method(s), including the rationale for selecting the translation method(s), and shall demonstrate congruence of *item*s and instructions with those of the *examination form* and/or *item bank* that was translated. To avoid potential problems in translation of terms specific or idiomatic to the *retail food industry*, translation should be accomplished with the consultation of food safety personnel competent in the languages of both the original and the translated version of the *food safety certification examination.*

4.15 Actual or potential conflicts of interest that might influence judgment or performance of *Examination Developers* shall be disclosed.

4.16 *Examination Developers* shall maintain a log and diary of the procedures and a list of the qualifications, identities, and *demographic data* of the persons who participated in *item* development, examination development, translations, setting the passing score, and the statistical analyses of the examination *item*s and of the full examination. Those materials shall be provided to the *accrediting organization* on demand.

All examinations shall be delivered and administered in a format that ensures the security of the examination (i.e. in a secured environment with a *test administrator*/*proctor*.) Un-proctored examinations are not acceptable regardless of the mode of administration.

4.17 **Examination Development Security.** The *certification organization* will demonstrate that procedures are developed and implemented to ensure that individual *item*s, *item banks, food safety certification examinations* presented in all media (printed, taped and computerized), test answer sheets and *examinee* scores are and remain secure. Demonstration shall include an overall examination security plan that covers each step in the examination development, culminating in the production of the examination.

4.18 **Periodic Review.** At least semiannually each *certification organization* shall report to the *accrediting organization,* providing a review of its *food safety certification examination(s)*. The report will include the following summary statistics for all examinations (for each examination used) administered during the preceding six months, as well as other information that may be reasonably requested by the *accrediting organization*:

A number of *food safety certification examinations* administered;
B. mean;
C. mode;
D. standard deviation;
E. range;
F. *reliability* coefficient;
G. number and percentage of *examinees* passing the examination; and
H. the statistics describing the performance of each *item* used on *food safety certification examinations* administered during the six-month period.

4.19 **Requirements for Examination Standardization.** *Certification organizations* shall specify conditions and procedures for administering all *food safety certification examinations* in a standard manner to ensure that all *examinees* are provided with the opportunity to perform according to their level of ability and to ensure comparability of scores. *Examination Booklets* shall be of high quality printing to ensure ease of reading.

SECTION 5 – FOOD SAFETY CERTIFICATION EXAMINATION ADMINISTRATION

5.0 ***Food Safety Certification Examination*** **Administration.** All sections of these ~~*Standards*~~ Standards apply to ~~Computer Based Testing (CBT)~~ *Computer Based Testing (CBT)* Administration except Section 5.1.

5.1 Security for *Examination Booklets.*

A. Securing *examination booklet.*
   1) Each individual *examination booklet* shall be secured by using one of the following methods both prior to and after administration:
      a. enclosing in a sealed tamper-resistant package;
      b. shrink-wrapping;
      c. sealing on all three open sides with each seal of sufficient size to cover at least one square inch of the front side and to overlap and cover the same amount of space on the back side of the *examination booklet*; or
      d. using any other technology that ensures that only the *examinee* can view the contents of the *examination booklet*.
   2) Only the *examinee* is allowed to break open the *examination booklet* packaging or seals.

B. Packaging by c*ertification organization.*
   1) Each individual *examination booklet* shall be securely sealed before packing.
   2) Secure tamper-resistant shipping material, such as Tyvek envelopes or similar materials that are designed to reveal any tampering or violation of the package's security, is required for all shipment of materials in all phases.
   3) Packaging must include a packing list that contains:
      a. *examination form* language(s) or version(s) enclosed; and
      b. quantity of examinations enclosed.

C. Shipping to the *test administrator/proctor* from the c*ertification organization.*
   1) Shipping shall be done by certifiable, traceable means, with tracking numbers so that the location can be determined at any given time.
   2) A signature is required upon delivery.
   3) Only an individual authorized by the *test administrator/proctor* may sign for the package.

D. Storage by *test administrator/proctor.*
   The package(s) of *examination booklet*s shall be secured at all times immediately upon delivery. Under no circumstances may *examination booklets*, *examinee* used answer sheets, or other examination materials be kept where other employees or the public has access.

E. Shipping to the *certification organization* from the *test administrator/proctor*

1) After examination administration, *examination booklets* and answer sheets shall remain in secure storage until returned to c*ertification organization.*

2) The following shall be in tamper-resistant shipping material:

a. all used and unused *examination booklets* for each examination administration;

b. examinees' used answer sheets; and

c. all required c*ertification organization* forms.

3) Shipping shall be done within two business days following the examination date by certifiable, traceable means, with tracking numbers so that the location can be determined at any given time.

F. Handling unused *examination booklets* that have been held for up to ninety days. The *test administrator/proctor* will:

1) ensure that all *examination booklets* are accounted for;
2) package *examination booklets* securely as described above; and
3) ship to the certification organization securely packaged and according to these *Standards* and the *Certification Organization*'s instructions.

5.2 Test Site Requirements.

Sites chosen for administering *food safety certification examination*s shall conform to all legal requirements for safety, health, and accessibility for all qualified *examinees*.

A. Additionally, the accommodations, lighting, space, comfort, and work space for taking the examination shall reasonably allow *examinees* to perform at their highest level of ability.

B. Requirements at each test site include, but are not limited to:

1) accessibility in accordance with the requirements of the Americans with Disabilities Act, shall be reasonably available for all qualified *examinees*, whether the examination administration occurs at the main examination location site, or at an alternative examination location site that meets the same location requirements as the main examination location site;
2) conformity to all fire safety and occupancy requirements of the jurisdiction in which they are located;
3) sufficient spacing between each *examinee* in the area in which the actual examination is conducted, or other appropriate and effective methods, to preclude any *examinee* from viewing another *examinee's* examination;
4) acoustics allowing each *examinee* to hear instructions clearly, using an electronic audio system if necessary;
5) lighting at each *examinee's* work space adequate for reading;
6) ventilation and temperature appropriate for generally recognized health and comfort of *examinees*;
7) use of private room(s) where only examination personnel and *examinees* are allowed access during the examination administration; and
8) no further admittance into the test site once examination administration has begun.

5.3 Test Site Language Translation.

A *certification organization* shall have a published, written policy regarding test site language translation of *food safety certification examinations*. If a *certification organization* allows test site language translation of a *food safety certification examination* when an *examination version* is not available in the *examinees'* requested language, the *certification organization* shall have a published, formal application process available to all *potential examinees*. Procedures shall include but not be limited to:

A. An application process for *potential examinees* that includes an evaluation and documentation component to determine the eligibility of the *potential examinee* for test site language translation,

B. An application process for translators that includes clear and precise qualifications that shall include but not be limited to the following:
   1) being fluent in both languages;
   2) have a recognized skill in language translation;
   3) trained in the principles of objective examination administration;
   4) have no personal relationship with the *examinee* (may not be another *examinee*, may not be a relative or friend of the *examinee* and may not be a co-worker, employer, or an employee of the *examinee*);
   5) not being a *Certified Food Protection Manager* nor having any vested interest in Food Protection Manager ~~certification~~ *certification* or conflict of interest;
   6) provide references or other proof attesting to the translator's competencies and professional acumen; and
   7) agree in writing to maintain the security of the examination.

C. A proctored environment where the translator and *examinee* are not a distraction to other *examinees*, and

D. A proctored environment where the translator is not active as the *test administrator*/*proctor*.

5.4 Scoring.

A. Only the *certification organization* may score the examination by methods approved by the *accrediting organization*. No official scoring is to be done at the test site.

B. *Food safety certification examination* scores will not be released as being official until verified and approved by the c*ertification organization*.

C. *Examinee* scores will be confidential, available only to the *examinee* and to persons or organizations approved in writing by the *examinee*.

D. Score reports will be available to *examinees* in a time frame specified in the application, which will not exceed fifteen business days following the administration

of the *food safety certification examination*. If there is a delay due to problems in verification or authentication of scores, *examinees* will be so informed and an approximate date for release of the scores will be announced. The c*ertification organization* will have ongoing communication with *examinees* and with the *test administrator/proctor* until the scores are verified and released.

5.5 ***Test Administrator/Proctor(s)*** **Role.** *Test administrators/proctors* shall have successfully completed the *certification organization's* specific training in examination administration and security procedures. They shall provide written assurance of maintaining confidentiality of examination contents, of adhering to the *certification organization's* standards and ethics of secure examination administration, and of agreeing to abide by the *certification organization's* policies, procedures, and rules.

5.6 ***Test Administrator/Proctor*** **Requirements.** To serve as a *test administrator/proctor* for an accredited *certification organization* the qualified individual shall complete the *certification organization's*:

A. signed Application;

B. non-Disclosure Agreement (NDA);

C. training program for *test administrators/proctors;* and

D. conflict of Interest Disclosure Agreement (can be a part of the NDA).

5.7 ***Test Administrator/Proctor*** **Renewal.** *Test administrators/proctors* shall renew the training program for *test administrators/proctors* and Non-Disclosure Agreement with the *certification organization* every three (3) years.

5.8 ***Instructor/Educator/Trainer*** **as** ***Test Administrator/Proctor*****.**
When a person acts as *an instructor/educator/trainer* and a *test administrator/proctor*, that person relinquishes the role of *instructor/educator/trainer* when acting in the role of *test administrator/proctor* and acts solely as a representative agent of the *certification organization*.

5.9 ***Test Administrator/Proctor*** **Responsibilities.**

A. Schedule examinations. *Food safety certification examination*s shall be scheduled far enough in advance to allow for timely shipment of supplies or pre-registration for computer-based examinations.

B. Ensure no destruction of *examination booklet* materials or computer equipment;

C. At all times:
   1) handle examination materials securely;
   2) ensure test site conformity;
   3) space *examinees* per protocol;
   4) ensure *examinees'* rights;
   5) ensure confidentiality of *examinees'* personal information;
   6) ensure standardized procedures are followed;

D. Before the examination:
   1) check *examinees'* identification;
   2) check for and exclude unauthorized objects;
   3) distribute examination materials;
   4) read instructions to *examinees* verbatim;
   5) ensure *examinees* complete information section of answer sheet or online registration form.

E. During the examination:
   1) supervise assisting ~~proctors~~ *proctors*;
   2) monitor *examinees* during examination;
   3) identify and document cheating incidents;
   4) check for and exclude unauthorized objects;
   6) identify and document environmental distractions.

F. After the examination
   1) collect and return *examination booklet*s and answer sheets to *certification organization* or close ~~computer based testing~~ *computer based testing* session;
   2) report possible security breaches and examination administration irregularities in compliance with the *certification organization's* policies.

5.10 The number of approved *proctors* assigned to a *test administrator* shall be sufficient to allow each *examinee* to be observed and supervised to ensure conformance to security requirements. There shall be no less than one *test administrator/proctor* for the first thirty-five *examinees*, plus one additional *test administrator* or *proctor* for each additional ~~35~~ thirty-five *examinees* or fraction thereof.

5.11 Examination Security.

A. All aspects of *food safety certification examination* administration are to be conducted in a manner that maximizes the security of the examinations, in keeping with the public protection mandate of the CFP. This shall be accomplished in a manner that ensures fairness to all *examinees*.

B. All *examinees* shall begin taking the examination at the same time. No *examinee* shall be admitted into the test site once examination administration has begun.

C. Where reasonable accommodations shall be made for otherwise qualified *examinees* under provisions of the Americans with Disabilities Act, care shall be taken to ensure that security of the examination is maintained. Arrangements shall be such that the *food safety certification examination* contents are not revealed to any test administration personnel with any conflict of interest. A written affirmation to that effect and a written nondisclosure statement from the individual who was chosen to assist the otherwise qualified *examinee* shall be provided to the *certification organization*.

–

5.12 The *certification organization* shall provide procedures to be followed in any instance where the security of a *food safety certification examination* is, or is suspected to be, breached.

A. Included shall be specific procedures for handling and for reporting to the *certification organization*, any suspected or alleged:
   1) cheating incidents;
   2) lost or stolen examination materials~~;~~
   3) intentional or unintentional divulging of examination *item*s by *examinees* or examination administration personnel; or
   4) any other incidents perceived to have damaged the security of the examination or any of its individual *item*s.

B. Corrective actions to guard against future security breaches shall be established and implemented.

C. Documentation of corrective actions and their effectiveness shall be made available to the *accrediting organization*.

5.13 ***Item* and Examination Exposure.**-
The *certification organization* shall have an *exposure plan* that:

A. controls for *item* and examination exposure;

B. accounts for the number of times an *examination item*, *examination form,* and *examination version* is administered;

C. ensures that no *examination form* is retained by any *examination administration* personnel for more than ~~90~~ ninety days;

D. at all times accounts for all copies of all used and unused *examination booklets*; and

E. systematically and actively demonstrates that every used answer sheet, *examination booklet*, and any other examination materials and answer keys are accounted for to prevent, reduce, or eliminate examination exposure.

5.14 ***Certification Organization's*** **Responsibility to** ***Test Administrators/Proctors.***

A. The *certification* o*rganizations* shall specify the responsibilities of *test administrator/proctor*, set minimum criteria for approval of *test administrators* /p*roctors*, and provide a training program to enable *potential examinees* to meet the approval criteria. Responsibilities, duties, qualifications and training of *test administrators*/*proctors* shall be directed toward assuring standardized, secure examination administration and fair and equitable treatment of *examinees*.

B. The *certification organization* shall define and provide descriptions for the roles of *test administrators/proctors,* and *certification organization* personnel clearly indicating the responsibilities for these roles. The *certification organization* shall demonstrate how it ensures that all certification personnel, *as well as test administrators/proctors,* understand and practice the procedures identified for their roles.

C. *Test administrator/proctor* training programs shall include:
   1) specific learning objectives for all of the activities of *test administrator/proctor*; and
   2) an assessment component that shall be passed before an *examinee* for *test administrator/proctor* will be approved.

5.15 **Test Administrator/Proctor Agreements.** The *certification organization* shall enter into a formal agreement with the *test administrator/proctor*. The formal agreement shall at a minimum address:

A. provisions that relate to code of conduct;

B. conflicts of interest; and

C. consequences for breach of the agreement.

5.16 The *certification organization* shall assess and monitor the performance of *test administrators/proctors* in accordance with all documented procedures and agreements.

5.17 The *certification organization* is not permitted to hire, contract with, or use the services of any person or organization that claims directly or indirectly to guarantee passing any certification examination. *Instructors/educators/trainers* making such a claim, whether as an independent or as an employee of another organization making the claim, are not eligible to serve as *test administrators/proctors* for any *certification organization.*

In order to retain the integrity of the *certification* process, 5.17 is intended to provide *Certification Organizations* a method of evaluating individuals' and/or organizations' claims to guarantee passing any *certification examination* if they are performing the role of *instructor/educator/trainer* and *proctor/administrator*. This area of the Standard does not apply to training organizations and their employees not contracted to a *Certification Organization*.

5.18 Policies and procedures for taking corrective action(s) when any *test administrator* or *proctor* fails to meet job responsibilities shall be implemented and documented. *Test administrators/proctors* that have been dismissed by the *certification organization* for infraction of policies or rules, incompetence, ethical breaches, or compromise of examination security will be reported to the *accrediting organization*.

5.19 The *certification organization* shall provide documentation that verifies compliance with the 1:35 ratio (*test administrator/proctor*: *examinees*).

5.20 Examination Administration Manual.
The *certification organization* shall provide each *test administrator/proctor* with a manual detailing the requirements for all aspects of the *food safety certification examination* administration process. The Examination Administration Manual shall include a standardized script for the paper examination *test administrator/proctor* to read to *examinees* before the examination commences. For computer based tests (CBT), standardized instructions shall be available for *examinees* to read.

5.21 Examination Scripts. Separate scripts/instructions may be created for different delivery channels or *certification organizations*. *Certification organizations* may customize elements of the scripts to fit their particular processes, but each script shall contain the following:

A. Introduction to the Examination Process
   1) composition of the examination (number of questions, multiple choice, etc.);
   2) time available to complete the examination;
   3) role of the *test administrator/proctor*;
   4) process for restroom breaks; and
   5) process for responding to *examinee* comments and questions.

B. Copyright and Legal Responsibilities
   1) description of what constitutes cheating on the examination;
   2) penalties for cheating; and
   3) penalties for copyright violations.

C. Examination Process
   1) maintaining test site security;
   2) description of examination components unique to the *certification organization* (*examination booklet*, answer sheet completion, computer process in testing centers, etc.);
   3) instructions for proper completion of personal information on answer sheets/online registration and *examination booklet*s;
   4) instructions on properly recording answers on answer sheets or online; and
   5) instructions on post-examination administration process.

SECTION 6.0 – COMPUTER-BASED TESTING (CBT)

6.0 **Computer-Based Test Development and Administration** All sections of these ~~*Standards*~~ Standards apply to ~~Computer Based Testing~~ *Computer Based Testing* (CBT) Administration except Section 5.1.

6.1 **Computer-Based Test Development.** *Examination specifications* for *computer-based testing* shall describe the method for development, including the *algorithm*s used for test *item* selection, the *item* response theory model employed (if any), and examination *equivalency* issues.

6.2 *Item*s shall be evaluated for suitability for computer delivery, be reviewed in the delivery medium, and be reviewed in the presentation delivery medium. Assumptions shall not be made that *item*s written for delivery via a paper/pencil medium are suitable for computer delivery nor should it be assumed that computer test *item*s are suitable for paper/pencil delivery.

6.3 When *examination forms* are computer-generated, whether in *Computer-Adaptive Testing* (CAT) or in a simple linear *algorithm*, the *algorithm* for *item* selection and the number of *item*s in the *item bank* from which the examination is generated shall ensure that the *item*s are protected from *overexposure*. *Item* usage statistics shall be provided for all available *item*s in the pool.

6.4 ***Computer-Based Testing*** **Administration.** Where examination environments differ (for example, touch screen versus mouse) evidence shall be provided to demonstrate equivalence of the *examinee*s' scores.

6.5 Tutorials and/or practice tests shall be created to provide the *examinees* adequate opportunity to demonstrate familiarity and comfort with the computer test environment.

6.6 If the time available for computer delivery of an examination is limited, comparability of scoring outcomes with non-timed delivery of the exam shall be demonstrated. Data shall be gathered and continually analyzed to determine if scoring methods are comparable.

6.7 Evidence of security in the *computer-based testing* environment shall be provided. Factors affecting test security include, but are not limited to, *examinee* workspace, access to personal materials, level of *examinee* monitoring, and *test encryption and decoding*.

6.8 Documentation of precautions to protect *examination forms* and the *item bank* from unauthorized access shall be provided.

6.9 Policies and procedures regarding the recording and retention of the *item sequence* and *item* responses for each *examinee* shall be developed and followed. Computer examinations using a unique sequence of *item*s for each *examinee* shall record the information necessary to recreate the sequence of *item*s and *examinee* responses on the computer examination.

6.10 Systems and procedures shall be in place to address technical or operational problems in examination administration. For example, the examination delivery system shall have the capability to recover *examinee* data at the appropriate point in the testing session prior to test disruption. Policies regarding recovery for emergency situations (such as retesting) shall be developed.

6.11 **Due Process.** *Examinees* shall be provided with any information relevant to *computer-based testing* that may affect their performance or score. Examples of such information might include but not be limited to: time available to respond to *item*s; ability to change responses; and instructions relating to specific types of *item*s.

SECTION 7.0 – CERTIFICATION ORGANIZATION RESPONSIBILITIES TO *POTENTIAL EXAMINEES, EXAMINEES* AND THE PUBLIC

7.0 A *certification organization's* Responsibilities to *Examinees* and the Public.

7.1 Responsibilities to *Potential Examinees* and/or *Examinees* for *Certification*. A *certification organization* shall:

A. not discriminate among *potential examinees* and *examinees* as to age, sex, race, religion, ethnic origin, disabilities or marital status and shall include a statement of non-discrimination in announcement of the *certification* program;

B. make available to all *potential examinees* and *examinees* information regarding formalized procedures for attainment of *certification* and provide evidence to the *accrediting organization* of the implementation of the policy;

C. have a formal policy for the periodic review of application and examination procedures to ensure that they are fair and equitable and shall give evidence to the ~~accreditation~~ *accreditation* organization of the implementation of the policy;

D. provide evidence that competently proctored testing sites are readily accessible;

E. provide evidence of uniformly prompt reporting of *food safety certification examination* results to *examinees*;

F. provide evidence that *examinees* failing the *food safety certification examination* are given information on general areas of deficiency;

G. provide evidence that each *examinee's food safety certification examination* results are held confidential; and

H. have a formal policy on appeals procedures for *potential examinees* and *examinees* questioning eligibility or any part of the *accredited certification program*.

7.2 Qualifications for Initial *Certification*. To become a *Certified Food Protection Manager* an individual shall pass a *food safety certification examination* from an *accredited certification program* recognized by the CFP. The *certificate* shall be valid for no more than ~~5~~ five years.

7.3 *Individual Certification* C*ertificates:*

A. Each *certification organization* will maintain a secure system with appropriate backup or redundancy to provide verification of current validity of individual *certification certificates*.

B. *Certificates* shall include, at a minimum:
   1) issue date/date examination was taken;
   2) length of time of *certification* validity;

3) name and *certification* mark of *certification organization;*
4) ANSI *accreditation* mark;
5) name of certified individual;
6) unique *certificate* number;
7) name of *certification*;
8) contact information for the *certification organization*; and
9) examination form identifier

C. Replacement or duplicate *certificates* issued through an *accredited certification organization* shall carry the same issue date, or date of examination, as the original *certificate*, and will be documented by the *certification organization*.

7.5 **Discipline of *Certificate* Holders and *Examinees*.** A *certification organization* shall have formal *certification* policies and operating procedures including the sanction or revocation of the *certificate*. These procedures shall incorporate due process.

7.6 ***Continued Proficiency*.** An *accredited certification program* shall include a process or program for assessing continued competence that includes an examination component at an interval of no more than five years. The outcome of the process or program shall demonstrate that the person has maintained the minimum competencies as determined by the current Job Task Analysis.

7.7 **Responsibilities to the Public and to Employers of Certified Personnel.** A *certification organization* shall maintain a registry of individuals certified. Any title or credential awarded by the *certification organization* shall appropriately reflect the Food Protection Manager's daily food safety responsibilities and shall not be confusing to employers, consumers, related professions, and/or other interested parties.

7.8 Each *accredited certification program* shall have a published protocol for systematically investigating problems presented by users of the Program, including specific concerns about examination *item*s, administration procedures, treatment of *examinees and potential examinees*, or other matters involving potential legal defensibility of the examination or program. The protocol will include a published time frame for reporting findings to the User.

7.9 **Misrepresentation.** Only Food Protection Manager *Certification* Programs that conform to all requirements of *Standards for Accreditation of Food Protection Manager Certification Programs* and are accredited by the agent selected by the CFP as the *accrediting organization* for such programs are allowed to refer to themselves as being accredited. Those programs may not make any other reference to the CFP in their publications or promotional materials in any medium.

SECTION 8.0 – CERTIFICATION ORGANIZATION RESPONSIBILITIES TO THE ACCREDITING ORGANIZATION

8.0 *Certification Organization* Responsibilities to the *Accrediting Organization*.

8.1 Application for *Accreditation*. *A certification organization*~~s~~ seeking *accreditation* for development and/or administration of a *certification* program shall provide at least the following information, as well as other information that might be requested by the *accrediting organization:*

A. the name and complete ownership of the *legal entity*.

B. the address, telephone/fax number(s) and other contact information of the *certification organization's* headquarters.

C. the name, position, address and telephone/fax/e-mail information of the contact person for projects related to the CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs.

D. such fiscal information as may be needed to establish evidence of ability to carry out obligations under these ~~standards~~ Standards.

8.2 Summary Information. A *certification organization* shall:

A. provide evidence that the mechanism used to evaluate individual competence is objective, fair, and based on the knowledge and skills needed to function as a *Certified Food Protection Manager*;

B. provide evidence that the evaluation mechanism is based on standards which establish *reliability* and *validity* for each form of the *food safety certification examination*;

C. provide evidence that the pass/fail levels are established in a manner that is generally accepted in the *psychometric* community as being fair and reasonable;

D have a formal policy of periodic review of evaluation mechanisms and shall provide evidence that the policy is implemented to ensure relevance of the mechanism to knowledge and skills needed by a *Certified Food Protection Manager*;

E provide evidence that appropriate measures are taken to protect the security of all *food safety certification examination*s;

F publish a comprehensive summary or outline of the information, knowledge, or functions covered by the *food safety certification examination*;

G make available general descriptive materials on the procedures used in examination construction and validation and the procedures of administration and reporting of results; and

H compile at least semi-annually a summary of *certification* activities, including number of *examinees*, number tested, number passing, number failing, and number certified.

8.3 Responsibilities to the *Accrediting Organization*. The *certification organization* shall:

A. make available upon request to the *accrediting organization* copies of all publications related to the *certification* program,

B. advise the *accrediting organization* of any proposed changes in structure or activities of the *certification organization*,

C. advise the *accrediting organization* of substantive change in *food safety certification examination* administration,

D advise the *accrediting organization* of any major changes in testing techniques or in the scope or objectives of the *food safety certification examination*,

E annually complete and submit to the *accrediting organization* information requested on the current status of the Food Protection Manager *Certification* Program and the *certification organization*,

F submit to the *accrediting organization* the report requirements information specified for the Food Protection Manager *Certification* Program, and

G be re-accredited by the *accrediting organization* at least every ~~5~~ five years.

SECTION 9.0 – MANAGEMENT SYSTEMS

9.0 Management Systems.

9.1. Each c*ertification* o*rganization* shall have a formal management system in place to facilitate continuous quality improvement and produce preventive and corrective actions. The management system shall contain the following three components.

A. Document control to include:
1) lists of all documents pertaining to the ~~certification organization~~ *certification organization*;
2) dates for documents approved for implementation by the ~~certification organization~~ *certification organization*;
3) the person(s) within the ~~certification organization~~ *certification organization* responsible for the documents; and
4) listing of individuals who have access to the documents.

B. Internal audits to include:
1) identification of critical activities;
2) data collection process and evaluation schedule;
3) audit methodology and evaluation process;
4) the person(s) authorized to perform audits; and
5) report audit findings and identify corrective action required.

C. A Management Review that includes:
1) a documented annual review of internal audit results;
2) a management group that conducts the review;
3) a review of the audit results to determine corrective actions needed;
4) a review of the audit results to determine preventive actions needed; and
5) the effectiveness of corrective and preventive actions taken.

ANNEX A

Guidelines for Regulatory Authorities Implementing Food Protection Manager Certification Programs

A**1**. Each permitted *food establishment* should have a minimum of one designated *Certified Food Protection Manager* who is accountable for food safety.

Documentation of *certification* of *Certified Food Protection Manager*(s) should be maintained at each *food establishment* and shall be made available for inspection by the *regulatory authority* at all times.

A2. A *Certified Food Protection Manager* is responsible for:

1) identifying hazards in the day-to-day operation of a *food establishment*;

2) developing or implementing specific policies, procedures or standards aimed at preventing foodborne illness;

3). coordinating training, supervising or directing food preparation activities and taking corrective action as needed to protect the health of the consumer; and

4) conducting in-house self-inspection of daily operations on a periodic basis to see that policies and procedures concerning food safety are being followed.

A3. **Qualifications for *Certification*.** To become a *Certified Food Protection Manager*, an individual shall pass a *food safety certification examination* from an accredited *certification organization* recognized by the CFP. The CFP recognizes the importance and need for the provision of food safety training for all food employees and managers. The CFP recommends the content of food protection manager training be consistent with paragraph 2-102.11 (C) of the most recent FDA Food Code. The CFP promotes the information contained in the FDA Food Code as well as content outlines based on job tasks analyses, provided on the CFP website, which may be of value in developing or evaluating training.

A4. Regulatory authorities should work with the *certification organization* on a mutually agreeable format, medium and time frame for the submission of score reports pertaining to the administration of *food safety certification examinations*.

ANSI
American National Standards Institute

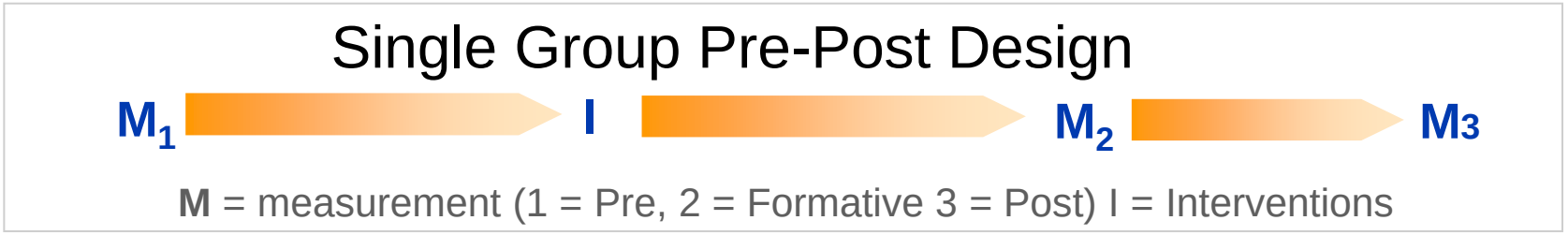
Security Evaluation Work Group
Baseline & Summative Self-Report Findings
2013-14

Donald J. Ford, Ph.D.
Lead Assessor, ANSI Certificate Accreditation Program &
Lead Evaluator, Certified Professional Food Manager Program

SEWG Background

- Work Group formed to address test security concerns involving the CPFM exam under ANSI CFP certification
- Dr. Ford, ANSI CAP Assessor, designed and conducted a 5 year evaluation study of past, current and future test security breaches and the impact of remedies that CFP implemented starting in 2011.
- Evaluation proceeded in three stages:
  1. Baseline study of the 2009-10 year to pilot test self-report data collection and establish a pre-assessment point from which to measure progress
  2. Interim study of the 2012-13 year to assess progress in addressing test security issues
  3. **Post-assessment of the 2013-14 year** and future years to measure progress and track trends in CPFM test security

Evaluation Methodology



- Self-reporting via questionnaire
- Data aggregated and reported as single group only (no within-group comparisons)
- Time Periods:
  - Baseline (Pre) – July 2009 – June 2010
  - Pilot (Formative) – July 2012 – June 2013
  - **Post (Summative) - July 2013 – June 2014**
  - Trending – Annually after 2014 as part of ANSI surveillance

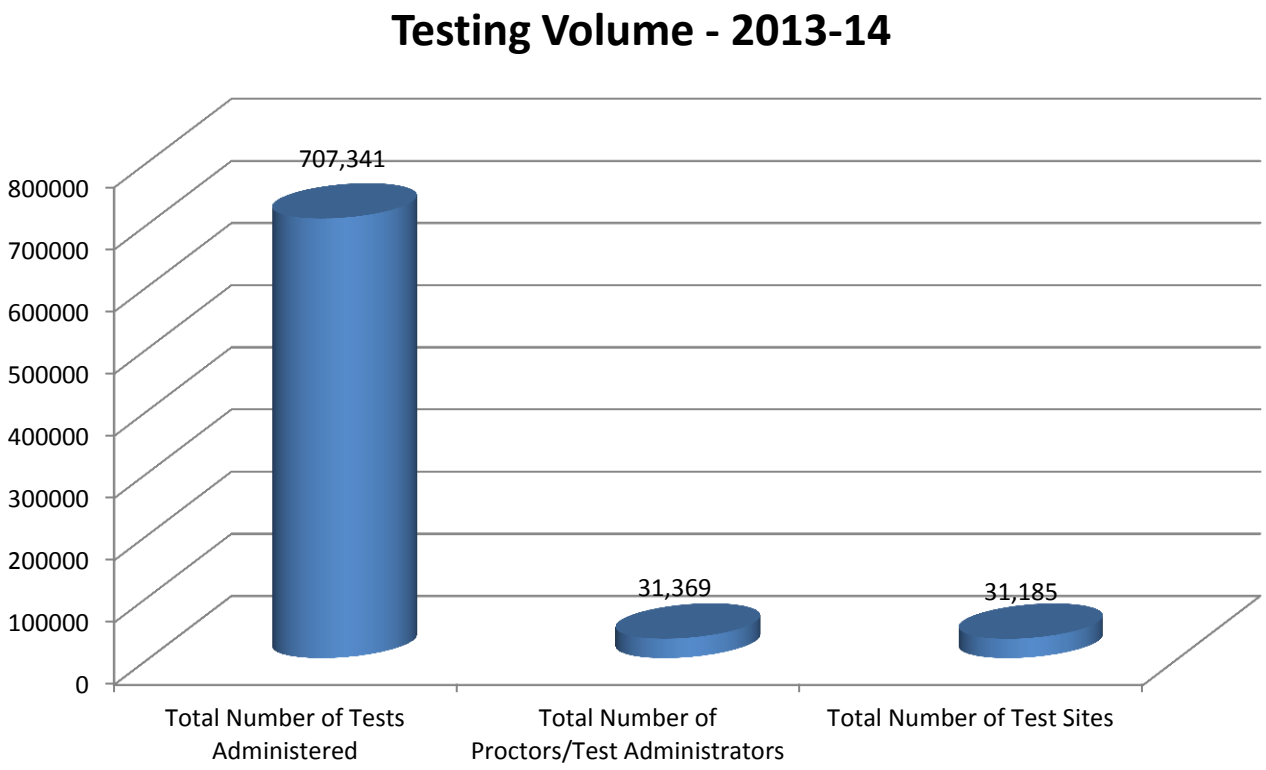
Summary of Evaluation Findings

- Small number of test security violations, but once is one too many
- About 4% of proctors/administrators are disciplinary problems, but numbers are declining
  - Better screening, selection, and discipline are working
  - 100% compliance on retraining achieved
- Test administration and shipping irregularities continue to be problematic
  - Better tracking and enforcement of existing rules needed
  - May be reaching theoretical limits of compliance, given current testing methods

Summary of Evaluation Findings (cont'd)

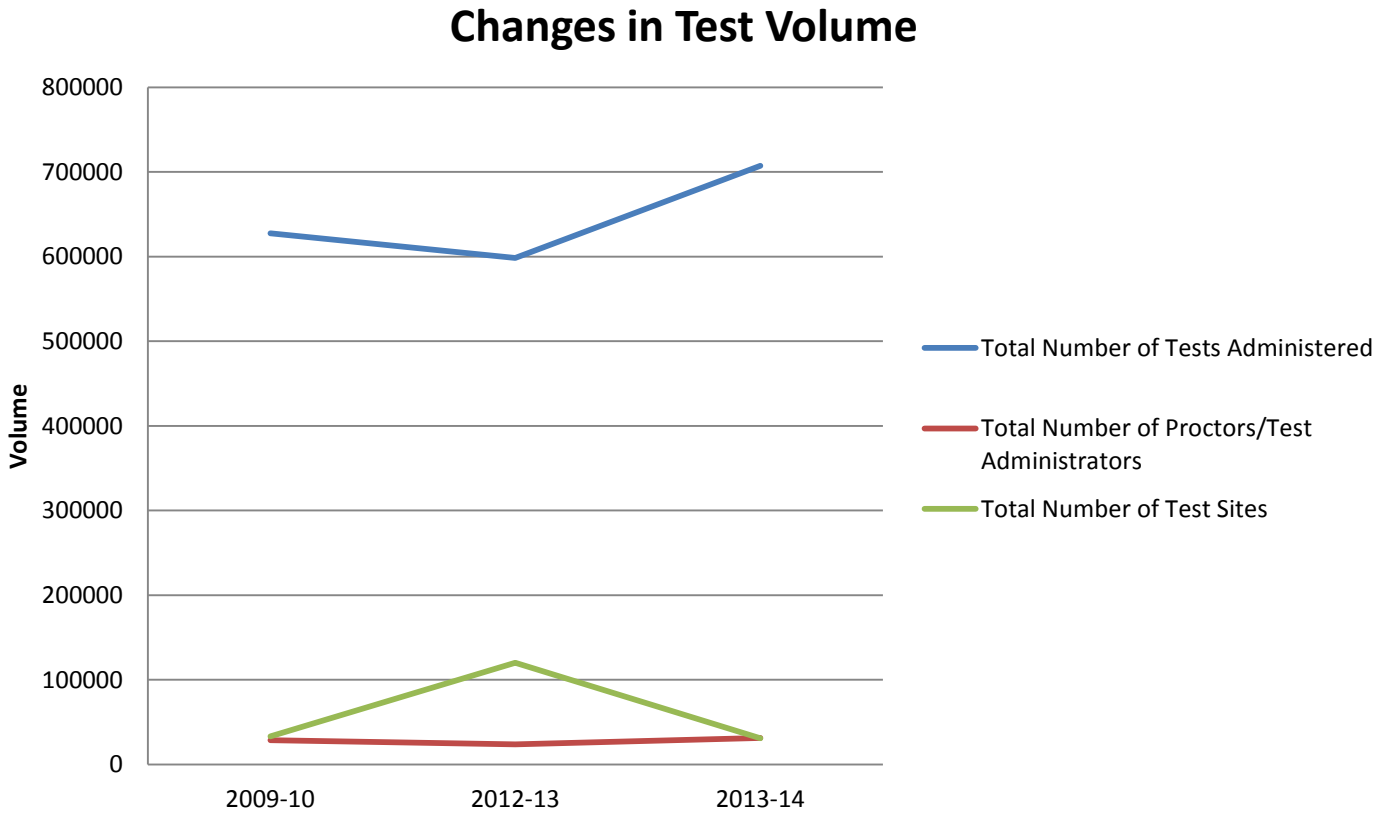
- Significant efforts being made to prevent test security breaches
  - Best practices should be disseminated to all providers
- Management QA System fully implemented in 2012-13
- Continue to monitor test security as part of ANSI annual surveillance

CPFM is a Big Deal



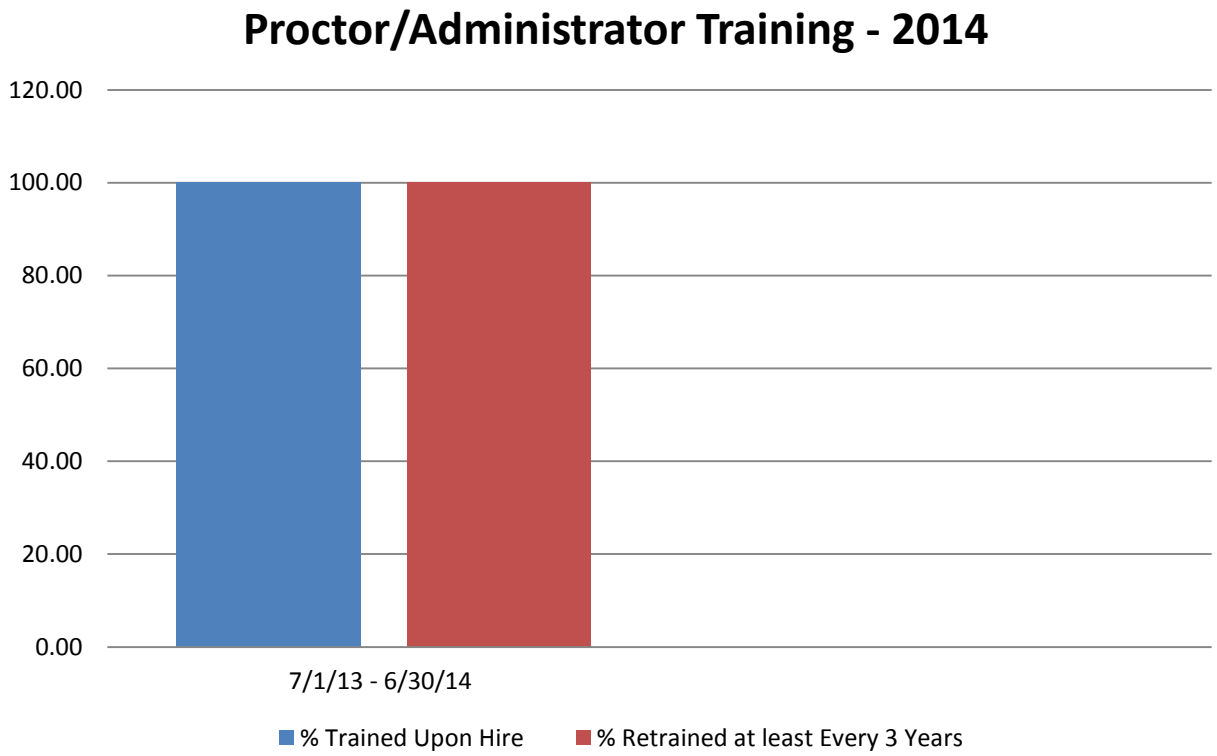
- Large numbers pose challenges for close policing

Testing Volume Trend: 2009-2014



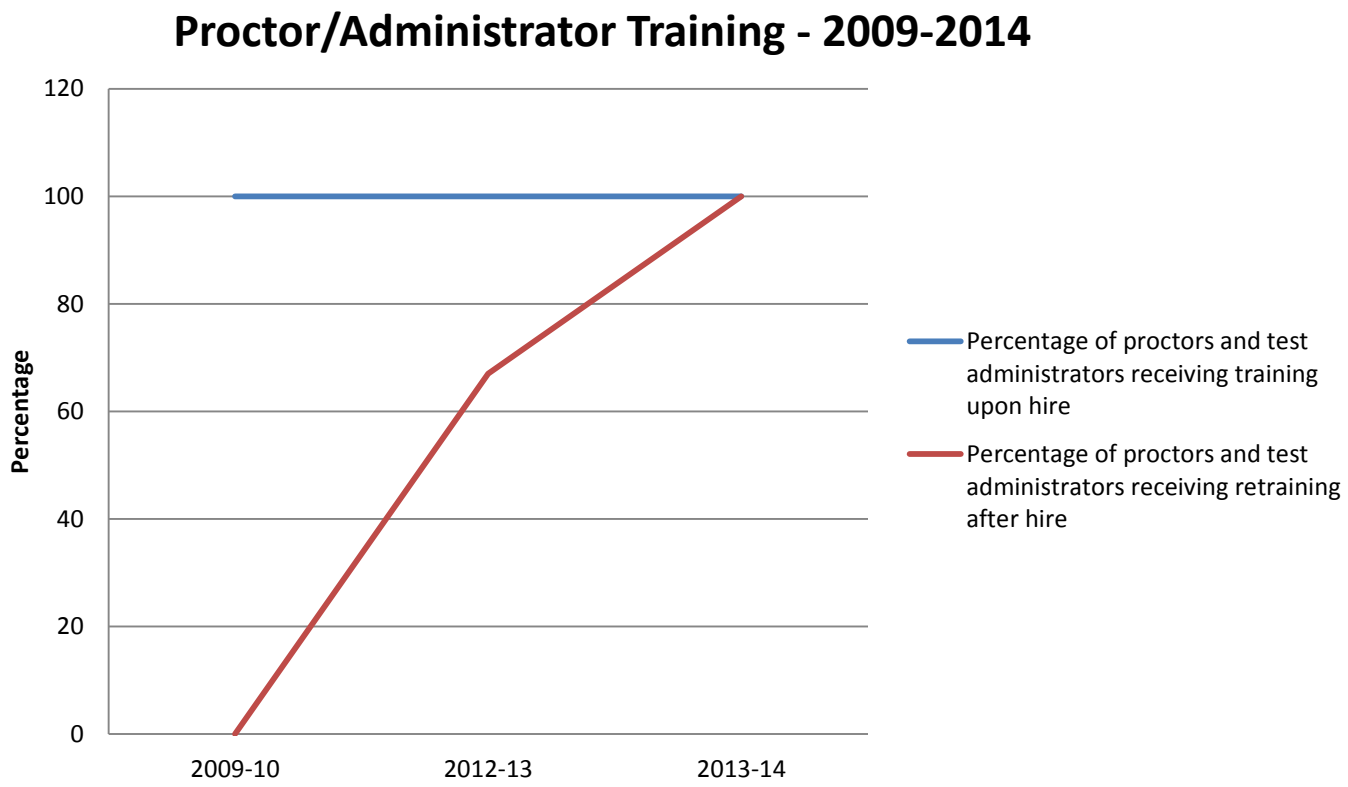
- Test Volume and Test Sites show no clear pattern; # of Proctors/Administrators shows little change.

Goal One: Provide Regular Training for Proctors/Administrators



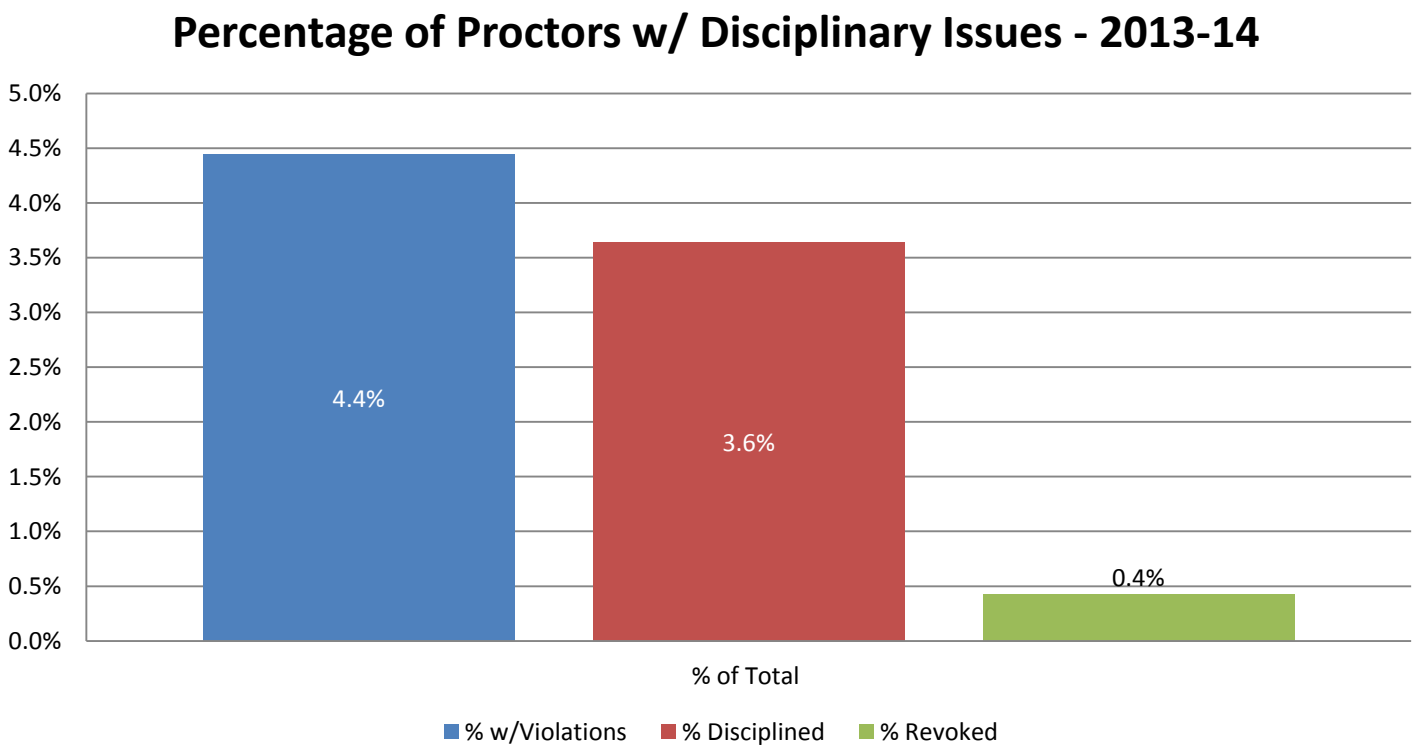
- Goal has been achieved with 100% compliance.

Change in Retraining: 2009-2014



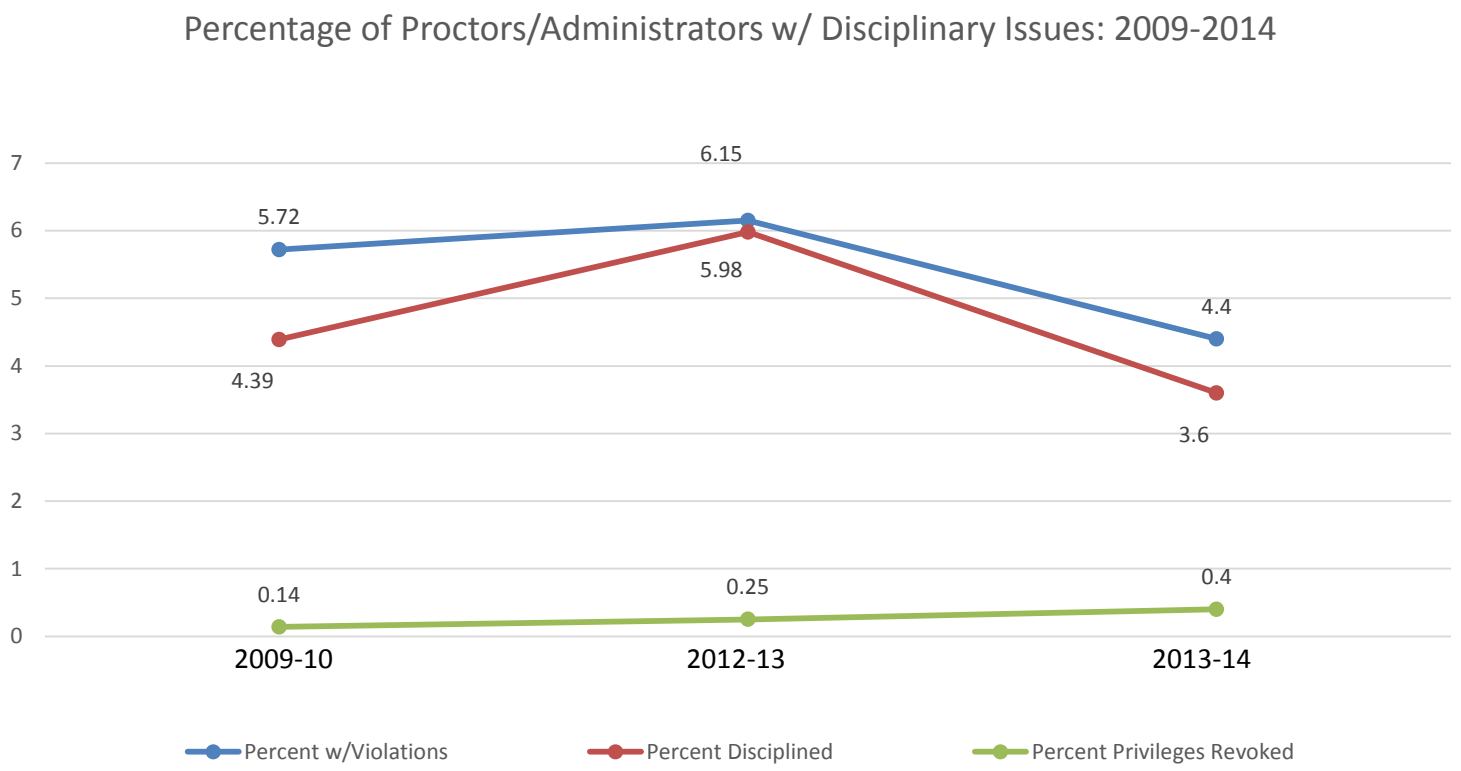
- All Retraining completed in 2014.

Goal One: Enforce Proctor/Administrator Disciplinary Actions



- In 2014, violations decreased while revocations increased, indicating greater enforcement.

Changes in Proctor/Administrator Disciplinary Actions: 2009-2014



- Disciplinary issues initially went up, then down, while revocations have steadily increased.

Primary Reasons for Violations - 2014

1. Failure to return exams/answer sheets on time
2. Failure to return all materials, or to sign/seal return envelopes
3. Failure to use a traceable shipping carrier
4. Failure to follow proctor guidelines, including not being present the whole time or allowing test-takers to self-proctor
5. Suspected/confirmed cheating or colluding with test takers

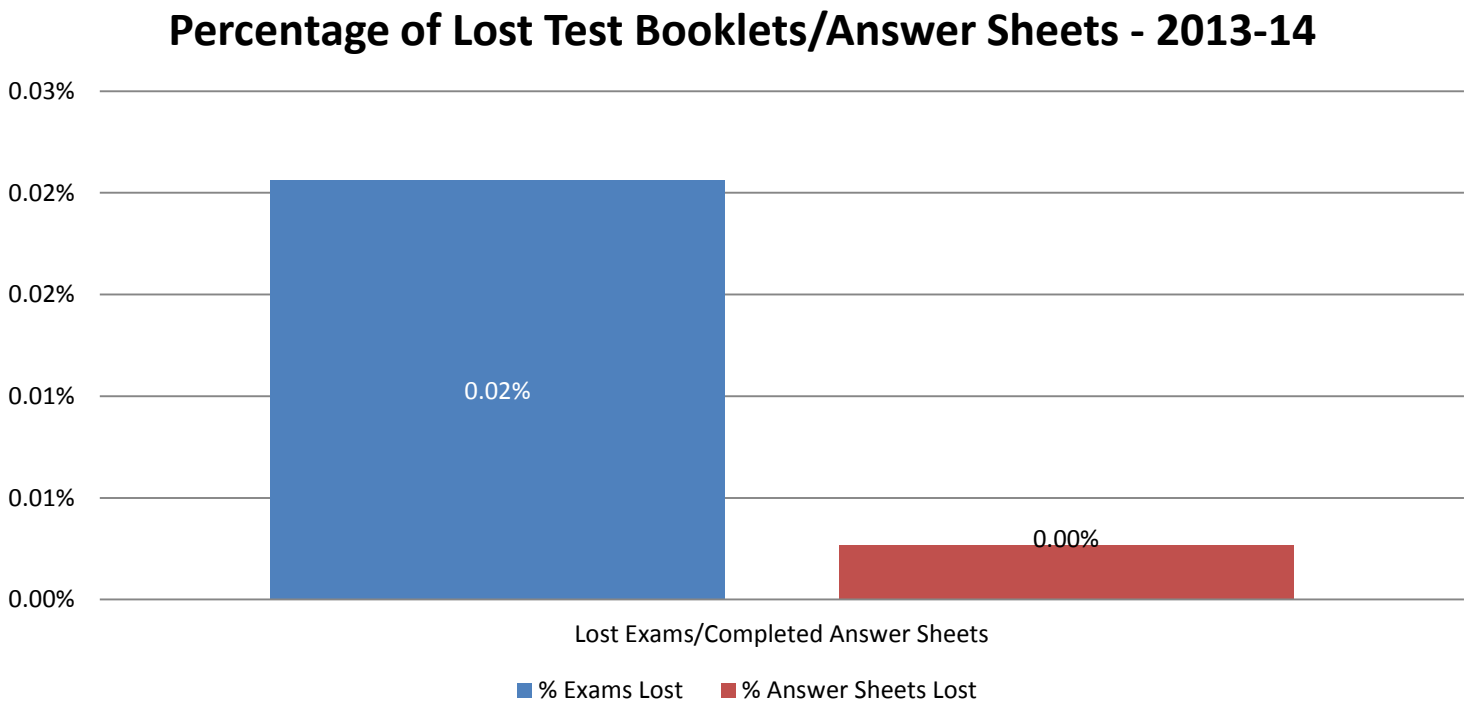
Most Common Disciplinary Actions

1. Warning for 1st offense, probation/suspension/ revocation for repeated offenses
2. One year probation/suspension for second offense
3. Revocation of privileges for colluding in cheating; suspected examinees required to re-test

Most Frequent Reasons for Revocation/ Suspension of Proctors

1. Resignation from the position (about 100 cases)
2. Confirmed/suspected case of cheating with proctor/administrator collusion, such as providing answers/coaching or allowing examinees to discuss test or use notes during exam (about 30 cases)

Goal Two: Reduce Exam Packaging and Shipping Irregularities



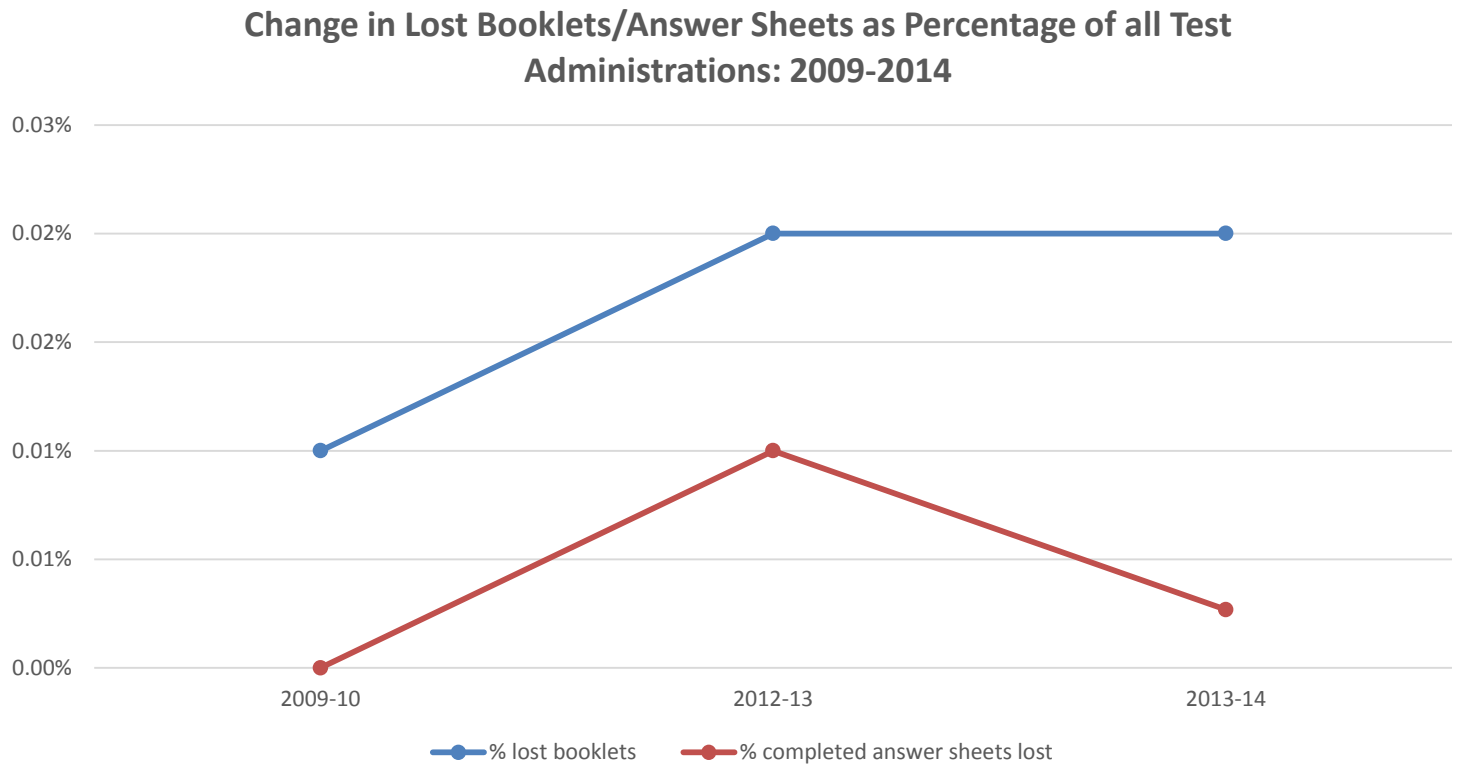
- In 2013-14, 2 out of 10,000 exams lost, the same rate as last year. Lost answer sheets are exceedingly rare.

Most Frequent Reasons for Lost Exams/ Answer Sheets: 2013-14

1. Proctors improperly disposed of unused exams – shredding or trashing
2. Carrier lost the package
   - Regular mail is not reliable
   - Even traceable carriers lose packages sometimes (19 answer sheets lost in 2013-14)
3. Proctors lost extra exams/answer sheets; presumed stolen

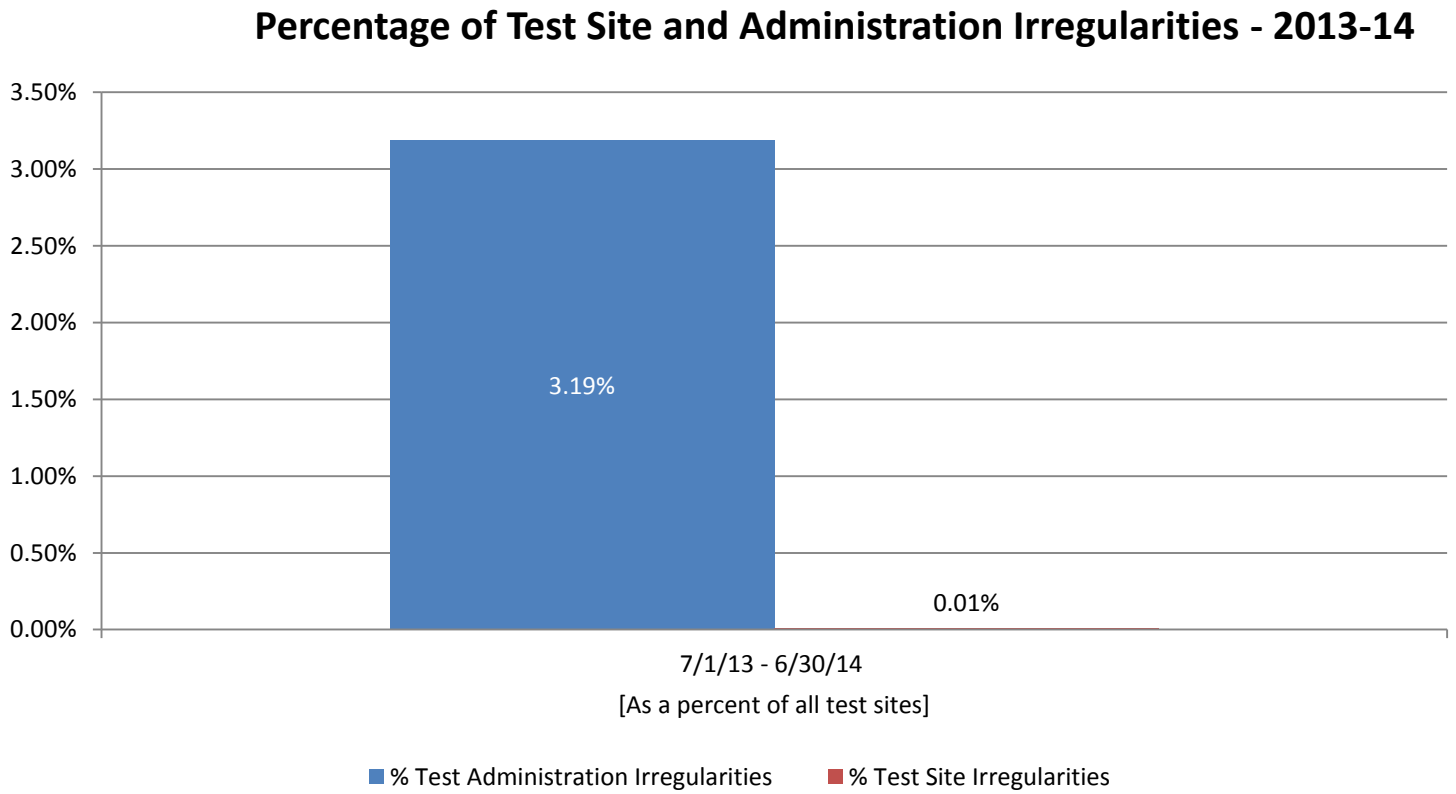
SEWG

Changes in Lost Materials: 2009-2014



- Increase in reported lost materials from 2009 to 2013, steady to decreasing in 2013-14.

Goal Three: Reduce Test Site Irregularities



- In 2013-14, Test Administration problems show big increase, while test site problems remain small.

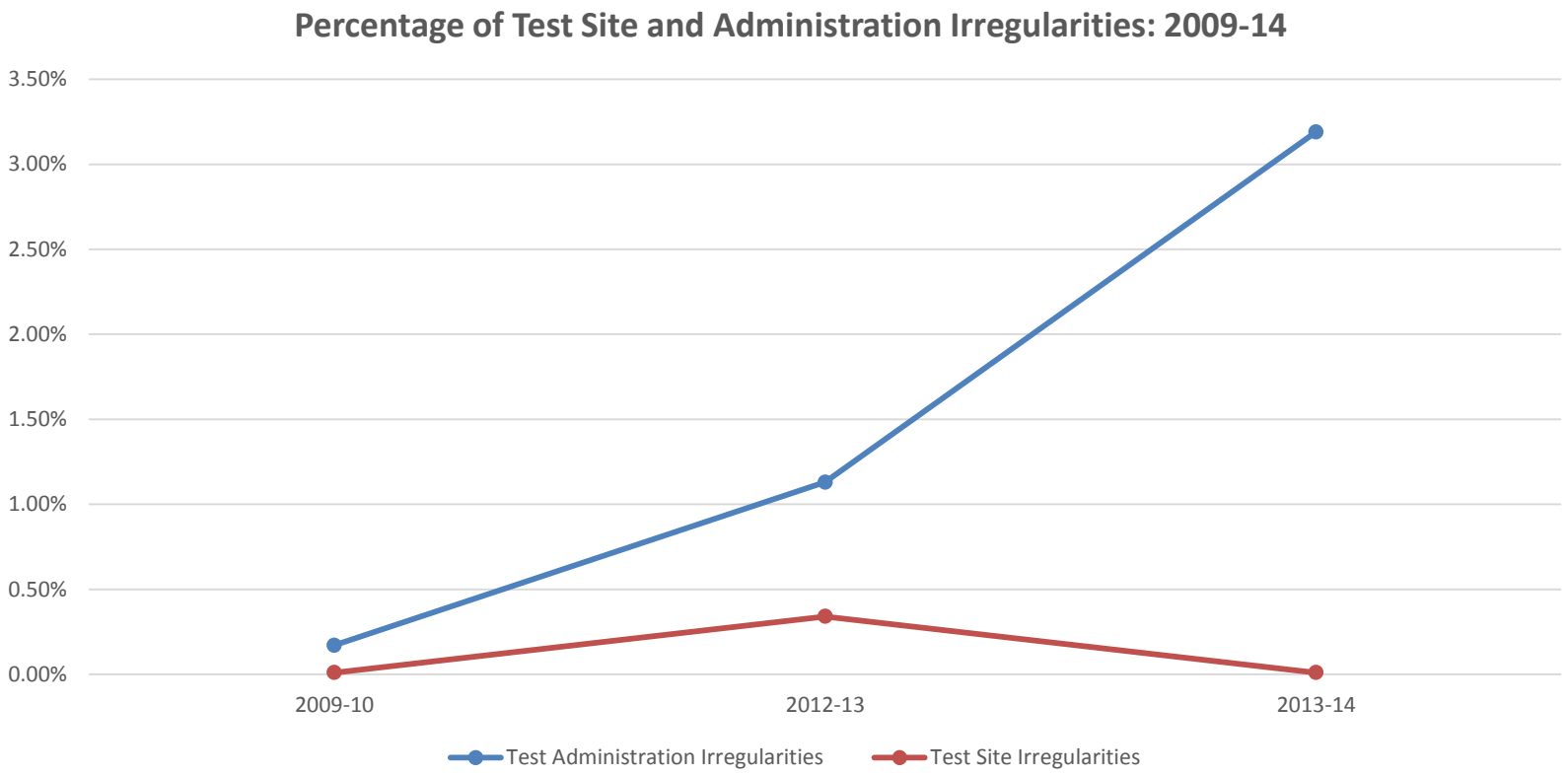
Most Frequent Reasons for Test Administration Irregularities

1. Failure to follow shipping policies for returning materials on time
2. Failure to properly return all materials via traceable carrier
3. Failure to follow policies and procedures for proctoring – partially unproctored or self-proctored exams
4. Cheating or collusion: candidates were allowed to talk in a foreign language during the exam, proctor colluded in cheating, candidates shared notes during exam

Most Frequent Reasons for Test Site Irregularities in 2014

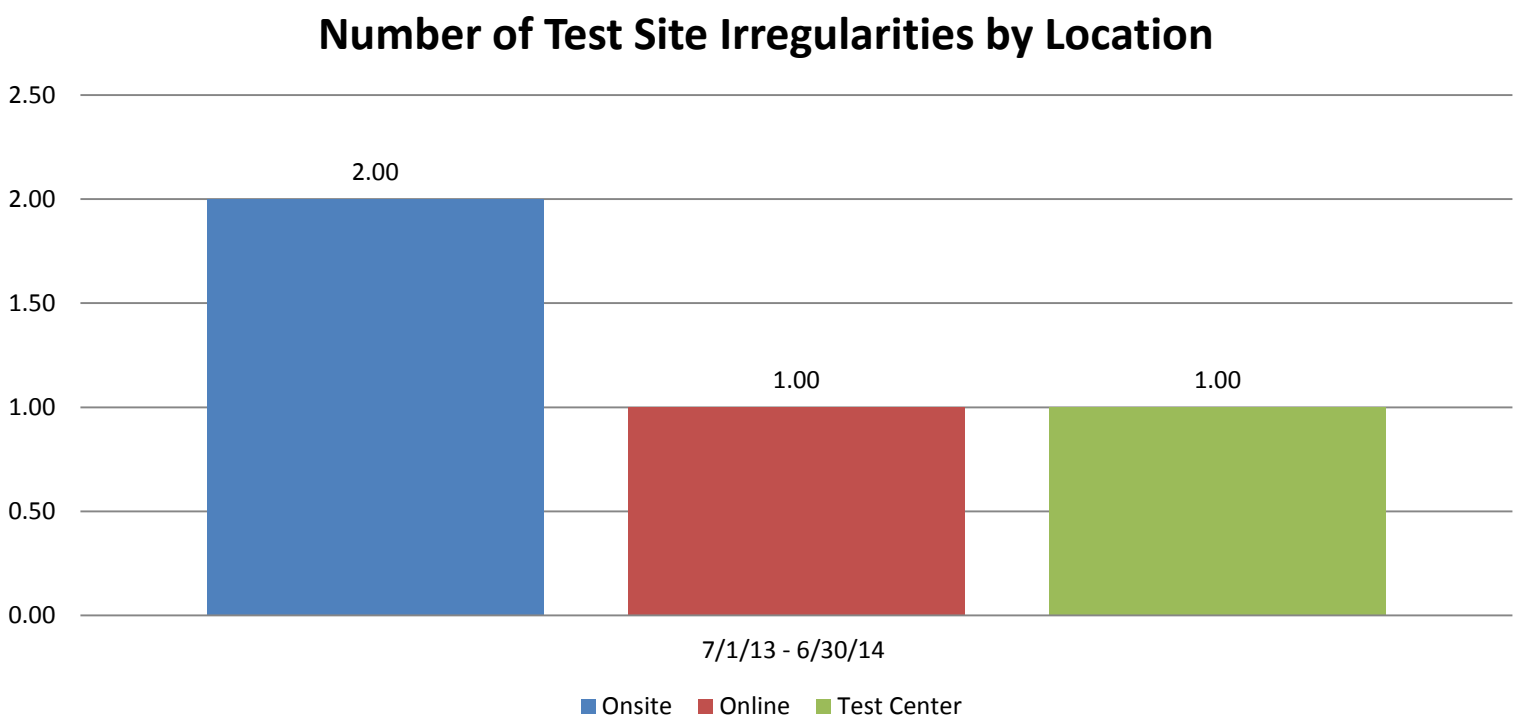
1. Candidate demographic changes (wrong name or other personal information at registration)
2. Exam was given in a restaurant during service or otherwise interrupted by outside noise
3. Examinees were allowed to sit too close together
4. Technical issue with online testing site hardware

Changes in Test Irregularities as Percentage of all Test Locations



- Increase in reported administration irregularities probably due to increased detection; test site problems decreasing.

Where Test Site Irregularities Occurred: 2013-14

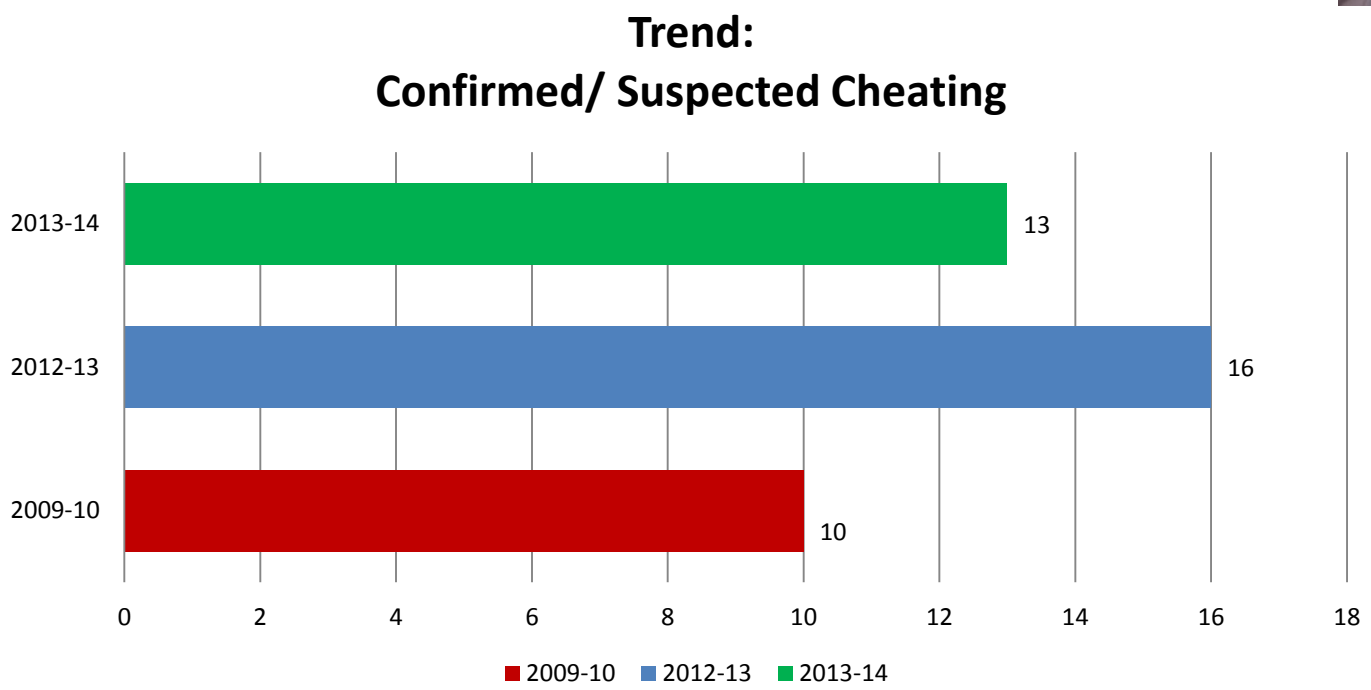


- Test site irregularities show decline across all sites.

Reasons for Site Irregularities – 2014

1. Candidate registration information was wrong – name or other personal information incorrect
2. Exam material delivery problem – materials did not arrive on time or items were missing
3. Testing in a public or noisy venue (restaurant during dining service)
4. Technical issue with online testing hardware/network

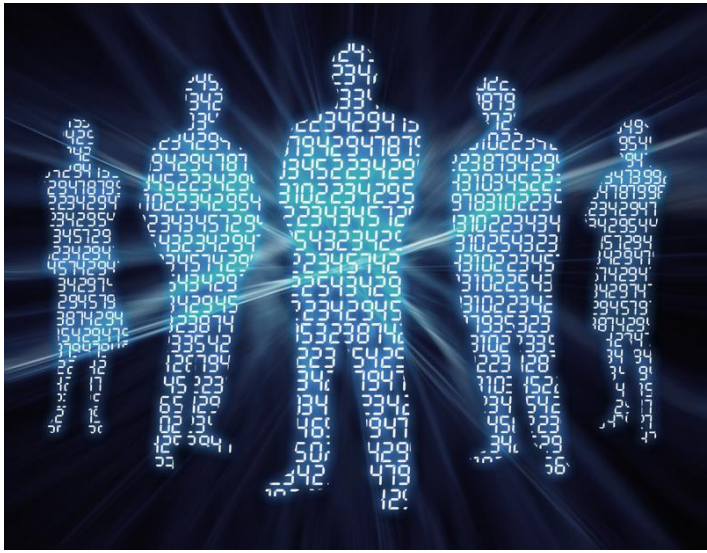
Goal Four: Reduce Cheating and Test Administration Irregularities



- Trend was up initially, but down last year. Better detection and enforcement today.

Data Forensics Employed to Combat Cheating

1. Item Analysis (4)*
2. Pass Rate Analysis – compare by group/proctor (2)*
3. Item Difficulty (p-value) Analysis (1)*
4. Point Biserial Correlation (1)*
5. Online exam time Analysis (1)*
6. Incident Response Investigation (3)*



*Numbers in () indicate how many providers report using this.

Most Frequent Corrective Actions Taken To Combat Cheating

1. Use multiple versions of the exam at each administration (4)*
2. Revoke proctor privileges for collusion (3)*
3. Enforce spacing and other environmental guidelines (2)*
4. Use biometrics to verify examinee identify (1)*
5. Require examinees to retest when cheating is suspected (2)*
6. Adopt better exam forensic analysis methods (1)*
7. Increase exam session audits (1)*

*Numbers in () indicate how many providers report using this.

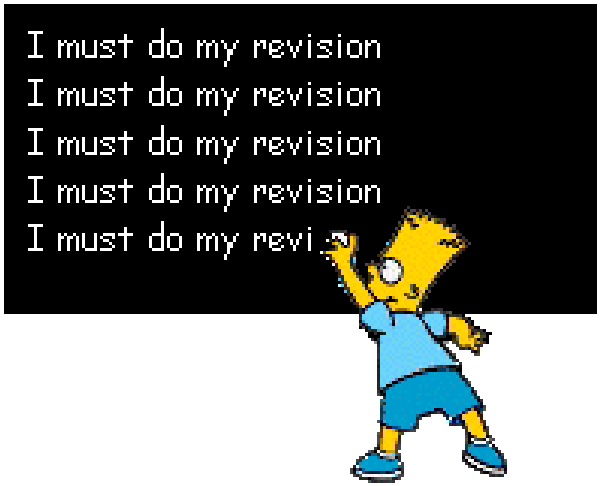
Test Versions and Revisions

Versions Employed:

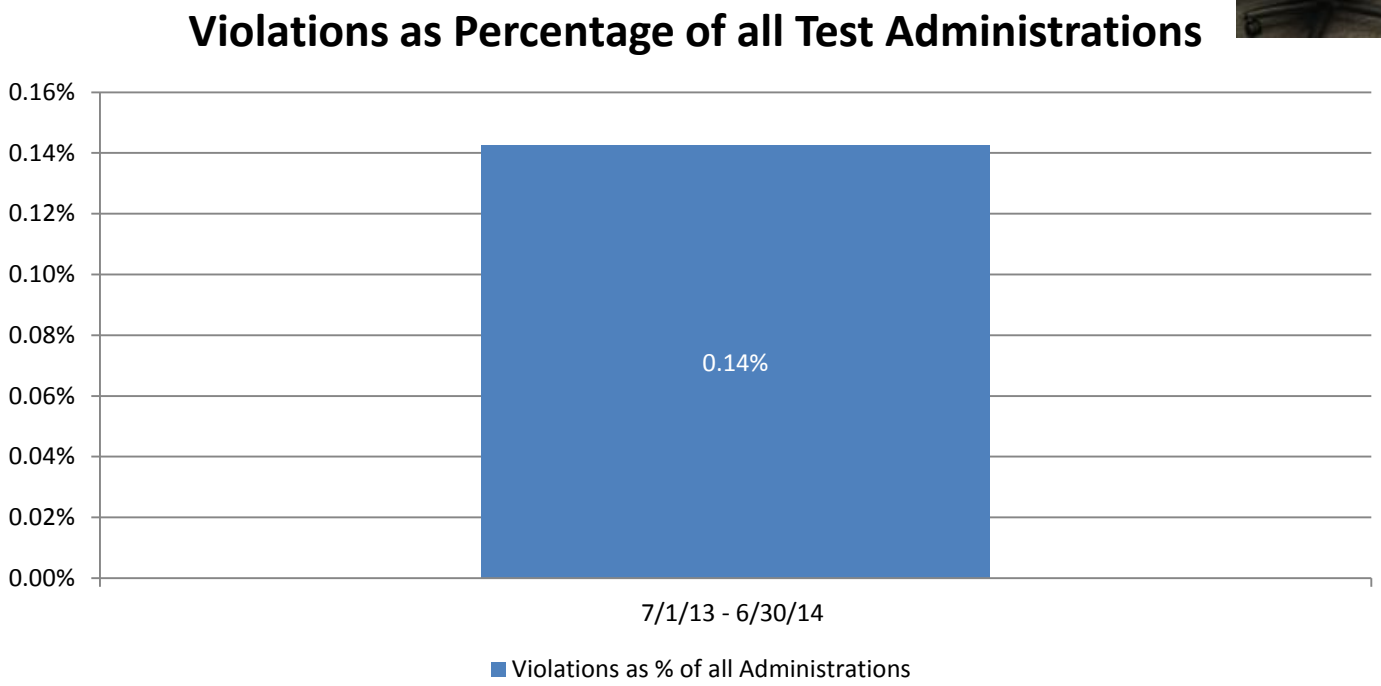
- Minimum of 2 versions/administration
- Maximum of 8 versions used
- Avg = 4

Revision Frequency:

- Minimum of yearly
- Maximum of monthly
- Avg = quarterly



Test Administration Violations



- One out of 1400 test administrations contains a violation, though most are minor.

Most Frequent Reasons for Test Administration Irregularities

1. Failure to return all test materials on time
2. More exam booklets opened than answer sheets
3. Failure to monitor examinees during entire exam
4. Self-administration of exam
5. Proctor collusion in cheating

Change in Percentage of Administration Violations: 2009-2014

- Decrease in percent of violations over last year shows progress.

Goal Five: Improve Test Quality Assurance

- 2009-10: Only 1 of 3 providers had QA system installed and it was incomplete
- 2012-13: All 4 providers had QA system in place, but still implementing some features
- 2013-14: QA system fully functional for all providers

This goals has been achieved by 100% of providers.

QA System Elements in Place -2014

- Document control (4)*
- Internal audit (3)*
- Management review (4)*
- Exam security plan (1)*
- External audit/certification (1)*

*Numbers in () indicate how many providers report having this in 2013-14.

Most Frequent Reasons for QA System Breaches

1. Failure to return test materials on time
2. Lost test booklets/completed answer sheets
3. Candidate demographic information missing/incorrect
4. Forensics uncovered possible cheating/collusion

Provider Perceptions of Test Security Breaches

- "After implementing all the changes [over the past 5 years], our quantity of breaches has dramatically decreased."
- "We are a trusted test development and delivery provider to more than 400 organizations worldwide. On their behalf, we securely deliver an average of 10 million exams per year. We serve as an industry gatekeeper, ensuring that people legitimately earn the credentials they seek to achieve, and thereby guaranteeing a fair testing experience for all who come through our doors."

Recommendations

- Proctors/Administrators:
  - Increase screening, selection and training standards
  - Continue to vigorously apply disciplinary actions against offenders
- Shipping Irregularities:
  - Use traceable carriers only, especially those with high reputation for security and reliability
  - Continue to enforce rules for shipping

Recommendations (cont'd)

- Test Sites/Administration:
  - Standardize test site requirements across all providers
  - Share best practices for administration
- Test Cheating:
  - Share best practices for data forensics and cheating detection
  - Encourage test-takers to report cheating (whistleblower hotline)
- QA System:
  - Fully implement all features for all providers
  - Use it as preventive mechanism and early warning system

Future Steps

- Present findings to key stakeholders
- Identify areas for further improvement
- Fine tune data collection methods as needed
- Include test security evaluation as part of ANSI annual surveillance and monitor trends

Thank you for the opportunity to work with CFP!
Don Ford

CFP Standards for Accreditation of Food Protection Manager Certification Programs (2012) and CFP Required Documentation	ISO/IEC 17024:2012 International Standard: Conformity assessment – General requirements for bodies operating certification of persons and ISO Required Documentation	U of H Evaluation	Committee Evaluation	Demonstration of Compliance Substantially Equivalent?	
2.0 Purpose of Certification					
3.3 If a certification organization provides both education and certification, the certification organization shall administratively and financially separate any education and certification functions that are specific to Food Protection Manager Certification to ensure that the certification program is not compromised. This may be satisfied if the governing structure documents to the accrediting organization the distinct separation of the two functions, confirming that no undue influence is exercised over either the education or the certification	**4.3.1** The certification body shall document its structure, policies and procedures to manage impartiality and to ensure that the certification activities are undertaken impartially. The certification body shall have top management commitment to impartiality in certification activities. The certification body shall have a statement publicly accessible without request that it understands the importance of impartiality in carrying out its certification activities, manages conflict of interest and ensures the objectivity of its certification activities. **4.3.6** The certification body shall identify threats to its impartiality on an ongoing basis. This shall include those	**YES**	**NO**	CFP 3.3 has more precision in regards to the separation of educational and certification functions. The intent of ISO 4.3.1 and 4.3.6 are similar describing impartiality, influence and threats. This is management and impartiality. What about ISO 5.2? Structure of the Certification body in relation to training and 5.2.3?	
process by virtue of the structure within the association, organization, agency or another entity.	threats that arise from its activities, from its related bodies, from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a body with a threat to				
3.4 Resources of Certification Organizations. The certification organization shall conform to all CFP standards for accreditation and demonstrate	**4.3.7** The certification body shall analyze, document and eliminate or minimize the potential conflict of interests arising from the certification of activities of persons. The certification body shall document and be able to demonstrate how it eliminates, minimizes or manages such threats. All potential sources of conflict of interest that are identified, whether they arise from within the certification body, such as assigning responsibilities to personnel, or from the activities of other persons, bodies or organizations, shall be covered. **4.3.8** Certification activities shall be	**YES**	**NO**	CFP 3.4 discusses conformity while ISO 9.2.6 discusses conformity when work is performed by a 3rd party. This is not exactly the same intent. ISO 10.2.7 goes into detail to discuss non- conformity issues.	

6		**6.1.7** The certification body shall require its personnel to sign a document by which they commit themselves to comply with the rules defined by the certification body, including those relating to confidentiality, impartiality and conflict of interests. NOTE Where permitted by law, an electronic signature is acceptable. **6.1.8** When a certification body certifies a person it employs, the certification body shall adopt procedures to maintain impartiality				
7	**4.0 Food Safety Certification Examination Development**					
8	**4.2** Each certification organization shall provide evidence that it meets the following professional requirements:					
9	**4.2 B** demonstrated experience in the development of psychometrically valid competency examinations;	**8.4a** The certification body shall have documents to demonstrate that, in the development and review of the certification scheme, the following are included: the involvement of appropriate experts;	**YES**	**NO**	The terms used here are experience vs. appropriate experts. One could argue that if the experts are appropriate that they will have demonstrated the proper experience necessary in the development of the exams. The use of "demonstrated experience" and "appropriate experts" can be interchanged. Certification assessors working with ANSI understand the relationship of the language and	
10	11	**7.4 Security** **7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches occur. **7.4.2** Security policies and procedures shall include provisions to ensure the security of	**YES**	**NO**	Security is an important issue for both organizations however, each group details different aspects. First, let's make sure that we understand that we're dealing with "standards'" not groups. That said, "Demonstrating capability to develop..." is very	

11	12	**10.2.4 Control of records** The certification body shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfillment of this International Standard. The certification body shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements. NOTE For requirements for records on applicants, candidates and certified persons, see also 7.1.	**YES**	**NO**	CFP 4.2 D is specific to archiving exam scores while ISO 10.2.4 describes overall procedures for all record keeping including exam scores. First, let's make sure that we understand that we're dealing with "standards"' not groups. That said, "Demonstrating capability to develop..." is very different from developing document policies and procedures as prescribed in 17024. ISO 17024 is very clear in the development of a documented management system that ensures the integrity of the entire certification process. For consumers there is the assurance that an individual taking that exam is certified by a program that has been documented and approved. The CFP standard remains weak	
12	**4.2 E** demonstrated evidence of an understanding of and willingness to abide by the principles of fairness and due process.	**8 Certification schemes**	**YES**	**NO**	These are essentially the same however, the wording is different. Terms such as demonstrate and document and implement are used respectively. I'm not sure the intent is the same for these two sections. The ISO Standard speaks specifically to the "fairness" of the exam, while the CFP Standard seems more directed to the overall process. Demonstrated evidence is, in of itself, a lower demonstration of performance than the specific	

13	**4.3** The certification organization shall provide complete information about the food safety certification examination, including that related to procedures and personnel involved in all aspects of the examination development and analysis. The information required for accreditation will include but is not necessarily limited to:	**8.4** The certification body shall have documents to demonstrate that, in the development and review of the certification scheme, the following are included: a) the involvment of appropriate experts; b) the use of an appropriate structure that fairly represents the interests of all parties significantly concerned, without any interest predominating; c) the identification and alignment of prerequisites, if applicable, with the competence requirements; d) the identification and alignment of the assessment mechanisms with the competence requirements;	**YES**	**NO**	While these clauses are similar, ISO details more information concerning the development of the certification scheme, the CFP document gives more specific direction in the following sub clauses. Again, ISO is more prescriptive in aligning measurement tools, industry experts, etc., as part of the policies and procedures. ANSI holds ISO accredited organizations to a higher standard in identifying subject matter experts and development	
14		e) a job or practice analysis that is conducted and updated to: - identify the tasks for successful performance; - identify the required competence for each task; - identify prerequisites (if applicable); - confirm the assessment mechanisms and examination content; - identify the re-certification requirements and interval. NOTE Where the certification scheme has been developed by an entity other than the certification body, the job or practice analysis might already be available as part of that work. In this case, the certification body can obtain details from the scheme			creation. The CFP standard remains open- ended and open to loose interpretation by both CBs and assessors. While, at face value, it may not seem like a weakness, it opens the door to less reputable firms achieving accreditation under CFP but delivering a program that may not effectively certify individuals.	
15	**4.3 A** complete description of the scope and usage of the examination;	**8.2** A certification scheme shall contain the following elements: a) scope of certification; b) job and task description; c) required competence; d) abilities (when applicable); e) prerequisites (when applicable); f) code of conduct (when applicable). NOTE 1 A code of conduct describes the ethical or	**YES**	**NO**	Again, CFP states “complete descript” and the ISO document gives specific directives. The open-ended nature of the CFP requirements leaves the standard open for interpretation and risks.	
16		personal behavior required by the scheme. NOTE 2 Abilities can include physical capabilities such as vision, hearing and mobility.				

17	**4.3 B** job analysis task list, with knowledge, skills, and abilities (KSAs);		**NO**	**YES**	The following CFP sub clauses give specific details that are not included in the ISO document. I would say yes here, that the intent is substantially equivalent to section 8.4 (e) of ISO The CFP Standard is specific to food safety and, because of the specificity, mandated development related to food managers. The more in-depth approach of 17024 allows CBs to develop against a specific	
18	**4.3 C** *examination specifications;*		**NO**	**NO**	The following CFP sub clauses give specific details that are not included in the ISO document. Section 8.4 (e) of ISO covers “a job or practice analysis”, “identify tasks”, “required competence for each task”, etc. Section 8.4 (e) of ISO covers “a job or practice analysis”, “identify tasks”, “required competence for each task”, etc.	
19					The CFP Standard is specific to food safety and, because of the specificity, mandated development related to food managers. The more in-depth approach of 17024 allows CBs to	
20	**4.3 D** The number of unduplicated items in the item bank;		**NO**	**NO**	The following CFP sub clauses give specific details that are not included in the ISO document. The CFP Standard is specific to food safety and, because of the specificity, mandated development related to food managers. The more in-depth approach of 17024 allows CBs to	

21	**4.3 E** statistical performance of each item in the bank;		**NO**	**NO**	The following CFP sub clauses give specific details that are not included in the ISO document. I would say YES here. 4.3E of CFP seems equivalent to 9.3.5 in ISO. 9.3.5 in ISO addresses collecting and maintaining statistical data, although not as specific as CFP which requires this on every item in the bank. The CFP Standard is specific to	
22					managers. The more in-depth approach of 17024 allows CBs to develop against a specific scheme / scope.	
23	**4.3 F** number of examination forms and evidence of their equivalence to each other;		**NO**	**NO**	The following CFP sub clauses give specific details that are not included in the ISO document. The CFP Standard is specific to food safety and, because of the specificity, mandated development related to food managers. The more in-depth approach of 17024 allows CBs to develop against a specific	
24	**4.3 G** description of method used to set passing score;		**NO**	**NO**	The following CFP sub clauses give specific details that are not included in the ISO document. The CFP Standard is specific to food safety and, because of the specificity, mandated development related to food managers. The more in-depth approach of 17024 allows CBs to	
25	**4.3 H** copies of all logs, diaries, and personnel lists and descriptions kept as required in the development process;		**NO**	**NO**	The following CFP sub clauses give specific details that are not included in the ISO document.	
26					The CFP Standard is specific to food safety and, because of the specificity, mandated development related to food managers. The more in-depth approach of 17024 allows CBs to	

27	**4.3 I** summary statistics for each examination form; and		**NO**	**NO**	The following CFP sub clauses give specific details that are not included in the ISO document. I would say YES here as above based on equivalency to 9.3.5 in ISO The CFP Standard is specific to food safety and, because of the specificity, mandated development related to food managers. The more in-depth approach of 17024 allows CBs to develop against a specific	
28	**4.3 J** names, credentials, and demographic information for all persons involved in the job analysis, item writing and review, and setting the passing score.	**8.4** The certification body shall have documents to demonstrate that, in the development and review of the certification scheme, the following are included: a) the involvement of appropriate experts; b) the use of an appropriate structure that fairly represents the interests of all parties significantly concerned, without any interest predominating;	**YES**	**NO**	CFP standard is much more prescriptive as to documentation of names, credentials, etc. Again, the specificity of 17024 leaves nothing to interpretation strengthening the value of the ISO standard.	
29		c) the identification and alignment of prerequisites, if applicable, with the competence requirements; f) the identification and alignment of the assessment mechanisms with the competence requirements; g) a job or practice analysis that is conducted and updated to: - identify the tasks for successful performance; - identify the required competence for each task; - identify prerequisites (if applicable); - confirm the assessment mechanisms and examination content; - identify the re-certification requirements and interval. NOTE Where the certification scheme has been developed by an entity other than the				

30	**4.4 Job Analysis.** The content validity of a food safety certification examination shall be based on a psychometrically valid job analysis developed by psychometricians and a demographically and technically representative group of individuals with significant experience in food safety. The representative group shall include but not necessarily be	**8.4b** The certification body shall have documents to demonstrate that, in the development and review of the certification scheme, the following are included: the use of an appropriate structure that fairly represents the interests of all parties significantly concerned, without any interest predominating;	**YES**	**NO**	ISO 8.4b uses the term "all interested parties" while the CFP lists specific segments of the food industry. The ISO standard is designed to support accredited organizations that wish to certify people in other professions. The open approach but specificity of the	
31	of the retail food industry, persons with local, state or national regulatory experience in retail food safety, and persons with knowledge of the microbiology and epidemiology of foodborne illness, and shall be sufficiently diverse as to avoid cultural bias and				That said, it is important here that the CFP standard remain prescriptive so it is not intended to certify individuals in other, unrelated or even related fields.	
32	**4.6** Detailed food safety certification examination specifications shall be derived from a valid study of the job analysis tasks and their accompanying knowledge, skills, and abilities (KSAs) and shall be appropriate to all aspects of the retail food industry. The job analysis shall include consideration of scientific data concerning factors contributing to foodborne illness and its epidemiology. The examination specifications, consisting of percentage weights or number of items devoted to each content		**NO**	**NO**	This clause is food safety specific and is outside of the scope of the ISO document. Again, this clause must be specific because the CFP program is food only. However assessed organizations must provide even more robust information detailed throughout standard 8.4 in the ISO Standard. In fact the ISO standard holds CBs to a higher standard	
33	**4.7** The certification organization or its contracted examination provider shall maintain a log and diary of the procedures and a list of the qualifications, identities, and demographic data of the persons who participated in development of the job analysis and of the food safety certification examination specifications. Those materials shall be provided to the	**6.1.5** The certification body shall maintain up-to-date personnel records, including relevant information, e.g. qualifications, training, experience, professional affiliations, professional status, competence and known conflicts of interest.	**NO**	**NO**	The people who participate in exam development (4.7) are very different from those who work for the CB. In 6.1.5 ISO seeks to ensure that those who work within the CB have the qualifications to effectively and fairly manage a certification program. This is	
34	**4.9** Psychometric Standards. Food safety certification examination development, including setting the passing score, shall be based on the most recent edition of Standards for Educational and Psychological Testing, developed jointly by the American Psychological Association, American Educational		**NO**	**NO**	I agree that there is not an equivalent section in the ISO standard for CFP section 4.9, but I disagree with this statement. This clause (4.9) although it does mention "food safety certification" is not food safety specific. It intends to utilize best practices of	

35	Education, and on all appropriate federal requirements (for example, Americans with Disabilities Act). Food safety certification examinations shall be revised as needed to be in compliance with changes in the Standards for Educational and Psychological Testing or in any of the federal requirements.				Educational Research Association, etc.) which are not food safety agencies. The ISO Standard does mandate demonstration of a criterion referenced passing score as well as overarching requirements for fairness. Again, because the CFP standard has been designed as industry- specific the need to be more prescriptive	
36	**4.11** The food safety certification examination shall be based on psychometrically valid procedures to ensure the relative equivalence of scores from various examination forms. The certification organization shall provide	**9.2.4** The certification body shall verify the methods for assessing candidates. This verification shall ensure that each assessment is fair and valid.	**YES**	**NO**	Documents discuss the validity and verification however, CFP 4.11 discusses the relative equivalence of scores from carious examination forms and the ISO document does not	
37					I would say NO here. 9.2.4 is more suited with the intent of 9.2.3 above which aligns with CFP 4.10. I do not think CFP 4.11 and ISO 9.2.4 are equivalent in intent at all. Equivalency is not the same as assessment methodology. Equivalency means that Sharon Wood and Larry Lynch take two different exams forms from the same CB; we have an equal opportunity to pass that exam. In this case we need to be sure that we have weighted the questions against specific criteria. The ISO standard does not presume a specific methodology is presumed so the CB must	

38	**4.13** When any form and/or item bank of the food safety certification examination is translated into a language other than that in which it is originally developed and validated, the developer of the examination shall provide evidence of content equivalency of the translated version with the original examination form and/or item bank. The developer shall provide a detailed description of the translation method(s), including the rationale for selecting the translation method(s), and shall demonstrate congruence of items and instructions with those of the examination form and/or item bank that was translated. To avoid potential problems in translation of terms specific or idiomatic to the retail food industry, translation should be accomplished with the consultation of food safety personnel competent in the		**NO**	**NO**	The ISO document does not discuss exams being translated into languages other than that which it was originally developed. If you go back and read 9.3.1 you'll see that it is a determinant of equivalence and validity. Because the CFP standard is industry specific it has to have language specific to translation. However CBs who develop exam programs under 17024 must demonstrate equivalence across a wide variety of spectra including language.	The ISO document does not discuss exams being translated into languages other than that which it was originally developed. If you go back and read 9.3.1 you'll see that it is a determinant of equivalence and validity. Because the CFP standard is industry specific it has to have language specific to translation. However CBs who develop exam programs under 17024 must demonstrate equivalence across a wide variety of spectra including language.
39	**4.14** Food safety certification examination developers shall maintain a log and diary of the procedures and a list of the qualifications, identities, and demographic data of the persons who participated in item development, examination development, translations, setting the	**6.1.5** The certification body shall maintain up-to-date personnel records, including relevant information, e.g. qualifications, training, experience, professional affiliations, professional status, competence and known conflicts of interest.	**YES**	**NO**	CFP 4.14 and ISO 6.1.5 discuss record keeping of individuals who contributed to the development of the materials. CFP 4.14 also discusses the administering of the exams and that they must be proctored. ISO	CFP 4.14 and ISO 6.1.5 discuss record keeping of individuals who contributed to the development of the materials. CFP 4.14 also discusses the administering of the exams and that they must be proctored. ISO 9.3.3 vaguely refers to this in terms of
40	items and of the full examination. The materials shall be provided to the accrediting organization on demand. All examinations shall be delivered and administered in a format that ensures the security of the examination (i.e. in a secured environment with a test administrator/proctor.) Un- proctored examinations are not acceptable regardless of the mode of administration.				See 4.7/6.1,5 for part 1. For the second part, Herein lies one of the greatest misconceptions of the ISO Standard. If you look at 9.3.3 it becomes the responsibility of the CB to develop and demonstrate the secure conditions for administering the exam. A presumption has been promulgated that the exam cannot be administered by	

41	**4.15** Examination Development Security. The certification organization will demonstrate that procedures are developed and implemented to ensure that individual items, item banks, food safety certification examinations presented in all media (printed, taped and computerized), test answer sheets and examinee scores are and remain secure. Demonstration shall include an overall examination security plan that covers each step in the examination development, culminating in the production of the examination.	**7.4 Security** **7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches occur. **7.4.2** Security policies and procedures shall include provisions to ensure the security of examination materials, taking into account the following: e) the locations of the materials (e.g. transportation, electronic delivery, disposal, storage, examination centre); f) the nature of the materials (e.g. electronic, paper, test equipment);	**YES**	**NO**	Again, both documents stress the importance of security however; ISO 7.4.1 and ISO 7.4.2 include the provisions necessary for ensuring the security of examination materials. Once again, herein lies one of the greatest misconceptions of the ISO Standard. If you look at 9.3.3 it becomes the responsibility of the CB to develop and demonstrate the secure conditions for administering the exam. A presumption has been	
42		development, administration, results reporting); h) the threats arising from repeated use of examination materials. **7.4.3** Certification bodies shall prevent fraudulent examination practices by: g) requiring candidates to sign a non-disclosure agreement or other agreement indicating their commitment not to release confidential examination materials or participate in fraudulent test-taking practices; h) requiring an invigilator or examiner to be present; i) confirming the identity of the candidate; j) implementing procedures to prevent any unauthorized aids from being brought into the examination area;			security process.	
43	**4.16** Periodic Review. At least semiannually each certification organization shall report to the accrediting organization, providing a review of its food safety certification examination(s). The report will include the following summary statistics for all examinations (for each examination used) administered during the preceding six months, as well as other information	**8.5** The certification body shall ensure that the certification scheme is reviewed and validated on an on- going, systematic basis.	**YES**	**NO**	4.16 references a review by the accrediting organization. 8.5 mandates a reviewed internally by staff and a scheme committee That review would ultimately be reviewed by an accrediting body.	

44	**4.16 A** number of food safety certification examinations administered;		**NO**	**NO**	These components are not included in the ISO document. Section 9.2.4 mandates the fairness of the exam. It must remain opened ended because the assessment methodology may be different. As a result, assessors would look at a variety of criteria that determine exam fairness and accuracy which is the ultimate outcome of measuring the various statistical outcomes of exam form analysis	
45	**4.16 B** mean;		**NO**	**NO**	These components are not included in the ISO document.	
46	**4.16 C** mode;		**NO**	**NO**	These components are not included in the ISO document	
47	**4.16 D** standard deviation;		**NO**	**NO**	These components are not included in the ISO document.	
48	**4.16 E** range;		**NO**	**NO**	These components are not included in the ISO document.	
49	**4.16 F** reliability coefficient;		**NO**	**NO**	These components are not included in the ISO document	
50	**4.16 G** number and percentage of examinees passing the examination; and		**NO**	**NO**	These components are not included in the ISO document.	
51	**4.16 H** the statistics describing the performance of each item used on food safety certification examinations administered during the six-month period		**NO**	**NO**	These components are not included in the ISO document.	
52	**5.0 Food Safety Certification Examination Administration**					

53	**5.0** *Food Safety Certification Examination Administration* . All sections of these Standards apply to Computer Based Testing (CBT) Administration except Section 5.1.	**ISO 9.3.2** The certification body shall have procedures to ensure a consistent examination administration. **ISO 7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches occur.	**NO**	**NO**	CFP is certainly more prescriptive. This is good and bad. The prescription reduces variability, but also restricts the exam providers ability to set their own industry best practices, and competitive advantage. The exam providers should be able to input processes according to industry best practices as part of their accreditation process. This fosters innovation and better products and services. The onus would be on ANSI to regulate "best practices". The other side, however, is that it also is much more subjective in interpretation of "best practices". ISO 9.3.2 and 7.4.1 may apply Agree ISO 17024 provides procedures and guidelines for the framework of the exam administration, CFP provides very specific procedures for the	

54	**5.1 Security for Examination Booklets.**	**7.4.2** Security policies and procedures shall include provisions to ensure the security of examination materials, taking into account the following: • the locations of the materials (e.g. transportation, electronic delivery, disposal, storage, examination center); • the nature of the materials (e.g. electronic, paper, test equipment); • the steps in the examination process (e.g. development, administration, results reporting); • the threats arising from repeated use of examination materials.	**NO**	**NO**	CFP goes into great detail to discuss many specific aspects of security while the ISO document states that policies and procedures shall be in place regarding the location of materials, the nature of the materials, the steps of the process regardless of the format (electronic or paper) and reducing threats. Upon CFP having an established foundation for the various aspects of exam security, appears that the requirement for security policies and procedures would be met. This difference is again prescription vs. subjectivity, best practices, and processes of exam providers. When all is said and done, what is the point of all the exam security if a signature is not required to receive exams? The process here is not the same. One is very prescriptive and one relies on the processes of an organization.	CFP goes into great detail to discuss many specific aspects of security while the ISO document states that policies and procedures shall be in place regarding the location of materials, the nature of the materials, the steps of the process regardless of the format (electronic or paper) and reducing threats. Upon CFP having an established foundation for the various aspects of exam security, appears that the requirement for security policies and procedures would be met. This difference is again prescription vs. subjectivity, best practices, and processes of exam providers. When all is said and done, what is the point of all the exam security if a signature is not required to receive exams? The process here is not the same. One is very prescriptive and one relies on the processes of an organization. If CFP section 5.9 does not have ISO equivalent, then CFP section 5.1 does not have ISO equivalent. ISO does not have detailed security; CFP is precise on examination booklet
55	**5.1A** *Securing Examination Booklets*	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent	One reviewer believed that since these are not 100% the same, than these are not equivalent
56	**5.1 A 1)** Each individual *examination booklet* shall be secured by using one of the following methods both prior to and after administration:	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	One reviewer believed that since these are not 100% the same, than these are not equivalent.
57	**5.1 A 1a.)** Enclosing in a sealed tamper-resistant package;	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	One reviewer believed that since these are not 100% the same, than these are not equivalent.
58	**5.1 A 1b.)** Shrink-wrapping;	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent	
59	**5.1 A 1c.)** Sealing on all three open sides with each seal of sufficient size to cover at least one square inch of the front side and to overlap and cover the same amount of space on the back side of the *examination booklet* ; or	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	

60	**5.1 A 1d.)** Using any other technology that ensures that only the examinee can view the contents of the *examination booklet*	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
61	**5.1 A 2)** Only the examinee is allowed to break open the *examination booklet* packaging or seals	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
62	**5.1 B** Packaging by *certification organization* .	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
63	**5.1 B 1)** Each individual *examination booklet* shall be securely sealed before packing.	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
64	**5.1 B 2)** Secure tamper-resistant shipping material, such as Tyvek envelopes or similar materials that are designed to reveal any tampering or violation of the package's security, is required for all shipment of materials in all phases.	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
65	**5.1 B 3)** Packaging must include a packing list that contains:	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
66	**5.1 B 3a.)** *Examination form* language(s) or version(s) enclosed; and	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
67	**5.1 B 3b.)** Quantity of examinations enclosed.	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
68	**5.1 C** Shipping to the *test administrator/proctor* from the *certification organization.*	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
69	**5.1 C 1)** Shipping shall be done by certifiable, traceable means, with tracking numbers so that the location can be determined at any given time	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
70	**5.1 C 2)** A signature is required upon delivery.		**NO**	**NO**	ISO does not specifically state that signatures are required. Nevertheless, this would not be of concern if is specified in our policies and procedures required in ISO 7.4.2.	
71	**5.1 C 3)** Only an individual authorized by the *test administrator/proctor* may sign for the package.		**NO**	**NO**	ISO does not specifically state that signatures are required. Nevertheless, this would not be of concern if is specified in our policies and procedures required in ISO 7.4.2. ISO does not require a signature.	

72	**5.1 D** Storage by *test administrator/proctor* . The package(s) of *examination booklets* shall be secured at all times immediately upon delivery. Under no circumstances may *examination booklets* , examinee used answer sheets, or other examination	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
73	**5.1 E** Shipping to the *certification organization* from the *test administrator/proctor*	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
74	**5.1 E 1)** After examination administration, *examination booklets* and answer sheets shall remain in secure storage until returned to *certification organization* .	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
75	**5.1 E 2)** The following shall be in tamper-resistant shipping material:	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
76	**5.1 E 2a.)** All used and unused *examination booklets* for each examination administration;	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
77	**5.1 E 2b.)** Examinees' used answer sheets; and	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
78	**5.1 E 2c.)** All required *certification organization* forms	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
79	**5.1 E 3)** Shipping shall be done within two business days following the examination date by certifiable, traceable means, with tracking numbers so that the location can be determined at any given time.	**7.4.2**	**NO**	**NO**	No time frames at all mentioned in ISO. Substantially UN-equivalent	
80	**5.1 F** Handling unused *examination booklets* that have been held for up to ninety days. The *test*	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
81	**5.1 F 1)** Ensure that all *examination booklets* are accounted for;	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
82	**5.1 F 2)** package *examination booklets* securely as described above; and	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	
83	**5.1 F 3)** Ship to the certification organization securely packaged and according to these *Standards* and the *Certification Organization's* instructions	**7.4.2**	**NO**	**NO**	One reviewer believed that since these are not 100% the same, than these are not equivalent.	

84	**5.2 Test Site Requirements.** Sites chosen for administering *food safety certification examinations* shall conform to all legal requirements for safety, health, and accessibility for all qualified examinees.	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration. **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored. NOTE Conditions can include lighting, temperature, separation of candidates, noise, candidate safety, etc. **9.3.4** When technical equipment is used in the examination process, the equipment shall be verified or calibrated where appropriate. **9.3.5** Appropriate methodology and procedures (e.g. collecting and maintaining statistical data) shall be documented and implemented in order to reaffirm, at justified	**NO**	**NO**	The CFP document is concerned with the specific testing site while the ISO document looks at consistency, criteria for conditions, and calibration of equipment. The ISO document is more precise in details however, the intent is compatible. These do not appear to be the same. One deals with ADA and the actual site. The ISO standard is mainly about exam develop design and process. It seems like 9.3.3 is compatible but the others are not exactly compatible. This section is about exam design & results & has nothing to	
85	examinees to perform at their highest level of ability.	NOTE Conditions can include lighting, temperature,				
86	**5.2 B 7)** Use of private room(s) where only examination personnel and examinees are allowed access during the examination administration; and		**NO**	**NO**	This is not addressed in the ISO document. This is important for a consistent and maximized learning and testing experience	
87	**5.2 B 8)** No further admittance into the test site once examination administration has begun		**NO**	**NO**	This is not addressed in the ISO document.	

88	**5.3 Test Site Language Translation**. A *certification organization* shall have a published, written policy regarding test site language translation of *food safety certification examinations* . If a *certification organization* allows test site language translation of a *food safety certification examination* when an *examination version* is not available in the examinees' requested language, the *certification organization* shall have a published, formal application process available to all potential examinees. Procedures shall include but not be limited to:	**9.2.5** The certification body shall verify and accommodate special needs, within reason and where the integrity of the assessment is not violated, taking into account national regulation [see 9.1.2 e)]. Also, **6.1.5** The certification body shall maintain up-to-date personnel records, including relevant information, e.g. qualifications, training, experience, professional affiliations, professional status, competence and known conflicts of interest. Also, 6.2.2.1 Examiners shall meet the requirements of the certification body. The selection and approval processes shall ensure that examiners: d) are fluent, both in writing and orally, in the language of examination: in circumstances where an interpreter or a translator is used, the certification body shall have procedures in place to ensure that it does not affect the validity of the examination;			ISO does not address translations "Special Needs" is defined as a physical disability, learning difficulties or behavioral problem. With this is mind, language translation is NOT a special need. CFP standard has specifics just for language translations.	ISO 9.2.5 and 6.1.5 and 6.2.2.1 clearly covers all 5.3 items. It is disconcerting that ISO item 6.2.2.1 was not referenced for this section during the comparison process.
89	**5.3 A** An application process for potential examinees that includes an evaluation and documentation component to determine the		**NO**	**NO**	This is not addressed in the ISO document.	
90	eligibility of the potential examinee for test site language translation,					
91	**5.3 B** An application process for translators that includes clear and precise qualifications that shall include but not be limited to the following:	**6.1.5** The certification body shall maintain up-to-date personnel records, including relevant information, e.g. qualifications, training, experience, professional affiliations, professional status, competence and known conflicts of interest.	**NO**	**NO**	This is not addressed in the ISO document.	This item is covered by ISO 6.1.5 and in detail in 6.2.2.1
92	**5.3 B 1)** being fluent in both languages;		**NO**	**NO**	This is not addressed in the ISO document.	
93	**5.3 B 2)** Have a recognized skill in language translation;		**NO**	**NO**	This is not addressed in the ISO document.	
94	**5.3 B 3)** Trained in the principles of objective examination administration;		**NO**	**NO**	This is not addressed in the ISO document.	

95	**5.3 B 4)** Have no personal relationship with the examinee (may not be another examinee, may not be a relative or friend of the examinee and may not be a co-worker, employer, or an employee of the examinee);	**4.3.6** The certification body shall identify threats to its impartiality on an ongoing basis. This shall include those threats that arise from its activities, from its related bodies, from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a body with a threat to impartiality. NOTE 1 A relationship that threatens the impartiality of the body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding) and payment of a sales commission or other inducement for the referral of new applicants, etc. NOTE 2 Threats to impartiality can be either actual or	**YES**	**NO**	CFP 5.3.B.4 discusses impartiality between translators and examinees while ISO 4.3.6 discusses impartiality in general terms may include personnel. Relationship in the standard is between the Translator and the examinee NOT the certification body. Section does not apply.	ISO 4.3.6 adds further clarification of requirements to 9.2.5 and 6.1.5
96		perceived. NOTE 3 A related body is one which is linked to the certification body by common ownership, in whole or part, and has common members of the board of directors, contractual arrangements, common names, common staff, informal understanding or				
97	**5.3 B 5)** Not being a *Certified Food Protection Manager* nor having any vested interest in Food Protection Manager certification or conflict of interest;	**9.4.4** The decision on certification of a candidate shall be made solely by the certification body on the basis of the information gathered during the certification process. Personnel who make the decision on certification shall not have participated in the examination or training of the candidate.	**YES**	**NO**	CFP 5.3.B.5 discusses vested interests between translators and examinees while ISO 9.4.4 discusses impartiality in general terms which may include personnel. Keep in mind, Translator might work for a college, business, or ethnic newspaper, etc.? ISO 9.4.4 does not apply because it is about the candidate who takes the exam NOT the translator	
98	**5.3 B 6)** Provide references or other proof attesting to the translator's competencies and professional acumen; and		**NO**	**NO**	This is not addressed in the ISO document.	

99	**5.3 B 7)** Agree in writing to maintain the security of the examination.	**6.1.7** The certification body shall require its personnel to sign a document by which they commit themselves to comply with the rules defined by the certification body, including those relating to confidentiality, impartiality and conflict of interests.	**NO**	**NO**	ISO 6.1.7 requires all personnel to sign a document committing to comply with all rules set by the certification body.	
100		Could be viewed differently if Translator is considered a member of the certification provider but how do you define that?			NO Keep in mind Translator might work for a College or business, or ethnic newspaper, etc.?	
101	**5.3 C** A proctored environment where the translator and examinee are not a distraction to other examinees, and	**9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored. NOTE Conditions can include lighting, temperature, separation of candidates, noise, candidate safety, etc.	**NO**	**NO**	CFP 5.3.C.A discusses vested interests between translators and examinees while ISO 9.3.3 discusses criteria for conditions in general terms.	ISO 9.3.3 further clarifies 9.2.5, 6.1.5 and 4.3.6
102	**5.3 D** A proctored environment where the translator is not active as the *test administrator/proctor* .	**6.2.3.1** The certification body shall have a documented description of the responsibilities and qualifications of other personnel involved in the assessment process (e.g. invigilators).			These sub clauses are similar however, ISO 6.2.3.1 is a generality. ISO does not specify translator as “other personnel” or if even permitted to be used	
103	**5.4 Scoring.**					
104		requirements have been met.				
105	**5.4 B** *Food safety certification examination* scores will not be released as being official until verified and approved by the *certification organization* .		**NO**	**NO**	This is not addressed in the ISO document.	
106	**5.4 C** Examinee scores will be confidential, available only to the examinee and to persons or organizations approved in writing by the	6.1.6 Personnel acting on the certification body's behalf shall keep confidential all information obtained or created during the performance of the body's certification activities, except as required by law or where authorized		**NO**	This is not addressed.	ISO does cover confidentiality is in 6.1.6 and 6.1.7

107	**5.4 D** Score reports will be available to examinees in a time frame specified in the application, which will not exceed fifteen business days following the administration of the *food safety certification examination* . If there is a delay due to problems in verification or authentication of scores, examinees will be so informed and an approximate date for release of the scores will be announced. The *certification organization* will have ongoing communication with examinees and with the *test*			**NO**	**NO**	This is not addressed in the ISO document.
108	**5.5 *Test Administrator/Proctor(s)* Role.** *Test administrators/proctors* shall have successfully completed the *certification organization's* specific training in examination administration and security procedures. They	**6.1.4** Documented instructions shall be provided to personnel describing their duties and responsibilities. These instructions shall be kept up-to-date. **6.1.7** The certification body shall require its personnel to sign a document by which they commit themselves to			**YES**	These sub clauses are equivalent. YES, but "Ethics" are missing from ISO.
109	shall provide written assurance of maintaining confidentiality of examination contents, of adhering to the *certification organization's* standards and ethics of secure examination administration, and of agreeing to abide by the *certification organization's* policies, procedures and rules.	comply with the rules defined by the certification body, including those relating to confidentiality, impartiality and conflict of interests.				
110	**5.6 B** non-Disclosure Agreement (NDA);	**6.1.7** The certification body shall require its personnel to sign a document by which they commit themselves to comply with the rules defined by the certification body, including those relating to confidentiality, impartiality				These sub clauses are equivalent.
111	**5.6 C** Training program for *test administrators/proctors* ; and	**6.1.3** The certification body shall define the competence requirements for personnel involved in the certification process. Personnel shall have competence for their specific tasks and responsibilities				These sub clauses are equivalent. This seems unnecessary to have in such detail. It should be sufficient to have a training program requirement and that each provider formulates their best process and strategy for accomplishing that. ANSI could then verify. ISO 6.1.3 applies not ISO 6.1.7

This is not covered by ISO and the CFP statement should be added.

112	**5.7 *Test Administrator/Proctor(s)* Renewal.** *Test administrators/proctors* shall renew the training program for *test administrators/proctors* and Non-Disclosure Agreement with the *certification organization* every three (3) years.		**NO**	NO	This seems a little illogical. A certification is good for 5 years, but the training for a proctor good for three? Part of the longevity and continued accreditation for providers is to have good processes in place, which ANSI will validate and review.	Further, the FDA Food Codes changes every 4 years. This 3 year requirement seem arbitrary. That the certification body have another valid criteria is reasonable.
113	**5.8 *Instructor/Educator/Trainer* as *Test Administrator/Proctor* .** When a person acts as an *instructor/educator/trainer* and a *test administrator/proctor* , that person relinquishes	**6.1.8** When a certification body certifies a person it employs, the certification body shall adopt procedures to maintain impartiality.	**NO**	**NO**	These clauses are similar however, they are not equivalent. The overall intent is the same.	
114	the role of *instructor/educator/trainer* when acting in the role of *test administrator/proctor* and acts solely as a representative agent of the *certification organization* .	**9.4.4** The decision on certification of a candidate shall be made solely by the certification body on the basis of the information gathered during the certification process. Personnel who make the decision on certification shall not have participated in the examination or training of the candidate. **5.2.3** Offering training and certification for persons within the same legal entity constitutes a threat to impartiality. A certification body that is part of a legal entity offering training shall: b) demonstrate that			The intent is very different; separation versus non-separation of trainer from proctor. ISO sections 9.4.4, 6.2.2.3 and 5.2.3 may apply. Also, an "examiner" by definition ISO 3.10 "person competent to conduct and score an examination, where the examination requires professional judgment." A Test Administrator/ Proctor cannot	
115	**5.9 *Test Administrator/Proctor* Responsibilities.** If section 5.9 of CFP standard does Not have ISO equivalent, then I do not believe that	If CFP Standard 5.1 is believed to have an ISO equivalent, then the closest ISO equivalents for some of the items in this section would be ISO sections 7.4.2, 7.4.3, 9.3.2, 9.3.3. Something to think about.				NOT CLEAR?????????????????
116	section 5.1 of CFP standards has an ISO equivalent either. Consistency in what is considered "Equivalent" & apple to apple comparison of the 2 standards					
117	**5.9 A** Schedule examinations. *Food safety certification examinations* shall be scheduled far enough in advance to allow for timely shipment of supplies or pre-registration for computer-based examinations.		**NO**	**NO**	This is not addressed in the ISO document.	

118	**5.9 B** Ensure no destruction of *examination booklet* materials or computer equipment;	**7.4.2** Security policies and procedures shall include provisions to ensure the security of examination materials, taking into account the following: a) the locations of the materials (e.g. transportation, electronic delivery, disposal, storage, examination center); b) the nature of the materials (e.g. electronic, paper, test equipment); c) the steps in the examination process (e.g. development, administration, results reporting); d) the threats arising from repeated use of examination materials	**NO**	**NO**	This is not addressed in the ISO document. ISO 7.4.2 a-d may apply	7.4.2 covers examination material security and FCP 5.9B, 5.9C, 5.9C1
119	**5.9 C** At all times:		**NO**	**NO**	This is not addressed in the ISO document.	
120	**5.9 C 1)** Handle examination materials securely;		**NO**	**NO**	This is not addressed in the ISO document. ISO 7.4.2 a may apply	
121						
122	**5.9 C 2)** Ensure test site conformity;	**9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored. Note: Conditions can include lighting, temperature, separation of candidates, noise, candidate safety, etc.	**NO**	**NO**	This is not addressed in the ISO document. ISO 9.3.3 may apply	ISO 9.3.3 covers CFP 5.9C2, 5.9C3
123	**5.9 C 3)** Space examinees per protocol;	**9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored. Note: Conditions can include lighting, temperature, separation of candidates, noise, candidate safety, etc.	**NO**	**NO**	This is not addressed in the ISO document. These seem more like internal processes that each provider should incorporate individually. ISO 9.3.3 may apply	

124	**5.9 C 4)** Ensure examinees' rights;	**6.1.7** The certification body shall require its personnel to sign a document by which they commit themselves to comply with the rules defined by the certification body, including those relating to confidentiality, impartiality and conflict of interests.	**NO**	**NO**	This is not addressed in the ISO document.	ISO 6.1.7 covers 5.9C4 and 5.9C5.
125	**5.9 C 5)** Ensure confidentiality of examinees' personal information;		**NO**	**NO**	This is not addressed in the ISO document.	
126	**5.9 C 6)** Ensure standardized procedures are followed;		**NO**	**NO**	This is not addressed in the ISO document.	Yes, ISO requires the certification body to provide their policies and procedures for ensuring standardized procedures are followed. Each certification body must demonstrate how their policies and procedures meet this standard.
127	**5.9 D** Before the examination:		**NO**	**NO**	This is not addressed in the ISO document.	Yes, ISO requires the certification body to provide their policies and procedures before the examination. Each certification body must demonstrate
128	**5.9 D 1)** Check examinees' identification;	**7.4.3 c** Certification bodies shall prevent fraudulent examination practices by: c) confirming the identity of	**NO**	**YES**	This is not addressed in the ISO document.	Not sure how 7.4.3c could not be seen as specificly covering 5.9D1
129		the candidate			SO 7.4.3 c may apply	
130	**5.9 D 2)** Check for and exclude unauthorized objects;	**7.4.3 d & e** Certification bodies shall prevent fraudulent examination practices by: d) implementing procedures to prevent any unauthorized aids from being brought into the examination area: e) preventing candidates from gaining access to unauthorized aids during the examination.	**NO**	**YES**	This is not addressed in the ISO document. ISO 7.4.3 d & e may apply	Not sure how 7.4.3d & e cannot be seen as specificly covering 5.9D2. unauthorized objects = unauthorised aids.
131	**5.9 D 3)** Distribute examination materials;	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration**.**	**NO**	**NO**	This is not addressed in the ISO document. ISO 9.3.2 may apply.	

132	**5.9 D 4)** Read instructions to examinees verbatim;		**NO**	**NO**	This is not addressed in the ISO document.	CFP 5.9 D4 should be added.
133	**5.9 D 5)** Ensure examinees complete information section of answer sheet or online registration form.	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration.	**NO**	**NO**	This is not addressed in the ISO document.	5.9 D5 This seems to be an obvouis requirement to the process and would be covered by 9.3.2.
134	**5.9 E** During the examination:	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration. **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored. Note: Conditions can include lighting, temperature, separation of candidates, noise, candidate safety, etc.	**NO**		This is not addressed in the ISO document. ISO 9.3.2 and 9.3.3 may apply	
135	**5.9 E 1)** Supervise proctors;		**NO**	**NO**	This is not addressed in the ISO document.	Yes, ISO requires the certification body to provide their policies and procedures
136	**5.9 E 2)** Monitor examinees during examination;		**NO**	**NO**	This is not addressed in the ISO document.	Yes, ISO requires the certification body to provide their policies and procedures
137						
138	**5.9 E 3)** Identify and document cheating incidents;		**NO**	**NO**	This is not addressed in the ISO document.	Yes, ISO requires the certification body to provide their policies and procedures for identifying and documenting cheating
139	**5.9 E 4)** Check for and exclude unauthorized objects;	**7.4.3 d & e** Certification bodies shall prevent fraudulent examination practices by: d) implementing procedures to prevent any unauthorized aids from being brought into the examination area: e) preventing candidates from gaining access to unauthorized aids during the examination	**NO**	**YES**	This is not addressed in the ISO document. ISO 7.4.3 d & e may apply.	Same as **5.9 D 2)** Check for and exclude unauthorized objects; and covered by 7.4.3d & unauthorized objects = unauthorised aids.
140	**5.9 E 6)** Identify and document environmental distractions.	**9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored. Note: Conditions can include lighting, temperature, separation of candidates, noise, candidate safety, etc.	**NO**	**NO**	This is not addressed in the ISO document.	9.3.3 "...shall be established, documented and monitored..."
141	**5.9 F** After the examination	**7.1.1** The certification body shall maintain records. ...particularly with respect to	**NO**	**NO**	This is not addressed in the ISO document.	ISO 7.1.1 covers 5.9F

142	**5.9 F 1)** Collect and return *examination booklets* and answer sheets to *certification organization* or close computer based testing session;	**7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security	**NO**	**NO**	This is not addressed in the ISO document.	ISO 7.4.1 covers both 5.9 F1 and 5.9F2
143	**5.9 F 2)** Report possible security breaches and examination administration irregularities in compliance with the *certification organization's* policies.		**NO**	**NO**	This is not addressed in the ISO document.	
144	**5.10** The number of approved *proctors* assigned to a *test administrator* shall be sufficient to allow each examinee to be observed and supervised to ensure	**9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored. Note: Conditions can include lighting, temperature, separation of candidates, noise, candidate safety, etc.	**NO**	**NO**	This is not addressed in the ISO document.	The current CFP statement is out of date. Where a single proctor can monitor 35 examinees taking a paper test where there is nothing on the table but the booklet and pencil, adequately monitoring 35 computer stations is much more problematic and the number of examinees per proctor most likely should be lowered. ISO 9.3.3 allows for this and any future modifications that might be needed to adequately secure the examination process.
145	conformance to security requirements. There shall be no less than one *test administrator/proctor* for the first thirty-five examinees, plus one additional *test administrator* or *proctor* for each additional 35 examinees or fraction					
146	**5.11 Examination Security.**					
147	**5.11 A** All aspects of *food safety certification examination* administration are to be conducted in a manner that maximizes the security of the examinations, in keeping with the public protection mandate of the CFP. This shall be accomplished in a manner that ensures fairness to all examinees.	**7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches occur. **7.4.2** Security policies and procedures shall include provisions to ensure the security of examination materials, taking into account the following: the locations of the materials (e.g. transportation, electronic delivery, disposal,		**NO**	This comparison is similar to previous sub clauses concerning security. Both entities are concerned with security issues and while the CFP document is specific in terms of food safety criteria, ISO 7.4 gives more specific direction concerning security than the CFP document. Disagree with that statement. Demonstration is NOT "Substantially Equivalent'	ISO 7.4.1, 7.4.2, 9.3.2, and 9.3.3 clearly cover the intent of 5.11A

148		materials. **9.3.2** The certification body shall have procedures to ensure a consistent examination administration. **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored. Note: Conditions can include lighting, temperature, separation of candidates, noise, candidate safety, etc.			
149	**5.11 B** All examinees shall begin taking the examination at the same time. No examinee shall be admitted into the test site once examination administration has begun.	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration.	**NO**	This is not addressed in the ISO document.	Though again somewhat of an obvious security proceedure requiring 5.11B be stated would have value.
150	**5.11 C** Where reasonable accommodations shall be made for otherwise qualified examinees under provisions of the Americans with Disabilities Act, care shall be taken to ensure that security of the examination is maintained. Arrangements shall be such that the *food safety certification examination* contents are not revealed to any test administration personnel with any conflict of interest. A written affirmation to that effect and a written nondisclosure statement from the individual who was chosen to assist the otherwise qualified examinee shall be provided to the *certification organization* .	**4.3.1** The certification body shall document its structure, policies and procedures to manage impartiality and to ensure that the certification activities are undertaken impartially. The certification body shall have top management commitment to impartiality in certification activities. The certification body shall have a statement publicly accessible without request that it understands the importance of impartiality in carrying out its certification activities, manages conflict of interest and ensures the objectivity of its certification activities. **4.3.2** The certification body shall act impartially in relation to its applicants, candidates and certified persons.	**YES**	The intent of these clauses are similar.	Adhering to the Americans with Disablitities Act is USA law and is a requirement. ADA would have to be a part of any USA accredted program and is covered by ISO 4.3.1, 4.3.2 and 7.4.1.
151					

152	**5.12** The *certification organization* shall provide procedures to be followed in any instance where the security of a *food safety certification examination* is, or is suspected to be, breached.	**ISO 7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches occur**.**	**NO**		This is not addressed in the ISO document. ISO 7.4.1 may apply; not as detailed as CFP.	Lacking the term Food Safety Certifcation Examination. This issue is covered by 7.4.1
153	**5.12 A** Included shall be specific procedures for handling and for reporting to the *certification organization* , any suspected or alleged:	**ISO 7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches occur**.**	**NO**	**NO**	This is not addressed in the ISO document. ISO 7.4.1 may apply; not as detailed as CFP.	7.4.1 not being so prescribed covers CFP items 5.12A, 5.12A1, 5.12A2, 5.12A3, 5.12A4, and is flexible so that any other not prescribed security issues would also have to be dealt with. Further, having this flexibly allows for future security measure requirements by the accediting agency without needing to seek an update the standands.
154	**5.12 A 1)** cheating incidents;	**ISO 7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take	**NO**	**NO**	This is not addressed in the ISO document. ISO 7.4.1 may apply; not as detailed as CFP.	
155	**5.12 A 2)** Lost or stolen examination materials;	**ISO 7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take	**NO**	**NO**	This is not addressed in the ISO document.	
156	**5.12 A 3)** Intentional or unintentional divulging of examination *items* by examinees or examination administration personnel; or	**ISO 7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches	**NO**	**NO**	This is not addressed in the ISO document. ISO 7.4.1 may apply; not as detailed as CFP.	
157	**5.12 A 4)** Any other incidents perceived to have damaged the security of the	**ISO 7.4.1** The certification body shall develop and document policies and procedures necessary to ensure	**NO**	**NO**	This is not addressed in the ISO document.	
158	examination or any of its individual *items* .	security throughout the entire certification process and shall have measures in place to take corrective actions when security			ISO 7.4.1 may apply; not as detailed as CFP.	

159	**5.12 B** Corrective actions to guard against future security breaches shall be established and implemented.	**ISO 7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches occur**.**	**NO**	**YES**	This is not addressed in the ISO document. ISO 7.4.1 may apply.	Same logic as the statement for the 5.12A group.
160	**5.12 C** Documentation of corrective actions and their effectiveness shall be made available to the *accrediting organization* .		**NO**	**NO**		
161	**5.13 *Item* and Examination Exposure.** The *certification organization* shall have an *exposure plan* that:	**ISO 7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches occur**.**	**NO**	**NO**	This is not addressed in the ISO document.	Same logic as the statement for the 5.12A group.
162	**5.13 A** Controls for *item* and examination exposure;		**NO**	**NO**	This is not addressed in the ISO document.	
163	**5.13 B** Accounts for the number of times an *examination item* , *examination form* , and *examination version* is administered;		**NO**	**NO**	This is not addressed in the ISO document.	
164	**5.13 C** Ensures that no *examination form* is retained by any *examination administration* personnel for more than 90 days		**NO**	**NO**	This is not addressed in the ISO document.	
165	**5.13 D** At all times accounts for all copies of all used and unused *examination booklets* ; and		**NO**	**NO**	This is not addressed in the ISO document.	
166						
167	**5.13 E** Systematically and actively demonstrates that every used answer sheet, *examination booklet* , and any other examination materials and answer keys are accounted for to prevent, reduce, or eliminate examination		**NO**	**NO**	This is not addressed in the ISO document.	
168	**5.14 *Certification Organization's* Responsibility to *Test Administrators/Proctors.***					

169	**5.14 A** The *certification organization* shall specify the responsibilities of *test administrator/proctor* , set minimum criteria for approval of *test administrators/proctors* , and provide a training program to enable applicants to meet the approval criteria. Responsibilities, duties, qualifications and training of *test administrators/proctors* shall be directed toward assuring standardized, secure examination administration and fair and equitable treatment of examinees.	**6.1.3** The certification body shall define the competence requirements for personnel involved in the certification process. Personnel shall have competence for their specific tasks and responsibilities. **6.1.4** Documented instructions shall be provided to personnel describing their duties and responsibilities. These instructions shall be kept up-to-date.	**NO**	**NO**	This is not addressed in the ISO document. ISO 6.1.3 and 6.1.4 may apply; nothing about providing a training program is in these sections.	Specifying training and test would be appropriate.
170	**5.14 B** The *certification organization* shall define and provide descriptions for the roles of *test administrators/proctors* , and *certification organization* personnel clearly indicating the responsibilities for these roles.	**6.1.4** Documented instructions shall be provided to personnel describing their duties and responsibilities. These instructions shall be kept up-to-date. Also, add **6.1.5** The certification body shall maintain up-to-date personnel records, including relevant information, e.g. qualifications, training, experience,		**NO**	These sub clauses are comparable however; the CFP asks the certification organization to demonstrate how it ensures that test administrators/proctors understand	ISO 6.1.3 better covers this issue than 6.1.4. If, "Personnel shall have competence for their specific tasks and responsibilities" there has to be a mechanism to demonstrate that. This is further covered by 6.1.5.
171	The *certification organization* shall demonstrate how it ensures that all certification personnel, as well as *test administrators/proctors* , understand and practice the procedures identified for their				their roles and responsibilities.	
172	**5.14 C** *Test administrator/proctor* training programs shall include:					
173	**5.14 C 1)** Specific learning objectives for all of the activities of *test administrator/proctor* ; and		**NO**	**NO**	This is not addressed in the ISO document.	Same as 5.14A
174	**5.14 C 2)** An assessment component that shall be passed before an examinee for *test admistrator/proctor* will be approved.		**NO**	**NO**	This is not addressed in the ISO document.	Same as 5.14A
175	**5.15 Test Administrator/Proctor Agreements.** The *certification organization* shall enter into a formal agreement with the *test administrator/proctor* . The formal agreement shall at a minimum address:	**6.1.7** The certification body shall require its personnel to sign a document by which they commit themselves to comply with the rules defined by the certification body, including those relating to confidentiality, impartiality and conflict of interests.			One could interpret ISO 6.1.7 which requires personnel to sign a document committing themselves to comply with the rules as a formal agreement suggested in CFP 5.15 ISO is not specific, too loosely worded.	6.1.7 requires a signed document that the applicant comply with the rules. These rules are an extention of security and are a signficant element of the ISO standards. Demonstation of 5.15 items would be required by the accrediting agency under ISO.

176	**5.15 A** Provisions that relate to code of conduct;		**NO**		This is not addressed in the ISO document.	
177	**5.15 B** Conflicts of interest; and	**6.1.7** The certification body shall require its personnel to sign a document by which they commit themselves to comply with the rules defined by the certification body, including those relating to confidentiality, impartiality	**NO**	**YES**	This is not addressed in the ISO document. YES	
178		**4.3.7** The certification body shall analyze, document and eliminate or minimize the potential conflict of interests arising from the certification of activities of persons. The certification body shall document and be able to demonstrate how it eliminates, minimizes or manages such threats. All potential sources of conflict of interest that are identified, whether they arise from within				
179	**5.15 C** Consequences for breach of the agreement.		**NO**	**NO**	This is not addressed in the ISO document.	If required to sign to comply with rules it is logical that consequences for not complying would have to be stated.
180	**5.17** The *certification organization* is not permitted to hire, contract with, or use the services of any person or organization that claims directly or indirectly to guarantee passing any certification examination. *Instructors/educators/trainers* making such a claim, whether as an independent or as an employee of another organization making the claim, are not eligible to serve as *test administrators/proctors* for any *certification*		**NO**	**NO**	This is not addressed in the ISO document. This is quite unclear. There is nothing wrong with the guarantee of passing an exam, so long that the actual guarantee context is correct. If a training provider lets you take their course or online training as many times as it takes to pass the exam	The current CFP statement on this issue needs to be a included to more clearly defind this issue.
181	*organization* .				then this is the business of the training provider not the exam provider. Guaranteeing can lead to past problems that lead to the tightening of the CFP Standards.	

182	**5.18** Policies and procedures for taking corrective action(s) when any *test administrator* or *proctor* fails to meet job responsibilities shall be implemented and documented. *Test administrators/proctors* that have been dismissed by the *certification organization* for infraction of policies or rules, incompetence, ethical breaches, or compromise of examination security will	**6.2.2.2** The certification body shall monitor the performance of the examiners and the reliability of the examiners' judgments. Where deficiencies are found, corrective actions shall be taken.	**YES**	**NO**	These sub clauses are comparable. Not comparable. An "examiner" by definition 3.10 "person competent to conduct and score an examination, where the examination requires professional judgment.	
183	**5.19** The *certification organization* shall provide documentation that verifies compliance with the 1:35 ratio (*test administrator/proctor* : examinees).		**NO**	**NO**	This is not addressed in the ISO document.	
184	**5.20 Examination Administration Manual.** The *certification organization* shall provide each *test administrator/proctor* with a manual detailing the requirements for all aspects of the *food safety certification examination* administration process. The Examination	**6.1.4** Documented instructions shall be provided to personnel describing their duties and responsibilities. These instructions shall be kept up-to-date. **9.3.2** The certification body shall have procedures to ensure a consistent examination administration**.**	**NO**	**NO**	This is not addressed in the ISO document. ISO 6.1.4 and 9.3.2 may apply; elements are missing ISO is too vague.	
185	Administration Manual shall include a standardized script for the paper examination *test administrator/proctor* or read to examinees before the examination commences. For computer based tests (CBT), standardized instructions shall be available for					
186	**5.21 Examination Scripts.** Separate scripts/instructions may be created for different delivery channels or *certification organizations* . *Certification organizations* may customize elements of the scripts to fit their particular processes, but each script shall contain the following:	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration.	**YES**	**NO**	These sub clauses are comparable. ISO 9.3.2 may apply.	
187	**5.21 A** Introduction to the Examination Process	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration.	**NO**	**NO**	This is not addressed in the ISO document. ISO 9.3.2 may apply. ISO is too vague.	
188	**5.21 A 1)** Composition of the examination (number of questions, multiple choice, etc.);	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration**.**	**NO**	**NO**	This is not addressed in the ISO document. ISO 9.3.2 may apply. ISO is too vague.	

189	**5.21 A 2)** Time available to complete the examination;	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration **9.3.3** Criteria for conditions for administering	**NO**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section.	
190		examinations shall be established, documented and monitored.			ISO 9.3.2 may apply. ISO is too vague.	
191	**5.21 A 3)** Role of the *test administrator/proctor* ;	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. ISO 9.3.2 may apply. ISO is too vague.	
192	**5.21 A 4)** Process for restroom breaks; and	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. ISO 9.3.2 may apply. ISO is too vague.	
193	**5.21 A 5)** Process for responding to examinee comments and questions.	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored**.**	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. ISO 9.3.2 may apply. ISO is too vague.	
194	**5.21 B** Copyright and Legal Responsibilities	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration.	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. ISO 9.3.2 may apply.	
195					ISO is too vague.	
196	**5.21 B 1)** Description of what constitutes cheating on the examination;	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration. **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored**.**	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. One reviewer thinks this is not correct because, the CFP section is about the Examination Script Content. No ISO sections cover impropriety in any manner implied or otherwise.	

197	**5.21 B 2)** Penalties for cheating; and	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. ISO 9.3.2 may apply. One reviewer thinks this is not correct because, the CFP section is about the Examination Script Content. No ISO sections cover impropriety in any manner implied or otherwise.	
198	**5.21 B 3)** Penalties for copyright violations.	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration**.** **9.3.3** Criteria for conditions for administering examinations shall be established	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. ISO 9.3.2 may apply	
199		monitored.			One reviewer thinks this is not correct, because, the CFP section is about the Examination Script Content. No ISO sections cover impropriety in any manner implied or otherwise. Ramifications too costly.	
200	**5.21 C** Examination Process	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration**.** **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored.	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. ISO 9.3.2 may apply. The CFP section is about the Examination Script Content. ISO has no	
201	**5.21 C 1)** Maintaining test site security;	**7.4.1** The certification body shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches occur. **7.4.2** Security policies and procedures shall include provisions to ensure the security of examination materials, taking into account the following: the locations of the materials (e.g. transportation, electronic delivery, disposal, storage, examination center);	**YES**	**NO**	As mentioned above, security issues are addressed in the CFP document however, ISO 7.4 includes more scenarios. ISO scenarios are for examination materials NOT test site security therefore it does not apply. ISO section is about maintaining test site security. This section is the “Examination Script” which ISO does not require.	

202		the nature of the materials (e.g. electronic, paper, test equipment); the steps in the examination process (e.g. development, administration, results reporting); 9.3.3 Criteria for conditions for administering examinations shall be established, documented and monitored. May be more				
203	**5.21 C 2)** Description of examination components unique to the *certification organization* (*examination booklet* , answer sheet completion, computer process in testing centers, etc.);	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration.	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. One reviewer disagrees because this is Maintaining test site security in the "Examination	
204	**5.21 C 3)** Instructions for proper completion of personal information on answer sheets/online registration and *examination booklets* ;	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration**.**	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. One reviewer disagrees, because this is Maintaining test site security in the "Examination	
205	**5.21 C 4)** Instructions on properly recording answers on answer sheets or online; and	**9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored.	**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than ISO in this section. ISO 9.3.3 is about conditions not	
206					examination itself. Don't think it applies. One reviewer disagrees, because this is in the "Examination Script" which ISO does not require	
207	**5.21 C 5)** Instructions on post-examination administration process.		**YES**	**NO**	These sub clauses are comparable however the CFP document is more specific than	
208	**6.0 Computer-Based Testing (CBT)**					

209	**6.0 Computer-Based Test Development and Administration.** All sections of these *Standards* apply to Computer Based Testing (CBT) Administration except Section 5.1.	**9.2.1** The certification body shall implement the specific assessment methods and mechanisms as defined in the certification scheme.	**NO**	**Yes**	This is not addressed in the ISO document. The intent is substantially equivalent. Just because ISO does not speak specifically to computer based testing does not mean it does not allow for computer based testing. ISO section 9.3.3 speaks to having requirements for the administration of examinations and ISO section 9.3.4 speaks to technical equipment used in the examination process needing to	
210	**6.1 Computer-Based Test Development.**	**9.3.4** When technical equipment is used in the examination process, the equipment	**NO**	**YES**	This is not addressed in the ISO document.	
211	*based testing* shall describe the method for development, including the *algorithms* used for test *item* selection, the *item* response theory model employed (if any), and examination *equivalency* issues.	calibrated where appropriate. **9.3.5** Appropriate methodology and procedures (e.g. collecting and maintaining statistical data) shall be documented and implemented in order to reaffirm, at justified defined intervals, the fairness, validity, reliability and general performance of each examination, and that all identified deficiencies are corrected.			ISO document is very vague and does not specifically address computerized testing but does generalize requirements for the examination process to be the same regardless of how it is administered and references that specific assessment methods and mechanisms as defined in the certification scheme. As stated above, just because ISO does not speak to use of computer administered tests directly does not mean they prohibit it. Within ISO it broadly requires there to be criteria in place to ensure that	
212	**6.2** *Items* shall be evaluated for suitability for computer delivery, be reviewed in the delivery medium, and be reviewed in the presentation delivery medium. Assumptions shall not be made that *items* written for delivery via a paper/pencil medium are suitable for computer delivery nor should it be assumed that computer test *items* are suitable for paper/pencil delivery.	**9.3.1** Examinations shall be designed to assess competence based on, and consistent with, the scheme, by written, oral, practical, observational or other reliable and objective means. The design of examination requirements shall ensure the comparability of results of each single examination, both in content and difficulty, including the validity of fail/pass decisions. **9.3.2** The certification body shall have	**NO**	**YES**	This is not addressed in the ISO document. ISO document (9.3.1) does not speak to computerized test questions but it does generally speak to the examination design be able to ensure comparability of results and 9.3.2 speaks to ensuring a consistent examination administration.	This is not addressed in the ISO document. ISO document (9.3.1) does not speak to computerized test questions but it does generally speak to the examination design be able to ensure comparability of results and 9.3.2 speaks to ensuring a consistent examination administration.

213	**6.3** When *examination forms* are computer- generated, whether in C*omputer-Adaptive Testing* (CAT) or in a simple linear *algorithm* , the *algorithm* for *item* selection and the number of *items* in the *item bank* from which the examination is generated shall ensure that the *items* are protected from *overexposure* . *Item* usage statistics shall be provided for all available *items* in the pool.	**7.4.2** Security policies and procedures shall include provisions to ensure the security of examination materials, taking into account the following: the locations of the materials (e.g. transportation, electronic delivery, disposal, storage, examination centre); the nature of the materials (e.g. electronic, paper, test equipment); the steps in the examination process (e.g. development, administration, results reporting); the threats arising from repeated use of examination materials.	**NO**	**YES**	This is not addressed in the ISO document. ISO Section 7.4.2 broadly speaks to having procedures in place to guard against security threats arising from the repeated use of examinations. Whereas CFP speaks directly to the use of linear algorithms to safeguard against security threats from overexposure of exam materials.	This is not addressed in the ISO document. ISO Section 7.4.2 broadly speaks to having procedures in place to guard against security threats arising from the repeated use of examinations. Whereas CFP speaks directly to the use of linear algorithms to safeguard against security threats from overexposure of exam materials.
214	**6.4 *Computer-Based Testing* Administration.** Where examination environments differ (for example, touch screen versus mouse) evidence shall be provided to demonstrate equivalence of the examinees' scores.		**NO**	**YES**	This is not addressed in the ISO document. ISO generally speaks in Section 9.3.1 to ensuring that the design of the examination be such to ensure comparability of the	This is not addressed in the ISO document. ISO generally speaks in Section 9.3.1 to ensuring that the design of the examination be such to ensure comparability of the scores.
215	**6.5** Tutorials and/or practice tests shall be created to provide the examinees adequate opportunity to demonstrate familiarity and comfort with the computer test environment.	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration.	**NO**	**NO**	This is not addressed in the ISO document. This is not mentioned in the ISO document. However, ISO does speak in Section 9.3.2 to having procedures to ensure consistent	This is not addressed in the ISO document. This is not mentioned in the ISO document. However, ISO does speak in Section 9.3.2 to having procedures to ensure consistent examination
216					administration. CFP speaks to the use of Tutorials and practice tests to familiarize examinees with the environment with the purpose of ensuring a consistent	administration. CFP speaks to the use of Tutorials and practice tests to familiarize examinees with the environment with the purpose of ensuring a consistent examination
217	**6.6** If the time available for computer delivery of an examination is limited, comparability of scoring outcomes with non-timed delivery of the exam shall be demonstrated. Data shall be gathered		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
218	**6.9** Policies and procedures regarding the recording and retention of the *item sequence* and *item* responses for each examinee shall be developed and followed. Computer examinations using a unique sequence of *items* for each examinee shall record the information necessary to recreate the sequence of *items* and examinee responses on the computer examination.	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration.	**NO**	**YES**	This is not addressed in the ISO document. The intent is substantially equivalent. Just because ISO does not speak specifically to item sequence for computer based tests does not mean the intent is not equivalent. ISO Section 9.3.2 broadly speaks to having procedures in place to	This is not addressed in the ISO document. The intent is substantially equivalent. Just because ISO does not speak specifically to item sequence for computer based tests does not mean the intent is not equivalent. ISO Section 9.3.2 broadly speaks to having procedures in place to ensure consistent exam administration.

219	**6.10** Systems and procedures shall be in place to address technical or operational problems in examination administration. For example, the examination deliver system shall have the capability to recover examinee data at the appropriate point in the testing session prior to test disruption. Policies regarding recover for emergency situations (such as retesting) shall be developed.	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration. **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored. NOTE Conditions can include lighting, temperature, separation of candidates, noise, candidate safety, etc. **9.3.4** When technical equipment is used in the examination process, the equipment shall be verified or calibrated where appropriate. **9.3.5** Appropriate methodology and procedures (e.g. collecting and maintaining statistical data) shall be documented and implemented in order to reaffirm, at justified defined intervals, the fairness, validity, reliability and general performance of each	**NO**	**YES**	This is not addressed in the ISO document. The intent is substantially equivalent. ISO 9.3.2-9.3.5 broadly speaks to examination criteria which include having procedures in place to ensure consistent exam administration. This may include procedures to address technical or operational problems.	This is not addressed in the ISO document. The intent is substantially equivalent. ISO 9.3.2-9.3.5 broadly speaks to examination criteria which include having procedures in place to ensure consistent exam administration. This may include procedures to address technical or operational problems.
220	**6.11 Due Process.** Examinees shall be provided with any information relevant to *computer-based testing* that may affect their performance or score. Examples of such information might include but not be limited to: time available to respond to *items* ; ability to change responses; and instructions relating to specific types of	**9.3.2** The certification body shall have procedures to ensure a consistent examination administration. **9.3.3** Criteria for conditions for administering examinations shall be established, documented and monitored.	**NO**	**YES**	This is not addressed in the ISO document. ISO 9.3.2 & 9.3.3 broadly speak to having criteria in place for exam administration and criteria for conditions for administering examinations. The intent seems to be equivalent.	This is not addressed in the ISO document. ISO 9.3.2 & 9.3.3 broadly speak to having criteria in place for exam administration and criteria for conditions for administering examinations. The intent seems to be equivalent.
221	**Section 7.0 Certification Organization Responsibilities to Examinees and the Public**					
222	**7.0 A *certification organization's* Responsibilities to Examinees and the Public.**					
223	**7.1Responsibilities to Applicants for *Certification* .** A *certification organization* shall:					
224	**7.1 E** Provide evidence of uniformly prompt reporting of *food safety certification examination* results to applicants;		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
225	**7.1 F** Provide evidence that applicants failing the *food safety certification examination* are given information on general areas of deficiency;		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
226	**7.3 *Individual Certification Certificates:***					
227		arrangements. NOTE For requirements for records on applicants, candidates and certified persons, see also 7.1.				

228	**7.3 B** *Certificates* shall include, at a minimum:					
229	**7.3 B 4)** ANSI *accreditation* mark;		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
230	**7.3 B 7)** Name of *certification* ;		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
231	**7.3 B 8)** Contact information for the *certification organization* ; and		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
232	**7.3 C** Replacement or duplicate *certificates* issued through an *accredited certification organization* shall carry the same issue date, or date of examination, as the original *certificate* , and will be documented by the *certification*		**NO**	**NO**	ISO also states that ownership of the certification is retained by the certifying body.	ISO also states that ownership of the certification is retained by the certifying body.
233	**7.4 THIS IS MISSING FROM THE OFFICIAL DOCUMENT**					
234	**7.5 Discipline of *Certificate* Holders and Applicants.** A *certification organization* shall have formal *certification* policies and operating procedures including the sanction or	**9.5.1** The certification body shall have a policy and (a) documented procedure(s) for suspension or withdrawal of the certification, or reduction of the scope of certification, which shall specify the subsequent actions	**NO**	**YES**	These sub clauses are similar however the terminology is different. CFP requests a formal policy while refers only to policy. Is the formality of this significant?	These sub clauses are similar however the terminology is different. CFP requests a formal policy while refers only to policy. Is the formality of this significant?
235	**7.9 Misrepresentation.** Only Food Protection Manager *Certification* Programs that conform to all requirements of *Standards for Accreditation of Food Protection Manager Certification Programs* and are accredited by the agent selected by the CFP as the *accrediting organization* for such programs are allowed to refer to themselves as being accredited. Those programs may not make any other		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
236	**8.0 Certification Organization Responsibilities to the Accrediting Organization**					
237	**8.1Application for *Accreditation.*** *A certification organization* seeking *accreditation* for development and/or administration of a *certification* program shall provide at least the following information, as well as other information					
238	**8.1 A** the name and complete ownership of the legal entity.	**4.1 Legal and contractual matters** The certification body shall be a legal entity, or a defined	**YES**	**NO**	These clauses are equivalent. Don't agree they are not equivalent	These clauses are equivalent. Don't agree they are not equivalent.

239		part of a legal entity, such that it can be held legally responsible for its certification activities. A governmental certification body is deemed to be a legal entity on the basis of its governmental status.			ISO states there must be a legal entity where CFP asks for the name and complete ownership. Potentially can see how ownership is different than focusing on the legal entity	ISO states there must be a legal entity where CFP asks for the name and complete ownership. Potentially can see how ownership is different than focusing on the legal entity aspect.
240	**8.1 B** The address, telephone/fax number(s) and other contact information of the *certification organization's*		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
241	**8.1 C** The name, position, address and telephone/fax/e-mail information of the contact person for projects related to the CFP Standards for *Accreditation* of Food Protection Manager *Certification*		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
242	**8.2 Summary Information**. A *certification organization* shall:					
243	**8.2 A** Provide evidence that the mechanism used to evaluate individual competence is objective, fair, and based on the knowledge and skills needed to function as a *Certified Food Protection Manager* ;	**5.1.2** The certification body shall document its organizational structure, describing the duties, responsibilities and authorities of management, certification personnel and any committee. When the certification body is a defined part of a legal entity, documentation of the organizational	**YES**	**NO**	These sub clauses are similar if the consideration is accepting ISO as an equivalent standard. However; when considering replacing the CFP Standards with ISO, the ISO document requires more specific rigorous	These sub clauses are similar if the consideration is accepting ISO as an equivalent standard. However; when considering replacing the CFP Standards with ISO, the ISO document requires more specific rigorous details concerning the
244		parts within the same legal entity. The party/parties or individuals responsible for the following shall be identified: policies and procedures relating to the operation of the certification body; implementation of the policies and procedures; finances of the certification body; resources for certification activities; development and maintenance of the certification schemes; assessment activities; decisions on certification, including the granting, maintaining, recertifying, expanding, reducing, suspending or withdrawing of the certification; contractual arrangements.			These sections are not similar. ISO is referring to certification body where CFP is referring to competency of Food Protection Manager. ISO 3.6 is a better match "competence: ability to apply knowledge and skills to achieve results". But this section is very vague and general. Agree that ISO 3.6 is a better match but is not as explicit as what is in the CFP Standards. Also there is great significance to the fact that the CFP Standards focus on a specific job: Food Protection Manager versus ISO which could be anything including a completely different standard of food safety	These sections are not similar. ISO is referring to certification body where CFP is referring to competency of Food Protection Manager. ISO 3.6 is a better match "competence: ability to apply knowledge and skills to achieve results". But this section is very vague and general. Agree that ISO 3.6 is a better match but is not as explicit as what is in the CFP Standards. Also there is great significance to the fact that the CFP Standards focus on a specific job: Food Protection Manager versus ISO which could be anything including a completely different standard of food safety knowledge.

245	**8.2 B** Provide evidence that the evaluation mechanism is based on standards which establish *reliability* and *validity* for each form of the *food safety certification examination* ;	**7.2.2** The certification body shall make publicly available without request information regarding the scope of the certification scheme and a general description of the certification process.	**YES**	**NO**	These sub clauses are similar if the consideration is accepting ISO as an equivalent standard. However; when considering replacing the CFP Standards with ISO, the ISO document requires more specific rigorous details concerning the	These sub clauses are similar if the consideration is accepting ISO as an equivalent standard. However; when considering replacing the CFP Standards with ISO, the ISO document requires more specific rigorous details concerning the examination reliability and validity.
					Disagree, these sections are not similar. ISO talks about making documents public where CFP demands evidence that mechanism is reliable, valid and complies with standard. Agree there is a significant difference between the specificity in the CFP standards and ISO is too vague to be certain these are sufficiently equivalent.	Disagree, these sections are not similar. ISO talks about making documents public where CFP demands evidence that mechanism is reliable, valid and complies with standard. Agree there is a significant difference between the specificity in the CFP standards and ISO is too vague to be certain these are sufficiently equivalent.
	8.2 C Provide evidence that the pass/fail levels are established in a manner that is generally accepted in the *psychometric* community as being fair and reasonable;		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
	8.2 D Have a formal policy of periodic review of evaluation mechanisms and shall provide evidence that the policy is implemented to ensure relevance of the mechanism to knowledge and skills needed by a *Certified Food Protection Manager* ;	**8.5** The certification body shall ensure that the certification scheme is reviewed and validated on an on- going, systematic basis.	**NO**	**NO**	This is not directly addressed in the ISO document. 8.5 is not talking about the periodic review of the evaluation mechanism but of the certification scheme. When you look to see what is included in the certification scheme there is not a direct requirement that specifically addresses having a policy of periodic review of evaluation mechanisms and	This is not directly addressed in the ISO document. 8.5 is not talking about the periodic review of the evaluation mechanism but of the certification scheme. When you look to see what is included in the certification scheme there is not a direct requirement that specifically addresses having a policy of periodic review of evaluation mechanisms and providing evidence that the policy is implemented to ensure the relevance
					and skills of a CFPM. ISO 8.5 would relate more to CFP standard 4.8	and skills of a CFPM. ISO 8.5 would relate more to CFP standard 4.8

8.2 E Provide evidence that appropriate measures are taken to protect the security of all *food safety certification examinations* :	**10.1 General** The certification body shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this International Standard. In addition to meeting the requirements of Clauses 4 to 9, the certification body shall implement a management system in accordance with either option A or option B, as follows: option A: a general management system which fulfills the requirements of 10.2; or option B: a body that has established and maintains a management system, in accordance with the requirements of ISO	**NO**	**NO**	ISO 10.1 comes closer to requiring the certification organization to provide evidence to the accrediting body that appropriate measures to protect exam security are in place. This comparison is similar to previous sub clauses concerning security. Both entities are concerned with security issues and while the CFP document is specific in terms of food safety criteria, ISO 7.4 gives more specific direction concerning security that the CFP document.	ISO 10.1 comes closer to requiring the certification organization to provide evidence to the accrediting body that appropriate measures to protect exam security are in place. This comparison is similar to previous sub clauses concerning security. Both entities are concerned with security issues and while the CFP document is specific in terms of food safety criteria, ISO 7.4 gives more specific direction concerning security that the CFP document.
8.2 F Publish a comprehensive summary or outline of the information, knowledge, or functions covered by the *food safety certification examination* :		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
8.2 G Make available general descriptive materials on the procedures used in examination construction and validation and the procedures of administration and reporting of results; and	**9.1.1** Upon application, the certification body shall make available an overview of the certification process in accordance with the certification scheme. As a minimum, the overview shall include the requirements for	**NO**	**NO**	CFP is more specific to exam. ISO more general to entire certification scheme process.	CFP is more specific to exam. ISO more general to entire certification scheme process.
	assessment process, the applicant's rights, the duties of a certified person and the fees.				
8.2 H Compile at least semi-annually a summary of *certification* activities, including number of applicants, number tested, number passing, number failing		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
8.3 Responsibilities to the *Accrediting Organization* . The *certification organization* shall:					
8.3 A Make available upon request to the *accrediting organization* copies of all publications related to the *certification* program,	**7.2.2** The certification body shall make publicly available without request information regarding the scope of the certification scheme and a general description of the certification process.	**MAYBE**	**NO**	The intent is similar but the specifics are not equivalent. We would like ANSI to weigh in on this. ISO states it should make it public. Not sure why any of these documents would be made public. CFP mandates these documents must be made available to accrediting	The intent is similar but the specifics are not equivalent. We would like ANSI to weigh in on this. ISO states it should make it public. Not sure why any of these documents would be made public. CFP mandates these documents must be made available to accrediting organization. These two sections are not equivalent.

8.3 B Advise the *accrediting organization* of any proposed changes in structure or activities of the *certification organization* ,	**10.2.3 Control of documents** The certification body shall establish procedures to control the documents (internal and external) that relate to the fulfillment of this International Standard. The procedures shall define the controls needed to: c) ensure that changes and the current	**NO**	**NO**	These clauses are not equivalent and we were not able to locate anything in the ISO Standards that is similar. There is a significant difference between notifying the accreditation agency before you do something versus after the	These clauses are not equivalent and we were not able to locate anything in the ISO Standards that is similar. There is a significant difference between notifying the accreditation agency before you do something versus after the fact and only as part of your annual documentation.
8.3 C Advise the *accrediting organization* of substantive change in *food safety certification examination* administration,		**NO**			
8.3 D Advise the *accrediting organization* of any major changes in testing techniques or in the scope or objectives of the *food safety certification examination* ,	**10.2.3 Control of documents** The certification body shall establish procedures to control the documents (internal and external) that relate to the fulfillment of this International Standard. The procedures shall define the controls needed to: approve documents for adequacy prior to issue; review and update as necessary and re-approve documents; ensure that changes and the current revision status of documents are identified; ensure that relevant versions of applicable documents are provided at points of use; ensure that documents remain legible and readily identifiable; ensure that documents of external origin are identified and their distribution controlled; prevent the unintended use of obsolete documents and	**NO**	**NO**	These clauses are not equivalent and we were not able to locate anything in the ISO Standards that is similar. There is a significant difference between notifying the accreditation agency before you do something versus after the fact and then only as part of your annual documentation.	These clauses are not equivalent and we were not able to locate anything in the ISO Standards that is similar. There is a significant difference between notifying the accreditation agency before you do something versus after the fact and then only as part of your annual documentation.
	apply suitable identification if they are retained for any purpose. NOTE Documentation can be in any form or type of medium.				
8.3 E Annually complete and submit to the *accrediting organization* information requested on the current status of the Food Protection Manager *Certification* Program and the *certification organization* ,		**NO**	**NO**	This is not addressed in the ISO document. This CFP section is vague and not quite sure what information the accrediting organization would request. I would think it is referring to irregularities or non-	This is not addressed in the ISO document. This CFP section is vague and not quite sure what information the accrediting organization would request. I would think it is referring to irregularities or non- conformities.
8.3 F Submit to the *accrediting organization* the report requirements information specified for the Food Protection Manager *Certification*		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.

8.3 G Be re-accredited by the *accrediting organization* at least every 5 years.		**NO**	**NO**	This is not addressed in the ISO document.	This is not addressed in the ISO document.
9.0 Management Systems					
	ISO Documentation Requirement • Management System policies • Objectives				
9.1 A. Document control to include: 1) lists of all documents pertaining to the certification organization; 2) dates for documents approved for implementation by the certification organization; 3) the person(s) within the certification organization responsible for the documents; and 4) listing of individuals who have access to the documents. CFP Documentation Requirement • List of documents • List of authorized individuals with access	**10.2.2** Applicable requirements of this International Standard shall be documented. The certification body shall ensure that the management system documentation is provided to all relevant personnel. **10.2.3** Control of documents The certification body shall establish procedures to control the documents (internal and external) that relate to the fulfillment of this International Standard. The procedures shall define the controls needed to: a) approve documents for adequacy prior to issue; b) review and update as necessary and re-approve documents; c) ensure that changes and the current revision status of documents are identified; d) ensure that relevant versions of applicable documents are provided at points of use; e) ensure that documents remain legible	**Partially**	**Partially**	Yes, CFP's 9.1 A 2. meets ISO 10.2.3 (a) requiring documents to system shall be approved. And, CFP's 9.1 A (3) meets ISO's 10.2.1 in that an authorized person is appointed for document control. No, ISO's 10.2.2 and 10.2.3 does not meet CFP's 9.1 A (4) because there is no requirement for a list of individuals who have document access. No, CFP's 9.1 A does not show how the documents are to be controlled; whereas, ISO's 10.2.3 defines the requirements for (b) reviewing, updating, and re-approving documents, (c) ensuring changes and current revision status are identified, (d) ensuring relevant versions	Yes, CFP's 9.1 A 2. meets ISO 10.2.3 (a) requiring documents to system shall be approved. And, CFP's 9.1 A (3) meets ISO's 10.2.1 in that an authorized person is appointed for document control. No, ISO's 10.2.2 and 10.2.3 does not meet CFP's 9.1 A (4) because there is no requirement for a list of individuals who have document access. No, CFP's 9.1 A does not show how the documents are to be controlled; whereas, ISO's 10.2.3 defines the requirements for (b) reviewing, updating, and re-approving documents, (c) ensuring changes and current revision status are identified, (d) ensuring relevant versions are at point of use, (e) documents legible and identifiable, (f) external document distribution controlled (g) control of obsolete documents
	ISO Documentation Requirement • Procedure for document control			In the instance of considering replacing the CFP Standards with ISO, the ISO document requires more specific rigorous tasks of the certification body in some areas but not in others. Agree sections are similar. ISO more specific and stricter for certification body. CFP section is very vague and general, lacks any specifics	In the instance of considering replacing the CFP Standards with ISO, the ISO document requires more specific rigorous tasks of the certification body in some areas but not in others. Agree sections are similar. ISO more specific and stricter for certification body. CFP section is very vague and general, lacks any specifics

	Standard and has proven stability. **10.2.6.4** The certification body shall ensure that: a) internal audits are conducted by competent personnel, knowledgeable in the certification process, auditing and the requirements of this International Standard; b) auditors do not audit their own work; c) personnel responsible for the area audited are informed of the outcome of the audit; d) any actions resulting from internal audits are taken in a timely and appropriate manner; e) any opportunities for improvement are identified. <u>ISO Documentation Requirement</u> • Procedures for internal audits • Report of audit results			performing internal audits. Maybe, CFP's 9.1.B (4) meets ISO's 10.2.6.4 (a). Both standards require authorized / competent individuals to conduct the audits; however, ISO has additional requirements for auditors. ISO 10.2.6.4 states that (b) auditors shall not audit their own work, and (c) personnel of the area being audited are informed of audit results. Maybe, CFP's 9.1.B (5) meets ISO's 10.2.6.4 (d, e) in that actions taken as a result of the audit are identified (corrective actions); however, ISO adds to this requirement a time limit for these actions and opportunities for improvement to be identified. In the instance of considering replacing the CFP Standards with ISO, the ISO document requires more specific rigorous	performing internal audits. Maybe, CFP's 9.1.B (4) meets ISO's 10.2.6.4 (a). Both standards require authorized / competent individuals to conduct the audits; however, ISO has additional requirements for auditors. ISO 10.2.6.4 states that (b) auditors shall not audit their own work, and (c) personnel of the area being audited are informed of audit results. Maybe, CFP's 9.1.B (5) meets ISO's 10.2.6.4 (d, e) in that actions taken as a result of the audit are identified (corrective actions); however, ISO adds to this requirement a time limit for these actions and opportunities for improvement to be identified. In the instance of considering replacing the CFP Standards with ISO, the ISO document requires more specific rigorous tasks of the certification body in some areas but not in others.

9.1 C. Management Review that includes: 1) a documented annual review of internal audit results: 2) a management group that conducts the review; 3) a review of the audit results to determine corrective actions needed; 4) a review of the audit results to determine preventive actions needed; and 5) the effectiveness of corrective and preventive actions taken. <u>CFP Documentation Requirement</u> • Results of Management Review	**10.2.5** Management Review **10.2.5.1** The certification body's top management shall establish procedure to review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of this International Standard. These reviews shall be conducted at least once every 12 months and shall be documented. **10.2.5.2** Review input The input to the management review shall include information related to the following: a) results of internal and external audits (e.g. accreditation body assessment); b) feedback from applicants, candidates, certified persons and interested parties related to the fulfillment of this International Standard; c) safeguarding impartiality; d) the status of preventive and correctives actions; e) follow-up actions from previous management reviews; f) the fulfillment of objectives; g) changes that could affect the			Maybe, CFP's 9.1.C (1) meets ISO's 10.2.5.1 Both standards require a management review to be conducted annually, and include corrective and preventive actions from results of audits as input to the review; however, ISO has several additional requirements. ISO's 10.5.2 also requires input to the review from: (a) external audits in addition to the internal audits, (b) applicant feedback, (c) information regarding safeguarding impartiality, (d) follow-up actions from previous management reviews, (e) fulfillment of determined objectives, (f) any changes affecting system, and (g) complaints. Maybe, CFP's 9.1.C (5) meets ISO's 10.2.5.3 (a)	Maybe, CFP's 9.1.C (1) meets ISO's 10.2.5.1 Both standards require a management review to be conducted annually, and include corrective and preventive actions from results of audits as input to the review; however, ISO has several additional requirements. ISO's 10.5.2 also requires input to the review from: (a) external audits in addition to the internal audits, (b) applicant feedback, (c) information regarding safeguarding impartiality, (d) follow-up actions from previous management reviews, (e) fulfillment of determined objectives, (f) any changes affecting system, and (g) complaints. Maybe, CFP's 9.1.C (5) meets ISO's 10.2.5.3 (a) The output / outcome from the management review for CFP is the effectiveness of corrective and preventive actions taken, and ISO's output from the review is the
	10.2.5.3 Review output The output from the management review shall include as a minimum decisions and actions related to the following: a) improvement of the effectiveness of the management system and its processes; b) improvement of the certification services related to the fulfillment of this International Standard: c) resource needs. <u>ISO Documentation Requirement</u>			processes, not just the effectiveness achieved from actions taken of correcting and preventing nonconformities.	processes, not just the effectiveness achieved from actions taken of correcting and preventing nonconformities.

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-024

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

FPMCC 2- Standards for Accreditation of Food Protection Mgr Certification

Issue you would like the Conference to consider:

The Food Protection Manager Certification Committee (FPMCC) proposes revisions to the Standards for Accreditation of Food Protection Manager Certification Programs to incorporate punctuation, italics, capitalization, and other non-substantive changes.

Public Health Significance:

Food establishments have fewer critical risk factors according to the CDC as stated in the endorsement letter to the Conference for Food Protection (dated April 5, 2006, and referenced on the Conference website) when food establishments employ managers who have a Food Protection Manager Certification in accordance with the Conference for Food Protection's Standards for Accreditation of Food Protection Manager Certification Programs.

Recommended Solution: The Conference recommends...:

approval of revisions to the *Standards for Accreditation of Food Protection Manager Certification Programs* to incorporate punctuation, italics, capitalization, and other non-substantive changes (See Content Attachment 3 attached to Issue titled: Report - Food Protection Manager Certification Committee).

Submitter Information:

Name:	Jeff Hawley, Chair
Organization:	Food Protection Manager Certification Committee
Address:	Harris Teeter, LLC701 Crestdale Rd
City/State/Zip:	Matthews, NC 28105
Telephone:	704-844-3098
E-mail:	jhawley@harristeeter.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-025

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Mandatory Food Protection Manager Certification for Persons in Charge

Issue you would like the Conference to consider:

This issue is seeking a modification of the 2013 FDA Food Code to require that the designated "Person in Charge" (PIC) of a Food Establishment be a certified food protection manager who has passed a test that is part of an accredited program, as defined by the FDA Food Code. This modification would allow the regulatory authority the flexibility to exempt food establishments from this requirement if the regulatory authority deems the operation poses minimal risk of causing or contributing to foodborne illness.

Public Health Significance:

(Note: numbers is square brackets [x] refer to references found in Attachment A.)

Foodborne pathogens impose over $15.5 billion (2013 dollars) in economic burden on the U.S. public each year [1]. CDC estimates that each year 48 million people in the U.S. get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases [2, 3]. Norovirus is the leading cause of foodborne illnesses for which a specific pathogen can be identified (58%), and accounts for 26% of foodborne illness hospitalizations and 11% of foodborne illness deaths. Nontyphoidal *Salmonella* causes 11% of foodborne illnesses, and accounts for the most foodborne illness hospitalizations (35%) and deaths (28%) [3].

On average, Americans eat out at retail food service establishments 4.5 times a week [4].CDC has consistently identified retail food service establishments as the location of about 60% of foodborne illness outbreaks since 1993 [5, 6]. Many of these outbreaks are associated with unsafe practices within the establishments. Surveillance data show that factors associated with poor food preparation practices within establishments contributed to 35% of restaurant outbreaks with a single etiology, and factors associated with food worker health and hygiene contributed to 64% of those restaurant outbreaks [7]. Twenty percent of food workers have reported working while sick with vomiting and diarrhea, and infected food workers cause about 70% of reported norovirus outbreaks from contaminated food [8, 9].

Public health agencies have recognized that restaurants and other retail food facilities are avenues of exposure of the public to foodborne illness pathogens. Based on the assumption that certification leads to greater food safety knowledge and managers with this knowledge will successfully implement active managerial control of risk factors associated with foodborne illness and outbreaks, many public health agencies have required retail food service establishment manager food safety certification and even food worker food safety training. For example, the Illinois Food Service Sanitation Code requires manager certification, and as of July 1, 2014, the Illinois Code requires food handler training [10]. According to the National Restaurant Association's ServSafe website, 25 states require manager food safety certification and individual counties in 11 additional states also require certification of managers [11].

Based at least in part on the same assumptions made by public health agencies regarding certification, and recognizing their vulnerability to foodborne illness and disease outbreaks, the food industry has taken a leadership role in supporting food safety training and certification for their employees. For example, several chains require manager certification, regardless of their jurisdiction's regulations.

The assumption that manager food safety knowledge and certification will support active managerial control of risk factors has a scientific basis. Published studies that show the benefits include the following.

- Brown et al. (2014) found that certified managers and workers had greater food safety knowledge than noncertified managers and workers. Other studies on this topic conducted in local settings have reached similar conclusions [12-15].
- Bogard et al. (2013) found that managers in restaurants with a certified manager reported better food safety practices than managers in restaurants without a certified manager [16]. Specifically, managers in restaurants with a certified food manager, compared to managers in restaurants without a certified food manager, more often said that:
    - Workers in their restaurant were required to tell a manager when they were sick with gastrointestinal illness symptoms.
    - They took the final cook temperature of hamburgers.
    - They did not serve undercooked (rare or medium-rare) hamburgers.
- Kassa et al. (2010) found that restaurants with certified managers had significantly fewer critical food safety violations than restaurants without certified managers. [17]
- Cates et al. (2009) found that restaurants with certified managers present during inspection were less likely than restaurants without certified managers present to have critical violations in five of seven inspection categories.[18]
- Hedberg et al. (2006) found that restaurants in which an outbreak had occurred were less likely to have a certified manager than restaurants in which an outbreak had not occurred [19].
- In 2009, FDA found that full service restaurants with a certified manager present during the inspection, compared to those without a certified manager present, had fewer occurrences of risk factors in three of five categories. In 2004, FDA found that

full service restaurants had fewer occurrences of risk factors in two of five categories [20, 21].

Data from these studies indicate that manager certification is related to increased manager food safety knowledge, better food safety practices and inspection scores, and fewer foodborne illness outbreaks.

The Conference for Food Protection currently recognizes four providers of food protection manager certification. They provide accessible training in different languages. For example, the web site of one of the four certification providers reports that more than 5 million foodservice professionals have been certified through its food protection manager certification program.[22] showing that high quality resources for training and certifying food managers are readily available. There may be other accredited certification programs (e.g., state certified programs) that meet the Conference standards and provide the same conveniences.

A food safety certification requirement for food service establishment Persons-in-Charge is supported by the facts that:

- a large proportion of foodborne illness outbreaks are associated with retail food service establishments, indicating a lack of active managerial control of risk factors,
- the existing body of evidence supporting a link between manager certification and retail food safety,
- many state and local public health agencies already require certification,
- quality training and certification resources are readily available,
- the food industry may benefit from manager certification through reduced health and economic risks of foodborne outbreaks.

Exemption

Some establishments pose lower foodborne illness risk than others. It is appropriate for state and local agencies, by way of codes and ordinances or by policy, to establish criteria for what types of permitted establishments could be exempt from the mandatory manager certification requirement and for determining the conditions under which the minimum number of certified food protection managers must be some number greater than one.

Factors to consider when establishing such criteria include the size and scope of the operation, the hours of operation, and the types of foods sold or served.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the 2013 FDA Food Code be modified as follows:

1. Requiring that the Person in Charge be a certified food protection manager who has passed a test that is part of an accredited program, as defined by the FDA Food Code.
2. Provide an exception to requiring the Person in Charge to be a certified food protection manager if the regulatory authority deems the establishment to pose minimal risk of causing or contributing to foodborne illness either at certain times of operation or based on the nature of food preparation.

Submitter Information:

Name:	Laura Brown
Organization:	Centers for Disease Control and Prevention
Address:	4770 Buford Highway, MS F-28
City/State/Zip:	Atlanta, GA 30341
Telephone:	404-310-8556
E-mail:	lrg0@cdc.gov

Supporting Attachments:

- "Attachment A - References"

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

Attachment A

References Supporting Issue - Mandatory Food Protection Manager Certification for Persons in Charge

1. Hoffmann, S., Maculloch, B., and Batz, M. 2015. *Economic Burden of Major Foodborne Illnesses Acquired in the United States, EIB-140.* U.S. Department of Agriculture, Economic Research Service. Available at: http://www.ers.usda.gov/publications/eib-economic-information-bulletin/eib140.aspx.
2. Scallan, E., Griffin, P., Angulo, F., Tauxe, R, and Hoekstra, R. 2011. Foodborne illness acquired in the United States—unspecified agents. *Emerg. Infect. Dis*. 17:16–22.
3. Scallan, E., Hoekstra, R., Angulo, R., Tauxe, R., Widdowson, M., Roy, S., Jones, J., and Griffin, P. 2011. Foodborne illness acquired in the United States—major pathogens. *Emerg. Infect. Dis*. 17:7–15.
4. Zagats. 2015. The state of American Dining in 2015. Available at: https://www.zagat.com/b/the-state-of-american-dining-in-2015.
5. Olsen, S., MacKinnon, L., Goulding, J., Bean, N., and Slutsker, L. 2000. Surveillance for foodborne disease outbreaks --United States, 1993-1997. *MMWR*. 49(SS01):1-51.
6. Centers for Disease Control and Prevention (CDC). 2015. *Surveillance for Foodborne Disease Outbreaks, United States, 2012, Annual Report*. Atlanta, Georgia: US Department of Health and Human Services, CDC, 2014. (Available at: http://www.cdc.gov/foodsafety/pdfs/foodborne-disease-outbreaks-annual-report-2012-508c.pdf.
7. Gould, H., Rosenblum, I., Nicholas, D., Phan, Q., and Jones, T. 2013. Contributing factors in restaurant-associated foodborne disease outbreaks, FoodNet sites, 2006 and 2007. *J Food Protect*. 76(11):1824-8.
8. Sumner, S., Brown, L., Frick, R., Stone, C., Carpenter, L., Bushnell, L., Nicholas, D., Mack, J., Blade, H., Tobin-D'Angelo, M., Everstine, K., and the Environmental Health Specialists Network Working Group. 2011. Factors associated with food workers working while experiencing vomiting or diarrhea. *J. Food Protect*. 74:215–220.
9. Hall, A., Wikswo, M., Pringle, K., Gould, H., and Parashar, U. 2014. Vital Signs: Foodborne Norovirus Outbreaks — United States, 2009–2012. *MMWR.* 63(22);491-495.
10. Illinois Department of Public Health. 2016. Available at: http://dph.illinois.gov/topics-services/food-safety/fssmc.
11. National Restaurant Association. ServSafe. 2016. Available at: https://www.servsafe.com/ss/regulatory/default.aspx?aliaspath=/Special-Pages/ssredirect.
12. Brown, L., Le, B., Wong, M., Reimann, D., Nicholas, D., Faw, B., Davis, E., and Selman, C. 2014. Restaurant manager and worker food safety certification and knowledge. *Foodborne Pathog. Dis*. 11(11):835-43.
13. Lynch, R., Elledge, B., Griffith, C., and Boatright, D. 2003. A comparison of food safety knowledge among restaurant managers by source of training and experience, in Oklahoma County, Oklahoma. *J. Environ. Health*. 66:9–14.

14. Manes, M., Liu, L., and Dworkin, M. 2013. Baseline knowledge survey of restaurant food handlers in suburban Chicago: Do restaurant food handlers know what they need to know to keep consumers safe? *J Environ Health*. 76:18–26.
15. DeBess, E., Pippert, E., Angulo, F., and Cieslak, P. 2009. Food handler assessment in Oregon. *Foodborne Pathog. Dis*. 6:329–335.
16. Bogard, A., Fuller, C., Radke, V., Selman, C., and Smith, K. 2013. Ground beef handling and cooking practices in restaurants in eight States*. J Food Prot*. 76(12): p. 2132-40.
17. Kassa, H., Silverman, G., & Baroudi, K., 2010. Effect of a manager training and certification program on food safety and hygiene in food service operations. *Environ. health insights*. 4:13:20.
18. Cates, S., Muth, M., Karns, S., Penne, M., Stone, C., Harrison, J., and Radke, V. 2009. Certfied kitchen managers: Do they improve restaurant inspection outcomes? *J. Food Protect.* 72:384–391.
19. Hedberg, C., Smith, S., Kirkland, E., Radke, V., Jones, T., Selman, C., and the EHS-Net Working Group. 2006. Systematic environmental evaluations to identify food safety differences between outbreak and nonoutbreak restaurants. *J. Food Protect.* 69:2697–2702.
20. U.S. Food and Drug Administration. 2010. 2009 *FDA report on the occurrence of foodborne illness risk factors in selected institutional food service, restaurant, and retail food store facility types*. Available at: www.cfsan.fda.gov/_dms/retrsk2.html..
21. U.S. Food and Drug Administration. 2005. 2004 *FDA report on the occurrence of foodborne illness risk factors in selected institutional food service, restaurant, and retail food store facility types (2004).* Available at: http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf.
22. National Restaurant Association. ServSafe. 2016. Available at: http://www.restaurant.org/Restaurant-Careers/Training-Education/ServSafe.

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-026

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Report - Constitution, Bylaws and Procedures (CBP) Committee

Issue you would like the Conference to consider:

The 2014 - 2016 Constitution, Bylaws and Procedures Committee has addressed recommendations from the 2014 Biennial Meeting and have prepared a report summarizing its work.

Public Health Significance:

The Constitution, Bylaws and Procedure Committee shall submit recommendations to improve the Conference administrative functions through proposals to amend the Constitution and Bylaws and Conference Procedures.

Recommended Solution: The Conference recommends...:

acknowledgement of the submitted committee report and appreciation for the work of the 2014 - 2016 Constitution, Bylaws and Procedures Committee members.

The Conference also recommends continued work by the Constitution, Bylaws and Procedures (CBP) Committee on charges assigned by the Executive Board to:

1. Review the Conference for Food Protection governing documents (Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Meeting Manual, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Issues 2012-II-001, 2012-II-004, and 2014-II-018)
2. Review Industry constituency on Council 1.
3. Report back to the Executive Board; and submit recommendations as Issues at the 2018 Biennial Meeting.

Submitter Information:

Name: Lee M. Cornman
Organization: CFP Constitution, Bylaws and Procedures Committee
Address: Florida Department of Agriculture and Consumer Services3125 Conner Boulevard, # 185
City/State/Zip: Tallahassee, FL 32399-1650
Telephone: 850.245.5595 / 850.245.5547
E-mail: Lee.Cornman@FreshFromFlorida.com

Content Documents:

- "CBP Committee Final Report"
- "2016 Constitution and Bylaws Roster"

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: Constitution, Bylaws and Procedures (CBP) Committee

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Executive Board

DATE OF REPORT: January 7, 2016

SUBMITTED BY: Lee M. Cornman, Chair

COMMITTEE CHARGE(s):

Constitutional Charges, as stated in Article XV, Section 3 of the Constitution:
1. Submit recommendations to improve Conference administrative functions through proposals to amend the Constitution and Bylaws.
2. Review proposed memorandums of understanding and ensure consistency among the memorandums of understanding, the Conference Procedures manual, the Constitution and Bylaws and other working documents.
3. Report all recommendations to the Board prior to Council II deliberations.
4. Follow the direction of the Board.

Issue #: 2014 II-018
Charge: The Conference recommends that the Constitution, Bylaws and Procedures Committee continue work on assigned charges to:
1. Review the Conference for Food Protection governing documents (Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Meeting Manual, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Originally assigned via Issues 2012 II-001 and 2012 II-004)
2. Review the CFP Commercialism Policy to discern whether it is sufficient to apply to situations where the CFP name or logo is used in an unsanctioned manner by entities other than the CFP. (Originally assigned at the August 2012 Executive Board Meeting).
3. Report back to the Executive Board; and submit recommendations as Issues at the 2016 Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. **Progress on Overall Committee Activities:**

   No constitutional charges were assigned this biennial period.

   Issue 2014 II-018 – Item 1: Vicki Everly, Issue Co-Chair and CBP Committee member, volunteered to assist in working on review of the CFP governing documents to facilitate the "merger and conformance of these documents" as directed above. A proposed outline was presented to and approved by the Executive Board at the August 2015 meeting to qualify and quantify the committee direction with this charge. This charge is a large undertaking and will continue during the 2016 – 2018 biennial period. It is anticipated that it will be completed for submittal as an Issue in 2018.

Issue 2014 II-018 – Item 2 – Revision of CFP Commercialism Policy: Committee identified concern that the current policy was specific to Issues submitted to the Conference for the Biennial Meeting and that it needs to be expanded to encompass broader misuse of the CFP name and/or logo by others. Committee discussion circled around a two-part policy that addresses the Issues themselves and any other Conference/Committee functions. David Crownover volunteered to review and draft a revised issue for consideration and deliberation. This draft was discussed via conference calls and submitted to all committee members for review and final approval. An Issue titled "Revision of CFP Commercialism Policy" was submitted to the CFP Executive Board for review and approval prior to submitting the Issue for deliberation at the 2016 Biennial Meeting.

Committee review and discussion of questions submitted by committee member as provided by constitutional charges:

A CBP Committee member submitted a series of four questions for deliberation and resolution by the committee. These questions were discussed as part of committee conference calls and as part of two CFP Executive Board Meetings. The questions and the subsequent resolutions/action items are as follows:

1. **Same issues submitted at subsequent Biennial Meetings** – Active discussion on this question and agreement from committee members that some tweaking of the process can be achieved to preclude this from occurring in the future. Based on the committee discussion, Issue Co-Chairs recommended a modification to the Issue submission form to provide declarative information to council members if an Issue was "discussed at a previous Biennial Meeting"; Issue form modification was approved by the Executive Board. In addition, Issue submission instructions have been modified to include "caution" about resubmittal without including new information or science; and, council members will be advised to review previous Issues as homework in prep for the Biennial Meeting.
2. **Prohibit forming a committee as the recommended solution –** General committee discussion was opposed to a declarative statement of no committees as a recommended solution but there was agreement that further clarification is needed for councils to create clearly stated, achievable charges if committee formation is recommended. There was also an identified need for better instructions to councils when crafting recommended solutions. The Executive Board and Issue Committee are working on this concern.
3. **Extracted No Action Issues –** Concern was expressed on creating a balance of opponent vs. proponent on an Executive Board committee formed to resolve an Extracted No Action Issue. There was active discussion on the Executive Board with a consensus that committee members will be selected to ensure all sides are represented and that someone on the committee was present during the entire deliberation in council.
4. **Defining Industry Constituency as relates to Council 1 –** Discussion by committee members indicated agreement that participation of non-regulated industry entities continues to grow. There was active discussion on how that may or may not impact the makeup of those identified as industry voting members. There was concern expressed that the Bylaws may be inconsistent with the new constituencies and there is a committee desire to review further. After discussion by the Executive Board, Brenda Bacon, Bill Hardister and Cas Tryba volunteered to continue to look at

council membership based on new membership categories and to look at regulated vs. non-regulated industry representation.

2. Recommendations for consideration by Council:

The Constitution, Bylaws and Procedures Committee recommends continued work to:
1. Review the Conference for Food Protection governing documents (*Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Meeting Manual*, position descriptions, conference policies, etc.) to facilitate a merger and conformance of these documents into a comprehensive "Conference for Food Protection Manual." (Issues 2012 II-001, 2012 II-004 and 2014 II-018).
2. Review Industry constituency on Council 1.
3. Report back to the Executive Board; and submit recommendations as Issues at the 2018 Biennial Meeting.

This committee further recommends approval of the draft "Revision of CFP Commercialism Policy."

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

"Report - Constitution, Bylaws and Procedures Committee Final Report"

"CBP 2 – Revision of CFP Commercialism Policy": See Issue 2014 II-018 – Item 2 above. The Constitution, Bylaws and Procedures Committee has developed an Issue as charged and provided the following recommendation (new language is underlined):

COMMERCIALISM POLICY (established 2000)

PURPOSE

This policy has been developed by the Executive Board to establish guidelines for the use of:
1. commercial names, logos, or other information in Issues submitted to the Conference and in Issues or documents developed through the Conference for Food Protection (CFP) committee process and,
2. the use of Conference for Food Protection intellectual property including the Conference for Food Protection name and/or logo, without the express approval of the CFP Executive Board.

POLICY

Approval for use of the Conference for Food Protection name and/or logo is done through request and approval via the Conference for Food Protection Executive Board.

Issue Submission:

The Conference for Food Protection shall not endorse the use of a product, process or service by brand name.
Issues submitted for consideration at a Biennial Meeting will be reviewed; and those where brand names are used in the Issue, rationale or solution will be rejected.

The Issue Submission Form will contain a statement that reads, "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."

Intellectual Property:
The use of Conference for Food Protection (CFP) name and/or logo for commercial, promotional and/or endorsement purposes is prohibited by any entity other than the CFP without the express approval of the CFP Executive Board. Prohibited usage may include, but is not limited to research, press releases, product promotions, etc.

Attachments:

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

1. **Attachment A Constitution, Bylaws and Procedures Committee Final Report Issue**

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

2. **Attachment B Constitution, Bylaws and Procedures Committee Roster**

Submitter Information:

☐ I am a first time Issue submitter *(checking this box will enable the Council Chair to contact you in advance of the Biennial Meeting to answer any questions about the process involved in presenting Issues to Council)*

	Contact #1	***Contact #2***
Name	Lee M. Cornman	
Organization	CFP Constitution, Bylaws and Procedures Committee	
Address *(line 1)*	Florida Department of Agriculture and Consumer Services	
Address *(line 2)*	3125 Conner Boulevard, #185	
City / State / Zip	Tallahassee, Florida 32399-1650	
E-mail	Lee.Cornman@FreshFromFlorida.com	
Telephone	850.245.5595 / 850.245.5547	

COMMITTEE MEMBER ROSTER (attached):

Committee Name:

Committee Name: 2014 - 2016 Constitution, Bylaws and Procedures

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Cornman	Lee	Chair	State	FL Dept. of Ag & Cons. Svcs	Tallahassee	FL	850.245.5595	lee.cornman@freshfromflorida.com
Hardister	Bill	Member	Local	Mecklenburg Co. HD	Charlotte	NC	704.336.5533	bill.hardister@mecklenburgcountync.gov
Gaither	Marlene	Member	Local	Coconino County HD	Flagstaff	AZ	928.679.8761	mgaither@coconino.az.gov
Everly	Vicki	Member	Local	City of Berkeley Env Health	Berkeley	CA	510.501.0417	vicki.everly2@gmail.com
Ball	James	Member	Industry	The Fresh Market	Greensboro	NC	336.217.4080	jamesball@thefreshmarket.net
Bacon	Brenda	Member	Industry	Harris Teeter	Matthews	NC	704.844.4443	bbacon@harristeeter.com
Tryba	Cas	Member	Industry	Big Y Foods	Springfield	MA	413.504.4451	tryba@bigy.com
Luebkemann	Geoff	Member	Industry	FL Rest & Lodging Assoc	Tallahassee	FL	850.224.2250 X249	geoff@frla.org
Crownover	David	Member	Industry	NRA ServSafe	Chicago	IL	312.715.5396	dcrownover@restaurant.org
Zameska	George	Member	Industry	Paster Training	Gilbertsville	PA	610.970.1776	george.zameska@pastertraining.com
Glenda	Lewis	FDA Consultant	Federal	FDA	College Park	MD	240.402.2150	glenda.lewis@fda.hhs.gov
Liggans	Girvan	FDA Consultant	Federal	FDA	College Park	MD	301.436.2937	girvan.liggans@fda.hhs.gov

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-027

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

CBP 2 – Revision of CFP Commercialism Policy

Issue you would like the Conference to consider:

Several past incidents have occurred where the Conference for Food Protection (CFP) name and/or logo have been used or misused, without the consent of the Conference body or the Executive Board, to endorse or promote a product, process or service by brand name. Examples of such incidents include an article in a food safety related publication concerning CFP committee activities and the use of the CFP name and/or logo endorsing training programs. Additionally, there has been recent concern expressed by CFP members on the endorsement of products, processes or services by brand name during CFP committee meetings. As a result, the CFP Executive Board charged the Constitution, Bylaws and Procedures Committee with reviewing the existing Commercialism Policy with regards to these concerns and to "discern whether it is sufficient to apply to situations where the CFP name or logo is used in an unsanctioned manner by entities other than the CFP."

Upon review and deliberation of these concerns, the Constitution, Bylaws and Procedures Committee has drafted a more comprehensive policy addressing the development of committee Issues and/or supporting documents, the Issue submission process, and the intellectual property of the Conference.

Public Health Significance:

The Constitution and Bylaws/Procedure Committee shall submit recommendations to improve the Conference administrative functions through proposals to amend the *Constitution and Bylaws and Conference Procedures*.

Recommended Solution: The Conference recommends...:

the current CFP Commercialism Policy (established 2000) be revised as provided below (language to be added is in underline format):

COMMERCIALISM POLICY

PURPOSE

This policy has been developed by the Executive Board to establish guidelines for the use of:

1) commercial names, logos, or other information in Issues submitted to the Conference and in Issues or documents developed through the Conference for Food Protection (CFP) committee process and,

2) CFP intellectual property including the Conference for Food Protection name and/or logo, without the express approval of the CFP Executive Board.

POLICY

Approval for use of the Conference for Food Protection name and/or logo is done through request and approval via the Conference for Food Protection Executive Board.

Issue Submission:

- *The Conference for Food Protection shall not endorse the use of a product, process or service by brand name.*
- *Issues submitted for consideration at a Biennial Meeting will be reviewed; and those where brand names are used in the Issue, rationale or solution will be rejected.*
- *The Issue Submission Form will contain a statement that reads, "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."*

Intellectual Property:

- *The use of Conference for Food Protection (CFP) name and/or logo for commercial, promotional and/or endorsement purposes is prohibited by any entity other than the CFP without the express approval of the CFP Executive Board. Prohibited usage may include, but is not limited to research, press releases, product promotions, etc.*

Submitter Information:

Name:	Lee M. Cornman
Organization:	CFP Constitution, Bylaws and Procedures Committee
Address:	Florida Department of Agriculture and Consumer Services3125 Conner Boulevard, #185
City/State/Zip:	Tallahassee, FL 32399-1650
Telephone:	850.245.5595 / 850.245.5547
E-mail:	Lee.Cornman@FreshFromFlorida.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 II-028

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Committee to Explore Technology Solutions for Implementing CFP Guidance

Issue you would like the Conference to consider:

Retail food establishments are at risk for emergencies or disasters that could endanger the safety of the food and products sold to consumers. To assist these establishments in managing such crises, the CFP developed "The Emergency Action Plan for Retail Food Establishments" (document available on the CFP website at www.foodprotect.org/media/guide/Emergency%20Action%20Plan%20for%20Retail%20food%20Est.pdf). This document offers guidance to retail food stores and food service establishments, including very large and very small entities, as to the steps necessary to protect the public's health when circumstances affect food safety.

Safety guidance can only be effective if its existence is known and its recommendations are properly executed. Retail food establishments must not only train their employees, but such training has to prepare them to react appropriately in a crisis. Barring such training, or in cases where the fully trained employee is absent, individuals responding to a crisis must have committed the guidance to memory or be able to read, understand, and implement the guidance (if it is even readily available) during high pressure situations.

Requiring or recommending that food establishments post or maintain paper copies of safety guidance is a solution for the past. Technology is available, or can be easily developed, to assist employees with implementing the guidance at the time of the crisis with little or no training, allowing them to respond to changing circumstances under stressful conditions without relying on prior training or printed safety manuals.

Public Health Significance:

Food service employees come from every demographic category and educational background. Many employees are minors, some are new to the workforce, and experience levels can vary greatly among establishments. The workforce continues to become increasingly tech savvy, and the effectiveness of safety guidance should not depend so heavily upon traditional teaching methods that are skewed toward those with greater

maturity, education, or experience. Well designed, simple to use technology that brings the solution to the employee can help level the playing field.

For example, in-car navigation systems are very common and freely available on smart phones to provide drivers with turn-by-turn directions for even the most complicated journeys. The majority of Americans today own smart phones. On demand, step-by-step instructions, much like GPS navigation, that help guide food service employees through a crisis would greatly increase the consistency of responses in the event they are activated. This, in turn, would enhance public safety by ensuring that safety guidance like the CFP's "Emergency Action Plan for Retail Food Establishments" is followed properly.

As things stand today, the utility of CFP's guidance, and therefore the public safety benefits of this guidance, is limited to those circumstances where food service employees are effectively trained as to their implementation or aware of their existence. Technology available at an employee's fingertips to guide them through the proper procedures in a time of crisis would greatly enhance public safety.

Recommended Solution: The Conference recommends...:

that a technology committee be formed and charged to:

1. Make recommendations to the Conference for Food Protection in regard to:

(a) exploring technology solutions to assist food service employees to more effectively implement the 2014 Conference for Food Protection "Emergency Action Plan for Retail Food Establishments, Second Edition" and any other existing or future safety guidance provided by the CFP as deemed appropriate; and

(b) determine potential revisions to CFP's guidance, recommending technology solutions or adopting standards for the use of such solutions.

2. Report Committee recommendations to the 2018 Conference for Food Protection Biennial Meeting.

Submitter Information 1:

Name:	Sean Monahan
Organization:	DoRightly, LLC
Address:	106 West Boston Street
City/State/Zip:	Seattle, WA 98119
Telephone:	206-849-6821
E-mail:	smonahan@dorightly.com

Submitter Information 2:

Name:	Robert Furnier
Organization:	DoRightly, LLC
Address:	6725 Miami Avenue, Suite 100
City/State/Zip:	Cincinnati, OH 45243
Telephone:	512-792-6720
E-mail:	bobfurnier@gmail.com

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.

Submitter Information 1:

Name:	Tom Ford
Organization:	Listeria Retail Guidelines Committee, Co-Chair
Address:	Ecolab7900 McCloud Dr
City/State/Zip:	Greensboro, NC 27409
Telephone:	336-931-2209
E-mail:	tom.ford@ecolab.com

Submitter Information 2:

Name:	Don Schaffner
Organization:	Listeria Retail Guidelines Committee, Co-Chair
Address:	Rutgers University65 Dudley Rd
City/State/Zip:	New Brunswick, NJ 08901
Telephone:	732-982-7475
E-mail:	schaffner@aesop.rutgers.edu

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

Committee Name:

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

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Schaffner	Donald	Co-Chair	Co-chair, Academia	Rutgers University	Freehold	NJ	(732) 982-7475	schaffner@aesop.rutgers.edu
Ford	Thomas	Co-Chair	Co-chair, Industry, Support	Ecolab	Greensboro	NC	(336) 931-2209	tom.ford@ecolab.com
Hernandez	Erik	Member	Industry, Processing	Boar's Head	Brooklyn	NY	718-456-3600 x1385	erik.hernandez@boarshead.com
Dykman	Laura	Member	Industry, Retail	Harmons Grocery	Salt Lake City	UT	(801) 957-8472	lauradykman@harmonsgrocery.com
Jennings	Allison	Member	Industry, Retail	Amazon	Seattle	WA	206-435-8625	Jennings, Allison <jealliso@amazon.com>
Kohl	Larry	Member	Industry, Retail	Delhaize America	Salisbury	NC	(704) 310-4149	Larry.Kohl@delhaize.com
McGuffey	Charles E.	Member	Industry, Retail	7-Eleven, Inc.	Dallas	TX	(972) 828-6844	charles.mcguffey@7-11.com
Seaman	Chuck	Member	Industry, Retail	Hy-Vee, Inc.	West Des Moines	IA	(515) 559-5736	cseaman@hy-vee.com
Tryba	Casimir M.	Member	Industry, Retail	Big Y Foods, Inc.	Springfield	MA	(413) 504-4450	tryba@bigy.com
Grinstead	Dale	Member	Industry, Support	Diversey	Sturtevant	WI	(262) 631-4433	dale.grinstead@sealedair.com
Hollingsworth	Jill	Member	Industry, Support	Food Safety Consultant				1jillh@gmail.com
Kowalczyk	Susan	Member	Regulator, Local	DuPage County Health	Wheaton	IL	(630) 221-7396	skowalcz@dupagehealth.org
Leber	Lindsey	Member	Regulator, Local	Huron County Public Health	Norwalk	OH	419-668-1652 Ext. 265	lleber@huroncohealth.com
Anderson	Timothy	Member	Regulator, State	WI, DoA, Div. Food Safety	Madison	WI	(608) 224-4716	timothy.anderson@wi.gov
Clendenin	Karla	Member	Regulator, State	FL, DACS	Tallahassee	FL		Karla.Clendenin@FreshFromFlorida.com
Johnson	Brian	Member	Regulator, State	RI Health Department	Providence	RI	(401) 222-7726	brian.johnson@health.ri.gov
Schvaneveldt	Jay	Member	Regulator, State	Utah DAF	Salt Lake City	UT	(801) 538-7149	nschvaneveldt@utah.gov
Brown	Bob	At Large	Retail Food Industry	Whole Foods Market	Austin	TX	(512) 944-7405	robert.brown@wholefoods.com
Cranford	Vanessa	At Large	Industry, Processing	Taylor Farms Florida	Orlando	FL	(407) 495-7333	vcranford@taylorfarms.com
Ewell	Harold	At Large	Food Industry Support	N2N Global	Longwood	FL	(412) 418-7018	ewell8194@comcast.net
Gilardi	Linda	At Large	Industry, Food Service	Compass Group	Charlotte	NC	(704) 328-3194	Linda.Gilardi@compass-usa.com
Gregro	Susan	At Large	Food Service Industry	Sodexo	Sinking Springs	PA	(610) 509-1796	susan.gregro@sodexo.com
O'Donnell	James	At Large	Food Industry Support	Hussmann Corporation	Bridgeton	MO	(314) 298-4778	james.odonnell@hussmann.com
O'Donnell-Cahill	Kathleen	At Large	Retail Food Industry	Wegmans Food Markets, Inc.	Rochester	NY	585-429-3623	Kathleen Odonnell-Cahil@wegmans.com
Pocius	Joseph	At Large	Processing Food Industry	Boar's Head Provisions	Petersburg	VA	(941) 685-5575	joseph.pocius@boarshead.com
Thesmar	Hillary	At Large	Food Industry Support	Food Marketing Institute	Arlington	VA	(202) 220-0658	hthesmar@fmi.org
Hale	Aggie	CFP Staff						
Rossow	Todd	Council chair						
Sarrocco-Smith	Davene	Council vice chair						
Barlow	Kristie	Member - Consultant	Federal Regulator	USDA FSIS	Washington	DC	202-690-7739	Barlow, Kristina - FSIS <Kristina.Barlow@fsis.usda.gov>
Jackson	Kelly	Member - Consultant	Federal	CDC			404-639-4603	gqv8@cdc.gov
Parish	Mickey	Member - Consultant	Federal Regulator	USFDA/CFSAN	College Park	MD	301-436-1728	mickey.parish@fda.hhs.gov
Webb	Brad	Member - Consultant	Federal Regulator	USDA FSIS	Athens	GA	706-546-2341	Brad.Webb@fsis.usda.gov
Williams	Laurie	Member - Consultant	Federal Regulator	USFDA/CFSAN	College Park	MD	(240) 402-2938	laurie.williams@fda.hhs.gov

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

Table of contents

Acknowledgements

2004-2006 *Listeria* Intervention Committee:
Cas Tryba, Co-Chair Big Y Foods, Inc.
Frank Greene, Co-Chair CT Department of Consumer Protection
Jill Hollingsworth, Food Marketing Institute
Joseph Corby, NY Department of Agriculture and Markets
Deborah Marlow, Field Operations and Enforcement, Retail Foods Division Texas Department of Health
Karen Reid, West Hartford-Bloomfield Health District
Kenneth Rosenwinkel, Jewel-Osco (Albertson‘s)
Roger Coffman, Lake County Health Department
Pam Williams, Yum!Brands, Inc.
Jan McCabe/Todd Rossow, Publix Super Markets, Inc.
Thomas P. Ford, Ecolab
Paul Uhler, TAS, Office of Policy, Program and Employee Development FSIS
Heather Hicks, Quesenberry (USDA lead) USDA-FSIS
Jenny Scott, Food Products Association
Richard H. Linton, Purdue University
Wayne Derstine, FL Department of Agriculture and Consumer Services
Mike Magner, Sheetz, Inc.
Thomas M. Foegle, Brinker International
William E. McCullough, Arby‘s Inc.
Sheri Dove, PA Department of Agriculture
Thomas L. Schwarz, International Inflight Food Service Association
Jon Woody, (FDA Lead) Center for Food Safety and Applied Nutrition U.S. FDA
Shirley Bohm, Center for Food Safety and Applied Nutrition U.S. FDA

2012-2014 *Listeria* guidelines Committee:
Catherine Addams-Hutt, NRA
Kristina Barlow, Member, USDA
William Henry Blade, RI Dep. Of Health
Matthew Colson, FL Dep. of Ag.
Michelle Danyluk, University of Florida
Thomas Ford, Ecolab
Christopher Gordon, VA Dep. Of Health
Dale Grinstead, Sealed Air
David Konop, Target
Sue Kowalczyk, Dupage Co. Dep of health
Larry Kohl, Delhaze
Kathleen O'Donnell, Wegman's
Haley F. Oliver, Purdue Univ.
Mickey Parish, FDA
Chuck Seaman, Hy-Vee
Katherine Simon, MN Dep of Health
Hilary Thesmar, FMI
Laurie Williams, FDA
Sharon Wood, HEB
Neil Ylanan, LSG Sky Chef

2014-2016 *Listeria* guidelines Committee:
Thomas Ford, Co-Chair, Ecolab
Donald Schaffner, Co-Chair, Rutgers University
Timothy Anderson, WI, DoA, Div. Food Safety
Kristie Barlow, USDA FSIS
Bob Brown, Whole Foods Market
Karla Clendenin, FL, DACS
Vanessa Cranford, Taylor Farms Florida
Laura Dykman, Harmons Grocery
Harold Ewell, N2N Global
Linda Gilardi, Compass Group
Susan Gregro, Sodexo
Dale Grinstead, Diversey
Erik Hernandez, Boar's Head
Jill Hollingsworth, Food Safety Consultant
Kelly Jackson, CDC
Allison Jennings, Amazon
Brian Johnson, RI Health Department
Larry Kohl, Delhaize America
Susan Kowalczyk, DuPage County Health
Lindsey Leber, Huron County Public Health
Charles E. McGuffey, 7-Eleven, Inc.
James O'Donnell, Hussmann Corporation
Kathleen O'Donnell-Cahill, Wegmans Food Markets, Inc.
Mickey Parish, USFDA/CFSAN
Joseph Pocius, Boar's Head Provisions
Todd Rossow, Council III Chair, Publix
Davene Sarrocco-Smith, Council III, Vice Chair Lake County Public Health District
Jay Schvaneveldt, Utah DAF
Chuck Seaman, Hy-Vee, Inc.
Hillary Thesmar, Food Marketing Institute
Casimir M. Tryba, Big Y Foods, Inc.
Brad Webb, USDA FSIS
Laurie Williams, USFDA/CFSA

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

Contents

Acknowledgements

Cas Tryba, Co-Chair
Big Y Foods, Inc.

Frank Greene, Co-Chair
CT Department of consumer Protection

Jill Hollingsworth
Food Marketing Institute

Jenny Scott
Food Products Association

Joseph Corby
NY Department of Agriculture and Markets

Richard H. Linton
Purdue University

Deborah Marlow
Field Operations and Enforcement, Retail Foods Division Texas Department of Health

Wayne Derstine
FL Department of Agriculture and Consumer Services

Karen Reid
West Hartford-Bloomfield Health District

Mike Magner
Sheetz, Inc.

Kenneth Rosenwinkel
Jewel-Osco (Albertson's)

Thomas M. Foegle
Brinker International

Roger Coffman
Lake County Health Department

William E. McCullough
Arby's Inc.

Pam Williams
Yum!Brands, Inc.

Sheri Dove
PA Department of Agriculture

Jan McCabe/Todd Rossow
Publix Super Markets, Inc.

Thomas L. Schwarz
International Inflight Food Service Association

Thomas P. Ford
Ecolab

Jon Woody (FDA Lead)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Paul Uhler, TAS, Office of Policy, Program and Employee Development FSIS

Shirley Bohm
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Heather Hicks Quesenberry (USDA lead)
USDA-FSIS

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:

Name:	Tom Ford
Organization:	Listeria Retail Guidelines Committee, Co-Chair
Address:	Ecolab7900 McCloud Dr
City/State/Zip:	Greensboro, NC 27409
Telephone:	3369312209
E-mail:	tom.ford@ecolab.com

Submitter Information 2:

Name:	Don Schaffner
Organization:	Listeria Retail Guidelines Committee, Co-Chair
Address:	Rutgers University65 Dudley Rd
City/State/Zip:	New Brunswick, NJ 08901
Telephone:	732-982-7475
E-mail:	schaffner@aesop.rutgers.edu

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
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.

Submitter Information 1:

Name:	Lori LeMaster
Organization:	Hand Hygiene Committee Co-Chair
Address:	TN Department of Health710 James Robertson Pkwy 4th Floor AJT
City/State/Zip:	Nashville, TN 37214
Telephone:	615-741-8531
E-mail:	lori.lemaster@tn.gov

Submitter Information 2:

Name:	Christina Bongo-Box
Organization:	Hand Hygiene Committee Co-Chair
Address:	Little Caesar's130 Coldstream Ct
City/State/Zip:	Canton, GA 30115
Telephone:	502-594-5915
E-mail:	christinabongo@gmail.com

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"

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: 08/2013

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

Noroviruses Using the Fingerpad Method and Quantitative Real-Time PCR". Food Environ. Virol 2011;3:35-42.

- Liu, Macinga, Fernandez, Zapka, Hsiao, Berger, Arbogast, Moe. "Comparison of the Activity of Alcohol-Based Handrubs against Human Noroviruses Using the Fingerpad Method and Quantitative Real-Time PCR." Food and Environmental Virology, December 2010.
- Macinga, Sattar, Jaykus And Arbogast. "Improved Inactivation of Noneveloped Viruses and Their Surrogates by a Novel Alcohol-Based Hand Sanitizer". Appl. Environ. Microbiol 2008;74(16):5047-5052.
- Amy J. Pickering , Alexandria B. Boehm , Mathew Mwanjali , And Jennifer Davis. Efficacy of Waterless Hand Hygiene Compared with Handwashing Soap: A Field Study in Dar es Salaam , Tanzania. Am. J. Trop. Med. Hyg 2010;82(2):270-278.
- Amy J. Pickering, Jennifer Davis And Alexandria B. Boehm "Efficacy of alcohol-based hand sanitizer on hands soiled with dirty and cooking oil" Journal of Water and Health 2011.
- Racicot, Kocher, Beauchamp, Letellier and Vaillancourt Assessing most practical and effective protocols to sanitize hands of poultry catching crew members. Preventive Vetinary Medicine 2013;111:92-99.
- Donald W. Schaffner* and Kristin M. Schaffner Management of Risk of Microbial Cross-Contamination from Uncooked Frozen Hamburgers by Alcohol-Based Hand Sanitizer. J. Food Protect 2007;70(1):109-113.
- Josie L. Traub-Dargatz, J. Scott Weese, Joyce D. Rousseau, Magdalena Dunowska,Paul S. Morley, David A. Dargatz. "Pilot study to evaluate 3 hygienic protocols on the reduction of bacterial load on the hands of veterinary staff performing routine equine physical examinations". Can Vet J 2006;47:671-676.

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

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	Telephone	Email
Bongo-Box	Christina	Co-Chair	Food Service Industry	Popeyes Louisiana Kitchen Inc	Atlanta	(404) 459-4718	christinabongo@gmail.com
LeMaster	Lori	Co-Chair	State Regulator	TN Department of Health	Nashville	(615) 741-7206	lori.lemaster@tn.gov
Adams Hutt	Dr. Catherine	Member	Food Service Industry	National Restaurant Association	Aubrey	(630) 605-3022	cadams@rdrsol.com
Buffer	Janet	Member	Retail Food Industry	The Kroger Company	Cincinnati	(513) 387-7332	janet.buffer@kroger.com
Carotenuto	Tony	Member	Federal Regulator	Navy and Marine Corps Public Health Center	Portsmouth	(757) 953-0712	anthony.carotenuto@med.navy.mil
Funk	Joshua	Member	Food Service Industry	KFC	Louisville	(502) 874-8899	joshua.funk@yum.com
Gaither	Marlene	Member	Local Regulator	Coconino County (AZ) Health Department	Flagstaff	(928) 679-8761	mgaither@coconino.az.gov
Huffman	Troy	Member	State Regulator	Nebraska Department of Health and Human Services	Lincoln	(402) 471-0387	troy.huffman@nebraska.gov
Johnson	Anna	Member	State Regulator	FL Dept of Agriculture	Deltona	(407)335-3497	anna.johnson@freshfromflorida.com
Oswald	Steve	Member	Retail Food Industry	Wakefern Food Corporation	Elizebeth	(908) 527-3624	steve.oswald@wakefern.com
Sanchez	Angela	Member	Food Service Industry	CKE Restaurants Holdings Inc.	Ontario	(714) 254-4556	asanchez@ckr.com
Schaffner	Donald	Member	Academia	Rutgers University	Freehold	(732) 982-7475	schaffner@aesop.rutgers.edu
Tracey	Stephen	Member	Retail Food Industry	Delhaize America/Food Lion	Salisbury	(704) 223-0320	smtracey@foodlion.com

Yasin	Jemal	Member	Local Regulator	District of Columbia, Department of Health	Washington	(202) 380-6595	jemalyasin@yahoo.com
Westbrook	Tim	Member	Retail Food Industry	Publix Super Markets, Inc.	Lakeland	(352) 989-7314	tim.westbrook@publix.com
Arbogast	James	At Large	Retail Food Industry	Gojo Industries, Inc.	Akron	(330) 255-6207	arbogasj@gojo.com
Buswell	Cheri	At Large	Food Service Industry	International Dairy Queen	Minneapolis	(952) 830-0224	cheri.buswell@idq.com
Deslauriers	Susan	At Large	Retail Food Industry	Big Y Foods	Springfield	(413) 504-4452	deslaurs@bigy.com
Horn	Jason	At Large	Food Service Industry	In-N-Out Burger	Baldwin Park	(626) 813-5326	JHorn@innout.com
Kreske	Dr. Audrey C.	At Large	Food Service Industry	Burger King Corporation	Miami	(305) 378-7432	akreske@whopper.com
Lowe	Ryan	At Large	Food Service Industry	Walt Disney Parks and Resorts	Lake Buena Vista	(407) 827-5524	ryan.m.lowe@disney.com
Patel	Jaymin	At Large	Retail Food Industry	Aramark	Philadelphia	(215) 409-7343	patel-jaymin@aramark.com
Samarya-Timm	Michele	At Large	Local Regulator	Somerset County Department of Health	Somerville	(908) 231-7155	SamaryaTim@aol.com
Shumaker	David	At Large	Retail Food Industry	GOJO Industries	Akron	(330) 255-6749	shumakerd@gojo.com
Snyder Ph.D.	Peter	At Large	Food Service Industry	SnyderHACCP	Roseville	651-646-7077	pete@snyderhaccp.com
Starobin	Dr. Anna	At Large	Retail Food Industry	Ecolab	Greensboro	(336) 854-8269	anna.starobin@ecolab.com
Cartagena	Mary	Consultant	FDA	FDA	College Park	240-402-2937	mary.cartagena@fda.hhs.gov
Otto	Jessica	Consultant	FDA - alternate	FDA	College Park	240-402-1876	jessica.otto@fda.hhs.gov

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	_____		

All information above the line is for conference use only.

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.

Submitter Information 1:

Name:	Lori LeMaster
Organization:	Hand Hygiene Committee Co-Chair
Address:	TN Department of Health710 James Robertson Pkwy 4th Floor AJT
City/State/Zip:	Nashville, TN 37243
Telephone:	615-741-8531
E-mail:	lori.lemaster@tn.gov

Submitter Information 2:

Name:	Christina Bongo-Box
Organization:	Hand Hygiene Committee Co-Chair
Address:	Little Caesar’s130 Coldstream Ct
City/State/Zip:	Canton, GA 30115
Telephone:	502-594-5915
E-mail:	christinabongo@gmail.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-005

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:

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]

Submitter Information 1:

Name:	Lori LeMaster
Organization:	Hand Hygiene Committee Co-Chair
Address:	TN Department of Health710 James Robertson Pkwy 4th Floor AJT
City/State/Zip:	Nashville, TN 37243
Telephone:	615-741-8531
E-mail:	lori.lemaster@tn.gov

Submitter Information 2:

Name: Christina Bongo-Box
Organization: Hand Hygiene Committee Co-Chair
Address: Little Caesar's130 Coldstream Ct
City/State/Zip: Canton, GA 30115
Telephone: 502-594-5915
E-mail: christinabongo@gmail.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-006

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

All information above the line is for conference use only.

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.

Submitter Information 1:

Name:	Lori LeMaster
Organization:	Hand Hygiene Committee Co-Chair
Address:	710 James Robertson Pkwy
City/State/Zip:	Nashville, TN 37243
Telephone:	TBD
E-mail:	Lori.LeMaster@tn.gov

Submitter Information 2:

Name:	Christina Bongo-Box
Organization:	Little Caesars Enterprises Inc
Address:	2211 Woodward Avenue
City/State/Zip:	Detroit, MI 48201
Telephone:	313-471-6689
E-mail:	christina.bongo-box@LCEcorp.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-007

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

All information above the line is for conference use only.

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.

Submitter Information 1:

Name:	Rob Green
Organization:	National Council of Chain Restaurants
Address:	1101 New York Avenue, NW, Suite 1200
City/State/Zip:	Washington, DC, DC 20005
Telephone:	202-626-8183
E-mail:	GreenR@nccr.net

Submitter Information 2:

Name:	Jason Horn
Organization:	In-N-Out Burger
Address:	13502 Hamburger Lane
City/State/Zip:	Baldwin Park, CA 91706
Telephone:	626-813-5326
E-mail:	JHorn@innout.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-008

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

All information above the line is for conference use only.

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]

Submitter Information:

Name:	Adam Inman
Organization:	Kansas Department of Agriculture
Address:	1320 Research Park Drive
City/State/Zip:	Manhattan, KS 66502
Telephone:	7855646764
E-mail:	adam.inman@kda.ks.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-009

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

All information above the line is for conference use only.

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]

Submitter Information:

Name:	Adam Inman
Organization:	Kansas Department of Agriculture
Address:	1320 Research Park Drive
City/State/Zip:	Manhattan, KS 66502
Telephone:	7855646764
E-mail:	adam.inman@kda.ks.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-010

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

All information above the line is for conference use only.

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.

Submitter Information:

Name:	Jim Mann
Organization:	Handwashing For Life
Address:	1216 Flamingo Parkway
City/State/Zip:	Libertyville, IL 60048
Telephone:	847-918-0254
E-mail:	jmann@handwashingforlife.com

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"

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.

Journal of Food Protection, Vol. 73, No. 12, 2010, Pages 2296–2300

Research Note

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

SARAH L. EDMONDS,[1]* JAMES MANN,[2] ROBERT R. McCORMACK,[3] DAVID R. MACINGA,[1] CHRISTOPHER M. FRICKER,[1] JAMES W. ARBOGAST,[1] AND MICHAEL J. DOLAN[1]

[1]*GOJO Industries, Inc., P.O. Box 991, Akron, Ohio 44309;* [2]*Handwashing for Life, 1216 Flamingo Parkway, Libertyville, Illinois 60048; and* [3]*BioScience Laboratories, Inc., 300 North Willson Avenue, Suite 1, Bozeman, Montana 59715, USA*

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

ABSTRACT

The risk of inadequate hand hygiene in food handling settings is exacerbated when water is limited or unavailable, thereby making washing with soap and water difficult. The SaniTwice method involves application of excess alcohol-based hand sanitizer (ABHS), hand ''washing'' for 15 s, and thorough cleaning with paper towels while hands are still wet, followed by a standard application of ABHS. This study investigated the effectiveness of the SaniTwice methodology as an alternative to hand washing for cleaning and removal of microorganisms. On hands moderately soiled with beef broth containing *Escherichia coli* (ATCC 11229), washing with a nonantimicrobial hand washing product achieved a 2.86 ($\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

* Author for correspondence. Tel: 330-255-6745; Fax: 330-255-6083: E-mail: edmondss@gojo.com.

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.

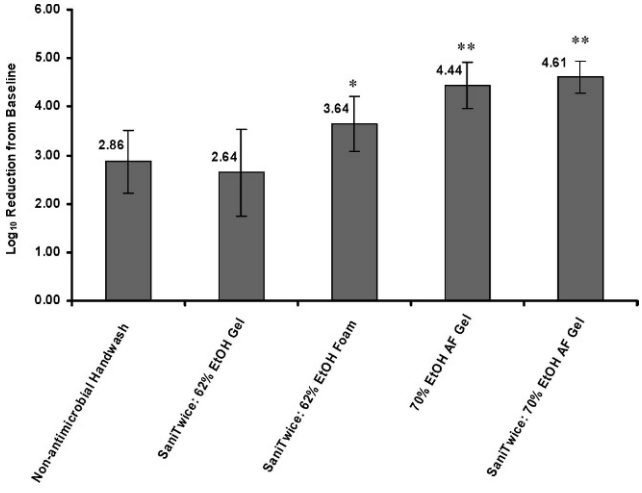


FIGURE 1. *Log reduction from baseline for microbial contamination of hands moderately soiled with contaminated beef broth after application of test products. Error bars represent standard deviation. Data are from two separate studies. In study 1 (*n = *11), nonantimicrobial hand washing product and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

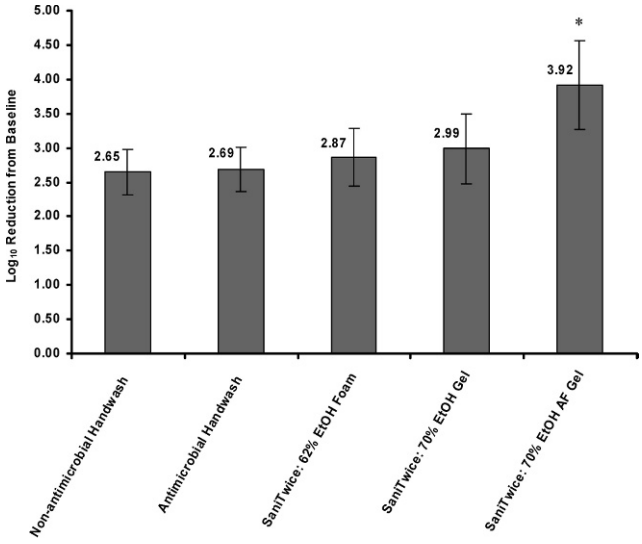


FIGURE 2. *Log reduction from baseline for microbial contamination of hands heavily soiled with contaminated uncooked hamburger after application of test products and protocols. Error bars represent standard deviation. Data are from study 3 (*n = *15), in which five test configurations were evaluated.* * 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.

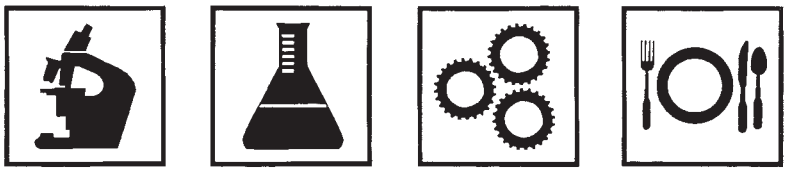
ACKNOWLEDGMENTS

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

REFERENCES

1. Bischoff, W. E., T. M. Reynolds, C. N. Sessler, M. B. Edmond, and R. P. Wenzel. 2000. Handwashing compliance by health care workers: the impact of introducing an accessible, alcohol-based hand antiseptic. *Arch. Intern. Med.* 160:1017–1021.
2. Bloomfield, S., A. Aiello, B. Cookson, C. O'Boyle, and E. Larson. 2007. The effectiveness of hand hygiene procedures in reducing the risks of infections in home and community settings including handwashing and alcohol-based hand sanitizers. *Am. J. Infect. Control* 35:S27–S64.
3. Buzby, J. C., and T. Roberts. 1997. The economics of enteric infections: human foodborne disease costs. *Gastroenterology* 136: 1851–1862.
4. Buzby, J. C., and T. Roberts. 2009. Economic costs and trade impacts of microbial foodborne illness. *World Health Stat. Q.* 50:57–66.
5. Centers for Disease Control and Prevention. 2002. Guidelines for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *Morb. Mortal. Wkly. Rep.* 51:1–56.
6. Centers for Disease Control and Prevention. 2009. Preliminary FoodNet data on the incidence of infection with pathogens transmitted commonly through food—10 states. 2008. *Morb. Mortal. Wkly. Rep.* 58:333–337.
7. Courtenay, M., L. Ramirez, B. Cox, I. Han, X. Jiang, and P. Dawson. 2005. Effects of various hand hygiene regimes in removal and/or destruction of *Escherichia coli* on hands. *Food Serv. Technol.* 5:77–84.
8. Curtis, V., and S. Cairncross. 2003. Effect of washing hands with soap on diarrhea risk in the community: a systematic review. *Lancet Infect. Dis.* 3:275–281.
9. Fendler, E. J., Y. Ali, B. S. Hammond, M. K. Lyons, M. B. Kelley, and N. A. Vowell. 2002. The impact of alcohol hand sanitizer use on infection rates in an extended care facility. *Am. J. Infect. Control* 30: 226–233.
10. Fendler, E. J., and P. Groziak. 2002. Efficacy of alcohol-based hand sanitizers against fungi and viruses. *Infect. Control Hosp. Epidemiol.* 23:61–62.
11. Green, L. R., V. Radke, R. Mason, L. Bushnell, D. W. Reimann, J. C. Mack, M. D. Motsinger, T. Stigger, and C. A. Selman. 2007. Factors related to food worker hand hygiene practices. *J. Food Prot.* 70:661–666.
12. Green, L. R., C. A. Selman, V. Radke, D. Ripley, J. C. Mack, D. W. Reimann, T. Stigger, M. Motsinger, and L. Bushnell. 2006. Food worker hand washing practices: an observation study. *J. Food Prot.* 69:2417–2423.
13. Guzevich, J., and M. Ross. 1999. Evaluation of risks related to microbiological contamination of ready-to-eat food by food preparation workers and the effectiveness of interventions to minimize those risks. Available at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ucm210138.htm. Accessed 25 March 2010.
14. Haas, C. N., J. R. Marie, J. B. Rose, and C. P. Gerba. 2005. Assessment of benefits from use of antimicrobial hand products: reduction in risk from handling ground beef. *Int. J. Hyg. Environ. Health* 208:461–466.
15. Hoffmann, S., P. Fischbeck, A. Krupnick, and M. McWilliams. 2007. Using expert elicitation to link foodborne illnesses in the United States to foods. *J. Food Prot.* 70:1220–1229.
16. Hugonnet, S., T. V. Perneger, and D. Pittet. 2002. Alcohol-based handrub improves compliance with hand hygiene in intensive care units. *Arch. Intern. Med.* 162:1037–1043.
17. Larson, E., and L. Bobo. 1992. Effective hand degerming in the presence of blood. *J. Emerg. Med.* 10:7–11.
18. Luby, S. P., M. Agboatwalla, J. Painter, A. Altaf, W. L. Billhimer, and R. M. Hoekstra. 2004. Effect of intensive handwashing promotion on childhood diarrhea in high-risk communities in Pakistan: a randomized controlled trial. *JAMA (J. Am. Med. Assoc.)* 291:2547–2554.
19. Lues, J., and I. Van Tonder. 2007. The occurrence of indicator bacteria on hands and aprons of food handlers in the delicatessen sections of a retail group. *Food Control* 18:326–332.
20. Michaels, B., C. Keller, M. Blevins, G. Paoli, T. Ruthman, E. Todd, and C. Griffith. 2004. Prevention of food worker transmission of foodborne pathogens: risk assessment and evaluation of effective hygiene intervention strategies. *Food Serv. Technol.* 4:31–49.
21. Montville, R., Y. Chen, and D. W. Schaffner. 2002. Risk assessment of hand washing efficacy using literature and experimental data. *Int. J. Food Microbiol.* 73:305–313.
22. Paulson, D. 1999. A suggested method for evaluating foodhandler/processor handwash formulations. *Dairy Food Environ. Sanit.* 19: 546–550.
23. Paulson, D., C. Riccardi, C. Beausoleil, E. Fendler, M. Dolan, L. Dunkerton, and R. Williams. 1999. Efficacy evaluation of four hand cleansing regimens for food handlers. *Dairy Food Environ. Sanit.* 19: 680–684.
24. Schaffner, D. W., and K. M. Schaffner. 2007. Management of risk of microbial cross-contamination from uncooked frozen hamburgers by alcohol-based hand sanitizer. *J. Food Prot.* 70:109–113.
25. Todd, E. C. D., J. D. Greig, C. A. Bartleson, and B. S. Michaels. 2007. Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 2. Description of outbreaks by size, severity, and settings. *J. Food Prot.* 70:1975–1993.
26. Todd, E. C. D., J. D. Greig, C. A. Bartleson, and B. S. Michaels. 2007. Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 3. Factors contributing to outbreaks and description of outbreak categories. *J. Food Prot.* 70:2199–2217.
27. Todd, E. C. D., J. D. Greig, C. A. Bartleson, and B. S. Michaels. 2008. Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 5. Sources of contamination and pathogen excretion from infected persons. *J. Food Prot* 71:2582–2595.
28. U.S. Food and Drug Administration. 1994. Tentative final monograph for health-care antiseptic drug products: proposed rule. *Fed. Regist.* 59:31441–31452.
29. U.S. Food and Drug Administration. 2004. FDA report on the occurrence of foodborne illness risk factors in selected institutional foodservice, restaurant, and retail food store facility types. Available at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm089696.htm#execsum. Accessed 25 March 2010.
30. U.S. Food and Drug Administration. 2009. Food Code 2009. Available at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/. Accessed 25 March 2010.
31. White, C., R. Kolble, R. Carlson, N. Lipson, M. Dolan, Y. Ali, and M. Cline. 2003. The effect of hand hygiene on illness rate among students in university residence halls. *Am. J. Infect. Control* 31:364–370.

Journal of Food Protection



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

SARAH L. EDMONDS,[1]* ROBERT R. McCORMACK,[2] SIFANG STEVE ZHOU,[3] DAVID R. MACINGA,[1] AND CHRISTOPHER M. FRICKER[1]

[1]*GOJO Industries, Inc., One GOJO Plaza, Suite 500, Akron, Ohio 44311;* [2]*BioScience Laboratories, Inc., 300 North Willson, Suite 1, Bozeman, Montana 59771; and* [3]*MICROBIOTEST, Microbac Laboratories, Inc., 105B Carpenter Drive, Sterling, Virginia 20164, USA*

Journal of Food Protection, Vol. 75, No. 7, 2012, Pages 1303–1309
doi:10.4315/0362-028X.JFP-11-449

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

SARAH L. EDMONDS,[1]* ROBERT R. McCORMACK,[2] SIFANG STEVE ZHOU,[3] DAVID R. MACINGA,[1] AND CHRISTOPHER M. FRICKER[1]

[1]*GOJO Industries, Inc., One GOJO Plaza, Suite 500, Akron, Ohio 44311;* [2]*BioScience Laboratories, Inc., 300 North Willson, Suite 1, Bozeman, Montana 59771; and* [3]*MICROBIOTEST, Microbac Laboratories, Inc., 105B Carpenter Drive, Sterling, Virginia 20164, USA*

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

ABSTRACT

Pathogenic strains of *Escherichia coli* and human norovirus are the main etiologic agents of foodborne illness resulting from inadequate hand hygiene practices by food service workers. This study was conducted to evaluate the antibacterial and antiviral efficacy of various hand hygiene product regimens under different soil conditions representative of those in food service settings and assess the impact of product formulation on this efficacy. On hands contaminated with chicken broth containing *E. coli,* representing a moderate soil load, a regimen combining an antimicrobial hand washing product with a 70% ethanol advanced formula (EtOH AF) gel achieved a 5.22-log reduction, whereas a nonantimicrobial hand washing product alone achieved a 3.10-log reduction. When hands were heavily soiled from handling ground beef containing *E. coli,* a wash-sanitize regimen with a 0.5% chloroxylenol antimicrobial hand washing product and the 70% EtOH AF gel achieved a 4.60-log reduction, whereas a wash-sanitize regimen with a 62% EtOH foam achieved a 4.11-log reduction. Sanitizing with the 70% EtOH AF gel alone was more effective than hand washing with a nonantimicrobial product for reducing 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).*

* Author for correspondence. Tel: 330-255-6745; Fax: 330-255-6083; E-mail: edmondss@gojo.com.

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.

ACKNOWLEDGMENT

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

REFERENCES

1. ASTM International. 2006. Standard test method for evaluation of the effectiveness of health care personnel handwash formulations. Designation E1174-06. ASTM International, West Conshohocken, PA.
2. ASTM International. 2009. Standard test method for evaluation of hygienic handwash and handrub formulations for virus-eliminating activity using the entire hand. Designation E2011-09. ASTM International, West Conshohocken, PA.
3. Beatty, M. E., P. M. Adcock, S. W. Smith, K. Quinlan, L. A. Kamimoto, S. Y. Rowe, K. Scott, C. Conover, T. Varchmin, C. A. Bopp, K. D. Greene, B. Bibb, L. Slutsker, and E. D. Mintz. 2006. Epidemic diarrhea due to enterotoxigenic *Escherichia coli*. *Clin. Infect. Dis.* 42:329–334.
4. Blanton, L. H., S. M. Adams, R. S. Beard, G. Wei, S. N. Bulens, M. A. Widdowson, R. I. Glass, and S. S. Monroe. 2006. Molecular and epidemiologic trends of caliciviruses associated with outbreaks of acute gastroenteritis in the United States, 2000–2004. *J. Infect. Dis.* 193:413–421.
5. Bloomfield, S., A. Aiello, B. Cookson, C. O'Boyle, and E. Larson. 2007. The effectiveness of hand hygiene procedures in reducing the risks of infections in home and community settings including handwashing and alcohol-based hand sanitizers. *Am. J. Infect. Control* 35:S27–S64.
6. Boyce, J. M., and D. Pittet. 2002. Guideline for hand hygiene in health-care settings; recommendations of the healthcare infection control practices advisory committee and the HICPAC/SHEA/APIC/IDSA hand hygiene task force. *Morb. Mortal Wkly. Rep.* 51: 1–45.
7. Burton, M., E. Cobb, P. Donachie, G. Judah, V. Curtis, and W. P. Schmidt. 2011. The effect of handwashing with water or soap on bacterial contamination of hands. *Int. J. Environ. Res. Public Health* 8:97–104.
8. Buzby, J. C., and T. Roberts. 2009. Economic costs and trade impacts of microbial foodborne illness. *World Health Stat. Q.* 50:57–66.
9. Centers for Disease Control and Prevention. 2010. Surveillance for foodborne disease outbreaks—United States, 2007. *Morb. Mortal. Wkly. Rep.* 59:973–979. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5931a1.htm?s_cid=mm5931a1_w. Accessed 7 August 2011.
10. Courtenay, M., L. Ramirez, B. Cox, I. Han, X. Jiang, and P. Dawson. 2005. Effects of various hand hygiene regimes in removal and/or destruction of *Escherichia coli* on hands. *Food Serv. Technol.* 5:77–84.
11. Curtis, V., and S. Cairncross. 2003. Effect of washing hands with soap on diarrhea risk in the community: a systematic review. *Lancet Infect. Dis.* 3:275–281.
12. Edmonds, S. L., J. Mann, R. R. McCormack, D. R. Macinga, C. M. Fricker, J. W. Arbogast, and M. J. Dolan. 2010. SaniTwice: a novel approach to hand hygiene for reducing bacterial contamination on hands when soap and water are unavailable. *J. Food Prot.* 73:2296–2300.
13. Fuls, J. L., N. D. Rodgers, G. E. Fischler, J. M. Howard, M. Patel, P. L. Weidner, and M. H. Duran. 2008. Alternative hand contamination technique to compare the activities of antimicrobial and nonantimicrobial soaps under different test conditions. *Appl. Environ. Microbiol.* 74:3739–3744.
14. Gehrke, C., J. Steinmann, and P. Goroncy-Bermes. 2004. Inactivation of feline calicivirus, a surrogate of norovirus (formerly Norwalk-like viruses), by different types of alcohol in vitro and in vivo. *J. Hosp. Infect.* 56:49–55.
15. Green, L. R., V. Radke, R. Mason, L. Bushnell, D. W. Reimann, J. C. Mack, M. D. Motsinger, T. Stigger, and C. A. Selman. 2007. Factors related to food worker hand hygiene practices. *J. Food Prot.* 70:661–666.
16. Greig, J. D., E. C. D. Todd, C. A. Bartleson, and B. S. Michaels. 2007. Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 1. Description of the problems, methods, and agents involved. *J. Food Prot.* 70:1752–1761.
17. Guzevich, J., and M. Ross. 1999. Evaluation of risks related to microbiological contamination of ready-to-eat food by food preparation workers and the effectiveness of interventions to minimize those risks. White paper. Available at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ucm210138.htm. Accessed 2 August 2011.
18. Haas, C. N., J. R. Marie, J. B. Rose, and C. P. Gerba. 2005. Assessment of benefits from use of antimicrobial hand products: reduction in risk from handling ground beef. *Int. J. Hyg. Environ. Health* 208:461–466.
19. Hoffmann, S., P. Fischbeck, A. Krupnick, and M. McWilliams. 2007. Using expert elicitation to link foodborne illnesses in the United States to foods. *J. Food Prot.* 70:1220–1229.
20. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. 1999. Topic Q5A. Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin, p. 24–25. International Conference on Harmonisation, Geneva.

21. Kampf, G., D. Grotheer, and J. Steinmann. 2005. Efficacy of three ethanol-based hand rubs against feline calicivirus, a surrogate virus for norovirus. *J. Hosp. Infect.* 60:144–149.
22. Karber, G. 1931. Beitrug zur kollektiven Behandlung pharmakologischer reihenversuche. *Arch. Exp. Pathol. Pharmakol.* 162:480–483.
23. Liu, P., Y. W. Chien, E. Papafragkou, H. M. Hsiao, L. A. Jaykus, and C. Moe. 2009. Persistence of human noroviruses on food preparation surfaces and human hands. *Food Environ. Virol.* 1:141–147.
24. Liu, P., D. R. Macinga, M. L. Fernandez, C. Zapka, H. M. Hsiao, B. Berger, J. W. Arbogast, and C. L. Moe. 2011. Comparison of the activity of alcohol-based handrubs against human noroviruses using the fingerpad method and quantitative real-time PCR. *Food Environ. Virol.* 3:35–42.
25. Luby, S. P., M. Agboatwalla, J. Painter, A. Altaf, W. L. Billhimer, and R. M. Hoekstra. 2004. Effect of intensive handwashing promotion on childhood diarrhea in high-risk communities in Pakistan: a randomized controlled trial. *JAMA (J. Am. Med. Assoc.)* 291:2547–2554.
26. Lues, J., and I. Van Tonder. 2007. The occurrence of indicator bacteria on hands and aprons of food handlers in the delicatessen sections of a retail group. *Food Control* 18:326–332.
27. Lynch, M., J. Painter, R. Woodruff, and C. Braden. 2006. Surveillance for foodborne-disease outbreaks—United States, 1998–2002. *Morb. Mortal. Wkly. Rep. Surveill. Summ.* 55:1–41.
28. Macinga, D. R., S. A. Sattar, L. A. Jaykus, and J. W. Arbogast. 2008. Improved inactivation of nonenveloped enteric viruses and their surrogates by a novel alcohol-based hand sanitizer. *Appl. Environ. Microbiol.* 74:5047–5052.
29. Michaels, B., C. Keller, M. Blevins, G. Paoli, T. Ruthman, E. Todd, and C. J. Griffith. 2004. Prevention of food worker transmission of foodborne pathogens: risk assessment and evaluation of effective hygiene intervention strategies. *Food Serv. Technol.* 4:31–49.
30. Montville, R., Y. Chen, and D. W. Schaffner. 2002. Risk assessment of hand washing efficacy using literature and experimental data. *Int. J. Food Microbiol.* 73:305–313.
31. Paulson, D. 1999. A suggested method for evaluating food handler/processor handwash formulations. *Dairy Food Environ. Sanit.* 19: 546–550.
32. Paulson, D., C. Riccardi, C. Beausoleil, E. Fendler, M. Dolan, L. Dunkerton, and R. Williams. 1999. Efficacy evaluation of four hand cleansing regimens for food handlers. *Dairy Food Environ. Sanit.* 19: 680–684.
33. Scallan, E., R. M. Hoekstra, F. J. Angulo, R. V. Tauxe, M. A. Widdowson, S. L. Roy, J. L. Jones, and P. M. Griffin. 2011. Foodborne illness acquired in the United Sates—major pathogens. *Emerg. Infect. Dis.* 17:7–15.
34. Schaffner, D. W., and K. M. Schaffner. 2007. Management of risk of microbial cross-contamination from uncooked frozen hamburgers by alcohol-based hand sanitizer. *J. Food Prot.* 70:109–113.
35. Scott, E., and S. F. Bloomfield. 1990. The survival and transfer of microbial contamination via cloths, hands and utensils. *J. Appl. Bacteriol.* 68:271–278.
36. Strohbehn, C., J. Sneed, J. Paez, and J. Meyer. 2008. Hand washing frequencies and procedures used in retail food services. *J. Food Prot.* 71:1641–1650.
37. Teunis, P. F., C. L. Moe, P. Liu, S. E. Miller, L. Lindesmith, R. S. Baric, J. Le Pendu, and R. L. Calderon. 2008. Norwalk virus: how infectious is it? *J. Med. Virol.* 80:1468–1476.
38. Todd, E. C. D., J. D. Greig, C. A. Bartleson, and B. S. Michaels. 2008. Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 5. Sources of contamination and pathogen excretion from infected persons. *J. Food Prot.* 71:2582–2595.
39. U.S. Food and Drug Administration. 2004. Healthy People 2010 progress review. 2004 challenges, barriers, strategies and opportunities. Available at: http://www.fda.gov/Food/ScienceResearch/ResearchAreas/HealthyPeople2010/ucm236488.htm#10-1. Accessed 2 August 2011.
40. U.S. Food and Drug Administration. 2008. FDA trend analysis report on the occurrence of foodborne illness risk factors in selected institutional foodservice, restaurant, and retail food store facility types. Available at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm223293.htm. Accessed 2 August 2011.
41. U.S. Food and Drug Administration. 2009. FDA report on the occurrence of foodborne illness risk factors in selected institutional foodservice, restaurant, and retail food store facility types. Available at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm224321.htm. Accessed 2 August 2011.
42. U.S. Food and Drug Administration. 2009. Food Code 2009. Available at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009. Accessed 2 August 2011.
43. Vivancos, R., A. Shroufi, M. Sillis, H. Aird, C. I. Gallimore, L. Myers, H. Maghoub, and P. Nair. 2009. Food-related norovirus outbreak among people attending two barbeques: epidemiological, virological, and environmental investigation. *Int. J. Infect. Dis.* 13: 629–635.
44. Widdowson, M. A., S. S. Monroe, and R. I. Glass. 2005. Are noroviruses emerging? *Emerg. Infect. Dis.* 11:735–737.
45. Wobus, C. E., L. B. Thackray, and H. W. Virgin. 2006. Murine norovirus: a model system to study norovirus biology and pathogenesis. *J. Virol.* 80:5104–5112. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1472167/?tool=pubmed. Accessed 11 August 2011.
46. World Health Organization. 2010. Initiative to estimate the global burden of foodborne diseases. Available at: http://www.who.int/foodsafety/foodborne_disease/ferg/en/index.html. Accessed 3 August 2011.

Journal of Food Protection, Vol. 78, No. 11, 2015, Pages 2024–2032
doi:10.4315/0362-028X.JFP-15-102

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

ANNA FABISZEWSKI DE ACEITUNO,[1]* FAITH E. BARTZ,[1] DOMONIQUE WATSON HODGE,[1] DAVID J. SHUMAKER,[2] JAMES E. GRUBB,[2] JAMES W. ARBOGAST,[2] JORGE DÁVILA-AVIÑA,[3] FABIOLA VENEGAS,[3] NORMA HEREDIA,[3] SANTOS GARCÍA,[3] AND JUAN S. LEON[1]

[1]*Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, Georgia 30322, USA;* [2]*GOJO Industries, Inc., Akron, Ohio 44311, USA; and* [3]*Departamento de Microbiología e Inmunología, Facultad de Ciencias Biológicas, Universidad Autónoma de Nuevo León, San Nicolás, Nuevo Leon 66451, México*

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

ABSTRACT

Effective hand hygiene is essential to prevent the spread of pathogens on produce farms and reduce foodborne illness. The U.S. Food and Drug Administration Food Safety Modernization Act Proposed Rule for Produce Safety recommends the use of soap and running water for hand hygiene of produce handlers. The use of alcohol-based hand sanitizer (ABHS) may be an effective alternative hygiene intervention where access to water is limited. There are no published data on the efficacy of either soap or ABHS-based interventions to reduce microbial contamination in agricultural settings. The goal of this study was to assess the ability of two soap-based (traditional or pumice) and two ABHS-based (label-use or two-step) hygiene interventions to reduce microbes (coliforms, *Escherichia coli,* and *Enterococcus* spp.) and soil (absorbance of hand rinsate at 600 nm [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-

* Author for correspondence. Tel: 404-712-8898; Fax: 404-712-8969; E-mail: anna.aceituno@emory.edu.

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

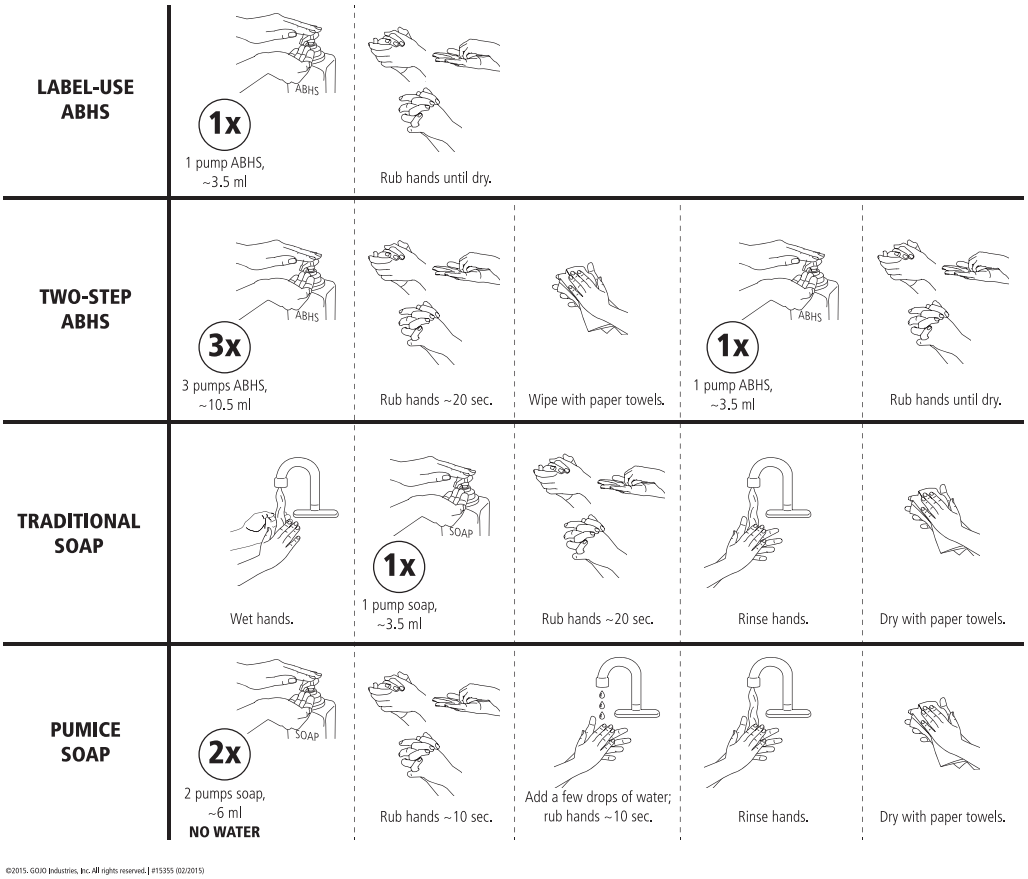


FIGURE 1. *Visual description of the two ABHS-based and two soap-based hand hygiene interventions. Illustrations in this figure are courtesy of GOJO Industries, Inc.*

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

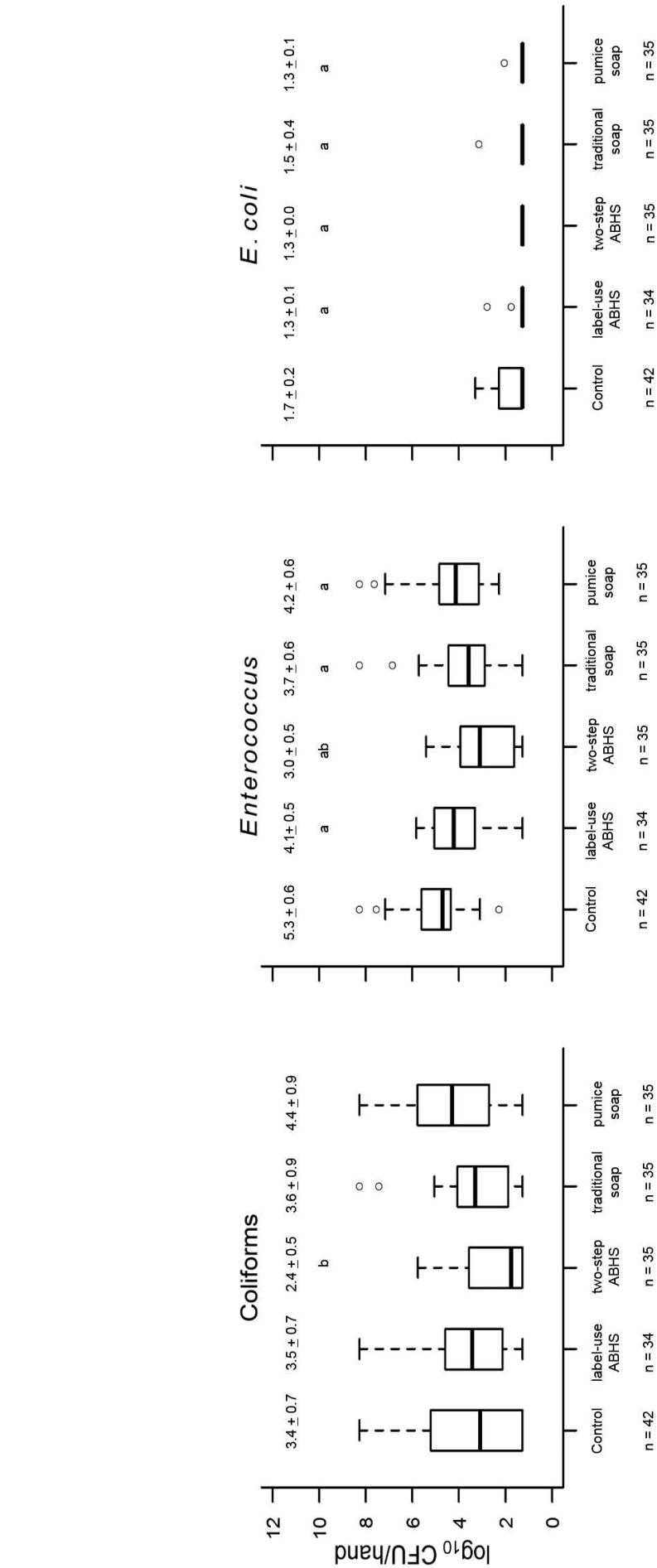


FIGURE 2. *Concentrations of coliform,* Enterococcus, *and* E. coli *bacteria in hand rinsate samples from the control group and four hand hygiene intervention groups of workers harvesting tomatoes. For each study group, the boxes display the quartiles (25th, 50th, and 75th) and whiskers extend to 1.5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

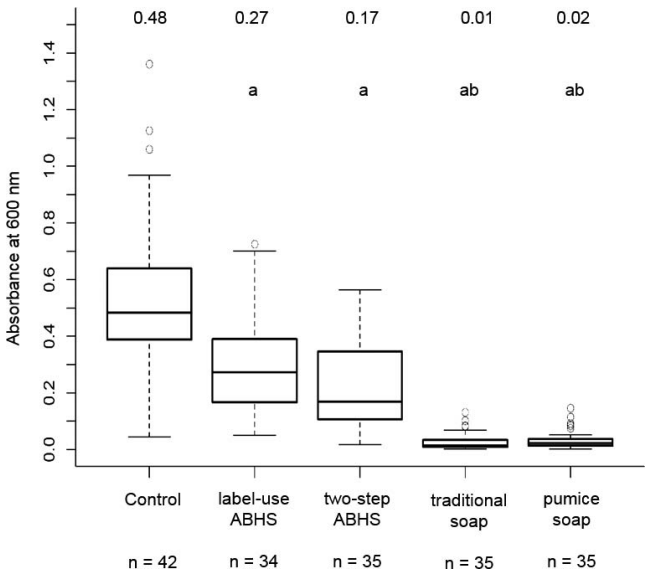


FIGURE 3. *Absorbance (at 600 nm) in hand rinsate samples from the control group and four intervention groups of workers harvesting tomatoes. For each study group, the boxes display the quartiles (25th, 50th, and 75th) and whiskers extend to 1.5 times the interquartile range. Any data points outside 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

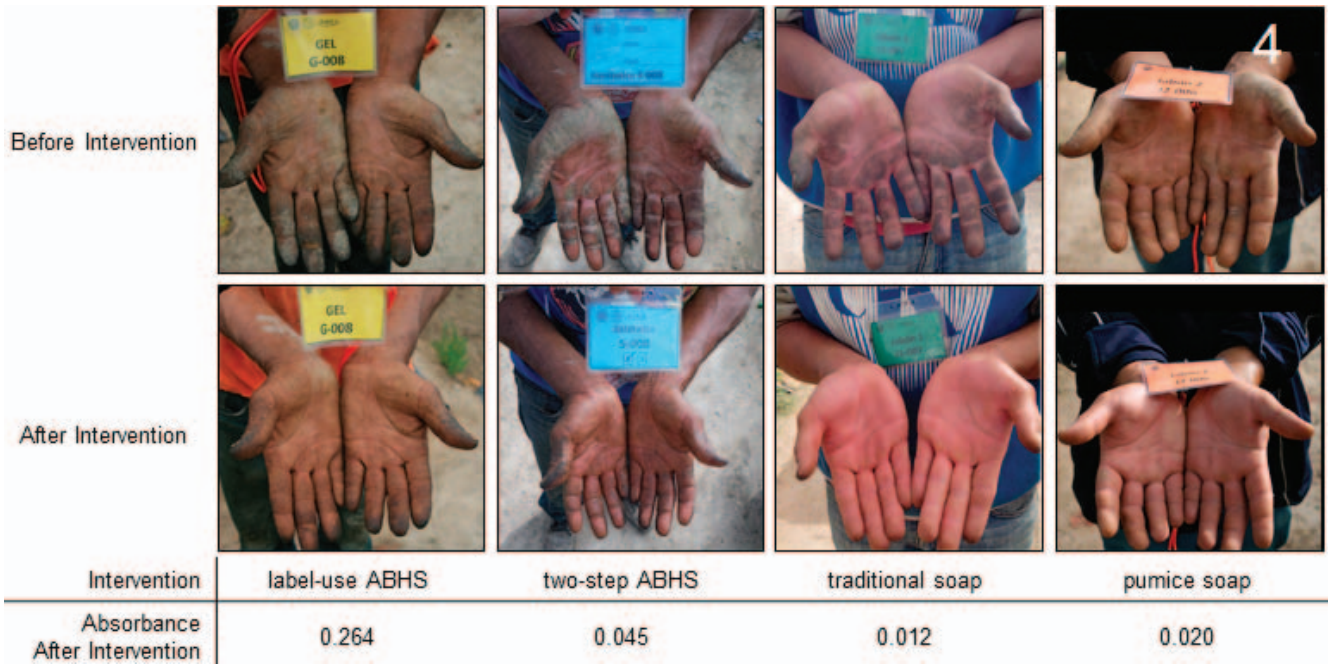


FIGURE 4. *Photographs of hands and corresponding individual hand rinsate absorbance readings from samples collected after intervention from study participants—workers harvesting tomatoes on a farm in Mexico. Photographs were taken immediately before and after each worker performed hand hygiene.*

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.

ACKNOWLEDGMENTS

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

REFERENCES

1. Aiello, A. E., R. M. Coulborn, V. Perez, and E. L. Larson. 2008. Effect of hand hygiene on infectious disease risk in the community setting: a meta-analysis. *Am. J. Public Health* 98:1372–1381.
2. Ailes, E. C., J. S. Leon, L. A. Jaykus, L. M. Johnston, H. A. Clayton, S. Blanding, D. G. Kleinbaum, L. C. Backer, and C. L. Moe. 2008. Microbial concentrations on fresh produce are affected by postharvest processing, importation, and season. *J. Food Prot.* 71:2389–2397.
3. Ali, Y., M. J. Dolan, E. J. Fendler, and E. L. Larson. 2001. Alcohols, p. 229–254. *In* S. S. Block (ed.), Disinfection sterilization and preservation. Lippincott Williams & Wilkins, Philadelphia.
4. Bloomfield, S. F., A. E. Aiello, B. Cookson, C. O'Boyle, and E. L. Larson. 2007. The effectiveness of hand hygiene procedures in reducing the risks of infections in home and community settings including handwashing and alcohol-based hand sanitizers. *Am. J. Infect. Control* 35:S27–S64.
5. Boehm, A. B., and L. M. Sassoubre. 2014. Enterococci as indicators of environmental fecal contamination. *In* M. S. Gilmore, D. B. Clewel, Y. Ike, and N. Shankar (ed.), Enterococci: from commensals to leading causes of drug resistant infection. Massachusetts Eye and Ear Infirmary, Boston.
6. Boyce, J. M., and D. Pittet. 2002. Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Society for Healthcare Epidemiology of America/Association for Professionals in Infection Control/Infectious Diseases Society of America. *Morb. Mortal. Wkly. Rep. Recommend. Rep.* 51(RR-16):1–45.
7. Calvin, L., and P. Martin. 2010. The U.S. produce industry and labor: facing the future in a global economy. Economic research report number 106. U.S. Department of Agriculture, Economic Research Service, Washington, DC. Available at: http://www.ers.usda.gov/media/135123/err106.pdf.
8. Critchlow, D. E., and M. A. Fligner. 1991. On distribution-free multiple comparisons in the one-way analysis of variance. *Commun. Stat. Theory Methods* 20:127–139.
9. Daniel, W. W. 1999. Biostatistics: a foundation for analysis in the health sciences, 7th ed., p. 571–606. John Wiley and Sons, Inc., Hoboken, NJ.
10. Davis, M. A., H. Sheng, J. Newman, D. D. Hancock, and C. J. Hovde. 2006. Comparison of a waterless hand-hygiene preparation and soap-and-water hand washing to reduce coliforms on hands in animal exhibit settings. *Epidemiol. Infect.* 134:1024–1028.
11. Edmonds, S. L., J. Mann, R. R. McCormack, D. R. Macinga, C. M. Fricker, J. W. Arbogast, and M. J. Dolan. 2010. SaniTwice: a novel approach to hand hygiene for reducing bacterial contamination on hands when soap and water are unavailable. *J. Food Prot.* 73:2296–2300.
12. Edmonds, S. L., R. R. McCormack, S. S. Zhou, D. R. Macinga, and C. M. Fricker. 2012. Hand hygiene regimens for the reduction of risk in food service environments. *J. Food Prot.* 75:1303–1309.
13. Fabiszewski de Aceituno, A., N. Heredia, A. Stern, F. Bartz, F. Venegas, L. Solis-Soto, J. Gentry-Shields, J. Leon, L.-A. Jaykus, and S. Garcia. 2016. Efficacy of two hygiene methods to reduce soil and microbial contamination on farmworker hands during harvest. *Food Control* 59:787–792.
14. Falkenhorst, G., L. Krusell, M. Lisby, S. B. Madsen, B. Bottiger, and K. Molbak. 2005. Imported frozen raspberries cause a series of norovirus outbreaks in Denmark, 2005. *Euro Surveill.* 10:E050922.2.
15. Heredia, N., L. Solis-Soto, F. Venegas, F. E. Bartz, A. M. Fabiszewski de Aceituno, L.-A. Jaykus, J. S. Leon, and S. Garcia. 2015. Validation of a novel rinse and filtration method for efficient processing of fresh produce samples for microbiological indicator enumeration. *J. Food Prot.* 78:525–530.
16. Hjertqvist, M., A. Johansson, N. Svensson, P. E. Abom, C. Magnusson, M. Olsson, K. O. Hedlund, and Y. Andersson. 2006. Four outbreaks of norovirus gastroenteritis after consuming raspberries, Sweden, June-August 2006. *Euro Surveill.* 11:E060907.1.
17. Jin, M., and B. Wang. 2014. Implementing multiple comparisons on Pearson chi-square test for an RxC contingency table in SAS. SAS technical paper 1544-2014. Proc. SAS Global Forum. SAS Institute, Cary, NC.
18. Johnston, L. M., L. A. Jaykus, D. Moll, J. Anciso, B. Mora, and C. L. Moe. 2006. A field study of the microbiological quality of fresh produce of domestic and Mexican origin. *Int. J. Food Microbiol.* 112:83–95.
19. Johnston, L. M., C. Moe, D. Moll, and L. A. Jaykus. 2006. The epidemiology of produce-associated outbreaks for foodborne disease, p. 37–72. *In* J. L. James (ed.), Microbial hazard identification of fresh fruit and vegetables. John Wiley and Sons, Inc., Hoboken, NJ.
20. Kruskal, W. H. 1952. A nonparametric test for the several sample problem. *Ann. Math. Stat.* 23:525–540.
21. Larson, E., and L. Bobo. 1992. Effective hand degerming in the presence of blood. *J. Emerg. Med.* 10:7–11.
22. Leon-Felix, J., R. A. Martinez-Bustillos, M. Baez-Sanudo, F. Peraza-Garay, and C. Chaidez. 2010. Norovirus contamination of bell pepper from handling during harvesting and packing. *Food Environ. Virol.* 2:211–217.
23. Lickness, J. 2014. Assessing microbial contamination on produce, environmental sources, and farm worker hands throughout the production process on farms and packing sheds in northern Mexico. M.S. thesis. Emory University, Atlanta.
24. Morton, H. E. 1950. The relationship of concentration and germicidal efficiency of ethyl alcohol. *Ann. N. Y. Acad. Sci.* 53:191–196.
25. Pickering, A. J., A. B. Boehm, M. Mwanjali, and J. Davis. 2010. Efficacy of waterless hand hygiene compared with handwashing with soap: a field study in Dar es Salaam, Tanzania. *Am. J. Trop. Med. Hyg.* 82:270–278.
26. Pickering, A. J., J. Davis, and A. B. Boehm. 2011. Efficacy of alcohol-based hand sanitizer on hands soiled with dirt and cooking oil. *J. Water Health* 9:429–433.

27. Pickering, A. J., T. R. Julian, S. Mamuya, A. B. Boehm, and J. Davis. 2011. Bacterial hand contamination among Tanzanian mothers varies temporally and following household activities. *Trop. Med. Int. Health* 16:233–239.
28. Racicot, M., A. Kocher, G. Beauchamp, A. Letellier, and J. P. Vaillancourt. 2013. Assessing most practical and effective protocols to sanitize hands of poultry catching crew members. *Prev. Vet. Med.* 111:92–99.
29. Ravaliya, K., J. Gentry-Shields, S. Garcia, N. Heredia, A. F. de Aceituno, F. E. Bartz, J. S. Leon, and L. A. Jaykus. 2014. Use of *Bacteroidales* microbial source tracking to monitor fecal contamination in fresh produce production. *Appl. Environ. Microbiol.* 80:612–617.
30. Schaffner, D. W., and K. M. Schaffner. 2007. Management of risk of microbial cross-contamination from uncooked frozen hamburgers by alcohol-based hand sanitizer. *J. Food Prot.* 70:109–113.
31. Seymour, I. J., and H. Appleton. 2001. Foodborne viruses and fresh produce. *J Appl. Microbiol.* 91:759–73.
32. Shapiro, S. S., and M. B. Wilk. 1965. An analysis of variance test for normality (complete samples). *Biometrika* 52:591–611.
33. Smith DeWaal, C., C. Roberts, and C. Catella. 2012. Outbreak alert! 1999-2008. Center for Science in the Public Interest, Washington, DC.
34. Todd, E. C. D., B. S. Michaels, J. Holah, D. Smith, J. D. Greig, and C. A. Bartleson. 2010. Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 10. Alcohol-based antiseptics for hand disinfection and a comparison of their effectiveness with soaps. *J. Food Prot.* 73:2128–2140.
35. Traub-Dargatz, J. L., J. S. Weese, J. D. Rousseau, M. Dunowska, P. S. Morley, and D. A. Dargatz. 2006. Pilot study to evaluate 3 hygiene protocols on the reduction of bacterial load on the hands of veterinary staff performing routine equine physical examinations. *Can. Vet. J.* 47:671–676.
36. U.S. Environmental Protection Agency. 1997. Water: monitoring & assessment. 5.11. Fecal bacteria. Available at: http://water.epa.gov/type/rsl/monitoring/vms511.cfm. Accessed 1 December 2014.
37. U.S. Environmental Protection Agency. 2000. Guidance for data quality assessment. practical methods for data analysis. EPA QA/G-9. U.S. Environmental Protection Agency, Washington, DC.
38. U.S. Food and Drug Administration. 2013. Food Code 2013, chap. 2, Management and personnel; part 2-3, Personal cleanliness. U.S. Food and Drug Administration, Public Health Service, College Park, MD. Available at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm181242.htm#part2-3. Accessed September 2015.
39. U.S. Food and Drug Administration. 2013. Food Safety Modernization Act proposed rule for produce safety. Standards for the growing, harvesting, packing, and holding of produce for human consumption (corrected version). 21 CFR Parts 16 and 112. FDA-2011-N-0921. U.S. Food and Drug Administration, Washington, DC.
40. U.S. Food and Drug Administration. 2013. Statistics applied to microbiological analysis, section 4.10. *In* ORA laboratory manual, vol. III. U.S. Food and Drug Administration, Office of Regulatory Affairs, Washington, DC.
41. van Elsas, J. D., A. V. Semenov, R. Costa, and J. T. Trevors. 2011. Survival of Escherichia coli in the environment: fundamental and public health aspects. *ISME J.* 5:173–183.
42. Wheeler, C., T. M. Vogt, G. L. Armstrong, G. Vaughan, A. Weltman, O. V. Nainan, V. Dato, G. L. Xia, K. Waller, J. Amon, T. M. Lee, A. Highbaugh-Battle, C. Hembree, S. Evenson, M. A. Ruta, I. T. Williams, A. E. Fiore, and B. P. Bell. 2005. An outbreak of hepatitis A associated with green onions. *N. Engl. J. Med.* 353:890–897.
43. World Health Organization. 2009. WHO guidelines on hand hygiene in health care. WHO Press, Geneva.

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	_____		

All information above the line is for conference use only.

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.

Submitter Information 1:

Name:	Rob Green
Organization:	National Council of Chain Restaurants
Address:	1101 New York Avenue, NW, Suite 1200
City/State/Zip:	Washington, DC, DC 20005
Telephone:	202-626-8183
E-mail:	GreenR@nccr.net

Submitter Information 2:

Name:	Jason Horn
Organization:	In-N-Out Burger
Address:	13502 Hamburger Lane
City/State/Zip:	Baldwin Park, CA 91706
Telephone:	626-813-5326
E-mail:	JHorn@innout.com

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	_____		

All information above the line is for conference use only.

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.

Submitter Information 1:

Name:	Zachary Eddy
Organization:	Sanitimer
Address:	318 Hopewell Drive
City/State/Zip:	McKinney, TX 75071
Telephone:	817-480-6484
E-mail:	zeddy@sanitimer.com

Submitter Information 2:

Name:	Charles Abraham
Organization:	Sanitimer
Address:	410 W 7th St, #503

City/State/Zip: Fort Worth, TX 76102
Telephone: 817-933-5399
E-mail: cabraham@sanitimer.com

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"

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.

Hand Washing Practices in a College Town Environment

Carl P. Borchgrevink, PhD
JaeMin Cha, PhD
SeungHyun Kim, PhD
The School of Hospitality Business
Michigan State University

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.

***Acknowledgements*:** An earlier, work-in-progress, version of this manuscript was presented at the 2011 International Council on Hotel, Restaurant, and Institutional Education Annual Conference.

Corresponding Author: Carl P. Borchgrevink, Associate Professor, The School of Hospitality Business, Michigan State University, 645 North Shaw Lane, 233 Eppley Center, East Lansing, MI 48824. E-mail: carlb@bus.msu.edu.

References

American Society for Microbiology. (2003). *Another U.S. airport travel hazard—dirty hands.* Retrieved from http://www.eurekalert.org/pub_releases/2003-09/asfm-aua091103.php

Bittner, M., Rich, E., Turner, P., & Arnold, W. (2002). Limited impact of sustained simple feedback based on soap and paper towel consumption on the frequency of hand washing in an adult intensive care unit. *Infection Control Hospital Epidemiology, 23*(3), 120–126.

Burton, M., Cobb, E., Donachie, P., Judah, G., Curtis, V., & Schmidt, W. (2011). The effect of hand washing with water or soap on bacterial contamination of hands. *International Journal of Environmental Research and Public Health, 8*(1), 97–104.

Centers for Disease Control and Prevention. (2012). *Hand washing: Clean hands save lives.* Retrieved from http://www.cdc.gov/handwashing/

Cohen, J. (1960). A coefficient of agreement for nominal scales. *Educational Psychology Measurement, 20*(1), 37–46.

Curtis, V., & Cairncross, S. (2003). Effects of washing hands with soap on diarrhoea risk in the community: A systematic review. *The Lancet Infectious Diseases, 3*(5), 275–281.

Drankiewicz, D., & Dundes, L. (2003). Hand washing among female college students. *American Journal of Infection Control, 31*(2), 67–71.

Edwards, D., Monk-Turner, E., Poorman, S., Rushing, M., Warren, S., & Willie, J. (2002). Predictors of hand washing behavior. *Social Behavior and Personality: An International Journal, 30*(8), 751–756.

Etter, J., & Laszlo, E. (2005). Evaluation of a poster campaign against passive smoking for world no-tobacco day. *Patient Education and Counseling, 57*(2), 190–198.

Fleiss, J. (1981). The measurement of interrater agreement. In *Statistical methods for rates and proportions* (pp. 212–236). New York: John Wiley & Sons.

Green, L.R., Selman, C.A., Radke, V., Ripley, D., Mack, J.C., Reimann, D.W., Stigger, T., Motsinger, M., & Bushnell, L. (2006). Food worker hand washing practices: An observation study. *Journal of Food Protection, 69*(10), 2417–2423.

Guinan, M.E., McGuckin-Guinan, M., & Sevareid, A. (1997). Who washes hands after using the bathroom? *American Journal of Infection Control, 25*(5), 424–525.

Guzewich, J., & Ross, M.P. (1999). *Evaluation of risk related to microbiological contamination of ready-to-eat foods by food preparation workers and the effectiveness of interventions to minimize those risks.* Silver Spring, MD: Food and Drug Administration, Center for Food Safety and Applied Nutrition. Retrieved from http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ucm210138.htm

Harris Interactive. (2010). *Survey of hand washing behavior (trended): Prepared for the American Microbiology Society and the American Cleaning Institute.* Retrieved from http://www.microbeworld.org/images/stories/washup/2010_handwashing_behavior_survey.pdf

continued on page 24

References *continued from page 23*

Hayes, M.C. (2002). *Hand washing behavior of women in public restrooms*. Missouri Western State University. Retrieved from http://clearinghouse.missouriwestern.edu/manuscripts/371.php

Johnson, H.D., Sholoscky, D., Gabello, K.L., Ragni, R.V., & Ogonosky, N.M. (2003). Gender differences in hand washing behavior associated with visual behavior prompts. *Perceptual and Motor Skills, 97*(3), 805–810.

Judah, G., Aunger, R., Schmidt, W., Granger, S., & Curtis, V. (2009). Experimental pretesting of hand-washing interventions. *American Journal of Public Health, 99*(S2), 405–411.

Landis, J., & Koch, G. (1977). The measurement of observer agreement for categorical data. *Biometrics, 33*(1), 159–174.

Larson, E., Bryan, J., Adler, L.M., & Blane, C. (1997). A multifaceted approach to changing hand washing behavior. *American Journal of Infection Control, 25*(1), 3–10.

Larson, E., McGeer, A., & Quiaishi, Z. (1991). Effect of an automated sink on hand washing practices and attitudes in high-risk units. *Infection Control Hospital Epidemiology, 12*(7), 422–428.

Mackintosh, C., & Hoffman, P. (1984). An extended model for transfer of microorganisms via the hands; differences between organisms and the effect of alcohol disinfection. *Journal of Hygiene, 92*(3), 345–355.

Mead, P.S., Slutsker, L., Dietz, V., McCaig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., & Tauxe, R.V. (1999). Food related death and illness in the United States. *Emerging Infectious Diseases, 5*(5), 607–625.

Merry, A., Millder, E., Findon, G., Webster, C., & Neff, S. (2001). Touch contamination levels during anaesthetic procedures and their relationship to hand hygiene procedures: A clinical audit. *British Journal of Anaesthesia, 87*(2), 291–294.

Nalbone, P., Lee, K., Suroviak, A., & Lannon, J. (2005). The effects of social norms on male hygiene. *Individual Differences Research, 3*(3), 171–176.

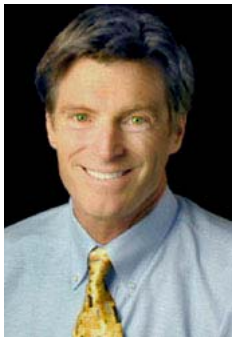
Patrick, D., Miller, T., & Findon, G. (1997). Residual moisture determines the level of touch-contact associated transfer following hand washing. *Epidemiology and Infection, 119*(3), 319–325.

QSR Magazine. (2009). *Are Americans washing their hands?* Retrieved from http://www.qsrmagazine.com/news/are-americans-washing-their-hands

Thumma, J., Aiello, A.E., & Foxman, B. (2008). The association between hand washing practices and illness symptoms among college students living in a university dormitory. *American Journal of Infection Control, 37*(1), 70–72.

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.

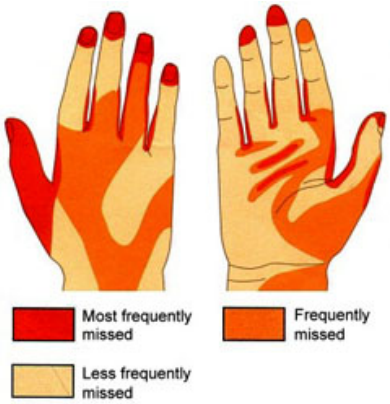
4.

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

[6] Foodborne disease: a focus for health education. WHO. 2000

Journal of Food Protection, Vol. 70, No. 3, 2007, Pages 661–666

Factors Related to Food Worker Hand Hygiene Practices†

LAURA R. GREEN,[1]* VINCENT RADKE,[2] RYAN MASON,[3] LISA BUSHNELL,[4] DAVID W. REIMANN,[5] JAMES C. MACK,[6] MICHELLE D. MOTSINGER,[7] TAMMI STIGGER,[8] AND CAROL A. SELMAN[2]

[1]RTI International, 2951 Flowers Road, Suite 119, Atlanta, Georgia 30341; [2]National Center for Environmental Health, Centers for Disease Control and Prevention, MS F-28, 4770 Buford Highway, Atlanta, Georgia 30341; [3]Tennessee Department of Health, 425 5th Avenue North, Cordell Hull Building—6th Floor, Nashville, Tennessee 37247; [4]Connecticut Department of Public Health, Food Protection Program, Division of Environmental Health, MS #51 FDP, 410 Capitol Avenue, P.O. Box 340308, Hartford, Connecticut 06134-0308; [5]Minnesota Department of Health, 410 Jackson Street, Suite 500, Mankato, Minnesota 56001; [6]Oregon State Public Health, Office of Environmental Public Health, 800 N.E. Oregon, Suite 608, Portland, Oregon 97232; [7]Colorado Department of Public Health and Environment, Consumer Protection Division, 4300 Cherry Creek Drive South, Denver, Colorado 80246; and [8]RARE Hospitality International, Inc., 8215 Roswell Road, Building 600, Atlanta, Georgia 30350, USA

MS 06-426: Received 7 August 2006/Accepted 24 October 2006

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.

* Author for correspondence. Tel: 770-488-4332; Fax: 770-488-7310; E-mail: lrg0@cdc.gov.

† 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.

REFERENCES

1. Allwood, P., T. Jenkins, C. Paulus, L. Johnson, and C. Hedberg. 2004. Hand washing compliance among retail food establishment workers in Minnesota. *J. Food Prot.* 67:2825–2828.
2. Altekruse, S., D. Street, S. Fein, and A. Levy. 1995. Consumer knowledge of foodborne microbial hazards and food-handling practices. *J. Food Prot.* 59:287–294.
3. Ansari, S., S. Sattar, V. Springthorpe, G. Wells, and W. Tostowaryk. 1988. Rotavirus survival on human hands and transfer of infectious virus to animate and nonporous inanimate surfaces. *J. Clin. Microbiol.* 26:1513–1518.
4. Campbell, M., C. Gardner, J. Dwyer, S. Isaacs, P. Krueger, and J. Ying. 1998. Effectiveness of public health interventions in food safety: a systematic review. *Can. J. Public Health* 89:197–202.
5. Clayton, D., and C. Griffith. 2004. Observations of food safety practices in catering using notational analysis. *British Food J.* 106:211–227.
6. Clayton, D., C. Griffith, P. Price, and A. Peters. 2002. Food handlers' beliefs and self-reported practices. *Int. J. Env. Health Res.* 12:25–39.
7. Cotterchio, M., J. Gunn, T. Coffill, P. Tormey, and M. Barry. 1998. Effect of a manager training program on sanitary conditions in restaurants. *Public Health Rep.* 113:353–358.
8. Ehiri, J., and G. Morris. 1996. Hygiene training and education of food handlers: does it work? *Ecol. Food Nutr.* 35:243–251.
9. Ehrenkranz, N., and B. Alfonso. 1991. Failure of bland soap handwash to prevent hand transfer of patient bacteria to urethral catheters. *Infect. Control Hosp. Epidemiol.* 12:654–662.
10. Fendler, E., M. Dolan, and R. Williams. 1998. Handwashing and gloving for food protection. Part I: examination of the evidence. *Dairy Food Environ. San.* 18:814–823.
11. Friedman, C., R. Hoekstra, M. Samuel, R. Marcus, J. Bender, B. Shiferaw, S. Reddy, S. Ahuja, D. Helfrick, F. Hardnett, M. Carter, B. Anderson, and R. Tauxe, for the Emerging Infections Program FoodNet Working Group. 2004. Risk factors for sporadic *Campylobacter* infection in the United States: a case-control study in FoodNet sites. *Clin. Infect. Dis.* 38(Suppl. 3):S285–296.
12. Green, L., and C. Selman. 2005. Factors impacting food workers' and managers' safe food preparation practices: a qualitative study. *Food Prot. Trends* 25:981–990.
13. Green, L., C. Selman, A. Banerjee, R. Marcus, C. Medus, F. Angulo, V. Radke, S. Buchanan, and the EHS-Net Working Group. 2005. Food service workers' self-reported food preparation practices: an EHS-Net study. *Int. J. Hyg. Environ. Health* 208:27–35.
14. Green, L. R., C. A. Selman, V. Radke, D. Ripley, J. C. Mack, D. W. Reimann, T. Stigger, M. Motsinger, and L. Bushnell. 2006. Food worker hand washing practices: an observation study. *J. Food Prot.* 69:2417–2423.
15. Guzewich, J., and M. Ross. 1999. Evaluation of risks related to microbiological contamination of ready-to-eat food by food preparation workers and the effectiveness of interventions to minimize those risks. Available at: http://www.cfsan.fda.gov/~ear/rterisk.html. Accessed 1 April 2006.
16. Jenkins-McLean, T., C. Skilton, and C. Sellers. 2004. Engaging food service workers in behavioral-change partnerships. *J. Env. Health* 15–19.
17. Jumaa, P. 2005. Hand hygiene: simple and complex. *Int. J. Infect. Dis.* 9:3–14.
18. Kaplan, L., and M. McGuckin. 1986. Increasing handwashing compliance with more accessible sinks. *Infect. Control* 7:408–410.
19. Kassenborg, H., K. Smith, D. Vugia, T. Rabatsky-Ehr, M. Bates, M. Carter, N. Dumas, M. Cassidy, N. Marano, R. Tauxe, and F. Angulo, for the Emerging Infections Program FoodNet Working Group. 2004. Fluoroquinolone-resistant *Campylobacter* infections: eating poultry outside of the home and foreign travel are risk factors. *Clin. Infect. Dis.* 38(Suppl. 3):S279–S284.
20. Kendall, P., L. Melcher, and L. Paul. 2000. Factors affecting safe food handling practices in restaurants. Unpublished data. Study conducted by the Department of Food Science and Human Nutrition, Colorado State University Cooperative Extension, Fort Collins.
21. Lynch, R., M. Phillips, B. Elledge, S. Hanumanthaiah, and D. Boatright. 2005. A preliminary evaluation of the effect of glove use by food handlers in fast food restaurants. *J. Food Prot.* 68:187–190.
22. Michaels, B., C. Keller, M. Blevins, G. Paoli, T. Ruthman, E. Todd, and C. Griffith. 2004. Prevention of food worker transmission of foodborne pathogens: risk assessment and evaluation of effective hygiene intervention strategies. *Food Service Tech.* 4:31–49.
23. Montville, R., Y. Chen, and D. Schaffner. 2001. Glove barriers to bacterial cross-contamination between hands to food. *J. Food Prot.* 64:845–849.
24. Montville, R., Y. Chen, and D. Schaffner. 2002. Risk assessment of hand washing efficacy using literature and experimental data. *Int. J. Food Microbiol.* 73:305–313.
25. Olsen, S., L. MacKinon, J. Goulding, N. Bean, and L. Slutsker. 2000. Surveillance for foodborne disease outbreaks—United States, 1993–1997. *Morb. Mortal. Wkly. Rep.* 49:1–51.
26. Pittet, D. 2001. Improving adherence to hand hygiene practice: a multidisciplinary approach. *Emerg. Infect. Dis.* 7:234–240.
27. Rennie, D. 1995. Health education models and food safety education. *J. R. Soc. Health* 115:75–79.
28. U.S. Food and Drug Administration. 2004. FDA report on the occurrence of foodborne illness risk factors in selected institutional foodservice, restaurant, and retail food store facility types (2004). Available at: http://www.cfsan.fda.gov/~dms/retrsk2.html. Accessed 1 April 2006.
29. U.S. Food and Drug Administration. 2005. Food code, 2005. Available at: http://www.cfsan.fda.gov/~dms/fc05-toc.html. Accessed 1 April 2006.

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.

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes conference on Food Protection
Address:	615 Englewood DR
City/State/Zip:	Roscommon, MI 48653
Telephone:	517-719-7919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name:	Karla Horne
Organization:	Great Lakes Conference on Food Protection
Address:	525 W AlleganPO Box 30017
City/State/Zip:	Lansing, MI 48909
Telephone:	231-357-0727
E-mail:	hornek@michigan.gov

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.

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]

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood Dr
City/State/Zip:	Roscommon, MI 48653
Telephone:	517-719-7919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name: Karla Horne
Organization: Great Lakes Conference on Food Protection
Address: 525 W AlleganPO Box 30017
City/State/Zip: Lansing, MI 48909
Telephone: 231-357-0727
E-mail: hornek@michigan.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-015

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:

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]

Submitter Information 1:
Name: M Peggy Wagner
Organization: State of Florida, Division of Hotels & Restaurants

Address: 798 71st Ave N
City/State/Zip: St. Petersburg, FL 33702
Telephone: 813 298 3385
E-mail: Margaret.wagner@myfloridalicense.com

Submitter Information 2:

Name: Joseph Birocco
Organization: State of Florida, Division of Hotels & Restaurants
Address: 2520 Beach Blvd S
City/State/Zip: Gulfport, FL 33707
Telephone: 813 326 9822
E-mail: Joseph.birocco@myfloridalicense.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-016

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:

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.

Submitter Information 1:

Name:	Mary Cartagena
Organization:	Food and Drug Administration
Address:	5100 Paint Branch ParkwayHFS-320 Rm 3B038
City/State/Zip:	College Park, MD 20740
Telephone:	240-402-2937
E-mail:	mary.cartagena@fda.hhs.gov

Submitter Information 2:

Name:	Aron Hall
Organization:	Centers for Disease Control and Prevention
Address:	1600 Clifton Road NE, MS A-34
City/State/Zip:	Atlanta, GA 30333
Telephone:	404-639-1869
E-mail:	ajhall@cdc.gov

Supporting Attachments:

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

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

1. Ahmed, S.M., et al., *Global prevalence of norovirus in cases of gastroenteritis: a systematic review and meta-analysis.* The Lancet infectious diseases, 2014. **14**(8): p. 725-730.
2. Bresee, J.S., et al., *The etiology of severe acute gastroenteritis among adults visiting emergency departments in the United States.* Journal of Infectious Diseases, 2012. **205**(9): p. 1374-1381.
3. Hall, A.J., et al., *Norovirus disease in the United States.* Emerging Infectious Diseases, 2013. **19**(8): p. 1198-1205.
4. Hall, A.J., et al., *Vital Signs: Foodborne Norovirus Outbreaks-United States, 2009-2012.* Morbidity and Mortality Weekly Report, 2014. **63**: p. 491-495.
5. Hoffmann, S., et al., *Annual cost of illness and quality-adjusted life year losses in the United States due to 14 foodborne pathogens.* Journal of Food Protection, 2012. **75**: p. 1292-1302.
6. Atmar, R.L., et al., *Norwalk virus shedding after experimental human infection.* Emerging infectious diseases, 2008. **14**(10): p. 1553.
7. Teunis, P.F., et al., *Norwalk virus: how infectious is it?* Journal of Medical Virology, 2008. **80**(8): p. 1468-1476.
8. Atmar, R.L., et al., *Determination of the 50% human infectious dose for Norwalk virus*. Journal of Infectious Diseases, 2014. **209**(7): p. 1016-1022.
9. Hall, A.J., et al., *Updated norovirus outbreak management and disease prevention guidelines*. 2011: US Department of Health and Human Services, Centers for Disease Control and Prevention.
10. Lopman, B., et al., *Environmental transmission of norovirus gastroenteritis.* Current Opinion in Virology, 2012. **2**: p. 96-102.
11. Hall, A.J., et al., *Epidemiology of foodborne norovirus outbreaks, United States, 2001-2008.* Emerging Infectious Diseases, 2012. **18**: p. 1566-1573.
12. Carpenter, L.R., et al., *Food worker experiences with and beliefs about working while ill.* Journal of Food Protection, 2013. **76**: p. 2146-2154.
13. Bureau of Labor Statistics. *Occupational employment statistics.* In: U.S. Department of Labor, ed, 2013.

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-017

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

All information above the line is for conference use only.

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>.

Submitter Information 1:

Name:	Dr. Ben Chapman
Organization:	NC State University/NoroCORE collaborative
Address:	Campus Box 7606
City/State/Zip:	Raleigh, NC 27695
Telephone:	919 809 3205

E-mail: benjamin_chapman@ncsu.edu

Submitter Information 2:

Name: Dr. Lee-Ann Jaykus
Organization: NC State University/NoroCORE collaborative
Address: Department of Food, Bioprocessing and Nutrition Sciences
City/State/Zip: Raleigh, NC 27695
Telephone: 919-513-2074
E-mail: lajaykus@ncsu.edu

Supporting Attachments:

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

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.

Clinical Infectious Diseases Advance Access published April 21, 2015

Detection and quantification of airborne norovirus during outbreaks in healthcare facilities

Laetitia Bonifait[1], Rémi Charlebois[1], Allison Vimont[2], Nathalie Turgeon[1], Marc Veillette[1], Yves Longtin[3], Julie Jean[2,4] and Caroline Duchaine[1,5,*]

[1]Centre de recherche de l'institut universitaire de cardiologie et de pneumologie de Québec, Québec, Canada

[2]Institut sur la nutrition et les aliments fonctionnels, Université Laval, Québec, Canada

[3]Lady Davis Institute of Medical Research at the Jewish General Hospital and McGill University Faculty of Medicine, Montreal, Canada

[4]Départements des sciences des aliments et de nutrition, Faculté des sciences de l'agriculture et de l'alimentation, Université Laval, Québec, Canada

[5]Département de biochimie, de microbiologie et de bio-informatique, Faculté des sciences et de génie, Université Laval, Québec, Canada

CORRESPONDING AUTHOR: Mailing address: Caroline Duchaine, Ph.D., Centre de Recherche de l'Institut Universitaire de Cardiologie et de Pneumologie de Québec, 2725 Chemin Ste-Foy, Québec, Canada, G1V 4G5. Phone: (418) 656-8711 ext. 5837. Fax: 418 656-4509. E-mail: Caroline.Duchaine@bcm.ulaval.ca

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.

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.

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

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

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.

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

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.

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

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).

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

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.

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.

ACKNOWLEDGEMENTS

We are thankful to "La table régionale de prévention des infections nosocomiales de la région 03" for having notified us when an outbreak occurred. We thank Dr. MC Roy and Dr. J Villeneuve for assisting us in recruiting centers. We also thank all patients who participated at this study. We acknowledge L Trudel for critical reading of this manuscript and JE Marcoux for English revision.

NOTES

Financial support: This work was supported by the Institut de Recherche Robert-Sauvé en Santé et en Sécurité du Travail (Grant # 099-9060) and the National Sciences and Engineering Council of Canada (Grant # RGPIN-2014-059000). C.D. is a FRSQ senior scholar and a member of the FRSQ Respiratory Health Network. Y.L. is a FRSQ-funded clinical research scholar.

Potential conflict of interest: All authors have no potential conflicts of interest; they both have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

REFERENCES

1. Hall A, Lopman B, Park G, Yen C, Gregoricus N, Parashar U. Updated norovirus outbreak management and disease prevention guidelines. MMWR Recomm Rep **2011**; 60: 1-18.
2. Barclay L, Park GW, Vega E, et al. Infection control for norovirus. Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases **2014**.
3. Huttunen R, Syrjanen J. Healthcare workers as vectors of infectious diseases. European journal of clinical microbiology & infectious diseases : official publication of the European Society of Clinical Microbiology **2014**.
4. Lai CC, Wang YH, Wu CY, Hung CH, Jiang DD, Wu FT. A norovirus outbreak in a nursing home: norovirus shedding time associated with age. Journal of clinical virology : the official publication of the Pan American Society for Clinical Virology **2013**; 56(2): 96-101.
5. Pothier P, Kaiser L. Norovirus disease today. Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases **2014**.
6. Rockx B, De Wit M, Vennema H, et al. Natural history of human calicivirus infection: a prospective cohort study. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America **2002**; 35(3): 246-53.
7. Iturriza-Gomara M, Lopman B. Norovirus in healthcare settings. Current opinion in infectious diseases **2014**; 27(5): 437-43.

8. Hall AJ, Lopman BA, Payne DC, et al. Norovirus disease in the United States. Emerging infectious diseases **2013**; 19(8): 1198-205.

9. Vinje J. Advances in Laboratory Methods for Detection and Typing of Norovirus. Journal of clinical microbiology **2014**.

10. Debbink K, Lindesmith LC, Baric RS. The state of norovirus vaccines. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America **2014**; 58(12): 1746-52.

11. Godoy P, Ferrrus G, Torner N, et al. High incidence of norovirus GII.4 outbreaks in hospitals and nursing homes in Catalonia (Spain), 2010-2011. Epidemiology and infection **2014**: 1-9.

12. Hirneisen KA, Kniel KE. Comparing human norovirus surrogates: murine norovirus and Tulane virus. Journal of food protection **2013**; 76(1): 139-43.

13. Chadwick PR, McCann R. Transmission of a small round structured virus by vomiting during a hospital outbreak of gastroenteritis. The Journal of hospital infection **1994**; 26(4): 251-9.

14. Marks PJ, Vipond IB, Carlisle D, Deakin D, Fey RE, Caul EO. Evidence for airborne transmission of Norwalk-like virus (NLV) in a hotel restaurant. Epidemiology and infection **2000**; 124(3): 481-7.

15. Marks PJ, Vipond IB, Regan FM, Wedgwood K, Fey RE, Caul EO. A school outbreak of Norwalk-like virus: evidence for airborne transmission. Epidemiology and infection **2003**; 131(1): 727-36.

16. La Rosa G, Fratini M, Della Libera S, Iaconelli M, Muscillo M. Viral infections acquired indoors through airborne, droplet or contact transmission. Ann Ist Super Sanità **2013**; 49(2): 124-32.

17. Nenonen NP, Hannoun C, Svensson L, et al. Norovirus GII.4 Detection in Environmental Samples from Patient Rooms during Nosocomial Outbreaks. Journal of clinical microbiology **2014**; 52(7): 2352-8.

18. Jones MK, Watanabe M, Zhu S, et al. Enteric bacteria promote human and mouse norovirus infection of B cells. Science **2014**; 346(6210): 755-9.

19. Wobus CE, Thackray LB, Virgin HWt. Murine norovirus: a model system to study norovirus biology and pathogenesis. Journal of virology **2006**; 80(11): 5104-12.

20. Parshionikar S, Laseke I, Fout GS. Use of propidium monoazide in reverse transcriptase PCR to distinguish between infectious and noninfectious enteric viruses in water samples. Applied and environmental microbiology **2010**; 76(13): 4318-26.

21. Wobus CE, Karst SM, Thackray LB, et al. Replication of Norovirus in cell culture reveals a tropism for dendritic cells and macrophages. PLoS biology **2004**; 2(12): e432.

22. Gendron L, Verreault D, Veillette M, Moineau S, Duchaine C. Evaluation of filters for the sampling and quantification of RNA phage aerosols. Aerosol Science and Technology **2010**; 44: 893-901.

23. Lindsley WG, Blachere FM, Davis KA, et al. Distribution of airborne influenza virus and respiratory syncytial virus in an urgent care medical clinic. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America **2010**; 50(5): 693-8.

24. Turgeon N, Toulouse MJ, Martel B, Moineau S, Duchaine C. Comparison of five bacteriophages as models for viral aerosol studies. Applied and environmental microbiology **2014**; 80(14): 4242-50.

25. Gonzalez-Hernandez MB, Bragazzi Cunha J, Wobus CE. Plaque assay for murine norovirus. Journal of visualized experiments : JoVE **2012**; (66): e4297.

26. Kageyama T, Kojima S, Shinohara M, et al. Broadly reactive and highly sensitive assay for Norwalk-like viruses based on real-time quantitative reverse transcription-PCR. Journal of clinical microbiology **2003**; 41(4): 1548-57.

27. Girard M, Ngazoa S, Mattison K, Jean J. Attachment of noroviruses to stainless steel and their inactivation, using household disinfectants. Journal of food protection **2010**; 73(2): 400-4.

28. Atmar RL, Opekun AR, Gilger MA, et al. Norwalk virus shedding after experimental human infection. Emerging infectious diseases **2008**; 14(10): 1553-7.

29. Chan MC, Sung JJ, Lam RK, et al. Faecal viral load and norovirus-associated gastroenteritis. Emerging infectious diseases **2006**; 12(8): 1278-80.

30. Davis C, Vally H, Bell R, Sheehan F, Beard F. Viral gastrointestinal outbreaks in residential care facilities: an examination of the value of public health unit involvement. Australian and New Zealand journal of public health **2014**; 38(2): 177-83.

31. Glass RI, Parashar UD, Estes MK. Norovirus gastroenteritis. The New England journal of medicine **2009**; 361(18): 1776-85.

32. Lopman B, Gastanaduy P, Park GW, Hall AJ, Parashar UD, Vinje J. Environmental transmission of norovirus gastroenteritis. Current opinion in virology **2012**; 2(1): 96-102.

33. Verani M, Bigazzi R, Carducci A. Viral contamination of aerosol and surfaces through toilet use in health care and other settings. American journal of infection control **2014**; 42(7): 758-62.

34. Johnson DL, Mead KR, Lynch RA, Hirst DV. Lifting the lid on toilet plume aerosol: a literature review with suggestions for future research. American journal of infection control **2013**; 41(3): 254-8.

35. Sawyer LA, Murphy JJ, Kaplan JE, et al. 25- to 30-nm virus particle associated with a hospital outbreak of acute gastroenteritis with evidence for airborne transmission. American journal of epidemiology **1988**; 127(6): 1261-71.

36. Thornley CN, Emslie NA, Sprott TW, Greening GE, Rapana JP. Recurring norovirus transmission on an airplane. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America **2011**; 53(6): 515-20.

37. Bert F, Scaioli G, Gualano MR, et al. Norovirus Outbreaks on Commercial Cruise Ships: A Systematic Review and New Targets for the Public Health Agenda. Food and environmental virology **2014**.

38. Siegel JD, Rhinehart E, Jackson M, Chiarello L, Health Care Infection Control Practices Advisory C. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. American journal of infection control **2007**; 35(10 Suppl 2): S65-164.

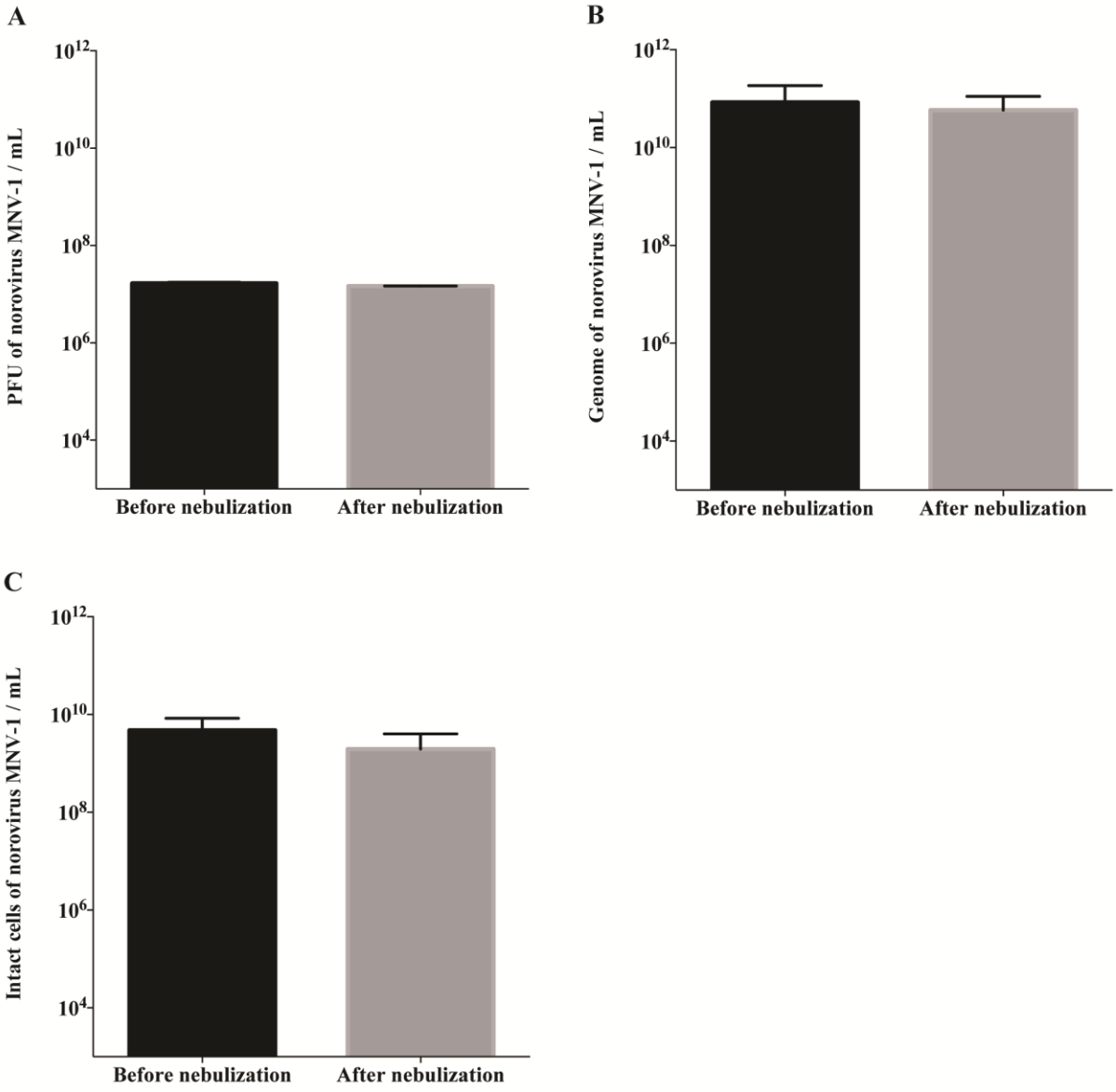
TABLE 1: Detection and concentration of norovirus GII RNA recovered from the air in patient rooms, hallways and nursing stations during 8 confirmed norovirus outbreaks, Quebec, 2012. Air samples were taken with the Coriolis µ® set at 200 L/min for 10 minutes.

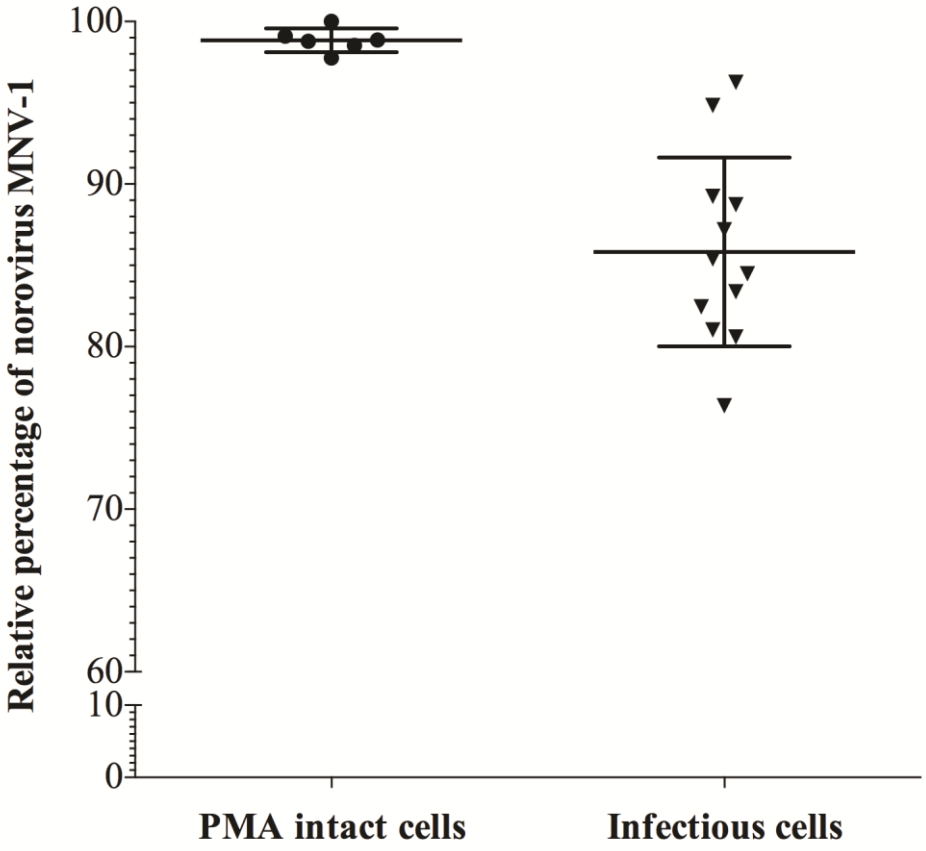
Healthcare centers Location	**Number of positive sample detected in the air**	**Range of Norovirus GII (Genome/m^3)**
Patient room	14/26	$1.46x10^1 – 2.35x10^3$
Nurse station	3/6	$1.35x10^1 – 1.22x10^2$
Hallway/Common area	6/16	$1.54x10^1 – 5.43x10^2$

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.





PLOS ONE

RESEARCH ARTICLE

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

Grace Tung-Thompson[1¶], Dominic A. Libera[2¶], Kenneth L. Koch[3], Francis L. de los Reyes, III[2‡*], Lee-Ann Jaykus[1‡]

1 Department of Food, Bioprocessing and Nutrition Sciences, North Carolina State University, Raleigh, North Carolina, United States of America, **2** Department of Civil, Construction and Environmental Engineering, North Carolina State University, Raleigh, North Carolina, United States of America, **3** Section on Gastroenterology, Wake Forest University School of Medicine, Winston-Salem, North Carolina 27157, United States of America

‡ These authors are faculty members who supervised the work.
¶ These authors were graduate students who performed the experiments.
* fldelosr@ncsu.edu

Citation: Tung-Thompson G, Libera DA, Koch KL, de los Reyes FL, III, Jaykus L-A (2015) Aerosolization of a Human Norovirus Surrogate, Bacteriophage MS2, during Simulated Vomiting. PLoS ONE 10(8): e0134277. doi:10.1371/journal.pone.0134277

Editor: Chris T. Bauch, University of Waterloo, CANADA

Received: February 20, 2015

Accepted: June 21, 2015

Published: August 19, 2015

Data Availability Statement: All relevant data are within the paper and its Supporting Information files.

Funding: This project was supported by the USDA-CSREES National Integrated Food Safety Initiative (NIFSI) project #2011-51110-31020 (http://www.nifa.usda.gov/nea/food/in_focus/safety_if_national.html). Partial support was also provided by Agriculture and Food Research Initiative Competitive Grant no. 2011-68003-30395 from the USDA National Institute of Food and Agriculture (http://www.nifa.usda.gov/funding/rfas/afri.html). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of this manuscript.

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.

doi:10.1371/journal.pone.0134277.t001

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

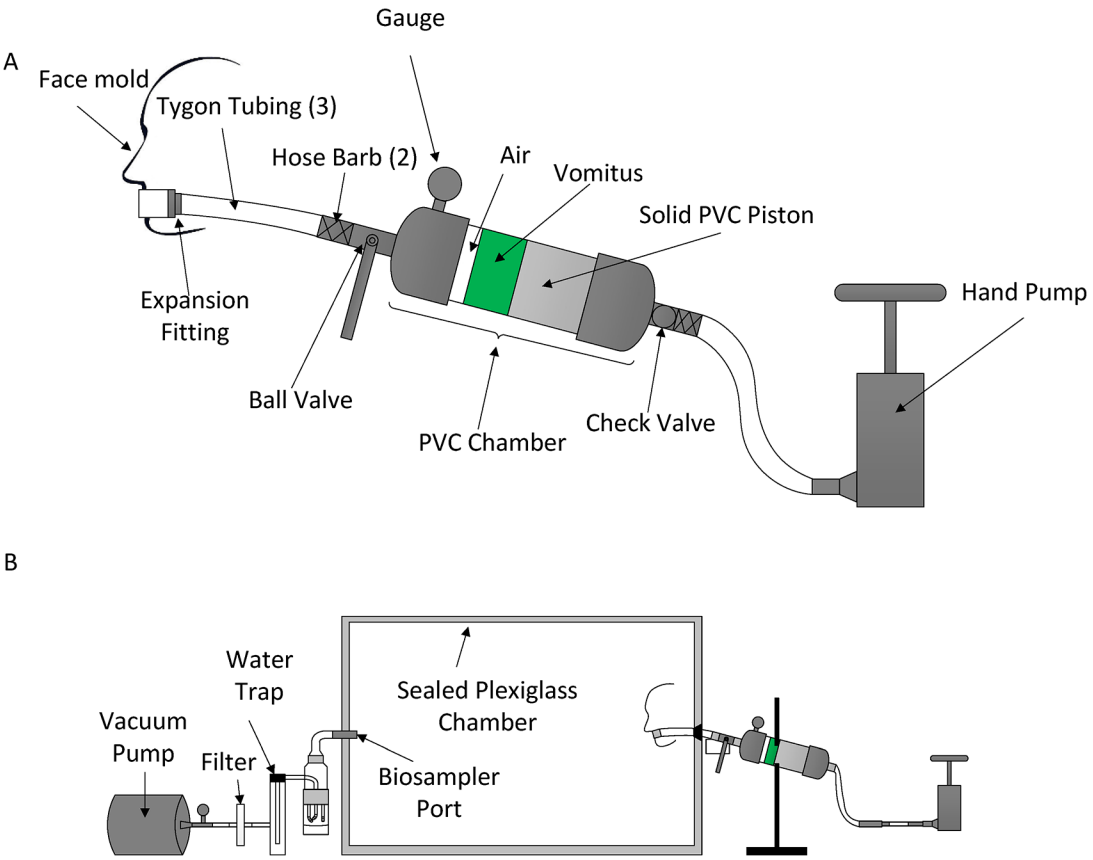


Fig 1. Schematic of Simulated Vomiting Device. (A) Diagram of the simulated vomiting device (B) Experimental set-up for capturing aerosolized virus.

doi:10.1371/journal.pone.0134277.g001

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

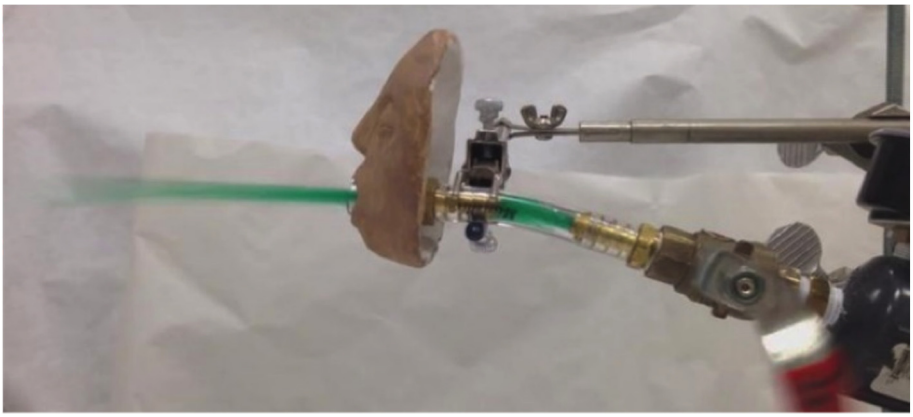


Fig 2. Photo of a Simulated Vomiting Episode. Projectile vomiting of colored simulated vomitus matrix.

doi:10.1371/journal.pone.0134277.g002

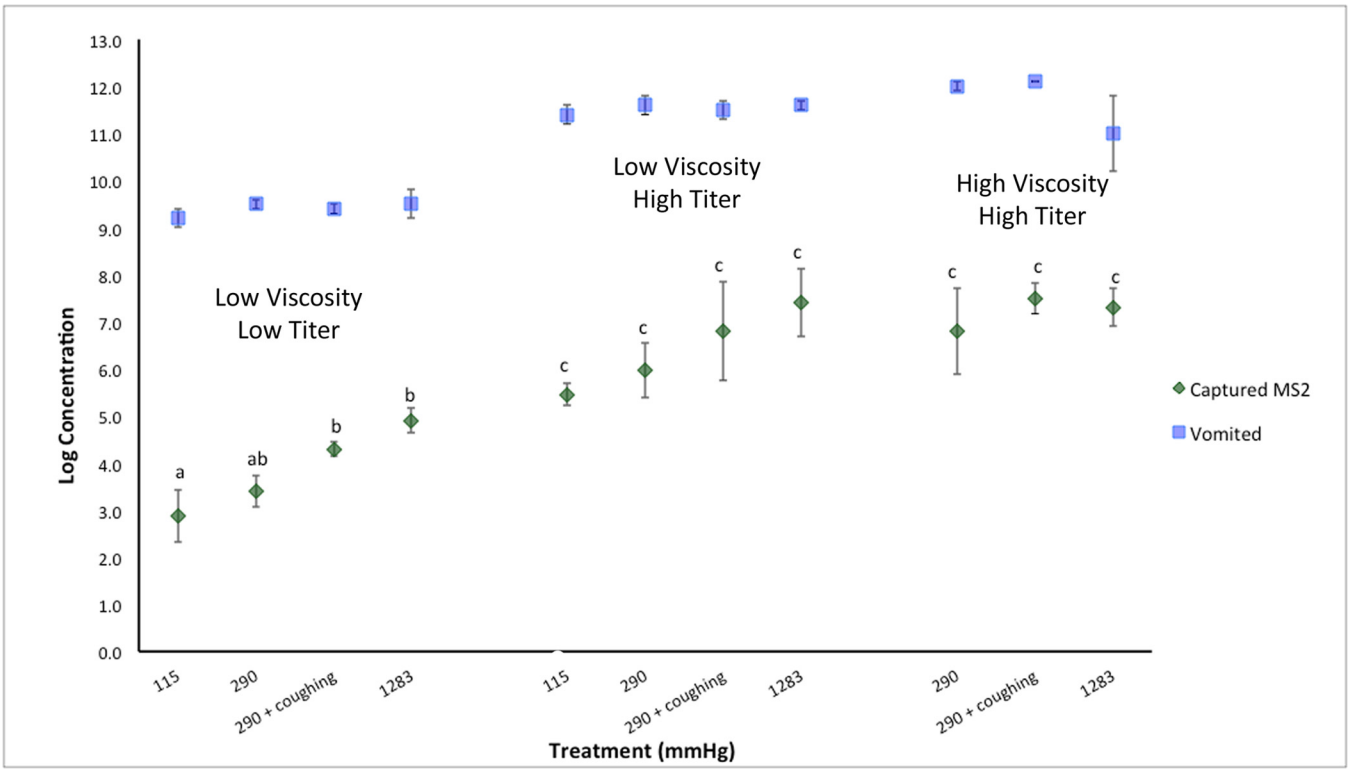


Fig 3. Aerosolization Experiments using bacteriophage MS2. Virus concentration "vomited" is designated by blue squares. Green diamonds show the amount of captured MS2 at designated pressures for simulated vomitus having low and high MS2 titer and of low and high viscosity. Error bars denote one standard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

doi:10.1371/journal.pone.0134277.g003

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 $p>0.05$.

doi:10.1371/journal.pone.0134277.t002

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)

Acknowledgments

We acknowledge K. Creme for challenging comments and insight as this work developed.

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.

References

1. Hall AJ, Wikswo ME, Manikonda K, Roberts VA, Yoder JS, Gould LH. Acute gastroenteritis surveillance through the National Outbreak Reporting System, United States. Emerg Infect Dis. 2013; 19: 1305–1309. doi: 10.3201/eid1908.130482 PMID: 23876187
2. Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis. 2011; 17(1):7–15. doi: 10.3201/eid1701.091101p1 PMID: 21192848
3. Greenberg HB, Wyatt RG, Kapikian AZ. Norwalk virus in vomitus. The Lancet. 1979; 1(8106):55.
4. Caul EO. Small round structured viruses: airborne transmission and hospital control. The Lancet. 1994; 343: 1240–1242. doi: 10.1016/S0140-6736(94)92146-6
5. Teunis PFM, Moe CL, Liu P, E Miller S, Lindesmith L, Baric RS, et al. Norwalk virus: How infectious is it? Journal of Medical Virology 2008; 80 (8): 1468–1476. doi: 10.1002/jmv.21237 PMID: 18551613
6. Atmar RL, Opekun AR, Gilger MA, Estes MK, Crawford SE, Neill FH, et al. Determination of the 50% human infectious dose for Norwalk virus. J Infect Dis. 2014; 209 (7): 1016–1022. doi: 10.1093/infdis/jit620 PMID: 24253285
7. Cheesbrough JS, Green J, Gallimore CI, Wright PA, Bown DW. Widespread environmental contamination with Norwalk-like viruses (NLV) detected in a prolonged hotel outbreak of gastroenteritis. Epidemiol Infect. 2000; 125 (1): 93–98. PMID: 11057964
8. Gallimore CI, Taylor C, Gennery AR, Cant AJ, Galloway A, Xerry J, et al. Contamination of the Hospital Environment with Gastroenteric Viruses: Comparison of Two Pediatric Wards over a Winter Season. J Clin Microbiol. 2008; 46 (9): 3112–3115. doi: 10.1128/JCM.00400-08 PMID: 18614656
9. Atmar RL, Opekun AR, Gilger MA, Estes MK, Crawford SE, Neill FH, et al. Norwalk Virus Shedding after Experimental Human Infection. Emerg Infect Dis. 2008; 14(10): 1553–1557. doi: 10.3201/eid1410.080117 PMID: 18826818
10. Todd ECD, Greig JD, Bartleson CA, Michaels BS. Outbreaks Where Food Workers Have Been Implicated in the Spread of Foodborne Disease. Part 5. Sources of Contamination and Pathogen Excretion from Infected Persons. J Food Prot. 2008; 72(12):2582–95.
11. Isakbaeva ET, Widdowson M-A, Beard RS, Bulens SN, Mullins J, Monroe SS, et al. Norovirus Transmission on Cruise Ship. Emerg Infect Dis. 2005; 11 (1): 154–8. doi: 10.3201/eid1101.040434 PMID: 15705344
12. Marks PJ, Vipond IB, Carlisle D, Deakin D, Fey RE, Caul EO. Evidence for airborne transmission of Norwalk-like virus (NLV) in a hotel restaurant. Epidemiol Infct. 2000; 124 (3): 481–487.
13. Lopman B, Gastañaduy P, Park GW, Hall AJ, Parashar UD, Vinje J. Environmental transmission of norovirus gastroenteritis. Current Opinion in Virology 2012; 2 (1): 96–102. doi: 10.1016/j.coviro.2011.11.005 PMID: 22440972
14. Beggs CB. The Airborne Transmission of Infection in Hospital Buildings: Fact or Fiction? Indoor and Built Environment. 2003; 12: 9–18. doi: 10.1177/1420326X03012001002
15. Eames I, Tang JW, Li Y, Wilson P. Airborne transmission of disease in hospitals. J R Soc Interface.2009; 6: S697–S702. doi: 10.1098/rsif.2009.0407.focus PMID: 19828499
16. Gralton J, Tovey E, McLaws M-L, Rawlinson WD. The role of particle size in aerosolised pathogen transmission: A review. Journal of Infection. 2011; 62 (1): 1–13. doi: 10.1016/j.jinf.2010.11.010
17. Dawson DJ, Paish A, Staffell LM, Seymour IJ, Appleton H. Survival of viruses on fresh produce, using MS2 as a surrogate for norovirus. Journal of Applied Microbiology. 2005; 98: 203–209. doi: 10.1111/j.1365-2672.2004.02439.x PMID: 15610433
18. Maillard JY, Beggs TS, Day MJ, Hudson RA, Russell AD. Effect of Biocides on MS2 and K Coliphages. Appl Environ Microbiol.1994; 60: 2205–2206. PMID: 16349309
19. Turgeon N, Toulouse M-J, Martel B, Moineau S, Duchaine C. Comparison of Five Bacteriophages as Models for Viral Aerosols Studies. Appl Environ Microbiol. 2014; 80: AEM.00767–14–4250. doi: 10.1128/AEM.00767-14
20. Koch KL. Nausea and Vomiting. In: Wolfe MM, editor. Therapy of Digestive Disorders. Philadelphia. 2006; pp. 1003–1117.
21. Fox RW, McDonald AT, Pritchard PJ. Introduction to Fluid Mechanics. Wiley Sons, Inc., editor Hoboken, NJ. 2004.
22. Kuo B, Urma D.Esophagus-anatomy and development. GI Motility online. 2006. doi: 10.1038/gimo6
23. Dijkstra PU, Hof AL, Stegenga B. Influence of mandibular length on mouth opening. Journal of oral rehabilitation. 1999.

24. Iqbal A, Haider M, Stadlhuber RJ, Karu A, Corkill S, Filipi CJ. A study of intragastric and intravesicular pressure changes during rest, coughing, weight lifting, retching, and vomiting. Surg Endosc. 2008; 22: 2571–2575. doi: 10.1007/s00464-008-0080-0 PMID: 18810545

25. Badman L. Water Matters: Proposed Changes to ANSI/NSF Standard 55-Ultraviolet Microbiological Water Treatment Systems. Water Conditioning and Purification. 2001; 43.

26. Su X, D'Souza DH. Grape Seed Extract for Control of Human Enteric Viruses. Appl Environ Microbiol. 2011; 77 (12): 3982–3987. doi: 10.1128/AEM.00193-11 PMID: 21498749

27. Sarkar A, Goh KKT, Singh H. Colloidal stability and interactions of milk-protein-stabilized emulsions in an artificial saliva. Food Hydrocolloids. 2009; 23: 1270–1278. doi: 10.1016/j.foodhyd.2008.09.008

28. Leith DE, Butler JP, Sneddon SL, Brain JD. Cough. Hoboken, NJ, USA: John Wiley & Sons, Inc. 1986. doi: 10.1002/cphy.cp030320.31 Nazaroff WW. Norovirus, gastroenteritis, and indoor environmental quality. Indoor Air. 2011. doi: 10.1111/j.1600-0668.2011.00735.x

29. Bonifait L, Charlebois R, Vimont A, Turgeon N, Veillette M, Longtin Y, et al. Detection and quantification of airborne norovirus during outbreaks in healthcare facilities. Clin Infect Dis. Advance Access published April 21, 2015. doi: 10.1093/cid/civ321

30. Harris JP, Ben A Lopman, Ben S Cooper, O'Brien SJ. Does spatial proximity drive norovirus transmission during outbreaks in hospitals? BMJ Open 2013; 3: e003060–e003060. doi: 10.1136/bmjopen-2013-003060

31. Nazaroff WW. Norovirus, gastroenteritis, and indoor environmental quality. Indoor Air. 2011. doi: 10.1111/j.1600-0668.2011.00735.x

32. Beggs CB, Kerr KG. The threat posed by airborne micro-organisms. Indoor and Built Environment. 2000; 9:241–245. doi: 10.1159/000057517

33. Booth CM. Vomiting Larry: a simulated vomiting system for assessing environmental contamination from projectile vomiting related to norovirus infection. Journal of Infection Prevention. 2014: doi: 10.1177/1757177414545390

34. Papineni RS, Rosenthal FS.The Size Distribution of Droplets in the Exhaled Breath of Healthy Human Subjects. Journal of Aerosol Medicine. 1997; 10: 105–116. doi: 10.1089/jam.1997.10.105 PMID: 10168531

35. Lindsley WG, Blachere FM, Thewlis RE, Vishnu A, Davis KA, Cao G, et al. Measurements of Airborne Influenza Virus in Aerosol Particles from Human Coughs. PLoS ONE. 2010; 5: e15100. doi: 10.1371/journal.pone.0015100 PMID: 21152051

36. Fabian P, McDevitt JJ, Houseman EA, Milton DK. Airborne influenza virus detection with four aerosol samplers using molecular and infectivity assays: considerations for a new infectious virus aerosol sampler. Indoor Air. 2009; 19: 433–441. doi: 10.1111/j.1600-0668.2009.00609.x PMID: 19689447

37. Hogan CJ, Kettleson EM, Lee MH, Ramaswami B, Angenent LT, Biswas P. Sampling methodologies and dosage assessment techniques for submicrometre and ultrafine virus aerosol particles. Journal of Applied Microbiology. 2005; 99: 1422–1434. doi: 10.1111/j.1365-2672.2005.02720.x PMID: 16313415

38. Zuo Z, Kuehn TH, Bekele AZ, Mor SK, Verma H, Goyal SM. Survival of Airborne MS2 Bacteriophage Generated from Human Saliva, Artificial Saliva, and Cell Culture Medium. Appl Environ Microbiol. 2014; 80 (9): 2796–2803. doi: 10.1128/AEM.00056-14 PMID: 24561592

39. Kotwal G, Cannon JL. Environmental persistence and transfer of enteric viruses. Current Opinion in Virology. 2014; 4: 37–43. doi: 10.1016/j.coviro.2013.12.003 PMID: 24413147

40. Verreault D, Moineau S, Duchaine C. Methods for sampling of airborne viruses. Microbiol Mol Biol Rev. 2008; 72: 413–444. doi: 10.1128/MMBR.00002-08 PMID: 18772283

41. Tseng C-C, Li C-S. Collection efficiencies of aerosol samplers for virus-containing aerosols. Journal of Aerosol Science. 2005; 36: 593–607. doi: 10.1016/j.jaerosci.2004.12.004

42. Utrup LJ, Frey AH. Fate of bioterrorism-relevant viruses and bacteria, including spores, aerosolized into an indoor air environment. Exp Biol Med (Maywood). 2004; 229(4): 345–350.

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	_____		

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 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

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood DR
City/State/Zip:	Roscommon, MI 48653
Telephone:	517-719-7919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name:	Karla Horne
Organization:	Great Lakes Conference on Food Protection
Address:	525 W AlleganPO Box 30017
City/State/Zip:	LAnsing, MI 48909
Telephone:	231-357-0727
E-mail:	hornek@michigan.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-019

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

All information above the line is for conference use only.

Issue History:

This 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.

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood Dr
City/State/Zip:	Roscommon, MI 48653
Telephone:	517-719-7919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name:	Karla Horne

Organization: Conference on Food Protection
Address: 525 W AlleganPO Box 30017
City/State/Zip: Lansing, MI 48909
Telephone: 231-357-0727
E-mail: hornek@michigan.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-020

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

All information above the line is for conference use only.

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

Submitter Information 1:

Name:	Ann Johnson
Organization:	FL Department of Agriculture
Address:	3236 Sardenia Terrace
City/State/Zip:	Deltona, FL 32738
Telephone:	407-335-3497
E-mail:	anna.johnson@freshfromflorida.com

Submitter Information 2:

Name:	Joetta DeFrancesco
Organization:	FL Department of Agriculture
Address:	10281 Enoch Lane
City/State/Zip:	Bonita Springs, FL 34135
Telephone:	239-206-0260
E-mail:	joetta.defrancesco@freshfromflorida.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-021

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

All information above the line is for conference use only.

Issue History:

This 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

Submitter Information:

Name:	Thomas Johnson
Organization:	Johnson Risk Solutions, LLC
Address:	1408 Northland Dr. #406
City/State/Zip:	Mendota Heights, MN 55120
Telephone:	651-587-0418
E-mail:	tomj@jdpinc.com

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	_____		

All information above the line is for conference use only.

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 within 4 hours 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 within 4 hours 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 within 4 hours 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

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood
City/State/Zip:	Roscommon, MI 48653
Telephone:	517-719-7919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name: Karla Horne
Organization: Great Lakes Conference on Food Protection
Address: 525 W AlleganPO Box 30017
City/State/Zip: Lansing, MI 48909
Telephone: 231-357-0727
E-mail: hornek@michigan.gov

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

Conference for Food Protection
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).*

Submitter Information 1:

Name:	Ann Johnson
Organization:	FL Department of Agriculture
Address:	3236 Sardenia Terrace
City/State/Zip:	Deltona, FL 32738
Telephone:	407-335-3497
E-mail:	anna.johnson@freshfromflorida.com

Submitter Information 2:

Name:	Joetta DeFrancesco
Organization:	FL Department of Agriculture
Address:	10281 Enoch Lane
City/State/Zip:	Bonita Springs, FL 34135
Telephone:	239-206-0260
E-mail:	joetta.defrancesco@freshfromflorida.com

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	_____		

All information above the line is for conference use only.

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.

Submitter Information:

Name:	Hilary Thesmar
Organization:	FMI
Address:	2345 Crystal DrSuite 800
City/State/Zip:	Arlington, VA 22202
Telephone:	202-220-0658
E-mail:	hthesmar@fmi.org

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	_____		

All information above the line is for conference use only.

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.*

Submitter Information 1:

Name:	Ann Johnson
Organization:	FL Department of Agriculture
Address:	3236 Sardenia Terrace
City/State/Zip:	Deltona, FL 32738
Telephone:	407-335-3497
E-mail:	anna.johnson@freshfromflorida.com

Submitter Information 2:

Name:	Joetta DeFrancesco
Organization:	FL Department of Agriculture
Address:	10281 Enoch Lane
City/State/Zip:	Bonita Springs, FL 34135
Telephone:	239-206-0260
E-mail:	joetta.defrancesco@freshfromflorida.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-026

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

All information above the line is for conference use only.

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.

Submitter Information 1:

Name:	Karl Matthews
Organization:	Rutgers University
Address:	65 Dudley Road
City/State/Zip:	New Brunswick, NJ 08901
Telephone:	848-932-5430
E-mail:	Matthews@aesop.rutgers.edu

Submitter Information 2:

Name:	Jill Hollingsworth
Organization:	Food Safety Consulting
Address:	29 BRIDGETOWN RD
City/State/Zip:	Hilton Head Island, SC 29928
Telephone:	843-341-6640
E-mail:	1jillh@gmail.com

Supporting Attachments:

- "Efficacy of Commercial Produce Sanitizers against Nontoxigenic Escherichia"

Journal of Food Protection, Vol. 76, No. 11, 2013, Pages 1838–1845
doi:10.4315/0362-028X.JFP-13-111

Efficacy of Commercial Produce Sanitizers against Nontoxigenic *Escherichia coli* O157:H7 during Processing of Iceberg Lettuce in a Pilot-Scale Leafy Green Processing Line

GORDON R. DAVIDSON, ANNEMARIE L. BUCHHOLZ, AND ELLIOT T. RYSER*

Department of Food Science and Human Nutrition, Michigan State University, East Lansing, Michigan 48824, USA

MS 13-111: Received 20 March 2013/Accepted 1 July 2013

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

* Author for correspondence. Tel: 517-355-8474, Ext 185; Fax: 517-353-8963; E-mail: ryser@msu.edu.

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

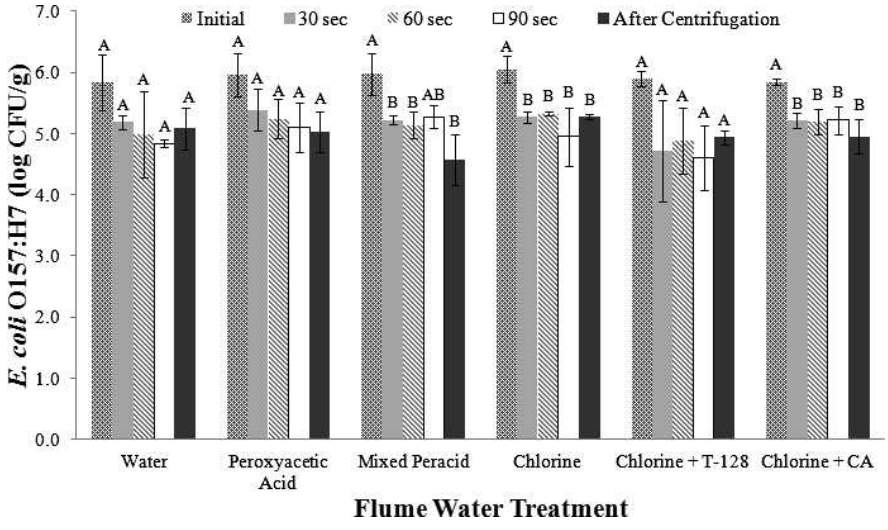


FIGURE 1. *Mean (±SD)* E. coli *O157:H7 populations on the iceberg lettuce inoculated at ~6 log CFU/g during and after processing (*n = *3). Means of the same wash water treatment with different letters are significantly different (*P ≤ *0.05).*

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,

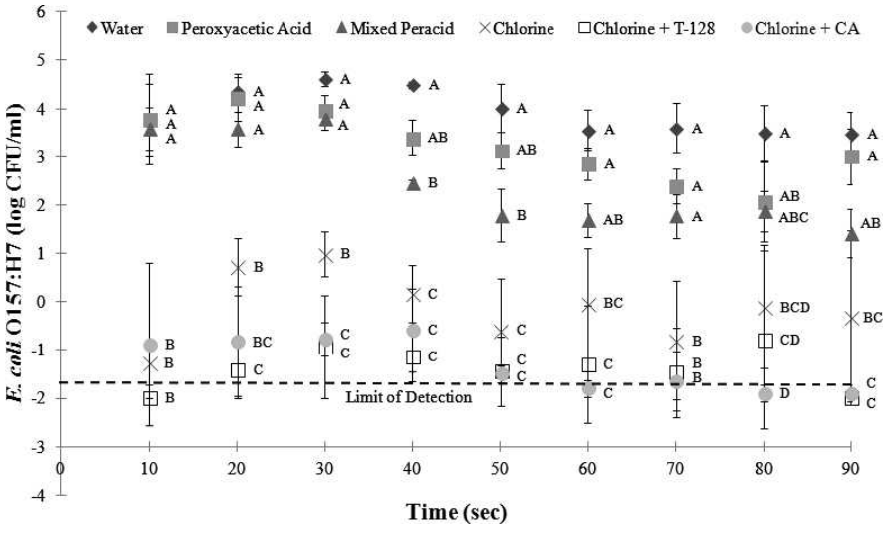


FIGURE 2. *Mean (±SD)* E. coli *O157:H7 populations in flume water during processing iceberg lettuce inoculated at ~6 log CFU/g (n = 3). Half the limit of detection was used to calculate the mean log value when a sample did not yield any colonies by direct plating. Means of the same product type with 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).

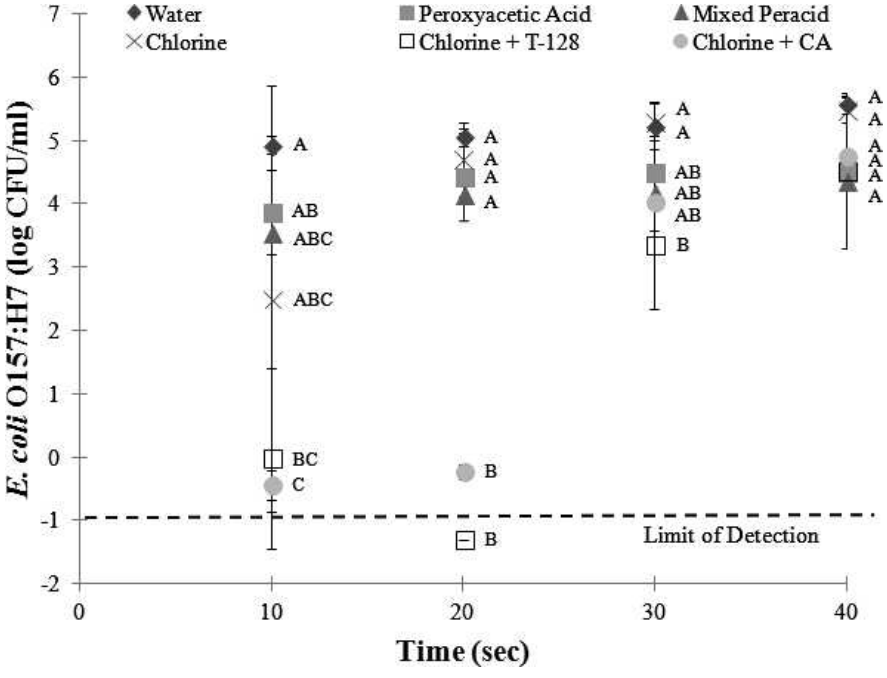


FIGURE 3. *Mean (±SD)* E. coli *O157:H7 populations in spent centrifugation water from iceberg lettuce inoculated at ~6 log CFU/g (n = 3). Half the limit of detection was used to calculate the mean log value when a sample did not yield any colonies by direct plating. Means of the same product type with different letters are significantly different (P ≤ 0.05).*

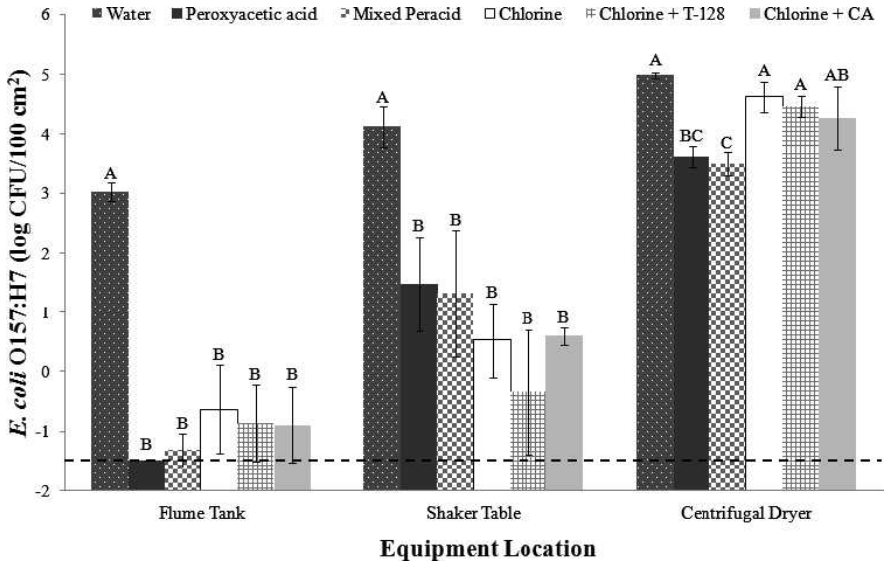


FIGURE 4. *Mean (±SD)* E. coli *O157:H7 populations on equipment surfaces after processing iceberg lettuce inoculated at ~6 log CFU/g* (n = *3). Half the limit of detection was used to calculate the mean log value when a sample did not yield any colonies by direct plating. Means of the same product type 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.

ACKNOWLEDGMENTS

Financial support for this study was provided by U.S. Department of Agriculture National Integrated Food Safety Initiative grant no. 2007-51110-03812 and Fresh Express, Inc., Salinas, CA. We thank Heinzen Manufacturing, Gilroy, CA, and Dorner Manufacturing, Hartland, WI, for portions of the produce processing line and Chelsea Kaminski, Lin Ren, Paul Sirmeyer, and Jake Thorns, for their technical assistance.

REFERENCES

1. Allende, A., J. McEvoy, Y. Tao, and Y. Luo. 2009. Antimicrobial effect of acidified sodium chlorite, sodium chlorite, sodium hypochlorite, and citric acid on *Escherichia coli* O157:H7 and natural microflora of fresh-cut cilantro. *Food Control* 20:230–234.
2. Allende, A., M. V. Selma, F. Lopez-Galvez, R. Villaescusa, and M. I. Gil. 2008. Impact of wash water quality on sensory and microbial quality, including *Escherichia coli* cross-contamination, of fresh-cut escarole. *J. Food Prot.* 71:2514–2518.
3. Beuchat, L. R. 1998. Surface decontamination of fruits and vegetables eaten raw: a review. Available at: http://www.who.int/foodsafety/publications/fs_management/en/surface_decon.pdf. Accessed 28 August 2012.
4. Beuchat, L. R., B. B. Adler, and M. M. Lang. 2004. Efficacy of clorine and a peroxyacetic acid sanitizer in killing *Listeria monocytogenes* on iceberg and romaine lettuce using simulated commercial processing conditions. *J. Food Prot.* 67:1238–1242.
5. Buchanan, R. L., S. G. Edelson, R. L. Miller, and G. M. Sapers. 1999. Contamination of intact apples after immersion in an aqueous environment containing *Escherichia coli* O157:H7. *J. Food Prot.* 62: 444–450.
6. Buchholz, A. L., G. R. Davidson, B. P. Marks, E. C. D. Todd, and E. T. Ryser. 2012. Quantitative transfer of *Escherichia coli* O157:H7 to equipment during small-scale production of fresh-cut leafy greens. *J. Food Prot.* 75:1184–1197.
7. Buchholz, A. L., G. R. Davidson, B. P. Marks, E. C. D. Todd, and E. T. Ryser. 2012. Transfer of *Escherichia coli* O157:H7 from equipment surfaces to fresh-cut leafy greens during processing in a model pilot-plant production line with sanitizer-free water. *J. Food Prot.* 75:1920–1929.
8. Buchholz, A. L., G. R. Davidson, R. E. Sloup, B. P. Marks, E. C. D. Todd, and E. T. Ryser. 2010. Tracking an *Escherichia coli* O157:H7 contaminated batch of leafy greens through a commercial processing line, T4-02. Abstr. Annu. Meet. IAFP, Anaheim, CA.
9. Burnett, A. B., M. H. Iturriaga, E. F. Escartin, C. A. Pettigrew, and L. R. Beuchat. 2004. Influence of variations in methodology on populations of *Listeria monocytogenes* recovered from lettuce treated with sanitizers. *J. Food Prot.* 67:742–750.
10. California Department of Public Health. 2007. Investigation of an *Escherichia coli* O157:H7 outbreak associated with Dole prepackaged spinach. Available at: http://www.cdph.ca.gov/pubsforms/Documents/fdb%20eru%20Spnch%20EC%20Dole032007wph.PDF. Accessed 3 October 2012.

11. Carlin, F., and C. Nguyen-The. 1994. Fate of *Listeria monocytogenes* on four types of minimally processed green salads. *Lett. Appl. Microbiol.* 18:222–226.
12. Center for Science in the Public Interest. 2008. Outbreak alert! 2008. Available at: http://www.cspinet.org/new/pdf/outbreak_alert_2008_report_final.pdf. Accessed 13 October 2012.
13. Center for Science in the Public Interest. 2009. The ten riskiest foods regulated by the US Food and Drug Administration. Available at: http://cspinet.org/new/pdf/cspi_top_10_fda.pdf. Accessed 2 October 2012.
14. Centers for Disease Contol and Prevention. 2012. Investigation update: multistate outbreak of *E. coli* O157:H7 infections linked to romaine lettuce. Available at: http://www.cdc.gov/ecoli/2011/ecoliO157/romainelettuce/032312/index.html. Accessed 20 February 2013.
15. Chase-Topping, M. E., I. J. McKendrick, M. C. Pearce, P. MacDonald, L. Matthews, J. Halliday, L. Allison, D. Fenlon, J. C. Low, G. Gunn, and M. E. Woolhouse. 2007. Risk factors for the presence of high-level shedders of *Escherichia coli* O157 on Scottish farms. *J. Clin. Microbiol.* 45:1594–1603.
16. Code of Federal Regulations. 2012. Title 21, Part 173.315. Chemicals used in washing or to assist in the peeling of fruits and vegetables. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=173.315. Accessed 16 September 2012.
17. Cooley, M., D. Carychao, L. Crawford-Miksza, M. T. Jay, C. Myers, C. Rose, C. Keys, J. Farrar, and R. E. Mandrell. 2007. Incidence and tracking of *Escherichia coli* O157:H7 in a major produce production region in California. *PLoS ONE* 2:e1159.
18. Foley, D. M., A. Dufour, L. Rodriguez, F. Caporaso, and A. Prakash. 2002. Reduction of *Escherichia coli* O157:H7 in shredded iceberg lettuce by chlorination and gamma irradiation. *Radiat. Phys. Chem.* 63:391–396.
19. Food and Agriculture Organization and the World Health Organization. 2010. CODEX Alimentarius: code of hygenic practice for fresh fruits and vegetables. Available at: http://www.codexalimentarius.org/standards/list-of-standards/en/. Accessed 20 February 2013.
20. Gil, M. I., M. V. Selma, F. López-Gálvez, and A. Allende. 2009. Fresh-cut product sanitation and wash water disinfection: problems and solutions. *Int. J. Food Microbiol.* 134:37–45.
21. Herdt, J., and H. Feng. 2009. Aqueous antimicrobial treatments to improve fresh and fresh-cut produce safety, p. 169–190. *In* X. Fan, B. A. Niemira, C. J. Doona, F. E. Feeherry, and R. B. Gravani (ed.), Microbial safety of fresh produce. Wiley-Blackwell, Ames, IA.
22. Herman, K. M., T. L. Ayers, and M. Lynch. 2008. Foodborne disease outbreaks associated with leafy greens, 1973–2006. Available at: http://wwwnc.cdc.gov/eid/pdfs/ICEID2008.pdf. Accessed 10 October 2012.
23. Huang, Y., and H. Chen. 2011. Effect of organic acids, hydrogen peroxide and mild heat on inactivation of *Escherichia coli* O157:H7 on baby spinach. *Food Control* 22:1178–1183.
24. Keskinen, L. A., and B. A. Annous. 2011. Efficacy of adding detergents to sanitizer solutions for inactivation of *Escherichia coli* O157:H7 on romaine lettuce. *Int. J. Food Microbiol.* 147:157–161.
25. Lemons, K. E. 30 July 2009. Antimicrobial compositions and methods of use thereof. U.S. patent 0192231 A1.
26. Li, Y., R. E. Brackett, J. Chen, and L. R. Beuchat. 2001. Survival and growth of *Escherichia coli* O157:H7 inoculated onto cut lettuce before or after heating in chlorinated water, followed by storage at 5 or 15°C. *J. Food Prot.* 64:305–309.
27. López-Gálvez, F., A. Allende, M. V. Selma, and M. I. Gil. 2009. Prevention of *Escherichia coli* cross-contamination by different commercial sanitizers during washing of fresh-cut lettuce. *Int. J. Food Microbiol.* 133:167–171.
28. Luo, Y. 2007. Fresh-cut produce wash water reuse affects water quality and packaged product quality and microbial growth in romaine lettuce. *Hortic. Sci.* 42:1413–1419.
29. Luo, Y., X. Nou, P. Millner, and B. Zhou. 2012. A pilot plant scale evaluation of a new process aid for enhancing chlorine efficacy against pathogen survival and cross-contamination during produce wash. *Int. J. Food Microbiol.* 158:133–139.
30. Luo, Y., X. Nou, Y. Yang, I. Alegre, E. Turner, H. Feng, M. Abadias, and W. Conway. 2011. Determination of free chlorine concentrations needed to prevent *Escherichia coli* O157:H7 cross-contamination during fresh-cut produce wash. *J. Food Prot.* 74:352–358.
31. Lynch, M. F., R. V. Tauxe, and C. W. Hedberg. 2009. The growing burden of foodborne outbreaks due to contaminated fresh produce: risks and opportunities. *Epidemiol. Infect.* 137:307–315.
32. Nou, X., and Y. Luo. 2010. Whole-leaf wash improves chlorine efficacy for microbial reduction and prevents pathogen cross-contamination during fresh-cut lettuce processing. *J. Food Sci.* 75:M283–M290.
33. Nou, X., Y. Luo, L. Hollar, Y. Yang, H. Feng, P. Millner, and D. Shelton. 2011. Chlorine stabilizer T-128 enhances efficacy of chlorine against cross-contamination by *E. coli* O157:H7 and *Salmonella* in fresh-cut lettuce processing. *J. Food Sci.* 76:218–224.
34. Ölmez, H. 2010. Effect of different sanitizing methods and incubation time and temperature on inactivation of *Escherichia coli* on lettuce. *J. Food Saf.* 30:288–299.
35. Palumbo, M. S., J. R. Gorny, D. E. Gombas, L. R. Beuchat, C. M. Bruhn, B. Cassens, P. Delaquis, J. M. Farber, L. J. Harris, K. Ito, M. T. Osterholm, M. Smith, and K. M. J. Swanson. 2007. Recommendations for handling fresh-cut leafy green salads by consumers and retail foodservice operators. *Food Prot. Trends* 27:892–898.
36. Parish, M. E., L. R. Beuchat, T. V. Suslow, L. J. Harris, E. H. Garrett, J. N. Farber, and F. F. Busta. 2003. Methods to reduce/eliminate pathogens from fresh and fresh-cut produce. *Compr. Rev. Food Sci. Food Saf.* 2:161–173.
37. Ryser, E. T., J. Hao, and Z. Yan. 2009. Internalization of pathogens in produce, p. 55–80. *In* X. Fan, B. A. Niemira, C. J. Doona, F. E. Feeherry, and R. B. Gravani (ed.), Microbial safety of fresh produce. Wiley-Blackwell, Ames, IA.
38. Sapers, G. M. 2001. Efficacy of washing and sanitizing methods for disinfection of fresh fruit and vegetable products. *Food Technol. Biotechnol.* 39:305–311.
39. Sapers, G. M. 2009. Disinfection of contaminated produce with conventional washing and sanitizing technology, p. 393–424. *In* G. Sapers, E. Solomon, and K. R. Matthews (ed.), The produce contamination problem: causes and solutions. Elsevier, Burlington, MA.
40. Seo, K. H., and J. F. Frank. 1999. Attachment of *Escherichia coli* O157:H7 to lettuce leaf surface and bacterial viability in response to chlorine treatment as demonstrated by using confocal scanning laser microscopy. *J. Food Prot.* 62:3–9.
41. Shen, C., Y. Luo, X. Nou, G. Bauchan, B. Zhou, Q. Wang, and P. Millner. 2012. Enhanced inactivation of *Salmonella* and *Pseudomonas* biofilms on stainless steel by use of T-128, a fresh-produce washing aid, in chlorinated wash solutions. *Appl. Environ. Microbiol.* 78:6789–6798.
42. Suslow, T. V. 2001. Water disinfection, a practical approach to calculating dose values for preharvest and postharvest applications. Publication 7256. University of California, Davis, Agriculture and Natural Resources. Available at: http://anrcatalog.ucdavis.edu/pdf/7256.pdf. Accessed 22 September 2012.
43. Suslow, T. V. 2006. Making sense of rules governing chlorine contact in postharvest handling of organic produce. Publication 8198. University of California, Davis, Agriculture and Natural Resources. Available at: http://anrcatalog.ucdavis.edu/pdf/8198.pdf. Accessed 22 September 2012.
44. Szabo, E. A., L. Simons, M. J. Coventry, and M. B. Cole. 2003. Assessment of control measures to achieve a food safety objective of less than 100 CFU of *Listeria monocytogenes* per gram at the point of consumption for fresh precut iceberg lettuce. *J. Food Prot.* 66:256–264.
45. U.S. Food and Drug Administration. 1998. Guidance for industry: guide to minimize microbial food safety hazards for fresh fruits and vegetables. Available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm#ii. Accessed 8 September 2012.
46. U.S. Food and Drug Administration. 2009. Guidance for industry: guide to minimize microbial food safety hazards of leafy greens; draft guidance. Available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174200.htm#fresh. Accessed 7 September 2012.
47. U.S. Food and Drug Administration. 2013. Standards for the growing, harvesting, packing and holding of produce for human consumption, a

proposed rule. Available at: https://www.federalregister.gov/articles/2013/01/16/2013-00123/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption. Accessed 20 February 2013.

48. Vorst, K. L., E. C. D. Todd, and E. T. Ryser. 2004. Improved quantitative recovery of *Listeria monocytogenes* from stainless steel surfaces using a one-ply composite tissue. *J. Food Prot.* 67:2212–2217.
49. Wachtel, M. R., L. C. Whitehead, and R. E. Mandrell. 2002. Association of *Escherichia coli* O157:H7 with preharvest leaf lettuce upon exposure to contaminated irrigation water. *J. Food Prot.* 65:18–25.
50. Weissinger, W. R., W. Chantarapanont, and L. R. Beuchat. 2000. Survival and growth of *Salmonella baildon* in shredded lettuce and diced tomatoes, and effectiveness of chlorinated water as a sanitizer. *Int. J. Food Microbiol.* 62:123–131.
51. Zeng, W., K. Vorst, W. Brown, B. Marks, F. Perez-Rodriguez, and E. Ryser. 2012. Monte Carlo simulation of *Escherichia coli* O157:H7 and *Listeria monocytogenes* growth in bagged salad greens during commercial transport, retail storage and display, T4-12. Abstr. Annu. Meet. IAFP, Providence, RI.
52. Zhang, G., L. Ma, V. H. Phelan, and M. P. Doyle. 2009. Efficacy of antimicrobial agents in lettuce leaf processing water for control of *Escherichia coli* O157:H7. *J. Food Prot.* 72:1392–1397.
53. Zhang, S., and J. M. Farber. 1996. The effects of various disinfectants against *Listeria monocytogenes* on fresh-cut vegetables. *Food Microbiol.* 13:311–321.

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.

Submitter Information:

Name: Dan Dahlman
Organization: Ecolab
Address: 370 Wabasha St. N
City/State/Zip: St Paul, MN 55102
Telephone: 6512503297
E-mail: dan.dahlman@ecolab.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-028

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

All information above the line is for conference use only.

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

Submitter Information 1:

Name:	Ann Johnson
Organization:	FL Department of Agriculture
Address:	3236 Sardenia Terrace
City/State/Zip:	Deltona, FL 32738
Telephone:	407-335-3497
E-mail:	anna.johnson@freshfromflorida.com

Submitter Information 2:

Name:	Joetta DeFrancesco
Organization:	FL Department of Agriculture
Address:	10281 Enoch Lane
City/State/Zip:	Bonita Springs, FL 34135
Telephone:	239-206-0260
E-mail:	joetta.defrancesco@freshfromflorida.com

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-029

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

All information above the line is for conference use only.

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).

<u>(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.</u>

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood DR
City/State/Zip:	Roscommon, MI 48653
Telephone:	517-719-7919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name:	Karla Horne
Organization:	Great Lakes Conference on Food Protection
Address:	525 W Allegan StPO Box 30017

City/State/Zip: Lansing, MI 48909
Telephone: 231-357-0727
E-mail: hornek@michigan.gov

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

Conference for Food Protection
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>

Submitter Information:

Name:	Veronica Bryant
Organization:	NC DHHS/EH Food Protection Branch
Address:	1632 Mail Service Center
City/State/Zip:	Raleigh, NC 27699
Telephone:	704-718-7866
E-mail:	veronica.bryant@dhhs.nc.gov

Supporting Attachments:

- "Microgreens- A New Specialty Crop"

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.

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.

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	_____		

All information above the line is for conference use only.

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>

Submitter Information:

Name:	Veronica Bryant
Organization:	NC DHHS/EH Food Protection Branch
Address:	1632 Mail Service Center
City/State/Zip:	Raleigh, NC 27699-1632
Telephone:	704-718-7866
E-mail:	veronica.bryant@dhhs.nc.gov

Supporting Attachments:

- "Cured meat products without direct addition of nitrate or nitrite: what are"

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.

Available online at www.sciencedirect.com
ScienceDirect
Meat Science 77 (2007) 136–147
MEAT SCIENCE
www.elsevier.com/locate/meatsci

Cured meat products without direct addition of nitrate or nitrite: what are the issues?

Joseph G. Sebranek [a,*], James N. Bacus [b,1]

[a] Department of Animal Science, Department of Food Science and Human Nutrition, 215 Meat Laboratory, Iowa State University, Ames, IA 50011, United States
[b] Technical Ingredient Solutions, LLC, 3518 NW 97th Blvd., Gainesville, FL 32606, United States

Received 2 March 2007; received in revised form 29 March 2007; accepted 30 March 2007

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.

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).

* Corresponding author. Tel.: +1 515 294 1091; fax: +1 515 294 5066.
E-mail addresses: sebranek@iastate.edu (J.G. Sebranek), jbacus@tingsol.com (J.N. Bacus).
[1] Tel.: +1 352 505 5550.

0309-1740/$ - see front matter © 2007 Elsevier Ltd. All rights reserved.
doi:10.1016/j.meatsci.2007.03.025

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.

References

Archer, D. L. (2002). Evidence that ingested nitrate and nitrite are beneficial to health. *Journal of Food Protection, 65*, 872–875.

Bacus, J. (2006). Natural ingredients for cured and smoked meats. In *Proceedings of the 59th reciprocal meat conference* (pp. 77–78), June 18–21, 2006. Champaign-Urbana, IL, USA.

Baseler, L. J. (2007) Unpublished data. Iowa State University, Ames, IA, USA.

Binkerd, E. F., & Kolari, O. E. (1975). The history and use of nitrate and nitrite in the curing of meat. *Food and Cosmetics Toxicology, 13*, 655–661.

Bourn, D., & Prescott, J. (2002). A comparison of the nutritional value, sensory qualities and food safety of organically and conventionally produced foods. *Critical Reviews in Food Science and Nutrition, 42*(1), 1–34.

Cantoni, C., Berretta, G., & Bianchi, M. A. (1978). Ammonia, nitrites and nitrates in sodium chloride. *Archivio Veterinario Italiano, 29*(5/6), 166–167 (Italian with English summary).

Casaburi, A., Blaiotta, G., Mauriello, G., Pepe, O., & Villani, F. (2005). Technological activities of *Staphylococcus carnosus* and *Staphylococcus simulans* strains isolated from fermented sausages. *Meat Science, 71*, 643–650.

Cassens, R. G. (1990). *Nitrite-cured meat*. Trumbull, CT: Food and Nutrition Press, Inc.

Cassens, R. G. (1997a). Composition and safety of cured meats in the USA. *Food Chemistry, 59*, 561–566.

Cassens, R. G. (1997b). Residual nitrite in cured meat. *Food Technology, 51*(2), 53–55.

Christiansen, L. N. (1980). Factors influencing botulinal inhibition by nitrite. *Food Technology, 34*(5), 237–239.

Code of Federal Regulations. (2006). Animals and animal products. 9 CFR 317.17, 9 CFR 319.2 and 9 CFR 424.21-23. Washington, DC. <http://www.access.gpo.gov/nara/cfr/waisidx_06/9cfrv2_06.html#301>. Accessed 28.12.06.

Cornforth, D. P., & Jayasingh, P. (2004). Colour and pigment. In W. K. Jensen, C. Devine, & M. Dikeman (Eds.), *Encyclopedia of meat sciences* (pp. 249–256). Oxford, UK: Elsevier Ltd.

Coughlin, J. R. (2006). Update on International Agency for Research on Cancer monograph on ingested nitrite and nitrate. In *Proceedings of the meat industry research conference*. <http://www.meatscience.orgPubs/mircarchiv/2006/default.htm>. Accessed 30.12..06. October 4–5, 2006, Hollywood, FL, USA.

Devcich, D. A., Pedersen, I. K., & Petrie, K. J. (2007). You are what you eat: Modern health worries and the acceptance of natural and synthetic additives in functional foods. *Appetite, 48*, 333–337.

Dreezens, E., Martijn, C., Tenbult, P., Kok, G., & deVries, N. K. (2005). Food and values: an examination of values underlying attitudes toward genetically-modified and organically grown food products. *Appetite, 44*, 115–122.

Fox, J. B., Jr., Sebranek, J. G., & Phillips, J. G. (1994). Kinetic analysis of the formation of nitrosylmyoglobin. *Journal of Muscle Foods, 5*, 15–25.

Heinerman, J., & Anderson, G. (2001). *Salt: Nature's fifth element*. Chico, CA: Ocean Press International.

Herrador, M. A., Sayago, A., Rosales, D., & Asuero, A. G. (2005). Analysis of a sea salt from the Mediterranean Sea. *Alimentaria, 360*, 85–90.

Honikel, K. O. (2004). Curing agents. In W. K. Jensen, C. Devine, & M. Dikeman (Eds.), *Encyclopedia of meat sciences* (pp. 195–201). Oxford, UK: Elsevier Ltd.

Husak, R. L. (2007). A survey of commercially available broilers originating from organic, free-range, and conventional production

systems for meat yield, composition and relative value. M.S. thesis, Iowa State University, Ames, IA, USA.

Kanner, J., & Juven, B. J. (1980). S-nitrosocysteine as an antioxidant, color-developing and anticlostridial agent in comminuted turkey meat. *Journal of Food Science, 45*, 1105–1108, 1112.

Kuhnlein, H. V. (1980). The trace element content of indigenous salts compared with commercially refined substitutes. *Ecology of Food and Nutrition, 10*(2), 113–121.

MacDonald, B., Gray, J. I., Kakuda, Y., & Lee, M. L. (1980). Role of nitrite in cured meat flavor: Chemical analysis. *Journal of Food Science, 45*, 889–892.

MacDonald, B., Gray, J. I., Stanley, D. W., & Usborne, W. R. (1980). Role of nitrite in cured meat flavor: sensory analysis. *Journal of Food Science, 45*, 885–888, 904.

MacDonald, B., Gray, J. I., & Gibbins, L. N. (1980). Role of nitrite in cured meat flavor: Antioxidant role of nitrite. *Journal of Food Science, 45*, 893–897.

Milkowski, A. L. (2006). The controversy about sodium nitrite. In *Proceedings of the meat industry research conference*. <http://www.meatscience.org/Pubs/mircarchiv/2006/default.htm>. Accessed 30.12.06. October 4–5, 2006, Hollywood, FL, USA.

Mitchell, R. (2006). Outrunning supplies. *Meat and Deli Retailer*. November, 2006. <http://www.meatanddeliretailer.com>. Accessed 28.12.06.

Møller, J. K. S., & Skibsted, L. H. (2002). Nitric oxide and myoglobins. *Chemical Reviews, 102*, 1167–1178.

Møller, J. K. S., Jakobsen, M., Weber, C. J., Martinussen, T., Skibsted, L. H., & Bertelsen, G. (2003). Optimization of colour stability of cured ham during packaging and retail display by a multifactorial design. *Meat Science, 63*, 169–175.

Morrissey, P. A., & Techivangana, J. Z. (1985). The antioxidant activities of nitrite and nitrosylmyoglobin in cooked meats. *Meat Science, 14*, 175–190.

National Academy of Sciences (1981). *The health effects of nitrate, nitrite and n-nitroso compounds*. Washington, DC: National Academy Press.

National Academy of Sciences (1982). *Alternatives to the current use of nitrite in foods*. Washington, DC: National Academy Press.

O'Connor, M. E. (2006). Natural raising claims – a discussion of current natural regulations and outlook towards the future. In *Proceedings of the meat industry research conference*. <http://www.meatscience.org/Pubs/mircarchiv/2006/default.htm>. Accessed 30.12.06. October 4–5, 2006, Hollywood, FL, USA.

Olesen, P. T., Meyer, A. S., & Stahnke, L. H. (2004). Generation of flavor compounds in fermented sausages – the influence of curing ingredients, *Staphylococcus* starter culture and ripening time. *Meat Science, 66*, 675–687.

Organic Trade Association. (2006). OTA Manufacturer Survey – Summary. <http://www.ota.com>. Accessed 28.12.06.

Pegg, R. B., & Shahidi, F. (2000). *Nitrite curing of meat. The n-nitrosamine problem and nitrite alternatives*. Trumbull, CT: Food and Nutrition Press, Inc.

Peters, J. M., Preston-Martin, S., London, S. J., Bowman, J. D., Buckley, J. D., & Thomas, D. C. (1994). Processed meats and risk of childhood leukemia (California, USA). *Cancer Causes and Control, 5*, 195–202.

Petrak, L. (2005). Retailers go natural. *Meat and Deli Retailer*. December, 2005. <http://www.meatanddeliretailer.com>. Accessed 30.12.06.

Pierson, M. D., & Smoot, L. A. (1982). Nitrite, nitrite alternatives and the control of *Clostridium botulinum* in cured meats. *Critical Reviews in Food Science and Nutrition, 17*, 141–187.

Preston-Martin, S., & Lijinsky, W. (1994). Cured meats and childhood cancer (Letters to the Editor). *Cancer Causes and Control, 5*, 484–485.

Preston-Martin, S., Pogoda, J. M., Mueller, B. A., Holly, E. A., Lijinsky, W., & Davis, R. L. (1996). Maternal consumption of cured meats and vitamins in relation to pediatric brain tumors. *Cancer Epidemiology, 5*, 599–605.

Saher, M., Lindeman, M., & Hursti, U.-K. K. (2006). Attitudes toward genetically modified and organic foods. *Appetite, 46*, 324–331.

Saltworks. (2006). Salt information. <http://www.saltworks.us/salt_info/si_gourmet_reference.asp>. Accessed 5.1.07.

Sarasua, S., & Savitz, D. A. (1994). Cured and broiled meat consumption in relation to childhood cancer: Denver, Colorado (United States). *Cancer Causes and Control, 5*, 141–148.

Sebranek, J. G. (1979). Advances in the technology of nitrite use and consideration of alternatives. *Food Technology, 33*(7), 58–62, 93.

Sebranek, J. G. (2006). Unpublished data.

Sebranek, J. G., & Fox, J. B. Jr., (1985). A review of nitrite and chloride chemistry: Interactions and implications for cured meats. *Journal of the Science of Food and Agriculture, 36*, 1169–1182.

Sebranek, J. G., & Fox, J. B. Jr., (1991). Rate of nitric oxide formation from nitrite as affected by chloride ion concentration. *Journal of Muscle Foods, 2*, 149–163.

Siderer, Y., Maquet, A., & Anklam, E. (2005). Need for research to support consumer confidence in the growing organic food market. *Trends in Food Science and Technology, 16*, 332–343.

Sindelar, J. J. (2006a). Investigating uncured no-nitrate-or-nitrite-added processed meat products. Ph.D. thesis. Iowa State University, Ames, IA, USA.

Sindelar, J. J. (2006b). Unpublished data. Iowa State University, Ames, IA, USA.

Sindelar, J. J., Cordray, J. C., Sebranek, J. G., Love, J. A., & Ahn, D. U. (in press a). Effects of varying levels of vegetable juice powder and incubation time on color, residual nitrate and nitrite, pigment, pH and sensory attributes of ready-to-eat uncured, emulsified frankfurter-style cooked sausage. *Journal of Food Science*.

Sindelar, J. J., Cordray, J. C., Sebranek, J. G., Love, J. A., & Ahn, D. U. (in press b). Effects of varying levels of vegetable juice powder and incubation time on color, residual nitrate and nitrite, pigment, pH and sensory attributes of ready-to-eat uncured ham. *Journal of Food Science*.

Stamler, J. S., & Meissner, G. (2001). Physiology of nitric oxide in skeletal muscle. *Physiology Reviews, 81*, 209–237.

Tompkin, R. B. (2005). Nitrite. In P. M. Davidson, J. N. Sofos, & A. L. Branen (Eds.), *Antimicrobials in food* (3rd ed.). Boca Raton, FL: CRC Press, Taylor & Frances Group.

USDA. (1995). Processing Inspector's Calculations Handbook (FSIS Directive 7620.3). <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7620-3.pdf>. Accessed 3.1.07.

USDA. (2005). Food standards and labeling policy book. <www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf>. Accessed 27.12.06.

Winter, C. K., & Davis, S. F. (2006). Organic foods. *Journal of Food Science, 71*(9), R117–R124.

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	_____		

All information above the line is for conference use only.

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.

Submitter Information:

Name:	Veronica Bryant
Organization:	NC DHHS/EH Food Protection Branch
Address:	1632 Mail Service Center
City/State/Zip:	Raleigh, NC 27699
Telephone:	704-718-7866
E-mail:	veronica.bryant@dhhs.nc.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-033

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

All information above the line is for conference use only.

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.

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood Dr
City/State/Zip:	Roscommon, MI 48653
Telephone:	517-719-7919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name:	Karla Horne
Organization:	Great Lakes Conference on Food Protection
Address:	525 W AlleganPO Box 30017
City/State/Zip:	Lansing, MI 48909
Telephone:	231-357-0727
E-mail:	hornek@michigan.gov

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	_____		

All information above the line is for conference use only.

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.

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood DR
City/State/Zip:	Roscommon, MI 48653
Telephone:	517-719-7919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name:	Karla Horne
Organization:	Great Lakes Conference on Food Protection
Address:	525 W AlleganPO Box 30017
City/State/Zip:	LAnsing, MI 48909
Telephone:	231-357-0727
E-mail:	hornek@michigan.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-035

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

All information above the line is for conference use only.

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.

Submitter Information 1:

Name:	Kristina Barlow
Organization:	USDA/FSIS
Address:	1400 Independence Ave., SW8th floor, Cube 128a, PPIII
City/State/Zip:	Washington, DC, DC 20250
Telephone:	202-690-7739
E-mail:	kristina.barlow@fsis.usda.gov

Submitter Information 2:

Name:	William Shaw
Organization:	USDA/FSIS
Address:	Patriot's Plaza III, Mail Stop 37821400 Independence Ave. SW
City/State/Zip:	Washington, DC, DC 20250
Telephone:	301-504-0852
E-mail:	William.shaw@fsis.usda.gov

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-036

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:

“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.

Submitter Information 1:

Name:	Jennifer Webb
Organization:	USDA/FSIS
Address:	Stop Code 3782, Patriots Plaza III, Cubicle 8-163A
City/State/Zip:	District of Columbia, DC 20250-3700
Telephone:	301-504-0854
E-mail:	Jennifer.webb@fsis.usda.gov

Submitter Information 2:

Name:	William Shaw

Organization: USDA/FSIS
Address: Patriot's Plaza III, Mail Stop 37281400 Independence Ave., SW
City/State/Zip: Wahington, D.C., DC 20024
Telephone: 301-504-0852
E-mail: william.shaw@fsis.usda.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-037

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:

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.

Submitter Information 1:

Name: Kristina Barlow
Organization: USDA/FSIS

Address: 1400 Independence Ave. SW8th Floor, Cube 128a, PPIII
City/State/Zip: Washington, DC, DC 20024
Telephone: 202-690-7739
E-mail: kristina.barlow@fsis.usda.gov

Submitter Information 2:

Name: William Shaw
Organization: USDA/FSIS
Address: Patriot's Plaza III, Mail Stop 37821400 Independence Ave., SW
City/State/Zip: Washington, DC, DC 20250
Telephone: 301-504-0852
E-mail: William.shaw@fsis.usda.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-038

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:

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).

Submitter Information:

Name:	Mary Cartagena
Organization:	Food and Drug Administration
Address:	5100 Paint Branch ParkwayHFS-320 Rm 3B038
City/State/Zip:	College Park, MD 20740
Telephone:	240-402-2937
E-mail:	mary.cartagena@fda.hhs.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-039

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:

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

Submitter Information 1:

Name:	Rebecca Krzyzanowski
Organization:	Great Lakes Conference on Food Protection
Address:	615 Englewood Dr
City/State/Zip:	Roscommon, MI 48653
Telephone:	5177197919
E-mail:	krzyzanowskir@michigan.gov

Submitter Information 2:

Name:	Karla Horne
Organization:	Great Lakes Conference on Food Protection
Address:	525 W AlleganPO Box 30017
City/State/Zip:	Lansing, MI 48909
Telephone:	231-357-0727
E-mail:	hornek@michigan.gov

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

Conference for Food Protection
2016 Issue Form

Issue: 2016 III-040

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:

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

<u>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.</u>

Submitter Information:

Name:	Thomas Johnson
Organization:	Qleantech Enterprises, LLC
Address:	1408 Northland Dr #406
City/State/Zip:	Mendota Heights, MN 55120
Telephone:	651-587-0418
E-mail:	tomj@jdpinc.com

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	_____		

All information above the line is for conference use only.

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.

Submitter Information:

Name:	Thomas Johnson
Organization:	QleanTech Enterprises, LLC
Address:	1408 Northland Dr #406
City/State/Zip:	Mendota Heights, MN 55120
Telephone:	651-587-0418
E-mail:	tomj@jdpinc.com

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