Conference for Food Protection
2012 Issue Form

Internal Number: 028
Issue: 2012 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.

Title:
Report - Plan Review Committee

Issue you would like the Conference to consider:
The Conference for Food Protection (CFP) Plan Review Committee seeks Council I's acknowledgement of its final committee report and requests that the committee be re-created to continue its review of the Permanent Outdoor Cooking Operations and the Mobile Food Establishment documents and present their findings at the 2014 CFP Biennial Meeting.
See additional Committee submitted Issues titled:

- Temporary Food Establishments 2011 Final Document
- Re-Creation of Plan Review Committee

Public Health Significance:
The Plan Review Committee has been tasked with the on-going development of the plan review documents for food establishments, temporary food establishments, mobile food establishments and permanent outdoor cooking operations. The objective of each document is to provide assistance to regulatory jurisdictions during the plan review process with an overarching goal of consistency and standardization.

Recommended Solution: The Conference recommends...:
1. Acknowledgement of the CFP Plan Review Committee Report including the following attachments (content attachments presented for approval as the Issue titled: Temporary Food Establishments 2011 final document):

- Temporary Food Establishments 2011 Final Document
- Attachment I - Application To Operate A Temporary Food Establishment
- Attachment II - Event Organizer Application To Operate Temporary Food Establishments
- Attachment III - Temporary Food Establishment - Expanded Process Flow

2. Thank the Committee members.

Submitter Information:
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Organization: Plan Review Committee
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Attachments:

- "Plan Review Committee Final Report"
- "Plan Review Committee Member Roster"
- "Temporary Food Establishments 2011 Final Document"
- "Attachment I - Application To Operate A Temporary Food Establishment"
- "Attachment III - Temporary Food Establishment - Expanded Process Flow"
- "Attachment II - Event Organizer Application to Operate Temporary Food Estab"

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

Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: Plan Review

COUNCIL (I, II, or III): I

DATE OF REPORT: January 3, 2012

SUBMITTED BY: Liza Frias

COMMITTEE CHARGE(s):
Re-creation of the committee to continue its review and update the following Conference for Food Protection Documents and present their finding at the 2012 CFP Biennial Meeting:

a. Temporary Food Establishment
b. Permanent Outdoor Cooking Operations

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The 2010-2012 Plan Review Committee met on a regular basis during the last two years by conference call to discuss the committee charges.

Charge 1 – Temporary Food Establishments

The committee worked on revising and updating the Pre-Operational Guide for Temporary Food Establishments (2000). The committee had participation from the FDA to revise and update the document. The committee recommends that the document titled "Temporary Food Establishments 2011 Final Document and its Attachments I, II and III" be accepted and posted on the CFP web site and that a letter be sent to the FDA requesting that this final version be made available on the FDA website.

Charge 2 – Permanent Outdoor Cooking Operations

Due to the resignation of the co-chair and competing time commitments placed on our FDA advisors, this committee was not able to complete the review and update of the Permanent Outdoor Cooking Operations. The committee is recommending re-creation of the Plan Review committee to begin its review.

Recommendation(s) for future charge:

The Committee recommends that the following charges be made to a re-created Plan Review Committee following the CFP 2012 Conference (submitted as Issue titled: Re-Create Plan Review Committee):

- Continue its review and update the following Conference for Food Protection Documents and present their finding at the 2014 CFP Biennial Meeting:
  a. Permanent Outdoor Cooking Operations (2003)
  b. Mobile Food Establishments (2006)

REQUESTED ACTION:
The Plan Review committee will submit three (3) issues at the 2012 Conference based on the recommendations of the committee. The issues are:

- Report – Plan Review Committee;
- Temporary Food Establishments 2011 Final Document; and
- Re-Create Plan Review Committee

ATTACHMENTS:

- Temporary Food Establishments 2011 Final Document
- Attachment I – Application to Operate a Temporary Food Establishment
- Attachment II – Event Organizer Application to Operate Temporary Food Establishments
- Attachment III – Temporary Food Establishment - Expanded Process Flow
- 2010-2012 Plan Review Committee Roster

Committee Name: 2010-2012 Plan Review Committee Roster

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
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Committee Name: 2010-2012 Plan Review Committee Roster

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Temporary Food Establishments 2011 Final Document

Prepared by the Plan Review Committee
Conference for Food Protection 2010-2012

TABLE OF CONTENTS

PREFACE

This document is intended to assist local health regulatory authorities and the food industry in understanding the review, approval and operation of Temporary Food Establishments. 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 document:

- Describes effective processes for reviewing plans and applications for safe operation of a Temporary Food Establishment (TFE).
- Is intended as a training tool for individuals responsible for conducting plan reviews and is used in Food and Drug Administration (FDA) -sponsored training courses on Temporary Food Establishments. It may also help event sponsors better understand the expectations of local regulatory inspectors.
- Was developed by the Conference for Food Protection's Plan Review Committee. It is intended to be consistent with the recommendations of the FDA as contained in the FDA Model Food Code. The FDA Model Food Code contains requirements for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer.

DEFINITIONS

The following definitions are excerpts from the FDA 2009 Model Food Code.

"Food establishment" includes "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."

"*Food establishment*" *does not include:*

(a) *An establishment that offers only pre*PACKAGED FOODS *that are not* POTENTIALLY HAZARDOUS (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* POTENTIALLY HAZARDOUS (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*;*

"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.

INTRODUCTION

Temporary food events, such as traveling fairs and carnivals, circuses, multicultural celebrations, special interest fundraisers, restaurant food shows, and other transitory gatherings, have become extremely popular and are held at an increasing frequency.

Many of these temporary food events have temporary food establishments with high risk food operations engaging in extensive preparation of raw ingredients; processes that include the cooking, cooling, and reheating of potentially hazardous foods; and advanced preparation of food several days prior to service.

The TFEs operate either indoors or outdoors and often have limited physical and sanitary facilities available. As such, TFEs present special challenges to regulatory authorities that have the responsibility to license/permit and inspect them.

TEMPORARY FOOD EVENT COORDINATION

Food preparation practices at temporary food events are to be in compliance with the regulatory authority. Because temporary events present particular concerns that are unique to nonpermanent food establishments, the following information should be provided along with information about the food items to be prepared and served, as required on the application:

- The number of expected patrons/day;
- Information on the number and type of toilet and handwashing facilities to be provided;
- Information on the equipment that will be utilized to ensure compliance with the Model Food Code;
- The exact location of the event identifying the availability of potable water, wastewater, solid waste facilities and services, and methods of dust control;
- Description of the water supply and wastewater and solid waste storage and removal provisions to assess if adequate facilities are provided on site or if additional supplies/services are needed;
- The location and source of electricity to be provided; and
- A list of names, telephone numbers, and addresses of the TFE operators, including the name of the designated staff person who will be on site during all hours of the operation of the event and who is responsible for compliance with food code requirements.

PLAN REVIEW AND APPLICATION PROCESS

No person, firm, or corporation is allowed to operate a food establishment (permanent or temporary) where food or beverages are served to the public without permits, licenses, or permission from the local regulatory authority. Licensing/permitting of Temporary Food Establishments may vary due to local regulatory requirements.

The plans and application for a TFE should include all the information necessary to assure that the physical and sanitary facilities are adequate to ensure safe food, in the same manner a permanent food establishment goes through plan review. It is recommended that a pre-event meeting be held between the regulatory authority and the applicant(s) and/or the primary food vendor(s) for the event to discuss the requirements that must be adhered to for safe operation of the TFE.

Prior to issuing a permit or license to a food establishment, either permanent or temporary, the local regulatory authority is responsible for performing a pre-operational plan review. The pre-operational review provides the opportunity to discuss areas of concern and should be conducted prior to the issuance of a permit/license. The regulatory authority may impose restrictions on the types of food to be prepared and served based upon the preparation and/or sanitary facilities available.

For large temporary events there is often an event organizer that is responsible for coordinating the temporary food establishments. In this situation, if the event organizer provides any of the required facilities (i.e., toilet and handwashing facilities, warewashing facilities, refuse or waste water services) that are to be utilized by a temporary food establishment, a separate application and permit may be required by the regulatory authority.

To obtain a permit/license for a Temporary Food Establishment, the permit applicant shall complete and submit an Application to Operate a Temporary Food Establishment (Attachment I) at least 30 calendar days before the event (§8-302.11).

Event coordinators providing infrastructure to multiple TFE are required to complete and submit an Event Organizer Application to Operate Temporary Food Establishments (Attachment II) at least 30 calendar days before the event (§8-302.11).

TEMPORARY FOOD ESTABLISHMENT CLASSIFICATIONS

Food establishment does not include an establishment that offers only prepackaged foods that are not potentially hazardous (Time/Temperature Control for Safety Foods).

TFE requirements should be risk based according to the food service operations that will occur.

Food Service (FS) Type 1

- Unpackaged nonpotentially hazardous food (Time/Temperature Control for Safety Food)
- Commercially processed packaged potentially hazardous food (Time/Temperature Control for Safety Food) in its original package (Receive-Store-Hold)

Food Service (FS) Type 2

- Food Preparation with no cook step (Receive-Store-Prepare-Hold-Serve)
- Preparation for same day service (Receive-Store-Prepare-Cook-Hold-Serve)
- Reheating of a commercially processed food item (Receive-Store-Reheat-Hold-Serve)

Food Service (FS) Type 3

- Complex food preparation (Receive-Store-Prepare-Cook-Cool-Reheat-Hot Hold-Serve)
- Large quantities of food being prepared (e.g., Olympics, Academy Awards, State Fairs)
- Using Time as a Public Health Control
- Serving a Highly Susceptible Population

An applicant may be required to complete and submit the Temporary Food Establishment Expanded Process Flow (Attachment III) based on the menu identified on the TFE application.

MONITORING AND PLANNING FOR TEMPORARY FOOD EVENTS

Due to the complexities of temporary food events, the local regulatory authority should develop a method to monitor and plan for these events so that the necessary resources are available to assist with the review and inspection of the temporary food establishments.

- Many events are scheduled on an annual basis and can be monitored by keeping a calendar of these events.
- Information on temporary events can be obtained from fliers, banners, newspaper and radio announcements, and local TV ads.
- A working relationship should be established with local visitor's associations or Chambers of Commerce as these organizations often maintains schedules of events.
- A working relationship should be established with managers/owners of fairgrounds, parks and other locations where temporary events are often held.

TEMPORARY FOOD ESTABLISHMENT OPERATIONS CHECKLIST

The following checklist provides an overview of the general requirements that should be considered when reviewing applications and conducting on-site inspections. The local regulatory authority may impose additional requirements based upon the type of food preparation and/or sanitary facilities available.

The applicable 2009 Model Food Code Sections have been italicized.

PERSONNEL

- **PERSON-IN-CHARGE (PIC):** A designated person must be on site during all hours of operations of the temporary food establishment. The PIC is responsible for ensuring compliance with health code requirements. *(§2-101.11, 2-103.11)*

- **CERTIFIED FOOD PROTECTION MANAGER**: At least one employee that has supervisory and management responsibility and authority to direct and control food preparation and service shall be a Certified Food Protection Manager for those temporary food establishments that are classified as Food Service Type 2 or Food Service Type 3. *(§2-102.12)*

- **EMPLOYEE HEALTH:** Employees with communicable diseases which can be transmitted through food shall be excluded and/or restricted from food activities. *(§2-201.11, 2-201.12, 2-201.13, 2-401.12)*

  There must be employee practices and behaviors established that can help prevent the spreading of viruses and bacteria to food. The Centers for Disease Control and Prevention (CDC) and FDA cite five highly infective pathogens that can be easily transmitted by food employees and cause severe illness. These five pathogens known as the Big Five are Norovirus, the Hepatitis A virus, Salmonella Typhi, Shigella spp., and Escherichia coli (E. coli) 0157:H7 or other Enterohmorrhagic or Shiga toxin-producing E. coli.

  Interventions must be used to prevent the transmission of foodborne illness. These interventions include (a) restricting or excluding ill food employees from working with food; (b) using proper handwashing procedures; and (c) eliminating bare hand contact with foods that are ready-to-eat (RTE).

  Proper management involves ensuring that food employees do not work when they are ill and having procedures for identifying employees who may transmit foodborne pathogens to food, other employees, and consumers. Symptoms that the person in charge (PIC) should be concerned with include: vomiting, diarrhea, jaundice (yellow skin or eyes), sore throat with fever, infected cuts and burns with pus on hands and wrists.

  Information and forms to aid in complying with Employee Health can be found in

the 2009 FDA Model Food Code and the Employee Health and Personal Hygiene Handbook.
(http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113827.htm)

- **HANDWASHING:** Food employees shall wash their hands upon entering the TFE or food preparation and service areas, immediately before engaging in food preparation, after using the toilet room, and as often as necessary to remove soil and contamination and to prevent cross contamination. *(§2-301.11, 2-301.12, 2-301.14, 2-301.15)*

- **HANDWASHING FACILITIES:** Handwashing facilities shall be located to allow convenient use by food employees in food preparation, food dispensing and warewashing areas. Handwashing sinks are to only be used for handwashing. A handwashing sign shall be posted at each handwashing sink. *(§5-204.11, 5-205.11, 5-202.12, 5-203.11, 6-301.11, 6-301.12, 6-301.14, 6-301.20)*

FS Type 1

- Packaged food only – Hand wash stations are not required if only commercially pre-packaged foods kept in their original containers will be provided to consumers.
- Unpackaged food that is not potentially hazardous (Time/Temperature Control for Safety) Food – Hand wash station that provides gravity feed tempered water. For example – A five gallon insulated container with a spigot which can be turned on to allow potable warm water to flow over one's hands into a waste receiving bucket of equal or larger volume. Hand soap, single-use dispensed towels, and a waste receptacle shall be provided. (See Below)

FS Type 2 – Self-contained portable unit with holding tanks for potable tempered water and waste water. Hand soap, single-use dispensed towels, and a waste receptacle shall be provided. (See Below)

FS Type 3 – Potable hot and cold running water under pressure to provide water at a temperature of at least 100°F. Hand soap, single-use dispensed towels, and a waste receptacle shall be provided.

Sample for Type 1


Sample for Type 2

- **HYGIENE:** Food employees shall maintain a high degree of personal cleanliness and shall conform to good hygienic practices during all working periods. *(§2-302.11)*
  - Food employees shall have clean outer garments, aprons and effective hair restraints. *(§2-304.11, 2-402.11)*
  - Food employees are not allowed to smoke or eat (including chewing gum) in the food preparation and service areas. A food employee may drink from a closed beverage container if the container is handled to prevent contamination of the employee's hands; the container; and exposed food, clean equipment, utensils and single-service/single-use articles. *(§2-401.11)*
  - All non-working, unauthorized persons should be restricted from food preparation and service areas. *(§2-103.11)*

- **NO BARE HAND CONTACT:** Employees preparing food may not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli paper, spatulas, tongs, single-use gloves or dispensing equipment. *(§3-301.11)*

FOOD SOURCE

- **SOURCE:** All food shall be obtained from sources that comply with law. All meat and poultry shall come from USDA or other acceptable government regulated approved sources. *(§3-201.11)*
  - Home canned foods are not allowed nor shall there be any home cooked or prepared foods offered at temporary food events. *(§3-201.11)*
  - Ice for use as a food or a cooling medium shall be made from potable water. *(§3-202.16)*
  - All Potentially Hazardous Food (Time/Temperature Control for Safety Food) (PHF/TCS) which is pre-cooked and pre-cooled off site for service at the temporary food establishment shall be prepared at an approved, permanent food establishment. *(§3-201.11)*

- **TRANSPORTATION:** Food shall be transported in a manner that protects the food from contamination and if a PHF/TCS food item shall be maintained at 135°F or above or 41°F or below. *(§3-202.15, 3-501.16)*

FOOD PREPARATION

- **FOOD CONTAMINATION:** All cooking and serving areas shall be protected from contamination. Consumers shall be prevented from accessing areas of the TFE where food, food-contact surfaces, and equipment are located. *(§2-103.11(B), 3-307.11)*

- **CROSS CONTAMINATION:** Food shall be protected from cross contamination by separating raw animal foods from ready-to-eat foods and separating types of raw animal foods from each other during storage, preparation, holding, and display. *(§3-302.11, 3-307.11)*

- Equipment and utensils (including knives, cutting boards, and food storage containers) shall be thoroughly cleaned and sanitized after being used for raw animal foods and before being used for ready-to-eat food. *(§3-304.11, 4-602.11)*

The following practices are only permitted with Food Service Type 1 classification

- **HANDLING OF UNPACKAGED NONPHF/TCS FOOD**
  During preparation, unpackaged food shall be protected from contamination. *(§3-305.14, 3-307.11)*

- **HOLDING OF COMMERCIALLY PROCESSED PACKAGED PHF/TCS FOOD:**
  PHF/TCS food shall be maintained at 135°F or higher or 41°F or below. *(§3-501.16)*

The following practices are only permitted with Food Service Type 2 classification

- **HOLDING OF PHF/TCS FOOD:** Potentially Hazardous Food (Time/Temperature Control for Safety Food) shall be maintained at 135°F or higher or 41°F or below. *(§3-501.16)*

- **COOKING:** Food shall be cooked to the minimum temperatures and times specified below**: *(§3-401.11, 3-603.11)*
  - **165°F for 15 seconds -** poultry; wild game animals; stuffing containing fish, meat, poultry or ratites; stuffed fish, meat, pasta, poultry or ratites.
  - **155°F for 15 seconds -** mechanically tenderized and injected meats; the following if they are comminuted: fish, meat (hamburgers), game animals commercially raised for food; pooled raw eggs; ratites.
  - **145°F for 15 seconds -** raw eggs that are broken and prepared in response to a consumer's order and for immediate service; fish and meat.

  **TFE operators should consult with the local regulatory authority if considering cooking roasts (whole beef, pork, cured pork (ham) and corned beef) or if serving or selling undercooked foods to ensure compliance with the provisions of the Model Food Code.

- **THAWING:** PHF/TCS food shall be thawed either under refrigeration that maintains the food temperature at 41°F or less, or as part of a cooking process. *(§3-501.13)*

- **REHEATING FOR HOT HOLDING OF COMMERCIALLY PROCESSED FOOD**
  - Food from a commercially processed, hermetically sealed container of food or from an intact package from a food processing plant shall be reheated to 135°F for hot holding. *(§3-403.11)*

The following two practices are only permitted at a Food Service Type 3 classification

- **COOLING:** PHF/TCS shall be cooled by an approved method in accordance with the following time and temperature criteria: *(§3-501.14 3-501.15)*

- Cooked PHF/TCS food shall be cooled within 2 hours from 135°F to 70°F and within a total of 6 hours from 135°F to 41°F or less.
- PHF/TCS food prepared from ingredients at ambient temperature shall be cooled within 4 hours to 41°F or less.

- **REHEATING FOR HOT HOLDING:** PHF/TCS food that is cooked and cooled at a permanent food establishment prior to delivery to the temporary food establishment shall be reheated so that all parts of the food reach a temperature of at least **165°F for 15 seconds if hot held**. *(§3-403.11)*
  - Reheating shall be done rapidly so that the food is between 41°F and 165°F for no more than 2 hours.
  - Cooked and refrigerated food that is prepared in response to an individual consumer order may be served at any temperature.

EQUIPMENT

Equipment used for cooking or for holding of PHF/TCS food shall be evaluated for approval based on a menu review, food service operations that will occur, and the length of the event. *(§4-301.11)*

- **COOKING DEVICES:** The local fire safety authority shall approve all cooking devices along with any additional safety considerations.
  - For safety reasons, cooking equipment, such as BBQs, propane stoves, and grills, should be roped off or otherwise segregated from the public *(§3-307.11).*
  - When barbecuing or using a grill, the cooking equipment should be separated from the public for a distance of at least 4 feet by roping off or by other means to protect patrons from burns or splashes of hot grease.
  - Charcoal and wood cooking devices are not recommended.
  - Propane stoves or grills may be approved as cooking devices.
  - All cooking of foods should be done towards the rear of the food booth.

- **COLD STORAGE:**
  - Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water. *(§3-303.12)*
  - Each refrigeration unit should have a numerically scaled thermometer accurate to ±3°F if scaled only in Fahrenheit or accurate to +/- 1.5°C if dually scaled in Celsius and Fahrenheit to measure the air temperature of the unit. *(§4-203.12, 4-204.112)*
  - **FS Type 1 and FS Type 2 -** An effectively insulated, hard sided, cleanable container with sufficient ice or other means to maintain PHF/TCS food at 41°F or below may be approved for the storage of small quantities of PHF/TCS food. *(§3-501.16, 4-301.11)*
  - **FS Type 2 and FS Type 3 -** Mechanical refrigeration units may be required to keep PHF/TCS food at 41°F or below. *(§3-501.16, 4-301.11)*

- **HOT STORAGE:** Hot food storage units shall be used to keep PHF/TCS food at 135°F or above. Electrical equipment, propane stoves, grills, etc. shall be capable of holding foods at 135°F or above. *(§3-501.16, 4-301.11)*

- **THERMOMETERS:** A thermocouple or metal stem thermometer shall be provided to check the internal temperatures of PHF/TCS hot and cold food items. Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to +/-1°C or if scaled only in Fahrenheit shall be accurate to +/-2°F in the intended use of range. Temperature measuring devices shall be equipped with a small diameter probe if thin foods are served. *(§4-302.12, 4-502.11)*

- **COUNTERS/SHELVES:** All food contact surfaces shall be non-toxic, smooth, easily cleanable, durable, nonabsorbent, and free of seams and difficult to clean areas. All other surfaces shall be finished so that they are easily cleanable. *(§4-101.11)*

FOOD AND UTENSIL STORAGE

- **DRY STORAGE:** All food, equipment, utensils, and single service items shall be stored at least 6" off the ground or floor on pallets, tables, or shelving. Food shall be protected from contamination and shall have effective overhead protection. *(§3-305.11, 3-305.12)*

- **FOOD DISPLAY:** All food and food contact surfaces shall be protected from consumer handling, coughing, sneezing or other contamination. *(§3-306.11, 3-306.12, 3-306.13)*
  - Use sneeze guards or other effective barriers for food on display.
  - Keep food covered, except for working containers of food.
  - Condiments shall be dispensed in single service type packaging, in pump-style dispensers, or in protected squeeze bottles, shakers, or similar dispensers which prevent contamination of the food items by food employees, patrons, insects, or other sources.
  - Knives, forks, and spoons that are not pre-wrapped shall be presented so that only the handles are touched.

- **IN-USE UTENSILS:** Food dispensing utensils shall be stored in the food with their handles above the top of the food and container; on a clean portion of the food preparation table or cooking equipment; or in a container of water if the water is maintained at a temperature of at least 135°F and the utensil and container is cleaned as necessary to preclude accumulation of soil residues. *(§3-304.12)*

CLEANING AND SANITIZING

Equipment food-contact surfaces and utensils shall be cleaned and sanitized when changing from working with raw foods to working with ready-to-eat foods; between uses

with raw fruits and vegetables and with PHF/TCS food; before using or storing a food temperature measuring device; and if used with PHF/TCS food shall be cleaned throughout the day at least every 4 hours; and at any time during the operation when contamination may have occurred. *(§4-602.11)*

- **WAREWASHING:** A commercial dishwasher or manual warewashing method should be utilized to wash, rinse, and sanitize equipment and utensils coming into contact with food. *(applicable sections in Chapter 4 Model Food Code)*

  FS Type 1 - The minimum requirements for a utensil washing set-up to wash/rinse/sanitize should consist of 3 basins, large enough for complete immersion of utensils, a potable hot water supply, and an adequate disposal system for the wastewater.

  FS Type 2 - A centralized three compartment sink that is supplied with hot and cold running water and approved wastewater disposal system for use by multiple food vendors may be permitted by the regulatory authority.

  FS Type 3 – A three compartment sink that is supplied with hot and cold running water and approved wastewater disposal system within the food establishment.

- **SANITIZING:** Chlorine bleach or other approved sanitizers should be provided for sanitizing food contact surfaces, equipment, and wiping cloths. Sanitizers shall be used in accordance with the EPA-registered label use instructions. An approved test kit shall be available to accurately measure the concentration of sanitizing solutions. *(§4-501.116, 4-703.11)*

- **WIPING CLOTHS:** Wiping cloths that are in use for wiping food spills shall be used for no other purpose and shall be stored clean and dry or in a clean sanitizing solution at the approved sanitizer concentration. *(§3-304.14)*

WATER SUPPLY AND WASTEWATER DISPOSAL

- **WATER:** An adequate supply of potable water shall be available on site for cooking and drinking purposes; for cleaning and sanitizing equipment, utensils, and food contact surfaces; and for handwashing. *(applicable sections in Chapter 5 Model Food Code)*
  - Water shall come from an approved public water supply or an approved well water supply. The water supply system and hoses carrying water shall be constructed with approved food contact materials. *Recommend labeling potable water hose.*
  - The water supply shall be protected with backflow devices to preclude the backflow of contaminants into the potable water supply. (§5-202.13, 5-202.14, 5-203.14, 5-203.15)
  - All hose and other connections to the potable water supply shall be maintained a minimum of 6" above the ground or top plane surface.

- A supply of commercially bottled drinking water or sanitary potable water storage tanks may be allowed if approved by the regulatory authority.

- **WASTEWATER DISPOSAL:** Wastewater shall be disposed in an approved waste water disposal system. Wastewater may not be dumped onto the ground surface, into waterways, or into storm drains; but shall be collected and disposed through an approved sewage disposal system. (§5-402.13)

PREMISES

- **FLOORS**: If graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other approved materials that are effectively treated to control dust and mud. *(§6-101.11)*

- **WALLS AND CEILINGS**: The TFE shall be covered with a canopy or other type of overhead protection, unless the food items offered are commercially prepackaged food items and dispensed in their original containers.
  - Walls and ceilings, when required, are to be of tight and sound construction to protect against the elements, windblown dust and debris, insects, or other sources that may contaminate food, food contact surfaces, equipment, utensils, or employees. *(§6-101.11)*
  - Window and door openings shall be protected from insects and rodents by 16 mesh to 1 inch screen, properly designed air curtain, or other effective means. *(§6-202.15)*

- **LIGHTING**: Adequate lighting by natural or artificial means shall be provided. Light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is exposed food; clean equipment and utensils; or unwrapped single-service and single-use articles. *(§6-202.11)*

- **REFUSE**: An adequate number of non-absorbent, easily cleanable refuse containers shall be provided both inside and outside of each TFE site. Refuse containers shall be removed at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents. Dumpsters shall be covered, rodent-proof, and non-absorbent. Grease shall be disposed of properly and shall not be dumped onto the ground surface. *(§5-501.13, 5-502.11, 5-502.12)*

- **TOILET FACILITIES**: An adequate number of approved toilet and handwashing facilities shall be provided for food employees at each event. The toilet facilities, preferably permanently established, should be conveniently located to the food preparation areas (within 500 feet of the food preparation areas) and be supplied with toilet tissue. An adequate number of toilet and handwashing facilities shall be provided for patrons at gatherings lasting longer than 2-3 hours. Toilets may consist of properly designed, operated, and maintained portable toilets. *(§5-203.12, 5-204.11, 6-302.11)*

- **CLOTHING STORAGE**: Personal clothing and belongings should be stored at a designated place in the TFE away from food preparation, food service and warewashing areas. *(§6-305.11, 6-403.11)*

- **TOXIC MATERIALS**: Poisonous or toxic materials shall be properly labeled and stored so they cannot contaminate food, equipment, utensils, and single-service and single-use articles. Only those chemicals necessary for the food service operation shall be provided. *(§7-202.11, 7-202.12)*

- **PESTS**: The TFE shall be maintained free of insects, rodents, and other pests. *(§6-202.15)*

APPLICATION TO OPERATE A TEMPORARY FOOD ESTABLISHMENT

TYPE or PRINT IN INK. Enter N/A where requested information does not apply. Leave NO BLANK SPACES.

TFE OPERATOR INFORMATION	EVENT INFORMATION
Name of Owner and DBA:	**Event Name:**
Mailing Address:	**Location:**
City/State/Zip Code:	**Address:**
Contact Information:	**City:**
Type of Organization: ☐ **For Profit** ☐ **Charitable – Not for Profit**	**Hours of TFE Operation (include time set-up will begin):**
Event Organizer's Name:	**Date(s) of Event:** **Anticipated Maximum Attendance at Peak Time:_____**
On-site (Person-in-Charge) Contact:	**Event Location:** ☐ Indoor Event ☐ Outdoor Event* * Event will occur regardless of the weather conditions: ☐ Yes ☐ No
On-site Contact Cell Phone:	**Facility Type:** ☐ Booth ☐ Mobile Food Establishment ☐ Permanent Building ☐ Food Cart

FOOD INFORMATION: LIST ALL FOOD/BEVERAGE PRODUCTS THAT WILL BE PREPARED, SOLD OR GIVEN AWAY.			
List Menu Item	Prepackaged	Prepared on site	Prepared at Other Location**

****For food items that will be prepared at other location provide the following information and obtain required signature from approved food establishment:**

Food Establishment Name	Name of Permit Holder
Address and City	Permit #
Signature of Permit Holder	Contact #

TEMPORARY FOOD ESTABLISHMENT REQUIREMENTS

Booth Construction

Overhead Covering □ Canvas □Wood □Other: _____

Floor □ Asphalt □Concrete □Wood □Other:_____

Walls □ Screens □Concrete □Wood □Other:_____

Booth supplied by: □ TFE Operator □ Event Organizer □ Rent from:_____

Sketch the general layout of the Temporary Food Establishment on page 3 of this application.

Utensils and Equipment □ Single-serve eating and drinking utensils □ Multi-use kitchen utensils Type of Utensil Washing Set Up: □ Three basin set-up □ Shared three compartment sink □ Three compartment sink within a food establishment Sanitizer to be used: □ Chlorine □ Quaternary Ammonia □ Iodine	**Handwashing Facilities** Provided by : □ Event Coordinator □ FE Operator Type of handwashing facility: □ Gravity-fed water with spigot/bucket □ Self-contained portable unit (with potable water and waste water holding tanks) □ Plumbed with hot and cold water under pressure ***Hand Soap, single-use towels, and trash receptacle must be provided at all handwashing sinks.***
Food Storage or Display Equipment Identify all holding equipment that will be used:	**Toilet Facilities for Food Employees** Provided by : □ Event Coordinator □ FE Operator
Cooking Equipment Identify all cooking equipment that will be used:	**Electrical Supply:** □ Refrigerator or Freezer available □ Lighting available
Food Transportation Identify how food will be transported to event:	**Refuse Removal** Identify responsible party for waste removal:
Food Employees Certified Food Manager available □ Yes □ No Name: _____ # of food employees: _____	**Liquid Waste Removal** Identify responsible party for liquid waste removal: Frequency of liquid waste removal: _____per day

A temporary food establishment permit will not be issued unless this application meets all local applicable requirements and those found in the FDA Model Food Code as summarized in the Temporary Food Establishment 2011 Final Document and the permit has been signed and approved by the regulatory authority. Additionally, the undersigned is aware that non-compliance may result in closure of the temporary food establishment.

Applicants Name (Print): _____Applicants Signature:_____

DO NOT COMPLETE INFORMATION BELOW – FOR OFFICE USE ONLY

Application Approved □ Yes □No* See reason below	Risk Category □ Food Service Type 1 □ Food Service Type 2 □ Food Service Type 3	Reviewer Signature/Title: _____/_____ Date:_____

*Reason(s) for Disapproval:

_____

_____

_____

_____

Sketch below the general layout of the Temporary Food Establishment indicating the location of the following:

1. Location of cooking and holding equipment
2. Location of handwashing and utensil washing facilities (if not using shared facilities)
3. Location of trash disposal containers
4. Location of work tables, food and single-service storage

Temporary Food Establishment - Expanded Process Flow

This form may be required by the regulatory authority based on the menu identified on the Application to Operate a Temporary Food Establishment.

List each food item and identify where each preparation step will be completed (TFE or PFE).

- **TFE – On-Site Temporary Food Establishment**
- **PFE – Permanent Food Establishment**

Food	Thaw How? Where?	Cut/Wash Assemble Where?	Cold Holding How? Where?	Cook	Cooling	Reheating	Hot Holding

EVENT ORGANIZER APPLICATION TO OPERATE TEMPORARY FOOD ESTABLISHMENTS

An event organizer/coordinator is required to complete an application if they are responsible for providing any shared facilities (e.g., handwashing, utensil washing, refuse collection) for temporary food establishments as part of a temporary event.

TYPE or PRINT IN INK. Enter N/A where requested information does not apply. Leave NO BLANK SPACES.

ORGANIZER INFORMATION	EVENT INFORMATION
Organizer/Coordinator DBA	**Event Name:**
Mailing Address:	**Location:**
City/State/Zip Code:	**Address:**
Event Organizer's Name:	**City:**
Event Organizer Contact Number:	**Hours of Event (include time set-up will begin):**
Type of Organization: ☐ **For Profit** ☐ **Charitable – Not for Profit**	**Date(s) of Event:**
On-site Contact Person:	**Event Location:** ☐ Indoor Event ☐ Outdoor Event* * Event will occur regardless of the weather conditions: ☐ Yes ☐ No
On-site Contact Cell Phone:	**Anticipated Maximum Attendance at Peak Time:_____**

Sketch the general layout of the event indicating the location of the following on page 3 of this application.

1. Temporary Food Establishments locations (if DBA is available, include on application)
2. Water supply
3. Toilet and handwashing facilities
4. Refuse disposal containers
5. Location of shared utensil-washing facilities
6. Refrigerated trailer, if provided
7. Location of animals, rides, attractions (include distance of TFE from all other facilities on plot plan.

An event organizer permit will not be issued unless this application meets all applicable requirements found in the Model Food Code as summarized in the Temporary Food Establishment document and the permit has been signed and approved by the regulatory authority. Additionally, the undersigned is aware that non-compliance may result in closure of the event and/or temporary food establishments.

Applicants Name (Please Print) _____ Applicants Signature: _____ Date _____

Number of temporary food establishments that will be participating in event: _____	
Utensil Washing ☐ Provided by Event Organizer ☐ Provided by Food Booths Type of sink:	**Food Storage** Refrigerated trailer provided for temporary food establishments ☐ Yes ☐ No Indicate location of refrigerated trailer on sketch.
Toilet Facilities **# of Toilet Facilities that will be provided based on local building codes: _____** ☐ Portable ☐ Existing restrooms available # of toilets and handwashing facilities to be provided for food employees: _____ ***Hand Soap, single-use towels, and trash receptacle must be provided at all handwashing sinks.***	**Refuse Disposal** Identify company responsible for refuse disposal: Is there a central refuse collection site? Indicate on plot plan ☐ Yes ☐ No
Potable Water Supply ☐ Public Water System ☐ Non-public water supply (Results of most recent water test must be submitted).	**Liquid Waste Removal** Identify responsible party for liquid waste removal: Frequency of liquid waste removal: _____per day
Electrical Supply How will electricity be provided to TFE? Contact local building department for applicable requirements.	

Approval of this application by this Regulatory Authority does **not** indicate compliance with any other code, law or regulation that may be required (i.e., federal, state, or local). Additionally, the undersigned is aware that non-compliance may result in closure of the temporary food establishments.

DO NOT COMPLETE INFORMATION BELOW – FOR OFFICE USE ONLY

Application Approved ☐ Yes ☐No* See reason below	Date	Reviewer Signature/Title

Permit Restrictions: _____

Permit Effective Dates: _____

*Reason(s) for Disapproval: _____

_____

_____

_____

_____

Sketch below the general layout of the Temporary Event indicating the location of the following:

1. Temporary Food Establishments
2. Water supply
3. Toilet and handwashing facilities
4. Trash disposal containers
5. Location of shared utensil-washing facilities
6. Refrigerated trailer, if provided
7. Location of animals, rides, attractions (include distance of TFE from all other facilities on plot plan.

Conference for Food Protection
2012 Issue Form

Internal Number: 029
Issue: 2012 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.

Title:
Temporary Food Establishments 2011 Final Document

Issue you would like the Conference to consider:
The Conference for Food Protection (CFP) Plan Review Committee seeks acceptance of the document titled "Temporary Food Establishments 2011 Final Document and Attachments I, II and III".

Public Health Significance:
The Plan Review Committee has been tasked with the on-going development of the plan review documents for food establishments, temporary food establishments, mobile food establishments and permanent outdoor cooking operations. The objective of this document is to assist regulatory authorities and the food industry in understanding the review; approval and operation of Temporary Food Establishments.

Recommended Solution: The Conference recommends...:
that the following documents be accepted and posted on the CFP website (NOTE: documents can be found attached to the Issue titled: Report - Plan Review Committee):

- Temporary Food Establishments 2011 Final Document
- Attachment I - Application To Operate A Temporary Food Establishment
- Attachment II - Event Organizer Application To Operate Temporary Food Establishments
- Attachment III - Temporary Food Establishment - Expanded Process Flow

The Conference further recommends that a letter be sent to FDA requesting that these documents also be made available on the FDA website.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 030
Issue: 2012 I-003

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

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Title:
Re-Create Plan Review Committee

Issue you would like the Conference to consider:
The Conference for Food Protection (CFP) Plan Review Committee requests that the committee be reinstated to continue its review of the existing Permanent Outdoor Cooking Operations and the Mobile Food Establishment documents and present their findings at the 2014 CFP Biennial Meeting.

Public Health Significance:
The Plan Review Committee has been tasked with the on-going development of the plan review documents for food establishments, temporary food establishments, mobile food establishments, and permanent outdoor cooking operations. The objective of each document is to provide assistance to regulatory jurisdictions during the plan review process with an overarching goal of consistency and standardization.

Recommended Solution: The Conference recommends...:
Re-creating the Plan Review committee following the CFP 2012 Biennial Meeting to continue its review and update of the following Conference for Food Protection documents and present their findings at the 2014 CFP Biennial Meeting:
a. Permanent Outdoor Cooking Operations (2003)
b. Mobile Food Establishments (2006)

Submitter Information:

Name: Liza Frias, Committee Chair
Organization: Plan Review Committee
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Conference for Food Protection
2012 Issue Form

Internal Number: 001
Issue: 2012 I-004

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

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Title:
Change definition of PHF/TCS to TCS

Issue you would like the Conference to consider:
Following issuance of the final report "Evaluation and Definition of Potentially Hazardous Foods" (Technologists, 2010) by the Institute of Food Technologists (IFT) on December 31, 2001 the recommendation was made to change the name of "potentially hazardous foods" or "PHF" to "temperature control for safety food" or "TCS". The report advised that use of both terms (e.g. PHF/TCS) during a transition phase would facilitate migration from one term to the next. Now over a decade since the IFT report, the transition term has been in common use in the FDA Food Code since 2005.

The definition of "Potentially Hazardous Food (Time/Temperature Control for Safety Food)", abbreviated PHF/TCS in the FDA Food Code, has now been in common use for over six years. While it has served its purpose for introducing the new term, the time has come to complete the migration to the new definition. The definition and abbreviation for "Potentially Hazardous Food (Time/Temperature Control for Safety Food)" or "PHF/TCS" should be modified to drop the reference to "potentially hazardous food" and "PHF". Instead, the definition should read "Time/Temperature Control for Safety Food" abbreviated as "TCS".

Public Health Significance:
By eliminating use of both terms, the final intent of the IFT report will be realized by simply using the term "Time/Temperature Control for Safety Food" or "TCS". Stakeholders that use the FDA Food Code will be able to communicate clearly with others and the public more effectively using this simple term. Emphasis on time and temperature in the name of this definition will focus attention on critical elements of food safety that can be effectively controlled.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the following change to the 2009 Food Code (as modified by the Supplement issued in 2011):

Replace the current definition "Potentially Hazardous Food (Time/Temperature Control for Safety Food)" abbreviated as "PHF/TCS" with the new term "Time/Temperature Control for Safety Food" abbreviated "TCS" throughout the entire FDA Food Code.

Submitter Information:

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Attachments:

- ""Technologists, 2010""

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Technologists, I. o. (2010, September 3). *Evaluation and Definition of Potentially Hazardous Foods.* Retrieved December 12, 2011, from www.fda.gov: http://www.fda.gov/Food/ScienceResearch/ResearchAreas/SafePracticesforFoodProcesses/ucm094141.htm

Conference for Food Protection
2012 Issue Form

Internal Number: 004
Issue: 2012 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.

Title:
Sore throat with fever

Issue you would like the Conference to consider:
Food and Drug Adminstration 2009 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 requirement is too strict considering the risk.

Public Health Significance:
A sore throat is a frequent symptom of the common cold or other acute respiratory tract infections. Strep throat is caused by Group A *streptococcus*.
Antibiotics are needed if a healthcare provider diagnoses you or your child with strep throat, which is caused by bacteria. Strep throat cannot be diagnosed by looking in the throat - a lab test must also be done. Antibiotics are prescribed for strep throat for the purpose of preventing rheumatic fever . If the test result shows strep throat, the infected patient should stay home from work, school, or day care until 24 hours after starting an antibiotic.
The following links are CDC references that do not support the need for such a strict requirement -
CDC 2011 Foodborne Illness Estimates located at

- http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html#annual

Top 5 pathogens contributing to foodborne illness

- http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS_updated4-13.pdf

Trends in Foodborne Illness in the US

- http://www.cdc.gov/foodborneburden/trends-in-foodborne-illness.html#foodnet

Get Smart: Know when antibiotics work - Sore throat

- http://www.cdc.gov/getsmart/antibiotic-use/URI/sore-throat.html

Changing this requirement will reduce a misplaced effort on rare foodborne illness. Change will promote reporting of symptoms. Requirements will be more in line with risk to public health.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) Section 2-201.13(G) be amended so that persons with sore throat and fever can return to work after being free of symptoms for 24 hours.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 057
Issue: 2012 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.

Title:
Report-Wild Harvested Mushroom Committee

Issue you would like the Conference to consider:
During the 2010 Conference for Food Protection Biennial Meeting in Providence, Rhode Island the Wild Harvested Mushroom committee was created and given the following charges as an outcome of Issue 2010 I-008:
The Conference recommends that the Council consider forming a committee to continue discussion of this issue and that the following language and attachments for consideration to be placed on the CFP website as guidance listing steps that states can use to develop and implement a wild harvested mushroom program for their state. The charges will be:
(1) Develop guidelines to help regulators address the issue of wild mushrooms in food establishments;
(2) Report back at the 2012 CFP;
(3) The name of the committee will be Wild Harvested Mushrooms Committee.
This Issue presents the Wild Harvested Mushrooms Committee's final report along with committee roster and requests acknowledgement of the attached report.
The Wild Harvested Mushrooms Committee worked to complete their charges by developing a model program that regulatory agencies can use when addressing the issue of wild harvested mushrooms in retail and food service establishments.

Public Health Significance:
Due to public health food safety concerns, regulatory agencies in many jurisdictions follow the lead of the US FDA model Food Code (*hereafter model Food* Code) in requiring that wild harvested mushrooms sold to the public be identified by "an approved mushroom identification expert" (2009 model Food Code, *Section 3-201.16*). However, the pathway both for becoming an "approved mushroom identification expert" and having a regulatory agency recognize one are not well established or defined. The model Food Code recommends that all food served to the public must come from safe sources. The model Food Code further stipulates that mushrooms species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert. However the model Food Code does not establish what constitutes the basis for approval of an identification expert. Due to the lack of established criteria and recognized training courses, some regulatory jurisdictions

entirely prohibit the sale of wild harvested mushrooms. Other states have a limited program to allow specific species to be sold. The model program proposed here addresses this "gap" in public health interventions by providing clear guidance for regulatory agencies to use when addressing the issue of wild harvested mushrooms in foodservice establishments.

Recommended Solution: The Conference recommends...:
acknowledgement of the Wild Harvested Mushrooms Committee's final report and recognize the effort that committee members put forth in completion of the charges issued by the 2010 biennial meeting.

Submitter Information:

Name:	Chris Gordon, Co-Chair
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Address:	Virginia Department of Health 109 Governor Street5th Floor-Office of Environmental Health Services
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Attachments:

- "Wild Harvested Mushroom Committee List"
- "CDC MMWR Wild Mushroom reports 2011"
- "Food Safety News-California Wild Mushroom statement"
- "New Hampshire statement on wild mushrooms"
- "Washington Post article on consumption"
- "Wild Harvested Mushroom Committee Final Report"

Committee Name: Wild Harvested Mushroom Committee

First Name	Last Name	Company /Employer Name	City	State	Role (Chair, Co-Chair, Vice Chair)
Lisa	Roy	Maine CDC Health Inspection Program	Augusta	ME	Co-Chair
Michaeline	Mulvey	Maine Task Force to Certify Wild Mushroom Foragers	Bowdoin	ME	Member
Robert	Brown	Whole Foods Market	Austin	TX	Member
Terrance	Powell	Los Angeles County Dept. of Public Health	Baldwin Park	CA	Member
Andrew	Harris	Summit County Health District	Stow	OH	Member
Kevin	Dreesman	Illinois Department of Health	Springfield	IL	Member
Christopher	Gordon	Virginia Department of Health	Richmond	VA	Co-Chair
Christine	Cox	Montana Department of HHS	Helena	MT	Member
Richard R.	Vergili	Culinary Institute of America	Hyde Park	NY	Member
Frederick J.	Angulo	USCDC	Chamblee	GA	Member
Thomas L.	Schwarz	International Flight Services Association	Burke	VA	Member
Lisa	Whitlock	Food & Drug Administration	Oakland	CA	Advisor
Katey	Kennedy	Food & Drug Administration	Portland	OR	Advisor

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People. Saving Money through Prevention.
Morbidity and Mortality Weekly Report (*MMWR*)

Environmental Health in MMWR — 1961–2010

Supplements
October 7, 2011 / 60(04);86-96

Henry Falk, MD
Consultant to Office of the Director, Office of Noncommunicable Diseases, Injury, and Environmental Health, CDC

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Introduction

As an epidemiology bulletin, *MMWR* has unique strengths and attributes. These include weekly publication (highlighting timeliness and frequency of reporting), rapid turnaround, a close relation with government practitioners of public health (federal, state, and local), and a clear mission of informing the public health community and the general public about new, reemerging, and ongoing threats to the public's health. With its integral relationship to CDC, *MMWR* also is a means of publishing major internal CDC reports, particularly surveillance reports.

The field of environmental health is particularly heterogeneous and diverse. Environmental threats can be categorized singly as particular toxins, chemicals, or risks (e.g., lead, mercury, dioxin, rats, and poisons), grouped by environmental media (e.g., air pollutants, water pollutants, and hazardous wastes), broadly demarcated by environmental place or setting (e.g., homes, communities, and rural environments), or more broadly by national versus global concerns. Similarly, environmental diseases can be categorized as diseases essentially caused by a specific environmental factor (e.g., heat stroke and carbon monoxide [CO] poisoning); diseases caused, triggered, or exacerbated by environmental risk factors (e.g., asthma); or chronic multifactorial diseases for which environmental risk factors are just one category of multiple risk factors (e.g., heart disease or cancer). Beyond disease, natural and human-made disasters (e.g., chemical, biologic, and nuclear/radiation), including terrorist events, are an essential focus of environmental health.

Given the attributes of *MMWR* and the breadth of environmental health, readers might anticipate that *MMWR* environmental health reports focus heavily on new or reemerging epidemic diseases, disaster situations, chemicals and toxins causing acute clinical illness, newly identified risk factors and threats for acute illness, and surveillance updates for tracking environmental disease. Indeed, such has been the case, particularly in *MMWR*'s early years; however, in recent years, coverage has broadened. This report provides an overview of *MMWR* as it related to environmental health during 1961--2010; the presentation of results follows the

outline of the environmental framework (Table 1) and highlights the public health problems addressed in *MMWR*.

Methods

MMWR online listings were searched by title for all weekly reports broadly related to environmental health; prior years (1960--1964) were searched manually in the print-edition archives. Environmental concerns such as dietary supplements and other sources of toxic and hazardous exposures were included. Occupational exposures were not included, except in rare instances where both occupational and environmental exposures might be considered part of the same event or exposure.

A total of 826 reports were identified and categorized by their main topic for more detailed review (Table 1). Often, multiple ways existed to aggregate particular environmental problems, but the category that seemed most applicable was selected arbitrarily to enable discussion of topics in the sections believed to be most reasonable; for example, childhood lead poisoning from traditional home remedies is discussed with other sources of lead poisoning rather than with dietary supplements because those exposures are integral to understanding the distribution of lead poisoning cases. In contrast, eosinophilia-myalgia syndrome (EMS) is discussed under epidemic illnesses rather than under dietary supplements because EMS cases constituted a major national epidemic of a new disease and is best considered in that context.

All reports about a single topic or incident are counted separately. In this report, areas that were prominently featured in *MMWR* during the period are highlighted to provide a sense of how *MMWR* covered environmental health during that period.

Certain problems that intersect with environmental health were not included, either because they are covered elsewhere in this volume or because of size limitations in this report (e.g., refugee health or ultraviolet radiation and skin cancer).

Results

Environmental Disease

Poisoning and Illness from Ticks, Mushrooms, Plants, Snakes, Rats, and Other Factors (62 Reports)

These case reports and clusters were heavily represented in the early years of *MMWR*: 14 reports of tick paralysis, all but two before 1981 (the more recent reports emphasize the potential diagnostic confusion with Guillain-Barré syndrome); 24 reports of mushroom and plant poisoning (heavily focused on mushroom poisoning in the early decades, with isolated reports of poisoning from jimsonweed, moonflower, water hemlock, elderberry, and ostrich fern and plants containing belladonna alkaloids in recent decades); and nine reports related to snake bites, rat-bite fever, lionfish stings, arachnidism, sea urchin harvesting, and moth-related dermatitis. The purpose of these reports was to alert the reader to their occurrence and the potential for serious consequences. Fifteen additional reports were related to urban rat control (14 were quarterly surveillance reports for 1979--1982, highlighting the success of the existing CDC urban rat control program at that time).

Childhood Lead Poisoning (110 Reports)

During 1961--2010, the incidence, prevalence, mortality, and clinical severity of childhood lead poisoning dramatically declined. *MMWR* served both as an early reporting mechanism to document declining rates nationally and among groups at high risk and as a rapid-alert mechanism to highlight the various ways that children were exposed to lead (Table 2).

The first report in 1969 demonstrated high rates of lead poisoning, clinical severity, and fatalities in Newark, New Jersey, from exposure to lead paint (*1*); recent reports on lead paint have served as a reminder that, although much less common, severe effects and death still occur from lead paint ingestion. Early reports from El Paso, Texas (*2*), and Kellogg, Idaho (*3*), alerted the country to the striking exposures to children living near lead smelters; the most recent lead report of exposure in Zamfara, Nigeria (*4*), demonstrated high lead levels and high fatality rates from crude gold mining and smelting operations overseas. Other sources of lead exposure frequently addressed in *MMWR* included lead in dust taken home by workers exposed occupationally, lead in traditional home medicines administered to children, and lead exposure from incorrectly glazed ceramic ware; 21 types of exposure sources were identified from *MMWR* articles (Table 2). These reports probably make up one of the most detailed collections of the myriad ways in which children have been exposed to lead throughout the last 5 decades. New sources of lead poisoning continue to appear and are often published in *MMWR*. For example, imported charms and necklaces (and a host of other toys) with extremely high lead levels continue to be sold.

After establishment of the Childhood Lead Poisoning Control Program at CDC in 1973, a series of 32 quarterly surveillance reports during 1974--1982 demonstrated the buildup and success of that screening program. Reports in 1991--1992 spoke to the reestablishment of those screening programs.

A most critical function of *MMWR* has been the early release of national surveillance data from the National Health and Nutrition Examination Surveys (*5*) in 1982, 1994, 1997, and 2005 (more recent updates are in CDC's National Center for Environmental Health/CDC National Reports on Human Exposure to Environmental Chemicals). These reports have documented the dramatic and continuing decline of blood lead levels among children, from 88% of children in the United States with levels of ≥10 μg/dL in 1976 to 0.6% of children in 2010. The national trend data have been widely used by the U.S. Environmental Protection Agency (EPA), U.S. Department of Housing and Urban Development, CDC, individual states, and others in the development and evolution of programs to eliminate childhood lead poisoning. Additionally, *MMWR* has alerted readers to the issuance of new CDC screening guidelines, new lead legislation, and key reports from state and local health departments on regional and local lead health problems.

Carbon Monoxide Poisoning (45 Reports)

Frequent MMWR reports on carbon monoxide poisoning have focused on surveillance updates (n = 14), primarily of U.S. mortality data, but also of emergency department rates and individual state data and on case or cluster reports (n = 3) that highlight the diverse ways that CO poisoning occurs. Guidance for prevention has been paramount in all of these reports.

The most recent reports on surveillance data, covering 1999--2004 (*6*), identified approximately 450 unintentional, nonfire-related poisoning deaths per year and 15,000--20,000 emergency department visits per year. A report in 1982 listed unintentional CO deaths of ≥1,500 per year.

The case/cluster reports can be grouped as follows:

1. Home-related (12 reports), all caused by incorrectly vented or malfunctioning gas-powered furnaces, hot water heaters, space heaters, or refrigerators. Also, incorrectly placed generators used during hurricanes and power outages frequently have been identified as a critical problem (see Natural Disaster section below).
2. Vehicle-related (nine reports), either caused by unvented indoor exhaust or close proximity to outdoor exhaust from vehicles, including automobiles, camper trucks,

tractors, houseboats, motorboats, and ski boats. Two instances involved portable cook stoves brought inside enclosed camping tents for warmth at night.

3. Commercial buildings with heavy gas-fueled equipment (10 reports) (e.g., ice resurfacing machines in skating arenas, sporting events involving monster trucks and tractor pulls, and indoor power washers and floor polishers).

New and Reemerging Epidemic Diseases (30 Reports)

Perhaps the most prominent function of *MMWR* is to alert the public health community, as well as the general public, to rapidly evolving and unfolding events surrounding occurrence of epidemic diseases; this is particularly true for new diseases or unusual forms of previously known epidemic diseases (Table 3).

- **Angiosarcoma of the liver**. This illness manifested as a cluster of four cases of this extremely rare disease among vinyl chloride polymerization workers (*7*); the initial *MMWR* article in 1974 considered vinyl chloride monomer as the causative agent. Subsequent studies confirmed the causal association and detailed the pathogenesis that includes hepatic fibrosis and portal hypertension as precursor conditions (*8*); national surveillance identified three other known causes of this disease. Identification of vinyl chloride as a carcinogen after >3 decades of widespread use led to dramatic lowering of acceptable occupational exposures and to greatly increased protection of the general population potentially exposed to vinyl chloride in different ways. The follow-up articles examined geographic clusters of these cases in Connecticut and Wisconsin and congenital malformations in two communities near production facilities; those reports did not link community environmental exposures to these findings. In 1997, as part of the celebration of CDC's 50th anniversary, MMWR reprinted the original 1974 report and a new editorial note (*9*).
- **Toxic oil syndrome.** The initial *MMWR* article, published in 1981, described approximately 1,300 persons in Spain hospitalized for atypical pneumonia of uncertain etiology (*10*). The second report, also published in 1981, documented that approximately 12,000 persons were hospitalized and included results of a case-control study that determined the epidemic's causative vehicle, illicit cooking oil sold by itinerant peddlers in unmarked bottles (*11*). The final article, which was published in 1982, one year after the start of the epidemic, characterized the decrease in new cases after protective actions and described the evolution of the disease into a chronic phase with pronounced neuromuscular and other findings (*12*). Although approximately 25,000 persons experienced this new disease, the specific etiologic agent was never identified (*13,14*).
- **Eosinophilia-myalgia syndrome.** The initial *MMWR* article, published in 1989, described three index patients in New Mexico with eosinophilia-myalgia syndrome (EMS) who had used L-tryptophan dietary supplements, and a preliminary report of additional cases in the state also was linked to ingestion of L-tryptophan (*15*). By the following week, *MMWR* was able to report results from four states that included two case-control studies linking illness with specific lots of L-tryptophan (*16*). Subsequent reports provided updates from national surveillance, added to knowledge about the clinical spectrum, and provided interim findings on potential contaminants in the L-tryptophan (*17*). With nine updates in <1 year, *MMWR* provided timely reporting of this rapidly developing epidemic. From the first report, *MMWR* also noted the clinical similarity of EMS to toxic oil syndrome.

Asthma (26 Reports)

All *MMWR* articles related to asthma appeared after 1989, and the majority related to asthma surveillance. *MMWR* articles have covered such topics as asthma deaths and hospitalization among adults and children and self-reported illness through the Behavioral Risk Factor Surveillance System (*18*). Selected reports have evaluated health-care use (e.g., use of inhaled medication and state and local programs). Asthma triggered by specific chemicals and events are covered elsewhere in this report.

Environmental Tobacco/Secondhand Smoke (21 Reports)

Almost all *MMWR* articles on environmental or secondhand tobacco smoke have appeared since 2000. Articles have covered such topics as biomonitoring data from the National Health and Nutrition Examination Survey, which has tracked cotinine levels among U.S. nonsmokers; levels have declined significantly during the past two decades---from a prevalence of 88% ≥0.05 ng/mL in the population aged ≥4 years (1988--1991) to 40% in the population aged ≥3 years (2007--2008) (*19*). Other *MMWR* articles have covered exposure to secondhand smoke as reflected in data from the Behavioral Risk Factor Surveillance System and other surveys.

A particular focus of *MMWR* has been the impact of state and local policies to reduce smoking in indoor worksites and in public places (e.g., the New York State comprehensive ban for such sites); undoubtedly, successful implementation of these policies has been a major reason for declining exposures. A recent *MMWR* report took this one step further by noting reduced hospitalization for myocardial infarction after implementation of a smoke-free ordinance in the city of Pueblo, Colorado.

Environmental Threats and Risks

Specific Chemicals, Toxins, and Risk Factors

Over the years, *MMWR* has published reports on the adverse effects of a wide array of chemicals (metals, organic compounds, and pesticides); dietary supplements; consumer products; drugs, devices, and therapeutics; and substances of abuse (Table 4 and 5). Most appear as single reports and covering them all here is not possible. Certain especially instructive reports from each category are mentioned below.

Pesticides (28 reports)

Almost all the *MMWR* reports focused on acute toxicity from inappropriate, unintended, or extremely high exposures. Reported illnesses and deaths included those from fumigants resulting from offsite drift from agricultural use of chloropicrin soil fumigant, phosphine release in a fumigated railroad boxcar, home fumigation with sulfuryl fluoride, and soil fumigation with methyl bromide. *MMWR* reported a widespread outbreak of food poisoning from aldicarb contamination of melons that occurred in California in 1985 (*20*); subsequent reports described poisoning from the illegal use of aldicarb as a rodenticide and from its mistaken use in food preparation. Illnesses and fatalities were reported from inappropriate use of methyl parathion for insecticide control in a home environment with multiple possible routes of exposure to children; a much earlier report from 1970 described poisoning among teenaged boys harvesting tobacco. Two widespread outbreaks of food contaminated with endrin were reported from Pakistan (*21*) and the Middle East.

Metals (24 reports)

The vast majority of *MMWR* reports on metals were related to mercury. The largest number addressed individual instances of elemental mercury exposure in homes, schools, or neighborhoods. Multiple reports detailed exposure investigations with potentially broad implications (e.g., identification of elevated mercury exposure from use of interior latex paint that led to changed regulations for such paints [*22*] and mercury poisoning among Hispanics in the Southwest from use of beauty creams produced in Mexico [*23*]). Articles on the challenges of addressing long-term exposure to low levels of toxins among vulnerable populations appeared only rarely; one such report contained a joint statement of the American Academy of Pediatrics and the U.S. Public Health Service on exposure to thimerosal in vaccines (*24*).

Organic compounds (25 reports)

The largest number of *MMWR* reports on organic compounds related to polychlorinated biphenyl (PCB) and dioxin exposures. The PCB-related reports were primarily about instances of high-level, acute exposures (e.g., from transformer fires and food contamination episodes). The dioxin reports focused on multiple prolonged inquiries into long-term effects of dioxin exposure among Vietnam War veterans, Missouri residents exposed to dioxin in soil, and residents near the release of dioxin by a chemical explosion in Seveso, Italy (*25*,*26*). Reports on dioxin exposures represented the infrequent instances in which *MMWR* published reports on the problem of long-term consequences of chemical exposure.

Substances of abuse (40 reports)

Reports related to substances of abuse frequently have been featured in *MMWR* throughout the past five decades. The reports often have related to specific episodes of apparently increased rates of overdoses and fatalities; reports have documented incidents where such increases were related to contaminants (e.g., cocaine containing the antihelminthic drug levamisole or heroin contaminated with scopolamine or clenbuterol). The most dramatic example was the identification of Parkinsonism after exposure to the street drug 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine, a potent analogue of meperidine (*27*). As noted elsewhere in this report, the reports from the Hazardous Substances Emergency Events Surveillance (HSEES) system on the acute public health consequences of methamphetamine laboratories have had a strong public health impact (*28*).

Dietary supplements (18 reports)

MMWR reports have appeared on lead poisoning from Asian traditional home remedies (discussed previously under childhood lead poisoning), arsenic poisoning from Hmong traditional remedies, agranulocytosis from a phenylbutazone-containing Chinese herbal remedy, and two reports of toxicity from a traditional Chinese remedy called Jin Bu Huan. The *MMWR* report on ingestion of raw carp gallbladders leading to acute hepatitis and renal failure is one of the most unusual food-related articles in this group.

Consumer products (21 reports)

The MMWR articles about consumer products constitute another remarkable collection of acute toxicity and fatalities related to unintended consequences from use of different types of products (e.g., death from digoxin-containing aphrodisiacs [29]). One recurring theme was toxicity from aerosol boot, shoe, and leather conditioner or sealants, with rapid identification of cases leading to product recalls. Another important theme was outbreaks of acute illness and death in neonatal nurseries during the predisposable diaper period (1960s--1970s): strong phenolic laundry detergents left residues that were absorbed through the skin of vulnerable newborns, leading to severe toxicity (30).

Drugs, devices, and therapeutics (12 reports)

This group comprises dramatic reports of rarely experienced toxicity and death from substances. It includes intentional cyanide poisoning from deliberate tampering with over-the-counter medications (*31*), severe toxicity and deaths among newborns exposed to benzyl alcohol preservatives in intravenous solutions, and severe barium toxicity from use of an absorbable barium salt for radiologic examinations (*32*).

Environmental Media

Water (60 reports)

Approximately half of the *MMWR* reports on environmental media related to recreational water --associated illness and its prevention. The strong environmental components in these reports emphasized such concerns as swimming pool and public spa inspections and guidelines (*33*) and injuries and illness from incorrectly used pool chemical disinfectants and chloramine vapors. Chemical contamination of drinking water was reported 10 times, from chlordane, nitrates/nitrites, sewage, phenol, caustic soda, and ethylene glycol; all of these involved elevated exposures and sometimes illness as well (e.g., methemoglobinemia from nitrite exposure). Other environmental aspects included red tides, Pfiesteria spp., fluoridation, outbreaks of disease related to Clostridium spp. and other waterborne microbes, and one report on inadequately filtered public drinking water. Only a few articles related to regulatory standards for chemicals in drinking water.

Air (13 reports)

For a brief period after reauthorization of the Clean Air Act in 1990 and the release of *Healthy People 2000* (*34*), a flurry of *MMWR* articles focused on the national impact of air pollution, particularly on the numbers of persons residing in counties exceeding EPA air standards and on the air pollution problems facing state and local health departments. *MMWR* coverage on this topic slowed after 1995.

Food (46 reports)

Eleven reports on surveillance and FoodNet (available at http://www.cdc.gov/foodnet/) focused primarily on trends of outbreaks and illness related to specific microbial sources. An article on safer and healthier foods, published as one of *MMWR*'s series on achievements in public health throughout the 20th century, emphasized the role of environmental advances (e.g., refrigeration and pasteurization). During 1960--1979, a total of 21 reports appeared on food poisoning from metals (copper, cadmium, antimony, zinc, chromium, and calcium), and seven more from nitrites, monosodium glutamate, and fluoride, primarily related to contamination of food from faulty equipment, incorrect preparation technique, or mistaken ingredients. Six more recent reports described unusual exposures (e.g., ammonia contamination of milk, niacin intoxication from bagels, and nicotine poisoning from ground beef).

Hazardous wastes (14 reports)

During the early 1990s, soon after the creation and establishment of the Agency for Toxic Substances and Disease Registry, *MMWR* published a short series of reports and alerts related to developments at that agency (e.g., a statement on the agency's priority health conditions and research strategies) and a short summary of the report on the public health implications of medical waste.

During the past six years, six reports have summarized findings from the Hazardous Substances Emergency Events Surveillance (HSEES) system (e.g., on hazardous substances released during rail transit in 18 states during a six-year period [*35*]) and on hazardous chemical incidents in U.S. schools for a six-year period. Certain of these HSEES reports on chemical releases and explosions in methamphetamine laboratories helped policymakers more closely regulate these illicit production facilities (Table 6).

Environmental Places

Healthy homes, healthy communities, and global environmental health (47 reports)

MMWR articles often include information about homes, communities, and global health, usually in the context of a specific problem (e.g., lead poisoning and asthma; hazardous waste disposal; and earthquakes, drought, and famine). During 1961--2010, five reports were related to homeless persons, usually in association with alcohol and substance abuse as risk factors for death, and five reports focused on elevated radon levels in homes. The built environment was a focus of nine reports, most of which considered how environmental features can promote physical activity among adults and children. Environmental features of infectious diseases figured prominently in 17 reports related to outbreaks on cruise ships (e.g., one report documenting the preventive role of regular ship inspections) and in 11 reports related to Legionnaires disease.

Disasters

Natural disasters (153 reports)

Before 1980, *MMWR* rarely reported on natural disasters; reports have escalated rapidly since then (Table 6). The increase undoubtedly reflects growing engagement by the public health community generally, and by CDC specifically, in disaster preparedness and response. At CDC, this corresponds to the creation of the National Center for Environmental Health in 1980 and its establishment of emergency response and disaster epidemiology units, as well as to the more recent creation of CDC's Office of Terrorism Preparedness and Emergency Response (now the Office of Public Health Preparedness and Emergency Response). The increase in natural disaster reports in *MMWR* has varied by the type of event: volcano reports essentially focused on Mount St. Helens in 1980; tornado reports peaked during the 1980s and 1990s; heat wave reports have been fairly level for the past three decades; and hurricane-related reports have increased steadily throughout the past five decades. This section highlights the findings in six of the most numerous categories. Most of the reports related to U.S. disasters; however, the drought and famine category was global, and the earthquake category mostly so.

- **Volcanoes.** Mount St. Helens came to life with a major eruption on May 18, 1980 (*36*); *MMWR* published a sequence of 14 reports to provide public health updates and recommendations. This series was a landmark in *MMWR's* initiating intense engagement on natural disasters; in addition to the *MMWR* sequence of reports, an *MMWR* report published on July 11, 1980, listed a series of 33 technical information bulletins from the Federal Emergency Management Agency. The health bulletins were all based on 23 Mount St. Helens volcano health reports from CDC that continued through February 1981 and were widely distributed throughout the Pacific Northwest. Both *MMWR* short summaries and the more detailed volcano reports covered a wide array of actual and potential health impacts (e.g., illness and death; respiratory health; safety for cleanup workers and loggers; impact on water systems and other key infrastructure; testing for toxic chemicals in the ash; levels of ash fall and monitoring of volcanic activity; and potential for long-term respiratory effects, including pneumoconiosis [*37*]).
- **Tornadoes.** The group of nine *MMWR* articles on tornadoes began with a landmark report of a 1979 tornado investigation in Wichita Falls, Texas; 44 persons were killed and 171 were hospitalized for injuries (*38*). Guidance regarding seeking shelter was reaffirmed; however, existing guidance on how to drive out of harm's way was demonstrated to be futile and led to updated recommendations. Subsequent reports highlighted the vulnerability of mobile homes and the need for shelter areas in mobile home parks, the frequent inadequacy and failure of warning systems and sirens, and guidance for adequate

sheltering and protection from injury and death. The last report specifically on tornadoes was published in 1997.

- **Heat waves.** The heat wave of summer 1980 led to descriptive epidemiologic and case-control investigations in St. Louis and Kansas City, Missouri. A total of 784 deaths and severe illnesses were attributed to the heat. In another landmark study that changed longstanding public health practice, the results demonstrated that even short periods in an air-conditioned environment were protective, whereas the then-common practice of distributing fans during heat waves was counterproductive. Because the sweating mechanism is compromised during the early stages of heat illness, delivery of hot air by fans exacerbates the situation (*39*). Reports of the Chicago heat wave in 1995 and of the heat wave in Europe in 2003 emphasized the vulnerability of older persons, infirm persons, and persons in socioeconomically deprived circumstances (*40*); multiple reports affirmed the effectiveness of having relief workers mobilize older persons for trips to air-conditioned environments (e.g., shopping malls). Recent reports also have highlighted other vulnerable groups for heat illness (e.g., farm workers and high school athletes).

  To provide timely public health guidance before the winter and summer seasons, MMWR has published approximately two dozen articles about hyperthermia and hypothermia, usually timed to appear before the winter or summer season begins. These reports have provided summary statistics on heat- and cold-related deaths in the United States, instructive case reports from multiple states highlighting risk factors, and updated public health guidance.
- **Earthquakes.** Reports have focused on assessments of mortality and morbidity (Italy, 1981; Loma Prieta, California, 1989; Philippines, 1990); coccidioidomycosis after the Northridge, California, earthquake in 1994; health-related needs assessments linked to response or surveillance (Turkey, 1999; Indonesia and Thailand tsunami, 2004), victim identification (Thailand tsunami, 2004), and surveillance (Haiti, 2010). These largely have been acute-phase reports related to early assessments of the magnitude of the problem and the extent of acute public health needs.
- **Hurricanes.** Hurricanes have been increasingly the most commonly reported category of natural disaster published in *MMWR*, although approximately half of all such reports (22/46) related to Hurricane Katrina. For the reports not related to Hurricane Katrina or Hurricane Rita, four major themes are apparent:
  --- Needs assessment surveys were reported in *MMWR* for Hurricanes Ike, Wilma, a cluster of Florida hurricanes in 2004 (three articles), Allison, Georges, Marilyn and Opal, and Andrew (two articles). Needs assessments usually targeted vulnerable groups (e.g., older persons or rural populations).
  --- CO poisoning from unsafe generator use was reported for Ike and the Florida cluster; also, one report involved dry ice--induced CO poisoning in the 2004 Florida cluster.
  --- Medical examiner mortality data were analyzed and reported in *MMWR* for the 2004 Florida cluster, Floyd, Marilyn and Opal, Andrew, and Hugo (two articles).
  --- Surveillance data were reported for illness and injury rates at Marilyn and Opal, Hugo, and Elena and Gloria. The only other reports were related to mosquito-control efforts at Andrew and evaluation of postdisaster work-related electrocutions from downed power lines after Hugo.

  Katrina was much more complex for multiple reasons, including the devastating destruction and flooding over multiple states, the approximately one million evacuees, the long time frame for restoring basic functions and repopulating New Orleans, and the extended periods spent by thousands of persons in shelters and temporary trailers. For Hurricane Katrina, four reports were published about rapid needs assessment, three on CO poisoning, one on mortality, and seven on surveillance for injury and illness in health-care facilities and evacuation centers. Reports related to the special features of Katrina included information about relief workers and occupational guidance, the ubiquitous mold problem, a norovirus outbreak in a shelter, two cases of toxigenic *Vibrio chlolerae* O1, and the substantial number of tuberculosis patients temporarily lost to follow-up during the chaos of the evacuation.

- **Drought and famine.** All seven reports describe investigations of major drought impact in Africa (Niger, 2005; Ethiopia, 2000; Somalia, 1987; Niger 1985; Burkina Faso, 1985; Chad, 1985; and Mauritania, 1983). These reports described collaboration among CDC, the U.S. Agency for International Development, United Nations' agencies (e.g., UNICEF), and country governments. These reports also described surveys that were conducted of children as the most vulnerable group, and relief efforts focused on nutritional status, respiratory and gastrointestinal disease, measles vaccination, and vitamin A and C deficiencies.

Biologic, chemical, radiation, and nuclear (four reports)

During 1961--2010, several additional reports were related to potential adverse effects of chemical warfare agents. With the growth of environmental programs at CDC---the National Center for Environmental Health was created shortly after, and largely as a result of, the 1979 Three Mile Island event---readers might anticipate more complete coverage of such events in the future. Perhaps as a reflection of that, the most recent *MMWR* covered in this report relates to radiologic and nuclear preparedness and summarizes a CDC Grand Rounds session (*41*); additional reports relate to potential adverse effects of chemical warfare agents.

Terrorism

World Trade Center attack (15 reports)

The sequence of 15 *MMWR* articles after the September 11, 2001, terrorist attacks was the second largest series of reports related to a single environmental event. The initial overview of activities in response to the attacks appeared on September 28, 2001 (*42*). Six of the reports related to occupational concerns: exposures to workers at and near the site, injury and illness rates among workers, use of respiratory protective equipment, and follow-up of first responders' mental and physical health. The themes of the initial environmental reports were similar to those in other disaster settings: community needs assessment; investigations of deaths; and surveillance for injuries and illness, including a review of syndromic surveillance (*43*). A pilot survey of airborne and settled dust in residences did not find evidence of substantive asbestos exposure, although dust of pulverized building materials was present (*44*). Follow-up reports tracked residents' respiratory and mental health. Subsequent publications have addressed these findings more fully and documented the elevated rates of new-onset asthma and posttraumatic stress disorder; the World Trade Center Registry was instrumental in enabling a thorough evaluation of these concerns (*45*). The ability to publish approximately a dozen detailed and pertinent follow-up reports about critical aspects of this disaster in less than a year demonstrates the unique value of *MMWR* to meet the need for accurate and timely information after such disasters.

Discussion

This review of 826 *MMWR* articles demonstrates the scope of *MMWR's* coverage of environmental health and the remarkable diversity and richness of the field. Over five decades, MMWR has reported on hazards and diseases both old and new. A reader of these reports is struck by all the ways that old and well-known hazards can resurface under unanticipated circumstances. For example, the *MMWR* reports on lead and CO poisoning and pesticides are full of new exposure pathways that constantly surprise. *MMWR* has been an excellent resource for highlighting and tracking surveillance data for environmental diseases (e.g., lead poisoning, CO poisoning, and asthma) and for reporting biomonitoring results that demonstrate population exposure trends for cotinine, lead, mercury, and other substances.

MMWR has been at its best in highlighting and tracking new outbreaks of disease, unfolding disasters (both natural and human-made), urgent public health scenarios, and the multiple

ways in which illness and death can occur from exposures to chemicals and hazards. It is a unique resource for timely updates of major events (e.g., Mount St. Helens; Hurricane Katrina; the 2001 attack on the World Trade Center, and epidemics, including the outbreak of EMS). It is an effective way to provide preliminary reports of complex investigations that highlight important public health messages (e.g., with the 1980 heat wave investigation or the toxic oil syndrome investigation). Additionally, it likely represents the most remarkable collection of reports on outbreaks, illness, and death in existence from pesticides to natural poisons, dietary supplements, home remedies, chemicals, and consumer products.

Over its five decades at CDC, *MMWR* reports on environmental health have focused mostly on acute, high-dose, clinically apparent, and urgent risks. This analysis of MMWR reports over 50 years shows this repeatedly --- scores of reports on acute outbreaks related to water pollutants, pesticides, and CO. During the 50 years, *MMWR* has focused much less on chronic, long-term risks from repeated low-level exposures and the policy and regulatory approaches that society employs to protect the public from such risks. This is understandable given that the *MMWR* weekly, with its traditional short, telegraphic form, was created to report on immediate threats to the public health. Authors have generally recognized that, for analyses that require more complex epidemiologic analyses and description, long-form peer-reviewed medical and public health journals are a more conducive forum, although the *MMWR* Surveillance Summaries do publish long-form compendiums of surveillance findings.

In recent years, this has begun to change as authors of longer-term studies have wished to capitalize on *MMWR's* appeal to the news media and the nation's public health readership. Even with its short format, the *MMWR* weekly now often publishes reports on long-term public health exposures and resultant illnesses, or on health behaviors. In *MMWR*'s next 50 years, as it continues to cover the field of environmental health and as that field increases in importance even beyond its current state, *MMWR* might consider periodic (i.e., monthly or quarterly) reports on environmental health policies, risk analysis, regulatory approaches, long-term epidemiologic studies, or other areas that can be meaningfully presented to the broader public health community. This might further enhance the critical value of *MMWR* to the field of environmental health.

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TABLE 1. Environmental framework/structural outline as applied to this *MMWR* review and number of *MMWR* articles for each topic* --- 1961--2010
Category
Environmental disease
Environmental poisons (62), childhood lead poisoning (110), carbon monoxide poisoning (45)
New and reemerging epidemic diseases (30)
Asthma (26)
Environmental tobacco/secondhand smoke (21)
Environmental threats and risks
Specific chemicals (pesticides [28], metals [24], organic compounds [25]); substances of abuse (40); dietary supplements (18); consumer products (21); drugs/devices/therapeutics (12); other (3)
Media: water (60), air (13), food (46), hazardous wastes (14)
Places: homes, communities, global (47)

Disasters
Natural (volcanoes, tornadoes, heat waves, earthquakes, hurricanes, drought/famine) (153)
Biological/chemical/radiation/nuclear (4)
Terrorism: World Trade Center/other (24)
* Total number of *MMWR* weekly reports = 826.

TABLE 2. Source of exposure, number of reports, location of investigation, and date of publication for lead poisoning investigations reported in *MMWR* --- 1961--2010

Source of exposure/risk factor	**No. *MMWR* reports**	**State/location (no. reports)**	**October 7, 2011s**
Folk remedies (primarily from Mexico and Asia)	10	CA (5); TX (2); CN, CO, FL, MA, MN, NH, NY (1 each)	7/9/2004; 8/9/2002; 1/22/1999; 7/16/1993; 9/8/1989; 11/16/1984;10/28/1983; 10/28/1983; 11/6/1981; 1/8/1982
Lead paint (fatalities, encephalopathy, and elevated exposures among children; home renovation and stripping paint)	8	NJ (3); NY (2); MA, NH, WI (1 each)	1/30/2009; 6/8/2001; 1/3/1997; 3/29/1991; 3/23/1979; 6/9/1978; 12/16/1977; 12/12/1970
Living near mining and smelting operations (El Paso, TX; Kellogg, ID; Zamfara, Nigeria)	7	TX (4), ID (2), Nigeria (1)	7/16/2010; 9/19/1997; 2/24/1978; 1/10/1976; 9/14/1974; 5/4/1974; 12/8/1973
Dust taken home from occupational exposure	7	CO (2); CA, ME, NC, TN, VT (1 each)	8/21/2009; 4/6/2001; 5/19/1989; 6/28/2005; 2/25/1977; 9/30/1977; 3/26/1976
Glazed ceramics	5	NY (2); AR, NJ, OR (1 each)	7/9/2004; 10/23/1992; 6/2/1989; 8/10/1974; 6/5/1971

Drinking water	4	DC (3); AZ, CA (1 each)	6/25/2010; 5/21/2010; 4/2/2004; 10/21/1994
Ingestion of charm/necklace	2	MN, OR (1 each)	3/31/2006; 6/18/2004
Imported candy from Mexico	2	CA (2); MI (1)	8/9/2002 (duplicate); 12/11/1998
Indoor firing range (student shooting team; National Institute for Occupational Safety and Health survey)	2	AK, multiple (1 each)	6/17/2005; 9/23/1983
Gasoline sniffing (tetraethyl lead exposure)	2	AZ, VA (1 each)	7/26/1985; 8/7/1981
Refugee children and adoptees (US)	2	NH, US (1 each)	1/21/2005; 2/11/2000
Chelation therapy-deaths from hypocalcemia	1	OR, PA, TX (1 each)	3/3/2006
Litarigio-antiperspirant/deodorant	1	RI (1)	3/11/2005
Dental offices	1	WI (1)	10/12/2001
Chewing plastic wire coating	1	OH (1)	6/25/1993
Moonshine/illicitly distilled alcohol	1	AL (1)	5/1/1992
Battery repair shop: living nearby	1	Jamaica (1)	7/14/1989
Intravenous amphetamine use	1	OR (1)	12/8/1989

TABLE 3. New and reemerging epidemic diseases broadly related to environmental factors reported in *MMWR* --- 1961--2010

Disease/syndrome	Date of initial report, location	Presentation	Date of follow-up reports

Hepatic angiosarcoma	2/15/1974, KY	Cluster of fatal liver cancer cases in vinyl chloride polymerization workers	6/21/1974; 7/25/1975; 3/5/1976; 2/7/1997
Toxic oil syndrome	5/25/1981, Spain	Atypical pneumonia, eosinophilia, and neuromuscular disease from illicit cooking oil	9/4/1981; 5/5/1982
Eosinophilia-myalgia syndrome	11/17/1989, NM	Eosinophilia, neuromuscular disease from L-tryptophan dietary supplement	11/24/1989;12/8/1989; 1/12/1990; 2/16/1990; 5/18/1990; 8/31/1990 (×2); 11/2/1990; 8/21/1991
Toxic hypoglycemic syndrome (Jamaican vomiting sickness)	1/31/1992, Jamaica	Profound hypoglycemia, vomiting, convulsions from ingestion of unripe ackee fruit	
Epidemic neuropathy*	3/18/1994, Cuba	Subacute optic and peripheral neuropathy likely from nutritional deficiency/tobacco smoking	
Renal failure†	8/2/1996, Haiti; 12/11/2009, Nigeria	Among children, from ingestion of diethylene glycol--contaminated acetaminophen syrup	
Acute idiopathic pulmonary hemorrhage among infants	12/9/1994, OH	Hypothesized/unproven association with water damage, mold, or fungi	2/3/1995; 1/17/1997;3/10/2000; 6/15/2001; 9/10/2004
Acute aflatoxicosis§	9/3/2004, Kenya	Jaundice from moldy, contaminated maize	
Gulf War illness	6/16/1995, Veterans	Unexplained illness/syndrome among Persian Gulf War veterans	

* CDC. Epidemic neuropathy---Cuba, 1991--1994. MMWR 1994;43:189--92.

† CDC. Fatalities associated with ingestion of diethylene glycol-contaminated glycerin used to manufacture acetaminophen syrup---Haiti, November 1995--June 1996. MMWR 1996;45:649--50; and CDC. Fatal poisoning among young children from diethylene glycol-contaminated acetaminophen---Nigeria, 2008--2009. MMWR 2009;58:1345--7.

§ CDC. Outbreak of aflatoxin poisoning---eastern and central provinces, Kenya, January--July 2004. MMWR 2004;53:790--3.

TABLE 4. Adverse effects of pesticides, metals, organics, and other exposures reported in *MMWR* --- 1961--2011

Pesticides (no. reports)	Metals (no. reports)*	Organic compounds (no. reports)	Other (no. reports)
Methyl parathion (4)	Mercury (21), including elemental mercury, thimerosal, organic mercury, and beauty cream	Dioxin (8); including in Vietnam War veterans; Missouri soil; and Seveso, Italy	Asbestos soil exposure (1)
Aldicarb (3)			Radiation (2)
Endrin (3)		Polychlorinated biphenyls (PCBs) (7)	
Mosquito control spray (3)	Thallium (2)	Polybrominated biphenyls (PBBs) (2)	
Fumigants (3)	Arsenic (1)	Dichlorodiphenyltrichloroethane (DDT) (2)	
Diazinon (2)		Trichloroethylene (TCE) (1)	
Lindane (1)		Gasoline spill (1)	
Rodenticide containing TETS (1)		Biodiesel, home production (1)	
DEET (1)		Toluene diisocyanate (1)	
Sulfuryl fluoride (1)		Compounds at Love Canal, Niagara Falls, New York (1)	
Chlorpyrifos (1)		1, 3-dichloropropene (1)	
Carbophenothion (Trithion) (1)			
Organophosphates, multiple (4)			

*Not including lead poisoning and selected problems highlighted elsewhere in this report.

TABLE 5. Adverse effects of substances of abuse, dietary supplements, consumer products, drugs, devices, or therapeutics reported in *MMWR* --- 1961--2011

Substances of abuse (no. reports)	Dietary supplements and unorthodox remedies (no. reports)	Consumer products (no. reports)	Drugs, devices, and therapeutics (no. reports)
Heroin (8)	Asian traditional remedies (4), including Chinese (3) and Hmong (1)	Aerosolized carpet shampoo and aerosol conditioner for shoes, boots, and leather products (4)	Nasopharyngeal radium irradiation/head and neck cancer (1)
Marijuana (6)			
Cocaine (5)	Herbal teas (3), including Kombucha, senna cathartics (1), foxglove (1), and pyrrolizidine alkaloids (1)		Benzyl alcohol preservatives/neonatal deaths (1)
Methamphetamine (5)		Hexachlorophene baths and newborn neuropathology (4)	
Gamma-Hydroxybutyric acid (2)			Diidohydroxyquin-induced blindness (1)
	Selenium (1)	Neonatal toxicity from use of phenolic laundry detergents in neonatal nursery (3)	Prilocaine-induced methemoglobinemia (1)
Isobutyl nitrite (1)	High-dose vitamin A (1)		
Ecstasy (1)	Turpentine/castor oil (1)	Pentachlorophenol exposure in log cabins (2)	Ephedrine and cryoglobulinemia vasculitis disease (1)
General/multiple (12)	Chaparral (1)	Limes and phototoxic dermatitis (1)	
	Gamma-butyrolactone as source of *gamma*-hydroxybutyrate (date-rape drug) (1)	Butyl caulk and toluene toxicity (1)	Cyanide tampering of Sudafed(r) (1)
		Naphthalene toxicity from mothballs (1)	Sporicidin device sterilant (1)
		Indoor paint containing Bis (tributyltin) oxide (1)	Undiluted 25% intravenous human

Kava (1)	Chlorine gas generated by mixing bleach with commercial phosphoric acid cleaner (1)	albumin and hemolysis (1)
Herbal supplement with aretemisinin (1)		Halofantrine and sudden death (1)
Pennyroyal oil (1)	Household lamp oil ingestion and toxicity (1)	Colchicine overdose from pharmaceutical compounding error (1)
Raw carp gallbladders (1)	Spray adhesive use in pregnancy (1)	
Mesotherapy (1)	Digoxin-containing aphrodisiacs and death (1)	Gadolinium contrast agent and renal disease (1)
Silicone filler injections (1)		
		Soluble barium sulfate contrast solution and overdose deaths (1)

TABLE 6. Number of *MMWR* articles related to natural disasters, by decade --- 1961--2010

Category	1961--1970	1971--1980	1981--1990	1991--2000	2001--2010	Total
Hurricanes			5	9	32	**46**
Heat waves	1	2	6	9	8	**26**
Extreme cold			4	7	7	**18**
Volcanoes		12	2			**14**
Earthquakes		1	3	2	6	**12**
Tornadoes		1	3	5		**9**

Winter storms/snow			1	6	1	**8**
Floods			2	5		7
Drought/famine			5	1	1	7
Lightning				1	1	**2**
Wildfires					2	**2**
General			1		1	**2**
Total	**1**	**16**	**32**	**45**	**59**	**153**

Wild Mushrooms Can Kill, California Health Officer Warns

by News Desk | Nov 26, 2011

Wild, edible mushrooms are a delectable treat but California issued a warning earlier this week to people who forage for them.

Mistakes in wild mushroom identification can result in serious illness and even death, cautions Dr. Ron Chapman, director of the California Department of Public Health (CDPH) and State Public Health Officer.

"It is very difficult to distinguish which mushrooms are dangerous and which are safe to eat. Therefore, we recommend that wild mushrooms not be eaten unless they have been carefully examined and determined to be edible by a mushroom expert," Chapman said.

Wild mushroom poisoning continues to cause disease, hospitalization and death among California residents. According to the California Poison Control System (CPCS), 1,748 cases of mushroom ingestion were reported statewide in 2009-2010. Among those cases:

- Two people died.

- Ten people suffered a major health outcome, such as liver failure leading to coma and/or a liver transplant, or kidney failure requiring dialysis.

- 964 were children under six years of age. These incidents usually involved the child's eating a small amount of a mushroom growing in yards or neighborhood parks.

- 948 individuals were treated at a health care facility. • 19 were admitted to an intensive care unit.

The most serious illnesses and deaths have been linked primarily to mushrooms known to cause liver damage, including Amanita ocreata, or "destroying angel," and Amanita phalloides, also known as the "death cap," according to the California health department's warning. (Food Safety News readers have pointed out that the most common cause of non-fatal, but still serious, mushroom poisoning in the U.S. is consumption of Chlorophyllum molybdites.)

Amanita ocreata and Amanita phalloides and other poisonous mushrooms grow in some parts of California year-round, but are most commonly found during the fall, late winter or spring rainy seasons.

Eating poisonous mushrooms can cause abdominal pain, cramping, vomiting and diarrhea. Anyone developing such symptoms after eating wild mushrooms should seek immediate medical attention; the toxins can cause liver damage and death.

CPCS said people who develop abdominal symptoms after eating wild mushrooms, or their treating health care providers, should immediately contact the poison control center at 1-800-222-1222.

Local mycological societies offer educational resources about mushroom identification, and may be able to help individuals identify whether mushrooms they have picked are safe or not.

More Headlines from For Foodies »

NH Department of Health and Human Services
129 Pleasant Street – Hugh Gallen State Office Park
Concord, NH 03301

PRESS RELEASE
FOR IMMEDIATE RELEASE
August 27, 2011

CONTACT
Public Information Office
603-271-6526
Twitter: NHDHHSPIO
Facebook: NHDepartmentOfHealthAndHumanServices

DHHS Issues Warning about Accidentally Eating Poison Mushrooms

Concord, NH – The New Hampshire Department of Health and Human Services (DHHS) Division of Public Health Services (DPHS) is warning residents to be cautious when consuming wild mushrooms. In general, eating wild mushrooms is dangerous unless you are an expert. It is recommended that children not eat any wild mushrooms and adults who eat them must first ensure they are safe. Recently, there has been an increase in emergency room visits related to New Hampshire residents eating potentially poisonous mushrooms.

"This increase is concerning because in the past we have seen cases of young children and young adults ingesting wild mushrooms and fungi and becoming ill," said Public Health Director Dr. José Montero, "but now we are seeing people of all ages affected. We want to make sure everyone is aware of the dangers that wild mushrooms can cause if they are poisonous, especially because mushrooms may be more abundant now with the wet weather we have been having."

In 2009, DPHS surveillance detected 8 cases of emergency room visits due to ingesting wild mushrooms. In 2010 that number was 11. So far in 2011 there have been 31, with 18 of them occurring in September alone. "While this is just one means of tracking illness caused by mushrooms and not necessarily comprehensive," said Montero, "the increase is alarming."

There is no approved treatment for mushroom poisoning. Symptoms may not begin until hours after ingestion and can include abdominal pain, nausea, vomiting, fever, severe diarrhea, a change in heart rhythm, and low blood pressure. There are many different types of mushrooms that grow in New Hampshire, and some of them are toxic. Small amounts of wild mushrooms often cause little or no effect when swallowed. However, as little as one bit of a poisonous mushroom can cause serious injury or death. Many toxic mushrooms look a lot like non-toxic ones.

If someone tastes or eats a wild mushroom, call the Northern New England Poison Control (NNEPC) right away at **1-800-222-1222**. Trained nurses and pharmacists staff the Poison Center 24-hour helpline. For more information, visit the NNEPC website at www.mmc.org/workfiles/mmc_services/Mushroom%202-7-06.pdf.

# # #

2 discover tasty mushrooms can be dangerous

Va., Md. men treated at D.C. hospital after dining on wild fungi

BY JOE STEPHENS

With the rainy weather recently, lawns are producing bumper crops of mushrooms. And doctors at Georgetown University Hospital are offering some advice:

No matter how tempting the fungi, don't yank them out of the ground and pop them into your mouth.

Doctors offer the cautionary tale of Frank Constantinopla, 49, who after a Sept. 12 rainstorm looked in wonder at his backyard in Springfield. "Oh, there're so many mushrooms," Constantinopla recalls thinking. "They look so lovely — I'm so lucky."

Constantinopla plucked a handful and stir-fried them with noodles.

"They tasted good."

Problems set in within hours and continued for days. Constantinopla and his wife grew weak, their stomachs ached, they vomited. Two days later, Constantinopla went to an emergency room and was transferred to Georgetown University Hospital for a possible liver transplant.

Doctors broke the news: Those lovely mushrooms were Amanita phalloides, a toadstool commonly known as the Death Cap.

No federally approved treatment exists for mushroom poisoning, but doctors won permission to give Constantinopla an experimental drug made from milk thistle, a flowering plant used in holistic remedies. It seemed to do the trick. By Saturday, Constantinopla was well enough to speak at a news conference.

"I'm lucky to still be alive," he said, smiling. His wife recovered without the drug.

About a week after Constantinopla's stir-fry mishap, Walter Lantz Jr., 82, a retired farmer, snacked on some fungi plucked near his home in Frederick. On Wednesday, he also ended up at Georgetown University Hospital, where the same experimental drug, silibinin, seemed to stem the damage to his liver. Lantz remains hospitalized but is expected to recover fully.

Doctors believe that Lantz ate Amanita bisporigera, a.k.a. Destroying Angel. Hospital officials said it was rare to see two mushroom-poisoning victims within a week.

Many toadstool victims don't associate their illness with mushrooms, because symptoms are delayed and progress through three stages, experts said. The first begins six hours to a day after ingestion and may include stomach pain, nausea, vomiting and diarrhea. After a day or two, victims often see symptoms abate. But three to five days later, liver and kidney damage can lead to jaundice and coma.

Up to a third of people who eat poisonous mushrooms may die.

Constantinopla, who has yet to return to his job at a hardware store, looked robust Saturday but vowed to never eat another mushroom — store-bought or otherwise.

"Don't eat those things," he said. "They might kill you."

stephensj@washpost.com

Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: **Wild Harvested Mushrooms Committee**

COUNCIL (I, II, or III): Council I

DATE OF REPORT: December 5, 2011

SUBMITTED BY: *Chris Gordon and Lisa Roy*

COMMITTEE CHARGE(s): *The Conference recommends that the Council consider forming a committee to continue discussion of this issue and that the following language and attachments for consideration to be placed on the CFP website as guidance listing steps that states can use to develop and implement a wild harvested mushroom program for their state. The charges will be:*

(1) Develop guidelines to help regulators address the issue of wild mushrooms in food establishments
(2) Report back at the 2012 CFP.
(3) The name of the committee will be Wild Harvested Mushrooms Committee.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

- The Wild Harvested Mushroom committee was given a broad charge to 'develop guidelines to help regulators address the issue of wild mushrooms in food establishments'. However when considered in the context of the preceding paragraph, it became clear that our mission was to provide viable resources and practical options for regulatory agencies to cope with this growing problem.

  Our committee proposes five important elements of a model program that regulatory agencies can use to regulate wild harvested mushrooms at retail and foodservice establishments as follows:

  1. *Replace 'wild mushroom identification expert' term with 'approved identifier',*
  2. *Developing resources & criteria to select wild mushroom species for service or sale,*
  3. *Establish record-keeping and traceability to assure safety of wild harvested mushrooms,*
  4. *Develop a wild harvested mushroom curriculum to train 'approved identifiers', and*
  5. *Create an exam so that approved identifiers can demonstrate their competence identifying different species of mushrooms.*

  This model program will permit a variety of wild harvested mushrooms to be sold to and by these facilities. Mushroom species vary from state to state and region to region. This model provides a method for regulatory agencies to create a species list for mushrooms approved for sale. This model also provides a basis for regulatory agencies to collaborate with colleges, universities and/or mycological organizations to approve wild mushroom identifiers. Perhaps most importantly, our model provides a mechanism that regulatory agencies can use, in the event of a foodborne illness outbreak related to wild harvested mushrooms, whereby effective public health interventions including traceback and recall can be quickly and efficiently initiated.

  1. **Replace 'wild mushroom identification expert' term with 'approved identifier'.** The Committee recommends that the Food and Drug Administration remove the term 'approved mushroom identification expert' from the Food Code as it appears in § 3-201.16 and replace it with 'approved identifier', as defined below, that more specifically clarifies the meaning.

     Approved Identifier: *One who has successfully completed a required course on identification of selected species of harvested mushrooms, the appropriate harvest, storage and preparation of those species, and who has demonstrated competence by passing an exam acceptable to the Regulatory Authority.*

2. **Developing resources & criteria to select wild mushroom species for service or sale.** Jurisdictions may choose to form a jurisdictional committee to determine which fresh, wild harvested mushroom species are appropriate for commercial harvest in their state. Representatives from the following groups may be considered for membership:

    - Regulatory agencies from departments that oversee restaurants, markets and farmers' markets;
    - Local Poison Centers;
    - Local mycological organizations;
    - Restaurant Associations;
    - College or university personnel who are competent identifiers of wild mushrooms;
    - Commercial wild mushroom foragers;
    - Wild Mushroom Brokers;
    - Chefs who serve fresh wild harvested mushrooms

    Criteria to Select Wild Mushroom Species. Individual states may use the following criteria to establish a list of wild mushroom species for harvest and sale to the public. Wild mushrooms on the approved list for an **approved identifier** may be sold to or by a food establishment. Wild Mushroom Species that are:

        - currently in commerce according to foragers, chefs and dealers in the jurisdiction;
        - easily identified with field characteristics as determined by the jurisdiction;
        - common, in a specific jurisdiction as determined by the committee;
        - generally considered a low allergic reaction risk as determined by the committee;
        - consideration may be given for wild mushrooms approved for sale in other states (to be imported from those states), if accompanied by appropriate records

3. **Establish record-keeping and traceability to assure safety of wild harvested mushrooms.** In order to assure traceability, the responsibility of the **approved identifier** must be delineated. Therefore each batch of mushrooms obtained from a wild mushroom approved identifier must be accompanied by a tag or label and include the following information:
    1. Approved identifier name
    2. Address & phone number
    3. Latin binomial name and locally used common name
    4. Harvest date
    5. Harvest location (town, county, township, etc)
    6. Harvest weight
    7. Name of forager if not harvested by an approved identifier

    The responsibility of foodservice establishments and retail stores is also taken into account and all foodservice establishments and retail or wholesale stores that receive wild harvested mushrooms should retain the wild harvested mushroom tag or label and make them available, upon request by the regulatory authority. The wild harvested mushroom tags are to remain attached to the container in which the wild harvested mushrooms were received until the container is empty. The tags are to be retained for at least sixty (60) calendar days from the date the container is emptied as illness may take up to two weeks to present, two more weeks for diagnosis, and up to thirty days for epidemiological investigation and traceback. Commingling of wild harvested mushroom lots is not recommended as it serves to confound traceback investigations and hinder efforts to remove implicated product from the food chain.

4. **Develop a wild harvested mushroom curriculum to train approved identifiers.** This is to be developed and administered by the jurisdictional committee. The curriculum should include general information about the following:
    - Mushroom anatomy as it relates to identification;
    - Mushroom toxins and case histories of poisonings;
    - Specific information regarding habitat, including information on areas that are considered inappropriate for harvest (treated areas, brownfields, etc.);
    - Proper collection, including information on proper harvesting and species conservation techniques ;
    - Information on areas where harvesting is not permitted, or permitted only with permission.

    The curriculum should also include specific information about the approved species including:
    - Latin binomial and approved common name;
    - Specific characteristics required for proper identification, including differentiating characteristics of similar toxic and non-toxic species;
    - Characteristics for determining that (if) the mushroom is in good condition;
    - Information about proper storage;
    - Information about proper preparation;
    - Information about regulations that the harvester must comply with.

5. **Create an exam so that approved identifiers can demonstrate their competence identifying different species of mushrooms.** This is to be developed and administered by individuals who have demonstrated competence as (an) educators and are competent in the field identification of wild harvested mushroom species in their jurisdiction, as verified by a mycological association or other educational institution. The Regulatory Authority may choose to have the exam designed by a psychometrician or standardized by a third party authority. If these are not deemed reasonable, the Regulatory Authority may use another technique to ensure that the exam is legally defensible.

    The exam should test individuals on the information in the curriculum with special emphasis on species identification. Use of photos is highly recommended. In some cases it may be appropriate to include a lab practicum with fresh samples of the approved species and their similar species to test identification skills. The passing score is to be determined by the Regulatory Authority. For the purposes of this recommendation, the ***trainer*** is defined as an individual who has demonstrated competence as an educator, competence in the field identification of wild mushroom species, and whose competence has been verified by a mycological association or educational institution recognized by the regulatory agency. Examples of organizations are North American Mycological Association (NAMA), Cooperative Extensions, Mycological Society of America, local or regional mycological associations, schools, colleges and universities. An advanced degree in Mycology does not necessarily qualify an individual as an approved trainer in the field identification of mushroom species.

6. **The Wild Harvested Mushroom Committee also recommends the committee be re-created** and charged to continue to working to "develop guidelines to help regulators address the issue of wild mushrooms in food establishments".
        - Committee to work with FDA to develop issues to be placed in FDA Food Code.
        - Committee to work on combining issues that are placed on CFP website into one document.
        - Refine educational curriculum and exam components.
        - Report back to CFP in 2014.

REQUESTED ACTION:

- The Wild Harvested Mushroom Committee will submit seven (7) issues at the Conference based on the recommendation of the committee.
    - Issue 1: Report-Wild Harvested Mushroom Committee
        - The issue will request the committee's report be acknowledged and that committee members be thanked.
        - Content Document: Wild Harvested Mushroom Committee Final Report
        - Supporting Attachments:
            - Wild Harvested Mushroom Committee List
            - CDC MMWR wild mushrooms report 2011
            - Food Safety News—California wild mushroom statement
            - New Hampshire statement on wild mushrooms
            - Washington Post article on consumption
    - Issue 2: Redefine 'approved mushroom identification expert' with **approved identifier**
        - Provides replacement term and definition for existing language
    - Issue 3: Resources and Criteria to Select Species of Wild Harvested Mushrooms
        - Outlines options that regulatory authorities can use to work with stakeholders to identify safe sources of wild harvested mushrooms
    - Issue 4: Wild Harvested Mushroom Recordkeeping and Traceability
        - Outlines options that regulatory authority and industry can use to maintain records of wild harvested mushrooms and respond in the event of illness or outbreak
    - Issue 5: Wild Harvested Mushroom Curriculum
        - Outlines minimum curriculum requirements for training approved identifiers
    - Issue 6: Wild Harvested Mushroom Exam
        - Outlines process for developing minimum exam contents for demonstration of knowledge
    - Issue 7: Re-create Wild Harvested Mushroom Committee
        - Outlines charges to develop guidelines to help regulators address the issue of wild mushrooms in food establishments

- Additionally, the committee would like to recognize all its members and thank them for their services:

Frederick Angulo US CDC Chamblee, GA	Robert Brown Whole Foods Market Austin, TX	Christine Cox Montana Dept. of HHS Helena, MT
Kevin Dreesman Illinois Dept. of Health Springfield, IL	Chris Gordon Virginia Dept. of Health Richmond, VA	Andrew Harris Summit County Health District Stow, OH
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COMMITTEE MEMBER ROSTER:

- The member roster is presented as an attachment to this report.

Conference for Food Protection
2012 Issue Form

Internal Number: 062
Issue: 2012 I-007

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

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Title:
Redefine "approved mushroom identification expert" in Food Code § 3-201.16

Issue you would like the Conference to consider:
By its own admission § 3-201.16 in Annex 3 of the 2009 FDA Food Code identifies that "regulatory authorities have expressed their difficulty in determining what constitutes a "wild mushroom identification expert" and enforcing the Food Code provisions associated with it." An attempt was made in 1998 by a Conference for Food Protection committee to more precisely provide guidance, however they were unable to provide the information in a useful way for stakeholders. Following two reported wild mushroom poisonings linked to exposure at food establishments in 2008 in Maine, the Health Inspection Program brought forward a proposal to the 2010 Conference for Food Protection (2010 Issue I-08) to overhaul § 3-201.16, but instead a committee was again charged to 'develop guidelines to help regulators address the issue of wild mushrooms in food establishments'.
Since 1993, this section has required an 'expert' to identify wild mushrooms. However after nineteen years, regulators are still having 'difficulty' identifying what an 'expert' is or how to evaluate one. Instead of documenting 'difficulty' with this section as described in Annex 3, this issue proposes a way forward to remove the challenges associated with this term to provide clarity for all stakeholders.

Public Health Significance:
Following the guidance set forth in the Food and Drug Administration's model Food Code, regulations in many jurisdictions require that wild harvested mushrooms sold to the public be identified by "an approved mushroom identification expert". However, the criteria for becoming an approved identifier are not identified or well established. The Food Code recommends that all food served to the public must come from safe sources. The Food Code stipulates that mushrooms species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert, but does not establish what constitutes the basis for approval of an identification expert. Some jurisdictions require the identification expert to be someone who has successfully completed an identification course provided either by a college, university or mycological society. Due to the lack of established criteria and recognized training courses, eleven states have now entirely prohibited the sale of wild

harvested mushrooms. Other states have a limited program to allow specific species to be sold.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting that Section 3-201.16 of the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows: (new language in underline format, language to be removed in strike-through)
1) remove the term 'approved mushroom identification expert' from Section 3-201.16 (A) and replace it with the term 'approved mushroom identifier' as noted below.
(A) Except as specified in ¶ (B) of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an APPROVED mushroom identifier ~~identification expert~~. P
2) include the definition noted below regarding an approved mushroom identifier.
Approved Mushroom Identifier: *One who has successfully completed a required course on identification of selected species of harvested mushrooms, the appropriate harvest, storage and preparation of those species; and who has demonstrated competence by passing an exam acceptable to the regulatory authority.*

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 058
Issue: 2012 I-008

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

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Title:
Resources and Criteria to Select Wild Mushroom Species

Issue you would like the Conference to consider:
This issue describes two of the five important elements of a model wild harvested mushroom program, which will permit a variety of wild harvested mushrooms to be sold to and by retail and foodservice establishments. Mushroom species vary from state to state and region to region. The recommended solution provides a method for jurisdictions to create a species list for mushrooms approved for sale or service. This will also provide a basis for regulatory agencies to collaborate with colleges, universities and/or local mycological organizations to approve wild mushroom identifiers.

Public Health Significance:
The trade of wild harvested mushrooms is an established and rapidly growing industry that impacts consumers through wholesale, retail and restaurant services. The inability of Regulatory Authorities to effectively regulate and approve individuals as competent to identify mushrooms fosters the back door trading of wild harvested mushrooms and poses a threat to the consumer population through the potential ingestion of mushrooms that have been misidentified.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that Annex 3 Section 3-201.16 of the 2009 Food Code (as modified by the Supplement issued in 2011) be amended to include the information noted below regarding recommended resources and criteria to select wild mushroom species. (new language in underline format).

Recommended Committee Resources

A regulatory authority may choose to form a committee to determine which fresh, wild harvested mushroom species are appropriate for commercial harvest in their state. Representatives from the following groups may be considered for membership:

- Regulatory agencies from departments that oversee restaurants, markets and farmers' market;
- Local Poison Centers;
- Local mycological organizations;
- Restaurant Associations;

- College or university personnel who are competent identifiers of wild mushrooms;
- Commercial wild mushroom foragers;
- Wild Mushroom Brokers;
- Chefs who serve fresh wild harvested mushrooms

Criteria to Select Wild Mushroom Species

Individual regulatory authorities may use the following criteria to establish a list of wild mushroom species for harvest and sale to the public. Wild mushrooms on the approved list for an approved mushroom identifier may be sold to or by a food establishment. Wild Mushroom Species that are:

- currently in commerce according to foragers, chefs and dealers in the jurisdiction;
- easily identified with field characteristics as determined by the jurisdiction;
- common, in a specific jurisdiction as determined by the committee;
- generally considered a low allergic reaction risk as determined by the committee;
- consideration may be given for wild mushrooms approved for sale in other states (to be imported from those states), if accompanied by appropriate records.

The Conference also recommends that the above language be incorporated into a single Wild Harvested Mushroom Guidance Document and posted on the CFP website so that state and local jurisdictions can use this information to develop and implement their own wild harvested mushroom program.

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Conference for Food Protection
2012 Issue Form

Internal Number: 059
Issue: 2012 I-009

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

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Title:
Wild Harvested Mushroom Record-Keeping and Traceability

Issue you would like the Conference to consider:
From 1960-2010, the CDC's *Morbidity and Mortality Weekly Report* documented at least twenty-four reports attributed to environmental health-related mushroom and plant poisoning (Henry Falk, 2011). More recently, the California Department of Public Health (CDPH) reported that 1,748 cases of mushroom ingestion were reported for 2009-2010 where two people died and ten others suffered major health consequences including liver failure or kidney dialysis (Food Safety News, 2011). Following heavy rains from a hurricane and tropical storm that affected the US east coast this past fall, the New Hampshire Department of Health and Human Services (Services, 2011) issued a warning regarding consumption of wild mushrooms and the Washington Post (Stephens, 2011) featured an article where two men went into liver failure after consuming wild mushrooms that were more abundant due to the wet weather. While the majority of these cases document recreational exposure as compared with food establishment exposure, these incidents of wild mushroom ingestion highlight the effects of foodborne intoxication and illness that follow. Along with this cautionary information, it is important to acknowledge that wild mushrooms can also be a healthy, edible source of nutritious food provided they are from a safe source. Unfortunately, the admitted "difficulty" that regulatory agencies have found when relying on the guidance provided by the FDA model Food Code (*hereafter model Food Code*) to define "approved wild mushroom identification expert" to assure safe sources has left regulators without sufficient avenues to address the issue of wild harvested mushrooms at retail and foodservice establishments (2009 FDA Food Code, Annex 3, Section 3-201.16). In fact, eleven states have gone on to ban the sale or service of wild harvested mushrooms at restaurants and farmers markets due to the lack of clearly identified safe sources from 'approved wild mushroom identification experts'.
This issue seeks to provide regulatory authorities with a mechanism for initiating prompt tracebacks or recalls if wild harvested mushrooms are implicated in a foodborne illness or outbreak following ingestion at a foodservice establishment or retail.
Sources:
Henry Falk, M. (2011). Environmental Health in MMWR-1961-2010. *Morbidity and Mortality Weekly Report* , 86-96.

Newsdesk. (2011, November 26). Wild Mushrooms Can Kill, California Health Officer Warns. *Food Safety News* .
Services, N. H. (2011, August 27). DHSS Issues Warning About Accidentally Eating Poison Mushrooms. Concord, New Hampshire.
Stephens, J. (2011, September 18). 2 Discover Tasty Mushrooms Can Be Dangerous. *Washington Post* . Washington, DC.

Public Health Significance:
In the event of a foodborne illness or outbreak related to wild harvested mushrooms, regulatory authorities that are responsible for assuring food safety must be able to conduct traceback investigations for implicated foods or initiate recalls as required. Additionally, food service operations and retail stores must have the ability to quickly segregate and remove implicated foods from sale or use.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be modified by placing into Annex 3, Section 201.16 guidelines indicated below for wild harvested mushroom recordkeeping and tracebacks (new language in underline format).
In order to assure traceability, the responsibility of the approved mushroom identifier must be delineated. Therefore each batch of mushrooms obtained from a wild mushroom approved identifier must be accompanied by a tag or label and include the following information:

1. Approved identifier name;
2. Address & phone number;
3. Latin binomial name and locally used common name;
4. Harvest date;
5. Harvest location (town, county, township, etc);
6. Harvest weight;
7. Name of forager if not harvested by an approved identifier;

All foodservice establishments and retail or wholesale stores that receive wild harvested mushrooms should retain the wild harvested mushroom tag or label and make them available upon request by the regulatory authority. The wild harvested mushroom tags are to remain attached to the container in which the wild harvested mushrooms were received until the container is empty. The tags are to be retained for at least sixty (60) calendar days from the date the container is emptied as illness may take up to two (2) weeks to present, two (2) more weeks for diagnosis, and up to thirty (30) days for epidemiological investigation and traceback. Commingling of wild harvested mushroom lots is not recommended as it serves to confound traceback investigations and hinder efforts to remove implicated product from the food chain.
The Conference also recommends that the above language be incorporated into a single Wild Harvested Mushroom Guidance Document and posted on the CFP website so that state and local jurisdictions can use this information to develop and implement their own wild harvested mushroom program.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 060
Issue: 2012 I-010

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

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Title:
Wild Harvested Mushroom Curriculum

Issue you would like the Conference to consider:
This issue describes one of the five important elements of a model wild harvested mushroom program, which will permit a variety of wild harvested mushrooms to be sold to and by retail and foodservice establishments.
The FDA Food Code specifies that mushrooms species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert, but does not establish what constitutes the basis for approval of an identification expert. Due to the lack of established criteria and recognized training courses the best way to protect public health is to provide education and training which includes a curriculum on how to safely and properly identify wild harvested mushrooms.

Public Health Significance:
The trade of wild harvested mushrooms is an established and rapidly growing industry that impacts consumers through wholesale, retail and restaurant services. The inability of regulatory authorities to effectively regulate and approve individuals as competent to identify mushrooms fosters the back door trading of wild harvested mushrooms and poses a threat to the consumer population through the potential ingestion of mushrooms that have been misidentified.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that Annex 3 Section 3-201.16 of the 2009 Food Code (as modified by the Supplement issued in 2011) be amended to include the information noted below regarding Curriculum for the Approved Mushroom Identifier (new language in underline format).
<u>Curriculum for the Approved Mushroom Identifier this is to be developed and administered by the committee established by the regulatory authority. The curriculum should include general information about the following:</u>

- <u>Mushroom anatomy as it relates to identification;</u>
- <u>Mushroom toxins and case histories of poisonings;</u>

- Specific information regarding habitat, including information on areas that are considered inappropriate for harvest (treated areas, brownfields, etc.);
- Proper collection, including information on proper harvesting and species conservation techniques; and
- Information on areas where harvesting is not permitted, or permitted only with permission.

The curriculum should also include specific information about the approved species including:

- Latin binomial and approved common name;
- Specific characteristics required for proper identification, including differentiating characteristics of similar toxic and non-toxic species;
- Characteristics for determining that (if) the mushroom is in good condition;
- Information about proper storage;
- Information about proper preparation; and
- Information about regulations that the harvester must comply with.

The Conference also recommends that the above language be incorporated into a single Wild Harvested Mushroom Guidance Document and posted on the CFP website so that state and local jurisdictions can use this information to develop and implement their own wild harvested mushroom program.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 061
Issue: 2012 I-011

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

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Title:
Wild Harvested Mushroom Exam

Issue you would like the Conference to consider:
This issue describes one of the five important elements of a model wild harvested mushroom program, which will permit a variety of wild harvested mushrooms to be sold to and by retail and foodservice establishments.
The FDA Food Code specifies that mushrooms species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert, but does not establish what constitutes the basis for approval of an identification expert. Due to the lack of established criteria and recognized training courses, the best way to protect public health is to provide education and training including an exam to demonstrate knowledge on how to safely and properly identify wild harvested mushrooms.

Public Health Significance:
The trade of wild harvested mushrooms is an established and rapidly growing industry that impacts consumers through wholesale, retail and restaurant services. The inability of Regulatory Authorities to effectively regulate and approve individuals as competent to identify mushrooms fosters the back door trading of wild harvested mushrooms and poses a threat to the consumer population through the potential ingestion of mushrooms that have been misidentified.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that Annex 3 Section 3-201.16 of the 2009 Food Code (as modified by the Supplement issued in 2011) be amended to include the information noted below regarding a Wild Harvested Mushroom Exam.
Exam for the Approved Mushroom Identifier
This is to be developed and administered by individuals who have demonstrated competence as a trainer and are competent in the field identification of wild harvested mushroom species in their jurisdiction, as verified by a mycological association or other educational institution. The regulatory authority may choose to have the exam designed by a psychometrician or standardized by a third party authority. If these are not deemed

reasonable, the regulatory authority may use another technique to ensure that the exam is legally defensible.

The exam should test individuals on the information in the curriculum with special emphasis on species identification. Use of photos is highly recommended. In some cases it may be appropriate to include a lab practicum with fresh samples of the approved species and their similar species to test identification skills. The passing score is to be determined by the regulatory authority.

For the purposes of this recommendation, the ***trainer*** is defined as an individual who has demonstrated competence as an educator, competence in the field identification of wild mushroom species, and whose competence has been verified by a mycological association or educational institution recognized by the regulatory agency. Examples of organizations are North American Mycological Association (NAMA), Cooperative Extensions, Mycological Society of America, local or regional mycological associations, schools, colleges and universities. An advanced degree in Mycology does not necessarily qualify an individual as an approved trainer in the field identification of mushroom species.

The Conference also recommends that the above language be incorporated into a single Wild Harvested Mushroom Guidance Document and posted on the CFP website so that state and local jurisdictions can use this information to develop and implement their own wild harvested mushroom program.

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Conference for Food Protection
2012 Issue Form

Internal Number: 015
Issue: 2012 I-012

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

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Title:
Re-create Wild Harvested Mushroom Committee

Issue you would like the Conference to consider:
Due to public health food safety concerns, regulatory agencies in many jurisdictions follow the lead of the US FDA model Food Code (*hereafter model Food* Code) in requiring that wild harvested mushrooms sold to the public be identified by "an approved mushroom identification expert" (2009 model Food Code, *Section 3-201.16*). However, the pathway both for becoming an "approved mushroom identification expert" and having a regulatory agency recognize one are not well established or defined. The model Food Code recommends that all food served to the public must come from safe sources. The model Food Code further stipulates that mushrooms species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert. However the model Food Code does not establish what constitutes the basis for approval of an identification expert. Due to the lack of established criteria and recognized training courses, some regulatory jurisdictions entirely prohibit the sale of wild harvested mushrooms. Other states have a limited program to allow specific species to be sold.

Public Health Significance:
Continuing the work of the Wild Harvested Mushroom Committee will assure that the committee's charge, issued in 2010 to "develop guidelines to help regulators address the issue of wild mushrooms in food establishments", is fully realized. Only when state and local regulators, who currently do not have clear way forward to address this issue, are able to assure the safety of wild mushrooms in food establishments will the work of the committee be complete.

Recommended Solution: The Conference recommends...:
re-creating the Wild Harvested Mushroom Committee for the next biennium with the following charges:

1. develop guidelines to help regulators address the issue of wild mushrooms in food establishments.
2. report back its findings and recommendations to the 2014 CFP Biennial Meeting.

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Conference for Food Protection
2012 Issue Form

Internal Number: 117
Issue: 2012 I-013

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

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Title:
HACCP-based Guidance for Meat and Poultry Processing at Retail

Issue you would like the Conference to consider:
The Food Safety and Inspection Service (FSIS), in collaboration with the Association of Food and Drug Officials (AFDO), is seeking input on comprehensive Hazard Analysis Critical Control Points (HACCP) guidance materials under development to assist in providing a uniform standard available for all regulatory jurisdictions to control meat and poultry processing activities at retail when a variance is required. This guidance is intended for developing or reviewing HACCP plans for multifaceted processing activities at retail (i.e., smoked, cured, fermented, jerky). Guidance materials previously developed by the Minnesota Department of Agriculture (DOA) are being further developed by FSIS and AFDO into comprehensive HACCP guidance materials to assist all regulatory jurisdictions in complying with FDA Food Code variance requirements.
[i] FSIS and AFDO jointly recommend that a Committee be formed so that input can be received from a wide variety of backgrounds on the guidance under development. By forming a Committee, this would ensure that this guidance provides acceptable, ready-to-use materials available to all regulatory jurisdictions to strengthen their control of meat and poultry processing at retail by utilizing HACCP-based guidance to meet variance requirements. Also, by forming a Committee, this will assure that input is received from a wide variety of backgrounds so that the guidance under development provides suitable guidance materials to control meat and poultry processing activities at retail when a variance is required.
[i] Minnesota Department of Agriculture. *Model HACCP Plans*, and *A Retail Food Establishment Guide for Developing a HACCP Plan*. Links are found at:
https://docs.google.com/open?id=0ByXV4y__bb1JMmQ3ZTFhODAtNzk0MC00MDExLTk5NTktYTgyMTA3NWUzNTk3
https://docs.google.com/open?id=0ByXV4y__bb1JNDM0NmQ4ZTEtNmYxNy00NzZhLTk1NTgtM2RjM2E3OTEzOTQ3

Public Health Significance:
Some retail processing activities under the Food Code (as per § 3-502.11 Variance Requirement), including much of the meat and poultry processing, would require a variance based on a HACCP plan. However, relatively few state and local jurisdictions have

procedures in place requiring that retailers have variances based on HACCP plans. FSIS believes that more guidance is needed on the preparation of HACCP Plans and HACCP-based variance requirements for multifaceted processing activities (i.e., smoked, cured, fermented, jerky), and currently available guidance is inadequate. In developing HACCP plans for meat and poultry processes, retail establishments must consider all possible hazards in accordance with Title 9 CFR 417.2 Hazard Analysis and Critical Control Point (HACCP) Systems.[i] Part 417.2 addresses pathogens of public health concern. Retail establishments are important settings for foodborne-disease outbreaks. If retail establishments do not address pathogen reduction in their HACCP plans, adulterated product may be released into commerce.

In accordance with the preface of the Food Code under "Advantages of Uniform Standards," a retail establishment may be granted a variance from their regulatory jurisdiction to use a specific federal food safety performance standard for a product or a process instead of compliance with applicable provisions in the Food Code. To show compliance with the federal performance standard, however, the retail establishment must demonstrate that processing controls are in place to ensure that the standard is being met similar to a federally inspected establishment. Therefore, a retail establishment's request for a variance based on a federal performance standard must be supported by a validated HACCP plan with record keeping and documented verification being made available to their regulatory jurisdiction.

All regulatory jurisdictions can strengthen their control of meat and poultry processing at retail by utilizing HACCP-based variance requirements if there were available ready-to-use guidance materials on how to accomplish this. While state and local jurisdictions would be the primary audience, such guidance can also be used by retailers to assist in developing their HACCP plans, as they would be able to learn what would be the expectations of their regulators. By forming a Committee, this will assure that input is received from a wide variety of backgrounds so that the guidance under development provides suitable guidance materials to control meat and poultry processing activities at retail when a variance is required.

[ii] Lynch, M., J. Painter, R. Woodruff, and C. Braden. 2006. Centers for Disease Control and Prevention. Surveillance for foodborne-disease outbreaks-United States, 1998-2002. MMWR Surveill. Summ. 55(SS10):1-42. Found at: http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5510a1.htm

Recommended Solution: The Conference recommends...:

1. That a Committee be established to:

(a) provide input on comprehensive Hazard Analysis Critical Control Point (HACCP) guidance materials under development by the Food Safety and Inspection Service (FSIS), in collaboration with the Association of Food And Drug Officials (AFDO),

(b) to assist in providing a uniform standard available for all regulatory jurisdictions in the evaluation of variance requests involving the processing of meat and poultry at retail, and

(c) to better control meat and poultry processing activities at retail, utilizing the attached guidance materials that are being further developed by FSIS and AFDO, *Model HACCP Plans for Retail Processing*, and *A Retail Food Establishment Guide for Developing a HACCP Plan - Meeting the Requirements of the FDA Food Code Variance in the Relation to Specialized Meat and Poultry Processing Methods*),

(d) report back to the 2014 Biennial Meeting.

2. That the Conference send a letter to FDA asking that they consider if and how these guidance materials, once finalized, can best be incorporated into:
(a) FDA Food Code Annex 2 (References, Part 3 - Supportive Documents);
(b) FDA Food Code Annex 4 (Management of Food Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors), and
(c) FDA's two HACCP Manual "Managing Food Safety ; A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments," and "Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems")

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Attachments:

- "HACCP Development for Retail Processing_1"
- "HACCP Development for Retail Processing_2"
- "HACCP Development for Retail Processing_3"
- "HACCP Development for Retail Processing_4"
- "HACCP Development for Retail Processing_5"

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A RETAIL FOOD ESTABLISHMENT GUIDE FOR DEVELOPING A HACCP PLAN

Meeting the Requirements of the FDA Food Code Variance in Relation to Specialized Meat and Poultry Processing Methods

Table of Contents

Section 1: Introduction to Food Safety Systems

About HACCP

What is HACCP?

The ***H***azard ***A***nalysis ***C***ritical ***C***ontrol ***P***oint system is a preventative system for assuring the safe production of food products. It is based on a common sense application of technical and scientific principles to a food production process.

The most basic concept underlying HACCP is that of prevention. The food processor/handler should have sufficient information concerning the food and the related procedures they are using, so they will be able to identify where a food safety problem may occur and how it will occur. If the 'where' and 'how' are known, prevention becomes easy and obvious, and finished product inspection and testing becomes needless. The HACCP program deals with control of factors affecting the ingredients, product and process. The objective is to make the product safely, and be able to prove that the product has been made safely. The where and how are the HA (Hazard Analysis) part of HACCP. The proof of the control of the processes and conditions is the CCP (Critical Control Point) part. Flowing from this basic concept, HACCP is simply a methodical and systematic application of the appropriate science and technology to plan, control and document the safe production of foods.

HACCP is not the only method in ensuring that safe food products are manufactured. The plan will be successful when other procedures are in place such as sanitation standard operating procedures (SSOP's) and by using good manufacturing practices (GMP's). Although the Food Code does not require them, these programs are fundamental in the development of a successful HACCP plan. SSOP's should include personal hygiene practices as well as daily sanitation of the food contact surfaces and equipment. Good sanitation practices are the foundation of manufacturing and preparing safe food.

HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution, and consumption of the finished product. For successful implementation of an HACCP plan, management must be strongly committed to the HACCP concept. A firm committed to HACCP by top management, provides company employees with the sense of importance of producing safe food.

HACCP Requirements in the Food Code

The Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service. One of the provisions of the Food Code is for retail food establishments that conduct certain food processes or operations to operate under a HACCP plan.

Retail Processes or Operations that Require a HACCP Plan:

1. Smoking or curing food, except for smoking done for the purpose of imparting flavor only, and not as a part of the part of the cooking process.
2. Using food additives or adding components, including vinegar, as a method to preserve food (rather than to enhance its flavor) or change food into a non-potentially hazardous food.
3. Using a reduced oxygen method of packaging food.
4. Food Establishments that apply for a variance to:
    - Use more than one tagged shellstock container at a time.
    - Deviate from required cooking times and temperatures for raw animal foods.
    - Use molluscan shellfish life support system display tanks to store and display shellfish that are offered for sale.

Additional Requirements

While the process of developing a HACCP plan is a rather universal one, there are some additional components that need to be included as part of the firm's HACCP plan. Section 4 provides details on the additional requirements such as standard operating procedures, duties of the person in charge. HACCP plans that cover reduced oxygen packaging operations must include several additional pieces of information.

Definitions:

CP Decision Tree: *A sequence of questions to assist in determining whether a control point is a CCP.*

Continuous Monitoring: *Uninterrupted collection and recording of data such as temperature on a strip chart, or a continuous recording thermometer*.

Control: *(a) To manage the conditions of an operation to maintain compliance with established criteria. (b) The state where correct procedures are being followed and criteria are being met.*

Control Measure: *Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.*

Control Point: *Any step at which biological, chemical, or physical factors can be controlled.*
Corrective Action: *Procedures followed when a deviation occurs.*

Criterion: *A requirement on which a judgment or decision can be based.*

Critical Control Point (CCP): *A point, step or procedure at which control can be applied and is essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level.*

Critical Defect: *A deviation at a CCP which may result in a hazard.*

Critical Limit: *A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.*

Deviation: *Failure to meet a critical limit.*

Food Code: *Minnesota Rules 4626*

HACCP: *A systematic approach to identification, evaluation, and control of food safety hazards.*

HACCP Plan: *The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of specific process or procedure.*

HACCP System: *The result of the implementation of the HACCP Plan procedures to be followed.*

HACCP Team: *The group of people who are responsible for developing, implementing and maintaining the HACCP system.*

Hazard: *A biological, chemical, or physical agent that is reasonably likely to cause a food to be unsafe for consumption.*

Hazard Analysis: *The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.*

Monitor: *To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.*

Prerequisite Programs: *Procedures, including Good Manufacturing Practices that address operational conditions providing the foundation for the HACCP system.*

Preventative Measure: *Physical, chemical, or other factors that can be used to control an identified health hazard.*

Sensitive Ingredient: *An ingredient known to have been associated with a hazard for which there is a reason for concern.*

Severity: *The seriousness of the effect(s) of a hazard.*

Step: *A point, procedure, operation or stage in the food system from primarily production to final consumption.*

Validation: *That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.*

Verification: *Those activities such as methods, procedures, or tests in addition to monitoring, that determines if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.*

An Introduction to Preliminary Steps

The development of a HACCP plan is a logical step-by-step process. Each step builds on the information gathered from the previous step. The process works better if you take some preliminary steps. You may wish to use the example forms located in Section 5 or you may want to create your own forms.

1. ***Assemble the HACCP Team***
   The first thing that must be done is to bring together individuals in your facility that has a working knowledge of the various processing steps and operations in your facility. This group will be your "HACCP team." It is understood that in some smaller establishments, the 'team' may be very small and may even consist of one person - the owner/operator.

2. ***Identify Products/Foods/Processes that must be covered by the HACCP plan***
   Next, the HACCP team should write a categorization of the types of potentially hazardous foods that are covered. Foods and processes with similar characteristics can be grouped together.

3. ***Develop a List of Ingredients, materials, equipment and recipes/formulations.***
   The third step is for the team to thoroughly review each product and write down all of the ingredients, materials, and equipment used in the preparation of a food and also to write down formulations or recipes that show methods and control measures that address the food safety concerns involved.

4. ***Develop a Process Flow Diagram***
   At the fourth step, the HACCP team will draw a flow diagram that shows all the steps in the production process (everything from receiving through distribution.)

5. ***Verify the Process Flow Diagram***
   The final step is to take this flow diagram and verify its accuracy. The HACCP team can do this by having an impartial person do a "walk-through" of the entire production process, checking to see if there is anything missing from the diagram. This should be done by someone who knows, or is familiar with the production process.

An Introduction to the 7 HACCP Steps

Principle 1: Conduct a Hazard Analysis

The hazard analysis looks at different factors that could affect the safety of your product. This analysis is done for each step in your production process. It's important to remember that you are dealing with *safety, not quality* issues.

The hazard analysis is actually completed in two stages. The first stage identifies food safety hazards that are present in your process. The second stage evaluates these food safety hazards as to whether they are *"reasonably likely to occur."* If the HACCP team decides that a food safety hazard is likely to occur, then they need to find and list any preventive measures that could be used to control those food safety hazards. Preventive measures are defined as: *"Physical, chemical, or other means that can be used to control an identified food safety hazard."*

INGREDIENT RELATED HAZARDS: *As you evaluate the hazards in your process, don't forget about ingredient related hazards. Everything that goes into your product needs to be evaluated. Ingredient specifications, provided by your supplier, should give you details on the materials/ingredients being sold, including statements that the materials/ingredients are of food grade and are free of harmful components.*

For example, *the ingredient specification for dried legumes (beans) might state that there will be fewer that 5 small rocks or stones per ten pound bag and that no harmful pesticides were used* in the growing process.

Principle 2: Identify Critical Control Points (CCP's)

A critical control point is defined as "A point, step or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

The HACCP team uses the list of food safety hazards and preventative measures they developed during the previous hazard analysis step to determine their critical control points. CCP's may include, but are not limited to:

- Chilling or freezing
- Cooking
- Certain processing procedures; smoking, curing, acidification

Steps that are CCP's in one facility may or may not be CCP's in your facility. When making a HACCP plan, each facility must look at the unique conditions present in that facility.

Principle 3: Establish Critical Limits for Each CCP

A critical limit is defined as "The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." Critical limits serve as boundaries of safety for each CCP. Often they are a numerical value (whether that is temperature, pH, etc.) that must be reached to assure that a food safety hazard has been controlled.

[A note about Critical Limits -- When your HACCP team establishes critical limits for your specific facility, know that those limits may never be less strict than the current regulatory standards.]

Principle 4: Establish CCP Monitoring Procedures

Monitoring is a fundamental part of any HACCP system. It consists of observations or measurements that check to see that your CCP's are operating under control.

Monitoring serves three main purposes:

First, it tells you when there's a problem at a CCP, and control has been temporarily lost. (This allows you to take corrective actions right away.)

Second, it tracks the system's operation and can help identify dangerous trends that could lead to a loss of control. (This allows you to take preventive action to bring the process back into control before it goes beyond the critical limits.)

Third, it provides written documentation of your compliance with the HACCP regulation. (This information can be used to confirm that your HACCP plan is in place and working right.) For each CCP the HACCP team will need to define the monitoring procedure and its frequency (hourly, daily, weekly, etc.) that best tracks that CCP. It's also important to thoroughly train the employee(s) that will be responsible for each monitoring procedure and frequency.

Monitoring Requires Precision

Monitoring a CCP is a big responsibility. Employees must be properly trained and need to understand the reasons for careful monitoring procedures.

Specify in your monitoring procedures, every important detail about...

- Who will do the monitoring
- What is being monitored
- When it is done, and
- How it is done

For example, when taking the temperature of a piece of meat, be specific as to where you took the temperature. Remember that all records and documents associated with a CCP's monitoring should be dated and signed or initialed by the person doing the monitoring and the results recorded.

Principle 5: Establish Corrective Actions

Corrective actions are defined as *"Procedures to be followed when a deviation occurs."* A deviation is defined as a *"failure to meet a critical limit."* Corrective actions are taken when monitoring shows you that a food safety hazard has gotten out of control at a CCP.

The best way to handle deviations is to have a plan of action already in place. In general, corrective action plans are used for:

1. Determining the disposition of non-complying product;
2. Correcting the cause of the non-compliance to prevent a recurrence; and
3. Demonstrating that the CCP is once again under control (this means examining the process or product again at the CCP and getting results that are within the critical limits).

As with the monitoring procedures, specific corrective action procedures must be developed for each CCP.

Principle 6: Establish Recordkeeping Procedures

Record keeping procedures are important in making and keeping an HACCP system effective. Every time monitoring procedures are done, corrective actions are taken, or production equipment is serviced, a detailed record of that activity is made. This continual recording of this information allows you to keep track of everything that goes on in your facility.

You can think of HACCP records in two ways, development forms and day-to-day "working" logs. The development forms are all of the supporting documentation that go into building your first HACCP plan. The "working" logs are the sheets of paper where you collect the details of what happen on the production floor. You may wish to use the example forms located in Section 5, or you may wish to create your own forms.

Generally, the records kept in the total HACCP system include the following:

- The HACCP plan itself and all supporting documentation.
- Records (including product codes) documenting the day-to-day functioning of the HACCP system such as daily monitoring logs, deviation/corrective action logs, and verification logs.

Principle 7: Establish Verification Procedures

Every establishment should validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and should verify that the plan is being effectively implemented.

1. ***Initial validation.*** Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP'S, critical limits, monitoring and record keeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

2. ***Ongoing verification activities.*** Ongoing verification activities include, but are not limited to:
    - The calibration of process-monitoring instruments
    - Direct observations of monitoring activities and corrective actions; and
    - The review of records.

3. ***Reassessment of the HACCP plan.*** Every establishment should reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; processing methods or systems; production volume; personnel; packaging: product distribution systems; or, the intended use or consumers of the finished product. One reassessment should be performed by an individual trained in HACCP principles. The HACCP plan should be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of the Food Code.

4. ***Reassessment of the hazard analysis.*** Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur should reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to changes in: raw materials or source of raw materials; product formulation; processing methods or systems; production volume; packaging; finished product distribution systems or the intended use or consumers of the finished product.

Verification procedures help makes the HACCP plan work correctly.

Section 2: The Preliminary Steps

Introduction

Now that you have a general understanding of HACCP, let's get down to the specifics. Developing a HACCP plan starts with the collection of important information. This fact-finding process is called the Preliminary Steps.

They are:

1. Assemble the HACCP team.
2. Identify Products and Processes
3. Develop a complete list of ingredients, raw materials, equipment, recipes and formulations.
4. Develop a process flow diagram that completely describes your purpose.
5. Verify the process flow diagram.

In order to show you how an HACCP plan is put together, we are going to show you examples of filled-out HACCP development forms. The thought of filling out all these forms can be a bit overwhelming at first; however, it is a straightforward process. We are going to be using an "Example Facility" to show you what each one of these forms might look like when completed.

Step 1: Assemble the HACCP Team

YOUR FIRST TASK in developing a HACCP plan is to assemble your HACCP team. The HACCP team consists of individual(s) who will gather the necessary information for your HACCP plan.

The HACCP team needs to be aware of the following:

- Your product/process
- Any food safety programs you already have
- Food safety hazards of concern
- The seven principles of HACCP

In a very small facility, perhaps only one individual is available to be on the HACCP team. This is perfectly acceptable; however, you can get help from as many people as you need to make the team function effectively.

The HACCP team will begin by collecting scientific data. Remember, the team isn't limited to internal resources. If needed, outside expertise may be available through regulatory agencies, state extension offices, trade or professional associations, consultants, universities and libraries.

However you decide to approach it, your HACCP team is ultimately responsible for building your HACCP plan.

Working with the "HACCP Team" Form

The Example Facility has six HACCP team members. One of whom is not only the general manager, but is also the owner. It is important to list all the team members and to state clearly what their HACCP team role is. (As you might think, filling out this form is relatively simple.) **Don't forget to sign and date the form.**

[**A note about the forms:** As with all HACCP forms and logs, the person who is responsible for an activity (whether it be drafting the forms, or doing the monitoring) should be the one who signs and dates the form or log.]

Step 1
HACCP Team Form

Team Members	Role
Cindy Jones	General Manager
Mary Weston	Quality Control
Mark Baker	Wet Room Supervisor
Susan Smith	Packing Supervisor
Joe Jones	Extension Service
Pam Smith	Local Microbiologist

Developed by: Cindy Jones *Date* 12/10/98

Step 2: Identify Products/Processes to be Covered

NEXT, make a complete listing of all the products and processes that must be covered under a HACCP plan. The foods should be categorized by the types of processes that must be covered. The Food Code requires HACCP plans for certain processes. In addition, the requirements for reduced oxygen packaged foods limit the types of foods that can be packaged in this manner.

Product/Process Description Form

The following is an example of a format that could be used to list the products covered. This sample lists many types products and processes for this establishment - a typical store would not likely have all of these processes.

Products/Processes Covered

Store Name *General J's Market*

Street Address *123 XYZ Street*

City *Anytown* State *MN* Zip Code *55555*

Products/Processes Covered under the HACCP Plan

Smoking/Curing
All Beef Summer Sausage, Ring Bologna, Smoked Turkey Drumsticks, Wieners, Snack Sticks, Beef Jerky, Bacon

Reduced Oxygen Packaging
All smokehouse products listed above
Sliced ham, sliced smoked turkey, sliced salami, hard cultured cheese (sliced and block), raw meats (cut and ground meat and poultry)

Food Additives
Acidified rice

Variances
Molluscan shellstock sold from life support tanks
Sale of more than one tagged box of molluscan shellstock at any one time
Deviation of required cook times and temperatures for roast beef

Developed by: *Cindy Jones* *Date* *12/10/98*

Step 3: Develop a Complete List of Ingredients, Materials, Equipment and Recipes/Formulations

THE THIRD STEP is for the team to thoroughly review each product or process and write down all of the ingredients, materials and equipment used in the preparation or sale of a food and also to write down formulations or recipes that show methods and control measures that address the food safety concerns involved.

The ingredients list may be as simple as the recipe format listed below or may be more detailed as shown on the following page. As you can see on the following examples, ingredients and materials fall into several categories. If the category does not apply to your product/process, you don't have to write anything in that space.

[If you use pre-packaged or pre-blended ingredients such as a seasoning mix, you can list it by blend (mix) name and just staple that products information to the back of your Ingredients Form.]

Be sure a recipe is listed for every product you produce.

Ring Bologna
FULL BATCH
50 lbs pork trim
50 lbs beef trim
6 lbs (1 full package) of xyz brand bologna seasoning
4 oz (1 full package) of Quick Cure with sodium nitrite
10 lbs. of water
Casings - natural beef casing
Also list procedures for producing the product.

Smokehouse Operations Formulation/Recipe

Step 3
Ingredients and Raw Materials Form

Product/Process Name: *Fully cooked, Ready-to-eat*

Product/Examples: *Beef Jerky*

Meat/Poultry and Byproducts	Nonmeat Food Ingredients	Binders/Extenders
50 lbs. Beef Rounds		
Spices/Flavorings	**Restricted Ingredients**	**Preservatives/Additives**
___ oz. Garlic ___ oz. Pepper (black) ___ oz. Soy Sauce	___ oz. Sodium Nitrite	
Liquid	**Packaging Materials**	**Other**
___ lb. Tap Water	Vacuum Plastic Pouch Assorted Labels	

Developed by: *Cindy Jones* *Date* *12/10/98*

An additional requirement is to include a listing of all equipment and materials *(such as packaging materials)* used for each product produced or each type of process. This information can be written in list form and be categorized for the different processes.

Equipment List

Store Name *General J's Market*

Street Address *123 XYZ Street*

City *Anytown* **State** *MN* **Zip Code** *55555*

Smokehouse Operations Equipment List

Walk-in Cooler: Brand _____ Size _____

Other products/Operations Supported _____

Grinder: Brand _____ Size _____

Mixer: Brand _____ Size _____

Stuffer: Brand _____ Size _____

Smokehouse: Brand _____ Size _____

Smoke generator/liquid smoke _____

Digital Thermometer _____

Assorted measuring container, hand utensils, lugs, totes, etc. _____

_____

Reduced Oxygen Packaging Equipment List

Slicer: Brand _____ Model # _____

Vacuum Packaging Machine _____

Digital Thermometer _____

Assorted knives, tongs, trays, lugs, totes, hand utensils, etc. _____

Vacuum plastic pouch _____

Scale/labeling machine _____

Step 4 & 5: Develop and Verify a Process Flow Diagram

AT STEPS 4 AND 5 the team will create a document that will be used over and over again in the HACCP plan development process. The HACCP team needs to look closely at the production process and make a flow diagram that shows all the steps used to prepare the product. You don't need to include steps that are not directly under your control, such as distribution.

The flow diagram doesn't need to be complex. Looking at your facility's floor plan can help you visualize the process from receiving to shipping. To find all the food safety hazards in your process you need to know exactly what steps that product/process goes through.

After the HACCP team has completed the flow diagram, it needs to be checked for accuracy. To do this, walk through the facility and make sure that the steps listed on the diagram realistically describe what occurs during the production process. If possible, have someone who didn't make the flow diagram do the "walk-through."

Working with the "Process Flow Diagram Development and Verification" Form

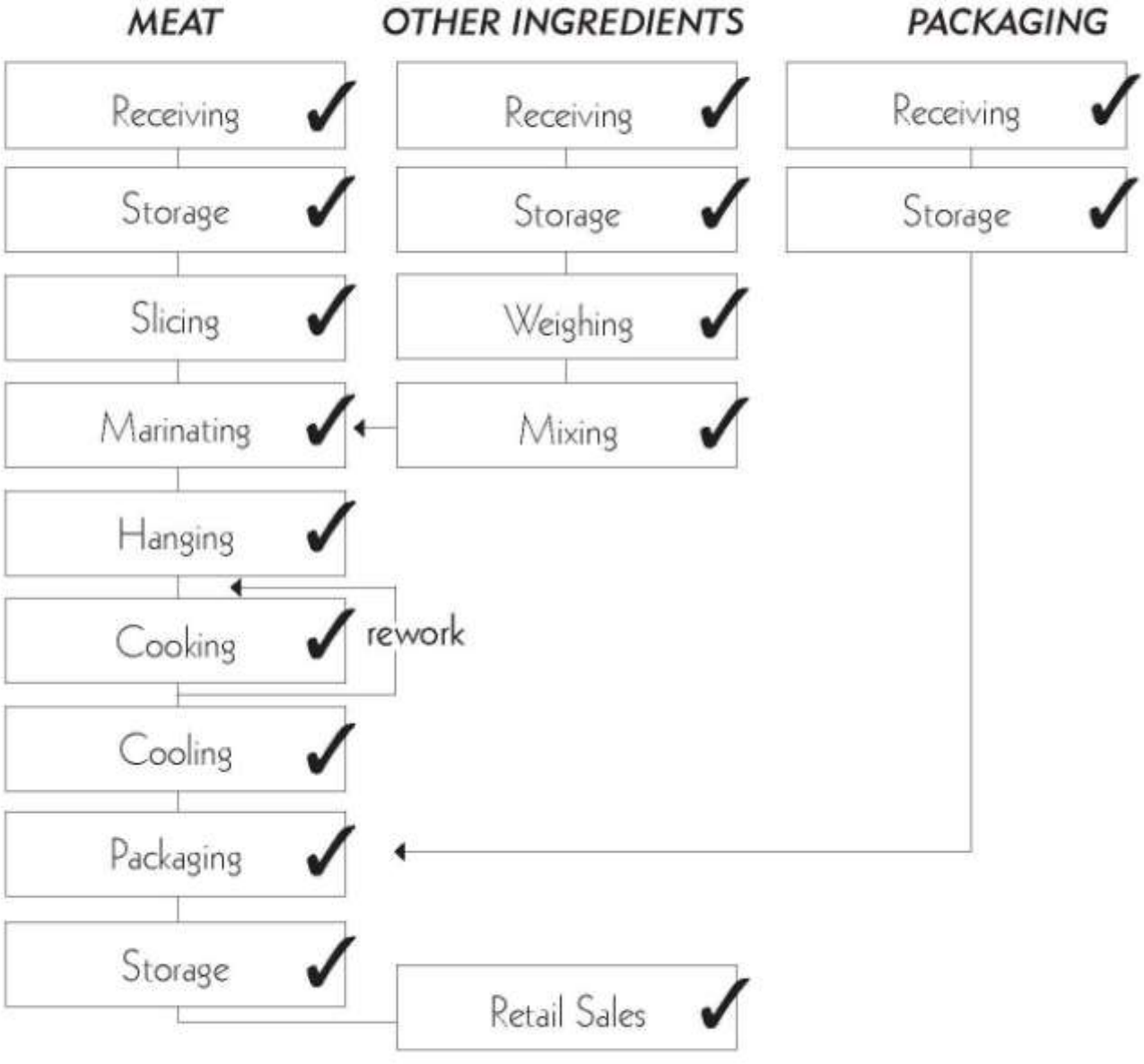
The Example Facility divided their flow diagram into three paths. Each of these paths represents one or more ingredients or raw materials. It made sense to combine certain categories. They grouped all meat items into "Meat", all-nonmeat food ingredients such as spices and preservatives into "Other Ingredients", which just left "Packaging Materials." These three categories represent the three main process routes that occur in their facility.

After the HACCP team completed their drawing, the flow diagram was **checked, signed and dated.** In the Example Facility as each step was verified they placed a check mark. The form must be **signed and dated** again after it is checked/reviewed.

Steps 4 & 5
Process Flow Diagram Development & Verification Form

Product/Process Name *Beef Jerky/Heat Treated, Shelf Stable*

Flow Diagram:



Developed by: *Cindy Jones* **Date** *12/10/98*

Verified by: *Mary Weston* **Date** *12/12/98*

Conclusion:

The Example Facility has successfully completed the fact-finding part of the HACCP development process. Your work through the preliminary steps should have produced two tangible pieces of information:

1. A comprehensive list of ingredients and raw materials, and
2. A step-by-step production process breakdown, laid out simply in a flow diagram.

With this information you are now ready to proceed to the next stage: Utilizing the 7 Principles of HACCP.

Section 3: Utilizing the 7 Principles of HACCP

Understanding Hazards and Controls

This section is about using the seven principles of HACCP. Already you have gathered all of the specific information about our facilities products and processes. Now you'll put that information to use. When you have worked through the principles of HACCP, you'll have a complete HACCP plan.

Before we start with the first principal, we need to quickly review two important ideas; Food Safety Hazards and Preventative Measures. Hazards are defined as any biological, chemical or physical property that is reasonably likely to cause food to be unsafe for human consumption.

Hazards are classified into these three categories: Biological, Chemical, and Physical.

Biological hazards can be bacteria, parasites, or viruses. Bacteria, parasites, or viruses that cause illness are called pathogens. In most cases, pathogens must grow or multiply in food to certain levels in order to cause foodborne illness. The following factors can affect the growth of pathogens:

Nutrients
Bacteria require food and water to carry on their life processes. Since what you are producing is a food product, nutrients are going to be available. Equipment that contains food residue can also be a nutrient source for bacteria.

Temperatures
Another essential factor that affects the growth of bacteria is temperature. Growth can occur over a wide range of temperatures from about 14°F to 194°F, but individual bacteria have much narrower temperature ranges for growth.

Time
It's not just the temperature that's the problem; it's the time at these temperatures that can affect growth of bacteria. The goal is to minimize the time of exposure of foods to temperatures where bacteria grow most quickly.

Moisture
The amount of available moisture in a food is measured as water activity. When substances like salt and sugar are added to water is tied up and is less available to the bacteria. The water activity of some foods is listed below:

Inhibitors
Foods can contain chemicals that are either natural or added that restrict or prevent growth of microorganisms. Salt is a good example of an added chemical that can inhibit growth of bacteria. Chemical preservatives like sodium nitrite, sodium benzoate, and calcium propionate can also inhibit the growth of microorganisms.

pH
pH shows how acid a food is. pH ranges from 0 – 14 with 7 being neutral. Foods with a pH of 4.6 and below are considered acid foods, like most fruit juices. Foods with a pH above 4.6 are said to be low acid, like meats and vegetables. Most bacteria don't grow very well in acid foods, so you can use pH to control the growth of bacteria. Generally, food is considered to be in a safe pH range when the final pH is 4.6 or below.

Atmosphere
Some bacteria require a specific type of atmosphere for growth. Microorganisms are categorized as aerobes, anaerobes, facultative anaerobes and microaerophilic. Aerobes require oxygen and include such bacteria as Bacillus. Anaerobes grow only in the absence of molecular oxygen. These organisms include Clostridium. Facultative anaerobes can grow whether the environment has oxygen or not. Microaerophilic is a term applied to organisms, which grow only in reduced oxygen environments. Knowledge of the atmosphere surrounding the food is an especially important consideration in determining which pathogens are likely to be a problem.

Food	Water Activity
Fresh meats, fish, fruits, and vegetables	0.98 or above
Cured meat, processed cheese, bread	0.93 – 0.98
Dried meat, aged cheddar cheese	0.85 – 0.93
Cereal, flour, jam, nuts, salted fish	0.60 – 0.85
Chocolate, honey, noodles	0.60 or below

Most bacteria will not grow when the water activity is 0.85 or less. Many yeasts and molds can grow below this

level but this is a spoilage concern and generally not a food safety concern.

Table 3-1 lists some of the most important characteristics of growth for common foodborne pathogens. The appendix at the end of this manual lists more detailed information on specific food borne bacterial pathogens. Use this information in evaluating your foods or processes for potential bacterial hazards.

Chemical Hazards

A wide variety of chemicals are routinely used in the production and processing of foods. Some examples of common types of chemicals are listed in table 3-2. While these types of chemicals may not be hazards if used properly, some can cause illness if not used properly. Therefore, the hazard analysis must consider whether any of these chemicals is used in a manner which creates a significant food safety problem.

Physical Hazards

Physical hazards are represented by foreign objects or extraneous matter that is not normally found in food. The presence of these items typically results in personal injuries such as a broken tooth, cut mouth, or a case of choking. Examples of Physical hazards are found in Table 3-3. In some instances, physical contaminants may also include "filth" such as mold mats, insects, and rodent droppings. Although extraneous matter normally categorized as filth may not actually injure a consumer, some of these items can also contribute biological hazards. For example, rodents and their droppings are known to carry Salmonella species.

Table 3-1

BACTERIA - CHARACTERISTICS OF GROWTH

Pathogens	Temperature for Growth (^oF)	pH	Minimum Water Activity (A_w)
Bacillus cereus	39 – 131	4.3 – 9.3	0.92
Campylabacter jejuni	86 – 113.7	4.9 – 9.5	0.99
Clostridium botulinum	38 – 118	A: 4.5 E: 5.9	A: 0.94 E: 0.97
Clostridium perfringens	50 – 125	5.0 – 9.0	0.93
Escherichia coli	45 – 121	4.0 – 9.0	0.95
Listeria monocytogenes	31 – 113	4.4 - 9.4	0.92
Salmonella	41 – 115	3.7 – 9.5	0.94
Shigella	43 – 117	4.8 – 9.3	0.96
Staphylococcus aureus	45 – 122	4.0 – 10	0.83
Vibrios	41 – 111	4.8 – 11	0.94 – 0.97
Yersinis enterocolitica	30 – 108	4.2 – 10	0.95

Table 3-2

EXAMPLES OF CHEMICAL HAZARDS	
Location	**Hazard**
Raw Materials	Pesticides, antibiotics, hormones, toxins, fertilizers, fungicides, heavy metals, PCB's
	Color additives, inks, indirect additives, packaging materials
Processing	Direct food additives -preservatives (high level of nitrates) -flavor enhancers -color additives
	Indirect food additives -boiler water additives -peeling aids -defoaming agents
Building and Equipment Maintenance	Lubricants, paints, coatings
Sanitation	Pesticides, cleaners, sanitizers
Storage and Shipping	All types of chemicals

Table 3-3

EXAMPLES OF PHYSICAL HAZARDS	
Cause	**Source**
Glass	Bottles, jars, light fixtures, utensils, gauge covers, thermometers
Metal	Nuts, bolts, screws, steel wool, wire, meat hooks
Stones	Raw materials
Plastics	Packaging materials, raw materials
Bone	Raw materials, improper plant processing
Bullet/BB shot/Needles	Animals shot in field, hypodermic needles used for injections
Jewelry/Other	Rings, watches, pens, pencils, buttons, etc.

Preventative Measures are defined as: "Physical, chemical or other means that can be used to control an identified food safety hazard." The following tables provide examples of preventive measures for Biological, Chemical, and Physical Hazards.

Table 3-4

EXAMPLES OF PREVENTATIVE MEASURES FOR BIOLOGICAL HAZARDS	
Pathogen	**Preventive Measure or Control**
Bacillus cereus	Proper handling and cooling temperatures of foods; thermal processing of shelf-stable canned food.
Campylobacter jejuni	Proper pasteurization or cooking; avoiding cross-contamination of utensils, equipment; freezing; atmospheric packaging.
Clostridium botulinum	Thermal processing of shelf-stable canned food; addition of nitrite and salt to cured processed meats; refrigeration of perishable vacuum packaged meats; acidification below pH 4.6; reduction of moisture below water activity of 0.93.
Clostridium perfringens	Proper handling and cooling temperatures of foods; proper cooking times and temperatures; adequate cooking and avoidance of cross-contamination by unsanitary equipment.
E-coli 0157:H7	Proper heat treatment; prevention of cross contamination; proper refrigeration temperatures.
Listeria monocytogenes	Proper heat treatments; rigid environmental sanitation program; separation of raw and ready-to-eat production areas and product.
Salmonella spp.	Proper heat treatments; separation of raw and cooked product; proper employee hygiene; fermentation controls; decreased water activity; withdrawing feed from animals before slaughter; avoiding exterior of hide from contacting carcass during skinning; antimicrobial rinses scalding procedures; disinfecting knives.
Shigella	Proper heat treatment; proper holding temperatures; proper employee hygiene.
Staphylococcus aureus	Employee hygiene; proper fermentation and pH control; proper heat treatment and post-process product handling practices; reduced water activity.
Vibrios	Proper heat treatment; prevention of cross-contamination; proper refrigeration temperatures.
Yersinia enterocolitica	Proper refrigeration; heat treatments; control of salt and acidity;

Table 3-5

EXAMPLES OF PREVENTIVE MEASURES FOR CHEMICAL HAZARDS	
Hazard	**Preventive Measure**
Naturally-occurring Substances	Supplier warranty or guarantee; verification program to test each supplier's compliance with the warranty or guarantee.
Added Hazardous Chemicals	Detailed specifications for each raw material and ingredient; warranty or letter or guarantee from the supplier; visiting suppliers; requirement that supplier operates with a HACCP plan.
In-Process Chemicals	Identify and list all direct and indirect food additives and color additives; check that each chemical is approved; check that each chemical is properly used; record the use of any restricted ingredients.

Table 3-6

EXAMPLES OF PREVENTIVE MEASURES FOR PHYSICAL HAZARDS	
Hazard	**Preventive Measure**
Foreign objects in raw materials	Supplier's HACCP plan; use of specifications, letters of guarantee; vendor inspections and certification; in-line magnets; screens, traps, and filters; in-house inspections of raw materials.
Foreign objects in packaging materials, cleaning compounds, etc.	Supplier's HACCP plan; use of specifications, letters of guarantee; vendor inspections and certification, in-house inspections of raw materials.
Foreign objects introduced by processing operations or employee practices	In-line metal detectors; visual product examinations; proper maintenance of equipment; frequent equipment inspections.

You should now be able to identify many types of hazards. You should also know where to begin looking for their preventative measures.

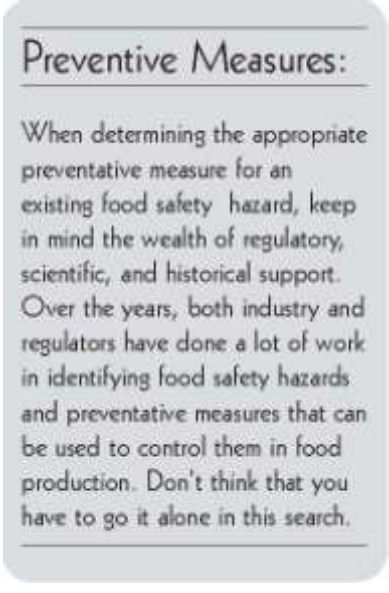
Principle 1: Hazard Analysis

Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventative measures.

A thorough hazard analysis is one of the keys to building an effective HACCP plan. The hazard analysis process involves identifying hazards that are reasonably likely to occur in the absence of control and their preventive measures. In the first "Identification" stage, the HACCP team identifies and lists food safety hazards that may be introduced or increased at each step in the production process.

Then, in the second "Evaluation" stage, each food safety hazards is evaluated based on how likely it is to occur. The term "reasonably likely to occur" is the ruler against which each hazard can be measured. Also during this evaluation stage the HACCP team investigates the appropriate preventative measures that will control the "likely to occur" food safety hazards.

[Hazards can vary greatly from one store to another due to differences in sources of ingredients, product formulations, processing equipment, processing methods, duration of the processes, and storage methods. Make sure that your hazard analysis takes into account what's unique about your establishment.]



Hazard Identification and Evaluation

The following steps can help you and the HACCP team gets started conducting your hazard analysis.

1. ***Here are some questions you can ask yourself to better understand the hazard identification process:***
    - Are additives or preservatives added to the product to kill or inhibit the growth of bacteria?
    - Will the amount of acidic ingredients affect the growth/survival of bacteria?
    - Does the product need to be refrigerated/frozen or kept dry in storage and during transit?

2. Second, look at the ***product ingredients*** that you listed earlier. In order to find all of the food safety hazards that are reasonably likely to occur, you need to know detailed characteristics about all the ingredients used in your process, as well as possible ingredient interactions.

    Here are some questions you can ask about the ingredients:
    - Could these ingredients contain any pathogenic bacteria, dangerous chemicals, or harmful physical objects?
    - If contaminated or mishandled, could the ingredients or materials support the growth of pathogenic bacteria?
    - Are hazardous chemicals used in growing, harvesting, processing or packaging an ingredient?
    - Is this ingredient hazardous if used in excessive amounts?

3. Third, determine if any food safety hazards exist for each processing step listed in the ***process flow diagram***.

   Here are some questions you can ask for each production step:

   - Could contaminants reach the product during this processing step?
   - Could this step create a situation where an ingredient, work in process, or finished product becomes contaminated with pathogens?
   - Could this step introduce a chemical or physical hazard into the product?

     Possibilities for the three questions above include: worker handling, contaminated equipment or materials, cross-contamination from raw materials, leaking valves or pipes, splashing, etc.

   - Could bacteria multiply during this process step to the point where they became a hazard? Consider product temperature, hold temperature, etc.

How can you be sure that you are producing safe food?

A properly functioning HACCP system assures the safety of your product. Critical Control Points exist in your establishment already. HACCP helps you to identify and use them to control food safety hazards. The system of HACCP, (specifically the correct identification and monitoring of CCP's) is what makes the answer to that question a sure thing.

KEEP GOOD NOTES: A summary of the HACCP team meetings and the reasons for each decision during the hazard analysis should be kept for future reference. These documents will be a great help to you when you have to review and update your hazard analysis and HACCP plan.

Finding Preventive Measures

Now that you have a good idea of what you're looking for in the way of hazards, use the example tables of preventive measures on pages 3-5 through 3-6 to use as a reference to find out some ways to keep those hazards under control.

It is sometimes the case that more than one preventive measure may be required to control a specific hazard, or that more than one hazard may be controlled by one preventive measure. As you go through the hazard analysis, you may recognize preventive measures already in place in your production processes.

The key to a successful hazard analysis is to link the preventive measures to the food safety hazards you have just identified.

Here's A Tip

When sitting down to figure out which steps in your process might or might not be CCP's, a common pitfall is to name too many.

Working with the "Hazard Analysis" Form

To explain how this form works, we are going to show you three production steps for which the Example Facility did a hazard analysis. The form is structured so that the three food safety hazard categories (chemical, biological, physical) are addressed in each of the four questions. Don't forget that you need to fill out the top of the form with the appropriate information, such as the product/process name, and the process steps from the flow diagram. You also need to sign or initial and date the form when it's complete.

The first production step we're going to look at is receiving meat.

1. For the first question all you need to do is state what food safety hazards are present at that step. The Example Facility listed pesticides, hormones, and antibiotics as a chemical hazard. They listed pathogenic bacteria as a biological hazard because bacteria are found on all raw meat. They also listed plastic and bone fragments as physical hazards because the meat comes to them in plastic sheaths.

2. The second question asks you to decide whether or not the hazard is reasonably likely to occur at that step. The Example Facility answered "No" for the chemical, "Yes" for the biological, and "No" for the Physical.

3. The third question is where you explain why you answered "Yes" or "No", to the question of "reasonably likely to occur." For the chemical hazard, the Example Facility's justification is that these sources are normally within defined limits. For the biological hazard they assume that the bacteria is on the meat prior to arrival, so that it continues to be a potential hazard. They said "No" to both the plastic and bone fragments because in both cases there has never historically been a problem with these types of physical hazards in their facility.

   [This "historical" basis for deciding whether a food safety hazard is "reasonably likely to occur" is perfectly legitimate. If your facility has a clean track record regarding a particular hazard, it's fine to include that information in your HACCP plan. All information must be documented.]

4. The final question on the hazard analysis form is the place where you write the specific preventive measure(s) that will control the hazard you said was likely to occur. With each shipment of meat the Example Facility receives they feel that the "Letter of Guarantee" from their supplier reasonably assures them the meat has been kept at a temperature adequate to control bacterial growth. However, just because they have one preventive measure hasn't stopped them from also having a second preventive measure. They also visually check the condition and temperature of the truck meat products, to make sure everything meets their standards.

HACCP Principle 1
Hazard Analysis Form

Product/Process Name: Beef Jerky/Heat Treated, Shelf Stable

Process Step from Flow Diagram: Receiving Meat

C: CHEMICAL	B: BIOLOGICAL	P: PHYSICAL
List the Hazards:		
Pesticides	Pathogens	Plastic
Hormones		Bone Fragments
Is the hazard reasonably likely to occur?		
☐ Yes ☒ No	☒ Yes ☐ No	☐ Yes ☒ No
What is the basis for your decision?		
No evidence of any historical occurence at this facility.	Loss of control in time/temp can promote harmful bacteria growth.	No evidence of any historical occurence at this facility from this product/source.

What preventative measures can be applied at this step to prevent, eliminate or reduce the hazard to an acceptable level?

Collect "Letter of Guarantee" from supplier that stipulates your requirements. If exceeds limits, product won't be accepted from supplier.

Developed by: Cindy Jones **Date** 12/13/98

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The second production step we're going to look at is cooking.

1. **List the hazards.** The Example Facility listed a chemical hazard of sanitizing chemicals because it's possible that traces of these substances could be on the equipment from the last time it was cleaned. They also listed a biological hazard because bacteria is unavoidable on all raw meat.

   [If you don't find a particular type of hazard at a step it's okay to write "Non Identified" as the Example Facility did.]

2. **Is it "reasonably likely to occur"?** They answered "No" for the chemical hazard, and "Yes" for the biological hazard.

3. **What is the basis for your decision?** The Example Facility decided the sanitizing chemicals wouldn't be a hazard likely to occur because their proper use is thoroughly covered by existing Sanitation Standard Operating Procedures (SSOP'S). They decided "Yes" for the biological hazard for the same reason as in the preceding process step.

   [When working on your HACCP plan, you might want to revisit your SSOP's]

4. **What are the preventive measures?** The Example Facility identified two preventive measures, cooking and water activity reduction for the biological hazard. They said this is because the cooking and the water activity reduction will help to reduce the hazard.

HACCP Principle 1
Hazard Analysis Form

Product/Process Name: Beef Jerky/Heat Treated, Shelf Stable

Process Step from Flow Diagram: Cooking

C: CHEMICAL	B: BIOLOGICAL	P: PHYSICAL
List the Hazards:		
Residues of sanitizing chemicals	Pathogen survival and growth in finished product.	(None Identified)
Is the hazard reasonably likely to occur?		
☐ Yes ☒ No	☒ Yes ☐ No	☐ Yes ☐ No (None Identified)
What is the basis for your decision?		
Proper use will address this issue.	Loss of control in time/temp or moisture level can promote harmful bacteria growth.	(None Identified)

What preventative measures can be applied at this step to prevent, eliminate or reduce the hazard to an acceptable level?

Smokehouse temperature is 190°F.

Developed by: Cindy Jones **Date** 12/13/98

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The third production step we're going to look at is cooling.

1. **List the hazards.** The Example Facility listed the biological hazard of cross-contamination because any time when you have raw and finished product in the same facility the possibility for the raw product to cross-contaminate the finished product exists. The Example Facility also listed plastic as a physical hazard because this is the step where they "Pull" the jerky strips off the cooking trees into large plastic barrels.

2. **Is it "reasonably likely to occur"?** The Example Facility answered, "No" for the biological, and "No" for the physical.

3. **What is the basis for your decision?** The Example Facility said that the biological hazard was not likely to occur because the raw and cooked products are strictly kept apart as called for in their SSOP's. They said "No" to the physical hazard because the plastic barrels that are used are made of an extremely sturdy type of plastic and there's never historically been a problem with plastic shavings at this facility getting into the jerky.

4. **What are the preventive measures?** There aren't any preventive measures listed here because no food safety hazards were found to be reasonably likely to occur.

These forms are just one way of documenting the hazard analysis process. An alternative form can be found on page 5-14.

HACCP Principle 1
Hazard Analysis Form

Product/Process Name: Beef Jerky/Heat Treated, Shelf Stable

Process Step from Flow Diagram: Cooling

C: CHEMICAL	B: BIOLOGICAL	P: PHYSICAL
List the Hazards:		
(None Identified)	Pathogen cross-contamination	Plastic

Is the hazard reasonably likely to occur?

C: CHEMICAL	B: BIOLOGICAL	P: PHYSICAL
☐ Yes ☐ No	☐ Yes ☒ No	☐ Yes ☒ No

What is the basis for your decision?

C: CHEMICAL	B: BIOLOGICAL	P: PHYSICAL
(None Identified)	SSOP's for separation	No evidence of any historical occurence at this facility.

What preventative measures can be applied at this step to prevent, eliminate or reduce the hazard to an acceptable level?

Developed by: Cindy Jones **Date** 12/13/98

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Principle 2: Identify Critical Control Points

A critical control point is defined as *"A point, step or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food hazard or reduce it to an acceptable level."* Everything in your HACCP plan revolves around the proper identification of CCPs.

Some of the most common CCPs are:

- Chilling or freezing to a specified temperature to prevent bacteria from growing.
- Cooking that must occur for a specific time and temperature in order to destroy bacteria.
- Prevention of cross-contamination between raw and cooked product.
- Certain processing procedures, such as filling and sealing cans, mixing and spicing, etc.
- "pH".
- Holding at proper refrigeration temperatures.

These are just a few examples of possible CCPs. Different facilities, preparing the same food, can identify different food safety hazards and different critical control points. Usually no two stores have the same floor plan, equipment, or ingredients. The CCPs you identify will reflect the uniqueness of your processing facility.

One of the tools used to help determine critical control points is a "CCP Decision Tree." The use of a Decision Tree to identify significant hazards is not necessary for you to meet regulatory requirements. However, the thought process may be helpful for your team; you want to make sure that your HACCP system meets regulatory requirements.

Working with the "CCP Decision Tree" Form

Critical Control Point Decision Tree

For the production of cooked products. Process Step Receiving Meat

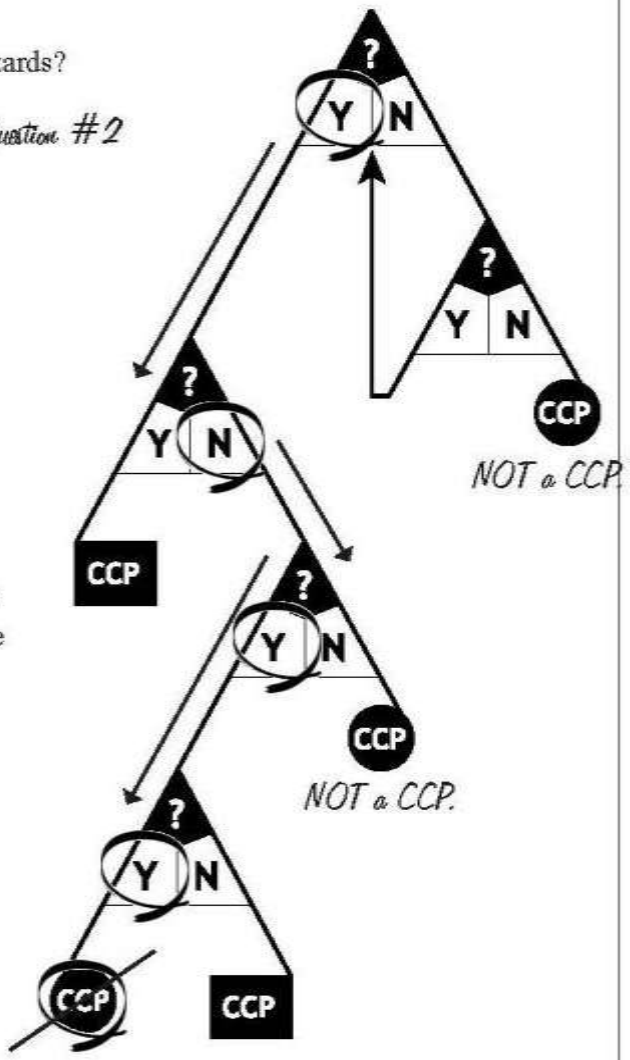
Question 1A
Do preventative measures exist for the identified hazards?
If no - go to Question 1B.
If yes - go to Question 2. Yes, go to Question #2

Question 1B
~~Is control at this step necessary for safety?~~
~~If no - not a CCP.~~
~~If yes - modify step, process or product and return to Question 1.~~

Question 2
Does this step eliminate or reduce the likely occurence of a hazard(s) to an acceptable level?
If no - go to Question 3.
If yes - CCP. No

Question 3
Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?
If no - not a CCP.
If yes - go to Question 4.

Question 4 Yes
Will a subsequent step eliminate the identified hazards or reduce the likely occurence to an acceptable level?
If no - CCP.
If yes - not a CCP.



Results:
Yes - so it's NOT a CCP.

BIOLOGICAL	CHEMICAL	PHYSICAL
☐ CCP#_____	☐ CCP#_____	☐ CCP#_____
☒ Not a CCP	☐ Not a CCP	☐ Not a CCP

Developed by: Cindy Jones **Date** 12/10/98
Verified by: Mary Weston **Date** 12/12/98

The second step they looked at was cooking.

Question 1a

The Example Facility answered "Yes" here because they had identified the preventive measure of cooking (i.e. time and temperature) for this step.

Question 1b

As in the receiving example, move onto question 2.

Question 2

The Example Facility said that "Yes" cooking would eliminate the hazard at this step. They stopped here at question 2 because they reached a positive result...their CCP. Thus, there wasn't any need to go on to questions 3 and 4.

[After finding all the CCP's in your process, the HACCP team needs to organize them. At the bottom of the CCP Decision Tree Form the Example Facility named the cooking CCP "CCP#01B". The "01" tells them what number the CCP is, and the "B" tells them it is a biological food safety hazard.]

Critical Control Point Decision Tree

For the production of cooked products. Process Step Cooking

–

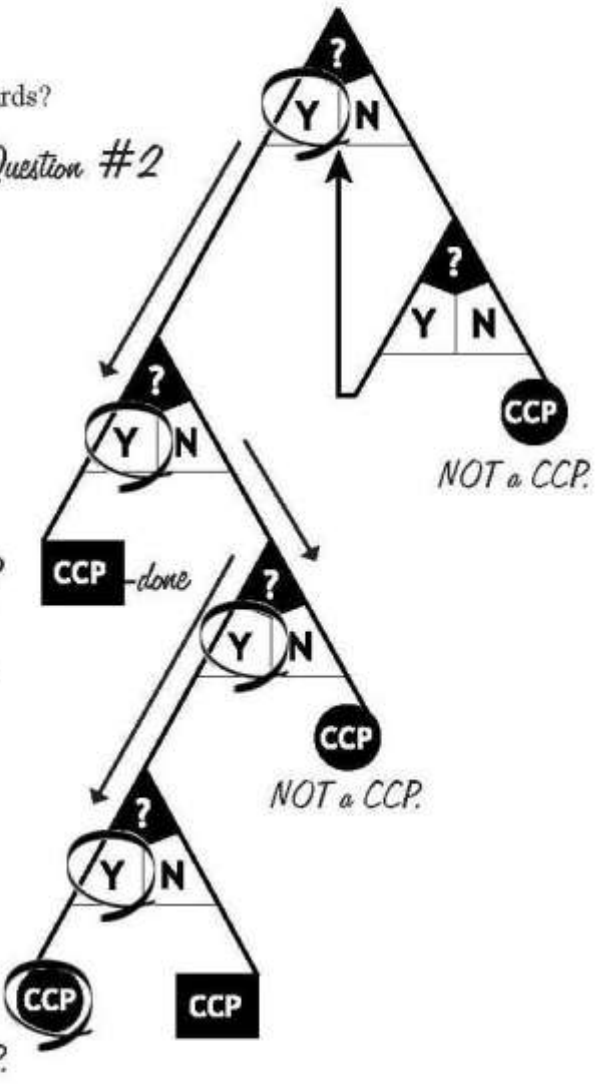
Question 1A
Do preventative measures exist for the identified hazards?
If no - go to Question 1B.
If yes - go to Question 2. *Yes, go to Question #2*

~~*Question 1B*~~
~~Is control at this step necessary for safety?~~
~~If no - not a CCP.~~
~~If yes - modify step, process or product and return to Question 1.~~

Question 2
Does this step eliminate or reduce the likely occurence of a hazard(s) to an acceptable level?
If no - go to Question 3.
If yes - CCP. *Yes, Identified as a CCP*

Question 3
Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?
If no - not a CCP.
If yes - go to Question 4.

Question 4
Will a subsequent step eliminate the identified hazards or reduce the likely occurence to an acceptable level?
If no - CCP.
If yes - not a CCP.



Results:

BIOLOGICAL	CHEMICAL	PHYSICAL
☒ CCP# #01B	☐ CCP#	☐ CCP#
☐ Not a CCP	☐ Not a CCP	☐ Not a CCP

Developed by: Cindy Jones **Date** 12/10/98

Verified by: Mary Weston **Date** 12/12/98

Principle 3: Establish Critical Limits for Each Critical Control Point

A critical limit is defined as "The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." You can think of a critical limit as a boundary of safety for a CCP. The critical limit is the numerical value that must be reached to assure that hazards have been controlled. An example would be that "all sausage products must be cooked to 155°F for 15 seconds."

Each CCP will have at least one (possibly more) preventive measures that need to be controlled to assure this prevention, elimination or reduction of food safety hazards. To be effective, each critical limit should be:

1. ***Based on proven factual information.*** A few ways that information and recommendations for appropriate limits can be obtained are: from regulatory requirements, scientific literature, and consultation with experts. If regulatory requirements exist they must be met or exceeded.

2. ***Objectives are measurable or observable, such as time and temperature.***

3. ***Appropriate and reasonable for the food product and operation.*** You should consider the type of equipment, the volume of product being produced, how the critical limit will be monitored and frequency of monitoring.

4. ***Specifics.*** When drafting your critical limits be specific in your language. Use action words, and be specific when naming people and equipment. An example could be "bake, uncovered in preheated 350°F oven to an internal temperature of 165°F for 15 seconds."

The HACCP team will find that many critical limits for your identified CCP's have already been established.

In some cases you'll need more than one critical limit to control a particular hazard. For example, the typical critical limits for cooked beef patties are time/temperature, patty thickness, and conveyor speed. It is important that you identify all the critical limits for each of your products.

Making sure each Critical Control Point has critical limits is the responsibility of each establishment. The HACCP team may want to get help from outside HACCP experts when establishing critical limits. Remember that the critical limits must be able to maintain control over the food safety hazard. Once the team has identified all the limits, enter them onto the Critical Limits form.

Here are some controls commonly used as preventative measures.

• *Time and Temp - The temperature "danger zone" for biological hazards is between 40°F and 140°F. Bacteria grows fast! They have the ability to multiply rapidly. Knowing this shows that controlling how long the product is in the danger zone (if at all) presents itself as an extremely effective critical limit.*

•*pH - The pH of a food product is the level of its acidity or alkalinity. The pH is measured on a scale of 0 to 14. The middle of the scale, pH=7.0, is considered neutral. Altering a food product's pH, such as adding an acidic substance like vinegar or soy sauce will decrease the growth rate of the bacteria.*

• *Water Activity - In addition to warm temperatures and a median pH, bacteria also need water to grow. Water activity (A_w) refers to the amount of water in a food product that is available, or free, for bacteria to use for growth and multiplication. Solutes (salts and vinegars), as well as dehydration, decrease the available water and can reduce bacterial growth.*

Working with the "Critical Limits" Form

For each CCP the Example Facility has a separate page of critical limits.

1. ***Under the "Limit" heading.*** The Example Facility noted an internal temperature of 165°F for 15 seconds as the established critical limit. They then decided that the preventive measure of cooking at 190°F oven temperature for 3 hours would satisfy the critical limit.

2. ***Under the "Source" Heading.*** The Example Facility's first source is regulatory and scientific. They decided to take the established regulatory limits and use them, but then they also sent out samples of their finished product to be scientifically analyzed. The results of the lab tests confirmed that their critical limits were enough.

   [The source is the "evidence" that backs up your critical limits. The source provides that the critical limits you cite will effectively control the food safety hazards. Sources for critical limits can be scientific, regulatory or historical. The HACCP team has to find at least one source for each of your critical limits, but you can always put more if you want.]

Documenting the Source

When determining your critical limits make sure you file your supporting documentation with your HACCP plan. This documentation will help validate that the limits have been properly established. These could be things such as letters from outside HACCP experts, or scientific reports, or lab test results. By holding onto these

supporting documents you also provide verification material when needed.

HACCP Principle 3
Critical Limits Form

Product/Process Name: Beef Jerky/Heat Treated, Shelf Stable

Process Step/CCP: Cooking CCP#01B

Critical Limits
Limit - (Time, Temp, pH, etc.)

Internal temperature: 165 degrees Fahrenheit for 15 seconds.

Preventive Measure: Oven temperature: 190 degrees Fahrenheit for 3 hours.

Source - (cite a regulation, scientific document, other resource)

Meets regulatory requirements

Laboratory tests and results

Developed by: Cindy Jones **Date** 12/14/98

Principle 4: Establish Monitoring Procedures

Monitoring involves a series of observations and/or measurements that are used to make sure a CCP is under control. The HACCP team can think of monitoring activities as the checks-and-balances for each CCP. When someone monitors, they are "checking to see" that the critical limits are being met.

What are the 3 things monitoring can do for you?

- Shows you when a deviation from a critical limit has happened. For example, an employee tests the temperature of some beef patties and discovers that the internal temperature has gone above the established critical limit of 40^{o}F. If not caught here, this would be a potentially serious health risk to consumers.

- Helps you identify trends in your process that will allow you to predict a loss of control at a CCP. For example, a facility may monitor the temperature of a cold storage area at 6 a.m., 8 a.m., and 10 a.m. Each time, the temperature is within acceptable limits, but it is steadily climbing toward the high end of the range. This information points towards a trend, and the facility should take action to prevent the temperature from exceeding the critical limits.

- Produces written records for use in future HACCP plan verification steps. Written monitoring records will prove very valuable to your operation, should a serious problem along the production line occur. The records you keep prove that your company has established and carried out effective monitoring techniques.

Monitoring procedures can be thought of as continuous or non-continuous.

- Continuous monitoring is the constant monitoring of a critical control point.
- Non-continuous monitoring is the scheduled monitoring of a critical control point.

Continuous monitoring is always preferred when feasible. Continuous monitoring at a CCP is usually done with built-in measuring equipment, such as a recording thermometer used at a cooking step. This type of monitoring is preferred because it yields a permanent record. To make sure these activities stay accurate, you need to regularly check the monitoring equipment to make sure that it is calibrated correctly.

If continuous monitoring isn't feasible for your CCP then the HACCP team will need to establish non-continuous monitoring procedures. Non-continuous doesn't mean random. The team should decide in the development phase what the monitoring schedule should be. When you use non-continuous monitoring, make sure that it's scheduled often enough to keep the food safety hazards under control. Expert advice from people with knowledge of practical statistics and statistical process control will be important in making your decisions. Types of non-continuous monitoring procedures include visual examinations, monitoring ingredient specifications, measurements of pH or water activity (Aw), taking product temperatures, etc.

Who's Responsible?

Make sure to assign a specific person to be responsible for the monitoring of a CCP. The Example Facility has a

designated shift leader/cook who is responsible for monitoring the cooking CCP. The person who actually does the monitoring must be the person who signs and dates all the records at the time of monitoring.

Monitoring will be most effective when:

- The HACCP plan clearly identifies the employee(s) responsible for monitoring.
- Employees are trained in the proper testing procedures, the established critical limits, the methods of recording monitoring results, and the actions to be taken when critical limits are exceeded.
- Employee(s) understand the purpose and importance of monitoring.

The last step in establishing your monitoring procedures is to develop the Monitoring Log(s) where the monitoring person will record the date for each CCP. Due to the variety of monitoring procedures, the HACCP team may need to developed different logs to record the monitoring data at different CCP's. When your HACCP system is up and running, you will use these logs to track the day-to-day HACCP activities. Sample logs are provided in the Appendix.

Working with the "Monitoring Procedures" Form

The form that is shown as an example on the next page is to be used as a tool in the development of your HACCP plan. The information on this form is the "Who, What, When and How" of monitoring.

For the Example Facility:

- The Who is the cook on duty.
- The What is the temperature of the oven.
- The When is non-continuously - every 60 minutes, (+ 5 minutes), and
- The How is with the oven temperature gauge.

The Example Store felt this type of non-continuous monitoring would be effective because of the consistent heat environment of the oven. Their logic was that if the temperature taken at the beginning and end of the cooking cycle was the same, it could reasonably be assumed that it was okay for the whole cooking cycle.

Remembering your Monitoring

The key to effective and reliable monitoring is to keep it simple and build it into the employees' normal routines. When establishing a time for the actual monitoring procedure, allow some flexibility. For example, if you say you will monitor a CCP at 10 a.m. and the person is not there at exactly 10 a.m., you could be opening yourself up for problems. It is suggested that you specify a period of time during which monitoring will occur. For example, write your time as "10a.m. +/-- 10 minutes"or "between the time period of 10 a.m. and 10:15 a.m."

HACCP Principle 4
Monitoring Procedures Form

Product/Process Name: Beef Jerky/Heat Treated, Shelf Stable

Process Step/CCP: Cooking CCP #01B

Monitoring Procedures - (Who, What, When, How)

The cook on duty records the oven temperature at intervals of 60 minutes, (±5 minutes) starting when a "lot" is placed in the oven and ending when the "lot" is removed from oven. Each oven is monitored individually using an oven temperature gauge.

Developed by: Cindy Jones **Date** 12/10/98

Principle 5: Establish Corrective Actions

Corrective Action can be defined as "Procedures to be followed when a deviation occurs." A deviation is defined as a "failure to meet a critical limit."

Deviations can and do occur. After the HACCP team has established strict monitoring procedures, the next step is to draft corrective actions to be taken immediately when there is a loss of control at a CCP.

Corrective action may include, but is not limited to the following procedures:

1. Identifying and eliminating the cause of the deviation,
2. Demonstrating that the CCP is once again under control. (This means examining the process or product again at that CCP and getting results that are within the critical limits.),
3. Taking steps to prevent a recurrence of the deviation,
4. Making sure that no adulterated product enters commerce, and
5. When to discard product.
6. Maintaining detailed records of the corrective actions.

If a deviation occurs that is not covered by a specific corrective action in your HACCP plan, or if some unforeseen hazard arises, appropriate steps should be taken. These steps shall include, but not be limited to:

1. Segregate and hold any affected product until its acceptability can be determined.
2. Determine the acceptability of the affected product for distribution.
3. Do not allow product that is injurious to health or is otherwise adulterated to enter commerce.
4. Reassess and, if necessary, modify your HACCP plan to properly address this type of deviation in the future.
5. Maintain detailed records of your actions.

Some examples of corrective actions are:

- Changing the process and holding the product for further evaluation.
- Empowering the monitoring personnel to stop the line when a deviation occurs. They should have the authority to hold all "lots" of a product not in compliance.
- Rely on an approved alternate process that can be substituted for one that is out of control at the specific CCP.
- Additional cooking time.
- Quickly cooling product.

Whatever type of corrective actions the HACCP team establishes, records for each one need to be kept that include:

- That the deviation was identified.
- The reason for holding the product, the time and date of the hold, the amount of the product involved, and the disposition and/or release of the product.
- The actions that were taken to prevent the deviation from recurring.
- The dated signature of the employee who was responsible for taking the corrective action.

As with monitoring logs, the HACCP team also needs to develop the log(s) for the corrective action results.

Working with the "Corrective Action Procedures" Form

The Example Facility's corrective action form outlines exactly what they think should be done if a problem occurs with the CCP#01B.

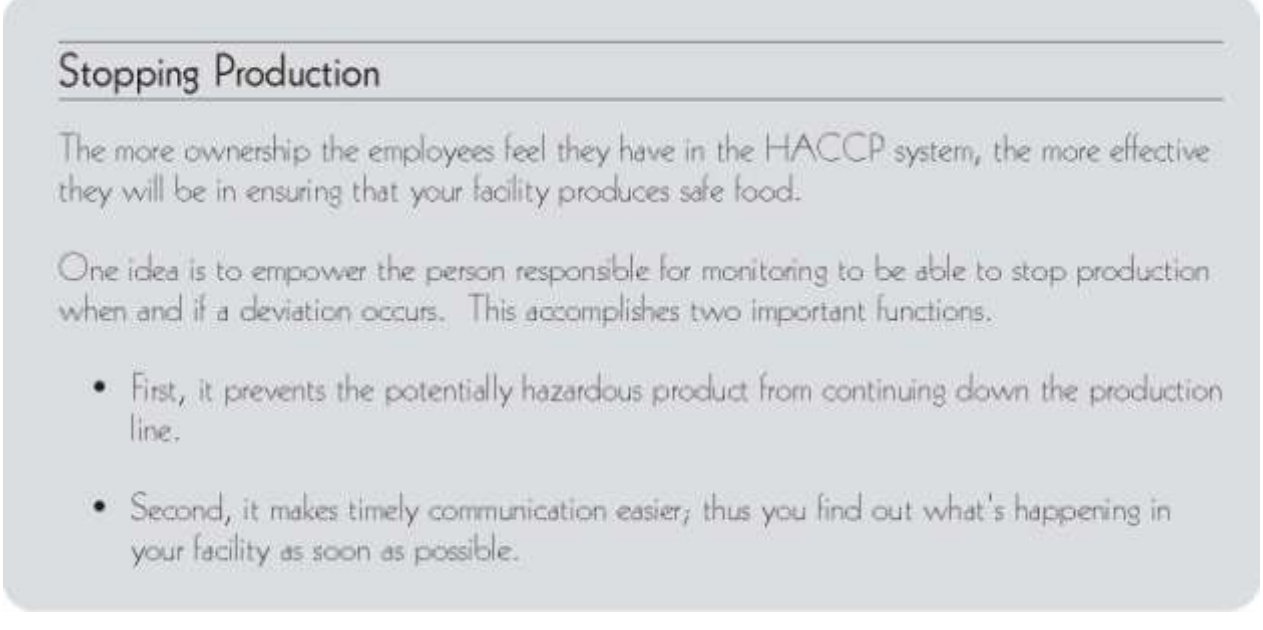
- **Under the "Problem" heading.**
  They state the critical limit that has been established for this CCP.

- **Under the "Disposition of Product" heading.**
  If a deviation occurs, they have noted that the initial disposition would be to hold the product "lot", and try to rework it if possible. The "rework" would consist of fixing the temperature and re-cooking the jerky.

- **Under "Corrective Action Procedures/Steps" heading.**
  As you can see, the Example Facility listed quite specific corrective actions for this CCP. Their directions are written concisely, and in the order they should be performed.

- **Under the "Who is Responsible" heading.**
  They are specific in naming a particular person.

- **Under the "Compliance Procedures" heading.**
  The Example Facility has projected that if this deviation happens at this CCP it will probably be because something went wrong with the thermostat in the oven. They list here what will probably need to be done to make sure this doesn't happen again. (If this deviation were to actually happen, the monitoring person would write on the corrective action log what he or she did to fix the problem, and what they did to make sure it wouldn't happen again.)



Stopping Production

The more ownership the employees feel they have in the HACCP system, the more effective they will be in ensuring that your facility produces safe food.

One idea is to empower the person responsible for monitoring to be able to stop production when and if a deviation occurs. This accomplishes two important functions.

- First, it prevents the potentially hazardous product from continuing down the production line.
- Second, it makes timely communication easier; thus you find out what's happening in your facility as soon as possible.

HACCP Principle 5
Corrective Action Procedures Form

Product/Process Name: Beef Jerky/Heat Treated, Shelf Stable

Process Step/CCP: Cooking CCP # 01B

Problem - (Critical limit exceeded)

Oven temp, below 190 degrees Fahrenheit

Disposition of product - (Hold, Rework, Condemn)

Hold, rework if possible.

Corrective action procedures/steps 1. Identify and segregate affected product, place on hold.

2. Rework if possible, otherwise condemn product: Reestablish correct cooking procedures (i.e. fix oven temp. settings, or move product to other oven for rework.)

3. Determine cause of deviation: broken oven thermostat.

4. Take steps to prevent recurrence: recalibrate/replace thermostat

5. Notify Quality Control Supervisor a.s.a.p.

Who is responsible for performing these corrective actions? John Smith - Cook on duty

Compliance procedures

Recalibrate/Replace oven thermostat.

Monitor CCP as usual during rework.

Developed by: Cindy Jones **Date** 12/14/98

Principle 6: Establish Record Keeping Procedures

The records you keep for HACCP can make all the difference! Good HACCP records - meaning that they are accurate and complete - can be a great help to you. Here's why:

- Records make it possible to trace ingredients, in-process operations, or finished products, should a problem occur.
- Records help you identify trends in your production line.
- Records serve as written documentation of your facility's compliance with the HACCP regulations.

Well maintained records protect both your customers and YOU.

Your HACCP records should include your development forms and your daily logs for each CCP. You should also keep your hazard analysis development forms, your CCP determination sheets, a list of critical limits for each food safety hazard, clear corrective action instructions, and a copy of your compiled HACCP plan. When first establishing your recordkeeping procedures, it's better to think of the different kinds of records you'll need in two ways.

First, there are records that are used for development for archival purposes; such as your Hazard Analysis, and your CCP decision making tool.

Second, there are records that you will work with on a day-to-day basis. These are the logs we've been discussing such as the monitoring or corrective action logs. As we've said before, the HACCP team will need to create these logs for each CCP in your process.

The Minnesota Food Code requires that you keep records on specified information; see page 4-3 for further detail. Regardless of the type of record, all HACCP records must contain at least the following information:

- Title and date of record.
- Product identification,
- Signature of employee making entry,
- A place for the reviewer's signature, and
- An orderly manner for entering the required data.

Tips on Designing Records

One way to approach development of the recordkeeping requirements of your HACCP system is to review the records you already keep, and see if they are suitable, in their present form or with minor modifications, to serve the purposes of your HACCP system. The best recordkeeping system is usually the simplest one that can easily be integrated into the existing operation.

Working with the "Recordkeeping Procedures" Form

- **Under the "Records" heading.**
  You can see that the Example Facility has filled out their Recordkeeping Form making sure to list both the development forms (the hazard analysis), and the logs.

[One last note about the records you keep. When developing and working with your forms and logs remember to use ink (ballpoint pen) - no pencils. On all records, whenever you make a change, mark through the original and initial. Do not erase, white out, or mark the original so that it is unreadable.]

Place a blank copy of all logs/forms in the HAACP plan to show how you record this information.

HACCP Principle 6
Recordkeeping Procedures Form

Product/Process Name: Beef Jerky/Heat Treated, Shelf Stable

Process Step/CCP: Cooking CCP # 01B

Records

Name and Location		
Name: Hazard Analysis Location: Office File Cabinet	Name: HACCP Plan Review Sheet - For each CCP Location: Oven Room Wall	Name: Monitoring Log - For each CCP Location: Oven Room Wall
Name: Deviation / Corrective Action Log Location: Oven Room Wall	Name: Process - Monitoring Equipment Calibration Log - For each CCP Location: Oven Room Wall	Name: Verification Procedures & Results Log - For each CCP Location: Oven Room Wall

Developed by: Cindy Jones **Date** 12/10/98

Principle 7: Establish Verification Procedures

Your team needs to decide on what procedures the facility will perform to verify that the HACCP system is working effectively and how often these actions will be performed. Verification uses methods, procedures, or tests in addition to those used in monitoring to see whether the HACCP system is in compliance with the HACCP plan or whether the HACCP plan needs modification. There are three types of verification. These are initial validation, ongoing verification, and reassessment of the HACCP plan.

Initial Validation

Validation is defined as" the specific and technical process for determining that the CCP's and associated critical limits are adequate and sufficient to control likely hazards." The initial validation of your HACCP plan is the process by which your establishment proves that what is written in the HACCP plan will be effective in preventing, eliminating, or reducing food safety hazards. This validation activity is the exclusive responsibility of your establishment.

You carry out this validation by gathering evidence that supports your HACCP plan. The data you bring together can come from many sources. Such sources may include scientific literature, product testing results, regulatory requirements, and/or industry standards. Companies have a lot of flexibility in the compilation of this information in regards to the sources and the amounts of such data.

[Most likely, you already have the majority of the validation information you need. When you conducted your hazard analysis and researched the sources for your critical limits, you were collecting data that could also be used to validate your entire HACCP plan.

Ongoing Verification

Verification is "the use of methods, procedures, or tests in addition to those used in monitoring, to determine whether the HACCP system is operating as intended." After a HACCP plan has been initially validated and put into action, verification activities continue on an ongoing basis.

Simply stated, you need to verify that your HACCP system is working the way you expected. There are several ways to do this, here are a few: (these aren't the only ones)

- Calibrate your monitoring equipment.
- Sample your product.
- Review your monitoring and corrective action logs.
- Personally inspect your facility's operations.

Whatever types of ongoing verification activities you decide to use, they should be included in your HACCP plan along with the specifics on your CCP's, critical limits, monitoring, and corrective actions. Also, the HACCP team needs to identify the schedules for conducting the verification checks.

Reassessment of the HACCP Plan

It is a good idea to reassess the adequacy of your plan at least once a year and whenever any new changes occur that could affect the hazard analysis or alter the HACCP plan. Here are a few, but not all, of the changes that would require modification to your HACCP plan.

1. Potential new hazards are identified that may be introduced into the process.
2. New ingredients are added, or when an ingredient supplier is changed.
3. The process steps or procedures are changed.
4. New or different processing equipment is introduced.
5. Production volume changes.
6. Personnel changes.

Your reassessment should include a review of the existing HACCP plan, including the product evaluation, hazard analysis, critical control points, critical limits, monitoring procedures, corrective actions and recordkeeping procedures.

Working with the "Verification Procedures" Form

It's important to remember that verification procedures are ongoing activities. For each CCP you will need a monitoring log, a deviation/corrective action log, and an equipment calibration log. These logs are the continual verification that HACCP is being done effectively.

(Like the monitoring form in principle 4, the information on this form is the "Who, What, When and How" of verification.)

For the Example Facility:

- The Who is the quality control supervisor.
- The What is each one of the three activities they need for their process,
- The When is specified after each activity, and
- The How would be determined as needed by the quality control supervisor.

Finishing Your HACCP Plan

Each form that is used in the development of the HACCP plan and the HACCP plan itself needs to be reviewed in its entirety and signed and dated by the responsible official on the HACCP team. This person must make sure that the HACCP plan is complete. This assures the HACCP team that only the most complete and up-to-date plan is being used.

The HACCP System

The HACCP Plan is a written document that is based on the 7 principles of HACCP. A HACCP System is the results of the implementation of the HACCP plan. It includes the written HACCP plan itself but also any records produced, verification data and any prerequisite programs (either written plans or records for GMPs and SSOPs)

The HACCP system produces real results. HACCP is a way of getting and keeping control over your entire production process.

HACCP Principle 7
Verification Procedures Form

Product/Process Name: Beef Jerky/Heat Treated, Shelf Stable

Process Step/CCP: Cooking CCP # 01B

Verification Procedures - (Who, What, When, How)

- Thermometer calibration - Weekly
- Random observation of monitoring - Daily
- Review relevant records - Daily, prior to shipment
- Deviation response review - Ongoing
- Quality Control Supervisor

Developed by: Cindy Jones **Date** 12/10/98

Section 4: Food Code Requirements

Introduction

HACCP is a universal preventative system for assuring the safe production of food products. The Preliminary Steps and Seven Principles of HACCP can be applied to most any food production process including agriculture production, food processing, retail food preparation, and distribution systems. Previous sections in this manual have focused on the basics of developing a HACCP plan.

The Food Code applies to retail food establishments such as grocery stores, restaurants, meat markets, convenience stores, bakeries, etc. Processes that require operation under a HACCP plan were previously discussed in Section 1. Also included there was timing of HACCP plans. It is important to note that new or extensively remodeled establishments must submit the HACCP plan to the regulatory authority before the start of operation for approval in conjunction with the facility plan review.

In this book, Section 2 focused on Preliminary Steps. Basically, the preliminary steps are a method to collect information that is used in developing the HACCP plan. The Food Code requires that some of the preliminary steps information become part of your official HACCP plan. Section 3 of this book focuses on developing the HACCP plan itself using the Seven Principles. The rule requires that most (although not all) of this information become part of your official HACCP plan. In addition, the Food code requires that the HACCP plan for your retail food establishment contain some additional components.

Contents of a HACCP Plan

When a food establishment is required to have a HACCP plan, the plan and specifications shall include:

1. A categorization of the types of potentially hazardous foods that are specified in the menu.
   **This information was collected in Preliminary Steps – Number 2. See page 1-5 for more information. Be sure that this is included as one of the documents in your official HACCP plan.*

2. A flow diagram by specific food or category types identifying critical control points and providing information on the following:
   a. Ingredients, materials and equipment used in the preparation of a food.
   b. Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.

   **This information was collected in Preliminary Steps – Number 3 and 4. See page 1-5 for more information. Be sure that this is included as one of the documents in your official HACCP plan.*

3. A statement of Standard Operating Procedures for the plan identifying:
   a. Critical control points.
   b. Critical limits for each critical control point.
   c. The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge.
   d. The method and frequency for the Person in Charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points. (verification)
   e. Action to be taken by the Person in Charge if the critical control points are not met. (corrective action)
   f. Records to be maintained by the Person in Charge to demonstrate that the HACCP plan is properly operated and managed.

   **Items 3a – f should all be included as part of your HACCP plan as developed in Section 3. The Person in Charge is ultimately responsible for ensuring that critical control points are monitored and corrective action is taken as necessary and that records are maintained to document this. The day-to-day activities could be assigned to an employee working in the HACCP operation.*

4. Additional scientific data or other information as required by the regulatory authority supporting the determination that food safety is not compromised by the proposal.

   **Types of information that might need to be included here are validation data, or data to support a variance.*

Compliance with the HACCP Plan

In order to be in Compliance with the HACCP Plan a licensee shall:

A. Comply with a properly prepared HACCP plan, and

B. Maintain and provide to the regulatory authority, on request, the records specified in part 4626.1735 , item A, sub-items (3) and (4) that demonstrate that the following are routinely employed:

1. Procedures for monitoring critical control points.
2. Monitoring of critical control points.
3. Verification of the effectiveness of an operation or process.
4. Necessary corrective actions if there is a failure at a critical control point.

When the rule requires that you prepare a HACCP plan for a certain operation, this HACCP plan does, in effect, become part of the rule for your establishment. You must comply with your properly prepared HACCP plan. By complying with the Standard Operating Procedures you have prepared as part of your HACCP plan and when you have followed the steps in this publication for developing a HACCP plan, you will have the necessary information to develop records that demonstrate that critical point monitoring procedures are detailed and followed, that the process is verified for effectiveness and that necessary corrective actions are taken as necessary.

Variances and the HACCP Plan

The REGULATORY AUTHORITY may grant a variance by modifying or waiving the requirements of the Food Code if in the opinion of the REGULATORY AUTHORITY a health HAZARD or nuisance will not result from the VARIANCE. Before a VARIANCE from a requirement of this Code is APPROVED, the information that shall be provided by the PERSON requesting the VARIANCE and retained in the REGULATORY AUTHORITY'S file on the FOOD ESTABLISHMENT includes:

1. A statement of the proposed VARIANCE of the Code requirement citing relevant Code section numbers;[Pf]
2. An analysis of the rationale for how the potential public health HAZARDS and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; [Pf] and
3. A HACCP PLAN if required

If the REGULATORY AUTHORITY grants a VARIANCE or a HACCP PLAN is otherwise required the PERMIT HOLDER shall:

1. Comply with the HACCP PLANS and procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver; [P] and
2. Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;

(A) Procedures for monitoring the CRITICAL CONTROL POINTS, [Pf]

(B) Monitoring of the CRITICAL CONTROL POINTS, [Pf]

(C) Verification of the effectiveness of the operation or process, [Pf] and

(D) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT. [Pf]

Reduced Oxygen Packaging

REDUCED OXYGEN PACKAGING (ROP) is defined as any packaging procedure that results in a reduced oxygen level in a sealed packaged. You may be more familiar with the term 'vacuum packaging' which is one type of reduced oxygen packaging method. Another term used is "Modified Atmosphere Packaging", this is a process that uses a gas flushing and sealing process in a one-time modification of the atmospheric contents of the package.

If reduced oxygen packaging is one of the processes that are included in your HACCP plan, the Food Code requires that additional information be included. These items can be included in the formal HACCP plan or as separate documents.

Reduced Oxygen Packaging Criteria

The HACCP plan shall:

1. Identify the food to be packaged.
   This information was collected in Preliminary Steps – Number 2. See page 1-5 for more information. If adequate detail was provided on this list, this requirement will have been met. Specific brand names of products would not need to be included as long as the products meet the requirements as listed in number 2 below. Be sure that this list is included as one of the documents in your official HACCP plan.

2. Limit the food to be packaged to a food that does not support the growth of Clostridium botulinum because the food:
   a. has a water activity of 0.91 or less
   b. has a pH of 4.6 or less
   c. is a food with a high level of competing organisms, including raw meat, raw poultry, or a naturally cultured standardized cheese, OR
   d. is a meat or poultry product that is
      i. cured at a state inspected or USDA inspected meat facility and received in an intact package, or
      ii. cured using approved substances (nitrates/nitrites)

The Food code limits the types of foods that can be packaged by a reduced oxygen method at the retail level. A store's HACCP plan must clearly state the foods that <u>can</u> be packaged using a reduced oxygen packaging method. Only specific products on this list can be reduced oxygen packaged. By limiting the types of food that can be Reduced Oxygen Packaged to those on the list, an additional barrier to the growth and toxin formation of Clostridium botulinum is provided and thereby helps to ensure a safe product.

In addition, except for fish that is frozen before, during, and after packaging, a food establishment shall not package fish using a reduced oxygen packaging method.

The following are examples of foods that <u>DO NOT</u> meet the above requirements and therefore <u>MAY NOT</u> be reduced oxygen packaged:

1. Cooked turkey *(including whole or sliced turkey breast)*
2. Cooked roast beef
3. Sandwich spread *(including ham salad, chicken salad, etc.)*
4. Cooked fresh sausage *(not cured/smoked such as bratwurst)*
5. Raw or smoked fish
6. Processed salads *(such as potato salad, cole slaw).*

3. Specify how the food will be maintained at 41°F or below.

   Maintaining the food at a temperature of 41°F or less is the primary barrier to the growth of Clostridium botulinum. Because temperature maintenance is such a vital factor to ensuring food safety, the method for ensuring this must be addressed in the HACCP plan.

4. Describe how the food will be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background with instructions to:
   a. Keep Refrigerated or Frozen
   b. Discard the food if within 14 calendar days of its packaging it is not served (if for on-premise consumption) or consumed (if served or sold for off premise consumption)

In addition to the normal mandatory labeling requirements, ROP foods must be labeled to include the above statements. These statements might be included on the same label with the other information or may be add-on stickers. As stated, these statements must be on the principal display panel (generally the front of the package) and must be conspicuous so that the consumer is readily made aware of these special requirements. For more information on mandatory labeling requirements, contact the Dairy and Food Inspection Division. Be sure that these labeling requirements are addressed in the HACCP plan as part of standard operating procedures.

The following is an example of the label with the required information:

5. Limit the shelf life to no more than 14 days from packaging to consumption, or the original manufacturer's "sell by" or "use by" date, whichever occurs first, unless a variance has been granted.

   Pathogens, including Listeria monocytogenes may be a hazard even at refrigeration temperatures. Therefore, it is necessary to limit the shelf life of ROP products. Ensure that this is addressed in the HACCP plan.

6. Include operational procedures that:
   a. Comply with specific requirements relating to contamination from hands.

   b. Identify a designated area and the method by which:
      i. Physical barriers or methods of separation of raw foods and ready to eat foods minimize cross contamination; and
      ii. Access to the processing equipment is restricted to responsible trained personnel familiar with the potential hazards of the operation

      As with any food processing operation, contamination between raw and ready to eat food can potentially create a serious food safety hazard. In addition, untrained personnel might contribute to hazardous food handling practices or the packaging of unapproved foods. Be sure operating procedures address these potential food safety hazards.

   c. Delineate cleaning and sanitization procedures for food contact surfaces.

      Properly cleaned and sanitized food contact surfaces are critical to ensuring a safe, sanitary operation. Use of approved cleaners and sanitizers will reduce levels of pathogenic organisms to prevent cross contamination of the product. Ensure that a complete, detailed operating procedure for cleaning and sanitizing is included in the HACCP plan.

7. Describe the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:
   a. Concepts required for a safe operation
   b. Equipment and facilities; and
   c. Procedures specified in sub-item 6 and Standard Operating Procedures for the HACCP plan.

A training program for employees conducting ROP operations is essential to producing a safe product. Areas to be included might be – limiting foods to be packaged, temperature control, separation of raw and ready to eat, employee health and hygiene. A thorough understanding of how equipment operates, product flow as well as the standard operating procedures for the facility will also add to product safety. Ensure that these items are addressed.

Section 5: Sample Forms

HACCP Team

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Team Members	Role

Developed by: _____ Date _____

Product/Process Covered

Store Name _____

Street Address _____

City _____State _____Zip Code _____

Product/Process Covered Under the HACCP Plan

Smoking/Curing

_____

_____

_____

_____

_____

Reduced Oxygen Packaging

_____

_____

_____

_____

_____

Food Additives

_____

_____

_____

_____

_____

Variances

_____

_____

_____

_____

_____

Developed by: _____ Date_____

Ingredients and Raw Materials

Store Name_____

Street Address _____

City_____State_____Zip Code _____

Product/Process Category _____

Product Examples _____

Meat Poultry and Byproducts	Nonmeat Food Ingredients	Binders/Extenders
Spice/Flavorings	Restricted Ingredients	Preservatives/Acidifiers
Liquid	Packaging Materials	Other

Developed by: _____ Date_____

Process Flow Diagram

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

Flow Diagram

Developed by: _____ Date_____

Verified by: _____ Date_____

Equipment List

Store Name _____

Street Address _____

City _____State _____Zip Code_____

Process

Developed by: _____ Date_____

Identifying Critical Control Points

Store Name_____

Street Address _____

City _____State _____Zip Code_____

Process/Step_____

Critical Control Point Decision Tree

Question 1A

Do preventative measures exist for the identified hazards?

If "no" - go to Question 1B.

If "yes" - go to Question 2.

Question 1B

Is control at this step necessary for safety?

If "no" - not a CCP

If "yes" - modify step, process or product and return to Question 1.

Question 2

Does this step eliminate or reduce the likely occurrence of a hazard(s) to an acceptable level?

If "no" - go to Question 3.

If "yes" - CCP.

Question 3

Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?

If "no" - not a CCP.

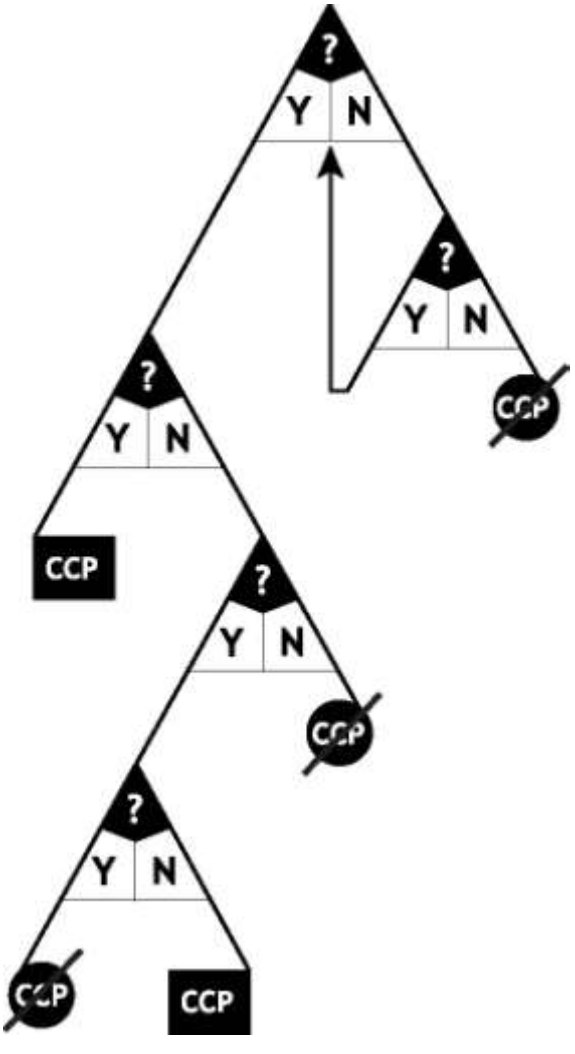
If "yes" - go to Question 4.

Question 4

Will a subsequent step eliminate the identified hazards or reduce the likely occurrence to an unacceptable level?

If "no" - CCP.

If "yes" - not a CCP.



BIOLOGICAL	CHEMICAL	PHYSICAL
☐ CCP#_____	☐ CCP#_____	☐ CCP#_____
☐ Not a CCP	☐ Not a CCP	☐ Not a CCP

Developed by: _____ Date_____

Critical Limits

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

Process Step/CCP _____

CRITICAL LIMITS

Limit *(time, temp, pH, etc.)* - _____

Source *(cite a regulation, scientific document, other resource)* - _____

Developed by: _____ Date_____

Monitoring Procedures

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

Process Step/CCP _____

MONITORING PROCEDURES

(Who, What, When, How*)* - _____

Developed by: _____ Date_____

Corrective Action Procedures

Store Name_____

Street Address_____

City _____State _____Zip Code_____

Product/Process Name_____

Process Step/CCP_____

Problem (critical limit exceeded*)* -_____

_____

_____

_____

Disposition of Product (hold, rework, condemn*)* -_____

_____

_____

_____

Corrective Action Procedure/Steps - _____

_____

_____

_____

Who is responsible for performing these corrective actions? - _____

_____

_____

_____

Compliance Procedures - _____

_____

_____

_____

Developed by: _____ Date_____

Recordkeeping Procedures

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

RECORDS

Name and Location

Developed by: _____ Date_____

Verification Procedures

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

VERIFICATION PROCEDURES

(Who, What, When, How*)* - _____

Developed by: _____ Date_____

Hazard Analysis Form

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name: _____

Process Step from Flow Diagram: _____

C: CHEMICAL	*B: BIOLOGICAL*	*P: PHYSICAL*
List the Hazards:		
Is the hazard reasonably likely to occur?		
❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No
What is the basis for your decision?		

What preventative measures can be applied at this step to prevent, eliminate or reduce the hazard to an acceptable level?

_____

_____

_____

Developed by: _____ ***Date*** _____

Hazard Analysis Worksheet

Store Name_____

Street Address _____

City _____State _____Zip Code_____

(1) Ingredient/ Processing Step	(2) Identify potential hazards introduced, controlled or enhanced at this time	(3) Are any potential food safety hazards significant? (YES/NO)	(4) Justify your decision for column 3	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (YES/NO)
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				

Developed by: _____ Date_____

HACCP Plan

Store Name_____

Street Address_____

City _____State _____Zip Code _____

Product/Process _____Date _____

(1) Critical Control Poin (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventative Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Freq-uency	Who			

HACCP Plan

Store Name_____ Store Address_____

Product/Process_____ Developed by_____ Date_____

CCP	Hazard	Critical Limits	Monitoring				Corrective Action(s)	Verification	Records
			What	How	Frequency	Who			

Appendix: Common Foodborne Bacterial Pathogens Sample HACCP Plans

Common Foodborne Bacterial Pathogens

Bacillus cereus

Bacillus cereus is an aerobic spore farmer. Two types of toxins can be produced, one results in diarrheal syndrome and the other in emetic syndrome.

RESERVOIR: WIDELY DISTRIBUTED IN THE ENVIRONMENT.

IMPLICATED FOODS: RICE, MEATS, DAIRY PRODUCTS, VEGETABLES, FISH, PASTA, SAUCES, PUDDINGS, SOUPS, PASTRIES AND SALADS.

B. cereus is widely distributed throughout the environment. It has been isolated from a variety of foods, meats, dairy products, vegetables, fish and rice. The bacteria can be found in starchy foods such as potato, pasta and cheese products, and food mixtures such as sauces, puddings, soups, casseroles, pastries and salads.

GROWTH REQUIREMENTS

TEMPERATURE (F) . . . . . 39 - 131
MINIMUM WATER ACTIVITY 0.92
PH . . . . . 4.3 - 9.3
MAXIMUM SALT (%) 18
ATMOSPHERE . . . . . AEROBE
SURVIVAL CONDITIONS . . . . . SALT-TOLERANT, SPORES ARE HEAT RESISTANT

This organism will grow at temperatures as low as 39°F, at a pH as low as 4.3, and at salt concentrations as high as 18%. Unlike other pathogens, it is an aerobe, and will grow only in the presence of oxygen. Both the spores and the emetic toxin are heat-resistant.

CONTROLS: REFRIGERATION CONTROL OF *BACILLUS CEREUS* CAN BE ACHIEVED THROUGH PROPER REFRIGERATION.

Campylobacter

Campylobacter jejuni infection, called Campylobacteriosis, causes diarrhea, which may be watery or sticky and maintain blood. Estimated numbers of cases of campylobacteriosis exceed 24 million per year, is considered the leading cause of human diarrheal illness in the United States, and is reported to cause more disease than *Shigella* and *Salmonella* spp. combined.

RESERVOIR: CHICKENS, COWS, FLIES, CATS, PUPPIES

IMPLICATED FOODS: RAW OR UNDERCOOKED CHICKEN, MEAT, SEAFOOD, CLAMS, MILK, EGGS, NON-CHLORINATED WATER, RECONTAMINATED READY-TO-EAT FOODS.

Raw and undercooked chicken, raw and improperly pasteurized milk, raw clams, and non-chlorinated water have been implicated in campylobacteriosis. The organism has been isolated from crabmeat. It's carried by healthy chickens and cows, and can be isolated from flies, cats and puppies.

GROWTH REQUIREMENTS

TEMPERATURE (F) . . . . . 86 - 113
MINIMUMWATERACTIVITY 0.99
PH . . . . . 4.39 - 9.5
MAXIMUMSALT (%) 1.5
ATMOSPHERE . . . . . MICROAEROPHILIC SURVIVAL CONDITIONS . . . . SENSITIVE TO DRYING, HEATING, DISINFECTION, ACID, AIR

The thing that makes "Campy" unique is its very special oxygen requirements. It's micro-aerophilic, which means it requires reduced levels of oxygen to grow: about 3-15% oxygen (conditions similar to the intestinal tract). Another point worth noting is that it will not grow at temperatures below 86°F, or at salt levels above 1.5%.

The organism is considered fragile and sensitive to environmental stresses like drying, heating, disinfection, acid and air which is 21% oxygen. It requires a high water activity and fairly neutral pH for growth.

CONTROLS: SANITATION TO PREVENT RECONTAMINATION; COOKING; PASTEURIZATION; WATER TREATMENT.

The controls are very basic: proper cooking and pasteurization, proper hygienic practices by food handlers to prevent recontamination, and adequate water treatment.

Clostridium botulinum

Clostridium botulinum is an anaerobic spore-former. Actually there are seven types of Clostridium botulinum - A, B, C, D, E, F and G - but the only ones we'll discuss here are type A, which represents a group of proteolytic bot, type E, which represents the nonproteolytic group. The reason for the distinction is in the proteolytic organisms' ability to break down protein.

This organism is one of the most lethal pathogens covered here. Symptoms include weakness and vertigo, followed by double vision and progressive difficulty in speaking, breathing and swallowing. There may also be abdominal distention and constipation. The toxin eventually causes paralysis, which progresses symmetrically downward, starting with the eyes and face, and proceeding to the throat, chest, and extremities. When the diaphragm and chest muscles become involved, respiration is inhibited, and death from asphyxia results. Treatment includes early administration of antitoxin and mechanical breathing assistance. Mortality is high - without the antitoxin, death is almost certain.

RESERVOIR: SOIL; FRESH WATER AND MARINE SEDIMENTS; FISH; MAMMALS

IMPLICATED FOODS: CANNED FOODS; ACIDIFIED FOODS; SMOKED AND UNEVISCERATED FISH; STUFFED EGGPLANT; GARLIC IN OIL; BAKED POTATOES; SAUTEED ONIONS; BLACK BEAN DIP; MEAT PRODUCTS; MARSCAPONE CHEESE.

Bot is widely distributed in nature and can be found in soils, sediments from streams, lakes and coastal waters, the intestinal tracts of fish and mammals, and the gills and viscera of crabs and other shellfish. Type E is most prevalent in fresh water and marine environments, while Type A is generally found terrestrially.

Bot has been a problem in a wide variety of food products: canned foods, acidified foods, smoked and uneviscerated fish, stuffed eggplant, garlic in oil, baked potatoes, sauteed onions, black bean dip, meat products, and marscapone cheese, to name just a few.

Two outbreaks in the 1960's involved vacuum-packaged fish (smoked ciscos and smoked chubs). The causative agent in each case was *C botulinum* type E. The products were packed without nitrates, with low levels of salt, and were temperature-abused during distribution, all of which contributed to the formation of the toxin. There were no obvious signs of spoilage because aerobic spoilage organisms were inhibited by the vacuum packaging, and because type E does not produce any offensive odors.

Three cases of botulism in NY were traced to chopped garlic bottled in oil, which had been held at room temperature for several months before it was opened. Presumably, the oil created an anaerobic environment.

GROWTH REQUIREMENTS	**TYPE A**	**TYPE E**
TEMPERATURE (F)	50 - 113	38 - 113
MINIMUM WATER ACTIVITY	0.94	0.97
PH	4.6 - 9.0	5.0 - 9.0
MAXIMUMSALT (%)	10	5
ATMOSPHERE	ANAEROBE	
SURVIVAL CONDITIONS	HEAT RESISTANT	

Type A and type E vary in their growth requirements. Minimum growth temperature for type A is 50°F, while type E will tolerate conditions down to 38°F. Type A's minimum water activity is 0.94, and type E's is 0.97 - a small difference on paper, but important in controlling an organism. The acid-tolerance of type A is reached at a pH of 4.6, while type E can grow at a pH of 5. A type A is more salt-tolerant; it can handle up to 10%, when 5% is sufficient to stop the growth of type E.

Although the vegetative cells are susceptible to heat, the spores are heat resistant and able to survive many adverse environmental conditions. Type A and type E differ in the heat-resistance of their spores; compared to E, type A's resistance is relatively high. By contrast, the neurotoxin produced by *C.bot* is not resistant to heat, and can be inactivated by heating for 10 minutes at 176°F.

CONTROLS: DESTRUCTION: THERMAL PROCESSING

PREVENTION OF TOXIN FORMATION: ACIDIFICATION, SALT, WATER ACTIVITY CONTROL, NITRITES, REFRIGERATION

There are two primary strategies to control *C. bot*. The first is destruction of the spores by heat (thermal processing). The second is to alter the food to inhibit toxin production - something which can be achieved by acidification, controlling water activity, the use of salt and preservatives, and refrigeration. Water activity, salt and pH can each be individually considered a full barrier to growth, but very often these single barriers - a pH of 4.6 or 10% salt - are not used because they result in a product which is unacceptable to consumers. For this reason multiple barriers are used.

One example of a product using multiple barriers is pasteurized crabmeat stored under refrigeration; here, type E is destroyed by the pasteurization process, while type A is controlled by the refrigerated storage. (Remember that type E is more sensitive to heat, while type A's minimum growth temperature is 50°F.)

Another example of multiple barriers is hot-smoked, vacuum packaged fish. Vacuum packaging provides the anaerobic environment necessary for the growth of *C. bot*, even as it inhibits the normal aerobic spoilage flora which would otherwise offer competition and give telltale signs of spoilage. So heat is used to weaken the spores of type E, which are then further controlled by the use of salt, sometimes in combination with nitrites. Finally spores of type A are controlled by refrigeration.

Vacuum-packaging of foods which are minimally processed, like sous vide products, allows the survival of *C. bot* spores while completely wiping out competing microflora. If no control barriers are present, the *C. bot* may grow and produce toxin, particularly if there is temperature abuse.

Given the frequency of temperature abuse documented at the retail and consumer levels, this process is safe only if temperatures are carefully controlled to below 38°F throughout distribution. Vacuum-packaging is also used to extend the shelf-life of the product. Since this provides additional time for toxin development, such food must be considered a high risk.

Clostridium perfringens

Clostridium perfringens is an anaerobic spore former and one of the most common agents of foodborne gastroenteritis. Perfringens poisoning, the disease caused by the organism, is characterized by intense abdominal cramps and diarrhea.

RESERVOIR: HUMANS, DOMESTIC AND WILD ANIMALS, SOIL, SEDIMENT

IMPLICATED FOODS: MEAT, POULTRY, GRAVY, CASSEROLES

C. perfringens is widely distributed in the environment and is frequently in the intestines of humans and many domestic and wild animals. Spores of the organism persist in soil and sediments.

C. perfringens has been found in beef, pork, lamb, chicken, turkey, stews, casseroles, and gravy.

GROWTH REQUIREMENTS

TEMPERATURE (F)	50 - 125
MINIMUMWATERACTIVITY	0.93
PH	5.0 - 9.0
MAXIMUM SALT (%)	7
ATMOSPHERE	ANAEROBIC
SURVIVAL CONDITIONS	HEAT-RESISTANT

Clostridium perfringens is a mesophilic organism. Since it is also a spore-former, it is quite resistant to heat, and temperatures for growth range from 50°F to 125°F. pH, water activity and salt ranges for growth are fairly typical.

CONTROLS: PROPER COOLING, HOLDING, AND REHEATING: EDUCATION OF FOOD HANDLERS.

Far from killing the spores, cooking encourages them to germinate when the product reaches a suitable temperature. Rapid, uniform cooling after cooking is needed. In virtually all outbreaks, the principal cause of perfringens poisoning is failure to properly refrigerate previously cooked foods, especially when prepared in large portions. Proper hot holding (above 140°F) and adequate reheating of cooked, chilled foods (to a minimum internal temperature of 165°F) are also necessary controls. The education of food handlers remains the critical aspect of control.

Escherichia coli

There are four classes of pathogenic *E. coli*; enteropathogenic (EPEC), enterotoxigenic (ETEC), enteroinvasive (EIEC), and enterohemmoragic (EHEC). All four types have been associated with food and water borne diseases.

EPEC - Gastroenteritis/infantile diarrhea - Outbreaks have been primarily associated with infants in day-care and nursery settings.

ETCA - Traveler's diarrhea - Contamination of water supplies or food does occasionally lead to outbreaks. Outbreaks have been associated with water and can be contaminated by raw sewage and on imported cheese.

EIEC - Bacillary dysentery - Contaminated water supplies can directly or indirectly (by contaminating food supplies) be the cause of outbreaks; infected food handlers can also be a source.

EHEC - Hemorrhagic colitis - All people are believed to be susceptible to hemorrhagic colitis. The strain E. coli 0157:H7 has become infamous following several outbreaks and probably countless more unreported illnesses. Foods commonly associated with illnesses are undercooked ground beef, unpasteurized apple cider, raw milk, fermented sausage, water and raw vegetables.

GROWTH REQUIREMENTS
TEMPERATURE (F) . . . . . 45 - 121
MINIMUM WATER ACTIVITY 0.95
PH . . . . . 4.0 - 9.0
MAXIMUMSALT (%) 6.5
ATMOSPHERE . . . . . FACULATIVE ANAEROBICE
SURVIVAL CONDITIONS . . . . . WITHSTANDS FREEZING AND ACID ENVIRONMENTS

E. coli are mesophilic organisms; they grow best at moderate temperatures, at moderate pH, and in conditions of high water activity. It has, however, been shown that some E. coli strains are very tolerant of acidic environments and freezing.

CONTROLS: PROPER COOKING; PROPER HOLDING TEMPERATURES; PERSONAL HYGIENE; EDUCATION; PREVENTING FECAL CONTAMINATION OF ANIMAL CARCASSES.

Food may be contaminated by infected food handlers who practice poor personal hygiene or by contact with water contaminated by human sewage. Control measures to prevent food poisoning therefore include educating food workers in safe food handling techniques and proper personal hygiene, properly heated foods, and holding foods under appropriate temperature controls. Additionally, untreated human sewage should not be used to fertilize vegetables and crops used for human consumption, nor should unchlorinated water be used for cleaning food or food contact surfaces.

Prevention of fecal contamination during the slaughter and processing of foods of animal origin is paramount to control foodborne infection of EHEC. Foods of animal origin should be heated sufficiently to kill the organism. Consumers should avoid eating raw or partially cooked meats and poultry, and drinking unpasteurized milk or fruit juices.

Listeria

Listeriosis, the disease caused by this organism, can produce mild flu-like symptoms in healthy individuals. In susceptible individuals, including pregnant women, newborns, and the immunocompromised, the organism may enter the blood stream, resulting in septicemia. Ultimately listeriosis can result in meningitis, encephalitis, spontaneous abortion and still birth.

RESERVOIR: SOIL, SILAGE, OTHER ENVIRONMENTAL SOURCES.

IMPLICATED FOODS: DAIRY PRODUCTS, VEGETABLES, MEAT,

POULTRY, FISH, COOKED READY-TO-EAT PRODUCTS.

L. monocytogenes can be isolated from soil, silage and other environmental sources. It can also be found in man-made environments such as food processing establishments. Generally speaking, however, the drier the environment, the less likely it is to harbor this organism.

L. mono has been associated with raw or inadequately pasteurized milk, cheeses (especially soft-ripened types), ice cream, raw vegetables, fermented sausages, raw and cooked poultry, raw meats, and raw and smoked fish.

L. mono is a psychotropic faculative anaerobe. It can survive some degree of thermal processing, but can also be destroyed by cooking to an internal temperature of 158°F for 2 minutes. It can also grow at refrigerated temperatures below 31°F. Reportedly, it has a doubling time of 1.5 days at 40°F. There is nothing unusual about this organisms pH and water activity range for growth. *L. mono* is salt-tolerant; it can grow in up to 10% salt, and has been known to survive in 30% salt. It is also nitrite-tolerant.

GROWTH REQUIREMENTS

TEMPERATURE (F)	31 - 113
MINIMUM WATER ACTIVITY	0.92
PH	4.4 - 9.4
MAXIMUM SALT (%)	10
ATMOSPHERE	FACULATIVE ANEROBE
SURVIVAL CONDITIONS	SALT AND NITRITE TOLERANT

CONTROLS: COOKING, PASTEURIZATION, PREVENTION OF RECONTAMINATION

Prevention of recontamination after cooking is a necessary control; even if the product has received thermal processing adequate to inactivate L. monocytogenes, the widespread nature of the organism provides the opportunity for recontamination. Furthermore, if the heat treatment has destroyed the competing microflora, L. mono might find itself in a suitable environment without competition.

Salmonella

There are four syndromes of human salmonellosis: Salmonella gastroenteritis, Typhoid fever; non-typhoidal Salmonella septicemia and asymptomatic carrier. Salmonella gastroenteritis may be caused by any of the Salmonella species other than Salmonella typhi, and is usually a mild, prolonged diarrhea.

True typhoid fever is caused by infection with Salmonella typhi. While fatality rates may exceed 10% in untreated patients, they are less than 1% in patients who receive proper medical treatment. Survivors may become chronic asymptomatic carriers of Salmonella bacteria. Such asymptomatic carriers show no symptoms of the illness, and yet are capable of passing the organisms to others (the classic example is Typhoid Mary).

Non-typhoidal Salmonella septicemia may result from infection with any of the Salmonella species and can affect virtually all organ systems, sometimes leading to death. Survivors may become chronic asymptomatic carriers of Salmonella bacteria.

RESERVOIR: DOMESTICATED ANIMALS AND FECES, WATER, SOIL, INSECTS

IMPLICATED FOODS: RAW MEAT, POULTRY, SEAFOOD, EGGS, DAIRY PRODUCT, YEAST, SAUCES, SALAD DRESSINGS, CAKE MIXES, CREAM FILLED DESSERTS, CONFECTIONERY, ETC.

Salmonella often live in animals - especially poultry and swine - as well as in a number of environmental sources. The organisms have been found in water, soil and insects, on factory and kitchen surfaces, and in animal feces. They can also survive in a variety of foods, including raw meats and poultry, dairy products and eggs, fish, shrimp and frog legs, yeast, coconut, sauces and salad dressing, cake mixes, cream-filled desserts and toppings, dried gelatin, peanut butter, orange juice, cocoa and chocolate.

GROWTH REQUIREMENTS

TEMPERATURE (F)	41 - 115
MINIMUMWATERACTIVITY	0.94
PH	3.7 - 9.5
MAXIMUM SALT (%)	8

ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . . . SENSITIVE TO MODERATE HEAT

Salmonella spp. are also mesophilic organisms which grow best at moderate temperatures and pH, and under conditions of low salt and of high water activity. They are killed rapidly by moderate heat treatment, yet mild heat treatment may give them the ability to develop heat resistance up to 185°F. Similarly, the organisms can adapt to an acidic environment.

CONTROLS: SANITATION TO PREVENT RECONTAMINATION, COOKING, PASTEURIZATION, PROPER HOLDING TEMPERATURES.

Ordinary household cooking, personal hygiene to prevent recontamination of cooked food, and control of time and temperature are generally adequate to prevent salmonellosis.

Shigela

There are actually four species of Shigella. Because there is little difference in their behavior, however, they will be discussed collectively.

Illness is Shigellosis, typical symptoms include fever, cramps, inflammation and ulceration of intestine, and diarrhea. This disease is easily transmitted from person to person.

RESERVOIR: HUMAN, ANIMAL

IMPLICATED FOODS: SALADS, RAW VEGETABLES, POULTRY, MEAT, FISH, FRUIT, DAIRY PRODUCTS, BAKERY PRODUCTS.

The only significant reservoir for Shigella is humans. Foods associated with shigellosis include salads (potato, tuna, shrimp, macaroni and chicken), raw vegetables, milk and dairy products, poultry, fruits, bakery products, hamburger and fin fish.

GROWTH REQUIREMENTS

TEMPERATURE (F) . . . . . 43 - 117
MINIMUM WATER ACTIVITY 0.96
PH . . . . . 4.8 - 9.3
MAXIMUM SALT (%) 5
ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . . . SURVIVES ACIDIC CONDITIONS

The growth conditions for *Shigella*, which are mesophilic organisms, are similar to those of *Salmonella*. *Shigella* can survive under various environmental conditions, including low acid.

CONTROLS: COOKING, PROPER HOLDING TEMPERATURES, SANITATION TO PREVENT RECONTAMINATION, ADEQUATE WATER TREATMENT.

Shigella can spread rapidly under the crowded and unsanitary conditions often found in such places as summer camps, refugee camps and camps for migrant workers, and at mass gatherings such as music festivals.

The primary reasons for the spread of Shigella in foods are poor personal hygiene on the part of food handlers, and the use of improper holding temperatures for contaminated foods; conversely, the best preventive measures would be good personal hygiene and health education. Chlorination of water and sanitary disposal of sewage would prevent waterborne outbreaks of shigellosis.

Staphylococcus aureus

Staphylococcus aureus produces a highly heat-stable toxin. Staphylococcal food poisoning is one of the most economically important foodborne diseases in the U.S., costing approximately $1.5 billion each year in medical expenses and loss of productivity. The most common symptoms are nausea, vomiting, abdominal cramps, diarrhea and prostration.

RESERVOIR: HUMANS, ANIMALS, AIR, DUST, SEWAGE, WATER

IMPLICATED FOODS: POULTRY, MEAT, SALADS, BAKERY PRODUCTS, SANDWICHES, DAIRY PRODUCTS.

Staph can be found in air, dust, sewage and water, although humans and animals are the primary reservoirs. *Staph* is present in and on the nasal passages, throats, hair and skin of at least one out of two healthy individuals. Food handlers are the main source of contamination, but food equipment and the environment itself can also be sources of the organism.

Foods associated with *Staph* include poultry, meat, salads, bakery products, sandwiches and dairy products.

Due to poor hygiene and temperature abuse, a number of outbreaks have been associated with cream-filled pastries and salads such as egg, chicken, tuna, potato, and macaroni.

GROWTH REQUIREMENTS
TEMPERATURE (F) GROWTH. . . . . 45 - 122
TOXIN PRODUCTION . . . . . 50 - 118
MINIMUM WATER ACTIVITY GROWTH 0.83
TOXIN PRODUCTION 0.85
PH . . . . . 4.0 - 10.0
MAXIMUM SALT (%) GROWTH 25
TOXIN PRODUCTION 10
ATMOSPHERE . . . . . FACULATIVE ANAEROBIC
SURVIVAL CONDITIONS . . . . TOLERANT OF HIGH SALT AND LOW MOISTURE

S. aureus grows and produces toxin at the lowest water activity (0.85) of any food pathogen. And, like type *A bot* and *Listeria*, *Staph* is quite salt-tolerant and will produce toxin at 10%.

CONTROLS: HEATING, PROPER EMPLOYEE HYGIENE, PREVENTION OF TEMPERATURE ABUSE

Foods which require considerable handling during preparation and which are kept at slightly elevated temperatures after preparation are frequently involved in staphylococcal food poisoning. And, while *S. aureus* does not compete well with the bacteria normally found in raw foods, it will grow both in cooked products and in salted products where the salt inhibits spoilage bacteria. Since Staph is a faculative anaerobe, reduced oxygen packaging can also give it a competitive advantage. The best way to control Staph is to ensure proper employee hygiene and to minimize exposure to uncontrolled temperatures. Remember that while the organism can be killed by heat, the toxin cannot be destroyed even by heating.

Vibrios

There are quite a few species of Vibrios, but only four will be covered.

Vibrio parahaemolyticus - The bacteria is naturally occurring in estuaries and other coastal waters. Illness is most commonly associated with fish and shellfish which are raw, undercooked or recontaminated after cooking.

Vibrio cholerae 01 - Epidemic cholera - Poor sanitation and contaminated water supplies will spread the disease; feces contaminated foods including seafood have also been associated with outbreaks.

Vibrio cholerae non-01 -The reservoir for this organism is estuarine water - illness is associated with raw oysters, but the bacteria has also been found in crabs.

Vibrio vulnificus - This organism also occurs naturally in estuarine waters. So far only oysters from the Gulf of Mexico have been implicated in illness, but the organism itself has been found in both the Atlantic and Pacific Oceans.

GROWTH REQUIREMENTS
TEMPERATURE (F) . . . . . 41 – 111
MINIMUM WATER ACTIVITY . . . . . 0.94 - 0.97
PH . . . . . 4.8 - 11.0
MAXIMUMSALT (%) . . . . . 5 – 10
ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . SALT TOLERANT; HEAT SENSITIVE

Vibrios are mesophilic and require relatively warm temperatures, high water activity and come neutral pH for growth, they also require some salt for growth, and are quite salt-tolerant. They are, however, easily eliminated by a mild heat treatment.

CONTROLS: COOKING, PREVENTION OF RECONTAMINATION, TIME/TEMPERATURE ABUSE, CONTROL PRODUCT SOURCE.

All the Vibrios can be controlled through cooking and the prevention of cross-contamination afterward. Proper refrigeration prevents proliferation, which is particularly important because of the short generation times for these species. To guard against cholerae, processors should know the source of the product and be cautious about importing from countries experiencing an epidemic.

Yersinia

Yersinia ssp: *Y. entercolitica*; Y. *pseudotuberculosis*; *Y. pestis* Of the 11 recognized species of *Yersinia*, three are known to be potentially pathogenic to humans:

enterocolitica, pseudotuberculosis and pestis. Only enterocolitica and pseudotuberculosis are recognized as foodborne pathogens. *Y. pestis*, the organism responsible for the black plague, is not transmitted by food.

Yersiniosos is often characterized by such symptoms as gastroenteritis with diarrhea and/or vomiting, but fever and abdominal pain are the hallmark symptoms. Yersinia infections mimic appendicitis, which has led to unnecessary operations.

RESERVOIR: LAKES, STREAMS, VEGETATION, SOIL, BIRDS, ANIMALS AND THEIR FECES

IMPLICATED FOODS: RAW VEGETABLES, MILK, ICE CREAM, CAKE, PORK, SOY, SALAD, SEAFOOD, CLAMS, SHRIMP

Yersinia can be found in raw vegetables, milk, ice cream, cakes, pork, soy products, salads, oysters, clams and shrimp. They are found in the environment, in such places as lakes, streams, soil and vegetation. They've been isolated from the feces of dogs, cats, goats, cattle, chincillas, mink, and primates; in the estuarine environment, many birds - among them, waterfowl and seagulls - may be carriers. The foodborne nature of Yersiniosis is well established, and numerous outbreaks have occurred worldwide.

GROWTH REQUIREMENTS

TEMPERATURE (F) . . . . . 30 - 108
MINIMUMWATERACTIVITY 0.95
PH . . . . . 4.2 - 10.0
MAXIMUM SALT (%) 7
ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . . . WITHSTANDS FREEZING AND THAWING; SENSITIVE TO HEATING AND SANITIZERS

CONTROLS: SANITATION TO PREVENT RECONTAMINATION; COOKING; PASTEURIZATION; WATER TREATMENT; PROPER HOLDING TEMPERATURES

Key factors for controlling Yersinia include proper cooking or pasteurization, proper food handling to prevent recontamination, adequate water treatment, and care taken to ensure that products are not time or temperature abused. Proper use of sanitizers is also an effective control. Essentially, to control Yersinia, it is necessary to keep things clean and moving.

Sample Plans

The following represents a sample Food Safety Plan for a fictitious company. Recognizing that the HACCP plan is only part of the food safety plan, additional supporting information is included on GMP's and SOP'S.

The plan is composed of the following sections:

- ***Plan for Smokehouse operations including:***
  - Equipment list
  - Formulation/Recipe
  - Flow Diagram
  - Standard Operating Procedures including Critical Control Points, Critical Limits, Monitoring, and Corrective Actions

- ***Plan for Reduced Oxygen Packaging Operations including:***
  - Equipment List
  - Flow Diagram
  - Standard Operating Procedures including Critical Control Points, Critical Limits, Monitoring, and Corrective Actions

Plan for ....

Also included is General information that might apply for all HACCP plans which includes:

- Training Program
- Standard Operating Procedures for Person in Charge
- Labeling
- Cleaning and Sanitizing Procedures
- Good Manufacturing Practices - Employee Practices

SAMPLE

Retail Food Establishment
Food Safety Plan

Including:

HACCP PLAN

For: Smokehouse Operations

Reduced Oxygen Packaging

GMP's/SOP's

Employee Practices

Cleaning and Sanitizing Procedures

Verifications Procedures by *Person in Charge*

Labeling Requirements

Training Program

J's Market
505 Saratoga St.
Anytown, MN

JANUARY 13, 2000

Smokehouse Operations Equipment List

Walk-in Cooler – brand _____ size _____

Other products/operations supported _____
Grinder
Mixer
Stuffer

Smokehouse - brand _____
Smoke generator/liquid smoke

Digital Thermometer
Assorted measuring containers, hand utensils, lugs, totes, etc.

Smokehouse Operations Formulation/Recipe

RING BOLOGNA

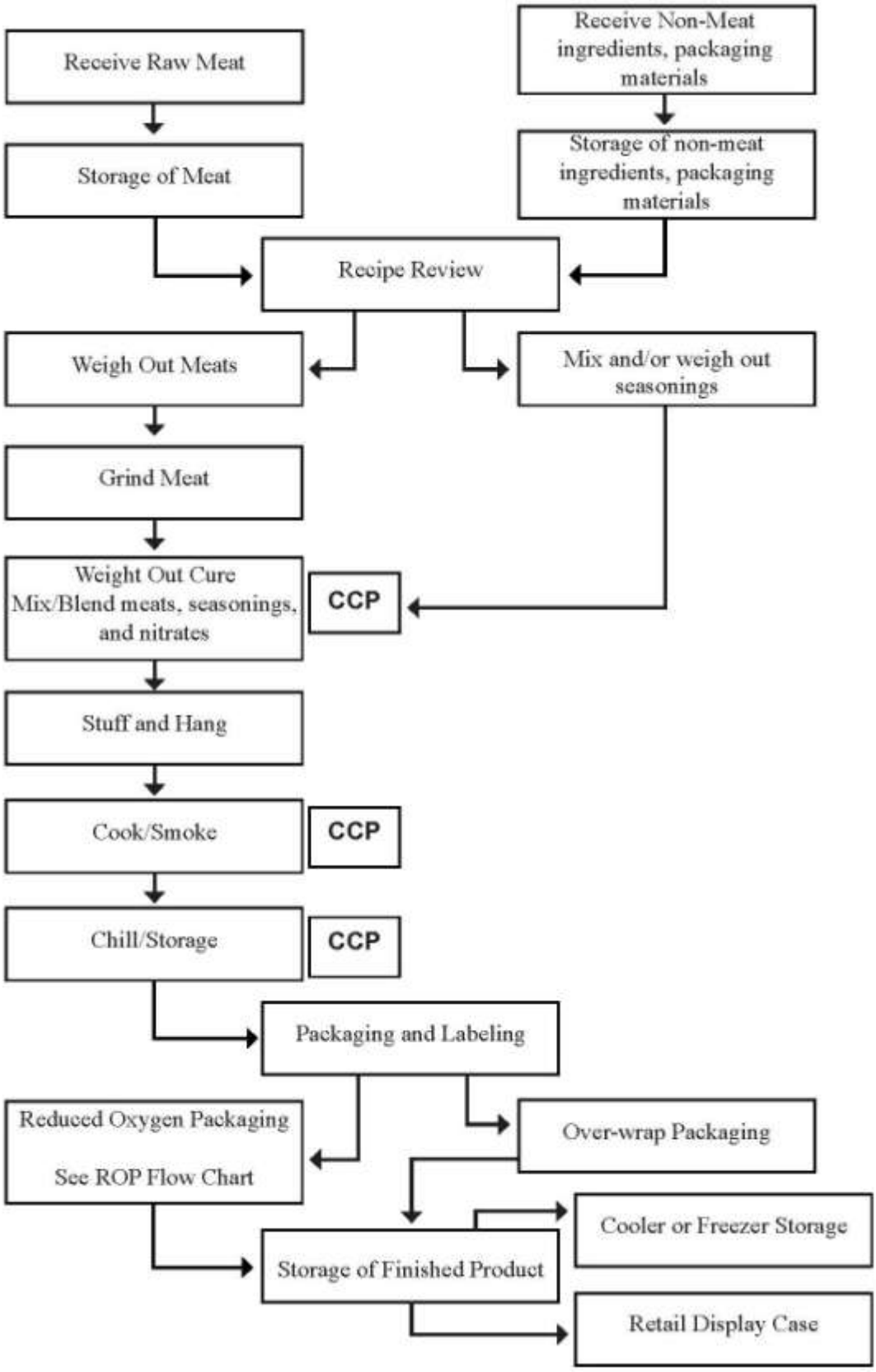
Full batch
- 50 pounds pork trim
- 50 pounds beef trim 6.5 (1 full packet) pounds of XYZ brand Bologna Seasoning
- 4 oz (1 full packet) of Quick Cure 10 pounds water

- Casings - Natural beef casing

Also include procedures for producing the product that show who food safety concerns are controlled.

Recipes to be included for every product

Smokehouse Operations Flow Diagram


Receive Raw Meat
Receive Non-Meat ingredients, packaging materials
Storage of Meat
Storage of non-meat ingredients, packaging materials
Recipe Review
Weigh Out Meats
Mix and/or weigh out seasonings
Grind Meat
Weight Out Cure Mix/Blend meats, seasonings, and nitrates
CCP
Stuff and Hang
Cook/Smoke
CCP
Chill/Storage
CCP
Packaging and Labeling
Reduced Oxygen Packaging
See ROP Flow Chart
Over-wrap Packaging
Cooler or Freezer Storage
Storage of Finished Product
Retail Display Case

Smokehouse Operations Standard Operating Procedures

CURED-SMOKED/COOKED SAUSAGE

1. Receiving/Storage of meat products, seasonings, fillers, cure agents, packaging materials, sawdust. Check the temperature of meat products on receipt. These products must be received at 41°F or less- products at higher temperatures should be rejected. Perishable products must be stored in refrigeration at 41°F or less or frozen at 0°F or less - Ensure that all products are stored under sanitary conditions to prevent contamination.

2. Ensure that facilities are clean and sanitary and in good condition and that equipment is clean and sanitary and is working properly and safely. Ensure that sawdust is in the smoke generator and install a temperature recording chart on the smokehouse.

3. Ensure that food handlers are in compliance with Employee Practices requirements in the Good Manufacturing Practices.

4. Review the recipe to confirm that all required ingredients, are on hand and assemble spices, fillers, cure agents, casings, packaging materials, etc in the work area.

5. Establish the size of the batch to be made. Almost all pre-mix units come packaged for 100 pounds of meat.

Example:

100.00	Lbs.	Meat	
6.50	Lbs.	Seasoning and filler (one bag)	
.25	Lb.	Cure (separate packet)	RESTRICTED INGREDIENT
10.00	Lbs.	Water	
116.75	Lbs.	Gross weight	

If less than a full batch is to be made, calculations must be made to reduce all ingredients by the same amount.

Examples of reduced batches are:

1/2 batch

50.00	Lbs.	Meat	
3.25	Lbs.	Seasoning and filler	
.125	Lb.	Cure	RESTRICTED INGREDIENT
5.00	Lbs.	Water	
58.375	Lbs.	Gross weight	

1/4 batch

25.00	Lbs.	Meat	
1.625	Lbs.	Seasoning and filler	
.0625	Lb.	Cure	RESTRICTED INGREDIENT
2.5	Lbs.	Water	

29.1875 Lbs. Gross weight

Weigh out meat, seasonings and fillers, and water. Do not necessarily assume that containers/pails/lugs/scoops of ingredients always weigh the same. Record entries for these ingredients on the batch record.

6. Grind the meat.

7. ***Critical Control Point* -** Weigh out cure and premix with at least 1 pint of water to provide better distribution with the other ingredients. Pre-mix seasonings with part of the remaining water. In the automatic mixer, mix meat with seasoning/water blend, fillers, remaining water, and cure /water blend.

   ***Critical Limit* -** For full batches (100 pounds), net weight of cure is .25 lbs; for 1/2 batch/50 pounds net weight of cure is .125 pounds; for 1/4 batch (25 pounds) net weight of cure is .0625 pounds. Because of the small amounts of cure required batches, weighing of cure ingredients must be done on a certified digital scale. Thoroughly mix ingredients, especially the cure mixture to ensure even distribution throughout the batch.

   Monitoring - Observe the mixing process to ensure complete distribution. Complete entries on the batch record. Attach seasoning and cure bag to batch record.

   Corrective Action - If errors are noticed before any further steps are completed, take the following steps:
   - If insufficient cure has been added, additional amounts up to the amount required in the recipe can be added and the batch re-mixed
   - If too much cure was added, additional meat and seasonings can be added to extend the batch and remixed. If errors are noted after the cook step, nothing can be done to save the batch and the entire batch must be discarded.

8. Stuff the mixed product into the appropriate size and type of casing for the product being made. Use only clean, fresh casings that have been stored properly to prevent contamination. Hang to product onto rods and into smokehouse. Insert temperature probe into product into sausage.

9. ***Critical Control Point* -** Smoke and Cook. Set smokehouse computer to the appropriate cycle for the product being produced. The smokehouse will automatically shut down when the programmed temperature is reached.

   Critical Limit - Minimum internal temperature of product are: Beef and Pork - 155°F for 15 seconds Poultry - 165°F for 15 seconds.

   Monitoring - Inspect temperature chart to ensure that the highest attained temperature has been met. Record the highest attained temperature on the Batch Record.

   Corrective Action - If minimum temperature has not been met, reset the smokehouse and re-cook until the minimum time and temperature have been met.

10. ***Critical Control Point* -** Cooling. The product must be rapidly cooled. This may be part of the smokehouse cycle if the unit has an internal shower. Showering with water will assist in bringing the temperature down. Next, the product must be removed from the smokehouse and placed in the cooler (which is at 41°F or less). This should happen immediately after the smokehouse cycle is completed as it is important that the cooling process begins right away.

When cooked product is placed into the cooler, ensure that it is placed so that it is protected from cross contamination by raw meat.

Critical Limit - Products must be cooled from 140°F to 70°F within 2 hours and from 70° to 41°F within another 4 hours.

Monitoring - Check internal temperature at 1 hour and 45 minutes, at 2 hours, and again at 6 hours. Record internal temperature on batch record.

Corrective Action - If the temperature taken at 1 hour 45 minutes is at 75° For greater, notify the Person in Charge and take immediate action to reduce the temperature. This can be accomplished by showering with cold water or if a greater temperature reduction is necessary, product could go into a water bath. If product does not meet the critical limits at 2 and 6 hours, it must be discarded.

1. **Packaging/Labeling** - if product is packaged by a Reduced Oxygen packaging method, refer to Standard Operating Procedures for ROP. If product is packaged by over-wrapping, ensure that packaging materials (trays, wrap) are in a sanitary condition and do not subject the food to cross contamination. Food employees must limit direct hand contact with exposed ready to eat food. Products be labeled with mandatory labeling requirements.
2. **Storage/Display** - Place packaged food into refrigerated storage, either retail display cases or cooler storage at 41°F or less.

Smokehouse Operations

J's Market
505 Saratoga St. W
Anytown MN 55555

Batch Record

Required to be completed for each product made as official record of monitoring critical control points.

PRODUCT _____ PRODUCTION DATE _____ CODE/LOT ID _____

FORMULATION:

Beef: _____ LBS Water: _____ LBS
Pork: _____ LBS Other: _____
Turkey: _____ LBS _____
Veal: _____ LBS _____

Seasonings: *Contents and Weight* _____

_____

_____

CURING AGENT: Critical Control Point

Type _____ Weight _____ Signature _____
How incorporated (mix, injected, soak, etc.) _____
Cure Lot Number _____
Other Processing _____

_____

_____

SMOKE/COOK: Critical Control Point

Temperature Checks: _____
FINAL INTERNAL TEMPERATURE* _____ *°F *Minimum cook temperature of 155°F (165°F for poultry)*
Signature _____

COOLING: Critical Control Point

Temperature Checks _____
Temp at 2 Hours* _____ **Must be 70°F or less*
Signature _____
Temp at 6 Hours* _____ *Must be 41°F or less
Signature _____

All CCP's Met? ❑ Yes ❑ No

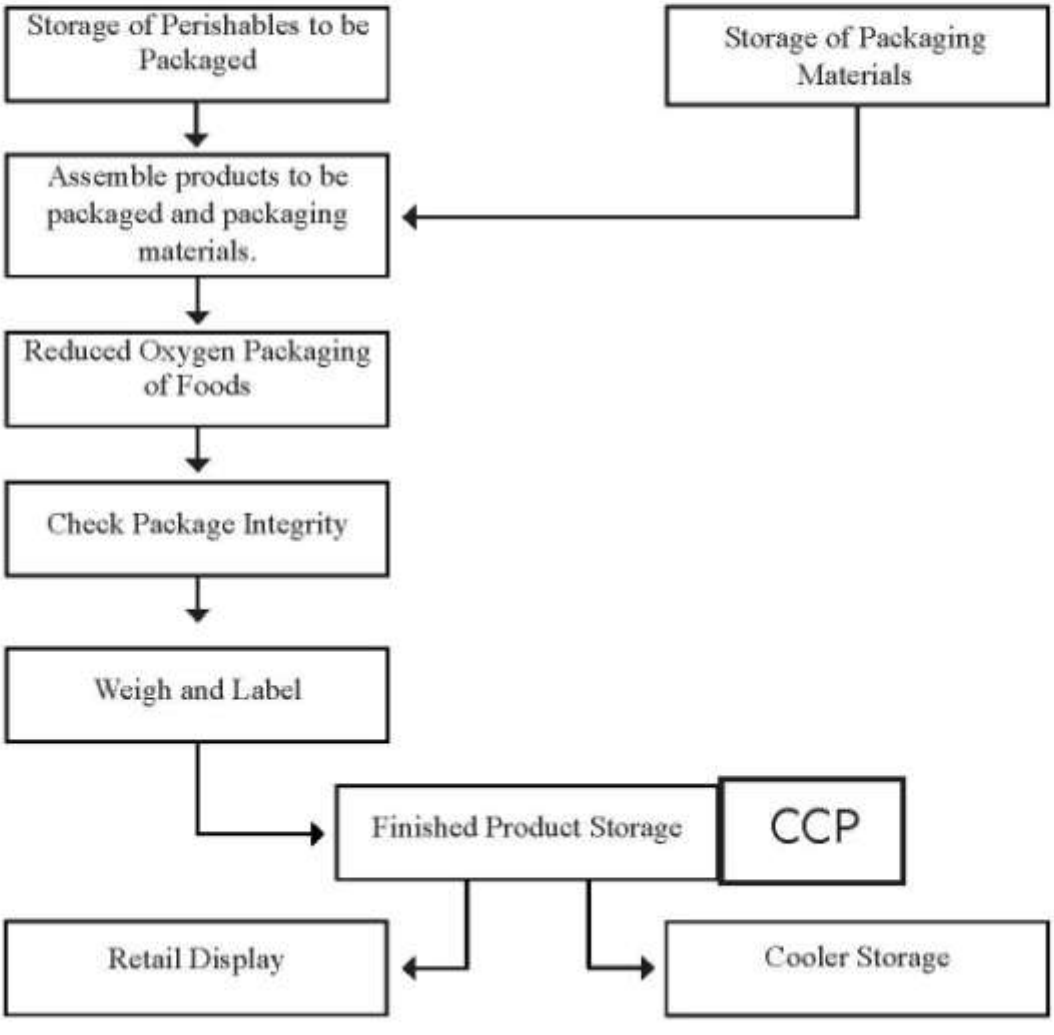
Signature _____

Reduced Oxygen Packaging

Equipment List

- Slicer - brand _____
- Vacuum Packaging Machine - _____
- Digital Thermometer
- Assorted knives, tongs, trays, lugs/totes, hand utensils

Flow Diagram



Reduced Oxygen Packaging Standard Operating Procedures

Only food handlers that are trained in the use of the reduced oxygen packaging equipment and process of reduced oxygen packaging and have a thorough understanding of the HACCP plan shall operate or conduct ROP operations.

1. Ensure that facilities in the area where ROP operations are to be conducted are clean and sanitary and are in good physical condition. ROP operations must only be conducted in the designated area in the meat department. No packaging of ready to eat foods can be conducted while raw foods are present or are being processed in the same room. Only properly cleaned and sanitized equipment is to be used in the operation.

2. Ensure that all equipment is operating properly and safely. Ensure that equipment involved in the ROP process has been properly cleaned and sanitized according to regulation and store policy. This equipment includes (but not limited to): tables, cutting boards, slicer, knives, tongs, trays,

3. Ensure that food handlers are in compliance with Employee Practices requirements in the Good Manufacturing Practices. This includes employee hygiene, handwashing, clean clothing, etc.

4. Assemble packaging materials, labels, etc. necessary to the operation.

5. Assemble products that are to be packaged.
   - Products to be ROP shall remain at room temperature no longer than 30 minutes during the packaging process, therefore, only remove sufficient quantities so that this is managed.
   - Products that can be ROP are limited to list provided.

6. Place foods in the packaging materials. Food Employees must limit direct hand contact with exposed, ready-to-eat food when deli tissues, spatulas, tongs, dispensing equipment, or other utensils can be used.

7. Place bags in vacuum machine ensuring that adequate space is provided around each package. Ensure that machine settings are appropriate for product being packaged. It is important that a full vacuum is provided or if using gas displacement, that the equipment is working properly. Start the machine and wait for the lid to open indicating that the process is complete

8. Remove packages from the machine. Visually check the seal to ensure that it is tight and that there are no food materials in the seal. Make a note of any indicators of a faulty seal such as wrinkles or an incomplete seal. Packages with a faulty seal should be re-packaged. Trim excess packaging as required.

9. Weigh and label each package. Ensure that all required information is provided on the label. Ensure that the shelf life is no longer than 14 days.

10. ***Critical Control Point *** Place packaged food into refrigerated storage, either retail display cases or cooler storage.

    Critical Limit -Temperature in storage must be 41°F or less. Products will be considered to be temperature abused if they are exposed to temperatures above 41°F for more than 4 hours.

    Monitoring - The designated employees of the meat department will check and record the actual temperature in both the walk-in cooler and retail case that contains in-store packaged products at intervals not to exceed 4 hours. If temperatures are out of range, notify the Person in Charge and move products to other approved

storage location that does meet temperature requirements. Record temperature on cold storage log.

Corrective Action -Discard temperature abused products. Make necessary adjustments or repairs to cooler or case prior to restocking. Document any corrective actions on the log.

11. Visually check ROP products on a daily basis in the retail case or as products in reserve storage are brought out to the retail case and check the package integrity (faulty seals, 'puffy' packages, holes, tears, or packages that may have otherwise lost their 'vacuum') and contents of the package (slime, mold, discoloration). Packages that do not meet the requirements should be destroyed. Also check for products that have passed their 'use by' date.

Cold Storage Log

Store Name _____

Store Address _____

Month/Year _____ Cooler/Location _____

DATE	TIME	TEMP.	S	TIME	TIME	S	DATE	TIME	TEMP.	S TEMP. TEMP.	S
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											

S= signature of person taking/recording temperature

If air temp is more than 45°, check product temperature;
If product temp is more than 41° but less than ___°, move product to another cooler, cool to 41 ° within 4 hours and make necessary repairs to case;
If product temperature is higher than ___°, discard product and make necessary repairs to the case
Any record noted above 41°F, must have explanation/corrective action noted below:

For example:
5/4 – temp at 45° – case on defrost – product temp - 39° - OK or
5/5 – temp at 50° – product temp 50° – 100 pounds of sausage product destroyed

Records Reviewed by: _____ Date: _____
Comments:

Labeling

Mandatory Labeling Information

1. Name of Product
2. Name, address including zip code of store
3. Net weight statement
4. Complete and detailed ingredients statement
5. On fresh/raw meat products, the Safe Handling Statement must be included
6. Nutrition facts may be required, contact the Minnesota Department of Agriculture

In addition, Reduced Oxygen packaged food labels must also include:

1. The Statement: **Keep Refrigerated or Frozen**
2. Instructions to discard the food if within 14 days of its packaging if it is not consumed
3. The shelf life must not be longer than 14 days from packaging to consumption or the original manufacturers "sell by"' or "use by" date, whichever occurs first.

Shelf life for various products will be as follows:

All in-store smokehouse products	XX days
Sliced cold cuts (ham, smoked turkey, salami, etc.)	XX days
Cheese (block or sliced)	XX days
Raw meats or poultry	XX days

Sample Label

Training Program - For Food Handlers Conducting Reduced Oxygen Packaging

Understanding the potential hazards associated with reduced oxygen packaging

While the process of packaging foods using a reduced oxygen method extends the shelf life, it also can pose a serious public health threat.

Generally, bacteria survive under conditions where there is oxygen is present - aerobic conditions - or where oxygen is not present anaerobic conditions. Some bacteria have the ability to adapt to either condition. Under traditional packaging conditions (aerobic conditions), spoilage bacteria would normally thrive and the product would spoil before the more hazardous types of bacteria might become a problem. During the process of 'vacuum packaging' or 'reduced oxygen packaging', the air inside the package (which is approximately 21 % oxygen) is eliminated, creating anaerobic conditions and thereby changing the types of bacteria that can survive in the package. Spoilage organisms are eliminated, but several types of pathogenic bacteria survive and actually thrive under these conditions. The pathogen of greatest concern is Clostridium botulinum. While botulism bacteria will normally be killed in a cooking step, spores of the bacteria may survive and could grow and produce toxin if the conditions are right. These conditions are similar to those that occur in a vacuum/reduced oxygen package. Other pathogens of concern may be Listeria monocytogenes, Yersinia enterocolitica, Campylobacter jejuni, and Clostridium perfringens.

Concepts Required for a Safe Operation

A thorough understanding of the of the HACCP plan, the use of the reduced oxygen packaging equipment, and the standard operating procedures are critical to a safe operation. Areas to focus on include: products that can be packaged, temperature control, prevention of cross contamination, and health and personal hygiene of food handlers.

Products that can be packaged by ROP

State regulations limit the types of foods that can be packaged. This store's HACCP plan defines the foods that can be packaged using reduced oxygen packaging. **Only specific products on this list can be reduced oxygen packaged**. Any addition to the above list must first have the approval of the PERSON IN CHARGE. Changes must be noted in the HACCP PLAN. Foods to be reduced oxygen packaged at the retail level must be limited to one that does not support the growth of Clostridium botulinum because of one of the following requirements:

1. has a water activity of 0.91 or less
2. has a pH of 4.6 or less
3. is a food with a high level of competing organisms, including raw meat, raw poultry, or a naturally cultured standardized cheese
4. is a meat or poultry product that was cured at a USDA meat plant and received in an intact package or cured using approved substances (nitrates/nitrites).

By limiting the types of food that can be ROP to those on the list, an additional barrier to the growth of Clostridium botulinum is provided and thereby helps to ensure a safe product.

In addition, except for fish that is frozen before, during, and after packaging, a food establishment shall not package fish using a reduced oxygen packaging method.

Following are examples of foods that do not meet the above requirements and therefore may NOT be reduced oxygen packaged: Cooked turkey (including whole or sliced turkey breast), cooked roast beef, sandwich spread (including ham salad, chicken salad, etc.), cooked fresh sausage (not cured/smoked such as bratwurst), fresh salads.

Temperature Control

Temperature control is a very important factor in keeping all potentially hazardous foods safe. But the extended shelf life and decreased oxygen concentration allows certain pathogens to multiply in reduced oxygen conditions. To reduce the potential for growth of these pathogens, products (packaged and unpackaged) must be stored at cooler temperatures of 41^{o} F or less. Employees must monitor the cooler temperatures at least every 4 hours to ensure that foods are not allowed to be out of the temperature requirements for extended periods of time.

Preventing Cross Contamination

Raw foods should be handled separately from cooked and ready to eat foods to avoid cross contamination. Utensils, equipment and work surfaces used for raw foods should be thoroughly cleaned and sanitized prior to using for cooked or ready-to-eat foods. In addition, ensure that ready-to-eat foods are stored so that blood or juices from raw products cannot drip or otherwise come into contact with them. Food handlers can also be a source of cross contamination through improper handwashing, or soiled clothing or aprons.

Employee Health and Hygiene

The health and personal hygiene of food handlers can also play a critical role in producing a safe ROP food. It is vital that employees working in this operation follow the Employee Practices guidelines in the Good Manufacturing Practices. (See Page xx). Particular attention should be paid to #1 - Handwashing procedures, #6 Clean Outer

Garments, and #1 0 - Food handling.

Cleaning and Sanitizing Procedures - Equipment Food Contact Surfaces

Properly cleaned and sanitized food contact surfaces are critical to ensuring a safe, sanitary operation. Use of approved cleaners and sanitizers will reduce levels of pathogenic organisms to prevent cross contamination of the product. Detergent cleaners suspend and help remove various food soils. Chemical sanitizers (chlorine, iodine, acid, or quaternary ammonia types) reduce the numbers of pathogens and other microorganism to insignificant levels.

The clean up process must be completed in accordance with the following procedures.

- **Pre-cleaning** - Equipment and utensils shall be pre-flushed, pre-soaked, or scraped as necessary to eliminate excessive food debris.

- **Washing** - Equipment and utensils shall be effectively washed to remove or completely loosen soils using manual or mechanical means. Only approved chemicals are to be used in this process. Approved chemicals for WASHING are: _____

- **Rinsing** - Washed utensils and equipment shall be rinsed to remove abrasives and to remove or dilute cleaning chemicals with water.

- **Sanitizing** - After being washed and rinsed, equipment and utensils must be sanitized with an approved chemical by immersion, manual swabbing, brushing, or pressure spraying methods. Exposure time is important to ensure effectiveness of the chemical. Approved chemicals and exposure times for SANITIZING are:
  _____
  _____

Ensure that an appropriate chemical test kit is available and routinely used to ensure that accurate concentrations of the sanitizing solutions are being used.

Frequency of Cleaning

Equipment, food contact surfaces and utensils shall be cleaned in a time frame as follows:

1. Before each use with a different type of raw animal food, including beef, fish, lamb, pork, or poultry;
2. Each time there is a change from working with raw foods to working with ready to eat foods;
3. Between uses with raw fruits or vegetables and with potentially hazardous foods;
4. At any time during the operation when contamination may have occurred.
5. If used with potentially hazardous foods, throughout the day at least once every four hours
6. Utensils and equipment that are used to prepare food in a refrigerated room that maintains the utensils, equipment, and food under preparation at 41°F or less and are cleaned at least once every 24 hours
7. Before using or storing a food thermometer.
8. For equipment used for storage of packaged or un-packaged food, including coolers, and the equipment is cleaned at a frequency necessary to eliminate soil residue.
9. For ice bins, at a frequency necessary to preclude accumulation of soil or mold.
10. Food contact surfaces of cooking equipment shall be cleaned at least once every 24 hours.

Non-food-contact surfaces of equipment shall be cleaned at a frequency necessary to prevent accumulation of soil residues.

Good Manufacturing Practices - Employee Practices

1. Hands are to be thoroughly washed in a designated hand sink with soap and water, paying particular attention to the areas underneath the fingernails and between the fingers by scrubbing thoroughly with a using a fingernail brush. Dry with single use towels. Handwashing is to be done at the following times:

    - after using the toilet, in the toilet room
    - after coughing, sneezing, using a tissue, using tobacco, eating, or drinking
    - after handling soiled equipment or utensils
    - immediately before engaging in food preparation activities
    - during food preparation as necessary to remove soil and prevent cross contamination
    - when switching between raw and ready-to-eat foods
    - other times as needed to maintain good sanitation

2. Fingernails must be kept trimmed, filed, free of nail polish, and maintained so the edges are cleanable and not rough.

3. Eating and drinking is prohibited in areas where contamination of exposed food, clean equipment, utensils, unwrapped single service and single use articles could occur. A food employee may drink from a closed beverage container in a food prep area as long as it is handled to prevent contamination.

4. Effective hair restraints must be worn in processing areas.

5. Smoking and other uses of tobacco are prohibited.

6. Clean outer clothing must be worn each day and changed as often as necessary throughout the day (when moving from a raw food operation to a ready-to-eat food operation).

7. Frocks and aprons used by employees are to be hung in a designated area when not in use. They are not to be worn in the toilet area, eating areas and locker rooms.

8. Foot wear is to be kept clean.

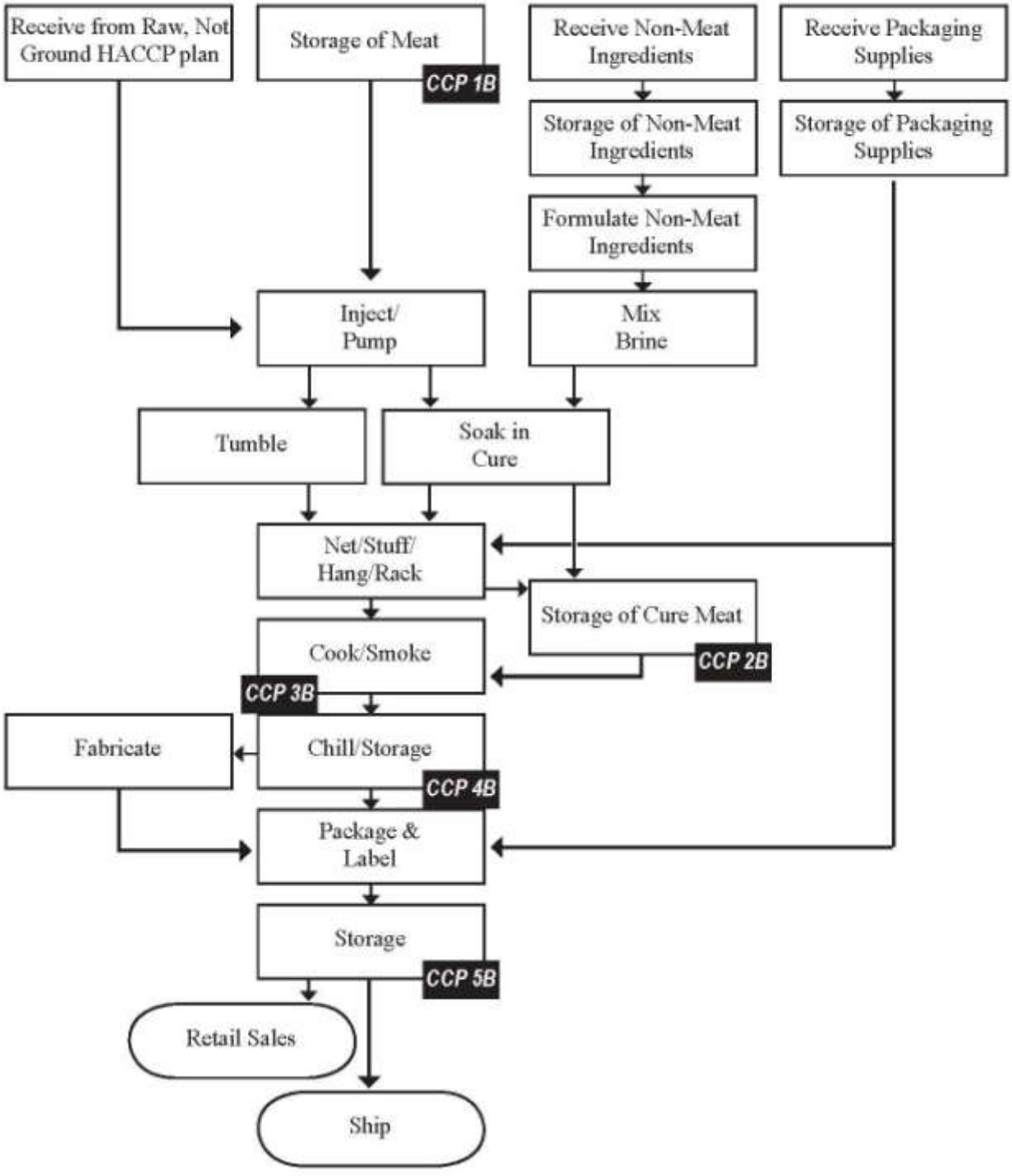
9. No jewelry (except a wedding band or other plain ring) is allowed during handling of food.

10. Food Employees shall report to the Person in Charge when they have a symptom caused by illness, infection, or other source that is:
    - associated with diarrhea, vomiting or other acute gastrointestinal illness
    - jaundice
    - a boil, infected wound or other lesion containing pus that is open or draining unless if on the hands or wrists, unless a finger cot or other impermeable cover protects the lesion and a single use glove is worn if on exposed portions of the arms, the lesion is protected by an impermeable cover.

The Person in Charge shall impose the proper restrictions and exclusions according to rule.

Flow Diagram for HACCP Category: Fully Cooked, Not Shelf Stable Whole Muscle Products

Example Product(s): Hickory Smoked Bacon, Hickory Smoked Boneless Ham



m a i
- e t n

Flow Diagram for Smoked Sausage

	POTENTIAL HAZARDS	CCP/CP	CRITICAL LIMITS	POTENTIAL HAZARDS	CORRECTIVE ACTIONS
RECEIVING	Rapid bacterial growth, spoilage, cross- contamination, foreign objects.	CP	Frozen items must be kept frozen. Chilled items must be kept at 40°F or below. No cross-contamination, foreign objects or spoilage.	Visual inspection. Use a digital thermometer.	Reject thawed frozen items. Reject chilled items above 40°F. Reject product with foreign objects.
STORAGE	Rapid bacterial growth, spoilage, cross- contamination, foreign objects.	CP	Temperature at 40°F or below. Any product stored above 70°F or a four-hour period must be discarded.	Record temperature every four hours. After normal working hours, the cooler will be on automatic alarm system.	Adjust cooler temperature. Discard any product that exceeds 70°F for more than four hours.
GRINDING	Rapid bacterial growth and cross- contamination.	CP	Utensils and equipment must be clean. Employees must meet personal sanitary standards.	Visual inspection.	Stop production and modify procedure.
MIXING	Insufficient mixing or amounts may result in poor distribution of cure.	CCP	Cure must be properly distributed, following uniform formulation mix.	Observe batch make slip, date and weight of product. Attach seasoning and cure bag.	Modify and re-blend, following uniform formulation mix.
STUFFING AND HANDLING	Cross- contamination between personnel and equipment.	CP	Utensils and equipment must be clean. Employees must meet personal sanitary standards.	Visual inspection.	Stop production and rework product.
COOKING AND SMOKING	Pathogens and bacterial spores may survive if product is not properly cooked.	CCP	Internal temperatures must be: Beef and Pork: 155°F Poultry: 165°F	Inspect temperature chart. Verify that the minimum time and temperature have been met.	Re-cook product until the minimum time and temperature have been met.
CHILLING	Surviving bacterial spores may germinate to vegetative cells if chilling is to slow.	CCP	Products must be cooled to 70°F within two hours, and to 40°F and below within another 4 hours.	Record internal temperature on batch make slip at two hours and six hours.	Discard any product not cooled to 40°F or below within six hours.
PACKAGING AND LABELING	Products may be incorrectly labeled. Outdated product may not be safe. Economic fraud. Cross-contamination.	CP	Overwrap product to prevent bacteria growth. Policies for rotation, disposal, and proper labeling must be followed. Follow good manufacturing practices.	Record the lot code and refrigeration statement. Follow proper procedures for coding and dating. Follow good manufacturing practices.	Reject or discard improper packaging. Discard outdated products.
DISPLAY	Improper temperature may result in rapid and progressive growth of pathogens.	CCP	Temperature must be maintained at 40°F or below. Products will be considered temperature-abused if they are exposed to temperatures above 40°F for more than six hours.	Check and record display case temperature every four hours.	Lower the thermostat. Discard any temperature-abused products.

PROCESS STEP	FOOD SAFETY HAZARD	REASONABLY LIKELY TO OCCUR	JUSTIFICATION FOR DECISION	IF YES IN COLUMN 3 What measures could be applied to prevent, eliminate, or reduce the hazard to an accepable level?	IS THE STEP A CRITICAL CONTROL POINT (CCP)?
Receive meat form raw, not ground HACCP Plan	B — None	B: — No			
	C — None	C: — No			
	P— None	P: — No			
Storage of meat	B — Pathogen Growth	B — Yes	Proper storage temperature suffiecient to prevent pathogen growth.	Temperature control to reduce a potential risk of pathogenic growth.	Yes (CCP 1B Holding Cooler)
	C — None	C — No			
	P — Foreign Materials (ex. overhead contamination)	P — None	Preventive maintenance and sanitation SOP's to prevent contamination.		
Receiving from chill	B — Pathogen Growth	B — No	Proper storage temperature sufficient to prevent pathogen growth.		
	C — Pathogen Growth	C — No			
	P — Foreign Materials (ex. overhead contamination)	P — No	Preventive maintenance and sanitation SOP's to prevent contamination		
Receive packaging supplies	B — Microbial Spores	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
	C — None				
	P — Foreign Materials	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
Receive non-meat ingredients	B — Microbial Spores	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
	C — None				
	P — Foreign Materials	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
Storage of packaging supplies	B — Microbial Spores	B — No	Letters of guarantee are on file for all packaging supplies and ingredients		
	C — None	C — No	Letters of guarantee are on file for all packaging supplies and ingredients. GMP's, routine samition, visual observation for container integrity.		
	P — Foreign Materials	P — No			
Receive non-meat ingredients	B — Microbial Spores	No	Letters of guarantee are on file for all packaging supplies and ingredients		
	C — None				
	P — Foreign Materials	No	Letters of guarantee are on file for all packaging supplies and ingredients		

PROCESS STEP	FOOD SAFETY HAZARD	RESEASONABLY LIKELY TO OCCUR	JUSTIFICATION FOR DECISION	IF YES IN COLUMN 3 What measures could be applied to prevent, eliminate, or reduce the hazard to an accepable level?	IS THE STEP A CRITICAL CONTROL POINT (CCP)?
Storage of non-meat ingredients	B — Micobial Spores	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
	C — None				
	P— None	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
Formulate non-meat ingredients	B — Pathogen Introduction	B — No	Responsible employee prepares according to formulation.		
	C — None	C — No			
	P — Foreign Materials (ex. metal)	P — No	Plant history indicated that metal contamination is not likely to occur.		
Mix brine	B — Pathogen Introduction	B — No	Sanitation SOP's to prevent cross-contamination.		
	C — Nitrate	C — No	Responsible employee prepares according to formulation.		
	P — Foreign Materials (ex. overhead contamination)	P — No	Plant history indicated that metal contamination is not likely to occur.		
Inject/pump	B — Pathogen Introduction	No	Sanitation SOP's to prevent cross-contamination.		
	C — Excessive Nitrate		Proper pump % for appropriate formulation.		
	P — None	No			
Tumble	B — Microbial Spores	No	Sanitation SOP's to prevent cross-contamination.		
	C — None				
	P — None	No			
Net/stuff/ hangrack	B — Microbial Spores	B — No	Sanitation SOP's to prevent cross-contamination.		
	C — None	C — No			
	P — None	P — No			
Storage of meat cure	B — Pathogen Growth	B — Yes	Proper storage temperature sufficient to prevent pathogen growth.	Temperature control to reduce a potential risk of pathogenic growth.	Yes (CCP 2B cured meat cooler)
	C — None	C — No			
	P — None	P — No			
Cook/smoke	B — Pathogen Reduction	Yes	Potential survivor and/or growth of pathogens with improper cooking.		Yes (CCP 3B)
	C — None				
	P — None				

PROCESS STEP	FOOD SAFETY HAZARD	REASONABLY LIKELY TO OCCUR	JUSTIFICATION FOR DECISION	IF YES IN COLUMN 3 What measures could be applied to prevent, eliminate, or reduce the hazard to an accepable level?	IS THE STEP A CRITICAL CONTROL POINT (CCP)?
Chill/storage	B — Pathogen Growth	B — Yes	Potential survival and/or growth of pathogens with improper chilling. Improper storage temperature can provide ambient temperature for both spoilage and pathogenic growth.	Temperature control to reduce a potential risk of pathogenic growth.	Yes (CCP 4B smoked meats cooler)
	C — None	C — No			
	P— Foreign Materials	P — No	Container integrity.		No
Fabricate	B — Pathogen Contamination (*Listeria monocytogenes*)	No	Potential contamination form envimmental sources. Pre-operational and operation sanitation can reduce the risk of contamination from the environment and cross-contamination between products.		No
	C — None	C — No			
	P — None	P — No			
Package and label	B — Pathogen Contamination	B — No	Sanitation Standard Operating Procedures are in place to prevent contamination.	.	No
	C — Nitrate	C — No			
	P — None	P — No			
Storage of finished product	B — Pathogen Growth	B — No	Improper storage temperature can provide ambient temperature for both pathogenic growth.	Temperature control to reduce a potential risk of pathogenic growth.	Yes (CCP 5B holding cooler)
	C — None	C — No			
	P — Foreign Materials	P — No	Container integrity.		No
Ship	B — Pathogen Growth	B — No	Low risk, temperature abuse is unlikely to occur, since truck temperatures are sufficient to prevent pathogen growth.		No
	C — None	C — No			
	P — Foreign Materials	P — No	Container integrity.		

CCP	CRITICAL LIMITS	MONITORING PROCEDURES & FREQUENCIES	MONITORING RECORDS	CORRECTIVE ACTIONS	VERIFICATION PROCEDURES & FREQUENCIES	VERIFICATION RECORDS
CCP 1B Holding Cooler Hazard: Pathogen Growth	The cooler temperature is not to exceed 40°F except for periods of defrost.	The temperature of the raw meat storage areas will be taken continuously by a computerized data recorder with an alarm.	Bi-weekly or as necessary a printout of the plant temperatures. Non-compliance Log	See the Corrective Action Report for the specific actions taken to bring the CCP under control. Corrective actions may include but are not limited to; Plant management will immediately notify maintenance personnel to repair the cooler. The temperature of the cooler will be brought into compliance as soon as possible. If the increased temperature effects product temperature, the product will be temporarily relocated in another cooler or freezer, a hold may be placed on the cooler to prevent cold air from escaping.	Thermometers. Alarms will be checked and if necessary calibrated on a monthly basis.	Thermometer Calibration Log Monthly Verification Log
CCP 2B Cured Meat Cooler	Same as CCP1B	The temperature of the cured meat storage areas will be taken continuously by a computerized data recorder with an alarm.	Same as CCP1B	Same as CCP1B	Same as CCP1B	Same as CCP1B
CCP 3B Internal Product Temperature	The minimal internal temperature must reach 148°F.	At the end of the cooking, the oven operator or designee will take and record the internal temperature per each product in the oven. The temperature will be taken with a calibrated thermometer.	Smokehouse Log Non-compliance Report	Specific corrective actions will be recorded for each deviation from the critical limit. Corrective actions may include but are not limited to: holding in the oven until the temperature is reached, recooking the product, reworking the product, or disposing of the product.	Thermometers will be calibrated on a monthly basis or as necessary. Daily review of production records by management Visual Observations of procedures will be conducted on a monthly basis or as necessary. Findings will be recorded on the Monthly Verification Log.	Thermometer Calibration Log Monthly Verification Log
CCP 4B Smoked Meat Cooler	Same as CCP1B	The temperature of the smoked meat storage areas will be taken continuously by a computerized data recorder with an alarm.	Same as CCP1B	Same as CCP1B	Same as CCP1B	Same as CCP1B
CCP 4B Holding Cooler	Same as CCP1B	The temperature of the finished and packaged product areas will be taken continuously by a computerized data recorder with an alarm.	Same as CCP1B	Same as CCP1B	Same as CCP1B	Same as CCP1B

Conference for Food Protection
2012 Issue Form

Internal Number: 119
Issue: 2012 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.

Title:
Beef Grinding Log Template for Retail Establishments

Issue you would like the Conference to consider:
The Food Safety and Inspection Service (FSIS) recommends that a CFP Committee be created to review the FSIS grinding log template and provide feedback to FSIS on its use at retail. The draft grinding log template will become the basis of the FSIS compliance guidelines that accompanies the planned proposed rule, "Records to be Kept by Official Establishments and Retail Stores That Grind or Chop Raw Beef Products". The FSIS proposed rule is expected to require establishments and retail stores to keep records that disclose the identity of the supplier of all source materials that they use in the preparation of raw ground or chopped product. FSIS is seeking feedback on the grinding log template and any additional comments on developing the log for use at retail.
In the interim, FSIS also recommends an update to the supporting documents for retail grinding logs in the Food Code Annex 2 (Page 305) so that retail establishments will have more detailed information on how to maintain grinding logs and understand its importance during recalls and outbreak investigations. Recently over the past few years, FSIS has been unable to determine the source suppliers of contaminated ground beef product because of inadequate retail grinding logs. FSIS developed and published a grinding log template and example on the FSIS website entitled "Sanitation Guidance for Beef Grinders" http://www.fsis.usda.gov/PDF/Sanitation_Guidance_Beef_Grinders.pdf. FSIS will consider the feedback from CFP for incorporation into a future FSIS compliance guideline that will accompany the FSIS rule.

Public Health Significance:
Ground beef contaminated with pathogens such as *Escherichia coli* O157:H7 or *Salmonella* is a known source of illness. During outbreak investigations, traceback of contaminated beef to the producing facility is often unsuccessful because of inadequate recordkeeping at retail establishments that grind beef products. FSIS enforcement strategy relies heavily on being able to identify the source material and the producing facility.
FSIS has reviewed foodborne investigations in which FSIS investigators found that retail facility grinding logs were a limiting factor for the Agency's ability to pursue public health investigations. FSIS conducted a retrospective review of 16 investigations (2006 through 2008) in which beef products were ground or reground at retail stores. In only 5 of 16 (30%)

of investigations, were records kept by the retail stores present and adequate to enable traceback to the official establishment supplying the beef. FSIS results are supported by Gould et al [Gould LH, Seys S, Everstine K, Norton D, Ripley D, Reimann D, et al. J Food Prot. 2011;74(6):1022-4] in a review of retail grinding records. Of 125 stores surveyed, 60(49%) kept grinding records. In those stores keeping grinding records, 22% of 176 records were judged complete (JFP 2011; 74:1022-1024). Schneider et al also reported a multistate outbreak with 42 illnesses. Investigators used shopper card information for 12 stores, but were unable to identify the identity of the source (JFP 2011, 74:1315-1319).
Additonal References:

- "Marler Clark calls on Hannaford to Release Meat Grinding Logs and Identify All Suppliers Linked to Salmonella Outbreak" 12/23/2011 - http://www.foodpoisonjournal.com/foodborne-illness-outbreaks/marler-clark-calls-on-hannaford-to-release-meat-grinding-logs-and-identify-all-suppliers-linked-to-s/
- Beef Grinding Logs Study: Restaurant Policies and Practices and Food Worker Practices/Behavior (CDC)http://www.cdc.gov/nceh/ehs/ehsnet/Restaurant_Policies_Practices.htm

Recommended Solution: The Conference recommends...:

1.) That a CFP Committee be created to:

a. review the FSIS grinding log template

b. Create a new committee to review the FSIS grinding log template and provide feedback to FSIS for consideration into the future FSIS compliance guide on retail grinding logs and on its use at retail

c. report back to the 2014 Biennial Meeting.

2.) That a letter be sent to the FDA to request amending the 2009 Food Code (as modified by the supplement issued in 2011) Annex 2 - Supporting Documents, References under Part 3, K Supplemental Documents (Page 305), using strike through to remove language and underline format to add language to read as follows:

K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

This document may be found at the web site for "Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7" http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf On October 7, 2002, USDA/FSIS published a Federal Register Notice (67 FR 62332) entitled, *E. coli* O157:H7 Contamination of Beef Products, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf in which the Agency discussed its views on the application of the Hazard Analysis and Critical Control Point (HACCP) system regulations with respect to *Escherichia coli (E. coli)* O157:H7 contamination.

USDA/FSIS announced <u>in 2002 </u>that there is sufficient new scientific data on the increased prevalence of *E. coli* O157:H7 in live cattle coming to slaughter and on its impact on public health to require that all establishments producing raw beef products reassess their HACCP plans, in light of these data.

Of particular concern to the USDA/FSIS is its ability to quickly and adequately traceback ~~*E. coli* O157:H7~~ contaminated product that is in commerce to its source and to remove it from

commerce. In Spring ~~March~~ 2004, FSIS began conducting sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground beef products at federally inspected establishments, retail facilities, as well as at import facilities. ~~the agency issued "FSIS Directive 10,010.1; revision 1, Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components" available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf. In this Directive, the Agency stated that, effective May 17, 2004, it would conduct sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground beef products at federally inspected establishments, retail facilities, as well as at import facilities.~~ Some of the products most likely to be sampled and tested at retail facilities are:

- Ground beef products produced from retail steaks and roasts.
- Manufacturing trimmings derived at retail.
- Ground beef that is formulated at retail by co-mingling in-store trim and trim from federally inspected establishments.
- Irradiated ground beef co-mingled with non-irradiated meat or poultry.

Additionally, ground beef products have been implicated as a transmission vehicle in foodborne outbreaks of infection with pathogens such as *Escherichia coli* O157:H7 and Salmonella. To facilitate product traceback and to meet regulatory requirements, USDA/FSIS expects retail facilities as well as federally inspected establishments to maintain and provide FSIS with access to all applicable records associated with the source material used for ground beef products. In cases where USDA/FSIS identifies adulterated ground beef, ~~*E. coli* O157:H7 ground beef in a product,~~ and a product recall is necessary, grinding logs will facilitate identifying the source of the product and narrowing the scope of the recall.

FSIS recently published "Sanitation Guidance for Beef Grinders" which contains an example of a fresh ground beef production log. The guidance is located at the following website: http://www.fsis.usda.gov/PDF/Sanitation_Guidance_Beef_Grinders.pdf

The following information would be used to facilitate traceback of contaminated ground beef products:

- *The manufacturer name of source material used for product produced*
- *The type of product or description of the purchased or received article(s).*
- *The establishment information from the label of source product used such as the name, address, and establishment number.*
- *The supplier lot numbers, product code or production or pack date of source materials used.*
- *Any other information that would be useful in the quick removal of adulterated product from the market or commerce such as time of grind, grinder sanitation records, and amount (in pounds) and lot/batch numbers, production codes, name and package size of products produced.*

In addition to the references cited above, the following references also provide information:

1. Federal Meat Inspection Act (21 USC Sec. 642).
2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.
3. Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products
4. Best Practices for Raw Ground Products

5. FSIS Sanitation Performance Standards Compliance Guide:
6. U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines For Establishments On The FSIS Microbiological Testing Program and Other Verification Activities For *Escherichia coli* O157:H7 http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf

~~The following information would be adequate for meeting federal transaction requirements:~~

- ~~The name or description of the purchased or received article(s).~~
- ~~The name, address, and establishment number of the seller of the articles purchased or received.~~
- ~~The supplier lot numbers and production dates of the articles purchased or received.~~
- ~~Any other information that would be useful in the quick removal of adulterated product from the market or commerce.~~

~~In addition to the references cited above, the following references also provide information:~~

~~1. Federal Meat Inspection Act (21 USC Sec. 642).~~

~~2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.~~

~~1. U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines For Establishments On The FSIS Microbiological Testing Program and Other Verification Activities For *Escherchia coli* O157:H7 http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010 1/ecolio157h7dirguid4-13-04.pdf~~.

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Attachments:

- "FSIS Sanitation Guidance for Beef Grinders"
- "Canadian Beef Good Retail Practices Ground Meat Management (Example Log)"
- "Multistate Outbreak of Multidrug-Resistant Salmonella Newport"
- "Recordkeeping Practices of Beef Grinding Activities Retail Establishments"
- "BIFSCO Best Practices For Retailer Operations Producing Raw Ground Beef"

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.

Sanitation Guidance for Beef Grinders

1. Good sanitation prevents the introduction of new bacterial hazards to controlled ingredients.

The objective of a beef grinder is to maintain the clean condition of the carcass, primal, subprimal, or coarse ground beef starting material.

a) The grinder should develop sanitation standard operating procedures (SOPs) that address, at a minimum, the cleaning of food contact surfaces, equipment, utensils, implements, and the processing areas. The SOPs should indicate the frequency with which these items will be cleaned and how the grinder will verify their cleanliness.

b) Systematic sanitizing of belts and implements is recommended, as it will break the chain of any contamination that slips through. Thus, rather than the contaminant being spread throughout the lot, it will be stopped or at least diminished.

c) Employees are in continuous contact with the product. Therefore, sanitation training and education, as well as supervision, are crucial. Keeping the processing areas clean and in good repair and keeping employee areas clean and in good repair set a personal tone for the operation. These are management choices, but can indirectly affect the product.

d) Desirable practices to instill in employees are:
   1) Removing outer clothing when leaving the processing area.
   2) Practicing personal hygiene, such as proper handwashing after using the toilet or before entering the processing area.

2. Sanitation procedures should prevent cross-contamination from equipment, personnel, traffic, air flow, tables, and floors to product.

3. Additional resources:

Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products:
Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products

Best Practices for Raw Ground Products:
http://www.fsis.usda.gov/PDF/Best_Practices_Raw_Ground_Products_08.pdf

FSIS Sanitation Performance Standards Compliance Guide:
http://www.fsis.usda.gov/Regulations_&_Policies/Sanitation_Performance_Standards/index.asp

Store Name: _____
Store Address: _____
_____

FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST

Employee Name: _____ Today's Date: _____

Time of Grind	Lot/ Batch Number (lot = same source material)	Exact Name/ Type of Product Produced	Package Size of Product Produced	Amount (in pounds) of Product Produced	Production Code of Product Produced	Manufacturer Name of Source Material Used for Product Produced	Supplier Lot Numbers, Product Code and/or Pack Date of Source Material Used	Establishment Information from label of Source Product Used (Est. #, ph #, contact info)	Establishment Information from label of Source Product Used (Est. #, ph #, contact info)	Grinder Cleaned and Sanitized? If Y, Date and Time	Comments

_____ _____
Signature of Store Management Reviewer Date

NEW WAVE STORE
123 Main Street
Anytown, USA, Zip Code

FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST

Employee name: John Williams

Today's Date: 12/14/11

Time of Grind	Lot/ Batch Number (lot = same source material)	Exact Name/ Type of Product Produced	Package Size of Product Produced	Amount (in pounds) of Product Produced	Production Code of Product Produced	Manufacturer Name of Source Material Used for Product Produced	Supplier Lot Numbers, Product Code and/or Pack Date of Source Material Used	Establishment Information from label of Source Product Used (Est. #, ph #, contact info)	Comments
0700-1000 AM	Lot 001	91/9 New Wave Ground Chuck	Catch-weight retail trays	1,250 lbs total of 91/9 Ground Chuck	121511-01 NWGB; Sell-by 12/20/11	Boneless Chuck, twenty-one 60 lb boxes from USA Beef Company	BB120311USA Packed on 12/03/11; BB120411USA Packed on 12/04/11	Est. 00321 M, (202)-123-4567, 898 Dodge St, Omaha, NE, 68104	Cleaned and sanitized grinder after Lot 001
1030-1130 AM	Lot 002 **From store-generated bench trim**	70/30 New Wave Ground Beef	2 lb. Trays	50/2 lb. trays	121511-03 NWGB; sell-by date 12/20/11	USA Company	BB120511USA Packed on 12/05/11 BB120711USA Packed on 12/07/11;	Est. 00321 M, (402)-123-4567, 898 Dodge St, Omaha, NE, 68104	Used trim from two different production lots from USA
	same	same	same	same	same	National Brand Beef	NBB120111, Packed on 12/01/11	Est. 15555 M, (903) 999-5454, 220 Locust St, Denton, TX 76201	Used trim from only one production lot of NBB product

Appendix II: Grinding Log

Ground Meat Production Log photocopy template on page 30.

How to Use the Grinding Log

1 Grinding Time & Date

Record the time and date when in-store grinding was initiated for the batch.

2 Ingredient Source and Supplier

Internal

In this column simply place a check mark if the trim was generated in-store during fabrication of cuts or if rework from the display case was used to create ground meats. If trim or ground meats was purchased from external suppliers, leave blank.

Supplier

If coarse ground meats or trim is purchased from an external supplier, record the name of the supplier in the space indicated.

3 Species

Record the species ground using the first letter of its name. Use **P** for pork and **B** for Beef.

4 Ingredient Production Date

Rework

If rework is utilized, record the original "packaged on date" of the product which was reworked.

Internal Trim

Record the "produced on date" for the trim was generated during in-store fabrication of cuts.

External

Record the production date from the box or chub.

Note: If ingredients have a different production date always start a new line on the grinding log.

5. Fresh or Frozen Storage

Record if ingredients were stored Fresh with an **F** or with a **Z** if ingredients were Frozen.

6. Date Acceptable

If ingredients were frozen and packaged to prevent freezer burn, they may be used 12 months after the production date. Place a check mark if criteria is met.

Observe store guidelines for fresh coarse ground meat and trim – ingredients stored at 0°C may be used longer than those stored at 4°C.

7. Quality Check

When opening ingredients verify that no off-odour is present and that visually ingredients appear satisfactory for ground meat production. Place a check mark if criteria is met.

Ground Meat Production Log

Retail I

1 Grinding Time and Date		2 Ingredient Source		3 Species	4 Ingredient Production Date	5 Fresh or Frozen Storage	6 Date Acceptable
Year: 2005 Month: July Time	Day	✓ = Internal	If ingredients are externally sourced indicate supplier name	**B** = Beef **P** = Pork		**F** = Fresh **Z** = Frozen	✓ = Good
9 am	11	✓		B	July 8	Z	✓
10 am	12		Packer A	P	July 11	F	✓

14 Grinder Sanitation Check Each day the grinder is used, before the start of production perform
the day. Remember that the grinder should also be completely cleaned between species. If the grind
increases in shelf life and product safety may also be gained by cleaning the grinder during the day.

Grinder Sanitation Check (Please Check and Initial): ☑ Mon. MK | ☑ Tues.

8. Ingredient Quantity

Place a check mark to indicate if kilograms or pounds are used as the unit of measurement.

Place the value in kilograms or pounds under the correct column for the ingredient type utilized.

9. Lean %

Record the lean % of each ingredient or use the selected abbreviation.

10. Meat Temperature

Record the temperature of the ingredients before grinding using a probe thermometer which is periodically checked for accuracy.

Ground meat and trim should always be kept at 4°C or lower. Optimal shelf-life will be achieved at temperatures closer to 0°C. It is especially important for food safety reasons that ground meat and trim be kept under 5°C as at this temperature if any dangerous *E. coli* bacteria are present they will not grow. Remember that meat temperature will rise due to friction from grinding.

11. Clip Check

When removing clips from chubs ensure they are all properly disposed of and then place a check mark.

12. Additional Information

This space can be used to record any information that the retailer wishes to capture (such as temperature of product exiting the grinder).

13. Staff Initial

The individual who is performing the grinding process should initial indicating information recorded is accurate.

14. Grinder Sanitation Check

Each day the grinder is used, before the start of production, perform an inspection to ensure that grinder is visually clean and dry. If satisfactory record your initials by the day.

Remember that the grinder should also be completely cleaned between species. If the grinder is used in warm conditions where air temperature is significantly greater than 4°C substantial increases in shelf-life and product safety may also be gained by cleaning the grinder during the day.

Records Storage

Grinding logs should be filed and kept on the premises for a period of at least one month.

Items Requiring Corrective Action

If during the course of filling out the grinding log you find that ingredients are not satisfactory for use, place the suspect ingredients in a location where they will not be used and inform your supervisor or take action according to your store policy. Record the details on the back of the grinding log so you may refer to it at a later time.

Location: Store Name

7	8				9		10	11	12	13
Quality Check ✓= Good	**Ingredient Quantity** ☑ Kilograms ☐ Pounds				**Lean %** F = fat trim, EX = extra lean, L = lean, R = regular, M = medium		**Meat Temp.** ☑ °C ☐ °F	**Clip Check** ✓= Good	**Additional Information** Post grinding temp.	**Staff Initial**
	Rework	Trim	Ground Meat	Whole Muscle	Type	Percentage				
✓		56			M		0	✓	1°C	MK
✓		50				75%	2	✓	3°C	TL

an inspection to ensure that grinder is visually clean and dry. If satisfactory record your initials by
er is used in warm conditions where air temperature is significantly greater than 4°C, substantial

TL | ☐ Wed. ____ | ☐ Thurs. ____ | ☐ Fri. ____ | ☐ Sat. ____ | ☐ Sun. ____

Ground Meat Production Log

Retail Location:

Grinding Time and Date Year: Month: Time / Day	Ingredient Source ✓ = Internal If ingredients are externally sourced indicate supplier name	Species B = Beef P = Pork	Ingredient Production Date	Fresh or Frozen Storage F = Fresh Z = Frozen	Date Acceptable ✓ = Good	Quality Check ✓ = Good	Ingredient Quantity ☐ Kilograms ☐ Pounds Rework / Trim / Ground Meat / Whole Muscle	Lean % F = fat trim EX = extra lean L = lean R = regular M = medium Type / Percentage	Meat Temp. ☐ °C ☐ °F	Clip Check ✓ = Good	Additional Information	Staff Initial
EXAMPLE 9 am / 11	✓	B	July 8	Z	✓	✓	56	M / 75%	0	✓		MK

Grinder Sanitation Check Each day the grinder is used, before the start of production perform an inspection to ensure that grinder is visually clean and dry. If satisfactory record your initials by the day. Remember that the grinder should also be completely cleaned between species. If the grinder is used in warm conditions where air temperature is significantly greater than 4°C, substantial increases in shelf-life and product safety may also be gained by cleaning the grinder during the day.

Grinder Sanitation Check (Please Check and Initial): ☐ Mon. ____ | ☐ Tues. ____ | ☐ Wed. ____ | ☐ Thurs. ____ | ☐ Fri. ____ | ☐ Sat. ____ | ☐ Sun. ____

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Research Note

Multistate Outbreak of Multidrug-Resistant *Salmonella* Newport Infections Associated with Ground Beef, October to December 2007

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MS 11-046: Received 30 January 2011/Accepted 15 April 2011

ABSTRACT

In late October 2007, an outbreak of multidrug-resistant *Salmonella* Newport infections affected 42 case patients in California, Arizona, Idaho, and Nevada. A case-control study implicated ground beef from one chain store. Despite detailed ground beef purchase histories—including shopper card information for several case patients—traceback efforts by both the U.S. Department of Agriculture, Food Safety and Inspection Service and the California Department of Public Health were unable to identify the source of contamination. Case patients consumed multiple types of ground beef products purchased at numerous chain store A retail locations. These stores had received beef products for grinding from multiple beef slaughter–processing establishments. Detailed retail grinding logs and grinding policies that prevent cross-contamination between batches of ground beef products are crucial in the identification of contaminated beef products associated with foodborne illness.

In late October 2007, the California Department of Public Health (CDPH) noted an increase in *Salmonella* Newport isolates resistant to chloramphenicol, a marker for multidrug resistance. Historically in California, clusters of multidrug-resistant (MDR) *Salmonella* infections have predominantly occurred among the Hispanic population and have often been associated with consumption of raw milk and/or raw milk products *(2)*. Previous outbreaks of MDR *Salmonella* Newport in the United States have been associated with consumption of ground beef *(11)*. Among the six initial cases of this outbreak, all were non-Hispanic, and the isolates shared an extremely rare pulsed-field gel electrophoresis (PFGE) pattern; this PFGE pattern accounted for only 0.2% of all *Salmonella* Newport isolates posted to the national PulseNet database at that time. In all, 42 MDR *Salmonella* Newport isolates with indistinguishable PFGE patterns by two enzymes were identified in California, Arizona, Nevada, and Idaho, from October to December 2007. A case-control study was conducted by the CDPH, the Arizona Department of Health Services, the California Emerging Infections Program, and the Centers for Disease Control and Prevention. This report summarizes the results of the epidemiologic investigation that linked these MDR *Salmonella* Newport infections to consumption of contaminated ground beef purchased from several grocery stores of the same chain (chain store A).

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MATERIALS AND METHODS

Epidemiologic investigation. A case was defined as a culture-confirmed MDR *Salmonella* Newport infection in a U.S. resident, with symptom onset on or after 1 October 2007 and an isolate matching the outbreak PFGE patterns (*Xba*I JJPX01.0422–*Bln*I JJPA26.0196). The CDPH Microbial Diseases Laboratory conducted a national PulseNet search to identify isolates with the outbreak patterns.

Hypothesis-generating questionnaires were administered by phone to case patients in California and Arizona during the first 2 weeks of November. Foods consumed by more than 50% of the case patients were included on the case-control study questionnaire. Case-control study interviews were conducted during the last week of November and the first week of December. Controls were defined as persons without self-reported diarrhea in the 2 weeks prior to interview and were matched to cases by age (younger than 18 years, 18 to 64 years, and 65 years and older) and neighborhood, using reverse address lookup, with the case patient's address as the anchor. Case patients provided information about foods consumed during the 7 days prior to the onset of illness. Controls provided information about foods consumed during the month of October to match exposure period to that of the case patients. Case patients and controls were asked about

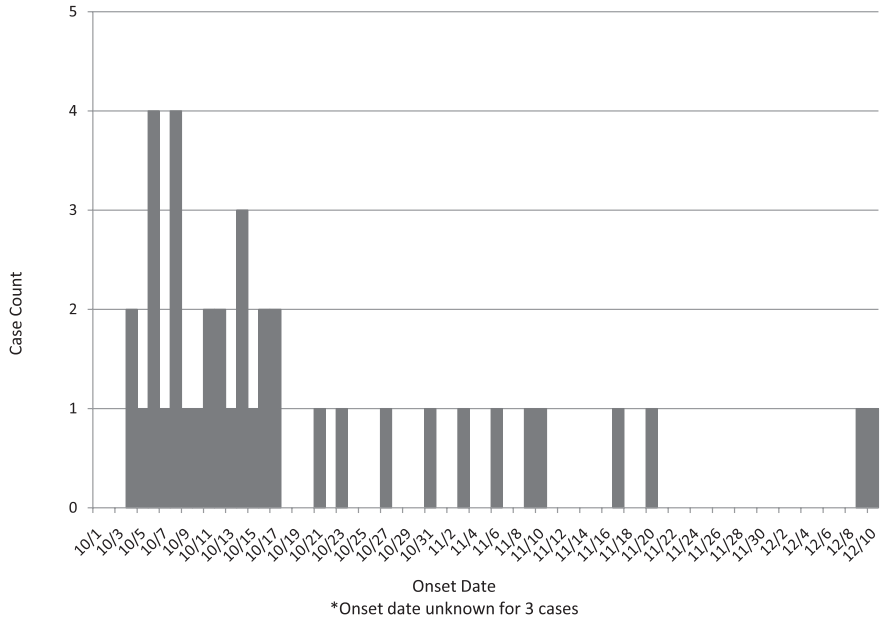

FIGURE 1. *Symptom onset date of MDR* Salmonella *Newport outbreak cases, October to December 2007, United States (*n = *39).**

consumption of ground beef, chicken, tomatoes, milk, cheese, eggs, bananas, and raw onions. Case patients were asked to provide grocery store shopper card information if available. Odds ratios and 95% confidence intervals were calculated with SAS 9.1 software (SAS Institute, Cary, NC). A two-tailed P value <0.05 was considered statistically significant.

Environmental investigation. Product isolates collected during the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) Pathogen Reduction–Hazard Analysis and Critical Control Point *Salmonella* Verification Testing Program are subject to PFGE and antimicrobial resistance testing at the U.S. Department of Agriculture, Agricultural Research Service *(6)*. Each *Salmonella* isolate is cut by a primary enzyme (*Xba*I) and, on request, by a secondary enzyme (*Bln*I). The PFGE patterns are uploaded to the VetNet database maintained by the Agricultural Research Service. A VetNet pattern search was conducted by the FSIS to match the unique PFGE *Xba*I pattern of the outbreak strain to isolates collected from meat and poultry establishments during FSIS *Salmonella* testing.

Grocery shopper card purchase information was sought from case patients. Using shopper card information, the FSIS and the CDPH conducted traceback investigations of case patients' ground beef purchases at multiple retail locations. Investigators met with store meat managers to review in-store grinding procedures and policies. Investigators reviewed grinding logs, and invoices for the day's ground beef purchased by case patients had been fabricated to identify specific beef suppliers of interest. Investigators conducted traceforward investigations at FSIS-regulated establishments where ground beef–positive *Salmonella* Newport isolates that exhibited the outbreak PFGE *Xba*I pattern were recovered in 2007.

RESULTS

Epidemiologic investigation. The CDPH Microbial Diseases Laboratory noted an increase in chloramphenicol-resistant *Salmonella* Newport isolates in late October 2007. A PulseNet search conducted on 31 October 2007 identified 10 isolates with the same pattern in the United States during the previous 60 days. In all, 42 isolates with a two-enzyme (*Xba*I and *Bln*I) PFGE match were identified between October 2007 and January 2008. Isolates from three California case patients were confirmed by the National Antimicrobial Resistance Monitoring System and met the System's definition of MDR *(1)*.

The 42 case patients were from California (22), Arizona (16), Nevada (3), and Idaho (1). Onset dates ranged from 4 October to 10 December 2007 (Fig. 1). The median age of case patients was 41 years (range, <1 to 94 years); 56% of the case patients were female. The majority (82%) of patients was non-Hispanic white. Twenty-five (74%) of 34 patients had bloody diarrhea. Seventeen (46%) of 37 patients were hospitalized; there were no deaths.

Fifteen case patients in California and Arizona completed the hypothesis-generating questionnaire. Twenty-one case patients and 36 controls were enrolled from the four states in the case-control study. In univariate analysis, no single food item was significantly associated with illness. There was a borderline-significant association with purchasing ground beef from chain store A (42% [8 of 19] of cases versus 18% [6 of 33] of controls, P value of 0.06) (Table 1). Case patients were more likely to have shopped for groceries at chain store A in the week prior to the onset of illness, as compared with controls during the month of October (81% of cases compared with 67% of controls, P value of 0.25), although the association was not statistically significant. Among case patients and controls who had shopped at chain store A, no single food item was associated with illness. However, among persons who consumed ground beef at home during the week prior to the onset of illness or in the month of October for controls, 80% of the case patients purchased their ground beef from chain store A compared with 26% of controls (odds ratio = 11.3, 95% confidence interval = 1.9 to 69.1, P value = 0.005). The investigation did not identify a link between any of the illnesses and ground beef purchased at other store chains. At

TABLE 1. *Food consumption and exposure history for cases and controls*

Exposure	No. (%) of cases	No. (%) of controls	Odds ratio	95% confidence interval	*P* value
Ground beef at home	12 (57)	28 (78)	0.38	0.1–1.2	0.1
Ground beef in restaurant	6 (40)	19 (56)	0.53	0.2–1.8	0.3
Ever cook ground beef	15 (79)	29 (81)	0.9	0.2–3.6	0.9
Chicken at home	12 (71)	31 (86)	0.39	0.1–1.6	0.18
Chicken at restaurant	12 (63)	22 (63)	10	0.3–3.2	1
Raw onion	7 (37)	22 (61)	0.37	0.1–1.2	0.09
Grocery shop at chain store A	17 (81)	24 (67)	2.1	0.6–7.7	0.25
Ground beef from chain store A	8 (42)	6 (18)	3.3	0.9–12	0.06

the time of the case-control study, none of the patients contacted for this investigation had leftover ground beef available for testing.

Traceback and traceforward investigations. FSIS investigators followed up on shopper card information collected from 11 case patients and visited nine Arizona, two California, and one Nevada chain store A locations. Based on the shopper card information, case patients had purchased multiple and various types (percent lean) of ground beef products prior to illness onset, but had not purchased ground beef patties. Seven establishments were identified that directly supplied beef products to chain store A locations in California, Arizona, and Nevada (Fig. 2). Four of the establishments (I, J, K, and L) provided primal cuts of beef to stores in all three states. Bench trim from the primal cuts was ground into 80% (80/20) lean ground beef at individual chain store A locations. Three establishments (B, C, and E) supplied ground beef products to chain store A locations. Establishment B, a grinding plant, supplied coarse ground beef for regrinding to stores in California, Arizona, and Nevada. Establishment C, a slaughter–processing establishment, supplied coarse ground beef to chain store A locations in Arizona for regrinding. Establishment E, a grinding plant, supplied preformed ground beef patties to chain store A locations in Arizona. Establishment A, a slaughter–processing plant, and establishment D, a processing plant, supplied both establishments B and E with boneless beef products for grinding. Establishment B also received boneless beef products from foreign establishment G (Fig. 2).

Chain store A locations did not regularly clean the grinder between batches of various blends of ground beef; it is likely that individual ground beef products were commingled with the subsequent batch of ground beef products. Additionally, the chain store locations did not record the sources of the bench trim on daily grinding logs, and information on the source of coarse ground beef was recorded incompletely or inaccurately at some stores. This made it difficult for the investigators to collect establishment and lot numbers for specific ground beef products purchased by case patients.

In September 2007 one *Salmonella* Newport ground beef isolate, indistinguishable (by *Xba*I) from the outbreak strain, was recovered during FSIS sampling at establishment E. Establishment E supplied ground beef patties to store chain A locations in Arizona and, as previously stated, no case patients reported consuming that type of ground beef. Establishment F, a small processing plant, was the source of a second 2007 FSIS ground beef isolate indistinguishable by two enzymes (*Xba*I and *Bln*I) from the outbreak strain.

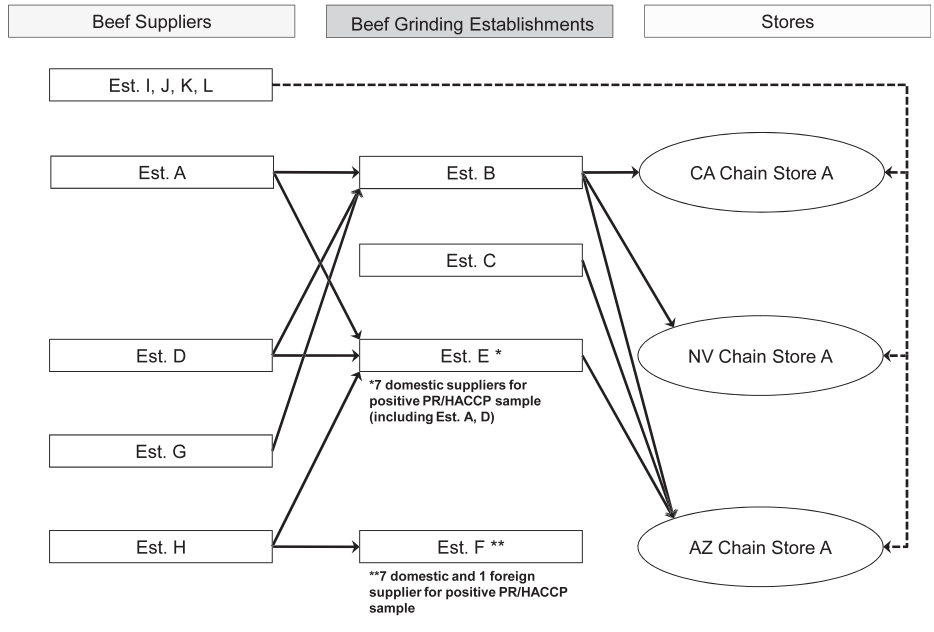

FIGURE 2. *Beef product suppliers for chain store A supermarkets.*

Time of Grind	Lot/ Batch Number (lot = same source material)	Type of Product Produced (e.g. 80/20, 93% lean)	Package size	Amount (in lbs.) of Product Produced	Production Code of Product Produced	Manufacturer Name -- Source Material Used for Product Produced	Product Code and/or Pack Date of Source Material	Establishment Number for Source Product	Comments	Initials
0700-0830 AM	Lot 001	91/9 Gold Standard Ground Chuck	Catch-weight retail trays	1,250 lbs total of 91/9 Ground Chuck	033109-01 GSGC; Sell-by 04/02/09	Boneless Chuck, twenty-one 60 lb boxes from USA Beef Company	BC031509 USA Packed on 03/15/09; BC031709 USA Packed on 03/17/09	Est. 00321 M	Cleaned and sanitized grinder after Lot 001; excess source material (approx. 10 lbs) made into RTE chili;switched source materials	John Doe ID # 222

FIGURE 3. *Ground beef production records at retail: information needed in grinding logs for traceback purposes.*

Establishment F could neither be linked to store chain A nor to establishments A, D, I, J, K, or L. Both establishments E and F did have a common foreign supplier of boneless beef, establishment H.

The FSIS issued a public health alert *(7)* on 20 December 2007, after an exhaustive FSIS investigation could not identify specific production lots that would be subject to a recall. The public health alert advised consumers not to consume ground beef that was ground and sold by chain store A locations between 19 September and 5 November 2007. The original alert was expanded on 15 February 2008 to include ground beef sold between 19 September and 25 November 2007, based on an additional case patient with illness onset of 10 December 2007, who reported a ground beef purchase at store chain A on 23 November 2007.

On 30 January 2008, a public health laboratory isolated *Salmonella* Newport from leftover frozen ground beef retrieved from a California case patient's freezer. The patient bought the ground beef from a chain store A location on 4 October 2007. On 8 February 2008, the CDPH confirmed that the isolate was MDR *Salmonella* Newport and matched the outbreak strain, with two enzymes by PFGE. The subsequent recovery of the outbreak strain from frozen ground beef confirmed the epidemiologic implication of ground beef from chain store A. Subsequent traceback activities by the FSIS confirmed that this product had been the first product ground at the chain store A location on 4 October 2007, and that establishment B was the sole source of that ground beef product.

DISCUSSION

Ground beef has been identified previously as the source for MDR *Salmonella* Newport and *Salmonella* Typhimurium infections *(4, 10)*. It is important to identify strategies to control MDR *Salmonella* from farm through processing. The judicious use of antibiotics in animal agriculture is important to decrease the emergence of resistant pathogens.

An outbreak of MDR *Salmonella* Newport occurred among residents of California, Arizona, Nevada, and Idaho in late 2007. The epidemiologic and laboratory evidence supported that this outbreak was due to consumption of ground beef purchased at chain store A. Because of chain store A's beef grinding policies, it is likely that individual ground beef products were routinely commingled with the next batch of ground beef, although incomplete grinding logs at some store locations hindered conclusive findings on this point.

Patients infected with MDR *Salmonella* have a greater risk of hospitalization and death compared with patients infected with drug-susceptible *Salmonella (5, 9)*. During this 2007 outbreak, almost half (46%) of all patients were hospitalized. State and national level surveillance systems for MDR *Salmonella* Newport need to be maintained to enhance detection of outbreaks. Once an outbreak is detected, epidemiologic studies and prompt collection of product (food) samples from case patients are the key to the identification of the source of the infections. Initiation of traceback activities early in an investigation enhances the identification of the source of the outbreak. Supermarket loyalty cards have proved an invaluable resource, providing detailed case patient purchase information. This information, combined with detailed and accurate retail recordkeeping, is crucial to the successful determination of the source of the contamination and the removal of potentially contaminated products from commerce *(8)*. Changes to retail supermarkets' ground beef policies and recordkeeping could aid investigations. When grinding beef in-store, retail supermarkets should consider separating batches of beef from different sources to prevent commingled product, which may result in the spread of contamination by pathogens, such as MDR *Salmonella* Newport or *E. coli* O157:H7. Retailers should maintain detailed records of grinding activities and logs (Fig. 3) that include documenting cleanup between grinds. Detailed grinding logs are essential for the successful traceback of contaminated beef when implicated in outbreaks and to allow focused, detailed, and prompt recalls to prevent additional infections *(3)*.

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Research Note

Recordkeeping Practices of Beef Grinding Activities at Retail Establishments

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ABSTRACT

Ground beef has been implicated as a transmission vehicle in foodborne outbreaks of infection with pathogens such as *Escherichia coli* O157:H7 and *Salmonella*. During outbreak investigations, traceback of contaminated beef to the producing facility is often unsuccessful because of inadequate recordkeeping at retail establishments that grind beef products. We conducted a survey in three states participating in the Environmental Health Specialists Network to describe beef grinding and recordkeeping practices at retail establishments. In each establishment that maintained grinding logs, three randomly selected records were reviewed to determine whether important data elements for traceback investigations were recorded. One hundred twenty-five stores were surveyed, of which 60 (49%) kept grinding logs, including 54 (74%) of 73 chain stores and 6 (12%) of 51 independent stores. One hundred seventy-six grinding records from 61 stores were reviewed. Seventy-three percent of the records included the establishment code of the source beef, 72% included the grind date and time, and 59% included the lot number of the source beef. Seventy-five percent of records noted whether trimmings were included in grinds, and 57% documented cleanup activities. Only 39 (22%) records had all of these variables completed. Of stores that did not keep grinding logs, 40% were unaware of their purpose. To facilitate effective and efficient traceback investigations by regulatory agencies, retail establishments should maintain records more detailed and complete of all grinding activities.

Consumption of beef, particularly ground beef, is a risk factor for infection with several foodborne pathogens, including *Escherichia coli* O157:H7 and *Salmonella (8, 10)*. Foodborne disease outbreaks with ground beef as a vehicle of infection are relatively common; in 2006, outbreaks caused by ground beef accounted for approximately 10% of outbreaks with a known food vehicle *(3)*. Contaminated ground beef ground at grocery stores or other retail establishments has been implicated in a number of outbreaks *(8)*. In some of these outbreaks, investigators found that although the retail establishment where the beef was ground or purchased could be identified, determining the source of the implicated beef supplied to the retail establishment was difficult or impossible. To identify the source of the contaminated product (traceback investigation), investigators must be able to determine what products were incorporated into each batch of ground beef, on what day, and whence these products originated. Additionally, records of beef grinding activities (grinding logs) can help investigators to identify other potentially contaminated batches of meat that might have originated at the same establishment, and other establishments that might have been affected by contaminated product (traceforward investigation). Difficulties in these investigations have been attributed to poor retail recordkeeping practices or to inadequate or incomplete grinding logs.

While establishments are required by both the Federal Meat Inspection Act (21 United States Code [U.S.C.] 642) and the Poultry Products Inspection Act [21 U.S.C. 460(b)] to keep records that will disclose fully and correctly all transactions involved in their business subject to the acts (including keeping bills of sales, invoices, bills of lading, and receiving and shipping papers), there are currently no U.S. Department of Agriculture (USDA) or state requirements to generate or maintain grinding logs. Because many USDA Food Safety and Inspection Service (FSIS) traceback activities have been impeded by lack of information, the FSIS and public health officials continue to encourage businesses to maintain production records such as grinding

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TABLE 1. *Summary of store characteristics and grinding activities in EHS-Net sites, by store type, 2008*

Characteristic	Store type:		
	All ($n = 125$)	Chain ($n = 74$)	Independent ($n = 51$)
Median no. (range) of grinds per week	7 (2–140)	10 (3–140)	7 (2–42)
Median no. (range) of kilograms per grind	18 (1–363)	23 (2–182)	14 (1–363)
Stores using trimmings for grinds (%)	78	91	61
Among stores using trimmings in grinds, those grinding separately (%)	78	90	52
Stores maintaining grinding logs (%)	49	74	12

logs that provide important information about how, when, and where product was prepared, shipped, received, stored, and handled.

The Environmental Health Specialists Network (EHS-Net) is a network of environmental health specialists and epidemiologists in nine states *(7)*. The network conducts special studies to evaluate food preparation and handling practices in restaurants and retail establishments. After a multistate outbreak of multidrug-resistant *Salmonella* Newport infections attributed to store-ground beef *(2, 6),* we initiated a study in EHS-Net sites to evaluate the prevalence of grinding logs in retail establishments. The primary objectives of this study were to describe how often retail establishments keep grinding logs and to determine the completeness of these grinding logs.

MATERIALS AND METHODS

Three EHS-Net sites (California, Minnesota, and Tennessee) participated in this survey. Each site surveyed a convenience sample of retail establishments that ground beef in their respective jurisdictions; the establishments were selected based on the site's schedule for routine facility inspections and a priori knowledge about whether each establishment ground beef in the facility. The survey was administered as part of routine facility inspections. The survey contained questions on the type and size of the store, the number of times beef was ground each week and the number of kilograms contained in each grind, and whether grinding logs were kept in the store. Each store that kept grinding logs was asked the reasons logs were kept (e.g., corporate requirement), for how long logs were kept, and where the logs were kept (e.g., in store, at corporate headquarters). Additionally, we asked if the establishment included trimmings (i.e., beef remnants typically produced during the cuttings of steaks and other cuts that are routinely incorporated into ground beef products) in beef grinds.

In each establishment that kept grinding logs, three records of individual grinds from the previous month were randomly selected and reviewed to determine whether data elements needed for traceback and traceforward investigations were completed. These data elements included the date and time the grind was performed, the type of product produced, the lot and establishment code of the source beef, whether cleanup was performed between grinds, and whether beef trimmings were included in the grind. Descriptive data analysis was performed with SAS, version 9.2, software (SAS Institute Inc., Cary, NC).

RESULTS

Of the 125 stores surveyed, 43 were in California, 33 in Minnesota, and 49 in Tennessee. Seventy-four (59%) stores were classified as chain stores, and 51 (41%) stores were classified as independent. Among the 70 chain stores for which ownership information was available, 58 were corporately owned or operated, and 12 were franchisee owned. Most of the stores (91 [73%]) were grocery stores, 14 (11%) were ethnic or international stores, 10 (8%) were butchers or meat markets, and 10 (8%) were another type of establishment.

Overall, the surveyed stores ground beef a median of seven times per week and ground a median of 18 kg per grind, but this differed between chain and independent stores (Table 1). Chain stores also ground more beef in each grind. Three-quarters of stores reported that they used beef trimmings in grinds, and this practice was more common in chain stores (91%) than it was in independent stores (61%). Among the 98 stores using trimmings in grinds, chain stores were also more likely than were independent stores to report grinding trimmings in batches separate from other beef grinds (90 versus 52%).

Overall, 61 (49%) stores kept grinding logs, including 55 (74%) chain stores, but only 6 (12%) independent stores. Among the stores that kept grinding logs, a number of reasons were cited for keeping them, including a corporate or franchise requirement (64%), for store records (23%), for state requirements (16%), for USDA requirements (11%), or another reason (21%). Most stores (39%) kept logs for 6 months to 1 year, 36% of stores kept logs for more than 1 year, 21% for 1 to 6 months, and 3% for less than 1 month.

Stores that did not keep logs were asked why not. The most common reason stated was that they did not know what logs were (35%). Other common reasons stated included because they were not required (21%), that they were supposed to keep them but did not (6%), and that they were too busy or it was too much paperwork to keep logs (5%).

We reviewed 179 grinding log records in the 61 stores that kept grinding logs. Overall, 22% of records included information for all of the data elements that are needed for a traceback or traceforward investigation. The remaining records were either only partially completed or the grinding logs did not record all of the necessary data elements; we did not distinguish between the two. Most records (164 [92%]) indicated the type of product (e.g., 90% lean) produced during that grind, whether trimmings were included in the grind (135 [75%]), the grind date and time (131 [73%]), the establishment code of the source beef (129 [72%]), and the production date of the source beef (120 [67%]). About half of records included the lot number of the source beef (106 [59%]) and whether cleanup was

performed after that grind or on that day (104 [58%]). Fewer records (69 [39%]) contained the ''use-by'' date of the source beef.

DISCUSSION

Accurate recordkeeping by retail establishments that grind beef is essential for complete and effective investigations during foodborne outbreaks associated with ground beef. In a survey of retail establishments in three states, we found that only half of stores kept grinding logs to document their beef grinding activities, and that grinding logs were more common in chain than they were in independent establishments. Among stores that kept logs, only a quarter maintained complete records needed to conduct a traceback investigation.

The FSIS relies heavily on records maintained by retailers to aid in traceback and traceforward investigations of products associated with illness and other food safety incidents, to determine quickly and effectively the source product, and to ensure that appropriate controls are implemented, because contaminated product can be widely distributed among retailers. With effective traceback and traceforward, contaminated products can be removed from the market in a fashion timelier and more complete, helping to prevent further cases of illness. When traceback and traceforward investigations cannot be completed because of incomplete information, illnesses could continue to occur *(4),* and recurrent outbreaks associated with the same source might occur *(1, 4).*

Our findings from this survey are consistent with those reported from recent investigations of outbreaks associated with beef products ground at retail establishments. In 2007 and 2008, the FSIS conducted 16 such investigations involving retail operations *(9).* Nine (56%) establishments kept grinding logs that contained sufficient information for traceback and traceforward activities; five of these nine investigations resulted in recall actions.

Meat grinding is an important source of cross-contamination in retail establishments *(5).* In the current study, just over half of the stores we surveyed documented cleanup after grinding beef in their grinding logs. We did not document or review the procedures used by each store for cleanup between grinds, and could not assess whether cleaning activities were sufficient to prevent cross contamination; similarly, we did not assess cleanup procedures in stores that did not keep grinding logs. If cleaning is not documented properly, it might be impossible for investigators to determine the source of a contaminated lot of beef.

Most stores that kept grinding logs cited keeping them to meet a corporate–franchise, state, or USDA requirement, although neither the USDA nor any of the states included in this study had regulations that required retail establishments to keep grinding logs. While it is heartening that many corporate chains and franchises do require their stores to keep records of grinding activities, only half of the establishments we surveyed even maintained records, and in particular, independent stores kept records of grinding activities less frequently. More work is needed to ensure that retail establishments maintain grinding logs that contain sufficient information for traceback and traceforward investigations.

This study had several limitations. First, we surveyed a limited number of stores, and stores were selected based on convenience rather than a sample more systematic or random. We included more than one store from some chains in the analysis, possibly biasing our findings to reflect the practices of selected corporations or company policies. While our findings were similar across all three participating sites, it is possible that the findings are not representative of other states or of other jurisdictions in the states included in this study. Last, although evidence from outbreak investigations supports the utility of grinding logs, the study was not designed to evaluate any establishment's safety benefits because of keeping grinding logs.

While proper recordkeeping will aid in more efficient and effective traceback and traceforward investigations, and might help to reduce the scope and duration of outbreaks, grinding logs are only one part of a range of activities that are essential to limit foodborne infections. Other interventions are needed to reduce the prevalence of pathogens such as *E. coli* O157 on beef products *(5),* and consumers should continue to be vigilant about preparation of ground beef products and prevention of cross-contamination in the home.

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Best Practices For Retailer Operations Producing Raw Ground Beef

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Revised April 2005

Best Practices for Retail Operations Producing Raw Ground Beef

Introduction:

Producers of raw ground, including ground beef, products recognize that these products have an inherent food safety risk due to the nature of the process and the lack of a sufficient "kill" step for biological hazards in the process. Therefore, it is extremely important that retail operations producing raw ground beef implement Best Practices to produce the safest products possible by increasing total process control throughout the process. This document focuses on retail operations that are grinding beef in the store, not the handling of ground product that is purchased in the final packaged form. For detailed information on developing a total food safety program the Food Marketing Institute (FMI) has developed a document entitled, "A Total Food Safety Management Guide: A Model Program for Category: Raw, Sold Ready to Cook Product: Ground Beef."

This document provides guidelines for grinding and can be used by retail operations to develop store specific programs. The guidelines are designed to provide a recommended set of practices and procedures that retail operations may want to adopt in their entirety or part to ensure optimal quality and food safety. It also addresses the issues of designing an effective lotting system and reprocessing ground products. These recommendations focus solely on the production of raw ground beef.

It should be noted that the following items are not fully addressed in this document, but they should be covered by existing retail operating procedures and/or other store-specific processing programs.

- Personnel — disease control, hygiene, clothing, training, etc.
- Retail Facility — construction and design, product flow, drainage, etc.
- Sanitary operations — general maintenance, cleaning and sanitizing, pest control, etc.
- Sanitary facilities and controls — water supply, plumbing, sewage disposal, rubbish and offal disposal, etc.
- Freezer and coolers — monitored and maintained to ensure temperature control, recording devices, alarms, etc.
- Equipment maintenance and calibration — adequate frequency for thermometers, recording devices, compressed air equipment, etc.

A training document (Attachment 1) developed by Costco is included in this document as an example, but it is recommended that each store develop store-specific information. Many of the items listed above are also addressed in 21 CFR Part 110 – Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food (Attachment 2) – which was developed by the Food and Drug Administration and can be used as a resource if more information on any of these areas is needed.

LOTTING

All retail grinding operations should have a lotting mechanism for coding and recording finished ground products to allow for tracing the product back through the system for tracing the product forward through the chain to determine when it was sold and how much was sold vs. disposed of at the store. Some retail operations may develop computerized bar codes or tracking systems that are very elaborate and detailed, and others may have simple handwritten documentation and box/package codes. Lotting is usually driven by some time factor (i.e., hour, shift, day, etc.) or by raw materials (i.e., sirloin, chuck, etc.) and is given a specific identification code. Creating smaller lots or utilizing a sub-lotting system for tracking information may help demonstrate/document process control and could possibly help minimize the economic impact of a recall from product that is ground in the store.

Regardless of the mechanism each store should have a record keeping system, and the following items may be considered for each identified lot/sub-lot.

- Raw material source(s) by vendor, including vendor lot identification, time used
- Data collected during process (product and/or storage temperatures, microbial data, etc.)
- Metal detector records, if used
- Equipment evaluation records (i.e., grinder checks)
- Bone collection records, if applicable
- Date placed in the case/date removed from the case and disposed of at the store, if applicable

If any abnormal condition(s) (odor, off color, etc.) are found during the grinding process then it is recommended that the product be segregated, that the grinder and all other equipment be cleaned and sanitized prior to reinitiating grinding process, and that a new lot /sub-lot is started when product begins. It is best if information can be documented to show what the problem was, the product(s) that were involved, how the product was handled, and that the equipment was cleaned and sanitized appropriately.

While retail operations may grind small or limited amounts of beef in the store, it is still important that retailers fully understand the importance of product identification and lotting. The concept of lotting systems in ground beef productions is a complex and detailed issue. The existing USDA definition for a lot, when there is a positive result for *E. coli* O157:H7, is “from full sanitation to full sanitation.” In most federally established commercial grinding operations this definition may impact a full day’s production of ground beef. However, proper documentation and controls (including product testing) may allow finished products to be sub-lotted under this definition to minimize the amount of affected products.

A retail operation may also consider sub-lotting under the context of the definition described above. If so, then the following types of documentation are useful:

- Batching records — These records should identify the types of raw materials used by its tracking codes; the amount used in each batch of formulated product, the time it was used and the grinder that it was ground in, if there is more than one grinder.
- Packaged product tracking systems — The finished products should be coded with the actual times they are packaged and placed in the retail case.
- Microbiological testing and tracking — If a retail store is sampling and testing finished formulated raw materials from each batch for potential microbial adulterants, then it should include the batch number samples, the time of the sample and a protocol tracking form for submission to the laboratory used for analysis. It is extremely important that a retail store clearly identifies what lots/sub-lots are represented by the sample being tested.
- Finished Product "Test and Hold" Programs — If a retail store is testing finished ground product for potential microbial adulterants, then it should place all of the product on hold until the laboratory testing is completed and the results are available.

Utilizing the guidelines provided above will allow retailers to better identify and document the amount of suspect or affected product. For example, if one composite sample for formulated products tested positive for *E. coli* O157:H7 during a day's production where all other composites tested negative, then the information discussed above may provide added assurance that sufficient controls were in place to minimize the amount of product affected and the impact of a recall.

Sub-lotting can also be used for other potential contamination such as a physical contaminant. Sub-lotting for physical contamination will require the following:
Batching records — These records should identify the types of raw materials used by its tracking codes, the amount used in each batch of formulated product, grinder head, the time the batch was formulated, the cleaning and inspections by authorized representatives.
In-process Control Records — These records should identify the types of control checks performed on metal detectors and other control instruments, the time checks were performed and the line and/or product code information.

REPROCESSED PRODUCT

Retail store grinding operations must address the use of reprocessed product and should not reintroduce product from one's day's production to the next. For the purpose of the best practices, a lot was defined as the finished product and a batch was defined as material that is in-process. The following categories are recommended to help distinguish between the types of raw materials being reintroduced and the points of entry into the grinding operation.

1. Distressed/Returned product — Retailers should dispose of all product that is returned by a customer or has been distressed at the store-level.

2. Out-of-date product — Out dated products should be discarded and should not be introduced into ground product. Use of products that are nearing the expiration date (i.e., round) will need to be properly identified and may impact the shelf-life of the ground product.

The recommendations provided above should help a retailer make decisions relating to the reprocessing of products. Each store will need to carefully consider the options and determine which one works best within their process based on amount of production, opportunities for further processing, etc. Each retailer is encouraged to develop written procedures for how it will handle and document these issues. Retailers should note that any time product is being reprocessed food safety considerations must come first.

BEST PRACTICES

The following guidelines for developing best practices for retail store that are grinding beef are recommended for voluntary consideration and use in developing store-specific procedures. These are not designed to control specific food safety hazards, but are intended to provide useful information to help stores produce safe and wholesome products. For detailed information on developing a total food safety program the Food Marketing Institute has developed a document entitled, "A Total Food Safety Management Guide: A Model Program for Category: Raw, Sold Ready to Cook Product: Ground Beef."

Raw Material Source:

Retail stores should encourage/support further actions at all sectors of the industry (from animal production to consumer) to reduce microbial contamination and foodborne illness. This is especially important for ground beef and the control of *E. coli* O157:H7. The responsibility for safe food depends upon all sectors working together to produce the safest food possible for consumers. Stores that produce ground beef are responsible for outlining the requirements for raw material suppliers and for establishing a procedure to verifying that all of the requirements are implemented and working as designed. From a retail store's perspective, there are three basic points that could be considered in selecting suppliers for raw materials for ground product(s).

A. Process Interventions and/or Controls for Food Safety
   1. HACCP
      Ensure that the supplier has a HACCP program that meets all regulatory requirements and has been validated to control the food safety hazards identified as reasonably likely to occur. Retail operations may want to verify that these programs are in place and implemented appropriately.
   2. For Beef, the following items are specific to *E. coli* O157:H7

a. Suppliers of beef should have validated process interventions and/or validated Critical Control Points (CCPs) in place to prevent, eliminate or reduce *E. coli* O157:H7 to a non-detectable level. Validation may include scientific literature and/or store specific validation using indicator organisms, and it should be specific to the process(es) being applied at the store. This can be incorporated into the retail store's purchase specifications or other store programs to ensure that all raw materials are produced using validated CCPs or process interventions. If a retailer is requiring testing for E. coli O157:H7, the specifications and testing protocol could be included in the purchase specifications. This is true for both domestic and imported suppliers of raw beef to be used in ground product(s).

B. Foreign Material Contamination:

Retail stores should track unacceptable inclusions, indigenous and foreign materials, found in raw materials to help identify trends in suppliers. These findings should be shared with the supplier to help them improve their process, and may be a factor in supplier selection for future orders. This should be included in specifications to the supplier outlining items that are not acceptable in the raw materials.

C. Testing / Prescreening Requirements:

1. Sampling and testing for *E. coli* O157:H7 (by supplier or retail store)
   There should be a written protocol for sample collection, lab analysis and proficiency testing, as well as the procedures for reporting the results. It is very important that the supplier and the customer fully understand what the sample represents (i.e., a single combo, a composite of 5 combos, an entire trailer load, etc.), and the steps to be taken in the event of a positive. Communication is extremely important for reporting the test results if the product is being transported to the customer while the test is pending to ensure that all positive product is handled according to the store's written protocol.
2. Other microbiological Testing (Salmonella, APC, TPC, coliforms, etc.)
   As above, there should be a written protocol for sample collection, lab analysis and proficiency testing, as well as the procedures for reporting the results. It is important to establish how the results will be used before data are collected. Most of these microbiological tests are used for tracking supplier trends over time; however, each store must clearly define how they are going to use the information and the consequences of failing to meet the testing requirements.
3. In-store microbiological testing
   If a retail store elects to conduct its own testing of raw materials and/or finished product, then it should notify the supplier because the results may impact the supplier's production and distribution of product.

Supplier Evaluations:

Raw material suppliers are critical to both food safety and quality aspects of producing ground products. Therefore, it is important that each new supplier is approved prior to using their products, and that there is a procedure for evaluating on-going suppliers. The following guidelines can be utilized to help design a system for evaluating suppliers.

A. New Supplier Approval:
   1. Each new supplier should provide written acknowledgement of the retailer's purchase specifications and willingness to comply.
   2. Each supplier should meet the guidelines outlined in the purchase specifications for microbial testing and profiling. For new suppliers a retail grinder may want to establish an intensified sampling program to determine if the supplier can consistently meet the specifications.
   3. Each store should have a supplier audit conducted on a specified frequency to ensure compliance with the purchase specifications and other programs. The audits may be conducted by the retail grinder or by a third-party auditor. The audit requirements should be provided to the supplier as part of the purchase specifications.
   4. Retailers should conduct quality inspections of incoming materials to ensure that they are acceptable. For new suppliers a retailer may want to intensify the sampling frequency to ensure consistency in meeting the requirements.

B. Ongoing Suppliers:
   1. Retail grinding operations should periodically provide an update of the purchase specifications to each supplier and request on updated acknowledgement of receipt of the specifications and a willingness to comply.
   2. Data should be collected and tracked on the following items to identify supplier trends and help make purchasing decisions:
      a. Microbial profile data — may include, but not limited to: *Salmonella*, *E. coli* O157:H7, generic *E. coli*, Total Plate Count (TPC), Aerobic Plate Count (APC), and coliforms.
      b. Retailers may want to include periodic verification of results with a third party analysis.
      c. Foreign object contamination
      d. Defect(s) (unacceptable indigenous inclusions)
      e. Store Audits Results
      f. Age of Product at receipt
      g. Temperature of Product at receipt
      h. On-time Delivery
      i. Other store specific requirements

Pre-Receipt of Raw Material(s) Verification:

Based on all of the purchase requirements and store specifications, it is important that a system of checks and balances are put in place to verify that the supplier is conducting their program as planned. This verification process will help minimize problems and increase the integrity of the entire supplier purchasing program.

A. Negative Pre-Screen for *E. coli* O157:H7

The best practice is to have a negative *E. coli* O157:H7 test result from the laboratory or the supplier prior to opening the trailer or receiving the product. This should include all documents related to product identification, written notification of the test results, bill of lading, seal number on load, if applicable, and other identification and tracking information.

If the product must be removed from the trailer prior to receiving the written negative test result, the retailer should have written and documented procedures for off-loading, tagging and holding all of the product to ensure that it is not used prior to receiving the negative test result for *E. coli* O157:H7. This will require good tracking documentation procedures and sufficient training of all employees involved in both receiving and production to prevent the use of the product. The retail store should refuse receipt of any raw materials that test positive for *E. coli* O157:H7.

B. Seal integrity (security)
The optimal process is to seal the truck and have one delivery stop; however, this is not always possible. If the delivery will include multiple stops, then there should be a procedure for re-sealing the load and a tracking system for each seal placed on the truck. This process will help maintain product integrity and security.

Receipt of Raw Material(s):

Receiving Meat

Incoming raw meat materials should be evaluated to ensure that they meet the store-established purchase specifications. Trucks, containers and carriers of raw materials should be evaluated upon receipt to ensure that the conditions meet store requirements for transporting meat. All containers/cartons should be intact. All incoming meat should be coded/identified for store use and for the in-store tracking system. Retailer should verify that the received product is identified on invoice and the product identified on microbiological test results, if applicable.

Specific items to consider:

1. Designated employee(s) should verify that the raw material is from a store approved supplier. Each retailer should set supplier requirements and maintain a list of approved suppliers.

2. Designated employee(s) should evaluate and document on a product receiving log the condition of the trailer, shipping container(s), and carriers of raw materials upon arrival, and should document the time the inspection was conducted. Items for evaluation may include:

   • Retailers should ensure that chemicals or other compounds that may contaminate the raw materials are not being transported on the trailer.
   - Cleanliness of trailer — no foreign materials, dirt, free of debris, free of off odors

• Temperature of trailer —temperature of the trailer must be acceptable to maintain product temperature. Retailer may set a specific temperature for the product and/or the trailer as part of the purchasing specifications. If specific temperatures are set, then there should be a written procedure that defines the action(s) that will be taken if the temperature does not meet the specification.
• General trailer condition — void of cracks, insulation in good condition, trailer door is sealed properly, paper on floors for carcass carriers, etc.

3. If the truck condition is acceptable, the designated employee should verify that the incoming material matches the store purchase specifications and/or required documentation is provided with the load. The following items may be included:

   • Species identity and/or origin
   • Domestic vs. foreign supply source
   • Boning date/ slaughter date
   • No foreign objects
   • Verification of intended use — verify product and box/combo identification matches the product ordered and the bill of lading, including the proper match for product and test results.
   • Supplier microbiological testing results, if required. If the supplier is required to test for *E. coli* O157:H7, then the material should not be used until the test results are received. Raw materials should be refused if it test positive for *E. coli* O157:H7. If the supplier is testing for generic *E. coli*, coliforms, TPC or other microorganisms that can be used to establish supplier trend data, then the product does not have to be held until the results are received. However, if specific accept/reject levels are set for any specific microorganism then the product should not be accepted until test results are received.
   • Packaging/pallet requirements — i.e., no metal fasteners or bands, pallets in good usable condition, slip sheets, covers on combos, plastic pallets, etc. It is important that package integrity is maintained and documented.
   • Age of raw material — recommend fresh products be used within $\leq$5days from fabrication; and frozen meat no more than 6 months from fabrication.

4. If the product meets the purchase specifications, then the designated employee should evaluate the actual condition of the raw materials. The following items are recommended for evaluation:

   • Temperature of raw materials (i.e., frozen $\leq$10°F; fresh $\leq$41°F or less). Each retailer should have a separate procedure for taking the temperature of incoming product and calibrating thermometers. Recommend both core and surface temperatures of the product.
   • Organoleptic evaluation of raw material for off odor, discoloration, improper appearance.
   • Material must have supplier code information and proper lot/load identification on materials.

5. If incoming raw materials pass the receiving inspection, then all raw materials should be placed into inventory and receive any retailer specific tracking/coding information prior to entering the storage area or being used in the grinder.

Use of Trimming Generated In-Store:

Some retail stores may decide to not use trimmings generated in the retail store in the production of ground beef. However, if trimmings are going to be used in the production of ground beef, then the retailer should develop and implement a tracking system to properly identify the source of the trimmings. It is recommended that in-store trimmings be ground within 24 hours, and should be stored under ≤41°F.

Non-meat Ingredients

Retailers will also need to make sure that all non-meat items ingredients, such as seasonings/spices, etc. meet the store-established specifications. After the retailer accepts the non-meat ingredients, then these items should be stored, handled and used in a manner that will maintain the integrity of the items.

Storage of Raw Material(s):

Raw materials should be used on a First-In/First Out (FIFO) basis or according to a store specified product rotation/inventory control schedule. Raw materials should be stored at temperatures that maintain proper product condition – temperature, integrity, etc. Frozen materials should be kept frozen, unless tempering or thawing is required prior to use. The packaging/pallet integrity must be maintained throughout the storage period to maintain the condition of the raw materials. Product identity in storage should allow for proper in-store tracking system.

Specific items to consider:

1. For shelf-life purposes place fresh raw materials into cold storage (i.e., ≤41°F or less) and frozen product into freezers (i.e., ≤10°F or less).

2. Develop retailer specific storage records or product identification, so product will be used on a FIFO basis or according to store product rotation/inventory control schedule.

3. Store raw materials to maintain package/pallet integrity. Boxed product should remained in closed box and combo bins should be covered during storage to prevent contamination.

4. Storage conditions should be maintained according to pre-requisite program requirements to ensure product integrity during storage.

5. Individual store security should address raw material and finished product storage areas.

Raw Material Processing:

Tempering/Thawing of Frozen Materials

If tempering or thawing is required prior to use, then it should be done in a time/temperature controlled manner that is adequately monitored and documented and verified. The product package integrity is important during this process. The product's traceability should be maintained throughout the tempering/thawing process. It is advisable to have a written program that outlines specific guidelines or procedures.

Specific items to consider:

1. Place frozen product in a tempering room that is ≤41°F and allow product to reach desired level of tempering or thawed state; actual time will vary depending on amount of product and type of packaging. (If the room temperature is higher than 41°F then one must evaluate the time/temperature relationship to reduce the risk of potential microbial growth on the surface of the product.) You may want to consider air temperature and velocity to ensure proper thawing.
2. The product should be monitored on a scheduled basis to prevent degradation of the package integrity and minimize product drip.
3. The product temperature should be monitored on a scheduled basis to ensure that the desired end temperature is not exceeded.
4. All of the products should maintain the store-specific tracking/coding information to ensure proper traceability of product from receiving through to final end products.

Grinding/Processing Records

Grinders should cleaned and sanitized between lots and should be document on the grinding logs. The grinding logs should include weighing, mixing, blending, coarse and final grinds, forming, packaging, and labeling and other specific aspects of the process. Throughout all of these steps the temperature of the product should be maintained. Steps should be taken to prevent species cross-contamination and proper labeling to maintain end-product identity. Procedures for ensuring proper endproduct characteristics (i.e., weights, size, shape, quantity, etc.) should be in place. The in-store tracking mechanism should allow for batch identification and time of batch production.

Specific items to consider for grinding:

1. Prior to initiating the grinding process, retailers should ensure that negative *E. coli* O157:H7 results have been received, if the raw material was subjected to testing.

2. Formulation of the product should utilize a grinding logs to document product identification and includes raw materials used, specific weights and amounts, fat

percent, etc. The formulation documentation should address quality characteristics, product specifications, and traceability both forward and backward in the production system.

3. Temperature monitoring of the backroom and the product to ensure integrity. The room temperature should be controlled and the actual time of processing should maintain product integrity, including maintaining the temperature below 41°F during production. A target of ≤50°F for the room is most often used and records of actual room temperatures should be maintained.

4. Defect inspection and elimination systems should be used when possible for bones, metal, etc.

5. Appropriate identification and tracking for traceability purposes should be maintained for all reprocessed product.

6. Retail employees should complete an evaluation of the equipment (grinders – plates and blades, defect eliminators, metal detectors, etc.) on a scheduled basis and the time of each evaluation should be recorded. It is important that this is performed during the production of ground beef, and that this information is reviewed prior to placing the packaged product in the retail display case. This will help minimize the risks associated with equipment malfunctions that can impact the product.

Packaging/Labeling:

It is important that the finished product is properly packaged and labeled to protect the integrity of the product and to provide appropriate handling and cooking instructions to the consumer.

Specific items to consider:

1. Package material must be approved for use with food.
2. Package materials must be stored in a manner to prevent contamination and the material must protect the finished product.
3. The product identification/tracking mechanism should identify specific processing lines used to produce this finished product. This may help narrow the product impacted if there is a problem with a particular processing line that does not impact the other lines.
4. Packaging and labeling employees are responsible for properly labeling end-products with product identity and proper code dates for example: expiration date, sell-by-date, use-by-date, production date and time, using a dating system according to the regulations for opening dating.
5. Packaging and labeling employees are responsible for including all safe handling and storage information according to each product's requirements, as well as specific cooking instructions. Safe handling labeling is required by USDA.

Storage of Finished Product and Products Displayed in Retail Case:

Finished products should be stored or placed in a retail case designated to maintain temperatures (≤41°F) over time to ensure product shelf-life and product safety. A FIFO or a store specified product rotation/inventory control schedule should be maintained for finished products. The package integrity should be maintained throughout the storage period to protect the condition of the finished product. Product identity in storage and during case display should allow for the in-store tracking system to be used for stock rotation and for recall and/or market withdrawal purposes.

Specific items to consider:

1. For shelf-life purposes place fresh product into cold storage and frozen product into freezers.
2. Utilize products in a specified time-period to maintain shelf-life requirements. Shelf-life of the product is dependent upon the type of product, type of package, temperature of storage, condition of incoming materials, etc. Therefore, each retailer should have specific guidelines for storing/displaying and utilizing finished products.
4. Storage/display conditions should be maintained according to pre-requisite program requirements to ensure product integrity during storage and display.

SYSTEM CHALLENGES TO MEASURE EFFECTIVENESS:

Recall Program and Mock stock recovery drills:

All retailers that grind beef should develop a recall program. The program should include mock recalls conducted on a periodic basis to ensure that the program works as planned. The recall program should include identification and tracking of raw materials, packaging, and finished products. The program must be able to cover all raw materials (meat, non-meat ingredients), packaging materials to the finished product. The program should identify all suppliers, customers, distributors and everyone involved in the process. The more details that are put in place prior to having a problem, the easier the recall or withdrawal will be if there is a problem. Retailers should have a tracking system to ensure that product that is pulled from the retail display case is documented (date pulled, amount, reason for pull, etc.).

Store Security:

Store security systems should address the security of the raw meat and the finished packaged product storage prior to being placed into the retail case. Access should be limited to designated employees only as part of the security program.

SANITATION:

Periodic sanitation practices must be followed to prevent the potential for product contamination. It is recommended that sanitation procedures should be a written schedule. Cleaning and sanitizing chemicals should be identified and stored separately from raw meat, grinding area and equipment, and finished products. It is recommended

that grinders and other equipment should be cleaned and sanitized between lots and documented on the grinder log.

HACCP IN A GRINDING OPERATION:

As we all know, HACCP is a process control system designed to prevent, eliminate or reduce to an acceptable level food safety hazards. The retailer should consider biological, physical, and chemical food safety hazards. This a raw process that has no scientific CCP for preventing, eliminating or reducing to an acceptable level microbial food safety hazards, such as *E. coli* O157:H7. Therefore, retailers that grind must focus on what can realistically be applied during the process to minimize the potential for growth of pathogens, if present on the raw material. These steps often involve time and temperature controls (i.e., raw material and finished product temperature during processing cold storage or other steps) to minimize the potential for growth.

All retailers that grind beef should be able to support the decisions that are made in the HACCP program and to use the documentation generated from the program to demonstrate product safety. For detailed information on developing a total food safety program the Food Marketing Institute has developed a document entitled, "A Total Food Safety Management Guide: A Model Program for Category: Raw, Sold Ready to Cook Product: Ground Beef."

Conference for Food Protection
2012 Issue Form

Internal Number: 069
Issue: 2012 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.

Title:
Addition to Original Containers and Records Section in the FDA Food Code,

Issue you would like the Conference to consider:
The 2009 FDA Food Code recognizes that consumers are at risk of foodborne illness from undercooked or improperly cooked meat items, particularly ground beef. Some retailers may grind intact beef or beef trim to produce ground beef "in house". While this practice is lawful, it may present an increased risk of foodborne illness to consumers, because intact beef may not be subject to the same rigorous pathogen control as ground beef. In addition, mixing of product from various suppliers and lots can spread contamination among the resulting ground product. Failure to adequately separate lots, clean and sterilize grinding equipment can contribute to the risk.

Public Health Significance:
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. Mixing of lots from the same or varied suppliers can spread contamination among resulting product. Outbreaks resulting from these products may be more difficult to trace as a result of the mixed nature of the product. Adequate recordkeeping is thus essential to provide traceback data for public health officials investigating an outbreak.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
3-203.13 Recordkeeping, Ground Product.
(A) Every FOOD ESTABLISHMENT that performs grinding or packaging of MEAT on PREMISES shall maintain adequate records sufficient to assist public health officials with traceback or other relevant investigation.
(1) Adequate records shall include:
(a) Producing store name, address, city/state/zip
(b) Date of each lot of store ground product produced, where a lot is defined as all identically labeled product produced from full equipment clean-up to clean-up
(c) Exact name/type of store ground product

(d) Amount of each lot of store ground product
(e) Sell by/use by date and/or production code of each lot of store ground product
(f) Other information used to identify store ground product
(g) Full name(s) and product code(s) of all source products used to formulate each lot of store ground product
(h) All Federal or State Establishment numbers of each source product contained in each lot of store ground product
(i) Each source product sell by, use by, or production date/code
(j) The source firm name, establishment number and use by/sell by/production date/code for all Shop trim/rework used in each lot of store ground product
(k) Bills of Sale (e.g. sales receipts) reflecting Item numbers for each ground beef product sold to consumers
(l) Invoice(s) and Bill(s) of lading for source product(s)

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

Conference for Food Protection
2012 Issue Form

Internal Number: 067
Issue: 2012 I-016

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

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Title:
Addition to Duties: Person in Charge Section 2-103.11 of FDA Food Code

Issue you would like the Conference to consider:
The FDA Food Code recognizes that consumers are at risk of foodborne illness from undercooked or improperly cooked meat items, particularly ground beef. Some food establishments-retailers as well as restaurants-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 intact beef may not be subject to the same rigorous pathogen control as ground beef.

Public Health Significance:
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 order such products undercooked (i.e., rare or medium rare), which is insufficient to kill pathogens.
It is thus imperative that those employees tasked with handling and grinding such meats (and those employees responsible for cleaning the grinding equipment, if different) are specially trained about the importance of rigorous cleaning for the prevention of foodborne illness, the logistics of cleaning, and the maintenance of appropriate records to assist in an outbreak investigation resulting from in house ground products.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting the addition of the underlined language to Section 2-103.11 of the FDA Food Code, *Duties: Person in Charge*:
2-103.11 Person in Charge.
(L) EMPLOYEES are properly trained in FOOD safety as it relates to their assigned duties; <u>with enhanced training for those employees who may be responsible for production and handling of "in house" ground beef, such as the grinding of MEAT, PRIMAL CUTS and WHOLE MUSCLE, INTACT BEEF;</u> and

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Conference for Food Protection
2012 Issue Form

Internal Number: 009
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Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Use of Consumer Advisory for Non-Continuous Cooking

Issue you would like the Conference to consider:
Add a new section to Section 3-401.14 of the FDA Food Code to allow for the service of raw intact whole muscle beef cooked using a non-continuous cooking process, to be served undercooked with an adequate consumer advisory as described in 3-401.11 (D).

Public Health Significance:
Section 3-401.11 (D) allows for the service of raw or undercooked animal products with the use of an adequate consumer advisory. This important and balanced public health approach, currently not allowed under Section 3-401.14, provides the same level of protection and fair consumer choice for raw or undercooked, or non-continuous and undercooked animal products, such as when large catered events either cook to order or when they partially cook, cool and cook to order. As long as consumers are informed with an adequate consumer advisory as outlined in 3-603.11, the same level of public health protection is assured.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:
Add new language to Section 3-401.14 indicated in underlined language below
3-401.14 Non-Continuous Cooking of Raw Animal Foods.
Raw animal FOODS that are cooked using a NON-CONTINUOUS COOKING process shall be:
(A) Subject to an initial heating process that is no longer than sixty minutes in duration; P
(B) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked POTENTIALLY HAZARDOUS FOOD (TIME /TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.14(A); P
(C) After cooling, held frozen or cold, as specified for POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.16(A) (2); P
(D) Prior to sale or service, cooked using a process that heats all parts of the FOOD to a temperature of at least 74°C (165°F) for 15 seconds; P

(E) Cooled according to the time and temperature parameters specified for cooked POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.14(A) if not either hot held as specified under ¶3-501.16(A), served immediately, or held using time as a public health control as specified under §3-501.19 after complete cooking; P and

(F) Prepared and stored according to written procedures that:

(1) Have obtained prior APPROVAL from the REGULATORY AUTHORITY; Pf

(2) Are maintained in the FOOD ESTABLISHMENT and are available to the REGULATORY AUTHORITY upon request; Pf

(3) Describe how the requirements specified under ¶ (A)-(E) of this Section are to be monitored and documented by the PERMIT HOLDER and the corrective actions to be taken if the requirements are not met; Pf

(4) Describe how the FOODS, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as FOODS that must be cooked as specified under ¶ (D) of this section prior to being offered for sale or service; Pf and

(5) Describe how the FOODS, after initial heating but prior to cooking as specified under ¶ (D) of this section, are to be separated from READY-TO-EAT FOODS as specified under ¶ 3-302.11 (D).

(G) Allow for the service of raw intact whole-muscle beef cooked using a non-continuous cooking process to be served undercooked with an adequate consumer advisory.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 090
Issue: 2012 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.

Title:
Report - Recall Evaluation Committee

Issue you would like the Conference to consider:
The Food Recall Evaluation Committee (REC) was tasked with the evaluation of current policy and practice of food recalls of the U.S. Food and Drug Administration and the U.S. Department of Agriculture, with the goal of providing feedback and recommendations that these agencies could consider in improving food recalls and recoveries.
The committee met via a series of webinars for the past 18 months. Membership included a diverse cross-structure of industry and regulators as well as academia and public interest representatives.
The committee believes we have reached consensus on the items included herein and detailed in the attached reports.

Public Health Significance:
Beyond question, the current system of recalling food products in the United States in case of real or purported health or quality issues is flawed. While part of the problem resides in the sheer complexity of the global food production and distribution system, the process of recalling a product is difficult for industry and incomprehensible to the general public. While new (pending) food safety legislation will address a few of the problems, there remains the need to overhaul and clarify the current recall classification and notification process.
Consider:

- FDA is guided by Ch. 7 of their 2009 Regulatory Procedures Manual/ 21CFR
- Recalling Firm is guided by "GUIDANCE FOR INDUSTRY" document by FDA
- Firms affected by the recall throughout the complex food system (distributers, sub-producers, brokers) have no official FDA guidance
- There is no time limit for executing a Class I Recall, or any other Class
- There are no minimum requirements for the information required in a recall notice
- There is no consideration of cost to benefit
- Current Classification system is ambiguous and confusing

Recommended Solution: The Conference recommends...:

- acknowledgement of the Food Recall Evaluation Committee (REC) report and attachments,
- thanking the Committee members for their efforts, and
- disbanding the Committee as the charges are completed.

Submitter Information:

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Attachments:

- "Final Roster 1_6_12"
- "Recall Evaluation Committee Final Report"

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Committee Name: Recall Evaluation Committee

First Name	Last Name	Company /Employer Name	City	State	Role (Chair, Co-Chair, Vice Chair)
David	Abney	Sonic Drive In	Oklahoma City	OK	Member
Laura	Adam	FDA	College Park	MD	Member
Dare	Akingbade	USDA	Wash DC	DC	Member
David	Armatis	Safe Foods First	San Francisco	CA	Member
Patti	Bailey	Yum! Brands, Inc.	Dallas	TX	Member
James	Baldwin	Price Chopper Supermarkets	Schenectady	NY	Member
Rick	Barney	Delhaize America	Tampa	FL	Member
Angela	Benton	Jetro/Restaurant Depot	College Point	NY	Member
Teresa	Bullock	Arkansas Department of Health	Little Rock	AR	Member
Mary	Cartagena	FDA	College Park	MD	Member
Gary	Coleman	Underwriters Laboratories, Inc.	Research Triangle Park	NC	Member
Drew	Falkenstein	Marler-Clark	Seattle	WA	Member
Kelli	Fall	NSF International	Ann Arbor	MI	Member
Laura	Fenton	Advance Food	Enid	OK	Member
Gary	Fleming	Cross Link Group			Member
Robert D.	Frappier	Ahold USA	Braintree	MA	Member
Liza	Frias	Supervalu	Fullerton	CA	Member
Joe	Graham	Washington State Department of Health	Olympia	WA	Member
John	Gurrisi	Darden Restaurants, Inc.	Orlando	FL	Member
Roger	Hancock	Recall Info Link	Boise	ID	Member
George	Hanssen	Nebraska Department of Agriculture	Lincoln	NE	Member
Craig K.	Harris	Michigan State University	Okemos	MI	Co-Chair
Jill	Hollingsworth	Food Marketing Institute	Arlington	VA	Member
Tim	Ihry	USDA	Omaha	NE	Member
Adam	Johnson	Wal-Mart	Bentonville	AR	Member
Larry	Kohl	Food Lion	Arlington	VA	Member
Don	Lane	The Kroger Co.	Cincinnati	OH	Member
Tressa	Madden	Oklahoma State Department of Health	Oklahoma City	OK	Member
Ernie	McCullough	ASI Food Safety Consultants	Cumming	GA	Member
Charles E.	McGuffey	7-Eleven, Inc.	Dallas	TX	Member
Sheri L.	Morris	PA Dept. of Agriculture/Food Safety & Laboratory Services	Harrisburg	PA	Member
Gina	Nicholson	The Kroger Company	Westerville	OH	Member
Kathleen	O'Donnell	Wegman's Food Markets			Member
Joel	Ortiz	Whole Foods Market	Austin	TX	Member

2012 Committee Lists for Program Booklet

Gregory	Pallaske	U.S. Foodservice	Rosemont	IL	Co-Chair
Richard	Parker	HEB	San Antonio	TX	Member
Angela	Paymard	N2N Global	Longwood	FL	Member
Larry	Payton	Tokyo Gardens Sushi	Houston	TX	Member
Stephen	Posey	Brinker International	Dallas	TX	Member
Terrance	Powell	Los Angeles County Dept. of Public Health	Baldwin Park	CA	Member
Gale	Prince	Your Food Safety Coach, LLC	Cincinnati	OH	Member
Ramona	Quintanilla	Proctor & Gamble	Cincinnati	OH	Member
John	Raulerson	Firehouse Restaurant Group	Jacksonville	FL	Member
David J.	Read	Minnesota Department of Agriculture	St. Paul	MN	Member
Karen	Reid	Walt Disney Parks and Resorts US	Lake Buena Vista	FL	Member
Robert	Reinhard	Sara Lee Corporation	Downers Grove	IL	Member
Kenneth	Rosenwinkel	Jewel-Osco/Supervalu	Itasca	IL	Member
Grant	Sherratt	Steton Technology	St. George	UT	Member
Mike	Sostrin	Walmart Stores Inc	Bentonville	AR	Member
Kristina	Stefanski	Ahold/The Stop & Shop Supermarket Company LLC	Quincy	MA	Member
Casimir M.	Tryba	Big Y Foods, Inc.	Springfield	MA	Member
Susan	Tyjewski	CKE Restaurants, Inc.	Ontario	CA	Member
Travis	Waller	Associated Food Stores, Inc.	Salt Lake City	UT	Member
Lisa	Weddig	Better Seafood Board	McLean	VA	Member
Tim	Westbrook	Publix Super Market	Orlando	FL	Member
Laurie	Williams	FDA	College Park	MD	Member
Sharon	Wood	H-E-B Grocery Company	San Antonio	TX	Member

Conference for Food Protection

Recall Evaluation Committee **Final report**

Council: **I**
Date: **01/31/2012**
Submitted by: **Greg Pallaske**

Committee Charges:

Clarify the system of classification for recalls established by USDA and FDA.

Create clarifying instructions and procedures that industry and consumers can easily understand and comply with.

Recommend enforceable and reasonable time frames for execution of recall communications and actions.

Clarify the information required to be included in supplier recall notifications.

Recommend expectations for the notification of end-users, including restaurant and retail customers as well as school and institutional food service.

Report back to the 2012 Biennial Meeting.

Committee Activities and Recommendations:

This document contains an overview of the discussions of the Recall Evaluation Committee of the past two years. Included are some suggestions and ideas that provide a background for the bullets provided in Committee Issue titled: Change in Definitions. These are not specific recommendations, but rather are intended to serve to provide a background into the concerns shared by many committee members.

Charge #1: Clarify the system of classification for recalls established by USDA and FDA.
For example, what is the difference between a "reasonable probability" (Class I) and a "remote probability" (Class II)? Many industry members believe the public does not distinguish between them; therefore, to the public, all recalls are "bad".

To address this issue, the committee felt that different terminology may be helpful. One set of terms under discussion was to use the word "recall" only for what is currently a Class I situation. Thus we defined "Food Recall" as *a health risk to the general public*, and generally agreed that a "food recall" should coincide with what the FDA generally defines as a "reportable food" or the USDA classifies as a Class I Recall.

The equivalent of what is currently a Class II recall was a bit more problematic

– many of us noted that historically, Class II's have been situations where a major allergen was not listed on the product label, and thought the term "Allergen Alert" would be appropriate. Other committee members felt the term was too narrow as not all Class II equivalents are caused by one of the big eight allergens. Their term of choice is "Food Alert". Either of these is defined as *a health risk to allergic/selected/sensitive populations*.

Finally, the term agreed upon for the equivalent of a Class III is "Food Notification", defined as *little or no health risk*.

A great deal of discussion centered on the difficulty on the part of industry and the public in distinguishing the differences between a Class I, II, and III Recall.

Regardless of the terminology used, the committee overwhelmingly agrees that recalls must be classified upon release. To better accomplish this goal, the committee recommends creation of a decision tree for classification of recalls, with the following stipulations:

- Tree should be transparent and readily available as a tool to industry and regulators
- The decision tree should be developed jointly with industry, regulators, and consumer representatives
- The tree is a guideline, not an absolute rule – regulators maintain final classification decision
- The same/ similar tree/ system should be followed by both FDA and USDA

Charge #2: Create clarifying instructions and procedures that industry and consumers can easily understand and comply with.

The committee's concern is that notifications do not clearly delineate the relative risks of the various categories of recalls. To correct this, the committee feels that:

- Recall announcements should clearly instruct public of severity of risk and tell them how to react accordingly
- Instructions should be different for each classification but standardized (public should always get same instructions for Class I, different for Class II, etc.)
- Affected, or potentially affected, industry sectors should be notified at the same time (or before) information is provided to the general public and media
- Announcements should be consistent and more specific consumer messages (for example, explaining the difference between recalls for pathogens that present a risk to the general public versus a recall for an allergen that only impacts a select portion of the population).

Furthermore:

- Guidelines established by the FDA and USDA, working jointly with

industry, should standardize industry best practices on what to do, and when, upon receiving notice of a recall.

- Expectations should differ by classification
- Expectations should be tailored to major industry segments – production, retail, foodservice – as each of these segments bears different responsibilities and reactions

Charge #3: Recommend enforceable and reasonable time frames for execution of recall communications and actions.

Currently, the recall initiating firm is the only entity in the distribution chain with written guidelines for recall actions. Our thoughts:

- Industry best practices should be established by the FDA/USDA and in place for secondary suppliers and distributors
- Expectations should be established for tracing one step forward and back within a defined time frame
- The government agency overseeing the recall should require that originating firm issues classified recall notice and contacts direct receivers
- FDA/USDA should establish expectations for timeliness in notifying next link in food chain
- Receivers should react immediately (defined as within 24 hours maximum – 4 hours for high-risk; or as defined by the FDA and USDA)
- Customers should be contacted/ notices posted as soon as possible (24 hours max- 4 hours for high-risk product recall) following the Food Safety Modernization Act (FSMA) guidelines
- Reports to Agency (product remaining, customers affected) should be submitted in a timely fashion

Note that the issue of retailers notifying consumers has already been addressed by FDA and the Food Marketing Institute (FMI) and therefore was not discussed here.

Charge #4: Clarify the information required to be included in supplier recall notifications.

- Identify the format of the communications downstream- start with existing models (USDA/FDA)
- All Recall Notices should follow the same format
- Identify minimum required information to properly identify the product - note that existing models exist with both government agencies but industry is not required to use them as a template
- Identify minimum best practices for notification, including times
- Classification of the recall should be determined by FDA/USDA and included upon release of the recall notification
- Standardized plain language assessment of risk should be included in the recall notice
- The recalling firm, including contact information, should be included
- Describe the recalled product in adequate detail so that it can be clearly identified and rapidly followed through distribution to the end user. This should

include:

- The product description or some surrogate—manufacturer and product name
- Producing establishment identification /plant numbers
- Brands/ sizes/ packaging/identifying information such as lot codes, manufacturing codes, "sell by" or "best by" dating, retail product UPC, shipping case UPC, etc.

- Provide instructions on how to return, destroy, get credit, or avoid a potential hazard
- Include the Distribution channel (retail, foodservice, etc.) including geographic information – this is especially important because firms and individuals want to know if they are NOT included in a recall.

Charge #5: Recommend expectations for the notification of end-users, including restaurant and retail customers as well as school and institutional food service.

- A Properly Classified recall notice should be publicized on FDA or USDA web site as well as the supplier web site – including instructions how to avoid or minimize harm
- All downstream recipients in the supply chain of a recall (including consumers when required) must be notified by verified phone, fax, or email (note that retail consumer notification is covered under a FSMA committee)
- Federal Agencies are urged to review best methods of communicating recalls to the general public, including use of modern technology.

Requested Action:

The Committee will submit three (3) Issues to the Conference.

1) To acknowledge the Committee report, thank the members, and disband the committee.

2) Requesting that a letter be sent to the FDA and USDA recommending the following

a. Change in definitions:

i. Replace Class I Recall with "Food Recall" defined as *a health risk to the general public*, and should coincide with what the FDA generally defines as a "reportable food" or the USDA Class I Recall

ii. Replace Class II Recall with "Allergen Alert" or "Food Alert" defined as *a health risk to allergic/selected/sensitive populations*.

iii. Replace Class III Recall with "Food Notification" defined as *little or no health risk.*

b. Creation of a decision tree for classification of recalls, with the following stipulations:

i. Tree should be transparent and readily available as a tool to

industry and regulators

ii. The decision tree should be developed jointly with industry, regulators, and consumer representatives

iii. The tree is a guideline, not an absolute rule – regulators maintain final classification decision

iv. The same/ similar tree/ system should be followed by both FDA and USDA

3) Requesting that a letter be sent to the FDA and USDA requesting they work together in collaboration with stakeholders on developing a uniform food recall system. Examples of what should be considered in this initiative include:

- A mechanism for working with industry and other stakeholders to further identify the specific changes needed to enhance the current recall system
- A uniform recall process be used by all federal food regulatory agencies
- A revised classification system that is prompt, transparent and meaningful to industry, regulatory, and the general public using consistent definitions for recall classifications
- Consistent information provided with every recall, especially a decision on the classification
- Clarifying instructions and procedures for industry and the public
- A mechanism for engaging relevant private-sector expertise in recall investigations and recall decisions
- Reasonable "best practice" time frames for execution of recall communications and actions including verification of notification
- Clear and consistent information in recall notifications to each segment of the supply chain including information that clearly identifies the product being recalled in sufficient detail
- Consistent protocol for audits and/or effectiveness checks
- Consistent and more specific consumer messages (for example, explaining the difference between recalls for pathogens that present a risk to the general public versus a recall for an allergen that impacts a select portion of the population)
- A single website and database for all food recalls with a consumer-friendly format

Roster: (see attached)

Conference for Food Protection
2012 Issue Form

Internal Number: 092
Issue: 2012 I-019

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

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Title:
Uniform Food Recall System

Issue you would like the Conference to consider:
The Recall Evaluation Committee requests that a letter be sent to the FDA and USDA requesting they work together in collaboration with stakeholders on developing a uniform food recall system that is easier to understand and contains guidelines and best practices that will make the process faster and more efficient.

Public Health Significance:
Beyond question, the current system of recalling food products in the United States in case of real or purported health or quality issues is flawed. While part of the problem resides in the sheer complexity of the global food production and distribution system, the process of recalling a product is difficult for industry and incomprehensible to the general public. While new (pending) food safety legislation will address a few of the problems, there remains the need to overhaul and clarify the current recall classification and notification process.
Consider:

- FDA is guided by Ch. 7 of their 2009 Regulatory Procedures Manual/ 21CFR
- Recalling Firm is guided by "GUIDANCE FOR INDUSTRY" document by FDA
- Firms affected by the recall throughout the complex food system (distributers, sub-producers, brokers) have no official FDA guidance
- There is no time limit for executing a Class I Recall, or any other Class
- There are no minimum requirements for the information required in a recall notice
- There is no consideration of cost to benefit
- Current Classification system is ambiguous and confusing

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA and the USDA requesting that they work together in collaboration with industry stakeholders on developing a uniform food recall system.
Examples of what should be considered in this initiative are:

- A mechanism for working with industry and other stakeholders to further identify the specific changes needed to enhance the current recall system
- A uniform recall process be used by all federal food regulatory agencies

- A revised classification system that is prompt, transparent and meaningful to industry, regulatory, and the general public using consistent definitions for recall classifications
- Consistent information provided with every recall, especially a decision on the classification
- Clarifying instructions and procedures for industry and the public
- A mechanism for engaging relevant private-sector expertise in recall investigations and recall decisions
- Reasonable "best practice" time frames for execution of recall communications and actions including verification of notification
- Clear and consistent information in recall notifications to each segment of the supply chain including information that clearly identifies the product being recalled in sufficient detail
- Consistent protocol for audits and/or effectiveness checks
- Consistent and more specific consumer messages (for example, explaining the difference between recalls for pathogens that present a risk to the general public versus a recall for an allergen that impacts a select portion of the population)
- A single website and database for all food recalls with a consumer- friendly format

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 018
Issue: 2012 I-020

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

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Title:
Recall Definitions and Decision Tree

Issue you would like the Conference to consider:
The Recall Evaluation Committee requests that a letter be sent to the FDA and USDA requesting they work together in collaboration with stakeholders on developing new terminology for Class I, II, and III recalls that is easier for industry, regulators, and the public to understand. Additionally, that a decision tree be developed that creates more transparency into how a recall should be classified.

Public Health Significance:
Food recalls are the last line of defense when a dangerous or violative food product has entered the marketplace. When a firm is unable to determine proper classification, the process slows down, causing potentially dangerous delays in public notification and distribution chain removal of the product from the marketplace.

Additionally, many suppliers and the general public do not understand the difference in the significance and danger associated with the various classes of recalls. The result is either apathy, where the public pays little attention because of the sheer volume of "noise", or they over-react and needlessly throw out and stop buying perfectly good products. The net result is an unnecessary loss of public confidence in our food supply, as well as a tremendous waste of food.

A great deal of discussion within the Committee centered on the difficulty on the part of industry and the public in distinguishing the differences between a Class I, II, and III Recall. For example, what is the difference between a "reasonable probability" (Class I) and a "remote probability" (Class II)? Many industry members believe the public does not distinguish between them; therefore, to the public, all recalls are "bad."

To address this issue, the Committee felt that different terminology may be helpful. One set of terms under discussion was to use the word "recall" only for what is currently a Class I situation. Thus we defined "Food Recall" as *a health risk to the general public*, and generally agreed that a "food recall" should coincide with what the FDA generally defines as a "reportable food" or the USDA equivalent thereof.

The equivalent of what is currently a Class II recall was a bit more problematic - many Committee members noted that historically, Class II's have been situations where a major allergen was not listed on the product label, and thought the term "Allergen Alert" would be

appropriate. Other committee members felt the term was too narrow as not all Class II equivalents are caused by one of the big eight allergens. Their term of choice is "Food Alert". Either of these is defined as *a health risk to allergic, selected, sensitive populations*. Finally, the term agreed upon for the equivalent of a Class III is "Food Notification", defined as *little or no health risk*.

Regardless of the terminology used, the Committee overwhelmingly agrees that recalls must be classified upon release. To better accomplish this goal, the committee recommends creation of a decision tree for classification of recalls, with the following stipulations:

• Decision tree should be transparent and readily available as a tool to industry and regulators.

• Decision tree should be developed jointly with industry, regulators, and consumer representatives.

• Decision tree is a guideline, not an absolute rule - regulators maintain final classification decision.

• The same/ similar tree/ system should be followed by both FDA and USDA.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA and USDA recommending the following:

a. Change in definitions:

- Replace Class I Recall with "Food Recall" defined as *a health* ***risk to the general public***, and should coincide with what the FDA generally defines as a "reportable food" or the USDA equivalent thereof
- Replace Class II Recall with "Allergen Alert" or "Food Alert" defined as *a health risk to* ***allergic/selected/sensitive populations***.
- Replace Class III Recall with "Food Notification" defined as *little or no health risk.*

b. Creation of a decision tree for classification of recalls, with the following stipulations:

- Decision tree should be transparent and readily available as a tool to industry and regulators.
- Decision tree should be developed jointly with industry, regulators, and consumer representatives.
- Decision tree is a guideline, not an absolute rule - regulators maintain final classification decision.
- The same/ similar decision tree/ system should be followed by both FDA and USDA.

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Conference for Food Protection
2012 Issue Form

Internal Number: 065
Issue: 2012 I-021

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

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Title:
New Recall Notification Section of the FDA Food Code (Section 3-603.12)

Issue you would like the Conference to consider:
The 2009 FDA Food Code recognizes that consumers may not receive adequate, timely information in the event of a food safety recall, and that retailers play an important role in disseminating critical public health information. Records kept by retailers in the ordinary course of business for marketing or promotional purposes can be extremely useful for notifying consumers and curtailing the spread of an outbreak. Grocery stores and vendors should, when otherwise maintaining customer purchasing data, make every reasonable effort to notify consumers in the event of a Class I Recall.

Public Health Significance:
Removal of contaminated foods is vital to minimizing the adverse impact on consumers and public health, including reducing the size of associated foodborne illness outbreaks. While retailers' actions are essential for rapid removal of recalled foods from shelves, this does not address products that have already been sold. A proposed Food Code amendment offers a solution to better inform consumers about outbreak-associated and recalled products.
Where retailers routinely collect consumer purchasing data, that information can be useful in identifying consumers who may have recalled product still in their homes. Retailers should access purchasing data and the associated consumer contact information to alert consumers to their previous purchases of products that are later associated with a Class I Recall. Such personalized notice will help consumers identify recalled product at home, and will establish the retailer as a source of important public health information.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
3-603.12 Recall Notification.
(A) Every FOOD ESTABLISHMENT that offers PACKAGED FOOD for purchase by consumers, and that collects data on the purchasing of that food (through customer loyalty cards or other data collection methods), shall, in the event of a Class I Recall of any FDA or USDA product sold by the FOOD ESTABLISHMENT, contact those consumers for which

data is available to indicate the purchase of a product, within the previous 60 days, that is now subject to a recall. Consumers may be contacted via email, text message, telephone, or regular mail, and contact must be initiated within a reasonable time from when the FOOD ESTABLISHMENT receives notice that the FOOD ESTABLISHMENT sold recalled product, not to exceed 2 days from that notice.

Submitter Information:
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Conference for Food Protection
2012 Issue Form

Internal Number: 066
Issue: 2012 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.

Title:
New Recordkeeping Section of the FDA Food Code (Section 3-603.13)

Issue you would like the Conference to consider:
The 2009 FDA Food Code recognizes that records kept by retailers in the ordinary course of business for marketing or promotional purposes can be extremely useful for public health officials investigating a foodborne illness outbreak and attempting traceback and attribution. Retailers should make every reasonable effort to give public health officials timely access to such records to assist in an outbreak investigation or for other such lawful and reasonable public health purposes.

Public Health Significance:
Where retailers routinely collect consumer purchasing data, that information is critical to identifying consumers who may have purchased products that are later implicated in an outbreak. That data has also proven to be of great importance to public health officials in performing traceback investigations and food attribution during and after an outbreak. Rapid identification of at-risk consumers (those who have purchased recalled product) is essential to curtailing the size and impact of an ongoing outbreak from contaminated products. Retailers should provide public health officials with customer purchasing data that may be helpful in the course of an outbreak investigation, in an effort to assist with attribution and containment of foodborne illness.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
3-603.13 Recordkeeping, Public Health Significance.
(A) Every FOOD ESTABLISHMENT that offers PACKAGED FOOD for purchase by consumers, and collects data on the purchasing of that food (through customer loyalty cards or other data collection methods), shall, provide public health officials upon request with timely access to customer purchasing data to assist in a public health investigation or for other such lawful purposes.

Submitter Information:
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Conference for Food Protection
2012 Issue Form

Internal Number: 095
Issue: 2012 I-023

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

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Title:
Shellstock Record Keeping

Issue you would like the Conference to consider:
Modification of the 2009 FDA Food Code to add language that addresses the use of shellstock being simultaneously used from different sources or growing areas. The facility's record-keeping system must be able to distinguish the shellstock that was served to each customer.

Public Health Significance:
The Interstate Shellfish Sanitation Conference (ISSC) continues to address illnesses associated with consumption of raw molluscan shellfish. Our primary focus is to improve our response time associated with illness outbreaks and to evaluate the effectiveness of control programs associated with pathogens which may result in illnesses.
These activities utilize illness investigation information from retail establishments. In recent years there has been improvement and the suggested change is intended to further improve the ability of illness investigators to accurately identify shellstock sources and growing areas. The ISSC and the Conference for Food Protection (CFP) have jointly worked to enhance record keeping at the retail level. In an effort to provide more accurate information which could be used for illness response and program evaluation, the need for this improvement was demonstrated in recent illness data reported by the Centers for Disease Control (CDC).

Recommended Solution: The Conference recommends...:
1. that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language underlined and deleted language shown with strikethrough):

Section 3-203.12, Shellstock, Maintaining Identification

(C) The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90 calendar days from the date that is recorded on the tag or label, as specified under ¶ B of this section, by: [Pf]

(1) Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under ¶ B of this section; [Pf] and

(2) If shellstock are being used from different sources or growing areas simultaneously that the system can distinguish the source and growing area of the shellstock that was served to each customer; [Pf] and

(~~2~~3) If shellstock are removed from its tagged or labeled container

and

2. that the Conference for Food Protection (CFP) *and* the Interstate Shellfish Sanitation Conference (ISSC) jointly write a letter to State retail food programs requesting that retailers be advised of shellstock identification record requirements for the purpose of improving compliance.

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Conference for Food Protection
2012 Issue Form

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

All information above the line is for conference use only.

Title:
Food Code Date Marking Provision(s) For Raw, Live In-shell SHELLSTOCK

Issue you would like the Conference to consider:
The 2009 FDA Food Code contains no clear guidance (or exception) regarding date marking of raw, live, in-shell MOLLUSCAN SHELLFISH (i.e., SHELLSTOCK) in a FOOD ESTABLISHMENT when the FOOD is served to the CONSUMER in a raw (i.e., not heated treated) form.
This issue submission seeks clarification from the Conference as to date marking of raw, live, in-shell SHELLSTOCK, received and cold held longer than 24 hours in a FOOD ESTABLISHMENT and served to the CONSUMER in a raw (non-heat treated) form.

Public Health Significance:
Per the 2009 FDA Food Code Section 1-201.10 Statement of Application and Listing of Terms, raw, live in-shell SHELLSTOCK served to the CONSUMER without cooking meets the definition of a commercially processed Ready-To-Eat (RTE) Potentially Hazardous [Time/Temperature Control for Safety Food] FOOD (PHF/TCS FOOD) which was previously harvested and subsequently PACKAGED by a FOOD PROCESSING PLANT before being received by a FOOD ESTABLISHMENT.
During the 2004 Conference for Food Protection (CFP) Biennial Meeting, the subject of Food Code date marking for RTE PHF/TCS FOOD was re-evaluated to focus the provision on "Very High" and "High Risk" foods while simultaneously exempting certain categories of FOOD from the date marking provision. The September 2003 document referenced by CFP, Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-To-Eat Foods, concluded raw seafood to be categorized as "Risk Designation Low" along with other FOOD such as preserved fish products. This designation suggests date marking of raw seafood (including raw, live in-shell SHELLSTOCK) would not be necessary, however neither the 2005 nor the 2009 Food Codes specifically exempt raw, live in-shell SHELLSTOCK from date marking [Section 3-501.17(F)(1-7) Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Date Marking] and no elaborative explanation is offered in Annex 3, 3-501.17 (pages 414-419) regarding raw, live in-shell SHELLSTOCK.
The only guidance in the Food Code is located in Annex 3, 3-201.15 Molluscan Shellfish (pages 374-375) which specifically identifies *Listeria monocytogenes* (and others) as a

pathogen of concern at harvest, a position that is elaborated on in recently published research (Moustafa A. et. al *Listeria spp.* in the coastal environment of the Aqaba Gulf; Suez Gulf and the Red Sea. Epidemiol. Infect. 2006; 134; 752-757) (Colburn KG et. al. *Listeria monocytogenes* in California coast estuarine environment. Applied Environ Microbiol 1990; 56; 2007-2011).

Regarding FOOD excluded from date marking, the 2009 FDA Food Code currently lists only the following commercially produced RTE PHF/TCS FOOD categories: deli salads prepared and packaged in a FOOD PROCESSING PLANT; hard and semi-soft cheeses; cultured dairy products; preserved fish products (with exceptions); shelf stable dry fermented sausages not labeled "Keep Refrigerated"; and shelf stable salt-cured products not labeled "Keep Refrigerated".

Once received by a FOOD ESTABLISHMENT, raw live in-shell SHELLSTOCK are typically cold held longer than 24 hours due to the quantity received. And while the Food Code does not specify the number of days raw, live in-shell SHELLSTOCK can be cold held, Annex 3 estimates a shelf-life up to fourteen (14) days [Section 3-203.12 Shellstock, Maintaining Identification; page 382]. This presents a serious potential challenge to REGULATORY AUTHORITIES that adopt and enforce date marking as recommended in the Food Code since date marking for commercially processed RTE PHF/TCS FOOD limits shelf-life to seven (7) days [Section 3-501.17 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Date Marking; and Section 3-501.18 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Disposition].

SHELLSTOCK served in a raw, live in-shell form to the CONSUMER are currently subject to a CONSUMER ADVISORY [Section 3-603.11 Consumption of Animal Foods that are Raw, Undercooked or Not Otherwise processed to Eliminate Pathogens; pages 97-98] and have been identified by FDA as a potential source of pathogen contamination, including *Listeria monocytogenes* [Annex 3; Section 3.201.15 Molluscan Shellfish; page 375].

Further, raw, live in-shell SHELLSTOCK can be harvested, transported and delivered to the FOOD ESTABLISHMENT at temperatures above 41° F [Section 3-202.11 Temperature; page 54] which can encourage the growth of pathogens such as *Listeria monocytogenes*.

Further, SHELLSTOCK are PACKAGED and shipped in netted bags or other non-reusable shipping containers, none of which are air-tight. Some of the non-reusable containers are opened at receiving to allow the FOOD ESTABLISHMENT to verify the condition and temperature of the raw, live in-shell SHELLSTOCK and the porous nature of the shipped non-reusable bags/containers does not discourage or prevent possible further contamination of the SHELLSTOCK under refrigerated storage in the FOOD ESTABLISHMENT.

In the FOOD ESTABLISHMENT, raw, live in-shell SHELLSTOCK are frequently removed from their original shipping container(s) to be: (1) displayed on ice; or (2) held in refrigerated drawers, cold-rails, walk-in-coolers or reach-in-coolers. These refrigerated environments are subject to splash, dust, condensation drips and other filth that may be contaminated with pathogens, including *Listeria monocytogenes*. These refrigeration units can also simultaneously hold other raw animal FOODS and/or other RTE PHF/TCS FOODS. And these refrigeration units can be subject to temperature variation above 41° F as documented in FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant and Retail Food Store Facility Types (2009) (see attached).

Recommended Solution: The Conference recommends...:

...the language of the 2009 FDA Food Code (as modified by the Supplement issued in 2011) be changed to clearly reflect that date marking provisions apply to raw, live in-shell SHELLSTOCK served to CONSUMERS upon request without cooking or other treatment. *(new language is in underline format; language to be deleted in strike-thru format)*

3-501.17(B) Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking.

(B) Except as specified in ¶¶ (D)-(F) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) prepared and PACKAGED by a FOOD PROCESSING PLANT shall be clearly marked, at the time the original container is opened in a FOOD ESTABLISHMENT and if the FOOD is held for more than 24 hours, to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded, based on the temperature and time combinations specified in ¶ (A) of this section and:[PF]

(1) The day the original container is opened in the FOOD ESTABLISHMENT shall be counted as Day 1;[Pf] ~~and~~

(a) Except for containers of raw, live in-shell SHELLSTOCK, Day 1 shall be the date or day the SHELLSTOCK are receiving in the FOOD ESTABLISHMENT if the SHELLSTOCK will be served upon CONSUMER request in a raw, RTE PHF/TCS form; [Pf] and

(2) The day or date marking by the FOOD ESTABLISHMENT may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on FOOD safety.[Pf]

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Attachments:

- "Listeria monocytogenes Risk Assessment"
- "FDA Report on the Occurrence of Foodborne Illness Risk Factors"
- "Listeria spp. in the coastal environment of the Aqaba Gulf, Suez Gulf and.."
- "Listeria Species in a California Coast Estuarine Environment"

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Listeria monocytogenes Risk Assessment: Executive Summary

FDA/Center for Food Safety and Applied Nutrition
USDA/Food Safety and Inspection Service
September 2003

Background

The U.S. Department of Health and Human Service, Food and Drug Administration's Center for Food Safety and Applied Nutrition (DHHS/FDA/CFSAN) conducted this risk assessment in collaboration with the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) and in consultation with the DHHS Centers for Disease Control and Prevention (CDC). The purpose of the assessment is to examine systematically the available scientific data and information to estimate the relative risks of serious illness and death associated with consumption of different types of ready-to-eat (RTE) foods that may be contaminated with *Listeria monocytogenes*. This examination of the current science and the models developed from it are among the tools that food safety regulatory agencies will consider when evaluating the effectiveness of current and future policies, programs, and regulatory practices to minimize the public health impact of this pathogen.

The Healthy People 2010 goals for national health promotion and disease prevention called on federal food safety agencies to reduce foodborne listeriosis by 50% by the end of the year 2005. Preliminary FoodNet data on the incidence of foodborne illnesses for the United States in 2001 indicated that the incidence of infection from *Listeria monocytogenes* decreased between 1996 and 2001 from 0.5 to 0.3 cases per 100,000 people per year. The level then reached a plateau. In order to reduce further the incidence to a level of 0.25 cases per 100,000 people by the end of 2005, it became evident that additional targeted measures were needed. The *Listeria monocytogenes* risk assessment was initiated as an evaluation tool in support of this goal.

Listeria monocytogenes is a bacterium that occurs widely in both agricultural (soil, plants and water) and food processing environments. Ingestion of *Listeria monocytogenes* can cause listeriosis, which can be a life-threatening human illness. In 2000, the CDC reported that of all the foodborne pathogens tracked by CDC, *Listeria monocytogenes* had the second highest case fatality rate (21%) and the highest hospitalization rate (90.5%). Serious illness almost always occurs in people considered to be at higher risk, such as the elderly and those who have a pre-existing illness that reduces the effectiveness of their immune system. Perinatal listeriosis results from foodborne exposure of the pregnant mother leading to *in utero* exposure of the fetus, resulting in fetal infection that leads to fetal death, premature birth, or neonatal illness and death. *Listeria monocytogenes* also causes listerial gastroenteritis, a syndrome typically associated with mild gastrointestinal symptoms in healthy individuals. This risk assessment focuses on the severe public health consequences.

Scope and General Approach

This risk assessment provides analyses and models that (1) estimate the potential level of exposure of three age-based population groups and the total United States population to *Listeria monocytogenes* contaminated foods for 23 food categories and (2) relate this exposure to public health consequences. The food categories consist of foods with a documented history of *Listeria monocytogenes* contamination. The models provide a means of predicting the likelihood that severe illness or death will result from consuming foods contaminated with this pathogen. These

predictions are interpreted and used to estimate the relative risks among the food categories. The foods considered in this risk assessment are ready-to-eat foods that are eaten without being cooked or reheated just prior to consumption. One food, frankfurters, may or may not be reheated prior to consumption and was considered as two separate food categories. The working assumption is that all the cases of listeriosis are attributed to the foods in 23 categories, so that the risk assessment could be 'anchored' to the United States public health statistics. However, it is recognized that additional foods or cross-contamination from raw foods before cooking to other RTE foods may also contribute to additional cases.

The published scientific literature, government food intake surveys, health statistics, epidemiological information, unpublished food product surveys acquired from state and federal public health officials and trade associations, and surveys specifically designed to augment the data available for the risk assessment are the primary sources of data used in this document. Expert advice on scientific assumptions was actively sought from leading scientists from academia, industry, and government. This included two formal reviews of the underlying model structure and assumptions by the United States National Advisory Committee on Microbiological Criteria for Foods. In addition, the risk assessment was initially published in draft form and public comments sought for six months.

While the risk assessment purposely did not look into the pathways for the manufacture of individual foods, the risk assessment model developed can be used to estimate the likely impact of control strategies by changing one or more input parameters and measuring the change in the model outputs. This process, referred to as conducting 'what-if' scenarios, can be used to explore how the components of a complex model interact. Several 'what-if' scenarios are detailed within the risk assessment to evaluate the impact of refrigerator temperature, storage times, and reduction of the number of organisms in foods at before it is sold, and reduction in the contamination levels in foods that support growth.

Results

The relative risk rankings, along with the corresponding risk estimates expressed in terms of both the predicted number of cases per serving and per annum, are provided in Summary Table 1. Both measures are important in understanding and interpreting the risks associated with foodborne listeriosis. The per serving value can be considered the inherent risk associated with the manufacturing, distribution, marketing, and use of the food category, and is reflective of the degree of *Listeria monocytogenes* control achieved. Examples of factors that influence the 'per serving' risk include the frequency of contamination, the extent of that contamination, the ability of the food category to support the growth of *Listeria monocytogenes*, the duration and temperature of refrigerated storage, and the size of the serving. The predicted relative risk per serving can be viewed as the relative risk faced by individual consumers when he/she consume a single serving of the various foods considered in this risk assessment. The 'per serving' risk is typically the value upon which risk management decisions related to a specific product are based.

Summary Table 4. Relative Risk Ranking and Predicted Median Cases of Listeriosis for the Total United States Population on a per Serving and per Annum Basis

Relative Risk	Predicted Median Cases of Listeriosis for 23 Food Categories	
	Per Serving	Per Annum Basis[b]

Ranking	Basis[a]					
	Food	Cases	Food	Cases		
1	**High Risk**	Deli Meats	$7.7x10^{-8}$	**Very High**	Deli Meats	1598.7
2		Frankfurters, not reheated	$6.5x10^{-8}$	**High Risk**	Pasteurized Fluid Milk	90.8
3		Pâté and Meat Spreads	$3.2x10^{-8}$		High Fat and Other Dairy Products	56.4
4		Unpasteurized Fluid Milk	$7.1x10^{-9}$		Frankfurters, not reheated	30.5
5		Smoked Seafood	$6.2x10^{-9}$	**Moderate Risk**	Soft Unripened Cheese	7.7
6		Cooked Ready-to-Eat Crustaceans	$5.1x10^{-9}$		Pâté and Meat Spreads	3.8
7	**Moderate Risk**	High Fat and Other Dairy Products	$2.7x10^{-9}$		Unpasteurized Fluid Milk	3.1
8		Soft Unripened Cheese	$1.8x10^{-9}$		Cooked Ready-to-Eat Crustaceans	2.8
9		Pasteurized Fluid Milk	$1.0x10^{-9}$		Smoked Seafood	1.3
10	**Low Risk**	Fresh Soft Cheese	$1.7x10^{-10}$	**Low Risk**	Fruits	0.9
11		Frankfurters, reheated	$6.3x10^{-11}$		Frankfurters, reheated	0.4
12		Preserved Fish	$2.3x10^{-11}$		Vegetables	0.2
13		Raw Seafood	$2.0x10^{-11}$		Dry/Semi-dry Fermented Sausages	<0.1
14		Fruits	$1.9x10^{-11}$		Fresh Soft Cheese	<0.1
15		Dry/Semi-dry Fermented Sausages	$1.7x10^{-11}$		Semi-Sof t Cheese	<0.1

16		Semi-soft Cheese	$6.5x10^{-12}$		Soft Ripened Cheese	<0.1
17		Soft Ripened Cheese	$5.1x10^{-12}$		Deli-type Salads	<0.1
18		Vegetables	$2.8x10^{-12}$		Raw Seafood	<0.1
19		Deli-type Salads	$5.6x10^{-13}$		Preserved Fish	<0.1
20		Ice Cream and Other Frozen Dairy Products	$4.9x10^{-14}$		Ice Cream and Other Frozen Dairy Products	<0.1
21		Processed Cheese	$4.2x10^{-14}$		Processed Cheese	<0.1
22		Cultured Milk Products	$3.2x10^{-14}$		Cultured Milk Products	<0.1
23		Hard Cheese	$4.5x10^{-15}$		Hard Cheese	<0.1

[a] Food categories were classified as high risk (>5 cases per billion servings), moderate risk (≤5 but ≥1 case per billion servings), and low risk (<1 case per billion servings).
[b] Food categories were classified as very high risk (>100 cases per annum), high risk (>10 to 100 cases per annum), moderate risk (≥1 to 10 cases per annum), and low risk (<1 cases per annum).

The second measure, the 'per annum risk,' is the predicted number of fatal infections per year in the United States for each food category. This value takes into account the number of servings of the food category that are consumed. The predicted per annum risk of serious illnesses for each food category can be thought of as the predicted relative total public health impact for each food category. Since the 'per annum' risk is derived from the 'per serving' risk, there is generally a higher degree of uncertainty associated with the former. The predicted per serving and per annum relative risks are used to develop risk rankings to compare the various food categories. In addition to presenting the 'most likely' relative risk rankings for the different population groups and food categories, the risk assessment provides the inherent variability and the uncertainty associated with these rankings.

Evaluation and Interpretation

The overall interpretation of the risk assessment requires more than just a simple consideration of the relative risk rankings associated with the various food categories. First, the interpretation of the results requires an appreciation of the fact that the values being compared are the median values of distributions that may be highly skewed (i.e., not evenly distributed). The use of median values was selected as being the appropriate method for comparing the overall relative risks among the different food categories. The quantitative results must be considered in relation to the associated variability and uncertainty (i.e., the confidence intervals surrounding the median) and interpreted in the context of both the epidemiologic record and how the food categories are manufactured, marketed, and consumed. A detailed consideration of the

quantitative and qualitative findings for each food category is provided in the risk assessment and its appendices.

A number of methods for objectively grouping the results were evaluated, and are discussed in detail within the risk assessment. One approach is cluster analysis. When performed at the 90% confidence level, this analysis groups the per serving rankings into four clusters and the per annum rankings into five. These clusters are used, in turn, to develop a two-dimensional matrix of per serving vs. per annum rankings of the food categories (Summary Figure 1). In this approach, the 'per serving' clusters are arrayed against the 'per annum' clusters. The matrix is then used to depict five risk designations: Very High, High, Moderate, Low, and Very Low.

The risk characterization combines the exposure and dose-response models to predict the relative risk of illness attributable to each food category. While the risk characterization must be interpreted in light of both the inherent variability and uncertainty associated with the extent of contamination of ready-to-eat foods with *Listeria monocytogenes* and the ability of the microorganism to cause disease, the results provide a means of comparing the relative risks among the different food categories and population groups considered in the assessment and should prove to be a useful tool in focusing control strategies and ultimately improving public health through effective risk management. As described above, cluster analysis techniques are employed as a means of discussing the food categories within a risk analysis framework. The food categories are divided into five overall risk designations (see Summary Figure 1), which are likely to require different approaches to controlling foodborne listeriosis.

	Decreased Risk per Annum ⟶			
	Clusters A and B	**Clusters C and D**	**Cluster E**	
Decreased Risk per Serving ↓	**Cluster 1**	**Very High Risk (Clusters 1-A, 1-B)** Deli Meats Frankfurters (not reheated)	**High Risk (Clusters 1-C, 1-D)** Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood	**Moderate Risk (Cluster 1-E)** No food categories
	Cluster 2	**High Risk (Clusters 2-A, 2-B)** High Fat and Other Dairy Products Pasteurized Fluid	**Moderate Risk (Clusters 2-C, 2-D)** Cooked RTE Crustaceans	**Moderate Risk (Cluster 2-E)** No food categories

		Milk Soft Unripened Cheese		
	Cluster 3	**Moderate Risk (Clusters 3-A, 3-B)** No food categories	**Moderate Risk (Clusters 3-C, 3-D)** Deli-type Salads Dry/Semi-dry Fermented Sausages Frankfurters (reheated) Fresh Soft Cheese Fruits Semi-soft Cheese Soft Ripened Cheese Vegetables	**Low Risk (Cluster 3-E)** Preserved Fish Raw Seafood
	Cluster 4	**Moderate Risk (Clusters 4-A, 4-B)** No food categories	**Low Risk (Clusters 4-C, 4-D)** No food categories	**Very Low Risk (Cluster 4-E)** Cultured Milk Products Hard Cheese Ice Cream and Other Frozen Dairy Products Processed Cheese

Summary Figure 1. Two-Dimensional Matrix of Food Categories Based on Cluster Analysis of Predicted per Serving and per Annum Relative Rankings

[The matrix was formed by the interception of the four per serving clusters vs. the per annum clusters A and B, C and D, and E. For example, Cluster 3-E (Low Risk) refers to the food categories that are in both Cluster level 3 for the risk per serving and Cluster level E for the risk per annum.]

Risk Designation Very High. This designation includes two food categories, Deli Meats and Frankfurters, Not Reheated. These are food categories that have high predicted relative risk rankings on both a per serving and per annum basis, reflecting the fact that they have relatively high rates of contamination, support the relatively rapid growth of *Listeria monocytogenes* under refrigerated storage, are stored for extended periods, and are consumed extensively. These products have also been directly linked to outbreaks of listeriosis. This risk designation is one that is consistent with the need for immediate attention in relation to the national goal for reducing the incidence of foodborne listeriosis. Likely activities include the development of new control strategies and/or consumer education programs suitable for these products.

Risk Designation High. This designation includes six food categories, High Fat and Other Dairy Products, Pasteurized Fluid Milk, Pâté and Meat Spreads, Soft Unripened Cheeses, Smoked Seafood, and Unpasteurized Fluid Milk. These food categories all have in common the ability to support the growth of *Listeria monocytogenes* during extended refrigerated storage. However, the foods within this risk designation appear to fall into two distinct groups based on their rates of contamination and frequencies of consumption.

- Pâté and Meat Spreads, Smoked Seafood, and Unpasteurized Fluid Milk have relatively high rates of contamination and thus high predicted per serving relative risks. However, these products are generally consumed only occasionally in small quantities and/or are eaten by a relatively small portion of the population, which lowers the per annum risk. All three products have been associated with outbreaks or sporadic cases, at least internationally.

  These foods appear to be priority candidates for new control measures (i.e., Smoked Seafood, Pâté and Meat Spreads) or continued avoidance (i.e., Unpasteurized Fluid Milk).
- High Fat and Other Dairy Products, Pasteurized Fluid Milk, and Soft Unripened Cheeses have low rates of contamination and corresponding relatively low predicted per serving relative risks. However, these products are consumed often by a large percentage of the population, resulting in elevated predicted per annum relative risks. In general, the predicted per annum risk is not matched with an equivalent United States epidemiologic record. However, the low frequency of recontamination of individual servings of these products in combination with their broad consumption makes it likely that these products are primarily associated with sporadic cases and normal case control studies would be unlikely to lead to the identification of an association between these products and cases of listeriosis.

  These products (High Fat and Other Dairy Products, Pasteurized Fluid Milk, and Soft Unripened Cheeses) appear to be priority candidates for advanced epidemiologic and scientific investigations to either confirm the predictions of the risk assessment or identify the factors not captured by the current models that would reduce the predicted relative risk.

Risk Designation Moderate. This risk designation includes nine food categories (Cooked Ready-to-Eat Crustaceans, Deli Salads, Fermented Sausages, Frankfurters-Reheated, Fresh Soft Cheese, Fruits, Semi-soft Cheese, Soft Ripened Cheese, and Vegetables) that encompass a range of contamination rates and consumption profiles. A number of these foods include effective bactericidal treatments in their manufacture or preparation (e.g., Cooked Ready-to-Eat Crustaceans, Frankfurters-Reheated, Semi-soft Cheese) or commonly employ conditions or compounds that inhibit the growth of *Listeria monocytogenes* (e.g., Deli Salads, Dry/Semi-dry Fermented Sausages). The risks associated with these products appear to be primarily associated with product recontamination, which in turn, is dependent on continued, vigilant application of proven control measures.

Risk Designation Low. This risk designation includes two food categories, Preserved Fish and Raw Seafood. Both products have moderate contamination rates but include conditions (e.g., acidification) or consumption characteristics (e.g., short shelf-life) that limit *Listeria monocytogenes* growth and thus limit predicted per serving risks. The products are generally consumed in small quantities by a small portion of the population on an infrequent basis, which results in low predicted per annum relative risks. Exposure data for these products are limited so

there is substantial uncertainty in the findings. However, the current results predict that these products, when manufactured consistent with current good manufacturing practices, are not likely to be a major source of foodborne listeriosis.

Risk Designation Very Low. This risk designation includes four food categories, Cultured Milk Products, Hard Cheese, Ice Cream and Other Frozen Dairy Products, and Processed Cheese. These products all have in common the characteristics of being subjected to a bactericidal treatment, having very low contamination rates, and possessing an inherent characteristic that either inactivates *Listeria monocytogenes* (e.g., Cultured Milk Products, Hard Cheese) or prevents its growth (e.g., Ice Cream and Other Frozen Dairy Products, Processed Cheese). This results in a very low predicted per serving relative risks. The predicted per annum relative risks are also low despite the fact that these products are among the more commonly consumed ready-to-eat products considered by the risk assessment. The results of the risk assessment predict that unless there was a gross error in their manufacture, these products are highly unlikely to be a significant source of foodborne listeriosis.

Conclusions

The following conclusions are provided as an integration of the results derived from the models, the evaluation of the variability and uncertainty underlying the results, and the impact that the various qualitative factors identified in the hazard identification, exposure assessment, and hazard characterization have on the interpretation of the risk assessment.

- The risk assessment reinforces past epidemiological conclusions that foodborne listeriosis is a moderately rare although severe disease. United States consumers are exposed to low to moderate levels of *Listeria monocytogenes* on a regular basis.
- The risk assessment supports the findings of epidemiological investigations of both sporadic illness and outbreaks of listeriosis that certain foods are more likely to be vehicles for *Listeria monocytogenes*.
- Three dose-response models were developed that relate the exposure to different levels of *Listeria monocytogenes* in three age-based subpopulations [i.e., perinatal (fetuses and newborns), elderly, and intermediate-age] with the predicted number of fatalities. These models were used to describe the relationship between levels of *Listeria monocytogenes* ingested and the incidence of listeriosis. The dose of *Listeria monocytogenes* necessary to cause listeriosis depends greatly upon the immune status of the individual.
    1. Susceptible subpopulations (such as the elderly and perinatal) are more likely to contract listeriosis than the general population.
    2. Within the intermediate-age subpopulation group, almost all cases of listeriosis are associated with specific subpopulation groups with increased susceptibility (e.g., individuals with chronic illnesses, individuals taking immunosuppressive medication).
    3. The strong association of foodborne listeriosis with specific population groups suggests that strategies targeted to these susceptible population groups, i.e., perinatal (pregnant women), elderly, and susceptible individuals within the intermediate-age group, would result in the greatest reduction in the public health impact of this pathogen.
- The dose-response models developed for this risk assessment considered, for the first time, the range of virulence observed among different isolates of *Listeria monocytogenes*.

The dose-response curves suggest that the relative risk of contracting listeriosis from low dose exposures could be less than previously estimated.>

- The exposure models and the accompanying 'what-if' scenarios identify five broad factors that affect consumer exposure to *Listeria monocytogenes* at the time of food consumption.
    1. Amounts and frequency of consumption of a ready-to-eat food
    2. Frequency and levels of *Listeria monocytogenes* in a ready-to-eat food
    3. Potential of the food to support growth of *Listeria monocytogenes* during refrigerated storage
    4. Refrigerated storage temperature
    5. Duration of refrigerated storage before consumption

Any of these factors can affect potential exposure to *Listeria monocytogenes* from a food category. These factors are 'additive' in the sense that foods where multiple factors favor high levels of *Listeria monocytogenes* at the time of consumption are typically more likely to be riskier than foods where a single factor is high. These factors also suggest several broad control strategies that could reduce the risk of foodborne listeriosis such as reformulation of products to reduce their ability to support the growth of *Listeria monocytogenes* or encouraging consumers to keep refrigerator temperatures at or below 40 °F and reduce refrigerated storage times. For example, the 'what-if' scenarios using Deli Meats predicts that consumer education and other strategies aimed at maintaining home refrigerator temperatures at 40 °F could substantially reduce the risks associated with this food category. Combining this with pre-retail treatments that decrease the contamination levels in Deli Meats would be expected to reduce the risk even further.

This risk assessment significantly advances our ability to describe our current state of knowledge about this important foodborne pathogen, while simultaneously providing a framework for integrating and evaluating the impact of new scientific knowledge on public health enhancement.

FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009)

EXECUTIVE SUMMARY

In 2008, the U.S. Food and Drug Administration's (FDA) National Retail Food Team conducted the third phase of a three-phase,10-year study to measure the occurrence of practices and behaviors commonly identified by the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks. Specifically, the study called for conducting data collection inspections of various types of foodservice and retail food establishments at five-year intervals to observe and document practices and behaviors that relate to the following CDC contributing factor categories associated with foodborne illness outbreaks within foodservice and retail food establishments, herein referred to as foodborne illness risk factors (risk factors):

- Food from Unsafe Sources
- Poor Personal Hygiene
- Inadequate Cooking
- Improper Holding/Time and Temperature
- Contaminated Equipment/Protection from Contamination

This 2009 report is the third report in a series and presents findings based on data collected in 2008. The first report in the study was issued in August 2000 and presented the findings from the first data collection effort in 1998. A second report was issued in 2004 and presented data collected in 2003. FDA intends to publish a report in 2010 that compares the results from the three data collection periods and examines what trends, if any, were observed.

The 2000 and 2004 reports called attention to the need for greater active managerial control of foodborne illness risk factors. They suggested that more innovative and effective strategies to improve food safety practices in retail and foodservice establishments were needed. The reports highlighted operational areas most in need of improvement including employee handwashing, cold holding of potentially hazardous foods (time/temperature control for safety foods), date marking of ready-to-eat foods, and cleaning and sanitizing of food contact surfaces.

In each phase of the study, FDA Regional Retail Food Specialists collected data during site visits of over 800 establishments representing nine distinct facility types. Direct observations, supplemented with information gained from discussions with management and food employees, were used to document the establishments' compliance status for 42 individual data items based on provisions in the *1997 FDA Food Code*. In each establishment, the compliance status for each data item was recorded in terms of IN Compliance, Out of Compliance, Not Observed (meaning the behavior or practice was applicable but not observed during the visit), or Not Applicable (meaning the behavior or practice did not apply to the establishment).

For each of the nine facility types, the percentage of observations recorded as Out of Compliance is presented for each risk factor and for the individual data items related to those risk factors most in need of priority attention. The percent Out of Compliance value for each risk factor was calculated by dividing the total number of Out of Compliance observations of data items in the

risk factor by the total number of observations (IN compliance and Out of Compliance) of data items in the risk factor. The percent Out of Compliance values for individual data items were calculated by dividing the total number of Out of Compliance observations for the individual data item by the total number of observations (IN and Out of Compliance) for the data item.

The data presented in this 2009 report indicate that some of the same risk factors and data items identified as problem areas in the 2000 and 2004 Reports remain in need of priority attention. This indicates that industry and regulatory efforts to promote active managerial control of these risk factors must be enhanced. The Out of Compliance percentages remained high for data items related to the following risk factors:

- Improper Holding/Time and Temperature
- Poor Personal Hygiene
- Contaminated Equipment/Protection from Contamination

For the improper holding/time and temperature risk factor, the high percent Out of Compliance values were most commonly associated with improper cold holding of potentially hazardous food (PHF)/time-temperature control for safety (TCS) food and inadequate date marking of refrigerated, ready-to-eat PHF/TCS Food.

Within the poor personal hygiene risk factor, the proper, adequate handwashing data item had the highest percent Out of Compliance value for every facility type. Percent Out of Compliance values for proper, adequate handwashing ranged from approximately 18% for meat departments to approximately 76% for full service restaurants.

Of the data items related to the contaminated equipment/protection from contamination risk factor, improper cleaning and sanitizing of food-contact surfaces before use was the item most commonly observed to be Out of Compliance in eight out of the nine facility types. Percent Out of Compliance values for this data item ranged from 18% in seafood departments to 64% in full service restaurants.

As in the 2004 Report, this 2009 report includes a comparison between the data collected from food establishments that had a Certified Food Protection Manager (CFPM) from a program recognized by the Conference for Food Protection and those that did not. The results of the study indicate that the presence of a Certified Food Protection Manager is positively correlated to the overall IN Compliance percentages in certain facility types, especially in delis, full service restaurants, seafood departments, and produce departments. Poor Personal Hygiene, Improper Holding/Time and Temperature, and Contaminated Equipment/Protection from Contamination appear to be the risk factors for which the presence of a certified manager had the most positive correlation.

The 2003 and 2008 data collection efforts included several supplemental data items that were not included in the 1998 data collection. While original 42 data items in the study remained the same from 1998 to 2008, the supplemental data items addressed changes made to the *FDA Food Code* since 1997. These items related to the cooking temperature for pork, the minimum hot holding temperatures, employee health, juice, eggs, and highly susceptible populations. Data gathered for the supplemental data items suggest that reducing the minimum hot holding temperature for PHF/TCS foods from 140ºF (60ºC) to 135ºF (57ºC) and reducing the minimum cooking temperature for pork from 155ºF (68ºC) to 145ºF (63ºC) had minimal effect on the industry's control of these risk factors.

Results from the 2008 data collection indicate that the recommendations made to foodservice and retail food operators and regulators in the 2000 and 2004 Reports need to be

reemphasized. Foodservice and retail food store operators must ensure that their management systems are designed to achieve active managerial control over the risk factors. Likewise, regulators must ensure that their inspection, education, and enforcement efforts are geared toward the control of the risk factors commonly found to be Out of Compliance.

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Listeria spp. in the coastal environment of the Aqaba Gulf, Suez Gulf and the Red Sea

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SUMMARY

Listeria monocytogenes is an important pathogen which causes an infection called listeriosis. Because of the high mortality rate (~30%) associated with listeriosis, and the widespread nature of the organism, it is a major concern for food and water microbiologists since it has been isolated from various types of foods, including seafood, as well as from the aqueous environment. To investigate the prevalence of this pathogen in the Aqaba Gulf (12 sites), Suez Gulf (14 sites) and Red Sea (14 sites), 200 water samples (collected during five sampling cruises in 2004), 40 fresh fish samples and 15 shellfish samples were analysed using the enrichment procedure and selective agar medium. All water samples were also examined for the presence *Listeria innocua* which was the most common of the *Listeria* spp. isolated, followed by *L. monocytogenes*, with a low incidence of the other species. During the whole year, the percentage of *Listeria* spp. and *L. monocytogenes* in 200 water samples was 20·5% (41 samples) and 13% (26 samples) respectively. In fresh fish (40 samples) it was 37% (15 samples) and 17·3% (7 samples) and in shellfish (15 samples) 53% (8 samples) and 33% (5 samples) respectively. In water samples, there was an association between the faecal contamination parameters and the presence of the pathogen; however, water salinity, temperature, dissolved oxygen and pH did not influence the occurrence of this bacterium. These results may help in the water-quality evaluation of the coastal environments of these regions.

INTRODUCTION

Listeria monocytogenes has been recognized as a human pathogen since 1929 [1] causing an infection called listeriosis which can be manifested through several different syndromes causing invasive illness. It can cause abortion during pregnancy, human meningitis, infection during the perinatal period, granulomatosis infantiseptica, sepsis, diarrhoea, pyelitis and 'flu-like' symptoms. The mortality rate of listeriosis is ~30% [2].

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In the early 1980s scientists recognized *Listeria* as a foodborne pathogen as human listerosis resulted from consuming food contaminated with this pathogen such as milk and dairy products, meat, poultry, vegetables, salads and seafood [3]. Moreover, *L. monocytogenes* has a saprophytic life and occurs widely in nature [4]. A variety of animals including domestic farm animals can carry the bacterium [5], and it can survive for long periods in a plant–soil environment [6]. *Listeria* spp. were isolated from the Mediterranean coast of Egypt, more specifically from the Eastern Harbour of Alexandria [7], while in the United States the bacterium was isolated from the California coast estuarine environment [6]. Scientists have proposed that the pathogen can survive for

a long time in a marine environment as it is a salt-tolerant organism [8–10].

In Egypt, the coastal water of Red Sea including the Suez Gulf and the Aqaba Gulf, may be contaminated by domestic and/or industrial sewage/wastes. Thus, the risk of the presence of such a pathogen in these contaminated areas is to be expected. *Listeria* spp. have been recovered from a variety of seafood [11–13]; in Egypt, they have been isolated from fresh fish [14] as well as from shellfish collected from the Eastern Harbour of Alexandria [7].

This work addresses the incidence of *Listeria* spp. as well as the faecal pollution bacteria indicators in the coastal marine water of the Aqaba Gulf, Suez Gulf and Red Sea. Testing of seafood, collected from the local markets along the investigated areas, for the presence of the pathogen was another goal of the study.

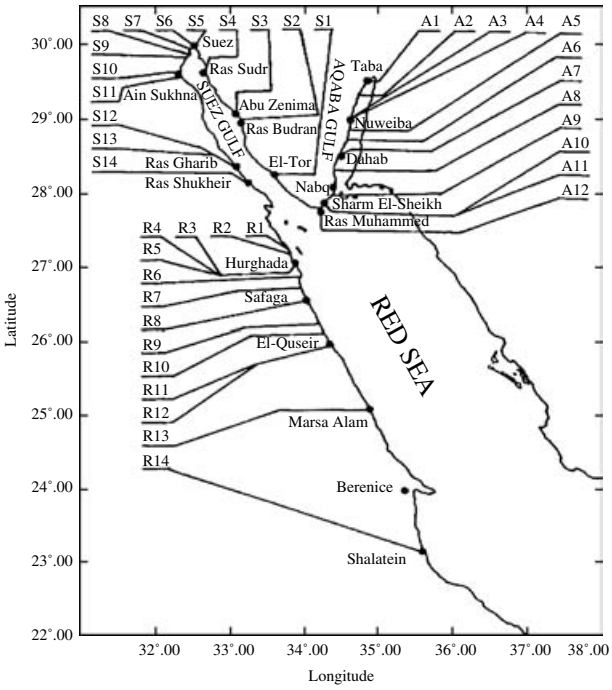

Fig. 1. Map showing names and codes of sampling locations at Aqaba Gulf (A), Suez Gulf (S) and Red Sea (R).

MATERIALS AND METHODS

Sampling sites

Coastal water samples were collected in five sampling cruises (bi-monthly intervals) during February to October 2004. The sampling sites along the Aqaba Gulf, Suez Gulf and Red Sea are shown in Figure 1. Water was sampled using 1-litre screw-cap bottles, with two sample bottles being taken at the same time/place from each site.

At each sampling cruise, one fresh fish sample, was purchased from the fish markets of the cities of Nuweiba, Sharm El-Sheikh, Suez, Ras Gharib, Hurghada, Safaga, El-Quseir and Shalatein; one shellfish sample was also purchased, but only from Nuwebia, Suez and Safaga.

All water samples were analysed immediately using an on-site mobile microbiological laboratory. At each sampling site, hydrographical parameters of the water samples including temperature (°C), salinity (‰), dissolved oxygen (mg/l and pH) were measured using CTD (YSI 6000, Yellow Springs, OH, USA). Fish and shellfish samples were collected in plastic bags and kept in the refrigerator of the mobile laboratory and were analysed within 6–12 h.

Bacteriological analysis

Water samples were examined for the presence of faecal pollution indicators of bacteria including total coliforms, *E. coli* and faecal streptococci using the membrane filtration technique (Gelman 0·45 μm membranes) as described by ISO 9308/1 [15], and ISO 7899/2 [16]. For detection of total coliforms, the membranes were fixed onto m-Endo-LES agar and incubated at 37 °C for 24 h; for detection of *E. coli*, m-FC agar was used followed by incubation at 44·5 °C for 24 h; however for faecal streptococci, m-Enterococcus agar was used and incubated at 37 °C for 48 h. The biochemical tests used for confirmation of the characteristic colonies as well as calculation of the final bacterial counts, per 100 ml of seawater, were done after the above-mentioned ISO examinations.

For detection of *Listeria* spp., the enrichment procedure based on the US Food and Drug Administration (FDA) technique [17] was used. One litre of each water sample was filtered. More than one membrane was used for each sample when needed. Then, the filter membrane(s) of each sample were scrubbed and manually crushed, using a sterile sharp glass rod, in a 500-ml volume sterile beaker containing 100 ml of *Listeria* enrichment broth base (LEB) (Oxoid CM 882 broth, Oxoid, Basingstoke, Hampshire, UK) supplemented with *Listeria* selective supplement (Oxoid SR 141). Membrane suspensions were transferred to sterilized conical flasks and kept at refrigerator temperature (4–8 °C) for 4 weeks.

Shellfish, after being scrubbed and rinsed with tap water, were opened aseptically and the flesh was collected. The flesh, or fish samples, were then blended in a sterile grinder to achieve homogenated slurries. Twenty-five grams of each representative slurry was directly suspended in 225 ml of LEB, and kept at refrigerator temperature (4–8 °C) for 4 weeks. The refrigerated enrichment cultures were then streaked onto Oxford formula selective agar medium (CM 856) plus *Listeria* selective supplement (SR 140) as described by Curtis et al. [18]. Plates were incubated at 35 °C for 48 h. Up to four colonies that were presumptively positive *Listeria*, with a black halo and a sunken centre, from each suspected positive plate were picked and purified onto trypticase soy agar (TSA) plates. For identification of the isolates a positive control of *L. monocytogenes* strain V7 (milk isolate) serotype 1 (obtained from the Department of Food Science, University of Wisconsin, Madison, WI, USA) served as a control in this work. This isolate was recovered by all media used in this study. Purified suspected isolates were viewed by the oblique light technique of Henry as described by the IDF [19]. Smears of suspected grey-blue colonies were Gram-stained and examined microscopically after streaking onto TSA plates and incubated at 35 °C for 18–24 h. Cultures displaying the correct morphology were tested for catalase, then stabbed into motility test medium (Difco, Detroit, MI, USA) and incubated at 25 °C to check for umbrella-shaped growth. Cultures that proved to be motile were tested for haemolysin using tryptose agar with 5% sheep blood. The isolates were streaked onto TSA slants, incubated at 35 °C for 18–24 h for further characterization to species using the criteria described by McLauchlin [2].

RESULTS AND DISCUSSION

Figure 2 shows the faecal pollution indicators represented as c.f.u./100 ml of the water samples examined during whole year, as well as the prevalence of *Listeria* spp. in the three studied areas.

In the Aqaba Gulf area *Listeria* spp. were detected in 10 out of 60 (17%) samples investigated during the whole year. Five of these contaminated samples (50%) were found to harbour *L. monocytogenes*. In the Suez Gulf area, 16 out of 70 (23%) samples investigated, proved to be contaminated by *Listeria* spp. Twelve (75%) of these contaminated samples were found to harbour *L. monocytogenes*. Along the coastal area of the Red Sea, only 15 out of 70 (21%) samples investigated were contaminated by *Listeria* spp., where nine (60%) of them harboured *L. monocytogenes*. These results indicated that Suez Gulf recorded the highest percentage for the presence of the bacterium. This may be due to the drainage of wastes and/or untreated sewage into the Gulf.

Generally, as illustrated in Table 1, *Listeria* spp. were detected in 21% ($n=41$) of the total examined water samples collected from all the investigated areas during the whole year ($n=200$). This percentage is lower than those reported at the Eastern harbour of Alexandria, where 9 out of 11 (82%), surface water samples were found to harbour *Listeria* spp. These results are similar to those reported in the United States where the percentage amounted to 33% of the examined marine waters collected from the California coast estuarine environment. Of these contaminated water samples ($n=41$), 63% ($n=26$) were found to harbour *L. monocytogenes*, however, *L. innocua* was the most predominant of the *Listeria* spp. since it was found in 80% ($n=33$) of the contaminated samples. At the same time a small percentage (5%) of other *Listeria* spp. was also detected ($n=2$).

In general, in the results obtained, *L. innocua* was more prevalent than *L. monocytogenes*, suggesting that it might be a very common organism in the coastal environment. Such an observation should, however, be made with care, since only a few colonies of the pathogen were picked up from the selective plates for identification. In this regard Seeliger [20] reported that *L. innocua* is a good indicator for *L. monocytogenes*, thus, when looking for sources of *Listeria*, the presence of both of these species is equally significant.

The present results indicated that there was an association between the faecal pollution indicators and the presence of the pathogen. As seen in Figure 2, the pathogen was detected in sites with high bacterial counts of the three faecal pollution indicators and never isolated from any site with low counts for these parameters. This association was to be expected since the bacterium is widely distributed in sewage [21] and the numbers of *Listeria* that are contributed to the environment by sewage and sewage sludge may be higher than those of *Salmonella* [22].

It should be noted that such an association between the presence of the pathogen and the faecal contamination indicators should not be considered as a general trend, since many factors/relations may interfere, e.g. distribution in water, sediments and biofilms,

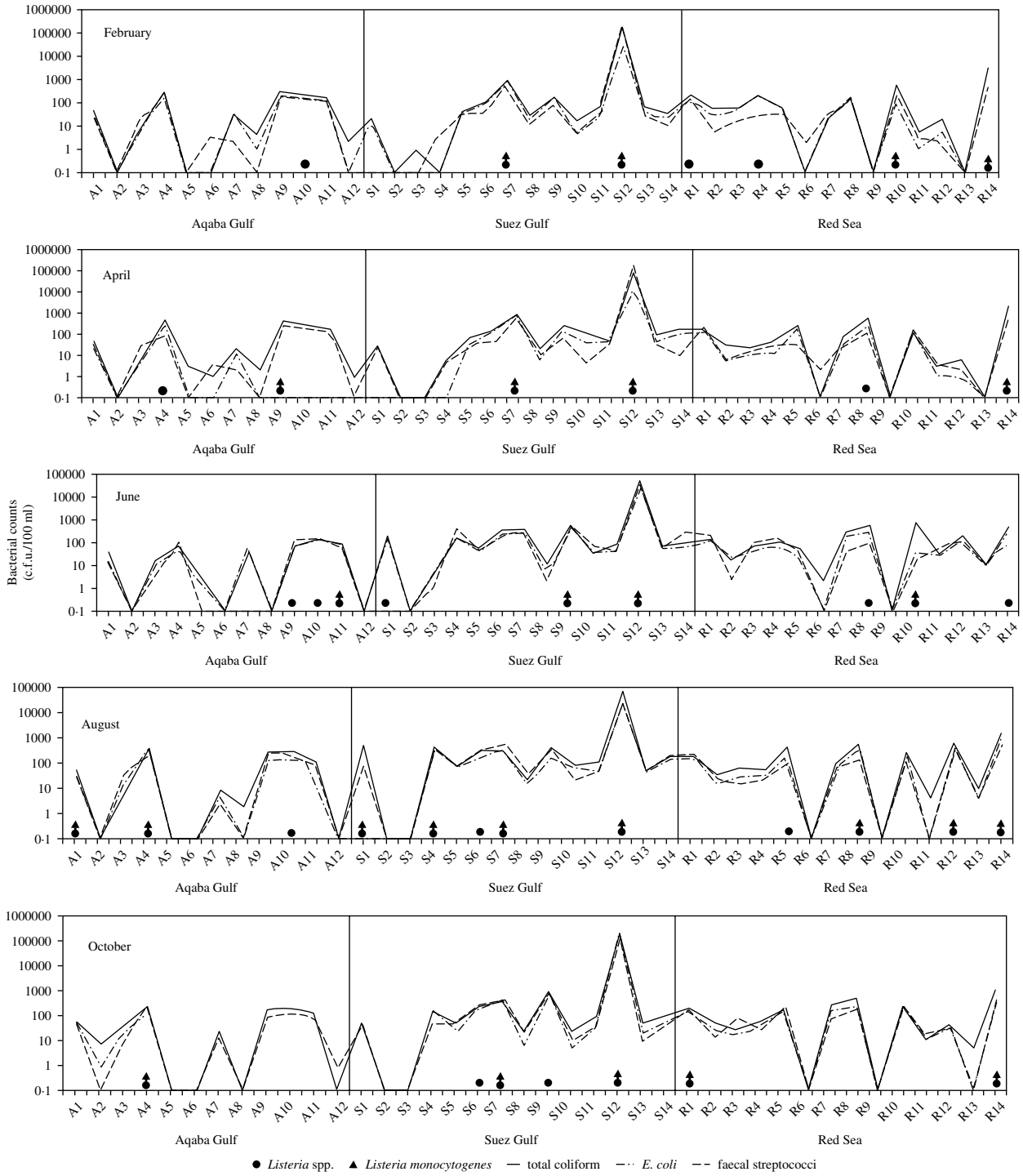

Fig. 2. Distribution of *Listeria* spp. and counts of faecal bacteria in coastal waters of Aqaba Gulf (A), Suez Gulf (S), and the Red Sea (R) during 2004.

seasonal variations, total bacterial load, relationship with indicators, etc. At least, our data give preliminary information on the behaviour of *Listeria* spp. in this coastal environment in an attempt to understand the epidemiology of this pathogen. At the same time, the recorded hydrographical parameters indicated that seasonal variation affected water temperature which ranged between 17·7 and 28·5 °C. A range of 39·2–42·6‰ for salinity was, however, recorded; the pH ranged from 7·8 to 8·5 and the dissolved oxygen

Table 1. *Number and percentage of water, fish and shellfish samples positive for* Listeria *spp.*

Sample	No. of examined samples	No. of positive samples				
		L. spp.	*L.m.*	*L.i.*	*L.m.* + *L.i.*	Other spp.
Water	200	41 (21%)	6 (3%)	13 (7%)	20 (10%)	2 (1%)
Fish	40	15 (38%)	3 (8%)	8 (20%)	4 (10%)	—
Shellfish	15	8 (53%)	1 (6%)	3 (20%)	4 (27%)	—

L. spp., *Listeria species*; *L.m.*, *Listeria monocytogenes*; *L.i.*, *Listeria innocua*; *L.m.* + *L.i.*, both species together.

Table 2. Listeria *spp. in fish and shellfish samples*

Location	Type	No. of samples	No. of samples positive for	
			Listeria spp.	*Listeria monocytogenes*
Fish				
Nuweiba	*Sigan*, *Hemiramphus*	5	2	1
Sharm El-Sheikh	*Lethrinus*, Shrimp	5	2	1
Suez	*Lethrinus*, *Sepia Hemiramphus*	5	3	2
Ras Garib	*Lethrinus*, *Mullus*	5	1	1
Hurghada	*Sigan*, squids, *Mullus*	5	1	—
Safaga	Shrimp, Sea bream	5	1	—
El-Quseir	*Lethrinus*, *Sigan*	5	2	1
Shalatein	*Lethrinus*, Sea bream	5	3	1
Total		40	15	7
Shellfish				
Nuweiba	*Lithophaga*, *Tridacna*	5	2	1
Suez	*Lambis*, caretshell Oyster	5	3	2
Safaga	*Lithophaga*, *Donax*	5	3	2
Total		15	8	5

between 6·3 and 9·5 mg/l. This variation in these hydrographical parameters, during the whole year, did not appear to affect the distribution of *Listeria* spp. and/or the bacteria of faecal pollution indicators in the investigated sites.

The incidence of *Listeria* spp. in the examined fish and shellfish samples is summarized in Table 2. As can be seen, *L. innocua* and *L. monocytogenes* were the only two species found in the investigated seafood samples. The incidence of *Listeria* spp. in the positive samples in relation to fish/shellfish type and the location where it was purchased is presented in Table 2.

In fish 38% ($n=15$) of the total examined samples ($n=40$) were found to be contaminated by *Listeria* spp. while 17·0% ($n=7$) were contaminated with *L. monocytogenes*. As observed in the coastal water samples, *L. innocua* was the most prevalent species since it was isolated from 30% ($n=12$) of the total samples examined (Table 1). These results are in accordance with reports by other authors [6] where the incidence of such a pathogen in fresh fish varied from very low to up to 50%, while a percentage ranging from 14·8 to 72·4% for the presence of *Listeria* spp. was also reported.

The highest frequency of *Listeria* spp. was recovered from shellfish where 53% ($n=8$) of the total examined samples ($n=15$) were contaminated with *Listeria* spp. and 33% ($n=5$) harboured *L. monocytogenes*. As was found in fish, *L. innocua* was the

most prevalent since it was isolated from 47% ($n=7$) of the total samples examined (Table 1). These results are a little higher than those reported by Colburn et al. [6] (they found a range from 12 to 44·4% for the presence of *Listeria* spp. and from 4·0 to 12·1% for *L. monocytogenes*). In general, the numbers of the samples examined, the pumping rate by shellfish which provokes the accumulation of microorganisms, the ability of *Listeria* spp. to survive in marine waters and the degree to which *Listeria* spp. are diluted are all different factors that may affect the uptake and retention of *Listeria* spp. by the shellfish; and consequently, the numbers of positive samples that might be affected. Moreover, the percentages of the pathogen in fish/shellfish could not be linked to the coastal environment only, this may also be linked to the market environment, although most fish markets in these areas are very close to the seashore.

In conclusion, faecal pollution bacteria as well as *Listeria* spp. were detected in some sites along the investigated areas. The polluted sites were located either in front of populated cities such as the Suez Gulf area or in front of the industrial/tourism activities in the other investigated areas. Consequently, the discharge of domestic raw/partially treated sewage onto the polluted sites should be taken into consideration. Our results may draw attention to the need to implement better hygiene and epidemiological practices in these areas. In order to avoid listerosis infection, fish and shellfish must be well-cooked before consumption.

DECLARATION OF INTEREST

None.

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Listeria Species in a California Coast Estuarine Environment

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***Listeria* species and *L. monocytogenes* were found in 81 and 62%, respectively, of fresh or low-salinity waters (37 samples) in tributaries draining into Humboldt-Arcata Bay, Calif., during a winter (January-February) sampling period. The incidence of *Listeria* species and *L. monocytogenes* in sediment (46 samples) from the same sites where water was sampled was 30.4 and 17.4%, respectively. One of three bay water samples contained *Listeria* species (including *L. monocytogenes*), while of 35 samples of oysters examined, only 1 was found positive for *Listeria* species (*L. innocua*). A given species or *L. monocytogenes* serogroup appeared to predominate in fresh water when domesticated animals (cows, horses) were nearby, whereas greater variety with no species predominance was observed in areas with no direct animal influence.**

Listeria monocytogenes has been implicated in recent foodborne outbreaks (7, 14–16, 20) which have focused attention on this organism and its modes of introduction into foods. A variety of animals including domestic farm animals can carry *Listeria* species in both infectious and latent states and are therefore considered potential vectors of this organism (3, 6, 8, 9, 12). It has been suggested (24, 26) that *Listeria* species are saprophytic and capable of surviving for long periods in a plant-soil environment. This factor may also play a role in transmission of this organism to foods.

Listeria species are present in aqueous environments such as river waters and sewage sludge (22) and most recently have been recovered from a variety of seafood products (23). Although *L. monocytogenes* can tolerate salt (4, 21), it is not known whether it can reach marine waters via freshwater tributaries or whether it is capable of prolonged survival in marine environments. Therefore, whether its presence in seafoods is due to environmental or postprocessing contamination or a combination of these and other factors is presently unknown.

This study was conducted to determine the incidence of *Listeria* species in freshwater tributaries draining into Humboldt-Arcata Bay, Calif. This estuary supports an active molluscan shellfishery and is impacted by humans and domesticated and wild animals.

MATERIALS AND METHODS

Samples and sites. Sediment, freshwater, saltwater, and oyster samples were collected over 13 consecutive days during January–February 1988. Specific sites sampled included those along various tributaries and portions of Arcata Bay (Fig. 1). Fresh water was sampled at sites 1 to 9, sediment samples were collected from sites 1 to 5 and 8, saltwater sampling locations were at sites 10 to 12, and oysters were from sites 13 to 17. Water and sediment samples were maintained at ambient temperature; oysters were kept on ice after sampling. All samples were analyzed within 6 h of collection by using an on-site mobile microbiological laboratory. At each sampling, water temperature was taken with a mercury thermometer and salinity was measured with either a salinometer (Beckman Instruments, Inc., Fullerton, Calif.) or a refractometer (Atago Co. Ltd., Tokyo, Japan). The visual observation of domesticated farm animals near the sampling site was noted. In each case in which the animals were present, they were within 200 m of the sampling site.

Sample collection. (i) Water. Water was sampled by three methods as follows. (A) Surface water samples were collected with sterile 4-liter screw-cap plastic bottles (Nalgene Labware Div., Nalge/Sybron Corp., Rochester, N.Y.) (sites 1 to 5 and 8, Fig. 1). (B) Sterile Moore swabs (sterile gauze pads) (2, 13, 18, 25) were suspended on a string for 7 to 8 days in situ approximately 1 m below the water surface at seven freshwater and three saltwater sampling stations (sites 1 and 4 to 12, Fig. 1). After 7 to 8 days, the swab was removed from the water, placed in a sterile plastic bag (Whirlpak; Nasco, Fort Attenson, Wis.), transported at ambient temperatures to the laboratory, and analyzed within 2 h. (C) A sterile Moore swab was placed within 2 h of collection in a 4-liter surface water sample in a plastic collection bottle and held in the laboratory at 22°C for 18 to 24 h. The Moore swab was then removed from the collection container and placed directly in 225 ml of nutrient broth (NB) (Difco Laboratories, Detroit, Mich.). For analysis of salt water (salinity, >30‰), only the examination of Moore swabs (method B) was used.

(ii) Sediment. Approximately 200 g of surface layer (2 to 5 cm) sediment was collected with sterile plastic scoops. Samples were placed in sterile Whirlpak bags. Sediment consistency was noted by visual observation (Table 1).

(iii) Oysters. Pacific oysters (*Crassostrea gigas*) in plastic mesh bags were attached to floats and suspended 0.5 to 2 m below the surface of Arcata Bay and not in contact with the bottom for 2 weeks before sampling. Bags contained 14 to 15 oysters. One bag was removed from each station at each sampling, and 12 oysters from each bag were analyzed.

Bacteriological analysis. (i) Water. A 1- to 2-liter volume was filtered through a 0.45-μm-pore-size 142-mm membrane filter (Millipore Corp., Bedford, Mass.). The filter was blended for 5 to 10 s in 225 ml of NB. All Moore swabs including those having an extended exposure in situ and those suspended in water samples in the laboratory were placed in 225 ml of NB.

(ii) Sediment. Sediments in plastic bags were mixed, and 25 g from each bag was added to 225 ml of NB.

(iii) Oysters. Oysters were scrubbed, rinsed with tap water, shucked, and blended for 90 s (1). Portions (25 g) of

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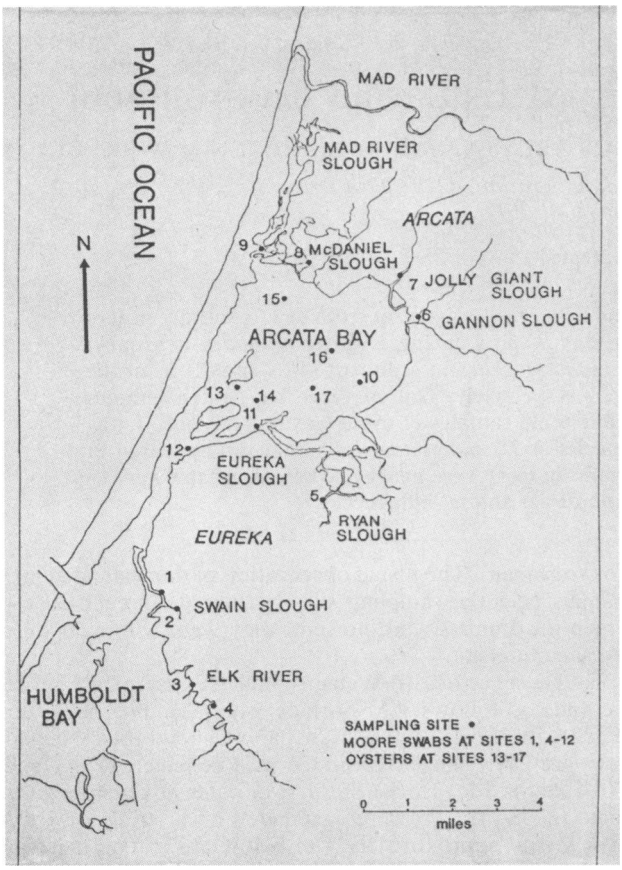

FIG. 1. Map of Humboldt-Arcata Bay area sampling sites. Fresh water, sites 1 to 9; sediment, sites 1 to 5 and 8; seawater, sites 10 to 12; and oyster, sites 13 to 17.

oyster homogenate were added to 225 ml of listeria enrichment broth (17) and to NB.

Enrichment and isolation procedures. The NB was incubated at 4°C (9, 22, 24) and after 7 and 28 days, 1 ml was transferred to 9 ml of thiocyanate-nalidixic acid nutrient broth (TN) (22) and incubated for 18 to 24 h at 35°C. Both undiluted and diluted (1:10, in 0.5% KOH) TN broth was streaked onto modified McBride agar (17) and incubated for 48 h at 35°C. The listeria enrichment broth was incubated and streaked as directed previously (17). A positive control consisting of *L. monocytogenes* V-7 serotype 1a:1 was inoculated into sterile NB and listeria enrichment broth, incubated, and recovered by all media used in this study.

Biochemical tests. The modified McBride agar plates were viewed by the oblique lighting technique of Henry (10, 17). Suspect gray-blue colonies, randomly selected, were stabbed into 7% sheep blood agar (Blood Agar Base no. 2; Oxoid Ltd., London, England) to detect the hemolysin reaction and into motility test medium (Difco) and held at 22°C for further confirmatory tests. Isolates were checked for purity by streaking onto tryptic soy agar containing 0.6% yeast extract (TSA-YE) (Difco) and incubated for 18 to 24 h at 35°C. Isolates from TSA-YE that were catalase positive and had characteristic tumbling motility in a wet mount were further characterized by the procedure described by Lovett (17).

L. monocytogenes isolates were serotyped (17) with Difco antisera for groups 1 and 4 and then further serotyped with more specific antisera provided by R. Bennett (Food and Drug Administration, Washington, D.C.). Final confirmation was conducted by colony hybridization (5, 11) with a ^{32}P-labeled oligonucleotide probe for the *Listeria* beta-hemolysin gene (5) supplied by F. M. Harrell (Food and Drug Administration, Minneapolis, Minn.).

RESULTS AND DISCUSSION

Fresh water. *Listeria* species were detected in 81% (n = 37) of freshwater samples. This is similar to the report of

TABLE 1. Distribution of *Listeria* species in freshwater and sediment samples

Source[a]	Sample type	No. of samples[b]	Temp (°C)	Salinity (‰)	Sediment composition	No. of samples positive for:					
						Listeria species	*L. monocytogenes* serotypes (1a:1/4b:6/4)	*L. innocua*	*L. seeligeri*	*L. welshimeri*	*L. ivanovii*
Elk River											
Site 1	Water	8*	8–12	5–17		7	0/4/0	3	1	4	0
	Sediment	3			Silt	0	0/0/0	0	0	0	0
Site 2+	Water	1	9.5	0.8		1	0/0/0	0	0	1	0
	Sediment	1			Silt	0	0/0/0	0	0	0	0
Site 3+	Water	2	7.5–11	0–0.6		2	2/2/0	0	0	1	0
	Sediment	4			Sand	3	1/0/0	0	1	1	0
Site 4+	Water	5*	8–10	0–0.7		4	0/4/0	1	0	1	0
	Sediment	4			Sand	3	0/1/0	0	0	2	0
Ryan Slough (site 5+)	Water	7*	6–11	0.2–1.2		6	0/4/1	0	2	2	0
	Sediment	22			Silt	6	1/5/0	1	1	1	0
McDaniel Slough (site 8)	Water	11*	8.5–12	0–0.7		10	5/3/1	2	8	6	1
	Sediment	12			Soil	2	0/0/0	0	2	0	0
Mad River, McDaniel Slough, delta+ (six sites in 1-mile [1.6-km] area)	Sediment	15	11–15	0–0.9	Peat	3	0/0/0	0	0	3	0

[a] +, Animals observed near sampling site.
[b] *, Total includes a Moore swab placed at this location for 7 to 8 days in addition to surface water samples collected.

Watkins and Sleath (22) of recovering *Listeria* species in all river waters (n = 7) sampled in the United Kingdom. *L. monocytogenes* (1a:1, 4b:6, or 4) was isolated from 62% of all water samples and was the most predominant of *Listeria* species (Table 1). A wide variety of *Listeria* species and, frequently, more than one species were isolated from each location (Table 1).

Two of the three techniques used here for analyzing freshwater samples, analysis of filters and analysis of Moore swabs incubated in the sample collection bottle in the laboratory, were effective for recovery of *Listeria* species at each sampling site. No *Listeria* species were recovered from Moore swabs suspended in situ for 7 to 8 days at each of seven freshwater sampling stations. Why organisms attached to Moore swabs in the laboratory but not to gauze suspended in situ is unknown. Perhaps attachment to gauze is affected by temperature, incubation time, salinity, or other conditions existing as a function of enclosure within the plastic sample container.

Sediment. *Listeria* spp. were recovered from 30.4% of 46 sediment samples collected at the same locations as the surface water samples (sites 1 to 5 and 8). The predominant species recovered, *L. monocytogenes*, was isolated from 17.4% of the 46 samples. Besides the sites sampled above, an additional 15 sediment samples having the consistency of peat were collected from the edges of a slow-flowing drainage system through grazing areas where sheep, cows, ducks, and geese were present. These samples were collected at six distinct sampling sites approximately 0.25 to 0.5 mile (0.4 to 0.8 km) apart in a delta region between McDaniel Slough and Mad River (Fig. 1). *L. welshimeri* was the only *Listeria* species isolated and was detected in 3 of the 15 samples (20%).

Despite the lower overall incidence of *Listeria* species in sediment compared with fresh water, the rate was similar to the 20.9% incidence of *Listeria* species recovered by Weis and Seeliger (24) from sediment in the south of the Federal Republic of Germany.

The proximity of domesticated animals to a sample site appeared to affect the incidence and predominant species recovered. Sediment samples from Elk River (sites 3 and 4) and Ryan Slough (site 5), which had domesticated animals nearby, had a higher incidence of *Listeria* species (75, 75, and 27.3%, respectively) than did sediment from those sites where animals were absent, such as from Elk River (site 1) (no *Listeria* species recovered) or McDaniel Slough, (site 8) (16.7%).

Distribution in fresh water and sediment. Why *Listeria* species are more prevalent in fresh water than in sediment was not determined but is probably due to a number of factors. Differences in species composition and levels of indigenous competing bacteria between different sample types and other conditions noted at the sample site such as the influence of animals, urbanization, changes in salinity due to tidal activity in the area, or sediment type (26) may also affect the apparent overall distribution and recovery of *Listeria* species in water compared with sediment at a given site.

These data indicate that the incidence of *Listeria* species remains high throughout the freshwater tributaries entering Humboldt-Arcata Bay. A given species or serogroup predominated in fresh water when domesticated animals were in close proximity to the sample site. For example, *L. monocytogenes* (4b:6) was predominant in water at Elk River (site 4). At site 3, *L. monocytogenes* serotypes 1a:1 and 4b:6 were predominant (cows were observed at both sites 3 and 4). *L. monocytogenes* (4b:6) was the main species isolated from waters of Ryan Slough, (site 5) (Table 1), where horses were observed. Both horses and cows can be sources of *Listeria* species (3, 8, 9, 12). The variety of *Listeria* species isolated from water appeared to be greater and no one particular species or serogroup predominated at sites without observable direct domesticated animal and/or human influence. This was illustrated at the Elk River (site 1) and McDaniel Slough (site 8) (Table 1), sites impacted by runoff from the urban area of Arcata, Calif. Direct animal influence was not observed at either site.

Slight variations in salinity due to tidal action did not appear to affect the distribution of *Listeria* species in this water system. Tidal influence was greatest for Elk River (site 1) (5 to 17‰ salinity); four *Listeria* species were recovered from 87% of samples from this location (Table 1). This is similar to data obtained at a site of negligible salinity (McDaniel Slough, site 8) where 90% of water samples were positive for *Listeria* species (five species isolated).

These data indicate that there was a consistent input of *Listeria* species from these freshwater tributaries draining into Humboldt-Arcata Bay. *Listeria* species could also be introduced to the bay via other sources. For example, *L. monocytogenes* (4b:6) and *L. innocua* were isolated from a water sample from an urban drain in Eureka, Calif., which emptied directly into Humboldt Bay. In addition, the influence of a large local seagull population observed here and the presence of other marine birds can also be a consistent source of *Listeria* species to the marine environment (6).

Bay water. Although Moore swabs suspended in situ were not effective for recovering *Listeria* species from fresh water, *Listeria* species were isolated from one (site 11) of three Moore swabs placed in situ in marine waters (sites 10 to 12). *Listeria* species recovered from this swab sample included *L. monocytogenes* 1a:1 and 1a:2, *L. innocua*, and *L. welshimeri*. The presence of *Listeria* species in marine water may indicate a recent contamination since a study (A. T. Fuad, S. D. Weagant, M. M. Wekell, and J. Liston, Abstr. Annu. Meet. Am. Soc. Microbiol. 1989, Q243, p. 370) has shown that *L. monocytogenes* levels decrease when low levels are inoculated into seawater. Effects of dilution by the large volumes of seawater in the marine environment may also result in lower levels of *Listeria* species in marine compared with fresh waters.

Oysters. *L. innocua* was isolated from 1 of 35 oyster samples analyzed from five different sites in Arcata Bay (Fig. 1) and was the only *Listeria* species found in oysters. This is the lowest incidence rate (2.8%) by sample type observed in this study (Fig. 2). The ability of *Listeria* species to survive in marine waters, the degree to which *Listeria* species are diluted, and the pumping rate by oysters are all factors that could affect the uptake and retention of *Listeria* species by oysters.

All *L. monocytogenes* isolated in this study gave a positive reaction with the oligonucleotide probe for the hemolysin gene. No other *Listeria* species isolated in this study reacted with the probe.

Conclusion. *Listeria* species were consistently recovered over a 13-day sampling period during the winter from freshwater tributaries draining into Humboldt-Arcata Bay. These tributaries, which are impacted by domestic farm animals, can contribute *Listeria* species to the Humboldt-Arcata Bay system. The incidence of *Listeria* species in sediments (30.4%) was much lower compared with the incidence in fresh water (81%). This difference could be due to a variety of reasons such as different levels of available nutrients,

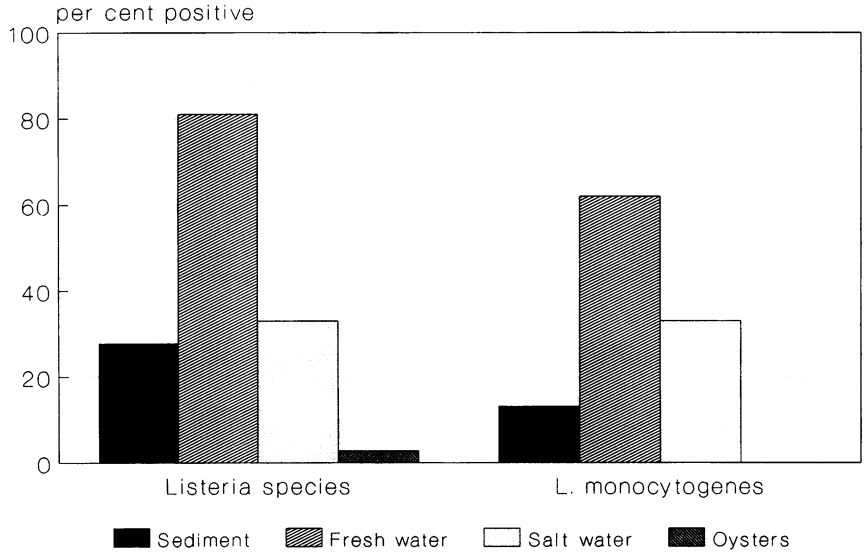

FIG. 2. Incidence of total *Listeria* species and *L. monocytogenes* by sample type.

presence of toxic compounds, and predation by other organisms (19). It is also possible that the lower incidence of recovered *Listeria* species could reflect an initiation of a viable but nonculturable state response by *Listeria* species to these various conditions. Although this survival strategy has not yet been demonstrated for *Listeria* species, it has been shown for a number of other microorganisms and is reviewed by Roszak and Colwell (19). Although the apparent incidence of *Listeria* species is lower in marine waters (33%) compared with fresh waters and was lowest in oysters (2.8%), *Listeria* species were detected throughout the watershed and therefore can be introduced to oysters raised there. These data suggest that the incidence of *Listeria* species is low in oysters held in this estuary during the winter months and most probably represents recent contamination from terrestrial sources.

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Conference for Food Protection
2012 Issue Form

Internal Number: 063
Issue: 2012 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.

Title:
Addition to Consumer Advisory, Section 3-603.11 of the Model Food Code

Issue you would like the Conference to consider:
The 2009 FDA Food Code recognizes that consumers should have notice regarding the risk of foodborne illness from raw or undercooked meats, poultry, seafood, shellfish, or eggs. However, the Consumer Advisory fails to provide adequate notice for persons to accurately assess the risk of severe illness and death from *Vibrio vulnificus* in raw oysters harvested from the Gulf of Mexico. An adequate advisory is modeled in title 17 of the California Code of Regulations § 13675 which provides a basis for the proposed addition to Section 3-603.11.
(http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/fdb%20Raw%20Oyst%20Sale%20Retail.pdf)

Public Health Significance:
Vibrio vulnificus in raw oysters harvested from the Gulf of Mexico poses a well-defined risk of severe illness and death to consumers with compromised immune systems, liver damage, diabetes, the genetic disorder hemochromatosis, and certain gastric disorders. *Vibrio* is associated with mild gastroenteritis in persons with healthy immune systems, and life-threatening infections in persons with pre-existing medical conditions. Each year 30 or more people are diagnosed with *V. vulnificus*-induced septicemia from raw oysters sourced to Gulf Coast waters and approximately half die from the infection. Even with aggressive treatment the case fatality rate is 30 to 40 percent and mortality is 100 percent if a patient is not treated within 72 hours of symptom onset. Because *V. vulnificus* presents as primary septicemia, a common disease with many causes, misdiagnosis almost certainly results in underreporting of the disease. It is critical that persons have adequate notice of the risk so that they will seek early medical care and inform their doctor they have eaten raw oysters. While the strongest prevention is to require all Gulf oysters shipped interstate to be treated post-harvest to eliminate the pathogen, the industry has resisted such requirements. The proposed warning is, therefore, consistent with industry preferences for consumer education in lieu of other controls. It is a critical requirement because other than self-identification, food establishments have no way of recognizing at-risk patrons. To the extent that patrons have adequate information about their own health status, the warnings may reduce the number of illnesses and deaths (with the attendant bad publicity associated with

news reports and lawsuits). Additionally, since consumer perceptions can alter choices, thus reducing demand, industry interests and public health walk hand-in-hand with providing adequate notice that allows at-risk populations to understand and assess the danger of consuming raw oysters.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 3-603.11, be amended as follows (new language shown with underline):
3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.*
(D) Every FOOD ESTABLISHMENT that offers raw oysters harvested from the Gulf of Mexico (any oyster harvested from the Gulf waters bordering the states of Alabama, Florida, Louisiana, Mississippi, or Texas) shall provide a written warning to any person who orders raw oysters, stating:
WARNING
THIS FACILITY OFFERS RAW OYSTERS FROM THE GULF OF MEXICO. EATING THESE OYSTERS MAY CAUSE SEVERE ILLNESS AND EVEN DEATH IN PERSONS WHO HAVE LIVER DISEASE, CANCER, DIABETES, OR OTHER CHRONIC ILLNESSES THAT WEAKEN THE IMMUNE SYSTEM. If you eat raw oysters and become ill, you should seek immediate medical attention. If you are unsure if you are at risk, you should consult your physician.
(E) Warnings under subsection (D) are not required whenever the FOOD ESTABLISHMENT has received a copy of a current verification letter from the dealer and tags or labels are as required by Section 3-202.18 of this Code demonstrating that the oysters have been subjected to an oyster treatment process sufficient to reduce *Vibrio vulnificus* to an undetectable level, as defined in the U.S. Food and Drug Administration Bacteriological Analytical Manual, 2004 Edition.

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

Conference for Food Protection
2012 Issue Form

Internal Number: 034
Issue: 2012 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.

Title:
Hand Antiseptics

Issue you would like the Conference to consider:
An update to the language in the 2009 FDA Food Code, Section 2-301.16 Hand Antiseptics is needed to account for the regulatory procedures that can also be used to make a hand sanitizer compliant with the Food Code. Due to the absence of any specific regulation in FDA's 21 Code of Federal Regulations (CFR) for hand antiseptics and indirect food contact, the Food Code serves as the sole guidance for the use of hand antiseptics in retail food facilities. These procedures are already referenced in Annex 3 of the Food Code (Chapter 2- 301.16 Hand Antiseptics) and therefore updating the language in Chapter 2 would help avoid any confusion and misunderstandings by Inspectors in the field.

Public Health Significance:
Chemicals may be poisonous or toxic if not used properly and in accordance with FDA regulations. The lack of clear and explicit guidance surrounding the use of hand antiseptics in food facilities poses a risk and could contribute to the improper use of chemicals that may subsequently cause public health issues such as the adulteration of food, or potentially acute and chronic effects to both the consumer and the employee of the food facility.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline and deleted language shown with strike-through):

2-301.16 Hand Antiseptics.

(A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, 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 b~~Be listed in the following sections and used up to the maximum allowable concentration permitted by that regulation:
(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~~ or
(c) Have components that have been appropriately cleared for use as hand sanitizers with incidental food contact through GRAS notifications/ affirmations or a Food Contact Notification (FCN) with FDA, and,
(3) Be applied only to hands that are cleaned as specified under § 2-301.12. [Pf]
(B) If a hand antiseptic ~~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. (1) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; [Pf] or
2. (2) Limited to situations that involve no direct contact with food by the bare hands. [Pf]

(C) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L chlorine. [Pf]

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Conference for Food Protection
2012 Issue Form

Internal Number: 097
Issue: 2012 I-027

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

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Title:
Use of Galvanized Metal with Acidic Foods

Issue you would like the Conference to consider:
Restricting the use of galvanized metals from contact with food except by local variance for the specific process it is intended to be used for.
Per the 2009 FDA Food Code Public Health Reasons for 4-101.15, zinc may leach into acidic foods if they contact galvanized metal. However, the solubility of zinc is subject not only to pH but also temperature and the corrosive environment of inorganic salts. The inorganic salts can come into contact with the metal from the food or disinfectants used as part of the process.

Public Health Significance:
Setting this guideline would place the requirement of providing data to the regulatory authority in order to acquire a variance.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
4-101.15 Galvanized Metal, Use Limitation.
Galvanized metal may not be used for UTENSILS or FOODCONTACT SURFACES of EQUIPMENT <u>unless, it is shown that zinc does not transfer to FOOD under its specified use.</u>[P]

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Conference for Food Protection
2012 Issue Form

Internal Number: 100
Issue: 2012 I-028

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

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Title:
Chemicals for Washing Fruits and Vegetables

Issue you would like the Conference to consider:
Clarify the language in 2009 FDA Food Code Section 3-302.15 Washing fruits and vegetables, to ensure chemicals used for washing fruits and vegetables follow manufacturer's directions or EPA registered label use instructions.

Public Health Significance:
Food Code Section 7-204.12 specifies that chemicals used to wash fruits and vegetables should meet the requirements specified in 21 CFR 173.315, Chemicals used in washing or to assist in the peeling of fruits and vegetables. In addition to identifying chemicals that may be used, 21 CFR 173.315 also states:
"(d) To assure safe use of the additive... The label or labeling of the additive container shall bear adequate use directions to assure use in compliance with all provisions of this section."
Adding language to the Food Code indicating that use directions should be followed would clarify requirements for safe use, and uphold the public health and consumer food standards set by the Code.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
3-302.15 Washing Fruits and Vegetables
(B) *Fruits and vegetables may be washed by using chemicals as specified under 7-204.12 and shall be used in accordance with the manufacturer's directions or EPA registered label use instructions*.

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Conference for Food Protection
2012 Issue Form

Internal Number: 099
Issue: 2012 I-029

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

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Title:
Testing for Hot Water Sanitizing

Issue you would like the Conference to consider:
The 2009 FDA Food Code addresses the failure of having test kits for chemical sanitizing (automatic dish machine) as a priority. However, nowhere in the food code does it require the same of hot water sanitization test kits. In fact the Code is silent on this issue (no specificity relating to hot water test kits). Unless a method of ascertaining the level of hot water sanitization occurring in the machine is identified (e.g., the surface of the utensil has met 160°F requirement), validating the machine's operational criteria cannot be objectively measured.

Validating whether the surface temperature has met the required 160°F requirement provides assurance that the utensil has been properly cleaned which includes sanitization. Failure to validate can have negative consequences as failure to validate a temperature of a potentially hazardous food item.

Public Health Significance:
Validation that efficacious sanitization is occurring is an important part of the overall cleaning procedure, whether through manual cleaning (3-compartment sink) or automatic (ware washing machines) cleaning. In automatic operations, heat treatment occurs when the final rinse spray is higher than the upper limit specified by the manufacturer's instructions.

It is commonly understood that if utensils are not cleaned properly, microorganisms are potentially transmitted via foods to other foods by utensils. Therefore, validating that cleaning and sanitization has occurred is an important component in the reduction of disease transmission via food.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-703.11(B), be amended as follows (new language shown with underline and deleted language shown with strike-through):

Hot water mechanical operations by being cycled through EQUIPMENT that is set up as specified under §§ 4-501.15, 4-501.112, and 4-501.113 and achieving a UTENSIL surface

temperature of 71°C (160°F) ~~as measured by an irreversible registering temperature indicator; P or~~ ***shall be validated by the use of a test kit or similar equipment***; or

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Conference for Food Protection
2012 Issue Form

Internal Number: 035
Issue: 2012 I-030

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

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Title:
Food Equipment Certification

Issue you would like the Conference to consider:
The 2009 FDA Food Code contains language in Chapter 4 - *Equipment, Utensils, and Linens* recognizing a single organization for the accreditation of certification programs for food service equipment. Specifically, Section 4-205.10 of the Food Code limits the acceptability of food equipment certification programs to those accredited by the American National Standards Institute (ANSI). ANSI, a private, non-governmental organization, is one of three nationally recognized, U.S. based accreditation bodies that are qualified to accredit product certification programs. The identification of ANSI as the sole (proprietary) source for qualified accreditation providers is unnecessarily restrictive.

Public Health Significance:
The reliance on properly accredited third- party certification programs to evaluate food service equipment to nationally recognized standards that address sanitation and safety is a reliable mechanism to establish compliance with Sections 4-1 and 4-2 of the Food Code. The establishment of clear requirements for determining the acceptability of accreditation bodies is consistent with current practice while supporting an open marketplace based on demonstrated compliance.

Both t*he American National Standards Institute (ANSI)* and the *International Accreditation Service (IAS)* are U.S. domiciled accreditation bodies that are signatory members of the *International Accreditation Forum (IAF),* meaning both organizations are recognized nationally and internationally as having equivalent levels of confidence for providing accreditation services. Accreditation is increasingly being used by regulators and the market as an impartial, independent and transparent means of assessing the competence of conformity assessment bodies.

Regulators in the United States increasingly rely on an integrated system of accreditation and certification to demonstrate that products and services comply with regulatory requirements. In the United States, examples of the reliance on systems of accreditation and certification include programs administered by the Environmental Protection Agency (EPA), the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC). The EPA Water Sense® and Energy Star® programs require that manufacturers submit products to an accredited certification agency for testing and evaluation in order to

establish compliance with established standards and criteria. Both programs establish qualification criteria for recognition of accreditation bodies based on a framework for accreditation developed by IAF. IAF provides the technical basis for the recognition of the competence of accreditation bodies. IAF conducts an initial onsite evaluation, routine surveillance and periodic re-evaluations of accreditation bodies to determine compliance with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Standard 17011 *Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies*. Accreditation bodies found to be operating accreditation programs that comply with these requirements become signatories to the IAF Multilateral Recognition Arrangement. The criteria for the accreditation of product certifying bodies is detailed in ISO/IEC Guide 65, *General requirements for bodies operating product certification systems* and the International Accreditation Forum (IAF) *Guidance on the Application of ISO/IEC Guide 65.*

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-205.1, be amended as shown below (new language shown with underline and deleted language shown with strike-through):

Acceptability

4-205.10 Food Equipment, Certification and Classification.

Food equipment that is certified or classified for sanitation by ~~an American National Standards Institute (ANSI) accredited~~ a certification program accredited by a U.S. domiciled accreditation body that is a signatory to the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) is deemed to comply with Parts 4-1 and 4-2 of this chapter.

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Attachments:

- "Food Equip Cert Issue Supporting Attachments"

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Supporting Attachments

1. 2009 FDA Food Code, Chapter 4, Part 4-2, item 4-205.10 - Web Address: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/ucm188064.htm#part4-2
2. U.S. EPA Water Sense® Product Certification, Version 2.0, Section 4.0, Sub-section 4.1 - Web Address: http://www.epa.gov/WaterSense/docs/cert_system_508.pdf
3. International Accreditation Forum website - Web Address: http://www.iaf.nu/
4. International Accreditation Forum MLA Information - Web Address: http://www.iaf.nu//articles/IAF_MLA/14
5. International Accreditation Forum List of United States Domiciled MLA Signatory Accreditation Bodies - Web Address: http://www.iaf.nu/articles/IAF_MEM_USA__all/112
6. IAS International - Web Address: http://www.iasonline.org

Conference for Food Protection
2012 Issue Form

Internal Number: 008
Issue: 2012 I-031

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

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Title:
Modify FDA Food Code §3-304.11 to include linens and napkins

Issue you would like the Conference to consider:
The current wording of FDA Food Code §3-304.11 states that "food shall only contact surfaces of: (A) equipment and utensils that are cleaned as specified under Part 4-6 of this Code and sanitized as specified under Part 4-7 of this Code; or (B) single-service and single-use articles." By limiting the surfaces that food may contact to only equipment, utensils, single-service and single-use articles, this section negates the allowance for linens and napkins where they are approved for use. Linens and napkins are not included in the definitions of equipment, utensils, and single-service or single-use articles in the Food Code. However Food Code §3-304.13 allows for their use when they are lining containers for the service of food provided they're replaced each time the container is refilled for a new customer.

Public Health Significance:
By emphasizing what is permissible for food contact and what is not, the Food Code can avoid providing conflicting guidance to stakeholders. By including linens and napkins in §3-304.11, the Food Code will clearly identify that linens and napkins can be used for food contact, as specified in §3-304.13, without confusion.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline and deleted language shown with strike-through):

3-304.11 Food Contact with Equipment and Utensils

FOOD shall only contact surfaces of:

(A) EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code and SANITIZED as specified under Part 4-7 of this Code;[P] or

(B) SINGLE-SERVICE and SINGLE-USE ARTICLES;[P]or

(C) Linens and napkins as specified in §3-304.13.

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Conference for Food Protection
2012 Issue Form

Internal Number: 056
Issue: 2012 I-032

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

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Title:
Allowance for a Direct Drain Connection in Warewashing Equipment

Issue you would like the Conference to consider:
Deleting the prohibition of a direct drain connection for warewashing sinks or warewashing machines from Section 5-402.11 of the 2009 FDA Food Code (as modified by the Supplement issued in 2011). This prohibition is in direct conflict with the major model plumbing codes such as the Universal Plumbing Code and the International Plumbing Code. Many localities adopt these codes, and this creates a tiered system whereby food establishments in localities without a plumbing code must submit to a requirement that establishments in areas with plumbing codes are often required not to comply with. In warewashing, the final step in the process is a sanitizing step with a solution with residual sanitizer or high temperature water. This step acts as a "fail-safe" to overcome the risk of an unnoticed sewage backup in the sink.

Public Health Significance:
There is minimal risk to public health from allowing a direct drain connection in a warewashing sink.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting an amendment to Section 5-402.11 of the 2009 Food Code (as modified by the Supplement issued in 2011) as specified below (deleted language is in strikethru format).

5-402.11 Backflow Prevention.

(A) Except as specified in ¶¶ (B)~~,~~ and (C)~~, and (D)~~ of this section, a direct connection may not exist between the sewage system and a drain originating from equipment in which food~~, portable equipment, or utensils are~~ is placed. P

(B) *Paragraph (A) of this section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building*.

~~(C) *If allowed by law, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.*~~

(~~D~~C) *If allowed by law, a ~~warewashing or~~ culinary sink may have a direct connection*.

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Conference for Food Protection
2012 Issue Form

Internal Number: 006
Issue: 2012 I-033

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

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Title:
Temp Measuring Device for Warewashing Machines w/Hot Water SANITIZING rinse

Issue you would like the Conference to consider:
The next revision of the FDA Food Code should require the Person-in-Charge of a food establishment that has a warewashing machine using a hot water sanitizing final rinse to have a temperature measuring device that measures the utensil surface temperature.
The Food Code currently requires under 4-302.14 Sanitizing Solutions, Testing Devices that "A test kit or other device that accurately measures the concentration in MG/L of SANITIZING solutions shall be provided" and furthermore under 4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration that the "Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device."
As far as hot water mechanical operations, the Food Code currently requires, in part, under 4-703.11(B) that "...Hot water mechanical operations...and achieving a UTENSIL surface temperature of 71 degrees C (160 degrees F) as measured by an irreversible registering temperature indicator."
In the case of hot water mechanical operations, the Food Code does not explicitly require both the availability and the use of an irreversible registering temperature indicator or similar device.
It should also be noted that the January 2000 FDA Plan Review Guide, *Part 8 - Warewashing Facilities*, under mechanical warewashing utilizing hot water for sanitization on page 81, states: "An approved maximum registering thermometer or high temperature test papers shall be available and used."
Reliance on the machine's fixed TEMPERATURE MEASURING DEVICE to determine if SANITIZATION has been achieved can be problematic as these devices are not routinely calibrated and may be in disrepair even if the machine itself is working properly. The use of a field temperature indicator (or similar) in conjunction with the fixed pressure gauge and fixed TEMPERATURE MEASURING DEVICE is appropriate to determine if SANITIZATION has been achieved.

Public Health Significance:
Effective SANITIZATION destroys organisms of public health significance that may be present on food equipment and utensils after cleaning or which may have been introduced into the rinse solution.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-302.13, be amended as follows (new language shown with underline):
Temperature Measuring Devices, Manual and Mechanical Warewashing
(A) In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.
(B) In mechanical WAREWASHING operations, an approved irreversible registering indicator or waterproof maximum registering thermometer shall be provided and used regularly for measuring the final rinse temperature at the utensil surface.

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Conference for Food Protection
2012 Issue Form

Internal Number: 031
Issue: 2012 I-034

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

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Title:
The 2009 FDA Food Code Introduced New Confusing Terms

Issue you would like the Conference to consider:
The new terms introduced into the 2009 FDA Food Code are not food safety-related terms that are relevant to educating the public, the regulated industry and regulatory officials. Removing the public health naming convention of identifying violations as risk factors, public health interventions, or good retail practices requires a re-education process that does not emphasize food safety or foodborne illness prevention. Significant progress has been made in linking the terms (risk factors, public health interventions, good retail practices) to a culture of food safety. We are concerned that use of the terms listed below will create confusion and set back progress in improving compliance in all facilities, particularly in "mom and pop" food service operations.

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.

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 Health Significance:

The main purpose of the FDA Food Code is to assist regulators and the regulated industry in prioritizing actions that proactively improve food employee behaviors and food preparation practices mitigating and eliminating the risk of foodborne illness.

The new terms and levels of priority introduced in the 2009 FDA Food Code are difficult for regulators to articulate and difficult for regulated industry to understand. Without clear understanding there is a high probability of reducing the effectiveness of the Code itself. Time and effort spent re-educating regulators, operators and employees would be better spent on reinforcing the food safety-related and well-understood terms already in use.

Recommended Solution: The Conference recommends...:

the re-creation of the Critical Item Committee. The re-established Committee will be charged with:

1. Using the food safety terminology below in lieu of the terms listed above, or
2. Recommending easily understood (common usage) replacement terms that must be tested using surveys of both regulators and regulated industry,
3. Report back to the 2014 Biennial Meeting on Committee Activities and submit Issues that recommend revsion to the body of the code to align with the the revised language, and strike the existing terminology from the code (Core, Priority, etc.).

Submitter offers the Proposed Revised language for the Committee's Consideration:

Good Retail Practices

1. "Good Retail Practices" means a provision in this Code that is not designated as a Risk Factor or intervention ITEM.
2. "Good Retail Practices " includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

Risk Factors and Intervention Items

1. "Risk Factor Item" means a provision in this Code whose application supports, facilitates or enables one or more RISK FACTOR items.
2. "Intervention 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. "Risk Factor Item" is an item that is denoted in this Code with a superscript Rf - ^{Rf}.
4. "Intervention Item" is an item that is denoted in this Code with a superscript I - ^{I}.

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Conference for Food Protection
2012 Issue Form

Internal Number: 106
Issue: 2012 I-035

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

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Title:
Updating of the Food Establishment Inspection Report

Issue you would like the Conference to consider:
We are requesting that the Conference consider the following proposal:
The current Inspection Form 3-A in the 2009 Food Code Annex 7 and Instructions for Marking form 3-B are based on old section designations of critical and non-critical. When the 2009 code was modified to reflect the three tier designations of Priority (P), Priority Foundation (Pf) and Core (C) these forms were not updated.
We would like FDA to format the Inspection Form 3-A and the Instructions for Marking Form 3-B in Annex 7 to reflect the (P), (Pf), and (C) designations.
We have submitted a draft (attached) of an Inspection Form 3-A that has been divided and grouped according to the (P), (Pf) designated violations in the upper part of the form and the (C) designated violations in the lower part of the form. A draft Instructions for Marking document 3-B has been developed to show the (P), (Pf) and (C) designations to ensure that inspection observations are accurately recorded on the Food Establishment Inspection Report.
The documents attached are presented as drafts. The documents submitted were developed for the State of Oklahoma and would need to be made "generic" for use in future Code publications.

Public Health Significance:
The Food Establishment Inspection Report is the official regulatory document that measures compliance of the establishment with regulatory requirements. The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment and to convey this information to the permit holder or person in charge (PIC) at the conclusion of the inspection.
Reformatting the Food Establishment Inspection Report (3-A) and Guidance Marking Document (3-B) by providing a uniform and consistent inspection process will help bring uniformity and assist permit holders in understanding the three-tier designations in jurisdictions that have adopted the 2009 Food Code.
The formatting of the document to reflect the Priority, Priority foundation and Core designations will communicate to the operator the severity of the violations and will provide

appropriate timeframes for corrective action, thereby reducing foodborne illness risk to the public.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting that the 2013 Food Code contain updated versions of the Food Establishment Inspection Report 3-A and Instructions for Marking Form 3-B that are currently provided in Annex 7 of the 2009 Food Code in order to reflect the Priority, Priority Foundation and Core designations.

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Attachments:

- "DRAFT Food Establishment Inspection Report- Page 1"
- "DRAFT Food Establishment Inspection Report - Page 2"
- "DRAFT Instructions for Marking Guide"

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Consumer Protection Division
Food Inspection Report
State Code OAC 310:257

Inspection Date	Inspection Time	Mgr. Cert	County #	Establishment#	License Expiration	Type	Class	Priority

Purpose of Inspection: 1 – Routine 2 – Compliance 3 – Issue License Application 4 – Complaint 5 – Other 6 – Out of Business 7 – Follow-Up Activity 8 – Reserved

Number of Repeat Risk Factor/Intervention Violations | **Follow-up:** | **On or Before Date:**

Establishment | **Owner**

Physical Address | **City** | **Zip Code** | **Phone #** / **Cell Phone #**

PRIORITY & PRIORITY FOUNDATION VIOLATIONS

Priority items are proven measures that are directly linked to the elimination, prevention or reduction of hazards associated with foodborne illness.
Priority Foundation items incorporate specific actions, equipment or procedures to control risk factors that contribute to foodborne illness.
NOTE: Items 1-35 Require Immediate Action or by date noted on Pg 2 - Not to exceed 10 days from date of inspection.

IN=in compliance **OT**=not in compliance **NO**=not observed **NA**=not applicable **CDI**=corrected on-site during inspection **R**=repeat violation

	IN	OT	NO	NA	● CDC Risk Factors & Food Code Interventions	CDI	R
Supervision/Licenses							
1					Valid license to operate; non-transferable		
2 ●					PIC present, demonstration of knowledge, performs duties		
3					Special processes (Variance, ROP, shellfish tanks, HACCP)		
Employee Health							
4 ●					Ill workers–PIC & EMP responsibilities: Report symptoms & diagnosis; Restrict/Exclude (removal, retain or adjust)		
Control of Hands as a Vehicle of Contamination							
5 ●					Hands clean, washed, maintained; Hand antiseptics		
6 ●					No Bare Hand Contact with Ready-to-Eat foods Or alternate methods; Glove limitations		
7					Adequate hand wash facilities: supplied, accessible; Toilets properly supplied		
Approved Source							
8 ●					Food, water, ice: obtained from approved source		
9 ●					Food in good condition, safe, unadulterated, segregated		
10 ●					Required records (shellstock tags, parasite destruction)		
Protection from Contamination							
11 ●					Food separated/protected; Proper tasting procedures; Self-serve operations; Single service use when required		
12					Disposition of returns, previously served, Reconditioned, unsafe food		
13					Prohibited animals; Prohibited food operation locations		
14					Sinks used for intended purposes		
15					Food equipment: improper use, operation (Materials, design)		
16					Insects, rodents, & other pests controlled		

	IN	OT	NO	NA	● CDC Risk Factors & Food Code Interventions	CDI	R
Time/Temperature Control for Safety (TCS)							
17 ●					Cooking time & temperatures; Plant food cooking		
18 ●					Reheating procedures for hot holding		
19 ●					Cooling time & temp; cooling methods		
20 ●					Hot holding temps; received at proper temp		
21 ●					Cold holding temps; received at proper temp		
22					Date marking and disposition		
23 ●					Time as public health control, procedures/records		
24 ●					Non-continuous cooking process / partial cook		
25					Adequate facilities/equipment to maintain food temps		
26					Probe thermometers provided & accurate		
Consumer Advisory, Highly Susceptible Populations							
27					Consumer advisory, Child menu, Allergen label		
28					Pasteurized food used; Prohibited food not offered Pasteurized eggs used where required		
Chemicals							
29					Food additives; approved, properly used		
30					Toxic substances properly identified, stored, used		
Warewashing, Food Contact Surfaces							
31					Warewash, sanitize equipment: Design, supplies, operated; Test strips; Temp gauges; Alarms		
32					Warewashing; Sanitize at ppm/temp		
33					Food contact surfaces of equipment & utensils clean		
Plumbing							
34					Water: adequate pressure, sufficient capacity		
35					Plumbing sewage system: design, approved, installed Cross-connection prohibited, air gaps, disposal		

CORE VIOLATIONS

Core items relate to general sanitation & maintenance, equipment design & maintenance, and physical facilities & structures.
NOTE: Items 36-58 must be corrected within 90 days or by date noted on Pg. 2.

		● Food Temperature Controls	CDI	R
36		Approved thaw methods; Active cool containers stored properly		
37		Thermometers provided, accurate, conspicuous		
Food Identification				
38		Food properly labeled, original container, honestly presented		
Prevention of Food Contamination				
39		Contamination prevented during food preparation, storage & display; Washing fruits/vegetables		
40		Personnel: clean, jewelry, hair restraints, FH Permits		
41		Eating, drink, tobacco use; No discharge from eyes, nose, mouth		
42		Wiping cloths: properly used & stored; Sponges prohibited		
Proper Use of Utensils				
43		In-use utensils proper storage, cleaning frequency; Utensils, equip & linens: properly stored, dried, handled; Linens clean		
44		Single-use, single-service articles: properly stored, used		
Utensils, Equipment and Vending				
45		Food & non-food contact surfaces cleanable, design		
46		Manual/Mechanical warewashing facilities: maintained, operated; Pressure guages, data plates; Use limitation, pre-cleaning		
47		Non-food contact surfaces clean; Cleaning frequency		

		● Physical Facilities	CDI	R
48		Plumbing sys: maintained, backflow device installed, inspected		
49		Toilet facilities: accessible, properly constructed, cleaned Self closures		
50		Break/locker areas: used, provided, maintained; Living areas separated; Laundry facilities		
51		Hand wash sinks: designed, clean, used; Proper signage		
52		Floors, walls, ceilings (premises): clean, free of litter; Removal of pests		
53		Floors, walls, ceilings (physical facilities): design, maintained, good repair; Outer openings protected		
54		Service Sinks; Maintenance & cleaning tools: use, storage		
55		Outdoor areas: constructed, maintained clean		
56		Garbage/refuse: properly disposed, fac constr, maintained		
57		Ventilation: installed, maintained; Lighting: adequate, shielded		
58		Other		

Any one of the following 3 requires a Follow-up Inspection:
1. Five (5) or more marked of any items flagged with a "●".
2. Eleven (11) or more marked of any items 1 - 35.
3. Six (6) or more marked of any items 1-35 Plus eight (8) or more of any items 36-58.

Oklahoma State Department of Health
1000 NE 10th Street, Oklahoma City OK 73117-1299
Telephone (405) 271-5243 Fax (405) 271-3458
Website: www.ok.gov/health

Consumer Protection Division

Food Inspection Report
State Code OAC 310:257

Establishment	**Establishment #**	**Date**

TEMPERATURE OBSERVATIONS

Item/Location	Temp	Item/Location	Temp	Item/Location	Temp

OBSERVATIONS AND CORRECTIVE ACTIONS

Item Number	Violations cited must be corrected within the time frames below	**Correct By**:

Comments:

Inspector Signature	**RS#**	**Inspector Phone #**
Person In Charge Name		**Person In Charge Signature**
Establishment Email		**Establishment Phone #**

OAC 310:257 - Subchapters & Paragraphs Listed Below
Good Retail Practices

	Food Temperature Control	
36	Microwave, Slacking, Thawing, Cooling methods	5-47; 5-55; 5-56; 5-58 b
37	Equipment thermometers provided, conspicuous	7-37 a-d
	Food Identification	
38	Food properly labeled, original container, honestly presented	5-2 f,g; 5-15 b; 5-19; 5-24; 5-39; 5-50 b; 5-65; 5-66; 5-67 a, b1-4, b6-7, c,d; 5-68
39	Contamination prevented during food preparation, storage & display Washing fruits and vegetables	5-17; 5-21 d; 5-23 a3-8; 5-27; 5-29; 5-32; 5-36; 5-37; 5-38; 5-40; 5-42; 5-44 b; 5-45; 5-71 8; 13-8 b
	Mobile pushcarts, retail food service establishment, commissary	17-2 a; 17-2 c; 17-4 d; 17-5 b; 17-6
40	Personnel: cleanliness, jewelry, hair restriants	3-16; 3-17; 3-20
41	Eating, drinking, tobacco; No discharge from eyes, nose, mouth	3-18; 3-19
42	Wiping cloths proper use & storage; Sponges prohibited 5-33;	5-33; 7-6; 7-102
	Proper Use of Utensils	
43	In-use utensils properly stored, cleaning frequency; Utensils, linens, equipment properly stored, dried, handled; Linens clean	5-31; 7-59 a,b; 7-96 thru 7-99; 7-101; 7-105 a,b,d 7-106, 7-107 b; 7-108; 7-109; 17-6
44	Single-use, single-service articles: properly stored, used	7-80; 7-81; 7-105 a,c; 7-106; 7-107 a,c
	Utensils, Equipment & Vending	
45	Food / non-food contact surfaces: cleanable, designed, constructed used	5-34 b,c,d; 5-35; 7-1 2,3,4,5; 7-2; 7-9; 7-10; 7-11; 7-12 1B, 2B; 7-13; 7-16 a2,b; 7-17 thru 7-21; 7-27; 7-28 1-4; 7-29 thru 7-34; 7-46 thru 7-49; 7-60 thru 7-64; 7-103; 7-104; 17-1 c
46	Manual/Mechanical warewashing facilities: maintained, operated; Pressure gauges, data plates; Use limitation, pre-cleaning; Design; drain boards	7-25; 7-38; 7-39; 7-43; 7-44; 7-45; 7-51 c,d,e,f 7-52; 7-57; 7-65; 7-66; 7-67; 7-69; 7-74; 7-76; 7-87 thru 7-91
47	Non-food contact surfaces clean; Equip/utensil cleaning frequency	7-82 b,c; 7-84; 7-85
	Physical Facilities	
48	Plumbing systems: maintained, backflow devices installed, inspected	9-14 b,c,d; 9-22; 9-24; 9-30 2; 9-31 2,3; 9-32 thru 9-36; 9-37 2-5; 9-39; 9-40; 9-42; 9-43; 9-44 b; 9-45; 9-47 b,c,d; 9-48; 9-51; 9-53
49	Toilet facilities: proper construction, accessible, supplied, cleaned; Self closures	9-19; 9-61; 11-14; 11-36; 11-47; 11-48
	Mobile pushcarts, retail food service establishment,	17-2 c2, d1; 17-4 f
50	Break rooms, Locker areas: used, provided, maintained; Living areas separate; Laundry facilities	7-54; 7-59 c; 7-100; 11-22; 11-33; 11-37; 11-49
51	Hand washing sinks designed, clean, used; Proper signage	9-13 b; 11-26; 11-27; 11-47
52	Floors, walls, ceilings (premises): clean, maintained free of litter Removal of pests	11-41; 11-42; 11-51; 11-53
53	Floors, walls, ceilings (physical facilities): properly designed, maintained, good repair; Outer openings protected Mobile food service establishment	11-1; 11-3 through 11-10; 11-15; 11-16; 11-40; 11-46 17-3 a
54	Service sinks; Maintenance and cleaning tools properly used & stored	7-86; 9-20; 11-45; 11-52
55	Outdoor areas: constructed, maintained, clean	11-2; 11-17; 11-18; 11-19
	Mobile Commissary & servicing area	17-5 e
56	Garbage & refuse: properly disposed, facilities constructed, maintained	9-55 thru 9-60; 9-62 thru 9-73; 11-20
57	Ventilation: installed, maintained; Lighting: adequate, shielded	7-22; 7-26; 7-53; 11-11; 11-12; 11-31; 11-32; 11-43

Instructions for Marking Guide – 2009 Food Code

Priority items- proven meausres that are directly linked to the elimination, prevention or reduction of hazards associated with foodborne illness.
Priority Foundation items- incorporate specific actions, equipment or procedures to control risk factors that contibute to foodborne illness.

Supervision	
1. IN OUT 15-12, 15-21 17-2(c)(3) & (d)(2) 17-3(b) & (d) 17-4(c) & (e) 17-5(c) Note: References above are based on Oklahoma State Department of Health (OSDH) Food Code	<u>Valid License to Operate; non-transferable</u> 15-12: Prerequisite for operation 15-21: Licenses not transferable <u>Mobile pushcarts</u> 17-2(c)(3): indoor carts shall have a licensed commissary within confines of facility 17-2(d)(2): outdoor carts shall have a licensed commissary <u>Mobile F. S. E</u> 17-3(b): shall remain at one physical location no more than 12 hours unless in conjunction with a single event or celebration 17-3(d): business name & OSDH license number clearly visible on outside of vehicle during operation <u>Mobile Retail F. S. E</u> 17-4(c): shall remain at one physical location no more than 12 hours unless in conjunction with a single event or celebration 17-4(e): business name & OSDH license number clearly visible on outside of vehicle during operation <u>Commissary & servicing area requirements</u> 17-5(c): Commissaries shall be licensed FSE if used for food production
●2. IN OUT 2-101.11[Pf] 2-102.11 [Pf] 2-103.11 [Pf]	<u>PIC present, demonstration of knowledge, performs duties</u> 2-101.11: Assignment 2-102.11: Demonstration 2-103.11: Person in Charge
3. IN OUT N/A 3-404.11(A)[P] 3-502.12 (A),(B4),(C),(E1) [P] 4-204.110(A) [P] 8-103.12(A)[P] 3-404.11(B)[Pf] 3-502.11 [Pf] 3-502.12(B) 1-3,5,6 [Pf] 3-502.12(D-1)(D-2a,f,g,h) [Pf] 3-502.12 (D3, D4) [Pf] 3-502.12 (E-2,3,4) [Pf] 4-204.110(B)[Pf] 8-103.11 [Pf] 8-103.12(B)[Pf] 8-201.14 [Pf]	<u>Special processes (Variance, ROP, shellfish tanks, juice, HACCP)</u> 3-404.11(A): Treating juice - (packaged under HACCP PLAN - 5 log reduction) 3-502.12(A): ROP, criteria-(ROP shall control C.bot and Listeria) 3-502.12(B 4): ROP, criteria-(14 days/use-by or sell-by) 3-502.12(C): ROP, criteria-(no ROP of fish unless maintained frozen) 3-502.12(E1): ROP cheese packaging 4-204.110(A): Molluscan shellfish tanks-(marked display only) 8-103.12(A): Conformance w/ approved procedures –(complies w/ HACCP plans) 3-404.11(B)Treating juice – (food establishment - label if not treated to reduce microorganisms) 3-502.11: Variance requirement 3-502.12(B) 1-3,5,6: ROP w/o a variance, criteria -(ROP HACCP plan requirements/instructions; proper discard, no BHC, physical barriers, training program) 3-502.12(D-1)(D-2a,f,g,h)(D3, D4): ROP w/o variance, cook-chill or sous vide 3-502.12 (E-2,3,4): ROP, cheese (HAACP, labeling, 30 day shelf life) 4-204.110(B): Molluscan Shellfish Tanks-(variance if offered for consumption) 8-103.11: Documentation of Proposed Variance & Justification 8-103.12(B): Conformance with approved procedures- (documentation, monitoring & records) 8-201.14: Contents of HACCP plan

Employee Health	
●4. IN OUT 2-201.11(A)(D)(F) [P] 2-201.12 [P] 2-201.13 [P] 2-201.11 (B)(E) [Pf]	<u>Ill workers – PIC & employee responsibilities; Report symptoms & diagnosis; Restrict/Exclude (removal, retain or adjust)</u> 2-201.11 (A,D,F): Responsibility of PIC to require reporting by food employees and applicants-(employee to report diagnosis, symptoms-excluded/restricted) 2-201.12: Exclusions and Restrictions 2-201.13: Removal, adjustment, or retention of exclusions and restrictions 2-201.11 (B,E): Responsibility of the PIC to require reporting by food employees and applicants
Control of Hands as a Vehicle of Contamination	
●5. IN OUT N/O N/A 2-301.11 [P] 2-301.12 [P] 2-301.14 [P] 2-301.15 [Pf] 2-301.16 [Pf] 2-302.11 [Pf]	<u>Hands clean, washed, maintained; Hand antiseptics</u> 2-301.11: Clean Condition (hands arms) 2-301.12: Cleaning Procedure (how to wash) 2-301.14: When to Wash 2-301.15: Where to Wash 2-301.16: Hand Sanitizers (CFR, how to use) 2-302.11: Maintenance (fingernails trimmed, no polish, gloves good repair)
●6. IN OUT N/O N/A 3-301.11(B) [P] 3-304.15(A) [P] 3-301.11(C) [Pf]	<u>No BHC with RTE foods or alternate methods</u> 3-301.11(B): Preventing Contamination from Hands (no bare hand contact with RTE-or shall use alternate methods) 3-304.15(A): Gloves, Use Limitation (if gloves used; one task only, discard when necessary) 3-301.11(C): Preventing contamination from hands-(Minimize bare hand/arm contact with exposed food that is not in a RTE form)
7. IN OUT 5-202.12(A) [Pf] 5-203.11(A) [Pf] 5-204.11 [Pf] 5-205.11 [Pf] 6-301.11 [Pf] 6-301.12 [Pf] 6-302.11 [Pf]	<u>Adequate/accessible handwashing facilities/soap/paper towels/toilet tissue</u> 5-202.12(A): Hand washing Facility, installation (water at 100°F at hand sink) 5-203.11(A): Numbers & Capacities, handwashing Facilities 5-204.11: Location & Placement, handwashing Facilities 5-205.11: Using a hand washing facility-(maintained, no other purpose) 6-301.11: Hand washing cleanser, availability 6-301.12: Hand drying provision 6-302.11: Toilet tissue, availability-(toilet paper available at toilets)
Approved Source	
●8. IN OUT 3-201.11(A) (B) [P] 3-201.12 [P] 3-201.13 [P] 3-201.14 [P] 3-201.15 [P] 3-201.16 [P] 3-201.17 [P] 3-202.13 [P] 3-202.14 [P] 3-202.16 [P] 3-202.110(B) [P], 3-303.11 [P] 5-101.11 [P], 5-101.13 [P] 5-102.11 [P], 5-102.12 [P] 3-201.11(C&E) [Pf] 3-202.110(A) [Pf] 5-102.13 [Pf]	<u>Food, water, ice: obtained from approved source</u> 3-201.11(A) (B): Compliance with food Law-(source, home prepared prohibited) 3-201.12: Food in a Hermetically sealed Container-(regulated food processor) 3-201.13: Fluid Milk and Milk Products 3-201.14: Fish 3-201.15: Molluscan Shellfish 3-201.16: Wild Mushrooms; 3-201.17: Game Animals 3-202.13: Eggs 3-202.14: Eggs and Milk Products, Pasteurized 3-202.16: Ice 3-202.110(B): Juice Treated –(pasteurized, raw sold from production site only) 3-303.11: Ice Used as Exterior Coolant, prohibited as ingredient 5-101.11: Approved system- (water); 5-101.13: Bottled drinking water 5-102.11: Quality, standards (water); 5-102.12: Non-drinking water <u>Food labeling/Water sampling/ Juice from approved processor</u> 3-201.11(C&E): Compliance with food law-packaged, frozen fish in raw form, whole-muscle intact beef (labeled, written specs.) 3-202.110(A): Juice treated –(HACCP system) 5-102.13: Sampling-(non-community H_20 sampled)

●9. IN OUT 3-101.11 P 3-202.15 Pf 6-404.11 Pf	Food in good condition, safe, unadulterated, segregated 3-101.11: Safe, Unadulterated and Honestly Presented 3-202.15: Package Integrity-(packages in good condition) 6-404.11: Distressed Merchandise, Segregated and Location
●10. IN OUT N/A 3-402.11(A) P 3-202.17(A) Pf , 3-202.18(A)Pf 3-203.12 Pf 3-402.12(A&C) Pf	Required records (shellstock tags, parasiste destruction) 3-402.11(A): Parasite destruction-(fish freezing requirements) 3-202.17(A):Shucked Shellfish, Packaging and Identification-(proper labels) 3-202.18(A): Shellstock identification-(proper labels) 3-203.12: Shellstock, maintaining identification-(Labels-90 days) 3-402.12(A&C): Records, creation and retention-(frozen records/letter from supplier)
Protection from Contamination	
●11. IN OUT N/O 3-301.12 P 3-302.11(A1)-a&b P 3-302.11(A2)P 3-304.11 P 3-306.11 P 3-306.13(A) P 4-502.12 P 3-306.13(B&C) Pf 4-302.11Pf	Food separated/protected; Proper tasting procedures; Self-service operation; Single service use when required 3-301.12: Preventing Contamination when Tasting 3-302.11(A1)-a&b; 3-302.11(A2): Packaged and unpackaged food-separation, packaging, and segregation-(Raw animal food separate from RTE and each other) 3-304.11: Food Contact with Equipment and Utensils Food separated/protected; Proper tasting procedures; Self-service operation; Single service use when required continued… 3-306.11: Food Display-(protection from self-serve food contamination/guards) 3-306.13(A): Consumer Self-Service Operations-(Raw not for self-service) 4-502.12: Single-service and Single-use Articles, required Use-(if inadequate ware washing) 3-306.13(B&C): Consumer Self-Service Operations-(RTE self-service protection/salad bars monitored) 4-302.11: Utensils, consumer self-service-(available for each food item)
12. IN OUT N/O N/A 3-306.14(A) P 3-701.11(A-D) P	Disposition of returns, previously served, Reconditioned, unsafe food 3-306.14(A): Returned Food and Re-Service of Food-(not re-served) 3-701.11(A-D): Discarding or reconditioning unsafe, unadulterated, or contaminated food
13. IN OUT N/O N/A 6-202.111P 2-403.11(A)Pf 6-501.115(A)Pf	Prohibited animals; Prohibited food operation locations 6-202.111: Private homes and living or sleeping quarters, use prohibition-(no food service operations) 2-403.11(A): Handling Prohibition-(employees may not touch animals) 6-501.115(A): Prohibiting Animals-(live animals not allowed)
14. IN OUT N/O 6-501.15 Pf	Sinks used for intended purpose 6-501.15: Cleaning maintenance tools, preventing contamination- (food prep/hand & ware washing sinks used for no other purpose)
15. IN OUT N/O 4-101.11(A) P 4-101.13(A) P 4-101.14(A) P 4-101.15P 4-101.13(B)P 4-101.13(C) P 4-102.11(A1)(B1)P 4-201.12P 4-204.110(A)P, 4-204.111 P 4-202.11Pf, 4-202.12A(1)Pf	Food equipment: improper use, operation (Materials,design) 4-101.11(A): Characteristics-(food contact material may not impart, must be safe) 4-101.13(A): Lead in ceramics, china, crystal, use limitation 4-101.14(A): Copper, Use Limitation, 4-101.15: Galvanized Metal, Use Limitation 4-101.13(B): Lead in Pewter Alloys, Use Limitation 4-101.13(C): Lead in solder and flux, Use Limitation 4-102.11(A1)(B1): Characteristics-(single-service/single-articles safe) 4-201.12: Food temperature measuring device-(no glass except candy) 4-204.110(A): Molluscan Shellfish tanks- (display tanks not for human consumption) 4-204.111: Vending Machine, Automatic Shutoff 4-202.11: Food-Contact Surfaces-(Multi-use; proper construction) 4-202.12A(1): CIP equipment-(cleaning & sanitizing through a fixed system)
16. IN OUT 11-50Pf(1,2,4)---OSDH code reference	Insects, rodents, & animals not present 11-50(1,2,4):Controlling Pests, (presence shall be controlled, inspections, no harborages)

Time/Temperature Control for Safety (TCS)	
●17. IN OUT N/O N/A 3-401.11A(1-3)&B(2)[P] 3-401.12(C)[P] 3-401.13 [Pf]	Cooking time & temperatures; Plant food cooking 3-401.11A(1-3) & B(2): Raw Animal Foods-(cook times and temperatures) 3-401.12(C): Microwave Cooking-(cook temp.) 3-401.13: Plant food cooking for hot hold
●18. IN OUT N/O N/A 3-403.11(A-D) [P]	Reheating procedures for hot holding 3-403.11(A-D): Reheating for Hot Hold
●19. IN OUT N/O N/A 3-501.14 [P] 3-501.15(A)[Pf]	Cooling time & temperature; cooling methods 3-501.14: Cooling-(time/temperature parameters) 3-501.15(A): Cooling methods
●20. IN OUT N/O N/A 3-202.11(D) [P] 3-501.16(A1)[P]	Hot holding temperatures, received at proper temperature 3-202.11(D): Temperature-(received at 135º) 3-501.16(A1): TCS food, hot and cold holding-(135º or above)
●21. IN OUT N/O N/A 3-202.11(A)(C) [P] 3-501.16(A2) [P] 3-501.16(B)[P] 3-202.11(E)(F) [Pf]	Cold holding temperatures, received at proper temperature 3-202.11(A)(C): Temperature-(received at 41º/eggs 45º) 3-501.16(A2): TCS, hot & cold holding-(41º or below) 3-501.16(B): TCS, hot & cold holding- (eggs refrigerated equipment ambient air of 45º or less) 3-202.11(E)(F): Temperature-(shipped and received frozen, no signs of temperature abuse)
22. IN OUT N/O N/A 3-501.18 [P] 3-501.17 [Pf]	Date marking & disposition 3-501.18: RTE, TCS Food, Disposition-(RTE must be discarded if date expired or no date) 3-501.17: RTE, TCS, date marking –(41º for 7 days & other procedural options)
●23. IN OUT N/O N/A 3-501.19(B)1,3,4[P] 3-501.19(C)1,4,5 [P] 3-501.19(A)(B2)(C2)(C3)[Pf]	Time as public health control, procedures/records 3-501.19(B)1,3,4 & 3-501.19(C)1,4,5: Time as a Public Health Control-(4hr/6hr start & discard times) 3-501.19(A)(B2)(C2)(C3): Time as a public health control –(RTE, TCS, Procedures/labeling)
●24. IN OUT N/O N/A 3-401.14(A-E) [P] 3-401.1(F)1-5 [Pf]	Non-continuous cooking process/ partial cook 3-401.14(A-E): Non-Continuous Cooking of Raw Animal Food-(procedures for partial cooking of meats) 3-401.1(F)1-5: Non-continuous Cooking of Raw Animal-(procedural requirements)
25. IN OUT N/O N/A 4-301.11 [Pf]	Adequate facilities/equipment to maintain food temperatures (hot/cold hold, cool, reheat) 4-301.11: Cooling, Heating, and Holding Capacities-(adequate equipment to maintain food temperatures)
26. IN OUT N/O N/A 4-203.11 [Pf] 4-203.12 [Pf] 4-204.112(E)[Pf] 4-302.12 [Pf] 4-502.11(B)[Pf]	Probe thermometers provided & accurate (food, air, dishmachines) 4-203.11: Temperature Measuring Devices, Food-(scaled & accurate) 4-203.12: Temperature Measuring Devices, Ambient Air and Water-(scaled & accurate) 4-204.112(E): Temperature Measuring Devices-(± 1º C or 2º F) 4-302.12: Food Temperature Measuring Device-(provided, thin tip when needed) 4-502.11(B): Good Repair and Calibration-(calibrated to manufacturer specs.)

Consumer Advisory, Highly Susceptible Populations	
27. IN OUT N/A 3-401.11(D2)[Pf] 3-602.11(B5)[Pf] 3-603.11[Pf]	<u>Consumer advisory / Child menu / Allergen labeling</u> 3-401.11(D2): Raw Animal Foods-(children's menu does not offer under cooked comminuted meat 3-602.11(B5): Food allergens –(major food allergen ingredient) 3-603.11: Consumption of animal foods that are raw, undercooked, or not otherwise processed to eliminate pathogens –(Consumer Advisory: disclosure/reminder)
28. IN OUT N/A 3-302.13[P] 3-801.11(A)2,3[P] 3-801.11B,C,E[P]	<u>Pasteurized food used; Prohibited foods not offered; Pastuerized eggs used where required</u> 3-302.13: Pastureized eggs, substitute for raw eggs for certain recipes 3-801.11(A)2,3[P] & 3-801.11B,C,E: Pasteurized foods, prohibited reservice, and prohibited food
Chemicals	
29. IN OUT N/A 3-202.12[P], 3-302.14[P]	<u>Food additives: approved, properly used</u> 3-202.12: Additives-(must use approved additives) 3-302.14: Protection from Unapproved Additives
30. IN OUT 7-201.11[P] 7-202.12(A,B)[P] 7-203.11[P] 7-204.11[P] 7-204.12(A)[P] 7-204.13[P] 7-204.14[P] 7-205.11[P] 7-206.11[P] 7-206.12[P] 7-206.13(A)[P] 7-207.11(B)[P] 7-207.12[P] 7-208.11(B)[P] 7-301.11[P] 6-501.111(C)[Pf], 7-101.11[Pf] 7-102.11[Pf], 7-202.11(A)[Pf] 7-202.12(C)[Pf] 7-207.11(A)[Pf]	<u>Toxic substances properly identified, stored, used</u> 7-201.11: Storage Separation-(separate from food) 7-202.12(A,B): Conditions of Use-(toxic items properly used and applied) 7-203.11: Poisonous or Toxic Material Containers-(can't put food in toxic item container) 7-204.11: Sanitizers, Criteria-(meet 40 CFR) 7-204.12(A): Chemicals for Washing Fruits and Vegetables, Criteria-(21 CFR) 7-204.13: Boiler Water Additives, Criteria 7-204.14: Drying Agents, Criteria-(21 CFR) 7-205.11: Incidental Food Contact, Criteria-(lubricants meet 21 CFR), 7-206.11 Restricted Use Pesticides, Criteria-(use according to 40 CFR), 7-206.12 Rodent Bait Stations-(covered, tamper resistant) 7-206.13(A): Tracking Powders, Pest Control and Monitoring-(no tracking powders) 7-207.11(B): Restriction and Storage-(employee medicines only) 7-207.12: Refrigerated Medicines, Storage-(stored in a container, identified) 7-208.11(B): Storage-(first aid supplies properly stored) 7-301.11: Separation-(toxic items for retail sale properly stored) 6-501.111(C): Controlling Pests-(methods to control are approved) 7-101.11: Identifying Information, Prominence-(toxic items labeled w/manufacturer) 7-102.11: Common Name-(working toxic item container labeled with common name) 7-202.11(A): Presence and Use, Restrictions-(on site only for food operations & maintenance) 7-202.12(C): Conditions of use –(application by Certified Operators only) 7-207.11(A): Restriction and Storage-(employee medicines only)

Ware washing, Food Contact Surfaces	
31. IN OUT N/A N/O 4-204.115 [Pf], 4-204.116[Pf] 4-204.117 [Pf], 4-301.12(A, B)[Pf] 4-302.14[Pf], 4-501.17 [Pf] 4-501.116[Pf]	<u>WW, sanitize equipment: design, adequate supplies, properly operated;</u> <u>Test strips, temperature gauges, alarms</u> 4-204.115: Warewashing Machines, Temperature Measuring Devices-(wash, rinse, sanitize temps measured); 4-204.116: Manual Ware washing Equipment, Heaters and Baskets-(integral heating device with baskets) 4-204.117: Warewashing Machine, Automatic dispensing of Detergents and Sanitizers-(automatically dispensed and have an alarm) 4-301.12(A, B): Manual Warewashing, Sink Compartment Requirements-(three compartments, adequate size) 4-302.14: Sanitizing Solutions, Testing Devices-(test kit required) 4-501.17: Warewashing Equipment, Cleaning Agents-(cleaning agent required) 4-501.116: Warewashing Equipment, Determining Chemical Sanitizer Concentration-(concentration determined using a test kit)
32. IN OUT N/A N/O 4-501.111 [P] 4-501.114[P] 4-703.12[P] 4-501.19[Pf] 4-501.110 [Pf] 4-501.112(A) [Pf]	<u>Ware washing sanitize as required at ___ ppm/temperature</u> 4-501.111: Manual Ware washing Equipment, Hot Water Sanitization Temperature 4-501.114: Manual and Mechanical Warewashing Equipment, Chemical Sanitization-temperature, pH, concentration, and hardness 4-703.12: Hot water and chemical (sanitization) 4-501.19: Manual Warewashing Equipment, Wash Solution Temperature 4-501.110: Mechanical Warewashing Equipment, Wash Solution Temperature 4-501.112(A): Mechanical Warewashing Equipment, Hot Water Sanitization Temperature
33. IN OUT N/A 4-602.11(A,C)[P] 4-702.11 [P] 4-601.11(A) [Pf]	<u>Food contact surfaces of equipment and utensils clean</u> 4-602.11(A,C): Equipment Food-contact Surfaces and Utensils-(cleaned and sanitized between uses) 4-702.11: Before Use After Cleaning-(sanitized before use) 4-601.11(A): Equipment, Food-contact Surfaces, Nonfood-contact Surfaces, and Utensils-(clean to sight and touch)
Plumbing	
34. IN OUT 5-103.11 [Pf] 5-103.12 [Pf] 5-104.11[Pf] 5-104.12[Pf]	<u>Water (hot and cold): adequate pressure, sufficient capacity</u> 5-103.11: Quantity and Availability, Capacity-(water source sufficient capacity to meet peek demands including mobiles and seasonals) 5-103.12: Pressure-(adequate pressure) 5-104.11: Distribution, delivery, and retention, system 5-104.12: Alt.water supply – (when interrupted delivered in approved containers/tanks)
35. IN OUT 5-101.12 [P], 5-201.11 [P] 5-202.11(A) [P] 5-202.13 [P] 5-202.14 [P] 5-203.14 [P] 5-205.12 [P] 5-205.14 [P] 5-205.15(A)[P] 5-301.11(A)[P] 5-302.16(A)[P] 5-303.11[P] 5-304.11[P] 5-304.14(A)[P] 5-402.11(A)[P]	<u>Plumbing/sewage system: designed, approved, installed;</u> <u>Cross-connections prohibited, air gaps, disposal</u> 5-101.12:System Flushing and Disinfection-(water system disinfected after repair, before use) 5-201.11: Materials approved 5-202.11(A): Approved System and Cleanable Fixtures-(installed according to law) 5-202.13: Backflow Prevention, Air Gap-(water supply air gap twice the diameter of H_2O line) 5-202.14: Backflow Prevention Device, Design Standard-(backflow properly designed) 5-203.14: Backflow Prevention Device, When Required-(preclude backflow, hose bibb if hose attached or required by law) 5-205.12(A): Prohibiting Cross Connection 5-205.14: Water Reservoir of Fogging Devices, Cleaning 5-205.15(A): System Maintained in Good Repair-(repaired according to law) 5-301.11(A): Materials, Approved-(mobile water tank materials safe) 5-302.16(A)Hose, Construction and Identification-(hoses for conveying water-safe) 5-303.11: Filter, Compressed Air 5-304.11: System Flushing and Disinfection-(tanks pumped, flushed, disinfected) 5-304.14(A): Tank, Pump, and Hoses, Dedication-(FOOD hoses no other purpose) 5-402.11(A): Backflow Prevention-(no direct connection with sewage and food/equipment sinks)

	Plumbing/sewage system: designed, approved, installed; Cross-connections prohibited, air gaps, disposal cont…
5-402.13[P]	5-402.13: Conveying Sewage-(sanitary sewage system, vehicles)
5-403.11[P]	5-403.11: Approved sewage Disposal System-(public or approved on-site system)
5-205.12(B) [Pf]	5-205.12(B): Prohibiting Cross Connection (identify non-potable H_20 piping)
5-205.13[Pf]	5-205.13: Scheduling Inspection for a Water System Device-(water treatment devices
5-402.14[Pf]	required inspections)
	5-402.14: Removing Mobile food Establishment Wastes-(approved waste servicing area)

Core items- relate to general sanitation & maintenance, equipment design & maintenance, and physical facilities & structures.

Food Temperature Control	
36.	Approved thaw methods; Active cool containers stored properly
3-401.12	3-401.12: Microwave Cooking (procedures; rotate, standing time)
3-501.12	3-501.12 : Time/temperature control for safety food (TCS), slacking
3-501.13	3-501.13 : Thawing
3-501.15(B)	3-501.15(B): Cooling Methods-(foods properly arranged, uncovered if no contamination)
37.	Thermometers provided, accurate, conspicuous
4-204.112(A-D)	4-204.112(A-D): Temperature Measuring Devices-(inside hot and cold holding/storage units; integral or permanently fixed)
Food Identification	
38.	Food properly labeled, original container, honestly presented
3-201.11 (F,G)	3-201.11 (F,G): Compliance with food Law-(meat and egg safe handling)
3-202.17(B)	3-202.17(B): Shucked Shellfish, Packaging and Identification-(no label, shall be subject to hold order)
3-203.11	3-203.11: Molluscan Shellfish, Original Container-(remain in container until sale or preparation)
3-302.12	3-302.12: Food Storage Containers, Identified with Common Name of Food
3-305.13	3-305.13: Vended TCS food, Original Container
3-402.12(B)	3-402.12(B): Records, creation and retention (supplier letter)
3-601.11	3-601.11: Standards of Identity-(packaged foods comply with 21 CFR, 9 CFR)
3-601.12	3-601.12: Honestly Presented-(foods offered, not mislead, no color wraps; lights, etc.)
3-602.11(A)(B1-B4)(B6-7)(C-D)	3-602.11(A)(B1-B4)(B6-7)(C-D): Food Labels-(packaged in FSE labeled under 21 CFR & 9 CFR, bulk foods for self-serve labeled)
3-602.12	3-602.12: Other Forms of Information-(warnings if required, date labels readable)
Prevention of Food Contamination	
39.	Contamination prevented during food preparation, storage & display; Washing fruits/vegetables
3-202.19	3-202.19: Shellstock, Condition-(clean, alive)
3-301.11(D)	3-301.11(D): Preventing Contamination from Hands(written policy)
3-302.11(A3-A8)(B)	3-302.11(A3-A8)(B): Packaged and Unpackaged Food-Separation, Packaging, and Segregation-(protect by clean sanitized equip. covered, cleaned packaging, separate unwashed fruits)
3-302.15	3-302.15: Washing Fruits and Vegetables-(shall be thoroughly washed prior to preparation)
3-303.12	3-303.12: Storage or Display of Food in Contact with Water or Ice-(packaged foods not allowed if entry of water, cans and bottles in draining ice)
3-304.13	3-304.13: Linens and Napkins, use Limitation-(only for lined containers changed after each use)
3-304.17	3-304.17: Refilling Returnables-(proper procedures)
3-305.11	3-305.11: Food Storage-(protected by properly stored, not exposed, 6 inches off floor)
3-305.12	3-305.12: Food Storage Prohibited Areas
3-305.14	3-305.14: Food Preparation-(protected while being prepared)
3-306.12	3-306.12: Condiments, Protection
3-306.14(B)	3-306.14(B): Returned food and Re-Service of Food-(Non-TCS food may be reserved under certain conditions)
3-307.11	3-307.11: Miscellaneous Sources of Contamination

3-801.11(H) 7-204.12(B)	Contamination prevented during food preparation, storage & display; Washing fruits/vegetables cont… 3-801.11(H): Pasteurized foods, Prohibited Reservices, and Prohibited Food (reserving packaged foods is limited under certain conditions) 7-204.12(B): Chemicals for Washing Fruits and Vegetables-(ozone allowed)
40. 2-303.11 2-304.11 2-402.11	Personnel: clean, jewelry, hair restraints, FH permits 2-303.11: Prohibition-(no jewelry except plain ring) 2-304.11: Clean Condition-(clean clothes) 2-402.11 : Effectiveness-(proper hair restraints)
41. 2-401.11 2-401.12	Eating, drinking, tobacco use; No discharge from eyes, nose, mouth 2-401.11: Eating, Drinking, or Using Tobacco 2-401.12: Discharges from the Eyes, Nose and Mouth
42. 3-304.14 4-101.16 4-901.12	Wiping cloths: properly used and stored; Sponges prohibited 3-304.14: Wiping Cloths, Use Limitation-(proper storage, approved use) 4-101.16: Sponges, Use Limitation-(not allowed on food contact surfaces or equip.) 4-901.12: Wiping Cloths, Air-Drying Locations-(air dry after laundered if no contamination)
Proper Use of Utensils	
43. 3-304.12 4-401.11(A&B) 4-801.11 4-802.11 4-803.11 4-803.12 4-901.11 4-903.11 (A),(B),(D) 4-903.12 4-904.11(B) 4-904.12 4-904.13	In-use utensils proper storage, cleaning frequency; Utensils, equipment & linens: properly stored, dried, handled; Linens clean 3-304.12: In-Use Utensils, Between-Use Storage 4-401.11(A&B): Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention-(proper storage utensils/linens) 4-801.11: Clean Linens-(clean linens separate from soiled) 4-802.11: Specifications-(linens, gloves, wiping clothes laundered) 4-803.11: Storage of Soiled Linens-(clean non-absorbent containers or laundry bags) 4-803.12: Mechanical Washing-(linens, except for wiping cloths must be mechanically laundered) 4-901.11: Equipment and Utensils, Air-drying Required-(utensils, equipment air-dried) 4-903.11 (A),(B),(D): Equipment, Utensils, Linens and Single-Service and Single-Use Articles-(proper storage, air drying/self-draining, 6” from floor) 4-903.12: Prohibition-(equip. utensils, linens prohibited storage) 4-904.11(B): Kitchenware and Tableware-(knives, forks, spoons properly presented) 4-904.12: Soiled and Clean Tableware-(removed to prevent contamination of clean tableware) 4-904.13: Preset Tableware-(protected, removed)
44. 4-502.13 4-502.14 4-903.11 (A),(C) 4-903.12 4-904.11(A),(C)	Single-use, single-service articles: properly stored, used 4-502.13: Single-service and Single-use Articles, use limitation-(not reused) 4-502.14: Shells, Use Limitation-(shells used only once) 4-903.11 (A, C): Equipment, Utensils, Linens and Single-Service and Single-Use Articles-(single use, single serve proper storage, protected) 4-903.12: Prohibition-(single use, single serve prohibited storage) 4-904.11(A),(C): Kitchenware and Tableware-(single use/serve properly presented, dispensed, wrapped)

Utensils, Equipment and Vending	
45.	Food & non-food contact surfaces cleanable, design
3-304.15(B,C,D)	3-304.15(B,C,D): Gloves, Use Limitation-(restrictions on slash and cloth gloves)
3-304.16	3-304.16: Using Clean tableware for Second Portions and Refills-(clean plates used
4-101.11(B,C,D,E)	at buffets, signage, except drink cups if properly handled)
4-101.12	4-101.11(B,C,D,E):Characteristics-(durable, sufficient weight, smooth, resistant)
4-101.17	4-101.12: Cast Iron, use Limitation
4-101.18	4-101.17: Wood, Use Limitation
4-101.19	4-101.18: Nonstick coatings, Use Limitation
4-102.11 (A2, B2)	4-101.19: Nonfood Contact Surfaces
4-201.11	4-102.11 (A2, B2) Characteristics-(single-use/serve clean no transfer of odors, colors, tastes)
4-202.12(A2, B)	4-102.11 (A2, B2) : Equipment and Utensils-(constructed to be durable)
4-202.13	4-202.12(A2, B): CIP Equipment-(self-draining, easily disassembled)
4-202.14	4-202.13: "V" Threads, Use Limitation
4-202.15	4-202.14: Hot Oil Filtering Equipment
4-202.16	4-202.15: Can Openers
4-202.17	4-202.16: Nonfood-Contact Surfaces-(easily cleanable)
4-204.12	4-202.17: Kick Plates, Removable
4-204.13(A-D)	4-204.12: Equipment openings, Closures and Deflectors
4-204.14	4-204.13(A-D): Dispensing Equipment, Protection of Equipment and Food
4-204.15	4-204.14: Vending Machine, Vending Stage Closure
4-204.16	4-204.15: Bearings and Gear Boxes, leakproof
4-204.17	4-204.16 : Beverage Tubing, Separation-(tubing and cold plates may not contact drink ice)
4-204.18	4-204.17: Ice Units, Separation of Drains
4-204.19	4-204.18: Condenser Unit, Separation
4-204.121	4-204.19: Can Openers on Vending Machines
4-204.122	4-204.121: Vending Machines, Liquid Waste Products
4-204.123	4-204.122 : Case Lot Handling equipment, Moveability
4-205.10	4-204.123: Vending Machine doors and Openings
4-402.11	4-205.10: Food Equipment, Certification and Classification
4-402.12	4-402.11: Fixed Equipment, Spacing or Sealing-(counter mounted; installed for
4-501.11	cleaning, sealed to counter, proper spacing, elevated on legs)
4-501.12	4-402.12: Fixed Equipment, Elevation or Sealing-(floor mounted; sealed or elevated)
4-501.13	4-501.11: Good Repair and Proper Adjustment
4-902.11	4-501.12: Cutting Surfaces-(cutting boards)
4-902.12	4-501.13: Microwave Ovens-(meet safety standards)
	4-902.11: Food-Contact Surfaces-(lubricants applied)
	4-902.12: Equipment-(reassembled no contamination to food contact surfaces)
46.	Manual/Mechanical WW facilities: maintained, operated; Pressure gauges, data plates; Use limitation, pre-cleaning
4-203.13	4-203.13 : Pressure Measuring Devices, Mechanical Warewashing Equipment-
4-204.113	(proper increments)
4-204.114	4-204.113 : Warewashing Machine, Data Plate Operating Specifications-(data plate
4-204.118	accessible, readable, required information)
4-204.119	4-204.114: Warewashing Machines, Internal Baffles
4-204.120	4-204.118: Warewashing Machines, Flow Pressure Device (provided)
4-301.12 C,D,E	4-204.119: Warewashing Sinks and Drainboards, Self-Draining
4-301.13	4-204.120: Equipment compartments, Drainage-(sloped drainage of condensate, drippage)
4-302.13	4-301.12 C,D,E: Manual Warewashing, Sink Compartment Requirements-
4-501.14	(alternative where approved, restrictions if 2 compartment, exemptions)
4-501.15	4-301.13: Drainboards
	4-302.13: Temperature Measuring Devices, Manual Warewashing
	4-501.14: Warewashing Equipment, Cleaning Frequency
	4-501.15: Warewashing Machines, Manufacturers' Operating Instructions-(operated according to instructions)

	Manual/Mechanical WW facilities: maintained, operated; Pressure gauges, data plates; Use limitation, pre-cleaning cont…
4-501.16	4-501.16: Warewashing Sinks, Use Limitation-(not used for handwashing)
4-501.18	4-501.18: Warewashing Equipment, Clean Solutions (maintained clean)
4-501.113	4-501.113: Mechanical Warewashing Equipment, Sanitization Pressure
4-501.115	4-501.115: Manual Warewashing Equipment, Chemical Sanitization Using
4-603.12	Detergent-Sanitizers-(detergent-sanitizer same for cleaning and sanitizing)
4-603.13	4-603.12: Pre-cleaning-(food debris scrapped or pre-washed)
4-603.14	4-603.13: Loading of Soiled Items, Warewashing Machines-(proper loading to
4-603.15	exposes and allows for draining)
4-603.16	4-603.14: Wet Cleaning-(procedure is effective)
	4-603.15: Washing, Procedures for Alternative Manual Warewashing Equipment
	4-603.16: Rinsing Procedures
47.	Non-food contact surfaces clean; cleaning frequency
4-601.11(B),(C)	4-601.11(B),(C): Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and
4-602.12	Utensils-(food contact- free of encrusted grease, dust, dirt accumulations)
4-602.13	4-602.12:Cooking and Baking Equipment-(frequency)
	4-602.13: Nonfood Contact Surfaces-(frequency)
Physical Facilities	
48.	Plumbing systems: maintained, backflow devices installed, inspected where required
5-203.15	5-203.15: Backflow Prevention Device, Carbonator
5-204.12	5-204.12: Backflow Prevention Device, Location-(located to be serviced and maintained)
5-205.15(B)	5-205.15(B)System Maintained in Good Repair-(plumbing in good repair-leaks)
5-301.11(B,C)	5-301.11(B,C): Materials, Approved-(mobile water tanks durable, smooth)
5-302.11	5-302.11: Enclosed System, Sloped to Drain (mobile water tank)
5-302.12	5-302.12: Inspection and Cleaning Port, Protected and Secured
5-302.13	5-302.13: "V" Type Threads, Use Limitation-(only if hose permanently attached)
5-302.14	5-302.14: Tank Vent, Protected
5-302.15	5-302.15: Inlet and Outlet, Sloped to Drain
5-302.16(B-E)	5-302.16(B-E): Hose, Construction and Identification-(hoses, durable resistant, smooth)
5-303.12	5-303.12: Protective Cover or Device-(water inlet, outlet and hose)
5-303.13	5-303.13: Mobile Food Establishment Tank Inlet
5-304.12	5-304.12: Using a Pump and Hoses, Backflow Prevention-(proper use to prevent backflow)
5-304.13	5-304.13: Protecting Inlet, Outlet, and Hose Fitting
5-304.14 (B)	5-304.14 (B): Tank, Pump, and Hoses, Dedication-(if used for food may be used for water if cleaned and sanitized)
5-401.11	5-401.11: Capacity and Drainage-(mobile sewage holding tank properly sized and drained)
5-402.11(B,C,D)	5-402.11(B,C,D): Backflow Prevention-(exceptions for floor drains & warewashing)
5-402.12	5-402.12: Grease Trap-(installed to be cleanable)
5-402.15	5-402.15: Flushing a Waste Retention Tank--- mobile
5-403.12	5-403.12: Other Liquid Wastes and Rainwater-(disposed according to law)
49.	Toilet facilities: accessible, proper construction, cleaned; Self closures
5-203.12	5-203.12: Toilets and Urinals-(required)
5-501.17	5-501.17: Toilet Room Receptacle, Covered
6-202.14	6-202.14: Toilet Rooms, Enclosed-(tight-fitting, self-closing door)
6-402.11	6-402.11: Toilet Rooms, Convenience and Accessibility
6-501.18	6-501.18: Cleaning of Plumbing Fixtures
6-501.19	6-501.19: Closing Toilet Room Doors

50. 4-301.14 4-401.11(C) 4-803.13 6-202.112 6-305.11 6-403.11 6-501.110	Break/Locker areas: used, provided, maintained; Living areas separated; Laundry facilities 4-301.14: Clothes Washers and Dryers-(required if laundering, except for wiping cloths) 4-401.11(C): Equipment, Clothes Washers and Dryers, and Storage Cabinets, contamination Prevention-(washer/dryer location) 4-803.13: Use of Laundry Facilities-(used only for establishment needs) 6-202.112: Living or Sleeping Quarters, Separation 6-305.11: Designation-(dressing rooms/areas/lockers provided if necessary) 6-403.11: Employee Accommodations, Designated Areas-(break rooms/locker rooms no contamination) 6-501.110: Using Dressing Rooms and Lockers-(shall be used, orderly storage)
51. 5-202.11(B) 5-202.12(B, C, D) 6-301.13 6-301.14 6-501.18	Handwash sinks designed, clean, used; Proper signage 5-202.11(B): Approved System and Cleanable Fixture-(hand sinks easily cleanable) 5-202.12(B, C, D): Handwashing Facility, installation(15 seconds if metered, automatic follows manufacturer installation) 6-301.13: Handwashing Aids and Devices, Use Restrictions-(food and mop sinks not for handwashing, not provided with soap and towels) 6-301.14: Handwashing Signage 6-501.18: Cleaning of Plumbing fixtures-(handsinks cleaned as necessary)
52. 6-501.12 6-501.13 6-501.112 6-501.114 **Cleaning issues**	Floors, walls, ceilings (premises): clean, free of litter; Removal of pests 6-501.12: Cleaning, Frequency and Restrictions-(often as necessary, least amount of food exposed) 6-501.13: Cleaning Floors, Dustless Method 6-501.112: Removing Dead or Trapped Birds, Insects, Rodents, and other Pests 6-501.114: Maintaining Premises, Unnecessary Items and Litter-(items only necessary to operations, no litter)
53. 6-101.11 6-201.11 6-201.12 6-201.13 6-201.14 6-201.15 6-201.16 6-201.17 6-201.18 6-202.15 6-202.16 6-501.11 6-501.17 **Construction and repair issues**	Floors, walls, ceilings (physical facilities): design, maintained, good repair; Outer openings protected 6-101.11: Indoor Areas, Surface Characteristics-(floors, walls, ceilings design, construction, LRV in prep and wash areas) 6-201.11: Floors, Walls and Ceilings-(smooth easily cleanable) 6-201.12: Floors, Walls, and Ceilings, Utility Lines-(exposed lines exposed) 6-201.13: Floor and Wall Junctures, Coved, and Enclosed or Sealed 6-201.14: Floor Carpeting, Restrictions and Installation 6-201.15: Floor Covering, Mats and Duckboards 6-201.16: Wall and Ceiling Coverings and Coatings 6-201.17: Walls and Ceilings, Attachments 6-201.18: Walls and Ceilings, Studs, Joists, and Rafters 6-202.15: Outer Openings, Protected-(tight fitting doors/windows; self-closing; screening) 6-202.16: Exterior Walls and Roofs, Protective barrier (walls and roofs protect from weather and vermin) 6-501.11: Premises, Structures, attachments, and Fixtures-(kept in good repair) 6-501.17: Absorbent Materials on Floors, Use Limitation
54. 4-603.11 5-203.13 6-501.16 6-501.113	Service sinks; Maintenance and cleaning tools properly used and stored 4-603.11: Dry Cleaning-(restrictions if used) 5-203.13: Service Sink-(mop sink required, cannot use toilets) 6-501.16: Drying Mops-(position to allow drying) 6-501.113: Storing Maintenance Tools-(stored properly to maintain areas)

55. 6-102.11 6-202.17 6-202.18 6-202.19	<u>Outdoor areas: constructed, maintained, clean</u> 6-102.11: Outdoor Areas, Surface Characteristics-(parking lot, driveways, sidewalks etc. constructed to be cleaned, minimize dust and mud) 6-202.17: Outdoor Food Vending Areas, Overhead Protection 6-202.18: Outdoor Servicing Areas, Overhead Protection 6-202.19: Outdoor Walking and Driving Surfaces, Graded to Drain
56. 5-501.11 5-501.12 5-501.13 5-501.14 5-501.15 5-501.16 5-501.18 5-501.19 5-501.110 5-501.111 5-501.112 5-501.113 5-501.114 5-501.115 5-501.116 5-502.11 5-502.12 5-503.11 6-202.110	<u>Garbage & refuse: properly disposed, facilities constructed, maintained</u> 5-501.1: Outdoor Storage Surface-(constructed to be durable, sloped to drain) 5-501.12: Outdoor Enclosure-(if used durable) 5-501.13: Receptacles-(durable, rodent resistant, leak-proof) 5-501.14: Receptacles in Vending Machines 5-501.15: Outside Receptacles-(lids, effective cleaning, no accumulations of litter) 5-501.16: Storage Areas, Rooms, and Receptacles, Capacity and Availability-(provided in food areas and toilet rooms) 5-501.18: Cleaning Implements and Supplies (other supplies as needed) 5-501.19: Storage Areas, Redeeming Machines, Receptacles and Waste handling Units, Location 5-501.110: Storing Refuse, Recyclables, and Returnables-(inaccessible to rodents) 5-501.111: Areas, Enclosures, and Receptacles in Good Repair 5-501.112: Outside Storage Prohibitions 5-501.113: Covering Receptacles 5-501.114: Using Drain Plugs 5-501.115: Maintaining Refuse Areas and Enclosures 5-501.116: Cleaning Receptacles 5-502.11: Frequency (removal) 5-502.12: Receptacles or Vehicles (removal method) 5-503.11: Community or Individual Facility (solid waste removal) 6-202.110: Outdoor Refuse Areas, Curbed and Graded to Drain
57. 4-202.18 4-204.11 4-301.14 6-202.11 6-202.12 6-303.11 6-304.11 6-501.14	<u>Ventilation: installed, maintained; Lighting: adequate, shielded</u> 4-202.18: Ventilation Hood Systems, Filters (design) 4-204.11: Ventilation Hood Systems, Drip Prevention 4-301.14: Ventilation Hood Systems, Adequacy 6-202.11 : Light Bulbs, Protective Shielding 6-202.12: Heating, Ventilation, Air Conditioning System (systems installed so as to not cause contamination) 6-303.11: Lighting, Intensity 6-304.11: Ventilation, Mechanical (sufficient to remove air odors/particulates) 6-501.14: Cleaning Ventilation Systems, Nuisance and Discharge Prohibition
58.	Other

Conference for Food Protection
2012 Issue Form

Internal Number: 053
Issue: 2012 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.

Title:
Designation of Water Temperature at Handwashing Sinks as a Core Item

Issue you would like the Conference to consider:
To designate Section 5-202.12 (A) of the 2009 FDA Food Code as a Core Item, thereby changing the designation of delivery of water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet from a Priority Foundation to a Core Item.

Public Health Significance:
FDA Food Code Chapter 5 [Plumbing, Water and Waste] Section 5-202.12, Handwashing Sink, Installation, paragraph (A), recommends that, "A handwashing sink shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet..." This provision is currently designated as a Priority Foundation Item even though the temperature is specific to plumbing equipment and is not included in the handwashing procedures in section 2-301.12.

Hand-washing is an important food safety practice and specific procedures for hand washing are included in the Food Code in Section 2-301.12. The mechanical action of washing one's hands, use of soap, length of time hands are washed, rinsing, hand drying and proper hand-wash training have all been noted as important factors in accomplishing proper hand washing. More specifically, paragraph 2-301.12 (B) recommends that "warm water" be used for hand washing and rinsing, without a specific water temperature. Therefore the water temperature alone will not contribute directly to the elimination, prevention or reduction to an acceptable level, hazard associated with foodborne illness as specified in priority item definition.

Sighting a specific threshold water temperature does not predicate successful hand-washing, which can be accomplished at various water temperatures. This is supported by the work of Michaels et al (2002, see attached) which concluded that there was no statistical difference in log reductions for both resident and transient bacteria during handwashing based on water temperature (see attachment). The results reported by Michaels confirm the observations made by Price (Price 1938) and Larson (Larson *et al*. 1980) indicating water temperature has little or no effect on the removal of bacteria from hands.

In summary, specific procedures such as handwashing frequency, length and technique have been shown to have a direct impact on the risk factors that contribute to foodborne illness, and therefore are aligned with the definition of a priority foundation item.
However, the temperature of water delivered at a handwashing sink does not directly contribute to the elimination, prevention or reduction (to acceptable levels) of the hazards associated with foodborne illness. The temperature of the water is more consistent with the definition of a Core Item, which relates to general sanitation, operational controls, sanitation standard operating procedures (SSOP), facilities or structures, equipment design, or general maintenance. The plumbing recommendations listed in section 5-202.12 are consistent with the definition of a core item.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline and deleted language shown with strike-through):
Section 5-202.12 Handwashing Sink, Installation.
(A) A HANDWASHING SINK shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet. ~~Pf~~ C

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Attachments:

- "Michaels, Barry, et al. (2002) "Water temperature as a factor in handwa"

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

Water temperature as a factor in handwashing efficacy

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

Abstract

For many years, sanitarians have specified that the hands of food service workers should be washed and rinsed in warm or hot water to reduce the risk of cross-contamination and disease transmission. In the food service environment, it has been suggested that handwashing with water at higher temperatures contributes to skin damage when frequent handwashing is necessitated, and that insistence on hot water usage is a deterrent to handwashing compliance. Separate handwashing studies involving different water temperatures and soap types (antibacterial versus non-antibacterial) were performed. The 'glove-juice' technique was employed for microbial recovery from hands in both studies. Initial work evaluated antimicrobial efficacy based on water temperature during normal handwashing with bland soap. Uninoculated, sterile menstrua (tryptic soy broth or hamburger meat) was used to study the effects of treatment temperatures (4.4°C, 12.8°C, 21.1°C, 35°C or 48.9°C) on the reduction of resident microflora, while Serratia marcescens-inoculated menstrua was used to evaluate treatment effects on the reduction of transient contamination. Results of this first study indicated that water temperature exhibits no effect on transient or resident bacterial reduction during normal handwashing with bland soap. The follow-up study examined the efficacy and skin irritation potential involving water temperatures with antimicrobial soaps. Hands of participants were contaminated with *Escherichia coli* inoculated ground beef, washed at one of two water temperatures (29°C or 43°C) using one of four highly active (USDA E2 equivalency) antibacterial soaps having different active ingredients (PCMX, Iodophor, Quat or Triclosan). Skin condition was recorded visually and with specialized instrumentation before and after repeated washing (12 times daily), measuring total moisture content, transepidermal water loss and erythema. Overall, the four soap products produced similar efficacy results. Although there were slight increases in Log_{10} reductions, visual skin irritation, loss of skin moisture content and transepidermal water loss at higher temperatures, results were not statistically significant for any parameter.

Introduction

A critical and thorough evaluation of simple handwashing procedures reveals numerous variables to be considered by food service managers in order to achieve maximum or appropriate de-germing of the hands and fingernail regions. Numerous studies have explored issues such as type of soap (i.e. antibacterial versus plain, liquid versus bar), amount of soap, nailbrush use, drying technique (i.e. cloth versus paper towels, paper towels versus air-drying), and application of instant hand sanitizers (postwash liquids). Previous studies indicate that these variables are crucial in achieving effective removal of transient bacteria from the hands under controlled testing conditions. Rarely mentioned in the scientific literature is testing to determine specific guidelines for water temperatures and flow rates. Many of the currently employed hand-

washing practices are based on untested traditions that could possibly result in compromised skin health. It is expected that warm or hot water would be beneficial in reducing bacterial counts from hands during handwashing, as heat provides energy for the increased solubility and melting of fats, oils and other soils which may serve as vehicles for bacterial transfer from hands. Warm/hot water, combined with the detergents present in soap, should theoretically provide greater emulsification of contaminating soils on the skin, resulting in a more efficient lifting of these soils for rinsing away.

Some food safety experts strongly recommend the use of antimicrobial soaps for food service workers, while others are now focusing on handwashing frequency. With the rise of antibiotic resistance, increased concern has been expressed with respect to antimicrobial soap usage. The reasoning has been that when warm/hot water is combined with antimicrobial soap, the temperature of activation is approached, accelerating chemical reactions and improving kill rates. Soil emulsification should allow for greater exposure of microorganisms in the contaminating soil to the antimicrobial active agents. Thus, bacterial population numbers may be reduced two ways: through soil emulsification and lifting/rinsing away, and inactivation provided by the antimicrobial agent(s) with higher temperatures doing a significantly better job. The infected food worker is the focus of improved hygiene measures, and food safety managers and regulators would be remiss to not try to optimize effectiveness. Asymptomatic food handlers have been identified as being responsible for approximately one-third of outbreaks traced back to the infected worker. Poor personal hygiene has been cited as a contributory factor in an average of 30% of foodborne illness outbreaks occurring in the U.S. between the years of 1973 and 1997 (Bean & Griffin 1990; Bean *et al*. 1996; Olsen *et al*. 2000). The vast majority of foodborne illness outbreak cases attributed to the infected food handler occurs in the food service environment (Michaels *et al*. 2002).

The main initiative in hand hygiene is the reduction of potentially pathogenic microorganisms from contaminated skin surfaces. Optimization of all variables involved in this task must not only provide sufficient removal and/or kill of potential pathogens, but must also refrain from damaging the skin, as this can affect handwashing compliance (Boyce and Pittet 2001) and seriously compromise food service safety. Skin damage associated with work from routine and frequent handwashing has also been seen to result in colonization of workers hands with potential pathogens.

With so many variables involved in such a 'simple procedure', it would make sense to explore and maximize all possible aspects of the process while minimizing negative collateral. This is especially important due to the many observations of food service workers revealing what is considered to be poor habits in handwashing techniques. Studies indicate that handwashing compliance drops considerably without supervision and monitoring, or in situations where skin damage occurs. This further amplifies the need to strengthen knowledge of all variables that might improve or weaken daily handwashing practices throughout the food processing and service industry.

As described by Price, two types of flora exist on the hands, transient and resident species (Price 1938). The transient flora is generally removed fairly easy. They do not have adhesion characteristics that hold them to the skins' surface and are somewhat suppressed by secretions and competitive exclusion by the resident flora (Dunsmore 1972). Resident flora is removed more slowly. Because of coevolution, resident flora have adapted to conditions on the skins' surface that cause rapid die-off of most transients. Invaginations such as the nail fold, hair follicles and sebum-producing sebaceous glands support a rich resident flora. Transient flora may consist of pathogens, spoilage bacteria or harmless environmental species. Under certain conditions, transient flora can change status and become permanent residents. Resident flora, as a rule, are not pathogenic types. Although colonization with coagulase-positive staphylococcus is fairly common (Noble & Pitcher 1978). Frequent or prolonged exposure of the skin to microbial contamination in soils, skin damage or fissures provide portals of entry to deeper tissue, and may result in many pathogenic bacteria found among the resident species (Price 1938; Kaul & Jewett 1981). Food workers in a number of different food industry segments (including catering and bakery) have been found colonized by varying numbers of potential pathogens (Seligman & Rosenbluth 1975).

The effective water temperature used for washing and rinsing hands was a topic of intense discussion at the U.S. Year 2000 Conference for Food Protection. This biannual conference assembles federal and state regulators, food safety academicians, food service industry scientists and safety managers to establish and recommend guidelines to the United States Food and Drug Administration (FDA) for inclusion into the FDA Model Food Code. This code, as adopted by individual US states, forms the basis for food safety regulation and enforcement activities to the food service industry. Several submitters of issues, brought before science and technology council (Council III), expressed their concern regarding the use of higher water temperatures as recommended of the food service/processing industry (Table 1). The United States Food and Drug

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

Submitter	Issue	Reason
L. Wisniewski (Select Concepts – Consulting)	'Warm Water'	1. Hand Discomfort Decreases Frequency
M. Scarborough (Georgia Department of Human Resources, Division of Public Health)	37.7°C (100°F)	1. No Science (43°C vs. 37.8°C) 2. Plumbing Code @ 100°F Max. (Safety Concerns)
J. Budd (Healthminder/Sloan Valve Company)	35°C (95°F)	1. No Scientific Basis 2. Max Soap Efficacy at 35°C 3. Hand Comfort 4. Hot Water Discourages Hand Washing
E. Rabotoski (Wisconson ConferenceFood Protection)	'Tempered' 29.5°C (85°F) to 43°C (110°F)	1. Hand Discomfort 2. Possible Scalding
B. Adler (Minnesota Department of Health)	Impose Temp. Range 43°C 110°F To 54.4°C (130°F)	1. Need upper limit or subject to OSHA 2. Food workers Don't Wash 25 Sec. So Cannot Scald.
Reimers (H.E.B. Grocery Company)	'Tempered' To Warm	1. No Science . 2. Max Soap Efficacy 3. 43°C Risks Injury 4. Waste Water as Wait for Temp. at 43°C

Administration (FDA) Food Code provides recommendations for the food service industry to follow regarding food handling practices, application of HACCP principles and personal hygiene implementation (US Public Health Service 1999; US Public Health Service 2001). The main goal of the FDA has been the creation of uniform practices throughout all of the United States. The 1999 FDA Food Code requires sinks used for handwashing to be equipped so as to be 'capable of providing water of at least 43°C (110°F), accomplished through use of a mixing valve or a combination faucet' [tap] (US Public Health Service 1999).

All but one of the submitters requested temperature decreases with the intent of improving hand comfort, as the discomfort associated with higher temperatures results in decreases in hand washing frequency or compliance. Several submitters note a lack of scientific information on the subject. There is concern that a minimum handwashing temperature of 43°C (110°F), in addition to causing discomfort, will result in injury or scalding and may even be in conflict with local plumbing codes. Two submitters point out that soaps currently available target maximum effectiveness at around 35°C (95°F). Two submitters requested that the minimum temperature of 110°F (43°C) be changed to warm water or that it be tempered to a range of 85°F (29.5°C) to 110°F (43°C). and finally, one submission sought to place an upper temperature limit of 130°F (54.4°C), for fear that these regulations would be subject to Occupational Safety and Health Administration (OSHA) scrutiny and criticism without a limit. Interestingly, it was noted in this submission, through reference to the Consumer Product Safety Commission, that second or third-degree burns have been shown to occur in the elderly at temperatures not much over 43°C (110°F). Council I and the General assembly of voting delegates passed a recommendation to lower the regulatory water temperature minimum to 29.5°C (85°F). In recognition of concern expressed by a number of stakeholders with regards to the issue of handwashing water temperature, the initial results of the work described in this report and the will of state voting delegates, the 2001 Food Code lowered the required handwash water temperature to 37.8°C (100°F) (US Public Health Service 2001).

The universe of food handling situations requiring effective personal hygiene spans from temporary handwash stations set up in produce fields and county fairs to advanced state of the art clean room style kitchens used to produce extended shelf life ready-to-eat foods sold at retail. In quick service restaurants, workers frequently switch between food and money handling. Due to the potential for money to carry potential pathogens, as described by Michaels, hands may require washing from up to 40 times or more in an 8-h shift (Michaels 2002). In many of these situations, it is difficult to provide water meeting strict temperature ranges. With regard to international settings, it is doubtful that underdeveloped parts of the world will easily be able to tap into warm/hot water supplies, much less into clean water sources at all. Water temperature shortcomings have been a common point of criticism by

food safety experts when reviewing handwashing procedures in the developing world as part of HACCP activities. Further, no matter where the location, it is difficult to manage and monitor food handlers to insure that minimum temperature levels are maintained during all handwashing activities. When subject to regulatory inspections, in the U.S., violations are given to food industry entities based on Food Code specifications. In some cases, based on accumulation of violations with water temperature being one of them, mandatory 48 h closure can result. This appears to be both costly and unnecessary based on the results of the studies described here.

In an extensive literature review of the effect of water temperature on hygienic efficiency, only two existing experimental studies shed light on this issue. Both of these involved hand sampling studies, in which the objective was to remove, identify and enumerate as many bacteria on the hands as possible, either as normal or transient flora. In hand scrubbing experiments, Price found that at temperatures from 24°C (75.2°F) to 56°C (132.8°F) there was no difference in de-germing rate (Price 1938). Since he scrubbed hands with a brush for a specific period of time, each in turn in a series of sterile wash basins, he might have been capable of seeing differences upon counting the flora in each basin. After conducting over 80 experiments in a 9-year period, Price concluded that the largest variable in determining the rate of removal of bacteria from the hands was the vigorousness of scrubbing. Other factors such as soap used or water temperature were less important. In later hand sampling experiments by Larson and others (implementing the glove juice method for recovery of microorganisms), no differences in isolation rates were seen at either 6°C (42.8°F) or 23°C (73.4°F) (Larson *et al.* 1980). While this information is inconclusive and does not answer questions concerning bacterial loads suspended in a confounding soil, they tend to indicate that there may not be a noticeable difference in efficacy over a range of temperatures from 6°C (42.8°F) to 56°C (132.8°F).

Various menstrua have been used for handwashing efficacy studies. For studies involving transient flora, the most often used soil is tryptic soy broth (TSB). Microorganisms exhibit good survivability, with even distribution of contaminating microorganisms into skin cracks, creases and invaginations being possible. Ground beef probably represents the most appropriate menstrua because of concern for risks of *E. coli* O157:H7 infection, but is only occasionally used (Sheena & Stiles 1982; Stiles & Sheena 1985). Meade and others have shown numerous sporadic cases of foodborne illness have been tied to poor personal hygiene after ground beef preparation (Mead *et al.* 1997). In addition, due to it's viscosity, thixotrophic properties and level of organic soil, it would appear to be a good surrogate for fecal material.

A review of pertinent literature was also undertaken to determine if, independent of efficacy, facts on skin damage support a lowering of the temperature. The Consumer Product Safety Commission (CPSC) has noted that residential water heater thermostat settings should be set at 49°C (120°F) to reduce the risk of the majority of tap water scald injuries. Although the majority of scalding attributed to the home occur in children under the age of five and the elderly, third-degree burns are known to result in a two second exposure to 66°C (150°F), six-seconds at 60°C (140°F) and 30 s at 54.4°C (130°F) (US Consumer Product Safety Commission 2000). As we age, our skin becomes thinner, loosing suppleness. This fact is important as many seniors are now actively involved in the food service industry. Due particularly to the elder risk, some have recommended that water be delivered from the tap at even lower temperatures of less than 43°C (110°F) (Stone *et al.* 2000).

The activity of soaps, friction and rinsing become crucial since the temperatures recommended in handwashing water alone would not provide thermal destruction of pathogenic microorganisms. Relevant to the discomfort issue associated with hot water is a previously conducted study by Horn and Briedigkeit involving dishwashing soaps (Horn & Briedigkeit 1967). In that study, participants were only able to withstand water temperatures at 43°C, 45°C, and 49°C (110°F, 113°F and 120°F), with tolerance levels due to discomfort peaking at one-minute (Horn & Briedigkeit 1967). Even though considerably longer than the 10–25 second exposure period that would result from handwashing, it is indicative of the fact that temperatures from 43°C and upwards (110°F and upwards) are at or near the human discomfort threshold.

Friction has been described as a key element in removing microbial contaminants from hands (Price 1938; Kaul & Jewett 1981). Friction applied during hand drying is instrumental in finishing the process (Madeline & Tournade 1980; Knights *et al.* 1993; Michaels *et al.* 2002). Removal of transient flora appears to be even more friction dependent than removing resident flora. Surfactant and antimicrobial compounds in soap are responsible for lifting soil and killing microorganisms suspended in the soil. When using bland soap to wash hands, handwashing efficacy appears to be dependent on the effects of surfactant action of the soap along with friction applied during the washing and rinsing process. Rinsing also provides the necessary removal by dilution. To facilitate appro-

priate rinsing of the hands, some personal hygiene consultants have suggested the practice of using thicker, higher viscosity soaps in larger doses, which would require a longer, more vigorous rinsing routine.

Price, upon noticing that in his scrubbing experiments that water temperature had little effect at degerming of the skin, commented that water applied to the skin at a given temperature quickly reaches equilibrium with normal skin surface temperature unless hands are totally immersed (Price 1938).

Skin oils derived from sebum are liquid in the sebaceous gland and solidify on the skin surface. Beef tallow has a melting point range between 35°C and 40°C (95°F and 104°F), while lard or butterfat are liquefied at around 30°C (86°F) (Lide 1990). If handwashing efficacy for both resident and transient floras embedded in both natural and artificially applied fats depended on thermal melting, then log10 reduction figures should have been greatest at the highest temperature and least at temperatures causing fats and sebum to congeal.

Fats such as tallow or lard are distinguished from oils in that the latter are liquids at room temperature. Hand soap formulations are designed to lift soil through their foaming action, dispersing and solubilizing organic soils through action of detergent surfactants. Primary micelles are formed, having hydrophilic and hydrophobic groups attached to each end of the surfactant monomer. Soaps with multiple surfactants form mixed micelles, which increases efficiency with various soil mixtures. In water and organic soil mixtures, these form complex micelle structures around hydrocarbon moieties (encapsulation) resulting in microemulsions. Thus, the soap provides a 'bridge' between the oily droplet and water, permitting the soapy water to 'wash away' greasy material.

Materials and methods

The quantity of soap used for handwashing has the ability to effect handwashing efficacy, as shown by Larson (Larson *et al*. 1987). Various investigators (Michaud *et al*. 1972, 1976; Ojajarvi 1980; Stiles & Sheena 1987; Mahl 1989; Larson *et al*. 1990; Rotter & Koller 1992; Miller & James-Davis 1994; Paulson 1994) have used soap amounts in the range of 2.5–5.0 mL in their handwashing efficacy protocols. The higher levels are considered excessive, except in the area of hospital infection control. Many food service operations set soap dispensers at 1 mL per pump, and employees often times use multiple pumps. For this study, 3 mL of soap was chosen to represent an amount found to be significantly effective in an earlier study described (Larson *et al*. 1987).

Determination of appropriate handwashing duration for these studies (15 s) was arrived at through review of various governmental regulatory standards, test method guidelines and food safety specialist recommendations along with previous handwashing study observations. Suggested lathering times by specific entities are: The 1999 FDA Food Code (US Public Health Service 1999) (20 s), The American Society for Testing and Materials (American Society for Testing and Material 1995) (15 s), The Association for Professionals in Infection Control and Epidemiology (APIC) (Jennings & Manian 1999) (minimum of 10 s), and The American Society for Microbiology (American Society For Microbiology 1996) (a 10–15 second vigorous scrub). Several studies support a washing duration of at least 10 s, with sufficient transient removal efficiency achieved by 30 s. A study by Stiles and Sheena involving workers in a meat processing facility determined that a wash of 8–10 s was too short for adequate soil removal from the hands (Stiles & Sheena 1987). A study by Ojajarvi compared a 15 second and 2 minute wash, with the latter providing only an additional 3% transient bacterial reduction (Ojajarvi 1980). One observational study in food service indicates average duration times of 20 s in a silver service restaurant kitchen (Ayers 1998).

In our first study, the effects of water temperature on the reduction of both resident (normal) and transient bacteria during handwashing was performed at each of the following temperatures: 4.4°C (40°F), 12.8°C (55°F), 21.1°C (70°F), 35°C (95°F), or 48.9°C (120°F). Two separate laboratories participated in this work. Silliker Laboratories (South Holland, IL, USA) was responsible for transient flora experiments while Bio-Science Laboratories (Bozeman, MI, USA) performed normal flora studies. For transient flora studies, the experimental subjects' hands were artificially contaminated with Serratia marcescens in Tryptic Soy Broth (TSB) or irradiated ground hamburger. Sterile, uninnoculated TSB and irradiated ground hamburger were used as confounding soils in testing for the reduction of the resident flora. Following hand contamination, baseline microbial counts were acquired using the 'glove-juice' method on one hand. Hands were moistened and washed/lathered for 15 seconds with 3 mL bland (nonantibacterial) soap, rinsed for 10 seconds (water flow rate of 7 L/minute) at the assigned water temperature (also used for the prelather moistening), and the opposing hand was then sampled using the same glove-juice technique. No drying of hands was performed, which would have had the effect of diminishing differences between experimental groups. Baseline and postwash readings were then compared to obtain bacterial reduction values. For this study, no skin condition assessments were performed.

The first study was performed using a non-antibacterial soap and examined temperature effects on bacterial reductions based on the solubility of greasy soils. It did not address the increased temperature effect on antimicrobial activation or possible skin damage. Therefore, the second study was undertaken, which not only involved a comparison of the microbial reduction effects of four antibacterial soaps at two different temperatures, but also evaluated skin conditions on the hands of participants throughout the study. The potential of each soap to cause negative skin changes at each water temperature combination was assessed by measuring the skin moisture content, rate of water loss from the skin, skin scaliness by computerized analysis of a digitized skin image, and by visual assessment of the dryness and erythema. This study was performed at BioScience Laboratories, employing eight subjects and using four different antimicrobial soaps, each having a different antimicrobial active ingredient. The soaps had antimicrobial activity equivalent to USDA E2 ratings (50-p.p.m. chlorine equivalency). The active ingredients in these products were Quaternary Ammonium (3% dual Quat formulation), Triclosan (1%), Parachlorometaxylenol (PCMX-3%), and Iodophor (7.5% PVP-I). Participants consisting of paid volunteers performed multiple handwashes during two five-day test periods (weeks one and two) seven days apart using *Escherichia coli* (ATCC #11229) contaminated gamma irradiated ground beef. On days one through five of weeks one and two, the skin condition was evaluated visually, for moisture content using the Corneometer® CM825, for total evaporative water loss using the TC350 Tewameter, and digitally using the Skin Visiometer® SV 500 with Visioscan® VC98. The visual skin dryness and erythema (redness) scoring was performed by a single blinded (unaware of subjects antimicrobial soap product/water temperature configuration) evaluator trained in assessment of skin damage or irritation using a 0–6 scoring system (see Table 2) as originally described by Griffith and others (Griffith *et al*. 1969). Log_{10} reduction data was determined with the first wash of days one, three and five under each water temperature condition. After handling the contaminated ground beef in a way to uniformly contaminate hands, one hand was sampled immediately (again, using the 'glove-juice' technique) for a baseline reading. The subjects' then washed both hands at the specific water temperature (85° ± 2°F for week one and 110° ± 2°F for week two) with their randomly assigned product with their opposing hand being sampled to establish microbial counts. Each subject then washed 11 consecutive times with their assigned test product each day drying hands between washes, then hands were evaluated visually and digitally 30 minutesfollowing the last wash. In all washing cases, lathering was performed for 15 seconds and rinsing for 10 seconds with three mL of the assigned test product.

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

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

*Griffith *et al*. 1969.

Results and discussion

After extensive statistical analysis of the results from the first set of experiments, it was determined that there was no significant difference in bacterial log_{10} reductions for either resident or transient bacteria at any of the test washing and rinsing temperatures. See Figs 1 and 2 for transient and resident flora data, respectively. Average log_{10} reduction results for each soap are presented in Fig. 3.

After extensive statistical analysis of the second experiment with antibacterial soaps involving the 2 sample *T*-test, Kruskal–Wallis test and Mann–Whitney test, no statistical difference in log_{10} reductions was detected between the two wash temperatures for any of the products or as a group. Overall, the four products produced similar handwashing efficacy results. Although most of the washes at the higher temperature did produce a slight increase in bacterial reductions, it was not enough to be considered statistically significant. Figure 4 shows Tewameter® readings measuring *trans* epidermal water loss, while Figs 5 and 6 show visual dryness and baseline adjusted Corneometer® values, respectively. Skin scaliness values using a Visiometer® are shown in Fig. 7. Along with the slight additional reduction of bacteria at the higher temperature was increased skin visual dryness, increased transepidermal water loss and decreased scaliness, also determined to be statistically insignificant. Skin scaliness is highest on day one and two at the higher temperature but for days three, four and five, this reverses.

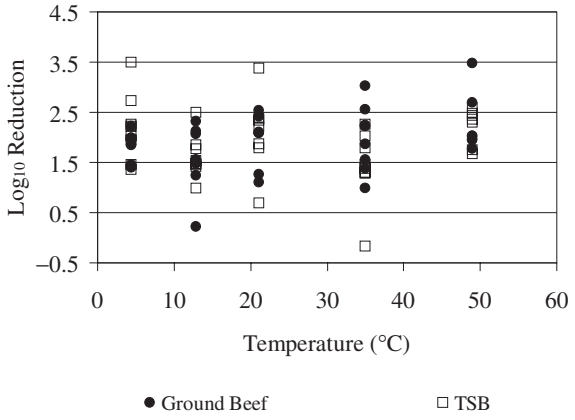

Figure 1 Handwashing efficacy (Log_{10} reduction) for transient flora (*S. marcescens*) in ground beef and TSB at selected water washing and rinsing temperatures.

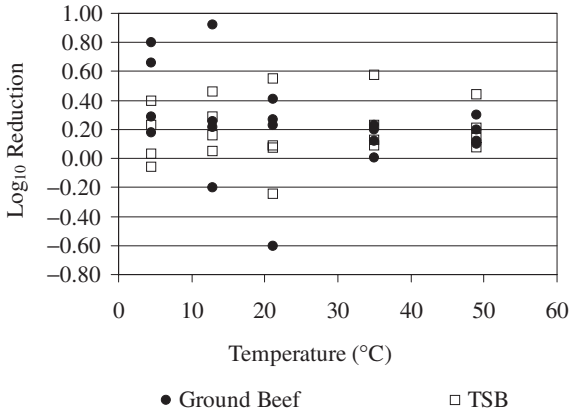

Figure 2 Handwashing efficacy (Log_{10} reduction) for resident flora in ground beef and TSB at selected water washing and rinsing temperatures.

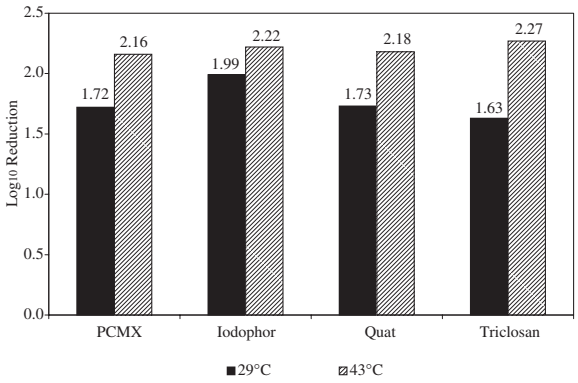

Figure 3 Average Log_{10} reduction of transient flora (*E. coli*) in ground beef using selected antimicrobial soaps.

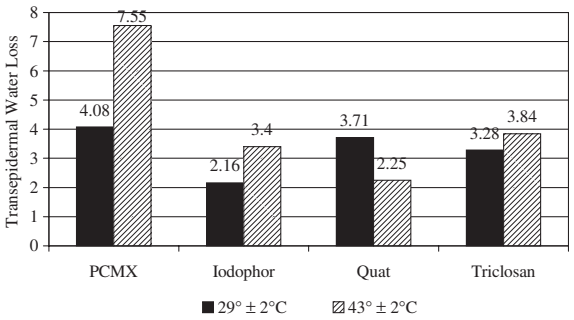

Figure 4 Average Tewameter® readings selected antimicrobial soaps at 2 different water temperatures.

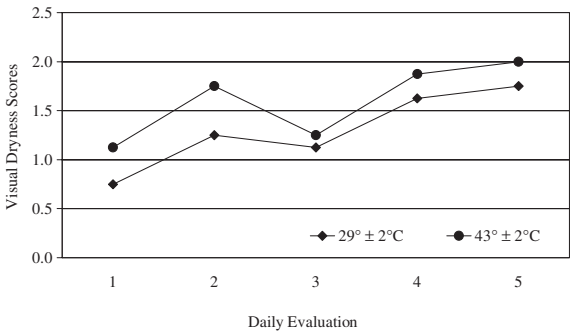

Figure 5 Average baseline-adjusted visual dryness scores (8 subjects) resulting from washing hands with 4 different E2 antimicrobial soaps for 5 days (12 ×/day).

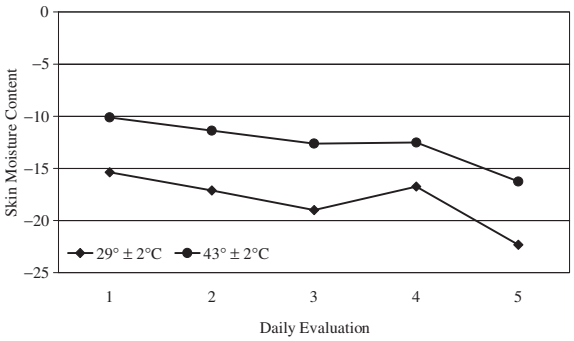

Figure 6 Baseline-adjusted Corneometer® readings (8 subjects) resulting from washing hands with 4 different antimicrobial soaps for 5 days (12 ×/day) at two different handwashing temperatures.

It is conceivable that the higher temperatures more rapidly removed loose layers of stratum corneum.

The results from both of these experiments are in agreement regarding the lack of hygienic benefits of washing hands at higher water temperatures and particularly at temperatures at the upper end of human tolerance, sometimes described as 'hot as you can stand'. From the first study, it is realized that higher water temperatures have no significant effect on the

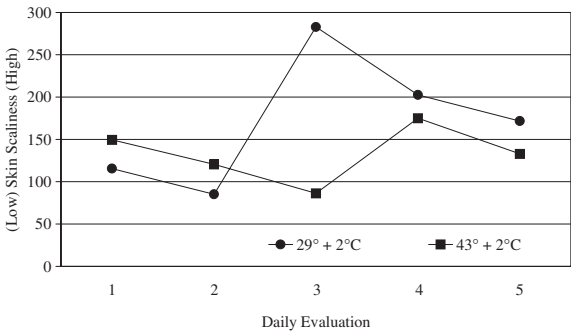

Figure 7 Average baseline-adjusted skin scaliness (8 subjects) resulting from washing hands with 4 different antimicrobial temperatures as measured using Visiometer®.

reduction of resident or transient bacteria in either easy to remove soil (TSB) or difficult to remove soil (ground beef) when using plain soap at a wide range of temperatures and using a standard hand wash. The second study provides additional support to the results of the first study by showing no statistically significant effect for the use of 110°F water (compared to 85°F water) to remove transient microorganisms embedded in ground beef from the hands when using any one of four different antibacterial based soaps or antibacterial soaps as a group. This experiment did show the trend toward higher kill as well as higher level of skin damage supporting propositions put forward by both camps. Log_{10} reductions do reflect slightly greater efficacy at higher temperatures but not at the level of significance expected, most probably due to the rapid equilibration to hand temperature described by Price (Price 1938).

Water has been identified as a skin irritant in its own rite, and part of this irritant potential can be exacerbated by temperature increase (Tsai & Maibach 1999). Repeated water exposure causes extraction or dilution of natural moisturizing factors in the stratum corneum. The water-holding property of the stratum corneum is provided in part by intercellular lipids and lipid rich sebaceous gland secretions (Noble & Pitcher 1978). The intercellular lipids, which when chromatographically fractionated, can be separated into cholesterol, cholesterol esters, phospholipids, free fatty acids, glycolipids and ceramide (Noble 1975; Imokawa *et al*. 1986). Loss of these lipid components results in a chapped and scaly skin appearance (Imokawa & Hattori 1985). Water induced irritation is known to exist in workers involved in continuous wet work, resulting in chapped and dry skin after wet work is completed (Halkier-Sorensen & Thestrup-Pedersen 1991).

Instances of primary irritant dermatitis to certain chemicals has been found to occur when hot water at 43°C (110°F) was used rather than lukewarm at 23°C–25°C (73°F–77°F) (Rothenborg *et al*. 1977). Detergent/surfactant formulations are known to cause changes to the stratum corneum such as disaggregation, swelling and morphological deterioration of corneocytes (Shukuwa *et al*. 1997). It has been found that heat plays a part in accelerating irritation of certain chemicals found in these detergent formulations. Berardesca and others found a significant difference between the temperatures of 20°C and 40°C (68°F and 104°F) in skin irritation to 5% sodium lauryl sulphate solution for a 4-day exposure period (Berardesca *et al*. 1995; Ohlenschlaeger *et al*. 1996). This irritation is documented using transepidermal water loss (TEWL) measurements, erythema (skin redness), skin reflectance, hydration (capacitance) and desquamation (stripping). Gross hand edema has been found to occur at temperatures between 35°C (95°F) and 45°C (113°F) when hands are completely immersed at those temperatures (King 1993). A significant increase in blood flow has also been shown in comparisons between 37°C and 43°C degrees (99°F and 110°F) (Nagasaka *et al*. 1987). Overall, these studies tend to show that food service workers derive no significant measurable benefit by using hot water (105°F +) to wash and rinse hands. Use of water at higher temperatures does seem to result in physiological changes collectively described as skin damage. There may be severe consequences of frequent use of hot water for handwashing at temperatures above 43°C (110°F), which can damage skin and heighten susceptibility to both allergens present in the food service environment and/or colonization (Larson *et al*. 1998). Rather, water temperature should be set at what is considered comfortable and generally conducive to handwashing.

The central components of effective handwashing thus consist of soap use in a way that promotes emulsification of soil (through vigorous friction/mechanical action) followed by thorough rinsing and drying, which again adds friction to the equation. Guidelines for handwashing in food service should probably not specify water temperature descriptors other than perhaps the word 'comfortable' when it comes to defining effective handwash standards. 'Warm' or 'tempered' would probably be acceptable, but more importantly as indicated by Jennings and Manian (1999), 'running water' should be to rinse away emulsified soils and associated transient contamination. Fingertips should be pointed down and hands rinsed and dried in a way to focus on parts of the hand that have shown to be missed during normal handwashing. This includes fingertips, thumbs and fingernail regions.

Conclusions

A review of the literature on the subject of handwashing water temperature requirements showed considerable variation with respect to expert opinion on optimal temperature for removal of microbial contaminants form hands. There in fact was a virtual absence of data to back up the various positions on the subject. Sanitarians and food safety experts have specified water temperatures varying from room temperature (running water) up to 'as hot as you can stand', the latter of which is probably in the range of from 49°C (120°F) to 55°C (131°F). Regulations in the US and elsewhere tend to focus on temperatures between 43°C (110°F) and 49°C (120°F). Concern that these temperatures could be detrimental to skin health without documented efficacy led to the experiments described here. Hands were contaminated with soils similar to those encountered in the food service environment. These soils contained marker bacteria allowing handwashing efficacy to be determined at specified water temperatures against both transient flora and resident flora simultaneously.

The initial experiment involved testing with bland non-antimicrobial soap at 5 temperatures from 4.4°C (40°F) to 49°C (120°F). Independent of soil or bacterial type (resident or transient) there was no significant difference in efficacy attributed to water temperature. In the second experiment antimicrobial soaps (4) were used having different antimicrobial active ingredients, at each of two water temperatures, 29.5°C (85°F) and 43°C (110°F). Skin condition was monitored with frequent handwashes (12 ×/day) for the second set of water washing temperature experiments. In this experiment, even though slightly higher efficacy with was seen with antimicrobial soaps at higher temperatures, overall, there was no statistical difference in efficacy as measured in Log_{10} reduction at the two water temperatures (regardless of soil or microflora types). Concomitant to the increase in efficacy at higher temperatures was a consistent trend for increases in measures of skin damage, such as skin moisture content, transepidermal water loss and erythema. This was also found not to be statistically significant.

Both the trend for higher efficacy of soaps with attendant skin damage at higher temperatures are grounded in theory. Under the conditions of these experiments neither was shown to be proven for practical application. Since efficacy is not markedly improved at higher temperatures but rather the real danger exists of skin damage, requirements for specific handwashing water temperature should be relaxed to improve acceptance of frequent handwashing by food workers at appropriate times to reduce foodborne illness potential. Water temperature should be in a comfortable range, perhaps tempered.

As has been shown by many previous researchers, overall handwashing effectiveness is more dependent on the vigorousness of execution than details such as the type of soap, the length of handwash or in this case water temperature. The results obtained in these experiments confirm the observations made by Price (Price 1938) and Larson (Larson *et al*. 1980) indicating water temperature had little or no effect on the removal of bacteria from hands. While their original reports dealt with optimizing skin sampling efficacy, for the types of experiments performed and described in the current report.

Unfortunately, food service regulatory authorities, health inspectors and environmental health officers in the US and elsewhere have fixated on handwashing water temperature because it is measurable and in the somewhat mistaken belief that higher temperatures would result in cleaner hands. Up until recently, the existence of adequate hygiene facilities (functioning toilet, toilet paper, functioning sink, soap and paper towels) and water temperature measurement were to some extent the only measurable qualities whereby food safety inspectors could cite food service facilities for violation. Poor personal hygiene is often used after the fact to describe as a contributing factor aiding to an outbreak. With handwash monitoring devices employees' handwashing can be monitored, documented and verified within the HACCP framework (Michaels 2002). With this new technology and information from this report indicating that water temperature for handwashing is relatively unimportant, perhaps regulatory authorities will be able to focus on other more important factors having a bigger impact on food safety.

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Conference for Food Protection
2012 Issue Form

Internal Number: 011
Issue: 2012 I-037

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

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Title:
Designation of Manual Warewashing Wash Solution Temperature as a Core Item

Issue you would like the Conference to consider:
To designate Section 4-501.19 of the 2009 FDA Food Code as a Core Item, thereby changing the designation for the provision that, "The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions" from a Priority Foundation to a Core Item.

Public Health Significance:
Effective manual warewashing in retail food establishments is dependent on a number of variables including the cleaning agent used, the type of manual washing processes, the equipment used, the volume and type of wares being washed, as well as where they originate (i.e., hot or cold environments). The temperature of the water used for washing is also a variable and no specific temperature is required to assure an effective process.

The washing step is intended to ensure that the wares/equipment being cleaned are visually free of soil prior to sanitization. The washing step is not intended to be a sanitizing step and therefore is not the step that reduces risk or impacts public health. A Priority Foundation item is, by definition, "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."

In practice, maintaining a specific wash solution temperature for manual warewashing can be challenging under certain situations such as washing in refrigerated environments in meat markets. To overcome this challenge, food retailers have worked with their chemical suppliers to provide cleaning agents (detergents) that work effectively in a variety of different environments and in various water temperatures with consistent results. Other methods such as applying force to the surface of wares via brush and/or spray devices have proven very effective in removing soil that can easily be rinsed prior to being sanitized, regardless of the water temperature. Employees are more likely to wash wares effectively and for a longer time if doing so in water that is comfortable and which achieves the intended purpose.

A Core Item is defined as "an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures,

equipment design, or general maintenance." Other provisions in the Food Code that recommend water temperatures for washing are not designated as Priority Foundation and changing Section 4-501.19 to a Core Item would be more appropriate and consistent. Furthermore, the CFP Criticality Committee (CFP, Crit Item, recommendation for changing a Food Code Section, Chapter 2 (part) 3 and 4 and terminology, summary 8-16-07) overwhelmingly (>77%) recommended that Section 4-501.19 be classified as a Core item and not a Priority Foundation.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-501.19, be revised to reclassify the designation from a Priority Foundation (Pf) item to a Core (C) item as indicated below (new language shown with underline and deleted language shown with strike-through):

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions. ~~Pf~~ C

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Conference for Food Protection
2012 Issue Form

Internal Number: 068
Issue: 2012 I-038

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

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Title:
Amendments to Public Information and Public Posting

Issue you would like the Conference to consider:
Rigorous health inspections are a critical component of an effective food safety system. The 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, compared with only 20 percent linked to home-prepared food. Although food establishments should be 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.
In some jurisdictions, consumers must submit a formal Freedom of Information Act request to the regulatory authority to access an inspection report. The addition of the following language to the Model Food Code will ensure public access to inspection results at the food establishment, improving consumer access and decision-making, without placing any additional or undue burden on food establishments. For more information, see http://www.cspinet.org/dirtydining/index.html.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be modified by adding new language in underlined format to Part 8-4 Inspection and Correction of Violations as noted below:
8-403.50 Public Information.
Except as specified in § 8-202.10, the regulatory authority shall treat the inspection report as a public document and shall make it available for disclosure to a person who requests it at the FOOD ESTABLISHMENT and otherwise as provided in law.
8-403.51 Public Posting.

The REGULATORY AUTHORITY shall make available the results of the inspection report by requiring the timely posting of the most recent inspection results in a clear and legible form at 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.

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Conference for Food Protection
2012 Issue Form

Internal Number: 064
Issue: 2012 I-039

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

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Title:
Addition to Section 8-4 Inspection and Correction of Violations

Issue you would like the Conference to consider:
The 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. In some jurisdictions, consumers must submit a formal Freedom of Information Act request to the regulatory authority to access an inspection report. The addition of the following language to the 2009 FDA Food Code will ensure public access to inspection results at the food establishment, improving consumer access and decision-making, without placing any additional or undue burden on food establishments. For more information, see http://www.cspinet.org/dirtydining/index.html.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended by adding language as follows:
8-403.50 Public Information.
Except as specified in § 8-202.10, the regulatory authority shall treat the inspection report as a public document and shall make it available for disclosure to a person who requests it at the FOOD ESTABLISHMENT and otherwise as provided in law.

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Conference for Food Protection
2012 Issue Form

Internal Number: 083
Issue: 2012 I-040

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

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Title:
Packaged Food Labeling Clarification

Issue you would like the Conference to consider:
Foods can be wrapped in non-durable containers for sale in food service establishments, including carry-out restaurants and delis. It is the interpretation of some regulatory authorities, that foods wrapped in non-durable packaging for self-service are required to be labeled per the current labeling law. There are violations that are currently being reported for this practice. Foods served in non-durable packaging in a food service establishment should not fall under the requirements of the labeling law which was meant for foods in durable packages from a food processing plant.

Public Health Significance:
It is important that all foods requiring labeling under the law are in fact labeled for the protection of the consuming public with special dietary or health needs. It is equally effective to have information available (foodservice employee, signage, written hard copy or online website) for foods in a foodservice environment that do not meet the "packaged" definition.
The 2009 Food Code defines "Packaged" as follows:
Packaged.
(1) "Packaged" means bottled, canned, cartoned, securely bagged, or securely wrapped, whether PACKAGED in a FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT.
(2) ***"Packaged"*** *does not include a wrapper, carry-out box, or other nondurable container used to containerize FOOD with the purpose of facilitating FOOD protection during service and receipt of the FOOD by the CONSUMER.*

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:
1) The FDA reinforces the legal definition of "packaged" in Section 1-201.10 (2), regarding the difference between durable and non-durable packaging.
2) The FDA adds language similar to the following to the next 2013 Food Code, Annex section 3 - Public Health Reasons/ Administrative Guidelines; Chapter 1 - Purpose and

Definitions, that describes the circumstances that labeling of foods in non-durable packaging is exempt:
a) Foods in non-durable packaging held in a cold display unit in the service line are available to the customer in a self-service format. Foodservice employees and/ or information are available to address ingredient questions.
b) "Grab-n-go" type items in kiosks in the front of a restaurant are available as a convenience to the customer in a self-service format. Foodservice employees and/ or information are available to address ingredient questions.

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Conference for Food Protection
2012 Issue Form

Internal Number: 091
Issue: 2012 I-041

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

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Title:
Reuse-Refill of Multi-use Tableware (To go containers)

Issue you would like the Conference to consider:
Amend 2009 FDA Food Code Sections 3-304.17 and 4-603.17 to allow for institutional type facilities (such as schools or assisted living communities) to provide reusable tableware/containers to consumers, who can then return the tableware for cleaning, sanitizing, and reuse by the food establishment. The consumer at the time of return, would receive cleaned and sanitized reusable tableware/containers that can be refilled with food.
Background:
Because of the trend toward recycling and attempting to limit the use of single service dishware in the waste stream, the PA Department of Agriculture has received several variance requests over the last few years to allow for colleges to use refillable containers that are provided to students by the food establishment. The variance requests have been reviewed and approved based on the limited scope of the consumers using the food establishment, as well as the following parameters:

- The reusable containers meet the criteria established in Chapter 4 for Equipment, Utensils and Linens, and are intended for multiple use.
- The facility establishes procedures for return of the containers that include, return area outside of any food preparation areas, inspection by a food establishment employee for general cleanliness and condition, and a direct pathway to the warewashing area which minimizes any potential cross contamination
- Food establishment accomplishes warewashing as required in the Food Code, and complies with storage and other handling requirements.
- A mechanism is in place to identify/verify the consumer population that is purchasing and returning reusable containers.

The trend toward recycling and environmental friendliness will continue - companies are manufacturing reusable containers and marketing them, especially in institutional settings, and more institutions will be looking at reducing waste and cutting costs. Since 2008, FDA has received several interpretation questions regarding re-use of to-go boxes and similar containers, and the Commonwealth of PA has received 2 requests to the Department of Agriculture, and at least one request through a County Health Department.
The 2009 Food Code prohibits a food establishment from refilling containers with PHF/TCS food in Section 3-304.17, and Section 4-603.17 prohibits cleaning and refilling containers,

other than beverages, unless by a food processing plant. Thus any jurisdiction that has facilities utilizing reusable food containers must make independent determinations through the variance process as to what is acceptable and required if approving the reuse or refilling of these multi-use food containers.

Public Health Significance:
Because of the trend toward recycling and attempting to limit the use of single service dishware in the waste stream, the Pennsylvania Department of Agriculture has received several variance requests over the last few years to allow for colleges to use refillable containers that are provided to students by the food establishment. The variance requests have been reviewed and approved based on the limited scope of the consumers using the food establishment, as well as the following parameters:

- The reusable containers meet the criteria established in FDA Food Code Chapter 4, Equipment, Utensils and Linens, and are intended for multiple use.
- The facility establishes procedures for return of the containers that include, return area outside of any food preparation areas, inspection by a food establishment employee for general cleanliness and condition, and a direct pathway to the warewashing area which minimizes any potential cross contamination
- Food establishment accomplishes warewashing as required in the Food Code, and complies with storage and other handling requirements.
- A mechanism is in place to identify/verify the consumer population that is purchasing and returning reusable containers.

The trend toward recycling and environmental friendliness will continue - companies are manufacturing reusable containers and marketing them, especially in institutional settings, and more institutions will be looking at reducing waste and cutting costs. Since 2008, FDA has received several interpretation questions regarding re-use of to-go boxes and similar containers, and the Commonwealth of Pennsylvania has received 2 requests to the Department of Agriculture, and at least one request through a County Health Department.
The current Food Code prohibits a food establishment from refilling containers with PHF/TCS food in Section 3-304.17, and Section 4-603.17 prohibits cleaning and refilling containers, other than beverages containers, unless performed by a food processing plant. Thus any jurisdiction that has facilities utilizing reusable food containers must make independent determinations through the variance process as to what is acceptable and required if approving the reuse or refilling of these multi-use food containers.
Non-uniformity in determining what criteria must be in place for approving variances related to reuse-refilling of these multi-use containers will result in jurisdictions establishing differing standards for the tableware/container, the types of food establishments that can use the reuseable tableware, the recordkeeping, and the food establishment handling, cleaning, and sanitizing, and storage of the reusable tableware.
Adding a standard set of provisions regarding when this practice is permitted will enhance uniformity among jurisdictions, provide a set of standards for industry to comply with, and protect the public.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting amendments to the 2009 Food Code (as modified by the Supplement issued in 2011), Sections 3-304.17 and 4-603.17 specifically,

and other affected Food Code sections FDA identifies, to allow food establishments operating in institutional type settings with known consumers to provide reusable tableware/containers which can be returned and reused/refilled by that food establishment. In amending those sections, language should:

1. identify specific criteria and procedures for food establishment approval of the process
2. verify the consumer population (eg, IDs, Swipe Cards)
3. confirm tableware/containers comply with 2009 Food Code Chapter 4 standards for Multi-use Equipment & Utensils
4. establish procedures for return/reuse of tableware/containers that include inspection by a food employee
5. establish procedures for limiting cross-contamination potential when tableware/containers are returned, inspected, cleaned and sanitized, and stored.

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Conference for Food Protection
2012 Issue Form

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

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Title:
Creation of Distribution and Storage, Transportation and Delivery Committee

Issue you would like the Conference to consider:
Food Safety and the prevention of food borne illnesses requires product protection, temperature control and other control steps throughout the food chain (from farm to fork). The process of distribution of food, food packaging, and sanitation chemicals to retail is one area that has been identified by studies (Interstate Food Transportation Project by Michigan Department of Agriculture and others), in publications (see attachments: 1) Food Safety Magazine - Maintaining the Cold Chain. 2) Food Logistics - Cold Chain Champions), and by the media (ABC News and Indiana videos available upon request) as one with food safety risks and opportunities. While Regulations are expected to be forthcoming via the Food Safety Modernization Act (FSMA)/Safe Food Transportation Act (SFTA), there exists a need to define and promulgate best practices and guidance documents in areas like temperature control, allergens, product protection, and other areas.

Public Health Significance:
Products must be protected from contamination, temperature abuse, and microbial growth to prevent food borne illnesses. Industry, Regulatory, Academia, Consumer Organizations, and others collaborating together to identify best practices assure these protections will add additional levels of food safety and consumer protection to the food chain.

Recommended Solution: The Conference recommends...:
the creation of a Distribution and Storage, Transportation and Delivery Committee. The Committee will be composed of Conference members from all constituencies especially subject matter experts in distribution, logistics and transportation. The Committee will be charged with:
1) Defining the scope of the distribution industry that will be addressed by the Committee, and identifying risks and opportunities for the Conference,
2) Soliciting best practices and existing documents that relate to distribution and storage of foods including Global Food Safety Initiative (GFSI) and other Standards to recommend best practices to the Conference,
3) Engaging with Federal and State agencies, especially those involved in Food Safety Moderization Act (FSMA)/Safe Food Transportation Act (SFTA) or existing transportation

inspection programs, to align proposed committee recommendations with regulatory requirements as they may be promulgated,
4) Reporting back to the 2014 Biennial Meeting summarizing its activities and recommending best practices in the areas of distribution and storage, transportation and delivery, and
5) Submitting Issues to the 2014 Biennial Meeting to recommend new FDA Food Code language and/or identify new charges for the Committee, if any.

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Attachments:

- "Food SAfety Magazine - Maintaining the Cold Chain"
- "Food Logistics - Cold Chain Champions"

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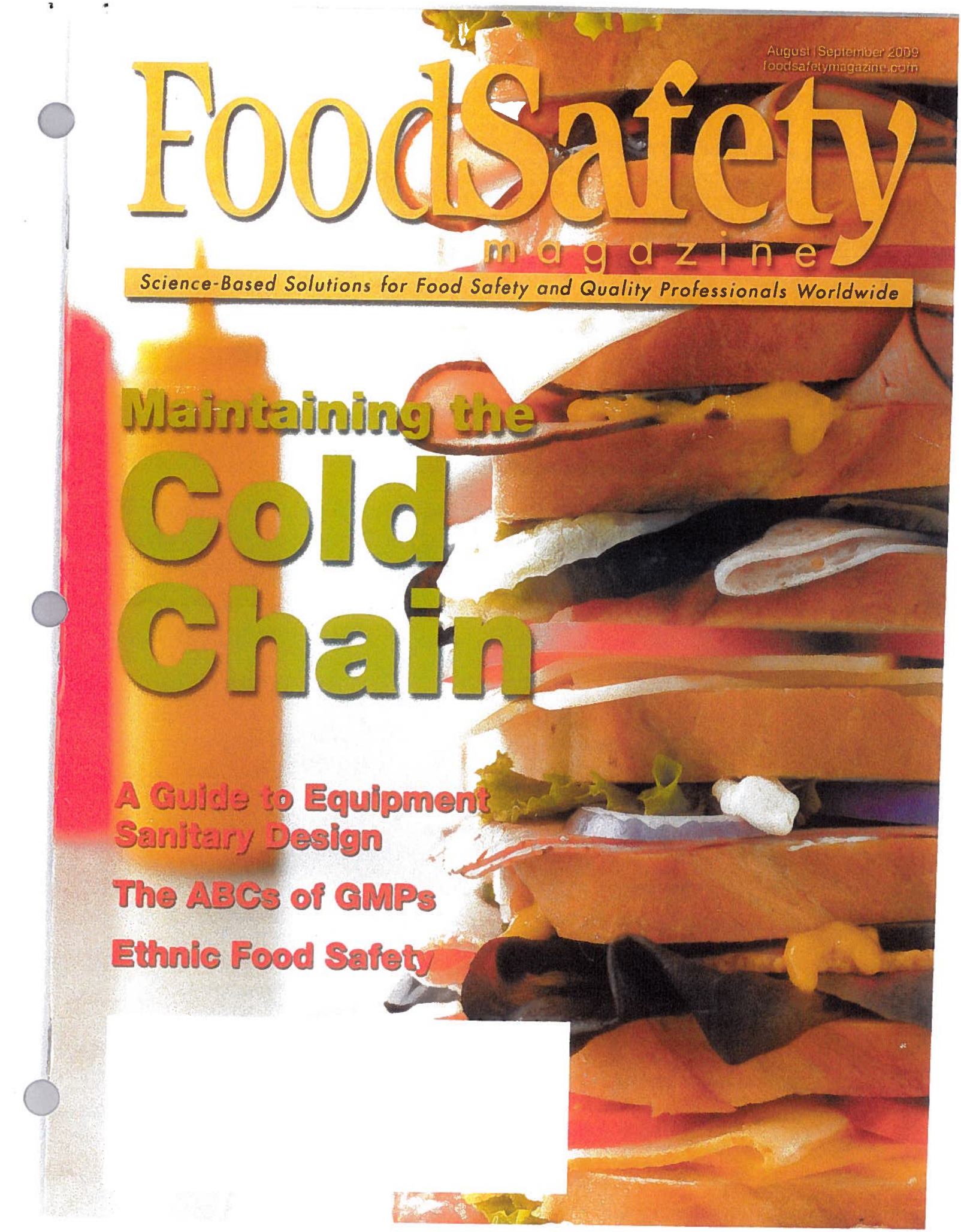
FoodSafety magazine

Science-Based Solutions for Food Safety and Quality Professionals Worldwide



Maintaining the Cold Chain

A Guide to Equipment Sanitary Design

The ABCs of GMPs

Ethnic Food Safety

FOODSERVICE DISTRIBUTION: Maintaining the Cold Chain

BY JORGE A. HERNANDEZ

Each day, millions of cases of product are delivered to restaurants, hospitals, universities and other food-away-from-home destinations. Moving these food products safely and efficiently from farm to fork requires an elaborate, highly coordinated series of links in a long chain of trading partners. Distributors serve as the intermediary between manufacturers and foodservice operators, procuring palletized and bulk inventory items from manufacturers, then breaking them down to case and unit quantities for foodservice operators.

While distribution may be the least highlighted link in the food safety chain, the safety and quality measures taken by successful distribution centers are no less important than the Hazard Analysis and Critical Control Point (HACCP) plan at the supplier's facility or the careful handling and preparation by the operator.

It's a Big, Big Distribution World

The U.S. distribution chain includes more than 15,000 companies operating thousands of warehouses and fleets of trucks. A typical broadline foodservice distributor may serve anywhere from 1,000 to 6,000 accounts from a single distribution center, and offer customers more than 10,000 food and non-food items. Other types include specialty distributors, which focus on specific product categories or customer segments; distribution systems, which serve large restaurant chains; and other businesses such as terminal markets and warehouse clubs.

In 2009, U.S. distributors' annual sales will be an estimated $211 billion, down from $217 billion in 2008 and $216 billion in 2007, according to Technomic Inc., a foodservice research and consulting firm. "The commercial foodservice market, particularly restaurants, is in a major slump, and distributors are a reflection of what the end-market is doing," says Robert Goldin, executive vice president of Technomic.

The largest distribution companies are Sysco Corp., headquartered in Houston, TX; U.S. Foodservice, based in Rosemont, IL; and Performance Food Group in Richmond, VA. Other major players included in Technomic's 2008 Power Distributors List include (in order of size): Gordon Food Service, Grand Rapids, MI; Reinhart FoodService, LaCrosse, WI; Services Group of America, Scottsdale, AZ; Maines Paper & Food Service, Conklin, NY; Shamrock Foods Co., Phoenix, AZ; Ben E. Keith Foods, Fort Worth, TX; and Cheney Brothers, Riviera Beach, FL.

"Customers should be aware of the food safety differences between distributors, especially in a down economy when many are making choices based on price."

It's All About Food Protection

Every distribution company has its own system for ensuring food protection, which includes food safety (protecting food from accidental contamination) and food defense (guarding food from intentional contamination).

"Best-in-class foodservice distributors go to great lengths and expense to protect the products they deliver," says Steve Potter, senior vice president of industry relations for the International Foodservice Distributors Association (IFDA), a trade association serving the foodservice distribution industry. Several federal agencies oversee food regulation and safety in America, including the U.S. Department of Agriculture (USDA), which regulates and monitors meat, poultry and egg products; the U.S. Food and Drug Administration (FDA), which ensures the safety of the production, processing, packaging and storing of domestic and imported foods; and the Centers for Disease Control and Prevention (CDC), which collaborates with USDA and FDA on disease surveillance and outbreak response.

Of the three, USDA and FDA interact most often with the foodservice supply chain. The "best practices" guidelines (more on these later) prepared by these agencies cover a multitude of processes, from general sanitation to packing and production to transportation and warehousing.

The common thread among best practices can be summed up in four words: "maintaining the cold-chain." A key part of every successful distributor's food safety program involves refrigerated docks, multiple refrigeration zones within distribution centers and multi-temperature trailers.

"In many ways, the transportation of food can be viewed as an extension of storage," writes Robert James Hart in his article "Food Science–The Transportation of Food," a scholarly examination of the chemical and molecular structure of foods and how they break down, for the book *Food Transportation*.[1] "A refrigerated [truck] is essentially a cold store on wheels. There may be additional engineering complications in designing and maintaining such a mobile storage facility, but the food science considerations are much the same."

Problems and Vulnerabilities

While food safety is a priority for every reputable distributor, it's often taken for granted by customers. Maintaining the cold chain from farm to fork is challenging. The average shipment–both inbound, from supplier to distribution center, and especially outbound to customers–consists of less-than-truckload quantities of food products. The number of products delivered to a customer can be in the hundreds. Each of these products must be loaded correctly to prevent cross-contamination with raw product and damage by heavier items at the bottom of a stack.. And they must be stored at the correct temperatures (frozen, refrigerated or dry) in the truck to maintain quality and safety. The food has to retain its chill throughout the multi-stop delivery process, especially in the heat of summer when the "reefers" (truck refrigeration units) have to work extra-hard to maintain temperature. In other words, there is plenty of opportunity for error.

Although food distribution companies must adhere to government regulations calling for greater food protection scrutiny (e.g., the Bioterrorism Act of 2002), enforcement is rare. On the supplier front, over-extended government food inspections run by FDA, USDA and state regulatory agencies continue to lag in both coverage and accuracy, as evidenced by the recent foodborne illness outbreak traced back to one less-than-scrupulous peanut processing company.

"Customers should be aware of the food safety differences between distributors, especially in a down economy when many are making choices based on price," says Greg Pallaske, director of regulatory compliance for food safety and quality assurance, U.S. Foodservice." That's why it's so important to evaluate the food safety policies and procedures and operations of your foodservice distribution company."

Frank Ferko, U.S. Foodservice's head of distribution food safety and quality assurance, agrees. "Most people are inward-looking when it comes to food safety," says Ferko, who has more than 33 years of experience in the restaurant, food processing and distribution businesses. "If you're in manufacturing, you

worry about food quality at your facility. If you're at a restaurant, you worry about your kitchen. That doesn't mean you can assume other areas are fully on target."

Areas of Food Safety Risk

The major areas of concern for food distributors start with the cold chain and time/temperature control, and include sanitation, cross-contamination and shipping logistics such as merge-in-transit. At the warehouse, food safety hot-spots include damaged goods and will-call.

Maintaining control of the cold chain is one of the biggest challenges for food distributors. Take mixed loads, for example, in which a trailer carries frozen, refrigerated and dry items in sections ideally separated by moveable bulkheads. There should also be chutes blowing the appropriately tempered air into the chilled compartments.

That's not always the case in the real world. "Some companies don't see a problem with putting frozen and refrigerated items in a trailer set at 26 °F and shipping the food halfway across the country," Ferko says. "We saw a lot of that last summer when gas prices rose above $4 per gallon, and companies were trying to cut corners."

> "Food safety works best when it is built into the overall design of both the facility and the trucks."

Combining frozen and refrigerated products is usually more of a food quality issue than a food safety issue, but it still ends up affecting operators' bottom lines. "French fries, for example, that are held at 20 °F and then brought back down to 0 °F will have moisture build-up on the surface," Ferko says. "When you dump them into the fryer, the surface moisture will cause problems with the oil and the fries will come out too dry."

Frozen breaded chicken held at too high a temperature suffers too, when moisture from the meat gets into the breading, which causes it to brown unevenly or flake off, while reducing the useable life of the fryer oil. Quality also takes a hit when refrigerated items are stored at the wrong temperature, as with delicate leafy greens that will freeze or wilt.

Certain foods–particularly seafood, sensitive pre-cut produce and ready-to-eat products–can become unsafe if not held at appropriate temperatures. Safety-conscious companies require time and temperature recorders for shipment of these foods. If the time-to-result indicates the temperature has exceeded safe limits, the best practice is to refuse the shipment and discard the product.

"We sometimes find that refrigerated seafood product shipped by vendors has been above 41 °F in the mid- to high-40 °F range for too long," Ferko says. "This can occur when the product is unloaded for redistribution to another truck, or when it's part of a longer-than-usual delivery that caused the truck's refrigeration unit to be turned off too long. In this case, the product should be rejected as unacceptable."

The practice of on-the-dock redistribution from one truck to another, called merge-in-transit or cross-docking, offers plenty of chances for temperature mishaps where food is involved *if* the docks are not refrigerated or if product sits for too long at the wrong temperature. The system was developed by retailers that ship dry foods or consumer goods as a way to speed deliveries while reducing warehouse and handling costs.

Companies using merge-in-transit should have refrigerated distribution docks and undergo a rigorous inspection process before such a program is implemented. In fact, U.S. Foodservice recently launched a pilot cross-docking program at two facilities in Chicago and one in Atlanta, with plans to expand the program to up to eight facilities throughout the country by next summer.

Returns and Will-Call

Returns and will-call areas, where customers can pick up product directly from the warehouse to meet last-minute needs, carry significant potential for both food safety and food defense to be compromised if the cold chain is not maintained. With returned product, the key point is to make sure that potentially unsafe product (food that has been out of the distributor's control) does not reenter the stream of outgoing goods for delivery to another, unsuspecting customer.

Reputable distributors will have a designated returns area, where all products are held for evaluation. Depending on results of the investigation, products will either be returned to the vendor, returned to shelves, donated to a food bank or destroyed.

Whether buying from a distributor, a terminal market or a warehouse club, "customers who want to put frozen or refrigerated product into their trunks and drive an hour or so back to their restaurant are creating risk," Ferko says. "The challenge lies in educating customers about transporting product safely. That said, you can't manage their business for them." Distributors should, however, limit customer access to the facility for their will-call business.

Food Defense Vulnerabilities

Protecting food from intentional contamination, a form of bioterrorism, is an issue that is sometimes overlooked. "Anyone with bad intentions can easily contaminate food–a customer at the salad bar, a restaurant employee, and so on," says Ferko, who sits on the food defense committee of the Conference for Food Protection. "Food defense is primarily about limiting access to products. It's also about understanding what might happen and monitoring who has access to food. If your company is limiting access by locking trucks, sealing cases within trailers with tamperproof tape, restricting access to distribution facilities, and performing background checks on new hires, you're already making progress on the food defense front."

Food defense measures taken by food companies are voluntary rather than mandated by government regulations. They're also relatively minimal, considering the critical nature of the nation's food supply and the shock wave that would ensue if a successful bioterrorism

attack on the food supply occurred.

"You do the things that are reasonable to protect the product, employees and customers," Ferko says.

A "Best Practices" Approach to Safe Food Distribution

For operators selecting a food distribution partner, or for distributors evaluating their own food safety operations, below is a series of questions followed by best practices suggested by regulatory agencies and the industry.

In the Distribution Center

What are some food safety aspects built into your distribution facility?

Food safety works best when it is built into the overall design of both the facility and the trucks. This includes having sufficient capacity for dry and refrigerated food products (chilled and frozen), providing easy access to all areas for cleaning, adequate insulation and temperature-control capacity. For facilities, it is important to restrict access by unauthorized entry through use of fences and locks, and of course, to have programs to prevent environmental contamination and infestation by insects or vermin.

How many temperature zones are in the distribution facility? How are they monitored?

A foodservice distribution warehouse typically has three temperature zones–ambient, cooler and frozen. Temperature ranges in the cooler area should properly protect meat, dairy and produce. The freezer should be at 0 °F or below. Larger facilities will have both an ambient and a refrigerated receiving dock area.

Best-in-class facilities are equipped with monitoring systems that track temperatures within each zone around the clock. Should a temperature go above or below the target range, the system sends a message (via email, text, fax or phone) to the warehouse manager so the situation can be corrected.

How do you ensure proper first-in, first-out product rotation at the warehouse?

Product rotation at distribution facilities is tracked and carefully managed. As each pallet of product is received on the dock, it is assigned a "license plate"–a bar code and a unique ID number that describes the contents. The product is then taken to the aisle and slot in which it will be stored, and the location number is entered into the system. Received product typically is placed into "reserve" slots. When the "pick" slot for that product becomes empty, warehouse staff will be directed by computer as to which pallet to insert next to ensure first-in, first-out accuracy.

How is food safety addressed in the picking process?

The slotting system at the warehouse is laid out in a manner that lets pickers assemble orders as they pass through the warehouse. As pickers move through aisles to fill food orders, they put the heaviest items on the bottom of the pallet for stability and to prevent damage. Typically, ambient products are placed with other ambient products, cooler with cooler and frozen with

Food Defense in Your Distribution System

An important part of safeguarding the nation's food supply involves protecting food in transit—90% of which is shipped by truck. Because of globalization, the journey that food takes from field to table can be thousands of miles, with many stops along the way. Challenges include the vast size of the area covered, the broad number of food distributors and their varied levels of knowledge about food defense, the relative lack of government regulation, the potential for unobserved access to food products, and a less-controlled setting that makes safeguards more challenging to implement. In short, today's world calls for food defense plans just as much as food safety plans.

A successful food protection program must focus on two areas: food defense and food safety. "Food defense" means preventing *intentional adulteration* by biological, chemical, physical or radiological agents. "Food safety" refers to guarding food against *unintentional* contamination.

"The distribution of ingredients and products is a vital component of our food delivery system, which is why it's important for food distributors and companies to know their suppliers and understand the food protection measures being used," says Jon Woody, policy analyst for the U.S. Food and Drug Administration's (FDA's) Office of Food Defense, Communication and Emergency Response.

Three food categories are considered to be especially vulnerable to contamination. Perishable products, such as meat or dairy products, must be monitored closely because their relatively short shelf-lives place an additional burden on the industry's ability to respond in a timely manner. The second category includes products that require extensive human interaction to be ready for market, such as produce or nuts that can come from multiple suppliers and are mixed and repackaged multiple times. The category of secondary ingredients, such as seasonings, breadings and peanut butter, is also especially susceptible to contamination.

Woody says food suppliers and distributors should have food defense plans in place that restrict access to facilities, and call for padlocks on truck trailers and regular, company-wide vulnerability assessments.

FDA's Center for Food Safety and Applied Nutrition (CFSAN) has released a number of initiatives designed to help suppliers, distributors and operators on the food defense front. Those initiatives are: ALERT (targeting foodservice managers), FIRST (aimed at employees, the first line of defense) and CARVER+Shock, a comprehensive online planning tool to help companies set food defense priorities. Information about all of them can be downloaded from the CFSAN Web site.

One other useful tool comes from the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). The FSIS *Guide to Developing a Food Defense Plan for Warehouse and Distribution Centers* is a 15-page, step-by-step document that includes evaluation forms covering everything from outside security to personnel to developing and implementing the overall plan.

The bottom line is that having a food defense plan helps suppliers, distributors and operators maintain the safety of the food products they handle—and most of all, helps protect everyone's business.

frozen to protect product integrity. Chemicals and cleaning products are segregated and placed separately on the delivery truck.

Who inspects incoming product for quality?

Distributors should have trained personnel inspecting the quality, condition and temperature of inbound products–especially perishable items. An in-house quality assurance program should include daily in-slot inspections of perishable products.

What happens to products that don't pass the quality test?

Products close to their expiration date or damaged while at the facility should be logged, segregated from other products for further inspection and returned to the supplier or dumped, if necessary.

Who inspects the facility? How often, and is it on a pre-determined schedule or by surprise?

Warehouse sanitation requires continuous effort at multiple levels. Supervisors should ensure floor and in-slot cleanliness on an ongoing basis. Audits should be regularly conducted by management. Many distributors contract with independent, third-party audit companies that conduct inspections at least once a year. Best-in-class companies hold inspections twice a year to identify and correct any food safety and sanitation issues. Distributors should be able to show you records of recent audit results.

On the Trucks

What are basic requirements for trucks to meet food safety standards?

Delivery vehicles should be of sturdy construction so as to permit easy rear- and side-door locking and sealing. Trucks should be sufficiently insulated and refrigerated so as to protect cargo against damage. Interior walls and floors should be clean and free of cracks or holes that could allow the entry of pests, vermin or dust, or negatively impact temperature control. As with the facility, the truck design should permit effective inspection, cleaning, disinfection and temperature control. Ideally, interior surfaces should be made of materials suitable for direct food contact, such as stainless steel or food-grade epoxy resins.

Regular cleaning programs are needed to keep the container interior free of dirt and debris. Equal attention to cleanliness is required for cargo pallets, load-securing devices and loading equipment such as hand trucks, forklifts and conveyors. When possible, transport vehicles should be reserved for "food use only" to reduce risks of cross-contamination.

What are your pre-loading procedures?

The pre-loading check should make sure that any residues from previous cargo have been removed. The cooling unit should be checked to make sure it's in good repair and operational. Portable bulkheads should be in good condition, free from tears or holes, and form a tight seal when in use. Air chutes (if present) should be properly in place for effective air circulation. Trailers should be pre-cooled at least an hour before loading to chill insulation and air.

How does a distributor handle loads that include both frozen and refrigerated products?

The optimum transport method for mixed loads is to use trailers with compartments set at different temperatures. These compartments are created through the use of portable, insulated bulkheads. Typically, frozen products are in the forward compartment at 0 °F or below, and cooler/dry product is in the rear at 41 °F or below. The practice of transporting frozen and refrigerated mixed loads in one compartment set at an intermediate temperature is not advisable for times longer than a few hours.

Cold Chain Assurance

How is the cold chain maintained during loading?

Product is typically brought to the dock in a sequence that minimizes the amount of time spent on the dock during loading and unloading. Best-in-class companies go to great lengths to ensure that product temperatures for meat, poultry and eggs do not exceed 40 °F before loading. Most larger distributors do their loading and unloading from refrigerated docks.

How is the product integrity maintained while in transit?

Once the truck pulls away from the dock, the product's safety and integrity becomes the responsibility of the driver. Leading companies have in-transit checks on temperature and refrigeration units. Some have implemented automatic time/temperature recording devices. Many also require warehouses to maintain log books documenting product condition upon arrival and during storage. A few companies have outfitted trucks with onboard computers and GPS systems so as to track location of product at all times.

What about unloading procedures? How is food safety ensured?

Product should be inspected for quality, damage and temperature (if appropriate) before being accepted at any point during the delivery process. Proper documentation is crucial to maintain records of product condition and packaging upon receipt. The documentation should also record temperature readings and note whether there was any sign of spillage, damage or pests. Perishable product should be moved immediately from the loading dock into the appropriate temperature zone in the warehouse or at the foodservice operation.

How are contaminated or returned products handled?

The distributor should have procedures for contaminated products to ensure they are separated from safe product. The procedures should cover products brought back by drivers upon their return to the warehouse. A monitoring plan and record-keeping system should document all steps taken. For food safety and food defense reasons, best-in-class companies would never sell a returned refrigerated/ready-to-eat product to another customer.

Useful links:

- International Foodservice Distributors Association, **www.ifdaonline.org**
- Center For Food Safety & Applied Nutrition, **www.foodsafety.gov/list**
- Conference For Food Protection, **www.foodprotect.org**
- Food Politics Blog, **www.foodpolitics.com**

A Matter of Balance

All of the food safety measures recommended by regulatory agencies and industry organizations–from a well-maintained refrigerated fleet to staff and driver training to inbound and outbound shipping standards–cost distributors both money and time.

"Food distribution is not just drayage–moving items from one point to another," Ferko says. "There's so much extra effort that we put into controlling the process to make sure product is safe."

Perhaps the most difficult question is, how do you put a value on doing the right thing? "What we do on the food safety front costs us time and money every day of the week," Ferko notes. "But it's all about delivering quality. The challenge is in choosing the right people and the right processes for the best reliability and safety, and negotiating a fair price that's acceptable to us and our customers. It's all about finding the right balance."

***Jorge A. Hernandez** is the senior vice president, Food Safety & Quality at U.S. Foodservice. He can be reached at (847) 232-5959; Fax (847) 232-5049; jorge.hernandez1@usfood.com*

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INSIDE: GMA 2010 Logistics Benchmark Study Results Revealed

Food Logistics

Information For Grocery and Foodservice Distributors/Manufacturers

Issue No. 120 March 2010

2010 INNOVATORS
Ten Companies To Watch

GLOBAL STUDY
Food Fraud In The Supply Chain

PLUS: STATUS REPORTS
- Fleet Maintenance Made Easy
- Connecting With Technology
- Lift Truck Update

Cold Chain Champions

Don Ratliff, Jaymie Forrest and Harvey Donaldson (from left) head up the newly launched Georgia Tech Integrated Food Chain Center.

COLD CHAIN CHAMPIONS

The newly launched Georgia Tech Integrated Food Chain Center will bring high value and market power to participants in the cold chain. By April Terreri

COOL COLLABORATORS: Jane Griffith of Wawa and Nick Pacitti of Sterling Solutions helped to pioneer the establishment of the Integrated Food Chain Center.

Finally, the food logistics industry will have a research and resource center to utilize for questions about and solutions to every aspect of managing and monitoring the food cold supply chain. The Georgia Tech Integrated Food Chain Center—formed by The Georgia Tech Supply Chain & Logistics Institute (SCL) at The Georgia Institute of Technology and by Sterling Solutions LLC—will be housed within SCL in Atlanta.

The Center—integrating academia with seasoned industry experts—will launch this May and will operate as an international center for applicable knowledge in the fragile cold chain.

Operation Integration

While a few other organizations operate in the cold chain, they are composed primarily of trade associations. This is the first time the industry will ever have a research center that will integrate all cold supply chain and logistics participants, including distributors, retailers, foodservice companies, distributors and transportation providers.

"There is currently no one entity that studies, researches and applies economically feasible industry-wide cold chain solutions," notes Nick Pacitti, partner with Sterling Solutions LLC, Memphis. "So this will be a center of knowledge providing research into specific areas affecting these respective participants. It will serve as a center of knowledge providing research into tracing and protecting perishable foods as they move through the cold supply chain."

The Center will focus on a number of areas of concern to the industry, including product safety, product quality, environmental impact and economic benefit. Funding will come from industry members and sponsors and through government grants.

The goal of bringing together all of these various players is to establish an overarching understanding among cold chain participants of their respective responsibilities for maintaining the cold chain and how those responsibilities affect cold chain management of the other participants downstream in the cold chain.

"One of the reasons for the Center is to mitigate the risks we saw in dollars spent on product for development, manufacturing, consumer testing and regulatory compliance," explains Pacitti. "These costs are at risk throughout the cold chain from supply to delivery because if the cold chain is not managed right, brand integrity, customer confidence and market share are at risk."

Jane Griffith, senior director of quality assurance and food safety for Wawa Inc., based in Wawa, PA., notes that she and Pacitti have been pursuing getting this concept established for a number of years, talking with colleges and universities about the feasibility of such a center.

'The food supply chain is a lot more complex than any other supply chain and the cold chain is the most fragile; the quality of food is dependent on how food products are handled at every touch point throughout the food chain.' —Don Ratliff, SCL

"But many of them didn't have the ability to really move the needle and help us bring all these central partners together," says Griffith. "When we approached Georgia Tech, they immediately saw the value to the industry and to the entire food supply chain. And since they have a reputation of expertise and strength in the supply chain anyway, it was a natural fit for them to do this."

Bill Hudson, president and CEO of Alexandria, VA-based Global Cold Chain Alliance, weighs in on the value to the industry of the Center. "As the Center will integrate the examination of the cold supply chain and the operation of the chain, we see this as a tremendous opportunity in bringing together the industry, academia, government and food science in order to study the challenges in food logistics."

Hudson adds that his organization also strives for integrity of refrigerated foods throughout the distribution chain. "We look forward to aligning our programs and our members' needs with the Center's mission."

Georgia Tech: The Natural Choice

John Bartholdi is research director for the Integrated Food Cold Chain Center. He points out that Georgia Tech's Supply Chain and Logistics Institute (SCL) has long been a global leader in supply chain and logistics.

"Georgia Tech's SCL is the largest industry/academic collaborative in the world, with research offices globally," he says. So the fit was perfect as the home for the new Center. A number of centers focused on food science do operate currently, most having grown out of schools of agriculture, explains Donald Ratliff, Ph.D. at SCL. "But there is no center focusing on the food supply chain and food logistics. So we are bringing something new and necessary to the industry through this Center."

Jaymie Forrest notes that for the last consecutive 19 years, Georgia Tech has been rated the top industrial engineering school in the country. "So in leveraging our systems and design engineering processes, coupled with our expertise in the supply chain and logistics arena, we offer this sweet spot of ours that brings a lot of value to the industry," says Forrest, director of business development at SCL.

SCL already has been involved in studying the temperature control chain as it relates to international shipments, continues Forrest. In fact, the institute has established several research centers throughout Asia, South America and Latin America. "These centers focus on logistics strategies," she explains.

"We are leveraging the knowledge we gather in order to collaborate and integrate the entire food chain." This knowledge will help inform the Center's work as anticipated international regulations become law.

"Its time has come for something like this Center," notes Jane Griffith, senior director of quality assurance and food safety for Wawa Inc. "Everyone saw there was the need for this, but nobody really understood what the best approach should be. I am so grateful that Georgia Tech has seen the value of this by embracing the concept and becoming an owner of this, helping all of us in the industry to move this along quickly." —*A.T.*

TEAMWORK: From left, Ratliff, Forrest and Harvey Donaldson, SCL managing director.

Chain Reaction: The Fragile Cold Chain

There has been increasing recognition in the last few years of the uniqueness of the food cold chain and food logistics, says Don Ratliff, Ph.D., at SCL at Georgia Tech.

"Our goal is to make sure that everyone understands the food chains," explains Ratliff, executive director of SCL. "They differ depending on where they originate—by product and by type of processing, for example. So we are not talking about just one food chain; there are many different food chains involved. What we hope will happen is that the issues causing trouble in any of these chains will bubble up so that we can address problems around quality, safety, energy efficiency and economics. The food passing through these supply chains has to be safe and of the highest quality, while also being economically feasible for the operators and for consumers."

The U.S. imports about 60 percent of all of the fruits and vegetables that the nation consumes. "So there is an increasing focus on food safety relative to products that are imported as well," says Ratliff. "The food supply chain is a lot more complex than any other supply chain and the cold chain is the most fragile; the quality of food is dependent on how food products are handled at every touch point throughout the food chain."

Methods that work in a typical food supply chain do not work effectively in a cold chain because the food is highly perishable and fluctuations in temperature and humidity, mishandling or expired codes can wreak havoc on the quality of the products and, by extension, on customer loyalty, notes Sterling Solutions' Paciti. He adds that about 25 percent of product is wasted due to poor handling or the inability to track shelf life.

As to ownership of the cold chain, there is not a single owner, but many. So cold chain management throughout the chain becomes an exercise in integrating the processes required by each participant as the food passes through the participant's portion of the cold chain. "If you know what the processes are up and down the chain, you can integrate all the processes so there is continuity in cold chain management up and down the chain," says Ratliff.

The industry strives to deliver safe, fresh, high-quality food products cost-effectively to consumers. However, just one error at any touch point along the cold chain can jeopardize product quality, freshness, brand image and food safety, no matter how excellent the cold chain management practices are downstream from the error.

"Most of the focus of research has been on how you deal with these touches within a facility and they have been one-point solutions," explains Ratliff. "But every handoff point has to be perfect; for instance, the handoff between production and transportation and between transportation and storage. We felt there was a need in the industry for an entity that would pull all of these groups together to guide cold chain technologies, management processes and methodologies."

To assure quality throughout the chain, the approach must change from one of inspecting all the food—which is not a realistic solution—to instituting a process that will incorporate quality in the chain. Thus, safety and quality will be consistent, similar to the philosophy of total quality management employed in the

Enhancing Traceability

IBM will act as an industrial advisory board member to the Integrated Food Cold Chain Center, reports Jane Snowdon, Ph.D., senior manager, industry solutions and emerging business, smarter building research, for the IBM T.J. Watson Research Center in Yorktown Heights, NY.

Jane Snowdon

"We will provide guidance and ideas to direct the Center's research agenda," Snowdon says. "We also anticipate fostering interactions with Georgia Tech and with the international ecosystem of university partners and industrial partners in joint workshops and seminars."

Of course, consumer confidence is won or lost based on the capability of cold chain participants to deliver safe and fresh food to consumers. In a study conducted last year, shortly after the tragic peanut debacle, IBM found that consumer confidence and trust in retailers, manufacturers and grocers is increasingly declining. "So now is really the time for all the players in the food supply chain to rebuild consumer confidence by modernizing the global supply chain so the production, safety, and quality of food can be improved," says Snowdon.

"I think what Georgia Tech is doing to bring together these stakeholders will really make a positive difference," continues Snowdon. "Now companies will have a trusted source of updated information relating to traceability. Companies will have brand empowerment because this information will enable them to make claims that they have real-time information about where their products are along the chain."

Supply chain efficiencies will enable companies to accelerate their product flows, thereby allowing them to reduce their inventory levels through increased supply chain visibility, explains Snowdon. Companies will be better able to protect their brand through risk mitigation by identifying risks and isolating contaminated products. Companies can assure regulatory compliance with individual retailer mandates and government regulations. "So traceability plays a very critical role in creating transparency that allows companies to mitigate recalls and support product marketing claims."

A few of IBM's traceability projects can offer ideas to the Center to drive technologies to enhance traceability. For instance, IBM is working with a major German food retailer who is applying RFID smart labels to meat products.

"The meat is tracked by the date it was placed into a refrigerated display case and the date it is removed from the case by a consumer," explains Snowdon. "This helps provide workable information for the store to monitor the freshness of the products while controlling the environment in which the products are stored. It also helps manage inventory levels by matching sales data. This is one example of how we are teaming with food retailers to ensure that food in the freezer stays fresh."

For a Norwegian food retailer, IBM developed a smarter food-tracking solution using RFID technology to track and trace meat and poultry from the farm to the store shelf. "Offering transparency throughout the cold chain ensures that food is maintained in optimal condition," Snowdon explains. "It also helps suppliers and grocers reduce their costs and improve food safety, thereby increasing consumer confidence."

Another practice worth noting in food traceability advancements is the example of A&P, who is applying bar codes to every individual egg in egg cartons. "These are examples of the shift we are seeing in our foods that provides more accountability in the food chain. So there is more information available today to do analytics to be able to look for trends and to more quickly pinpoint and react to any type of problem in the food chain before it becomes a problem. The next wave will be to use information to help us make better business decisions that can help mitigate recalls." —*A.T.*

automotive industry. "Rather than randomly testing product as it is delivered, it is less expensive to develop and coordinate a cold chain standard upstream starting at the producer and ending downstream at the store," explains Sterling's Pacitti.

Common concerns in the industry will be on the Center's agenda, such as improving supply chain efficiencies, monitoring traceability and quality, minimizing waste and spoilage, and improving bottom-line performance. Cold chain management is evolving into a regulatory tool, notes Pacitti. "It must be done right or the stakes are high."

The repository of information and research the Center will contain on supply chain management technology and product quality characteristics will have market appeal to cold chain participants. The Center will also promote a deep understanding of the economics relative to the development, production and distribution of perishable foods.

Front And Center: Numerous Opportunities

The Center will collaborate with the industry, academia and the federal government in information sharing and in pilot studies. It will bring value to the industry as well as to all partners of the cold supply chain, Wawa's Griffith points out. "It will provide research on technologies and processes for us to monitor and improve cold chain efficiencies, which is really critical to the industry and it is something that we hadn't had before in the industry," she says.

'We will be looking for guidance from Georgia Tech as to where there is opportunity for value to occur as we move inventories of highly perishable products.'

—Chris Lofgren, Schneider National

It will be an important link in assuring safe, high-quality foods from sources throughout the globe. "Consumers expect strawberries in December, but they don't understand that we have to source foods from faraway places to be able to offer them year-round," says Griffith. "The only way we can provide consumers with safe, high-quality food is through a system assuring efficient and effective cold chain management."

The integrated philosophy brings enhanced value to the industry. "It's critical to our industry that the Center develop solutions in joint research projects involving industry players and academia who can offer recom-

Transportation: Critical Point In Cold Chain Management

Transportation is a critical element in the cold chain, notes Nick Pacitti, partner with Sterling Solutions LLC in Memphis. "The transportation piece in the food cold chain is referred to as 'the last mile' in the supply chain and it is the area in the cold chain that places food at its most vulnerable if temperature abuse occurs," he says.

Numerous environmental conditions can cause temperatures to fluctuate, including the number of times doors are opened to deliver products, the volume delivered, time of year (summer opposed to winter) and geographic area (south or north).

"Most carriers cannot tell you when there is an issue, except when there is a major reefer breakdown," continues Pacitti. "Some will say they do what their customers tell them to do, which in many cases relates to what the temperature of the trailer should be. Temperature abuse plays havoc on product and most of this happens in the final mile of delivery."

Carriers and logistics providers must manage temperatures in a more scientific way, asserts Pacitti. "The Center offers a resource for carriers and their customers to come to learn the best way to protect products and to recognize that product abuse is a cumulative process. Cold chain management is evolving into a regulatory tool, as well as into a supplier-retailer-specific requirement."

Jane Griffith notes that the Center's mission to integrate all participants in the cold chain will bring independent haulers into the fold. "This is a very large group that needs to understand their role and responsibility in maintaining the cold chain," says Griffith, senior director of quality assurance and food safety for Wawa Inc. "Many of us use them and sometimes they are not as aware of their responsibilities as they could be. So we see the educational opportunities the Center will offer helping greatly to improve this situation."

Risk management is a critical element for transportation providers to consider. Phil Dunavant notes that he expects the Center to bring discipline to the transportation process. "I believe it will help us raise the bar relative to the capabilities of independent haulers," says Dunavant, COO of Memphis-based ReTrans Inc. The company is a multi-modal transportation provider working with independent haulers nationwide.

Protecting the safety and quality of food is a major concern especially considering the number of participants in the cold chain, Dunavant continues. "So from a risk management perspective, we want to make sure that our carriers have the required controls in place to provide the proper environment for the food cold chain."

Phil Dunavant

He envisions guidance from the Center will help relative to establishing KPIs that measure carrier performance. "We expect that the Center will shed light on what is needed out there to ensure that carriers are responsible in making the cold chain even more efficient. It will offer carriers a better understanding of their responsibility to maintain the cold chain and it will also give them an exposure to what the rules are and what is expected of them."

Transportation is, after all, the integrating function of the cold chain, reminds Chris Lofgren, president and CEO of Schneider National in Green Bay, WI. "We will be looking for guidance from Georgia Tech as to where there is opportunity for value to occur as we move inventories of highly perishable products. I think the Center will help us leverage information and communication and how that relates to understanding how the information flows relative to the physical flow of goods. This information will help us learn how we can drive efficiencies even further as we identify additional opportunities."

Lofgren looks for guidance from the Center in how to balance backhauls with refrigerated equipment. "The value you generate across that asset is diminished if you are not using it to transport refrigerated or temperature-controlled products. So we hope to learn how to have these operations work a lot more efficiently." —*A.T.*

mendations in advancing the effectiveness of cold chain management," says John Owen, vice president of logistics for the Midwest/Southeast supply chain services region of Minneapolis-based Supervalu Inc.

Employing a multi-disciplinary role in cold chain management, the Center will bring numerous opportunities to the industry, including:

Ongoing research: Laboratory simulations of things such as how temperature and humidity fluctuations affect product quality and shelf life will provide the industry with actionable information.

"We will develop thresholds and trigger points across the cold chain," says Pacitti. "This will alert us hours before something goes wrong that there is a problem brewing so we can be proactive and fix the problem. Then we can begin to manage shelf life by integrating quality, traceability and replenishment strategies."

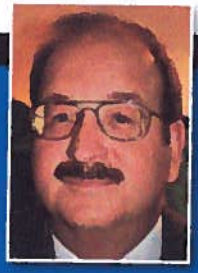
Next practices will direct methods of how to be more efficient in delivering perishable product from both a quality and economic perspective, Pacitti says.

SCL's Ratliff notes that industry will be a major participant in helping identify top problems. "Industry members will work with us to help resolve these problems. It is our desire to have regular ongoing projects that will monitor food as it moves through the chain as we examine things like temperature and humidity from end to end."

Supervalu's Owen looks to the Center to provide ongoing cold chain research to protect food throughout the chain. "The issue that any one particular company has is really an extension of the problems the industry faces," he says. "We deal with very sensitive products that need to be handled at critical temperatures and humidity. So anything that improves these processes helps all of us in the industry."

Suggesting technology solutions: The Center expects to determine how various technologies can be utilized effectively yet affordably, says Jaymie Forrest, director of business development for SCL. "We plan to work with companies who develop these technologies so we can determine how best to use their technologies," she says.

Griffith looks forward to emerging technology from the Center's research. "This is very essential to Wawa and we would like to see how this research can translate monitoring the cold chain into product traceability. If we can couple these two aspects—cold chain management and traceability—that will be a big win for many organizations in the food industry.



'Considering the ongoing regulatory activity focused on food safety, the industry must take the lead. The Center will be an important partner in this endeavor.'

—Frank Ferko, U.S. Foodservice

Traceability is something everyone needs to truly understand to be able to manage the cold chain properly."

These technology solutions should interface easily among participants and should be cost effective and affordable to everyone, she adds.

Another developing area relates to how to manage replenishment strategies while keeping very small inventories. "We are evaluating and understanding technologies that instantly capture data and report that your product sold so much of a percent of inventory on a particular day. This information converts into a production plan for the following day. So what happens at the cash register is critical in developing production and replenishment plans," notes Pacitti.

Assuring food safety: There is nothing more important to the strength of U.S. Foodservice's business than food safety, stresses Frank Ferko, director of distribution food safety and quality assurance for U.S. Foodservice headquartered in Rosemont, IL.

"As food safety leaders in the industry, we are acutely aware that the food cold chain really needs a world-class program like this Center," says Ferko. "The industry needs sophisticated educational and research programs that can provide analytical evidence to drive further development in the cold chain and distribution logistics."

Establishing standards: There are a number of organizations developing international standards for the food chain, SCL's Ratliff notes. While they focus primarily on providing services to their members (composed of a subset of service providers to the food chain), Ratliff explains the distinction of the Center is that it is focused on bringing together in an integrated approach to the chain all of the stakeholders, such as produc-

Continued Research And Development

The Georgia Tech Integrated Food Chain will address the following issues:

- **Temperature control (stability and challenge) testing:** Provides cumulative supply chain effects of time, temperature and other environmental effects on product quality.
- **Food and distribution engineering:** Provides abuse testing to determine product design and packaging and distribution methods.
- **Cold chain assessment and audit.**
- **Predictive modeling:** Provides predictions of the deterioration process.
- **Supply chain modeling:** Develops models and methodology for designing supply chains to optimize costs.
- **Automated data capture and processing:** Engineers onboard vehicle systems for automatic data capture.
- **Performance reporting and index:** Provides customer- and product-specific performance ratings.
- **Supply chain management technology:** Develops technologies and methodologies for visibility, tracking, and tracing.
- **Continuing education and certification:** Provides a learning center for cold chain participants.
- **Supply chain management technology showcase:** Demonstrates how technologies perform.
- **Sustainable energy management:** Assesses and correlates the impact to product quality of temperature management.
- **Risk and loss assessment and management:** Assesses vulnerabilities leading to product loss, quality deterioration and public health hazards.
- **Policy analysis:** Develops policies and models of success at regional, national and global levels for resilient and sustainable food chains.
- **Benchmarking and analytics:** Provides industry and best-in-class comparisons contributing to sustainable and resilient food chains. —*A.T.*

ers, processors, transportation providers, exporters, importers, wholesalers, distributors and retailers.

Currently, there are no cold chain standards to drive assurance and customer loyalty, adds Pacitti. "The costs of information have contributed to market failures in perishable product safety provisions, thus making the design of effective interventions difficult. Cold chain standards can reduce product safety risks and companies are seeking comprehensive answers to product integrity and supply chain effectiveness in light of the rapid rise in public health issues."

Pacitti reports that the Center will develop cold chain standards, processes and applications that will help overcome the expense of setting and monitoring levels of microbial food-borne pathogens and other product threats. "The Center will provide an economy of scale for solutions that the majority of perishable supply chain members would not be able to design or afford," he says.

Providing educational opportunities: Ferko at U.S. Foodservice reports his company intends to utilize the Center for educational opportunities and research partnerships.

"We have been looking for an academic partner for some time and the Center presents a solution for our team to enhance our performance. We would like to work with the Center to develop science-based metrics that measure food safety and quality within the cold chain," says Ferko. "We would also like to share some of the results of our own programs back to the Center, as I think there could be many valuable give-and-take opportunities between the industry and academia."

The Center expects to be on the cutting edge of advancing processes and technology, notes Owen at Supervalu. "We are always considering ways to further develop our associates, so the Center will offer us this great educational opportunity."

As a leader in supply chain and logistics, Georgia Tech also lends itself as a recruitment resource, he adds.

Griffith perceives the Center as an excellent source for educational opportunities for both herself and for members of her team at Wawa.

"We will use the Center as a resource for research on how to improve product quality throughout the cold chain. That might mean that they develop a standard for us of maximum temperature a product can reach before its quality begins to deteriorate or before we have a food safety issue," she says.

Informing regulations: The impact to the industry of government regulations will be another facet of the Center's research component, notes David Sterling, partner at Sterling Solutions.

"The amount of food safety regulations on the horizon could fundamentally impact how the industry does business. There is no true focal point for this kind of study today. The Center will be able to translate governmental regulations to indicate to the industry what the impact will be on their businesses," says Sterling. "Our goal is to be proactive and have a voice in governmental discussions as they relate to regulations."

Ferko at U.S. Foodservice notes: "Considering the ongoing regulatory activity focusing on food safety, it is especially important for the industry to take the lead. I think the Center will be an important partner in this endeavor."

Supervalu's Owen looks to the Center to examine best practices and best processes as they relate to regulations coming from various branches of the government. The industry can look to the Center to recommend regulations relative to food products sourced internationally, he adds.

Providing economical benefits: Of particular interest to Owen will be the methods the Center will develop to expand the cold life in the perishable portion of the grocery distribution business. "Applying these methods to our business and to the industry will be beneficial and will provide great economic value as well," he says.

'We deal with very sensitive products that need to be handled at critical temperatures and humidity. So anything that improves the process helps us all in the industry.'

—John Owens, Supervalu Inc.

Owen is also looking to the Center to discover ways for companies to lower their energy costs while maintaining cold chain integrity. "Many of our facilities of ours are very large and use a lot of electricity. We are always looking for ways to become more efficient."

Learning sustainability efficiencies: Ferko notes that sustainability aspects are a priority at U.S. Foodservice. He says the company was able to reduce the production of carbon dioxide by 22,000 metric tons in 2008. "We did this by simply reducing idle times, installing maximum speed controls, and routing deliveries more efficiently."

He adds that the company, involved in its own research projects, would like to work with the Center in developing other initiatives that reduce undesirable impacts on the environment. "We look forward to interactions between Georgia Tech, our company and the industry to find more of these kinds of environmental solutions."

Integration Articulation

Through the resources of the Center, improved applications can be brought to market a lot quicker. "Where you have consensus among different groups like government, private industry, and academia, this will provide a great resource for the industry to really be certain that we have the world's leading cold chain environment and that we are protecting food integrity all the way to the consumer," says Supervalu's Owen.

"I work very hard at Wawa to assure our cold chain is the very best we can provide, yet I know there are opportunities to improve," says Griffith. "Improvements will translate to increased shelf life, increased product quality, increased availability of products throughout the year to my consumers and increased consumer confidence that Wawa's products are high in quality. Of course, all of these things translate to a profit, which makes Wawa very happy."

The only other way to ensure safe food is to pasteurize or irradiate everything, notes Griffith. "But nobody wants to eat food that has been overprocessed. Going down that road is just not what the consumer wants. Everyone throughout the world wants the safest and freshest food possible. Having this Center as a resource will help us monitor and improve every aspect of the cold chain, and it will provide us with a deeper understanding of the processes that need to be implemented in order for the industry to manage and maintain an effective and efficient cold chain," she adds. ❀

For more information about the Georgia Tech Integrated Food Chain Center, go to www.sci.gatech.edu or call 404-894-2343. The Center can also be reached via email at ifc@sci.gatech.edu.

Conference for Food Protection
2012 Issue Form

Internal Number: 102
Issue: 2012 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.

Title:
Cottage Industry/Direct Producer to Consumer Sales

Issue you would like the Conference to consider:
Many states are adopting exceptions and special rules for cottage industries and direct producer to consumer sales. These types of sales include both packaged and unpackaged non PHF/TCS foods processed in residences and sold from the residence over the internet, at roadside stands, and at Farmer's Markets. The inconsistencies and in sometimes complete exemption from regulatory oversight are concerning from a safety persepective. We respectfully request that the Conference for Food Protection establish a Cottage Industry Committee to develop a proposal for the 2014 Conference that more completely addresses cottage industries and direct producer to consumer sales.

Public Health Significance:
States and local jurisdictions have adopted a variety of exemptions and policies with relationship to cottage industry/direct to consumer sales. The most significant public health issue is that jurisdictions without scientific input have developed a variety of standards, exception, and exemptions. This creates a system where a cottage industry/direct to consumer sales may or may not be regulated and inspected. From a state perspective, we see surrounding states that have exempted places from regulation, but the individuals are seeking to come to events and make sales in our State. For example, acidified foods, cheeses, eggs, and other processed foods are subject in some jurisidictions to these exceptions and exemptions. Furthermore, complete and thorough labeling is a concern to individuals with allergies or sensitivities.

Recommended Solution: The Conference recommends...:
creating a Committee to develop a proposal for the 2014 Biennial Meeting that more completely addresses cottage industries and direct producer to consumer sales. We respectfully suggest the Committee undertake the following charges:

- define Cottage Industries and Direct Producer to Consumer Sales
- identify exemptions from the Food Code
- establish labeling requirements
- write advisory statements as appropriate
- recommend Cottage Industry registration requirements

- require the Committee to submit a report at the 2014 Biennial Meeting along with Issues they identify.

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

Conference for Food Protection
2012 Issue Form

Internal Number: 109
Issue: 2012 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.

Title:
Report - Constitution and Bylaws/Procedures Committee

Issue you would like the Conference to consider:
The 2010 - 2012 Constitution and Bylaws/Procedures Committee has addressed recommendations from the 2010 Biennial Meeting and from the Executive Board and have prepared a report summarizing its work.

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...:
acknowledgement of the submitted report and appreciation for the work of the 2010 - 2012 Constitution and Bylaws/Procedures Committee members.
The Conference further recommends that the Constitution and Bylaws/Procedures Committee be assigned the following charges:
Charge: Continue work on charges previously assigned by the Executive Board to:
1. Research "scope" of Executive Board authority concerning direct approval of policy and procedures changes by the Executive Board rather than approval through Issue submission at the Conference Biennial Meetings.
2. Clarify the "scope" of activities assigned to committees that includes:
a) Development of a process of expanding or adding committee charges between biennial meetings.
b) Clarification of language in Conference Procedures Section VIII (D), (F.5.), (H.2.).
3. Clarify what the Executive Board may, under the Constitution and Bylaws and Conference Procedures, do with extracted Issues.
Charge: Review and consolidate the existing *Conference for Food Protection Constitution and Bylaws*, *Conference for Food Protection Procedures* and *Conference for Food Protection Biennial Meeting Manual, position descriptions, conference policies, etc.,* into a comprehensive "*Conference for Food Protection Manual*".

Charge: Report back to the Executive Board; and, submit recommendations as Issues at the 2014 Biennial Meeting.

Submitter Information:

Name: Lee M. Cornman, Chair
Organization: Constitutions and Bylaws Committee
Address: FL Dept of Agriculture and Consumer Services3125 Conner Blvd. MS C-18
City/State/Zip: Tallahassee, FL 32399
Telephone: 850.245.5595 Fax: 850.488.7946
E-mail: Lee.Cornman@FreshFromFlorida.com

Attachments:

- "Attachment A: Constitutions and Bylaws/Procedures Committee Final Report"
- "Attachment F: Constitutions and Bylaws/Procedures 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
Constitution and Bylaws/Procedures Committee FINAL Report

COMMITTEE NAME: Constitution and Bylaws/Procedures Committee

COUNCIL (I, II, or III): Executive Board

DATE OF REPORT: December 17, 2011

SUBMITTED BY: Lee M. Cornman, Chair

COMMITTEE CHARGE(s):

Charges Established by Issue 2010 II-035:

The Constitution and Bylaws (C&B) Committee develop guidelines regarding committee structure, participant responsibilities, membership size, and constituency representation and report back to the Executive Board no later than the August 2011 Executive Board Meeting with recommendations regarding proposed changes to policies and/or governing documents.

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.

Charges Established by the Executive Board:

1. Add a "statement of neutrality" to the Council Chair and Vice-Chair position description.
2. Clarify the use of "Conference" and "Biennial Meeting" in the Constitution, Bylaws, and Procedures.
3. Research "scope" of Executive Board authority concerning direct approval of policy and procedures changes by the Executive Board rather than approval through Issue submission at the Conference Biennial Meetings.
4. Clarify the "scope" of activities assigned to committees that includes
    a) Development of a process of expanding or adding committee charges between biennial meetings
    b) Clarification of language in Conference Procedures Section VIII (D), (F.5.), (H.2.).
5. Clarify what the Executive Board may, under the Constitution and Bylaws and Conference Procedures, do with extracted Issues.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Issue 2010 II-035: The Constitution and Bylaws Committee develop guidelines regarding committee structure, participant responsibilities, membership size, and constituency representation and report back to the Executive Board no later than the August 2011 Executive Board Meeting with recommendations regarding proposed changes to policies and/or governing documents.

Status: Research was conducted on minimum/maximum committee membership guidelines from other groups including Association of Food and Drug Officials (AFDO), International Association of Food Protection (IAFP), National Environmental Health Association (NEHA), etc. Most described a minimum number of committee members without specifying a maximum number. The Constitution, Bylaws/Procedures (C&B) Committee discussed the language currently provided in CFP Committee Member position description as follows: *Committee membership is generally composed of at least eleven (11) members: the Chair, Vice Chair and two (2) representatives from state regulatory, two (2) representatives from local regulatory, two (2)*

representatives from industry, and one (1) from an academic institution, and one (1) consumer representative, and one (1) representative from a federal agency. This language essentially defines a minimum committee number with constituency structure.

A proposal was made that consideration be given to using the current CFP Council structure and constituencies as defined in the Constitution and Bylaws (Article XI, Section 2) as a general guide for determining a maximum committee size and structure for committees. If a Committee Chair does not receive sufficient applicants in the appropriate constituencies, they may confer with the Council Chair to seek applicants from the Conference membership making every reasonable effort to maintain constituency balances. (Committee membership discussion is limited to Council committees only (i.e., those established or re-created following every Biennial Meeting) – membership on Standing Committees or Executive Ad Hoc Committees is defined by the CFP Executive Board.)

Active discussion resulted in a mixed opinion on providing a minimum/maximum committee membership size. The C&B Committee was in agreement to the minimum size of 11 voting members as currently defined by the CFP Committee Member position description. However, there was divergence as to defining a maximum number of committee members. Several different solutions to this issue were offered by C&B Members that would include participation from all Conference Members who apply for a committee membership. These recommendations were offered to the Executive Board for review, for discussion and recommendations for next steps. The Executive Board deliberated this issue and requested that the committee continue to deliberate this issue and provide a single recommended action for determining the maximum size of a council committee along with provisions for future turnover in council committee membership.

After further review and deliberation, the committee drafted a proposed revision to the Constitution and Bylaws that establishes a minimum of 11 voting members and a maximum of 23 voting members for council committees. Any volunteers for a committee beyond the 23 voting members will be included as "at-large" non-voting members. The maximum size voting membership is the Committee Chair, Vice Chair, four (4) representatives from state regulatory, four (4) representatives from local regulatory, eight (8) representatives from industry, one (1) from an academic institution, one (1) consumer representative, and three (3) elective representatives that may be selected from any Conference constituency. The proposed language noted below includes procedures for managing unbalanced constituencies, member changes in constituencies, and changes to membership between Biennial Meetings.

Additionally, a proposal was received from FDA representatives that Section VIII, Paragraph D of the *CFP Conference Procedures* be moved into Article XIV, Section 1, of the *CFP Constitution and Bylaws* with minor revisions. This amendment is also consistent with the charge specified in Issue 2010 II-035 and relevant to identification of committee membership. This language clarifies the appointment of committee chairs and committee members with Board approval and the appointment of Federal participants to each committee as a non-voting member. Language amendment is provided below:

See Issue titled: ***Council Committee Size and Constituency***.

CFP Conference Procedures
VIII. Committees

A. - C. No change.

~~D. Appointment of Members~~

~~1. The incoming Council Chairs appoint the Chairs of each Committee formed within their Council with the concurrence of the Conference Chair. The Conference Chair will confirm the appointment of the Committee Chair and then notify the person of their appointment. Once confirmed, the Committee Chair will select the remaining members of the Committee and submit them to the Conference Chair for final Board approval. Accepting a committee chair or member assignment requires a commitment of time and~~

~~resources as described in the Constitution and Bylaws.~~

~~2. Federal participants (FDA/USDA/CDC) may appoint a member and an alternate for each Committee. The member participates in discussion but does not vote. The alternate may act in the member's place if the member is unable to attend~~.

E. - J. No language change – renumbering only as paragraphs D through I.

CFP Constitution and Bylaws
Article XIV Committees

Section 1. All appointments to Council Committees shall be made to provide a balance in representation of the stakeholders in the particular matter under consideration.

Subsection 1. The incoming Council Chairs appoint the Chairs of each Committee formed within their Council with the concurrence of the Conference Chair. The Conference Chair will confirm the appointment of the Committee Chair and then notify the person of their appointment. Once confirmed, the Committee Chair will select the remaining members of the Committee and submit them to the Conference Chair for final Board approval.

Subsection 2. Federal participants (FDA/USDA/CDC) may appoint a member and an alternate for each Committee. The member participates in discussion but does not vote. The alternate may act in the member's place if the member is unable to attend.

Section 2. – 5. No change.

Article XV Duties of the Committees

Section 8. Council Committee Size and Constituency: Committee membership discussion is limited to Council committees only. Membership on Standing Committees or Executive Board Ad Hoc Committees is defined by the CFP Executive Board.

Subsection 1. Committee size.

Voting membership for council committees should be comprised of at least eleven (11) voting members with a maximum of no more than twenty-three (23) voting members.

a. Minimum size: Voting membership for a minimum size committee is the Chair, Vice Chair, two (2) representatives from state regulatory, two (2) representatives from local regulatory, two (2) representatives from industry, one (1) from an academic institution, one (1) consumer representative, and one elective (1) representative which may be selected from any Conference constituency.

b. Maximum size: Voting membership for a maximum size committee is the Chair, Vice Chair, four (4) representatives from state regulatory, four (4) representatives from local regulatory, eight (8) representatives from industry, one (1) from an academic institution, one (1) consumer representative, and three elective (3) representatives that may be selected from any Conference constituency.

c. Any committee comprised of membership numbers between the minimum and maximum shall make every reasonable effort to maintain constituency balances.

Subsection 2. The Chair and Vice Chair of a council committee may be selected from any of the Conference constituencies as approved by the Council Chair and the Executive Board, provided each is from a different constituency. If a Committee Chair does not receive sufficient volunteers in the appropriate constituencies, they shall confer with the Council Chair to seek

volunteers from the Conference membership making every reasonable effort to maintain constituency balances. The Committee Chair, in conference with the Council Chair and/or Executive Board, shall have the flexibility to fill vacancies in the voting membership with unbalanced constituency representation if deemed necessary to reach a minimum of 11 voting committee members. All proposed committee members must be approved by the Executive Board in accordance with Article XIII, Section 6, Subsection 4 of the Constitution and Bylaws.

Subsection 3. A maximum of 23 voting members are permitted on a council committee**.** All volunteers not selected for a voting position shall be offered an "at-large" non-voting position on the committee. There is no limit to the number of at-large non-voting members that may participate. At-large members will be included and allowed to participate in all committee functions, including but not limited to, meetings, conference calls, emails, deliberations, research and activities, but will not have an individual vote on committee actions. All voting members and at-large non-voting members shall be identified as such on the committee roster along with their respective constituency.

Subsection 4. In the event a council committee voting member departs such committee during a biennial cycle, an at-large member of the same constituency as the departing member shall be selected by the Council Chair to fill the vacancy, subject to approval by the Council Chair and Executive Board in accordance with Article XIII, Section 6, Subsection 4 of the Constitution and Bylaws. If a council committee voting member changes constituency during a biennial cycle, and there is no vacancy in that members new constituency, the member will need to transition from service as a voting member on that committee and may continue to serve as an at-large non-voting member for the remainder of the biennial cycle. This transition will occur upon notification to the Committee Chair.

Subsection 5. The Chair of a council committee that continues over more than one biennial cycle shall assess the immediate previous committee membership to ensure at least 50% of the ongoing committee's voting membership are new members that did not serve as voting members on the immediate previous committee. This will ensure that an increased number of at-large members or others have an opportunity to participate as a voting member over time when there are a large number of volunteers.

The 2010 – 2012 Constitution and Bylaws/Procedures Committee also looked at the organization's governing documents to develop definitions for each of the existing constituencies as identified in Article IV of the *Constitution and Bylaws*. The Committee has created definitions for each of the existing constituencies that represent the Conference for Food Protection membership. Current constituencies include: Regulatory – Local, State, District/Territory and Federal; Industry – Retail, Food Service, Processing and Vending; Academia; and Consumer. While each constituency is identified in the *Conference for Food Protection Constitution and Bylaws* by title, these constituencies do not currently have a clear definition for what comprises each.

Additionally, the Committee has sought to create definitions for several new constituencies that incorporate the expanding types of members who seek to be active participants in the Conference process. The largest majority of current members in the Conference for Food Protection are categorized as "other" because they do not fall within the existing definitions for Conference constituencies. New constituencies for consideration by the Conference include: Food Industry Support, Emeritus (retiree), and Student; and, the Vending Industry constituency has been expanded to include the Distribution Food Industry as a shared constituency titled 'Vending and Distribution Food Industry".

Creation of the new constituencies does not alter representation to the CFP Executive Board, the Councils, or to the Conference Voting Delegates as currently prescribed in the *CFP Constitution and Bylaws*. See language noted below and Issue titled: ***Definitions for Conference Constituencies***.

Article III Registration and Membership

Section 5. Membership in the Conference is classified into constituencies that are representative of the key stakeholder groups which support the objectives of Article I and facilitate the requirements of Article IV. The Conference constituencies are defined as follows:

Subsection 1. Regulatory is comprised of those officers, agents or authorized representatives having authority over the regulation of food establishments, production, processing, vending, or distribution, or has oversight for prevention of foodborne illness in accordance with rule and/or law in their respective governmental jurisdiction. Sub-categories of this constituency include:

a. Local Regulator = government employee or agent representing a territorial division of local government with responsibility for regulation of food establishments, production, processing, vending or distribution, or has oversight for prevention of foodborne illness.

b. State Regulator = government employee or agent representing a territorial division of state government with responsibility for regulation of food establishments, production, processing, vending or distribution, or has oversight for prevention of foodborne illness.

c. Federal Regulator = government employee or agent representing a program or agency of the Federal Government with responsibility for regulation of food establishments, production, processing, vending or distribution, or has oversight for prevention of foodborne illness.

d. District/Territory Regulator = government employee or agent representing the U.S. District of Columbia or one of the six U.S. Territories with responsibility for regulation of food establishments, production, processing, vending or distribution, or has oversight for prevention of foodborne illness.

Subsection 2. Industry is comprised of those employees, agents or executives representing business entities that operate food establishment(s), production, processing, vending, or distribution; or, providers of an industry related service to such food operations; or, representatives of a professional organization or trade association that promotes, supports and/or markets to/for the food industry or its related services. Sub-categories of this constituency include:

a. Food Service Industry = employees, agents or executives representing business entities that operate food service establishments. Examples include, but are not limited to, restaurants of all sizes/types/styles of service, caterers, military food service, institutional and other health care food service, schools and university food service, common carrier food service (planes, trains, etc.), corporate food service operations, and government food service.

b. Retail Food Industry = employees, agents or executives representing business entities that operate retail food establishments. Examples include, but are not limited to, grocery stores, supermarkets, convenience stores, retail pharmacies, produce markets, roadside stands, department stores, warehouse sales clubs, seafood markets, retail bakeries, military base PX/groceries, and liquor stores.

c. Processing Food Industry = employees, agents or executives representing business entities that manufacture, process, package or label food items for wholesale sale. Examples include, but are not limited to, commercial food manufacturing, canning, packaging, commercial bakeries, commercial meat slaughter and processing, packing houses and distribution centers, farming and agricultural processing and packing operations, ice processing, and packing plants.

d. Vending and Distribution Food Industry = employees, agents or executives representing business entities that own and/or operate food companies that vend or distribute food either

wholesale or retail. Examples include, but are not limited to, coffee and food vending service companies, service companies, commissaries, food supply chain operators, wholesale distributer, shipping lines, brokers, equipment manufacturers, and suppliers of products and services to operating service companies.

Subsection 3. Food Industry Support = employees, agents or executives representing business entities that provide direct or support services to food service establishments, retail food establishments, processing food operations, vending and distribution food operations. Examples include, but are not limited to, professional organizations, trade associations, pest control companies, auditing firms, standards associations, consultants, cleaning and sanitation management operations, training and/or testing companies or services, equipment and supply operations, software and technology, dieticians or dietary managers, media and legal representatives.

Subsection 4. Academia = academic professionals employed by a college or university involved in education or research involving food sciences, food operations, or food safety. Examples include, but are not limited to, professors, adjunct instructors, researchers, teaching assistants, and extension agents.

Subsection 5. Consumer = employees, agents or executives representing consumer advocacy organizations supporting food safety, food wholesomeness, allergen awareness, food policy matters and food standards and guidelines.

Subsection 6. Emeritus = members retired or honorably discharged from full-time work and no longer receiving compensation for work related to the Conference's mission. This constituency is designed for those professionals who, prior to retirement, were members of any Conference stake holder group in good standing of the Conference for Food Protection for at least three biennial cycles (6 years). Previous membership does not have to be in contiguous biennial cycles. An emeritus member may participate as an attendee/observer in all usual Conference functions such as attending the Biennial Meeting, including workshops, Council deliberations, Assembly of Delegates, and social functions. Emeritus members may serve as a member of a Council committee, as a Council Committee Chair and participate and vote in constituency caucus meetings. The Executive Board may elect to assign an emeritus member to participate in other Conference related activities.

Subsection 7. Student = any student enrolled in a two-year, four-year, or graduate program in a college or university involving food sciences, food operations or food safety. A student member may participate as an attendee/observer in all usual Conference functions such as attending the Biennial Meeting, including workshops, Council deliberations, Assembly of Delegates, and social functions. Student members may serve as a member of a Council committee. The Executive Board may elect to assign a student member to participate in other Conference related activities.

Charges Established by the Executive Board:

1. Add a "statement of neutrality" to the Council Chair and Vice-Chair position description.

Status: Essentially, this is an agreement by Council Chairs and Vice Chairs to refrain from lobbying any particular issue or expressing a personal opinion about any particular issue during any Council Sessions or open Conference forum at the Biennial Meetings. Council Chairs/Vice Chairs have been verbally agreeing to maintain "neutrality" during the proceedings of the Biennial Meetings since 2006 and this proposal formalizes that agreement. Conditions are provided where the individuals in these positions may express a personal opinion during Caucus Meetings or during Council deliberation provided the Chair/Vice-Chair has officially relinquished their chair in accordance with Roberts Rules of Order. Newly proposed language is noted below; see Issue titled: **Statement of Neutrality for Council Chair / Council Vice-Chair**,

and *Attachment B: Council Chair Position Description Neutrality Statement,* and *Attachment C: Council Vice-Chair Position Description Neutrality Statement* for the proposed full language of each.

Council Chair Neutrality

- In order to maintain their neutrality during Council deliberations, the following rules of conduct shall apply to the Council Chair during the biennial conference:
  - Outside the Council deliberations, the Chair shall refrain from publicly voicing a personal opinion on an Issue that is before the Council in such a manner or extent that it may call into question his or her ability to remain neutral when the Issue ultimately reaches the Council floor.
  - May answer questions related to a specific Issue during Council deliberations if the intent of the response is to objectively educate or clarify the Council, presenter or person approved to address the Council.
  - May offer personal opinions in the following situations:
    I. Outside of council deliberations, including constituency consensus meetings and caucuses, with the clarification that one is offering a personal opinion and not speaking as the Council Chair.
    II. During Council deliberations, only when one's position as Chair has been clearly relinquished to someone else (per Robert's Rules of Order Newly Revised).

Council Vice Chair Neutrality

- In order to maintain their neutrality during Council deliberations, the following rules of conduct shall apply to the Council Vice Chair during the biennial conference:
  - Outside the Council deliberations, the Vice Chair shall refrain from publicly voicing a personal opinion on an Issue that is before the Council in such a manner or extent that it may call into question his or her ability to remain neutral when the Issue ultimately reaches the Council floor.
  - May answer questions related to a specific Issue during Council deliberations if the intent of the response is to objectively educate or clarify the Council, presenter or person approved to address the Council.
  - May offer personal opinions in the following situations:
    I. Outside of council deliberations, including constituency consensus meetings and caucuses, with the clarification that one is offering a personal opinion and not speaking as the Council Vice Chair.
    II. During Council deliberations, only when one's position as Vice Chair has been clearly relinquished to someone else (per Robert's Rules of Order Newly Revised).

2. Clarify the use of "Conference" and "Biennial Meeting" in the Constitution, Bylaws, and Procedures.

Status: The 2010 – 2012 Constitution and Bylaws Committee has reviewed the *Conference for Food Protection Constitution and Bylaws* and the *Conference for Food Protection Procedures* documents to identify where the terms "Conference", "Conference for Food Protection" and "Biennial Meeting" have been used interchangeably or incorrectly. These documents have been expanded and revised over the years with numerous writers/editors. As a result, there are locations within each document where clarification is needed to accurately represent whether a portion of text refers to the Conference for Food Protection as the organization or, refers to the Conference of Food Protection as the Biennial Meeting, and vice-versa. An in-depth review was completed to discern the meaning of each passage and provide the appropriate terminology. See Issue titled: ***Clarification of Terminology in Conference Governing Documents*** and *Attachment D: CFP Constitution and Bylaws / Procedures with Editorial Corrections* for the full language with annotated changes.

3. Research "scope" of Executive Board authority concerning direct approval of policy and procedures changes by the Executive Board rather than approval through Issue submission at the Conference Biennial Meetings.

4. Clarify the "scope" of activities assigned to committees that includes

a) Development of a process of expanding or adding committee charges between biennial meetings

b) Clarification of language in Conference Procedures Section VIII (D), (F.5.), (H.2.).

5. Clarify what the Executive Board may, under the Constitution and Bylaws and Conference Procedures, do with extracted Issues.

Status: The Constitution and Bylaws/Procedures Committee was unable to complete the charges identified in numbers 3 – 5 above and will include these as continuation charges for the 2012 – 2014 Constitution and Bylaws/Procedures Committee as Executive Board charges.

Recommended Charges for 2012 – 2014 Constitution and Bylaws/Procedures Committee:

Along with the above Executive Board continuation charges noted above, the Constitution and Bylaws/Procedures Committee proposes development of a 2012 Issue charging this committee with incorporating the *Constitution and Bylaws*, the *Conference Procedures*, the *Conference Biennial Meeting Manual*, position descriptions, Conference policies, etc., into a comprehensive "Conference for Food Protection Manual" that would be divided into multiple "chapters" including the documents listed above and any other relevant items, each as a separate chapter. The *Constitution and Bylaws* will remain as a stand-alone document, potentially as Chapter 1 of the manual, with each of the other complimentary Conference documents as parts of an all-inclusive handbook that can be indexed and cross-referenced. There are areas for improvement in each of these documents (chapters) in the conformance of terminology and language between documents. Also, combining the documents into one master manual will help guarantee that any updates or corrections are performed across the entire manual to ensure that documents match accordingly. The combined and cross-referenced document can be posted to the CFP website in a format similar to the FDA Food Code where each chapter, table of contents, index, etc. shows as an individual link that is part of the whole CFP Manual. See Issue titled: ***Merger and Conformance of CFP Governing Documents***.

REQUESTED ACTION:

Committee submitted Issues =

- Report - Constitutions and Bylaws/Procedures Committee (with Attachments A and F)
- Council Committee Size and Constituency
- Definitions for Conference Constituencies
- Statement of Neutrality for Council Chair / Council Vice Chair (with Attachments B and C)
- Clarification of Terminology in Conference Governing Documents (with Attachment D and E)
- Merger and Conformance of CFP Governing Documents

Committee submitted Content Documents =

- Attachment A: Constitution and Bylaws/Procedures Committee Final Report
- Attachment B: Council Chair Position Description Neutrality Statement
- Attachment C: Vice-Council Chair Position Description Neutrality Statement
- Attachment D: Editorial Revision to CFP Guidance Documents – Bylaws
- Attachment E: Editorial Revision to CFP Guidance Documents - Procedures

COMMITTEE MEMBER ROSTER:

Attachment F: Constitutions and Bylaws/Procedures Committee Roster

Committee Name:

Committee Name: Constitution and Bylaws/Procedures **Attachment F**

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	Address	City	State	Zip	Telephone	Email
Cornman	Lee	Chair	State	FL Dept. of Ag & Cons. Svcs	3125 Conner Blvd, MS C-18	Tallahassee	FL	32399-1650	850.245.5595	lee.cornman@freshfromflorida.com
Hendy	Ruth	Vice-Chair	State	Texas DSHS	PO Box 149347	Austin	TX	78714	512.834.6753	ruth.hendy@dshs.state.tx.us
Hale	Aggie	Member	State	FL Dept. of Ag & Cons. Svcs	3125 Conner Blvd, MS C-18	Tallahassee	FL	32399-1650	850.245.5520	aggie.hale@freshfromflorida.com
Everly	Vicki	Member	Other	Self - Consultant	41407 Millinium Terrace	Fremont	CA	94538	510.501.0417	vicki.everly2@gmail.com
Hardister	Bill	Member	Local	Mecklenburg Co. HD	700 N Tryon St., STE 208	Charlotte	NC	28202	704.335.5533	bill.hardister@mecklenburgcountync.gov
Mitchell	Cassandra	Member	Local	Fairfax Co HD	10777 Main St., STE 111	Fairfax	VA	22030	703.246.8438	cassandra.mitchell@fairfaxcounty.gov
Levee	Terry	Member	Industry	Food Marketing Institute	2345 Crystal Drive, Ste 800	Arlington	VA	22202	202.220.0659	tlevee@fmi.org
Grover	Steven	Member	Industry	Steak 'N Shake	36 S Pennsylvania St	Indianapolis	IN	46204	317.656.4580	steven.grover@steaknshake.com
Ferko	Frank	Member	Industry	US Foodservice	6133 N River Road	Rosemont	IL	60018	847-232-5896	frank.ferko@usfood.com
Linton	Richard	Member	Academia	Ohio State University	190 North Oval Mall	Columbus	OH	43210-1358	614.247.7881	linton.60@osu.edu
Liggans	Girvan	FDA Consultant	Federal	FDA	5100 Paint Branch Pkwy	College Park	MD	20740	301.436.2937	girvan.liggans@fda.hhs.gov
Cartegena	Mary	FDA Consultant	Federal	FDA	5100 Paint Branch Pkwy	College Park	MD	20740	301.436.2937	mary.cartegena@fda.hhs.gov

Conference for Food Protection
2012 Issue Form

Internal Number: 110
Issue: 2012 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.

Title:
Statement of Neutrality for Council Chair / Council Vice-Chair

Issue you would like the Conference to consider:
In response to a directive from the Executive Board, the 2010 - 2012 Constitution and Bylaws/Procedures Committee has created language to further clarify the role of Council Chairs and Council Vice-Chairs during their service at a Biennial Meeting. New language has been added to the position descriptions directing each to maintain their neutrality with regards to any specific issue during Council deliberations.
The Chair and Vice-Chair shall refrain from publicly voicing a personal opinion on an issue before the Council they serve. They may answer questions related to issues if the intent is to educate or provide clarification. Personal opinions on a specific issue may only be offered outside of council deliberations if clearly identified as a personal opinion or, during deliberations if their position as Chair/Vice Chair has been officially relinquished in accordance with Robert's Rules of Order.

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 addition of a statement of neutrality (noted below; new language underlined), as developed by the Constitution and Bylaws Committee, in the position descriptions for Council Chair and Council Vice-Chair.
Council Chair Neutrality
In order to maintain their neutrality during Council deliberations, the following rules of conduct shall apply to the Council Chair during the biennial conference:

- Outside the Council deliberations, the Chair shall refrain from publicly voicing a personal opinion on an Issue that is before the Council in such a manner or extent that it may call into question his or her ability to remain neutral when the Issue ultimately reaches the Council floor.

- May answer questions related to a specific Issue during Council deliberations if the intent of the response is to objectively educate or clarify the Council, presenter or person approved to address the Council.
- May offer personal opinions in the following situations:
    - Outside of council deliberations, including constituency consensus meetings and caucuses, with the clarification that one is offering a personal opinion and not speaking as the Council Chair.
    - During Council deliberations, only when one's position as Chair has been clearly relinquished to someone else (per Robert's Rules of Order Newly Revised).

Council Vice Chair Neutrality

In order to maintain their neutrality during Council deliberations, the following rules of conduct shall apply to the Council Vice Chair during the biennial conference:

- Outside the Council deliberations, the Vice Chair shall refrain from publicly voicing a personal opinion on an Issue that is before the Council in such a manner or extent that it may call into question his or her ability to remain neutral when the Issue ultimately reaches the Council floor.
- May answer questions related to a specific Issue during Council deliberations if the intent of the response is to objectively educate or clarify the Council, presenter or person approved to address the Council.
- May offer personal opinions in the following situations:
    - Outside of council deliberations, including constituency consensus meetings and caucuses, with the clarification that one is offering a personal opinion and not speaking as the Council Vice Chair.
    - During Council deliberations, only when one's position as Vice Chair has been clearly relinquished to someone else (per Robert's Rules of Order Newly Revised).

Submitter Information:

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E-mail: Lee.Cornman@FreshFromFlorida.com

Attachments:

- "Attachment B: Council Chair Position Description Neutrality Statement"
- "Attachment C: Council Vice-Chair Position Description Neutrality Statement"

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
COUNCIL CHAIR
Position Description

At the end of the Conference for Food Protection (CFP) biennial meeting, each Council Vice Chair assumes the position of Council Chair subject to Conference Chair appointment and Executive Board (Board) approval. The Council Chair ensures the Council responsibilities are carried out during the two years between biennial meetings and manages the Council deliberations during the biennial meeting.

Responsibilities and Duties

- Supports the objectives of CFP as stated in Article I of the *Constitution and Bylaws*.

- Has a thorough knowledge of the *Constitution and Bylaws*, *Conference Procedures,* and *Biennial*
- *Meeting Information Manual.*
- Has a working knowledge of *Robert's Rules of Order/Parliamentary Procedure*.

- Attends all CFP Board meetings.

- Supervises and trains the Council Vice Chair in the execution of all duties assigned to the Council Chair.

- Supervises the formation and functioning of committees assigned to the Council:
    - Receives committee sign-up sheets at the close of the biennial meeting.

    - Selects Committee Chairs within sixty (60) days of the biennial meeting and submits their names to the Conference Chair for Board approval.

    - Assists Committee Chairs in the selection of committee members, ensures that the committee membership is representative of CFP, and submits the membership list to the Board for approval no later than the fall Board meeting following the biennial meeting.

    - Supervises the activities of all committees assigned to the Council to ensure that the assignments of the biennial meeting are being handled in a timely fashion.

    - Assures committee reports are submitted in a timely manner so a Council summary report can be written and submitted it to the Conference Chair and Executive Director at least thirty (30) days prior to each Board meeting.

  - Ensures final committee report(s) and Issue(s) are completed and submitted to the Issues Chair no later than the Issue submission deadline, seventy-five (75) days prior to the biennial meeting.

- Ensures that the Issues assigned to the Council are handled during the two years between Conferences.

- Prepares a written Council summary report on the status of assigned Issues and committee activities and submits the report to the Conference Chair and Executive Director at least thirty (30) days prior to each Board meeting.

- Establishes Council membership as set forth in Article IX of the *Constitution and Bylaws:*

  - Reviews Council applications as submitted during the summer preceding the biennial meeting.

  - Selects Council members ensuring balanced representation as described in Article IX and the Appendix of the *Constitution and Bylaws*

  - Provides the names of nominated Council members and alternates for appointment by the Conference Chair and approval by the Board at the fall Board meeting prior to the next biennial meeting.

  - Notifies all Council applicants of their appointment status.

  - Maintains communication with Council members prior to the biennial meeting and ensures pre-registration to confirm ability to serve on the Council.

- Attends Council member orientation session during the biennial meeting.

- Manages the Council deliberation process as described in Article XI of the *Constitution and Bylaws* and Section V of the *Conference Procedures:*

  - During Council deliberations votes on Issues only in the event of a tie.

  - Assigns the Council Vice Chair to supervise the activities of the Council Scribe and Runner.

  - Verifies that all Issues are properly recorded at the end of each day of Council deliberations and
  - that the electronic copy of Issues is delivered to the Executive Director.

  - Prepares the Council Summary Report at the conclusion of Council deliberations for presentation

- to the Assembly of State Delegates as described in Section VII of the *Conference Procedures*.

- Consults with the incoming Council Chair to determine suitable Council Vice Chair candidates for recommendation, subject to Board review and approval and Conference Chair appointment.

- Assists incoming Conference Chair in the preparation of the final Conference recommendations pursuant to Section IX, *Conference Procedures*.

Council Chair Neutrality

- In order to maintain their neutrality during Council deliberations, the following rules of conduct shall apply to the Council Chair during the biennial conference:

  - Outside the Council deliberations, the Chair shall refrain from publicly voicing a personal opinion on an Issue that is before the Council in such a manner or extent that it may call into question his or her ability to remain neutral when the Issue ultimately reaches the Council floor.

  - May answer questions related to a specific Issue during Council deliberations if the intent of the response is to objectively educate or clarify the Council, presenter or person approved to address the Council.

  - May offer personal opinions in the following situations:

    I. Outside of council deliberations, including constituency consensus meetings and caucuses, with the clarification that one is offering a personal opinion and not speaking as the Council Chair.

    II. During Council deliberations, only when one's position as Chair has been clearly relinquished to someone else (per Robert's Rules of Order Newly Revised).

Selection Criteria

- A member in good standing of CFP.

- Commits to serving two (2) years as Council Chair and has the approval and support of their employer.

CONFERENCE FOR FOOD PROTECTION
COUNCIL VICE CHAIR
Position Description

At the end of the Conference for Food Protection (CFP) biennial meeting the newly elected Conference Chair, with approval by the Executive Board (Board), appoints the Council Vice Chair. The Council Vice Chair assists the council Chair in carrying out the Council's assigned charges throughout the two years between biennial meetings as well as during Council deliberations at the biennial meeting.

Responsibilities and Duties

- Supports the objectives of CFP as stated in Article I of the *Constitution and Bylaws*.
- Has a thorough knowledge of the *Constitution and Bylaws, Conference Procedures, and Biennial Meeting Information Manual.*
- Has a working knowledge of *Robert's Rules of Order/Parliamentary Procedure.*
- Attends CFP Board meetings.
- Assumes the duties of the Council Chair in the event the Council Chair is unable to fulfill required duties during the two (2) year term until a new Council Chair of the same constituency is appointed by the Board.
- Assists the Council Chair in selecting Committee Chairs.
- Works with the Council Chair and Committee Chairs as they select Committee members.
- Assists the Council Chair in ensuring that Committees are actively working on their assignments:
    - Committee assignments are being deliberated through face-to-face meetings or conference calls.
    - Committee membership is current and constituency balance is maintained.
    - Committee reports are written and submitted to the Council Chair at least thirty (30) days prior to the Board meeting.
    - Ensures that final committee reports and Issue(s) are completed and submitted to the Issues Chair seventy-five(75) days prior to the biennial meeting.

- Works with the Council Chair and Committee Chairs to nominate Council members and alternates, as set forth in Article IX of the *Constitution and Bylaws*, from persons who have submitted applications to the Executive Director during the summer preceding the biennial meeting.

- Assists the Council Chair during the deliberation of the Issues assigned to the Council.

- During Council deliberations, in the absence of the Council Chair, votes on council Issues only in the event of a tie.

- Attends the Scribe/Runner Orientation and supervises the activities of the Council Scribe and Runner.

- Attends the Council member orientation session during the biennial meeting.

- Assists the Council Chair in verifying that all Issues are properly recorded at the end of each day of Council deliberations and that the electronic copy of Issues is delivered to the Executive Director.

- Assists the Council Chair in preparing the Council Report for presentation to the assembly of State Delegates.

- Consults with the outgoing Council Chair to determine suitable Vice Chair candidates and makes a recommendation to the Conference Chair subject to Board review and approval.

Council Vice Chair Neutrality

- In order to maintain their neutrality during Council deliberations, the following rules of conduct shall apply to the Council Vice Chair during the biennial conference:

  - Outside the Council deliberations, the Vice Chair shall refrain from publicly voicing a personal opinion on an Issue that is before the Council in such a manner or extent that it may call into question his or her ability to remain neutral when the Issue ultimately reaches the Council floor.

  - May answer questions related to a specific Issue during Council deliberations if the intent of the response is to objectively educate or clarify the Council, presenter or person approved to address the Council.
  - May offer personal opinions in the following situations:

    I. Outside of council deliberations, including constituency consensus meetings and caucuses, with the clarification that one is offering a personal opinion and not speaking as the Council Vice Chair.

II. During Council deliberations, only when one's position as Vice Chair has been clearly relinquished to someone else (per Robert's Rules of Order Newly Revised).

Selection Criteria

- A member in good standing of CFP.

- Commits to serving two (2) biennial Conference meetings, i.e two (2) years as Council Vice Chair and two (2) years as Council Chair; and have the approval and support of their employer.

Conference for Food Protection
2012 Issue Form

Internal Number: 111
Issue: 2012 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.

Title:
Clarification of terminology in Conference governing documents

Issue you would like the Conference to consider:
The 2010 - 2012 Constitution and Bylaws/Procedure Committee has reviewed the *Conference for Food Protection Constitution and Bylaws* and the *Conference for Food Protection Procedures* documents to identify where the terms "Conference", "Conference for Food Protection" and "Biennial Meeting" have been used interchangeably or incorrectly. These documents have been expanded and revised over the years with numerous writers/editors. As a result, there are locations within each document where clarification is needed to accurately represent whether a portion of text refers to the Conference for Food Protection as the organization or, refers to the Conference of Food Protection as the Biennial Meeting and vice-versa. An in-depth review was completed to discern the meaning of each passage and provide the appropriate terminology.

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 editorial revision of the *Conference for Food Protection Constitution and Bylaws* and the *Conference for Food Protection Procedures* documents to correct and clarify the use of the terms "Conference", "Conference for Food Protection", and "Biennial Meeting" as appropriate.
For the full language with annotated changes, see:

- Attachment D: Editorial Revisions to CFP Guidance Document - Bylaws
- Attachment E: Editorial Revisions to CFP Guidance Document - Procedures

Submitter Information:
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Attachments:

- "Attachment D: Editorial Revisions to CFP Guidance Documents - Bylaws"
- "Attachment E: Editorial revisions to CFP guidance documents - Procedures"

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

CONSTITUTION AND BYLAWS 2010

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TABLE OF CONTENTS

Conference for Food Protection
Constitution and Bylaws

As revised April 12, 2006

Preface

The following comments serve as a historical preface to the Constitution and Bylaws for the Conference for Food Protection.

The Conference for Food Protection dates back to the 1971 Conference on Food Protection held in Denver, Colorado. It was sponsored jointly by the Food and Drug Administration (FDA) and the American Public Health Association (APHA). The purpose of the Conference was to provide an inter-professional dialogue on the microbiological aspects of food safety for individuals representing industry, government and consumers.

The Second National Conference for Food Protection was held in Washington, D.C. in 1984. The 1984 Conference expanded its scope to cover toxicological, as well as microbiological concerns. The purpose of the 1984 Conference was:

> "To share perspectives on the toxicological and microbiological aspects of food safety problems in the United States; to identify the needs, direction and opportunities of food production, processing, handling and regulation through the year 1990; and to establish an organization for the continuing study of food safety problems and for promotion of the recommendations of the Conference."

The 1984 Conference was organized into seven committees: Toxicology; Microbiology; Good Manufacturing and Quality Control; Standards and Regulations; Education and Training; New Foods Processing and Packaging; and Conference Program Committees, with selected individuals also serving as resource persons who prepared "white papers" on various issues that were to be discussed at the Conference. In addition to the federal, State and local health officials who had been invited to the 1971 Conference, the 1984 Conference included industry, academic and consumer representatives. The 1984 Conference adopted a recommendation that a continuing Conference organization be established and that a constitution and bylaws be developed based upon a draft presented at the Conference. It was agreed that the objectives of the Conference would be:

- To identify emerging problems of food safety;
- To address the problems of food safety on a regular basis;
- To formulate recommendations for the solution of the identified problems;
- To follow up on the recommendations of the Conference so that they will be incorporated into public policy and in industry practice;

- To evaluate the effectiveness of the Conference recommendations; and

- To establish a working liaison with professional and trade associations, academic institutions and government agencies concerned with food safety.

Following the 1984 Conference, the Constitution and Bylaws were finalized and the Conference was incorporated in 1985. The National Sanitation Foundation (NSF) agreed to support the Conference financially and a Conference Executive Director was hired.

The 1986 Conference for Food Protection was held in Ann Arbor, Michigan. The 1986 Conference was again organized into seven committees representing the major science and technical aspects of food protection. A 25-member Executive Committee selected the topics to be discussed and requested "white papers" from technical experts. In addition to the committees, five Councils were formed representing the interests of the participants at the Conference.

Although the purposes of these Conferences were well established and accepted, the organization and procedures of the Conference were long debated. In the early meetings of the Steering Committee preparing for the 1984 Conference, the idea of emulating the National Conference on Interstate Milk Shipments (NCIMS) was introduced. Individuals working during this Conference to write a new constitution began introducing NCIMS-type structure into the Conference organization. This was the first step leading to the current Constitution and Bylaws.

The second step was action taken at the 1984 Conference to reaffirm the intent to model the Conference after the NCIMS. The following is quoted from the Proceedings of the 1984 Conference:

> "An Organizational Model: from the beginning it was the intention of the organizers of the Second National Conference that it should include an effort 'to establish an organization for the continuing study of food safety problems and for the promotion of the recommendations of the Conference'. What the organizers had in mind in making that a goal of the Conference was to establish, in the area of food safety, something akin to the Interstate Milk Shipments Conference and the more recent Interstate Shellfish Sanitation Conference, so that a national dialogue on food safety might continue on a regular, periodic basis." (page 369)
>
> "A National Conference for Food Protection should be established as an ongoing Conference and be structured similarly to the National Conference on Interstate Milk Shipments. One of the Conference's primary purposes should be to promote the formulation and use of uniform model laws and regulations among all government agencies to assure uniform interpretations and implementation and to eliminate duplication of services. Its membership should consist of federal, State and local food regulatory officials, academia and representatives from industry. It should be governed by an Executive Board with representatives from federal, State and local agencies and industry." (Recommendation No. 10, Standards and Regulations Committee -- approved by the Conference, page 266).

The draft Constitution and Bylaws adopted by the 1984 Conference were, according to its authors, not meant to be a fully workable source for forming and operating the Conference model after the NCIMS. It was intended as an interim document that would be upgraded to provide a more authoritative foundation for Conference actions.

The final step in the decision to upgrade the Conference organization was taken at the 1986 Conference. The Program Committee reported that:

> "It was the unanimous view of the committee that the Conference should operate as an action organization, existing not merely to identify problems and formulate recommendations, but to resolve issues through the implementation of recommendations, much as the Weights and Measures Conference and the Interstate Milk Shippers do. Specific recommendations in this regard will be presented prior to the next Conference." (Page 410, Proceedings)

To accomplish this, the 1986 Conference agreed:

- To develop a State regulatory ratification mechanism whereby each of the 50 States will have one vote; and

- To create a Constitution and Bylaws Committee to review the entire Constitution and Bylaws and to formulate recommendations for the Executive Committee to consider.

The Constitution and Bylaws Committee approached the review process with three principal needs in mind. First, the Constitution needed to allow for the continuing study of food safety problems, but with a more limited focus. To achieve this, the following changes were made:

1. The objective of the Conference placed greater emphasis on food safety at the point of ultimate sale to consumers through food services, retail food stores and food vending, and continued to identify and address problems in production, processing, packaging, distribution, sale and service of food;

2. The seven committees were condensed into three councils to provide a balance between discussing the science and technology of food safety issues and developing various certification guidelines, procedures and models; however, as in the other two Conference examples, separate committees in each discipline area could still function to deliberate and review issues.

The second principle that guided the review process was the need for the Conference to be more successful in promoting food safety, mutual respect and uniformity. This was accomplished through the following changes:

1. The final actions taken by the Conference regarding such items as food safety controls, certification procedures and Memoranda of Understanding, were to be

adopted by the regulatory delegates of the Conference with the advice of industry and other non-regulatory members;

2. The Constitution created a Council on Laws and Regulations; a Council on Administration, Certification and Education; and a Council on Science and Technology that provided vehicles by which the Conference could deliberate on all food safety issues and promote more uniform and effective food safety controls.

The final guiding principle was the need to ensure that the Conference would provide a national and, to the extent possible, international dialogue on food safety on a regular, periodic basis; and that this dialogue would be among representatives of regulatory, industry and other non-regulatory organizations. To accomplish this, the Constitution and Bylaws provided for the following:

1. The name of the Conference remained unchanged consistent with the recommendation made by the 1986 Program Committee. In order to increase international information exchange, the Pan American Health Organization (PAHO) and the World Health Organization (WHO) were added. The Food and Agricultural Organization (FAO) was already a member of the Conference;

2. The role that industry plays in the Conference is substantial. Industry is fully represented on all councils, committees and the Executive Board. Industry representatives alternate as Chair and Vice-Chair on all councils. Industry representatives are elected through industry caucuses. Industry's concerns and advice are fully considered since problems submitted to the Conference are assigned to one of the councils. Regulatory delegates vote on each council's recommended actions;

3. The Science and Technology Council provided a forum for discussion by all concerned parties of the scientific and technological aspects and principles underlying the problems faced by government and industry in their mutual goal of trying to provide safe foods for consumers and could include formation of individual committees for each scientific discipline.

The Constitution and Bylaws attempt to intertwine these guiding principles so that in pursuing one, each would be pursued. This interdependence is critically important if the Conference recommendations are going to command the respect of the food regulators and the food industry that would be called upon to implement the recommendations. As was stated by Mr. Archie Holliday in his comments on the 1988 proposed Constitution and Bylaws:

> "The most important need for an organization of this kind is to have its recommendations respected by the community called upon to implement them. Without the results of our deliberations commanding the highest respect attainable, getting together to identify and study food safety problems will be of little or no value to enough people to support a viable organization. The strength of the organization structure now being proposed by your Constitution and Bylaws Committee is that it provides the means to balance the interests of

> regulatory and industry people while providing an open forum for the consideration of ideas from any source. At the same time, matters that are supported by the voting delegates will have endured such a process as to command the utmost of respect."

The Constitution and Bylaws are one step in an evolving process to develop a viable permanent Conference. The next was also discussed by Mr. Archie Holliday in his comments on the Constitution:

> "One should be careful not to conclude that a food service oriented structure would prohibit the free and open study of the wider range of food safety problems. When the values of NCIMS and ISSC organizational structures are discussed, we often fail to acknowledge the importance of procedures to successful operation of these bodies. Well defined, established procedures will be essential to the effectiveness of the Conference operating under our proposal. Procedures should remain as a separate entity from the Constitution and Bylaws. When the new Constitution and Bylaws are adopted, the Executive Board should immediately begin the process of establishing procedures to be approved by the Conference. It is in this process that attention can be given to how broad the scope of the Conference should be. The adoption and revision of Conference procedures should receive the same careful consideration as the adoption of Conference recommendations."

The Constitution and Bylaws Committee and the Executive Board believed that the Constitution and Bylaws proposed and accepted at the 1988 Conference provided a workable and proven approach that should be followed to develop an effective voice for present and future issues of food safety.

Preamble

The Conference for Food Protection, hereinafter referred to as the Conference or CFP, is incorporated as a non-profit organization under the laws of the State of Virginia to carry out the objective stated in the Constitution and Bylaws of the Conference.

Constitution and Bylaws

Article I Objective

Section 1. The objective of the Conference shall be to promote food safety and consumer protection by:

Subsection 1. Identifying and addressing problems in the production, processing, packaging, distribution, sale and service of foods;

Subsection 2. Focusing on and facilitating the food protection programs governing the food service, retail food store and food vending segments of the food industry;

Subsection 3. Adopting sound, uniform procedures which will be accepted by food regulatory agencies and industry;

Subsection 4. Promoting mutual respect and trust by establishing a working liaison among governmental agencies, industry, academic institutions, professional associations and consumer groups concerned with food safety;

Subsection 5. Promoting uniformity among States, territories and the District of Columbia. Territories include American Samoa, Guam, Northern Mariana Islands, Puerto Rico, The Trust Territory and the U.S. Virgin Islands.

Subsection 6. Utilizing as the primary channels for dissemination of information:

The United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) in matters under their purview, such as food production, meat and poultry processing and consumer information; and The United States Department of Health and Human Services/Public Health Service/Food and Drug Administration (HHS/PHS/FDA) in matters under their purview, such as food processing and assistance to food regulatory agencies based on the model food codes and related documents.

Article II Organization and Operation

Section 1. The Conference shall be directed by the delegates of the States, territories and District of Columbia, who join together with representatives of industry, academic institutions, professional associations and consumer groups to achieve the objective of the Conference.

The Conference shall include an Assembly of State Delegates, hereinafter referred to as the Assembly; an Executive Board, hereinafter referred to as the Board; officers; an Executive Director, Executive Assistant, Executive Treasurer, Councils; Committees; Standing Committees (see Article XIII); and any member of the Conference as described in Article III, Sections 1 and 2.

Section 2. The Conference shall meet at least biennially during even-numbered years with additional meetings as the need arises as determined by the Board.

Section 3. The Conference identifies food safety issues by receiving Issues submitted by interested persons. The Conference addresses Issues by assigning them to appropriate Councils or Committees for consideration. Council membership is balanced between government and industry interests. Aspects of Issues may also be assigned to Committees for study, procedure development or for other reasons. All committees that are assigned to a Council shall submit a report to the Council Chair and Conference at least ninety (90) days preceding the CFP Biennial ~~Conference~~ Mmeeting. Councils then make recommendations to the Assembly, which is composed of delegates designated by the States, each territory and the District of Columbia. The Assembly considers and votes to approve or reject Council recommendations. CFP Biennial Meeting ~~Conference~~ participation is open to all interested individuals who choose to become members and attend. Individuals may serve as appointed or elected members on the Board, Councils, and Committees; or as a participating registered member.

The Conference shall consider issues related to food safety that are submitted on approved forms and within specified time frames. Any interested person may submit an Issue for consideration. At least one hundred and fifty (150) days preceding the CFP Biennial ~~Conference~~ Mmeeting, the Executive Director shall notify members of the Conference of the time and place of the CFP Biennial ~~Conference~~ Mmeeting. Each notice shall include information for submitting Issues, and a statement that all Issues, shall be submitted to the Conference at least ninety (90) days preceding the CFP Biennial ~~Conference~~ Mmeeting. Issues are to be assigned to appropriate Councils by the Issue Committee. At least forty (40) days preceding the CFP Biennial ~~Conference~~ Mmeeting, the Executive Director shall make available to members of the Conference copies of the final committee reports and Issues, including Constitution changes that have been received and assigned for CFP Biennial Meeting ~~Conference~~ deliberation.

The Board may submit special Issues to the Councils at the beginning of the CFP Biennial ~~Conference~~ Mmeeting as necessary.

Councils are to deliberate their Issues and report their recommendations on each to the Assembly. The Assembly considers and votes on recommendations it receives from the Councils.

Article III Registration and Membership

Section 1. Any persons interested in promoting the objective in Article I may attend the CFP Biennial ~~Conference~~ M~~m~~eetings by registering their name, address, and the business they represent with the Executive Treasurer using forms provided and paying the registration fee established by the Board under Article V, Section 10 and 12.

Section 2. Persons who are interested in promoting the objective in Article I but who can not attend the CFP Biennial ~~Conference~~ M~~m~~eeting may become members of the Conference by applying to the Executive Treasurer using forms provided and paying the membership fee established by the Board under Article V, Section 12.

Section 3. Persons paying the Conference membership fee through the Executive Treasurer's office or by paid registration at the CFP Biennial ~~Conference~~ M~~m~~eetings are members of the Conference and are entitled to be on an official list to receive copies of the CFP Biennial Meeting ~~Conference~~ proceedings and other Conference matters determined by the Board to be of interest to all members of the Conference.

Section 4. Conference membership begins at the time of payment of membership fee. Membership paid as part of the CFP Biennial Meeting ~~Conference~~ registration begin on the first day of one CFP Biennial ~~Conference~~ M~~m~~eeting and end the day prior to the next CFP B~~b~~iennial ~~Conference~~ M~~m~~eeting.

Article IV Composition of Organizational Components and Eligibility Requirements for Service In Official Capacities

Section 1. The Assembly shall consist of persons attending the Conference meeting and qualified as voting delegates under Article XVII, Section 5.

Section 2. To be eligible to serve on the Board, Councils, Committees, or as Issue Chair or Program Chair; individuals must be members of the Conference and must be in attendance at the CFP Biennial ~~Conference~~ M~~m~~eeting at which they are appointed or elected; or shall have attended the CFP Biennial ~~Conference~~ M~~m~~eeting immediately preceding the one at which they are appointed or elected. This requirement in respect to Councils and Committees may be waived by consent of the Board.

Section 3. Board Membership

Subsection 1. The Board shall be composed of twenty-three (23) voting members as follows:

a) Six (6) members from State food regulatory agencies (one (1) from each CFP region);

b) Six (6) members from local food regulatory agencies (one (1) from each CFP region);

c) Three (3) members from federal agencies (one (1) from FDA, one (1) from USDA, and one (1) from CDC);

d) Six (6) members from the food industry with at least one (1) each representing food processing, food service, retail food stores and food vending;

e) One (1) member from an academic institution; and

f) One (1) member representing consumers.

Subsection 2. Regulatory agency, industry, academic institution and consumer Board members shall be elected by a caucus of registrants in each respective group. State and local regulatory Board members shall be elected in regional caucuses of regulatory registrants. Regulatory Board members shall be appointed by the head of their agency.

Subsection 3. Such elected Board members shall serve through three (3) general CFP Biennial M~~m~~eetings of the Conference. Elected Board members may succeed themselves unless reelection would extend the total of consecutive service to more than twelve (12) years.

The terms of elected Board members shall be staggered so that one-third (1/3) of the members are elected at each CFP Biennial ~~Conference~~ M~~m~~eeting.

Subsection 4. The Board shall have non-voting Ex-Officio members as follows:

a) The Immediate Past Chair of the Board;

b) The Chair and Vice Chair of each Council;

c) The Conference Program Chair;

d) Representatives from regulatory agencies regulating retail food operations in other countries of the world, such as Canada, Mexico, etc.

e) The Executive Director, Executive Treasurer, Executive Assistant;

f) The Conference Issue Chair, and

g) The Conference Constitution and Bylaws/Procedures Chair.

Section 4. The Board shall elect a Chair and Vice-Chair from its membership after caucus elections are held during each biennial meeting of the Conference and they may retain their positions at the pleasure of the Board as long as they are officially members of the Board. The Board Chair and Vice-Chair shall be the Chair and Vice-Chair of Conference meetings. The Board shall retain the services of a qualified person to act as an Executive Director, Executive Treasurer, and Executive Assistant. The Executive Treasurer shall be bonded. The compensation of the Executive Director, Executive Treasurer, and Executive Assistant shall be set by the Board.

Section 5. The Immediate Past Chair of the Board shall continue to serve on the Board until replaced by the next retiring Chair. If the Immediate Past Chair of the Board is unable for any reason to continue to serve on the Board, the position shall remain vacant until filled by the next retiring Chair. Immediate Past Chairs shall serve on the Board as non-voting members unless re-elected to the Board in a capacity other than as Immediate Past Chair.

Article V Duties of the Assembly and the Board

Section 1. The Assembly with recommendation from a Council or the Board shall approve or reject all recommendations including those pertaining to the Constitution and Bylaws, any Conference procedures, all Memoranda of Understanding or other formal agreements and other necessary actions including resolutions; and establish Conference policies and positions on all subjects related to the objective of the Conference except as delegated (by the Assembly) to the Board. If a recommendation is approved, it shall be referred to the Board for appropriate disposition. If a "No Action" recommendation is rejected, the Issue will be referred to the Board for its consideration.

Section 2. The Board shall manage the affairs of the Conference.

Section 3. The Board shall meet prior to each CFP Biennial ~~Conference~~ M~~m~~eeting and after the meeting closes. The Chair shall call special meetings of the Board at any time at the request of two-thirds (2/3) of its voting members. In addition, the Chair is empowered to call special meetings of the Board at any time, as the need arises, with the concurrence of two-thirds (2/3) of the voting Board members.

Section 4. The Board may, at the discretion of the Chair, utilize a mail service, electronic mail, or fax ballots to establish a position, action or confirm telephone c~~C~~onference call votes. Only an authorized ballot approved by the Board shall be used. Once such a position or action has been taken, the Board shall notify all Conference members.

Section 5. The Board shall direct the Chair, Executive Director, and Program Chair in the preparation of the programs for each meeting of the Conference.

Section 6. The Board shall set the time and place of the meetings of the Conference.

Section 7. If voting members of the Board are unable to participate in a Board meeting, they may not send a substitute, but may forward by mail, email, or FAX, information for consideration by attending members of the Board. Voting and ex-officio members may participate through a telephone cC~~C~~onference call.

Section 8. Voting Board members who fail to attend two (2) consecutive Board meetings and who fail to show cause why they were absent may have their positions declared vacant by the Chair.

Section 9. If a vacancy occurs for any reason in Board membership between biennial meetings, the Chair with concurrence of the Board may fill the vacancy with a person representing the same discipline as the person being replaced until the next biennial meeting at which time the vacancy shall be filled by a qualified person who is properly elected.

Section 10. The Board shall direct the Executive Treasurer to collect registration and membership fees as necessary to defray the costs of the operation of the Conference. The Board shall cause an annual audit to be made of the Executive Treasurer's financial reports.

Section 11. The Board shall authorize the form used to tally votes in meetings of the Board and Assembly.

Section 12. The Board shall establish the registration and membership fees identified in Article III.

Section 13. The Board shall approve an annual budget for the fiscal year established by the Board.

Section 14. The Board shall appoint Committees as necessary to accomplish the Conference objective.

Section 15. The Board shall approve the membership of each Standing Committee.

Article VI Duties of the Chair

Section 1. The Chair shall preside at all meetings of the Assembly and Board, except as provided in Article VII, Section 1.

Section 2. The Chair shall assist the Executive Director in arranging CFP Biennial ~~Conference~~ Mmeetings.

Section 3. The Chair with the approval of the Board shall appoint Council Chairs and Vice-Chairs.

Section 4. The Chair shall appoint Council consultants required in Article X.

Section 5. The Chair shall appoint Chairs of the Conference Standing Committees established in Article XV, Section 2.

Section 6. The Chair, with the approval of the Board, shall appoint qualified persons to Councils and Committees as provided in the Constitution and Bylaws.

Section 7. The Chair shall appoint a Local Arrangements Committee to assist in planning the physical facilities for the next CFP Biennial ~~Conference~~ M~~m~~eeting.

Section 8. The Chair shall appoint a parliamentarian to advise on matters of parliamentary procedures at Board and Assembly meetings.

Section 9. The Chair, with Board approval, may retain clerical assistance for the Conference.

Section 10. Between Conference meetings the Chair shall require from each Council Chair a report of the status of implementation of each approved recommendation originating in the respective Council and this information shall be provided to the Conference participants.

Section 11. The Chair shall perform all other responsibilities and duties as detailed in the Conference Chair position description.

Article VII Duties of the Vice-Chair

Section 1. In the event the Chair is unable to perform the duties of the Chair, the Vice-Chair shall act as Chair.

Section 2. When acting as Chair, the Vice-Chair shall perform all the necessary duties for the Conference as outlined in Article VI.

Section 3. The Vice-Chair shall perform all other responsibilities and duties as detailed in the Conference Vice-Chair Position Description.

Article VIII Duties of the Executive Director

Section 1. The Executive Director shall ensure that the minutes of each meeting of the Assembly and the Board are recorded and transcribed.

Section 2. The Executive Director shall tally and record all voting of the Assembly on a form authorized by the Board.

Section 3. The Executive Director shall notify all members of the time and place of the next CFP Biennial ~~Conference~~ M~~m~~eeting, and of Issues that are to be deliberated.

Section 4. The Executive Director shall accomplish the duties outlined in Article VI, Section 10; and Article XVII, Section 1, Subsections 2, 3, 4, and Section 4.

Section 5. The Executive Director shall maintain an up-to-date list of the qualified delegates designated as required by Article XIV.

Section 6. The Executive Director shall retain, subject to Board's approval, a qualified person to serve as Executive Assistant, and shall direct and oversee duties assigned to the Executive Assistant.

Section 7. The Executive Director shall perform all responsibilities and duties as detailed in the Executive Director Position Description.

Article IX Duties of the Executive Treasurer

Section 1. The Executive Treasurer shall collect registration and membership fees and shall pay bills as directed by the Board. The Executive Treasurer shall obtain a receipt for all disbursements and shall make all such receipts a part of Board records.

Section 2. The Executive Treasurer shall prepare a proposed annual budget for presentation to the Board.

Section 3. The Executive Treasurer shall prepare all budget and financial reports.

Section 4. The Executive Treasurer shall perform all responsibilities and duties as detailed in the Executive Treasurer Position Description.

Article X Duties of the Executive Assistant

Section 1. The Executive Assistant manages the information on the CFP website with the assistance of the Executive Director and a professional webmaster and publishes the CFP newsletter.

Section 2. The Executive Assistant maintains the CFP membership database; creates reports and rosters, and develops mailing lists.

Section 3. The Executive Assistant assists the Executive Director with development of a Standard Operating Procedures Manual to include Position Descriptions, Board policies and Scripts for presentations and is responsible for their maintenance.

Section 4. The Executive Assistant records, transcribes, and distributes Board meeting minutes.

Section 5. The Executive assistant assists the Executive Director with the Delegate process to include outreach and rosters.

Section 6. The executive Assistant assists the Executive Director with the preparation of the biennial meeting program, provides onsite assistance to the Director at the biennial meeting and compiles biennial meeting proceedings with the assistance of the Executive Director.

Section 7. The Executive Assistant shall perform all responsibilities and duties as detailed in the Executive Assistant Position Description.

Article XI Councils

Section 1. There shall exist three (3) Councils in the Conference to provide for continuity of action in carrying out the objective of the Conference.

Subsection 1. The Councils shall be known as Council I, Council II and Council III.

Section 2. Each Council shall have a Chair, Vice-Chair and twenty (20) other members to be appointed by the Conference Chair with the approval of the Board. Except as specified in Article X, Section 3, Subsection 3, the term for a Council member shall begin at appointment and expires upon adjournment of the fall Board meeting following the CFP Biennial ~~Conference~~ M~~m~~eeting. If a Council member cannot attend a CFP Biennial ~~Conference~~ M~~m~~eeting, the member's term expires and the Conference Chair may appoint a member who can attend the Council meeting during the CFP Biennial ~~Conference~~ M~~m~~eeting.

Subsection 1. Of the twenty-two (22) members of Councils I and II, nine (9) plus one Chair or Vice-Chair shall be selected from regulatory agencies; one (1) shall be from a national, state or local consumer organization; one (1) shall be from academia; and nine (9) plus one Chair or Vice-Chair from industry.

Subsection 2. Eight (8) of the food regulatory agency representatives on Councils I and II shall be equally apportioned among state and local agencies and two (2) members shall be from the territories, District of Columbia, or federal jurisdictions that regulate commercial or institutional operations. If two (2) members can not be obtained from the territories, District of Columbia or federal food inspection programs, these positions may be filled from State or local food regulatory agencies. The ten (10) industry representatives shall be apportioned so at least one (1) member represents food processing, two (2) members represent food service, two (2) members represent retail food stores and one (1) member represents food vending.

Subsection 3. Of the twenty-two (22) members of Council III at least five (5) shall be from State and local regulatory agencies, at

least five (5) from industry, up to ten (10) at-large plus a Chair and Vice-Chair. The industry representatives shall include at least one (1) each from food processing, food service, retail food stores and food vending. At large members may include members representing federal agencies, Academia, and other stakeholder groups.

Subsection 4. If sufficient designated members are not available at a CFP Biennial ~~Conference~~ M~~m~~eeting to complete a Council's membership, the Conference Chair may appoint other members to the Council so long as the balance between regulatory and industry is maintained as specified.

Section 3. The Council Chair and Vice-Chair shall select twenty (20) Council members from persons holding membership in the Conference and offer their names for Conference Chair appointment and Board confirmation.

Subsection 1. The Council Chair shall, after appointment, serve through one (1) CFP Biennial ~~Conference~~ M~~m~~eeting. The Council Vice-Chair shall, after appointment, serve through two (2) consecutive CFP Biennial ~~Conference~~ M~~m~~eetings, one (1) as Vice-Chair and the second as Chair.

Subsection 2. On Councils I and II when the Council Chair represents a food regulatory agency, the Vice-Chair shall be an industry representative. If the Council Chair represents industry, the Vice-Chair shall be a food regulatory agency representative. The Chair and Vice-Chair from Council III shall be from one of the following disciplines – Regulatory, Industry, or Academia and at no time shall both the Chair and Vice-Chair represent the same group.

Subsection 3. The term for the Council Chair and Vice-Chair shall begin at the conclusion of the scheduled CFP Biennial~~Conference~~ M~~m~~eeting and last through the fall Board meeting following the next biennial CFP Biennial ~~Conference~~ M~~m~~eeting. At the end of the outgoing Chair's term, the Vice-Chair shall assume the position of Chair and a new Vice-Chair shall be appointed as set forth in Subsection 2 of this Section.

Section 4. Each member of the Council, other than the Vice-Chair, shall have one vote. The Council Chair shall only vote to break a tie. The Council Vice Chair shall only vote when acting as Chair.

Article XII Council Consultants

The following agencies and international organizations may each provide a non-voting consultant for each of the Councils:

a. Centers for Disease Control and Prevention (CDC);

b. U. S. Environmental Protection Agency (EPA);

c. U. S. Food and Drug Administration (FDA);

d. U. S. Department of Agriculture (USDA);

e. Food and Agriculture Organization (FAO);

f. Pan American Health Organization (PAHO);

g. World Health Organization (WHO);

h. The Dominion of Canada; and

i. Others as deemed appropriate by the Board.

Article XIII Duties and Responsibilities of Councils

Section 1. Council I: Council on Laws and Regulations

Subsection 1. Issues submitted to the Conference dealing with laws, regulations and model codes governing the safety of food shall be assigned to Council I by the Conference Issue Committee.

Section 2. Council II: Council on Administration, Education, and Certification

Subsection 1. Issues submitted to the Conference dealing with matters relating to the Constitution and Bylaws, Conference procedures, memoranda of understanding, program evaluation, education, training and certification and the like shall be assigned to Council II by the Conference Issue Committee.

Section 3. Council III: Council on Science and Technology

Subsection 1. Issues submitted to the Conference dealing with science and technology shall be assigned to Council III by the Conference Issue Committee.

Section 4. Councils shall deliberate on all assigned Issues. Council Chairs shall report the recommendations of their Councils to the Assembly.

Section 5. When a Council recommends "No Action" on an assigned Issue, the Council Chair shall record the reason why "No Action" was recommended.

Section 6. Duties of the Councils between CFP Biennial ~~Conference~~ Meetings

Subsection 1. Following the CFP Biennial ~~Conference~~ M~~m~~eeting, the Conference Chair shall contact the Council Chairs to review the recommendations approved by the Assembly of State Delegates and to plan for the implementation of approved recommendations originating in their respective Councils.

Subsection 2. During the period between biennial meetings, the Council Chairs, shall monitor, encourage, and proactively support the progress of implementation of approved recommendations originating in their respective Councils.

Subsection 3. Council Chairs shall prepare a written report on the status of implementation of approved recommendations originating in their respective Councils or on the activities of committees assigned to their Council. These reports shall be submitted to the Conference Chair 30 days prior to each Board meeting or more frequently at the request of the Conference Chair.

Subsection 4. The new Council Chairs shall submit for Board approval the names of committee chairs and membership of all committees assigned to their Council by the fall Board meeting following the CFP Biennial ~~Conference~~ M~~m~~eeting.

Article XIV Committees

Section 1. All appointments to Conference Committees shall be made to provide a balance in representation of the stakeholders in the particular matter under consideration.

Section 2. The following standing committees shall be established:

Subsection 1. Audit Committee;

Subsection 2. Constitution and Bylaws/Procedures Committee;

Subsection 3. Issue Committee;

Subsection 4. Managers Training, Testing and Certification Committee;

Subsection 5. Nominating Committee;

Subsection 6. Program Committee;

Subsection 7. Resolutions Committee; and

Subsection 8. Strategic Planning Committee.

Section 3. Other committees may be established as necessary to accomplish the Conference objective. Such committees may be for the purpose of focusing Conference resources around specific scientific disciplines, for studying multi-faceted issues, for developing new procedures or for other purposes.

Subsection 1. Local Arrangements Committee shall be established for each CFP Biennial ~~Conference~~ M~~m~~eeting.

Section 4. A committee may establish its own bylaws establishing operational procedures that may include, but are not limited to, objectives, organization and operation, duties and responsibilities. Bylaws of a committee must be approved by the Board.

Section 5 By the Fall Board meeting following the CFP Biennial ~~Conference~~ M~~m~~eeting, the Standing Committee Chairs shall submit the names of their members to the Board for approval.

Article XV Duties of the Committees

Section 1. The Issue Committee shall review all Issues submitted at least ninety (90) days before the CFP Biennial ~~Conference~~ M~~m~~eeting. The Issue Committee shall assign for Council deliberation those Issues that have met the Issue acceptance criteria specified in the Conference Procedures Manual. Issue assignments shall be made in accordance with Article XII, Section 1, Subsection 1; Section 2, Subsection 1; and Section 3, Subsection 1.

Section 2. The Program Committee shall be responsible for the educational workshop and the Reports and Updates session at the biennial meeting.

Section 3. The Constitution and Bylaws/Procedures Committee shall submit recommendations to improve Conference administrative functions through proposals to amend the Constitution and Bylaws. The Committee shall review proposed memorandums of understanding and ensure consistency among the memorandums of understanding, the Conference Procedures manual, the Constitution and Bylaws and other working documents. The Committee shall report all recommendations to the Board prior to Council II deliberation and shall follow the direction of the Board.

Section 4. The Resolutions Committee shall report to the Board. Except for thank you resolutions, the Resolutions Committee shall prepare all necessary resolutions for Board approval.

Section 5. The Audit Committee shall report to the Board. Except when a certified public accountant conducts an audit of the Conference's financial records, the Audit Committee shall audit the Conference's financial records annually.

Section 6. The Managers Training, Testing and Certification Committee shall report to the Board. The Food Protection Managers Training, Testing and 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.

Section 7. All Committees, including Standing Committees, shall submit their reports in a timely prescribed manner as specified under Article II, Section 3 as follows:

Subsection 1. Committees assigned to a Council, to their respective Councils; and

Subsection 2. Standing Committees to the Conference Chair and Executive Director.

Article XVI Duties of States, Territories and District of Columbia

The States, territories and the District of Columbia shall be responsible for designating and keeping the Executive Director informed of the name(s) and address(es) of the person(s) designated to represent them in the Assembly.

Article XVII Rules of the CFP Biennial ~~Conference~~ Meeting

Section 1. Registration – All participants must register.

Section 2. CFP Biennial ~~Conference~~ M~~m~~eetings shall be at least two (2) days duration except this requirement may be waived for special meetings called by the Board.

Section 3. Except for additional meetings as provided for in Article II, Section 2, the Conference will meet each even numbered year.

Section 4. Robert's Rules of Order shall prevail, unless specified rules are established.

Section 5. FDA, CDC, and USDA Reports shall be presented.

Article XVIII Rules of the Assembly

Section 1. Meetings of the Assembly shall include the following:

Subsection 1. Call to order by the Chair;

Subsection 2. Roll call of States, Territories and the District of Columbia and the announcement of the names of the delegates who will vote for each in the Assembly;

Subsection 3. Approval of the minutes of the previous meeting;

Subsection 4. *Report of the Executive Director and Executive Treasurer;*

Subsection 5. Council Chair Reports, Resolutions and other new business;

Subsection 6. Assembly voting;

Subsection 7. Authorization that may be required by the Assembly for the Board to conclude and implement any necessary recommendations prior to the next CFP Biennial ~~Conference~~ Mmeeting; and

Subsection 8. Adjournment.

Section 2. Each State shall be entitled to one (1) full vote and each territory and the District of Columbia shall be entitled to one-half (½) vote in the Assembly. When a State has more than one (1) State food regulatory agency enforcing food laws and regulations for food processing, food service, retail food stores and food vending, the vote may be divided into appropriate fractions. State agencies within each State must agree among themselves regarding apportioning the one (1) vote.

Section 3. Only a registrant at the CFP Biennial ~~Conference~~ Mmeeting who is a representative of a State, territory or District of Columbia food regulatory agency responsible for the enforcement of food laws and regulations for food processing, food service, retail food stores or food vending is entitled to be a delegate in the Assembly. When any State is represented by more than one food regulatory agency, the vote may be cast together as one vote or separately as a fraction of a vote. Representatives of States with more than one regulatory agency delegate

certified in compliance with the provisions of Section 4 of this Section may, during any meeting of the Assembly, reassign their voting privilege to another duly certified delegate from their State by giving written notice of such action to the Conference Chair. When a State is represented by only one agency, the State's delegate may cast a full vote for that State in the Assembly.

Section 4. At least one hundred and fifty (150) days prior to a CFP Biennial ~~Conference~~ M~~m~~eeting the Executive Director shall send to the food regulatory agency or agencies in each State, territory and District of Columbia participating in the CFP Biennial Meeting ~~Conference~~ a notice of the forthcoming meeting. Each notice shall include a current copy of Article II, Section 3 and Article XVII , Sections 2 through 6 and 9 of the Constitution and Bylaws.

Section 5. Each Agency shall report to the Executive Director on approved forms the following:

Subsection 1. The agency's officially designated regulatory responsibility regarding food processing, food service, retail food stores and food vending;

Subsection 2. The name of the delegate and the alternate, if any; and

Subsection 3. Designation of the vote to which that person is entitled, whether one (1) vote or a fraction of one (1) vote.

Section 6. In the event that more than one (1) delegate is designated and the sum of the votes designated for the delegates is greater than one (1), the Executive Director shall reject, void and return the reports to the agencies for correction. Such revision shall be submitted to the Executive Director at least forty-five (45) days before the CFP Biennial ~~Conference~~ M~~m~~eeting.

Section 7. Delegates shall record their names with the Executive Director and shall cast their votes in the Assembly when called by announcing "yes", "no" or "abstain" for one (1) vote; or "yes", "no" or "abstain" for the appropriate fraction of one (1) vote.

Section 8. Voting in the Assembly shall be recorded by the Executive Director as "yes", "no" or "abstain".

Section 9. If delegates wish to caucus, they may pass when their names are called for the purpose of caucusing and then shall vote when the second roll is called.

Section 10. To adopt in the Assembly:

Subsection 1. A quorum must be present. A quorum is defined as the presence of registered voting delegates from at least two-thirds (2/3) of the States with designated official delegates in attendance at the CFP Biennial ~~Conference~~ M~~m~~eeting.

Each territory and the District of Columbia shall count as one half (½) State in constituting a quorum.

Subsection 2. To change a procedure adopted at a previous CFP Biennial ~~Conference~~ Mmeeting or to make a change in the Constitution and Bylaws requires a two-thirds (2/3) majority vote.

Subsection 3. Other actions require a simple majority unless specifically covered by Robert's Rules of Order.

Article XIX Parliamentary Authority

Section 1. The rules of parliamentary procedure comprised in the current edition of Roberts Rules of Order, Newly Revised, shall govern all proceedings of the Conference and the Executive Board, subject to such special rules as have been or may be adopted.

Article XX Dissolution of the Conference

Section 1. Upon the dissolution of the Conference, assets shall be distributed for one or more exempt purposes within the meaning of section 501(c)(3) of the Internal Revenue Code, or tax code, or shall be distributed to the federal government, or to a State or local government, for a public purpose. Any such assets not so disposed of shall be disposed of by the Court of Common Pleas of the county in which the principal office of the corporation is then located, exclusively for such purposes or to such organization or organizations, as said Court shall determine, which are organized and operated exclusively for such purposes.

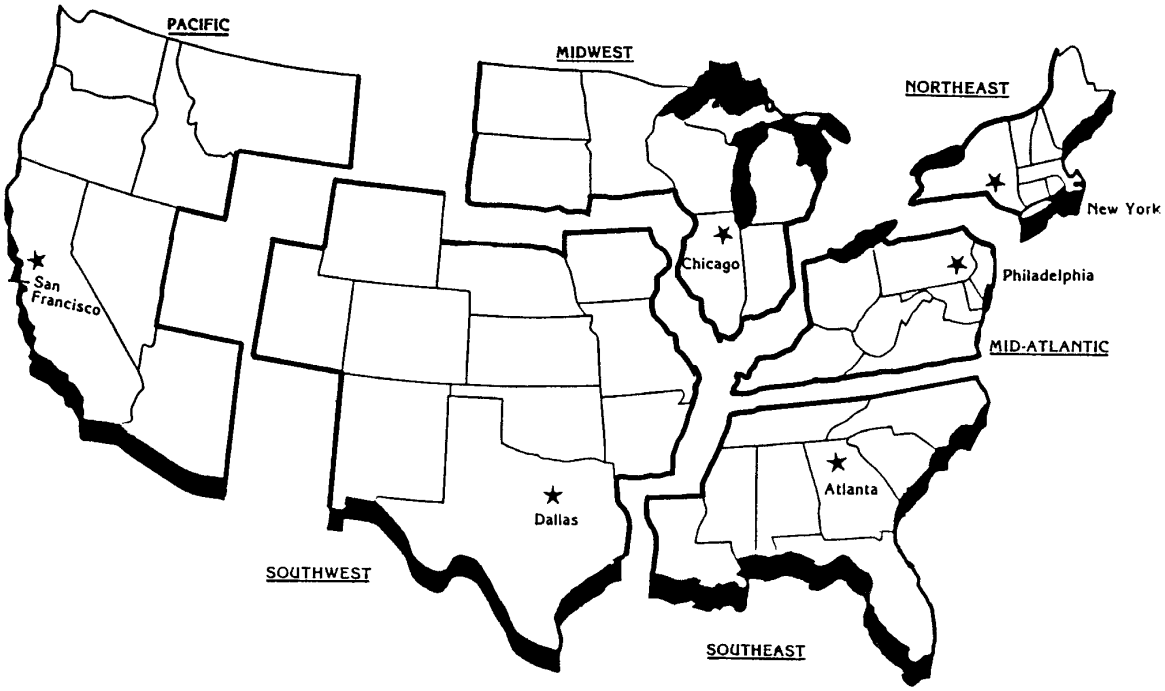
Article XXI Amendments to the Constitution and Bylaws

Section 1. The Constitution and Bylaws may be amended at a duly called CFP Biennial ~~Conference~~ Mmeeting, the delegates having had thirty (40) days notice from the Executive Director of such proposal to amend as provided in Article II, Section 3 and Article VIII, Section 3.

Section 2. Amendments to the Constitution and Bylaws will become effective at the close of the biennial meeting at which they are adopted.

Appendix

Map of CFP Regions*

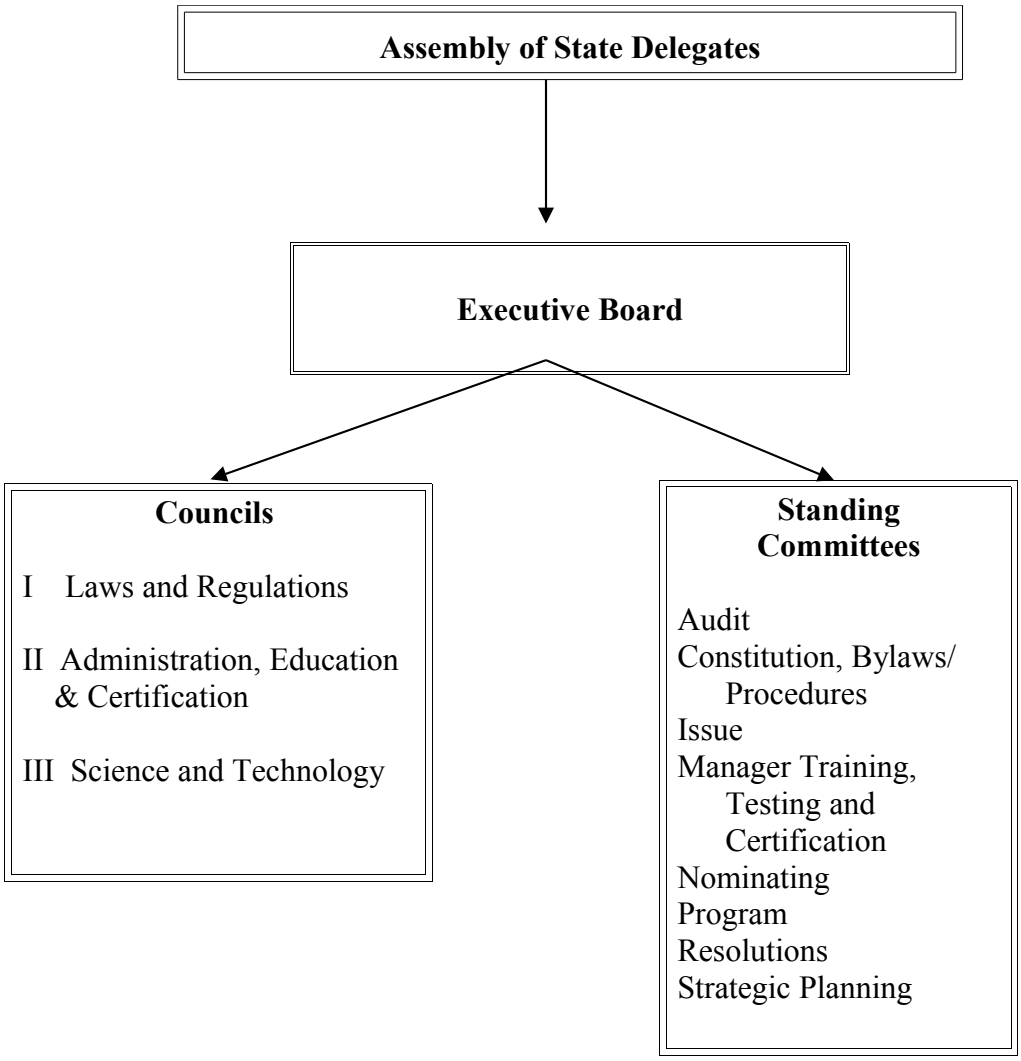


Non-contiguous states and territories not shown on map

*Used in Allocating Members of Executive Board

Mid-Atlantic	Midwest	Pacific	Southeast	Northeast	Southwest
	IL	AK	AL	CT	AR
DE	IN	AS	FL	MA	CO
DC	MI	AZ	GA	ME	IA
KY	MN	CA	LA	NH	KS
MD	ND	CM	MS	NY	MO
OH	SD	GU	NC	RI	NE
NJ	WI	HI	PR	VT	NM
PA		ID	SC		OK
VA		MT	TN		TX
WV		NV	VI		UT
		OR			WY
		TT			
		WA			

Conference for Food Protection Organizational Chart



Organizational Structure Composition
Assembly of State Delegates

Role:	Approves or rejects all Council recommendations
Chair and Vice-Chair:	Conference Chair and Vice-Chair preside at meetings of the Assembly
Delegates:	Designated by 57 food regulatory agencies representing: 50 States 6 Territories • American Samoa • Guam • Northern Mariana Islands • Puerto Rico • Trust Territory • U.S. Virgin Islands 1 District of Columbia
Voting:	$53^{1/2}$ total possible 50 States have 1 vote each; those States with multiple State regulatory jurisdictions may divide vote equitably 6 Territories and DC have ½ votes each

Executive Board

Role:	Manages the affairs of the Conference
Chair and Vice-Chair:	Elected from Board Voting Membership
Members:	23 elected to staggered terms by caucus of registrants in each respective group; federal members are appointed by agency head
Voting	6 State regulatory agencies (1 each per CFP Region)
	6 Local regulatory agencies (1 each per CFP Region)
	3 Agencies (FDA, USDA and CDC))
	6 Food Industries
	1 Academic Institution
	1 Consumer Representative
Non-Voting Ex-Officio	1 Immediate Past Chair
	3 Chairs of each Council
	3 Vice Chairs of each Council
	1 Program Chair
	1 Issue Chair
	1 Constitution and Bylaws/Procedures Chair
	4 International Representatives ;(i.e. Canada, Mexico, etc.)
	1 Executive Director
	1 Executive Treasurer
	1 Executive Assistant

Councils

Role: Deliberate assigned Issues and develop recommendations for Assembly consideration

Chairs and Vice-Chairs: 2 appointed by Conference Chair with approval of Board. For Councils I and II, if the Chair has a regulatory affiliation, the Vice-Chair is to be an industry affiliate, and vice versa. The Chair affiliation alternates back and forth each term.

Members: 20 selected by Council Chair and Vice-Chair for appointment by Conference Chair with approval of Board

I. Council on Laws and Regulations

Regulatory (including Chair or Vice Chair)

4 Local
4 States
2 Territorial, DC
or Federal

Industry (including Chair or Vice Chair)

1 Food Processing
2 Food Service
2 Food Store
1 Food Vending
4 Not specified

Consumer and Academia

1 Consumer
1 Academic

II. Council on Administration, Education and Certification

Membership allocated as shown in Council I

III. Council on Science and Technology

5 Regulatory agencies (min.) selected from State and Local
5 Food industry (min.) with at least 1 each from food processing, food service, food stores and food vending

	10 At-large including consumer and academia and may include federal and other
Consultants:	9 possible 4 Designated Federal Agencies 3 Designated International Organizations Additional if necessary, as deemed by the Board.
Voting:	Chair votes only to break a tie; Vice-Chair does not vote.

Committees

Appointments

All appointments to Conference Committees shall be made to provide a balance in representation of the stakeholders in the particular matter under consideration.

Standing Committees:

Audit Committee

Role: Except when a certified public accountant conducts an audit of the Conference's financial records, the Audit Committee audits the Conference's financial records annually. Committee reports to the Board.

Chair: Appointed by Conference Chair

Constitution and Bylaws/Procedures Committee

Role: Submits recommendations to improve Conference administrative functions through proposals to amend the Constitution and Bylaws. Reviews proposed memoranda of understanding and ensure consistency among the memoranda of understanding, the Conference Procedures manual, the Constitution and Bylaws and other working documents. Reports all recommendations to the Board prior to Council II deliberation and follows the direction of the Board. Committee reports to the Board.

Chair: Appointed by Conference Chair

Issue Committee

Role: Reviews all Issues submitted to Conference and assigns to Councils for deliberation. Committee reports to the Board.

Chair: Appointed by Conference Chair

Managers Training, Testing and Certification Committee

Role: Reports to the Board. Works with the accreditation organization for food protection manager certification programs to:

a. Establish and refine policies and standards to which certifiers may conform in order for them to be accredited;

b. Provide Conference input into the development of accreditation standards for certifying organizations specific to food protection manager certification programs;

c. Develop strategies for enhancing equivalence among food protection manager certificates issued by certifiers; and

d. Promote universal acceptance of certificates issued by accredited certifiers.

Chair: Appointed by Conference Chair

Nominating Committee

Role: Selects the nominee for the Conference Chair and Vice Chair. Committee reports to the Board.

Chair: Immediate Past Chair of the Conference

Program Committee

Role: Assists in planning and arranging of CFP Biennial ~~Conference~~ Mmeeting. Committee reports to the Board.

Chair: Appointed by Conference Chair

Resolutions Committee

Role: Except for thank you resolutions, the Resolutions Committee prepares all necessary resolutions for Board approval. Committee reports to the Board.

Chair: Appointed by Conference Chair

Strategic Planning Committee

Role: Develops a strategic plan which includes better ways to market the Conference as well as short-range and long-range strategic issues using the mission and vision of the Strategic Plan as guidance. Committee reports to the Board.

Chair: Appointed by Conference Chair

Other Committees

Appointed as needed to carry out Conference objectives.

Timeline for Conference Activities

This chart outlines the "When, Whom and What" of actions that are to be taken.

7

Line 0----------0-------- 0----------0---------- --0-------
-150 -90 -40 During Conference Afterwards

1.	At least 150 days preceding CFP Biennial ~~Conference~~ M~~m~~eeting	Executive Director (Art. II, Sec. 3 and Art. XVII, Sec. 4)	Announces to members the time and place of CFP Biennial ~~Conference~~ M~~m~~eeting, and provides forms for submitting Issues and proposals
2.	By 90 days preceding CFP Biennial ~~Conference~~ M~~m~~eeting	Any person (Art. II, Sec. 3)	May submit Issues which must be submitted on approved forms by this deadline
		Program Committee (Art. II, Sec. 3 and Art. XIV, Sec. 1)	Reviews properly submitted Issues and assigns each for Council deliberation
3.	By 90 days preceding CFP Biennial ~~Conference~~ M~~m~~eeting	All Committees (Article II, Section 3)	Shall submit a report to the appropriate Council and Conference
4.	By 40 days preceding CFP Biennial ~~Conference~~ M~~m~~eeting	Executive Director (Article II, Section 3)	Make available to members Committee reports and copies of Issues which have been properly submitted and assigned to Council
5.	During CFP Biennial ~~Conference~~ M~~m~~eeting	Councils (Art. II, Sec. 3 and Art. XII, Sec. 4)	Deliberate assigned Issues and develop recommended actions for Assembly consideration
		Assembly (Art. V, Sec. 1)	Approves or rejects actions recommended by Councils
6.	During CFP Biennial ~~Conference~~ M~~m~~eeting		Submits approved actions to States and Board for implementation
			May return rejected actions to originating body explaining basis for rejection or reassignment
		Board (Art. V, Sec. 1)	Distributes Assembly actions to Conference members for implementation
7.	Following CFP Biennial		

~~Conference~~ Mmeeting		

CONFERENCE FOR FOOD PROTECTION

BIENNIAL MEETING / CONFERENCE PROCEDURES 2008

Jeff Lineberry, Executive Director
1302 Silver Spur Circle
Lincoln, CA 95648
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E-mail: jlineber@earthlink.net
Website: www.foodprotect.org

Table of Contents

Prepared by: Constitution and Bylaws / Procedures Committee

As Amended by 2004 CFP Biennial ~~Conference~~ Meeting (Chandler, Arizona)

As Amended by 2006 CFP Biennial ~~Conference~~ Meeting (Columbus, Ohio)

As Amended by 2008 CFP Biennial ~~Conference~~ Meeting (San Antonio, Texas)

As amended by 2012 CFP Biennial Meeting (Indianapolis, Indiana)

Conference for Food Protection
Biennial Meeting / Conference Procedures

I. Introduction

Biennial Meeting /Conference Procedures are intended to supplement the Constitution and Bylaws in the conduct of Conference meetings and other Conference business.

II. Conference/Biennial Meeting Orientation

A brief orientation shall be conducted for attendees at the beginning of the CFP Biennial ~~Conference~~ Mmeeting. The orientation is solely for the purpose of explaining and answering questions relative to the structure of the Conference and procedures governing its operation.

III. Conference Resolutions

Resolutions that have been submitted in writing and have received prior approval by a majority of the Executive Board shall be presented for voting at the Assembly meeting.

IV. Conference Issues

A. Issue Submission

1. The Executive Board shall approve an Issue Submission Form.

2. Within the time specified in the Constitution and Bylaws, the Issue Submission Form shall be made available to Conference members and to other interested parties by 150 days prior to the Biennial Meeting.

3. Issue submissions shall be made electronically through the internet. Issues may be submitted to the Executive Board only in the event of a late-breaking food safety Issue. Current instructions for submission and the form are available through the internet on the Conference web site or from the Executive Director.

    a. For the purpose of this Section a late-breaking food safety Issue is defined as an Issue that specifically relates to an event, practice or circumstance creating a situation requiring the immediate attention of the Conference that has occurred between the deadline of the Conference Issue submission deadline and the Biennial Mmeeting.

4. The deadline for Issues and their attachments is the date specified in the Constitution and Bylaws.

B. Issue Acceptance Criteria

1. In order for the Issue to be accepted by the Conference and considered for Council deliberation, all sections of the form must be completed. The Issue must be described completely, with its impact on retail distribution identified. The food protection or public health aspect of the Issue must be clearly stated to be easily understood. A suggested solution or rationale for the Issue must be sufficiently detailed to cover all aspects of the submission.

2. When the recommended solution is to change the wording of a document, such as the Food Code or a Conference document, the portion of the document to be changed must be accurately identified, the change that is requested must be specified (e.g., actual language for replacement, addition, change or deletion), and the recommended language provided.

3. A late-breaking food safety Issue submitted after the deadline may be considered for assignment to a Council if it has first been presented to the Conference Executive Board for review and acceptance. The Conference Executive Board shall inform the Issue Committee Chair of its decision to accept or reject any Issue submitted after the Issue deadline**.**

C. Issue Withdrawal Criteria

1. The Issue submitter can remove the Issue from the Conference before it has been assigned by the Issue Committee to a Council.

2. Once an Issue has been assigned to a Council, the Council is required to review the Issue, and at that time they can vote to remove the Issue.

D. Issue Committee Assignment of Issues to Councils

1. Immediately after the deadline for Issue submission, the Issue Committee reviews submitted Issues for their compatibility with the Conference objective, as stated in the Constitution and Bylaws, and for their public health significance and completeness.

2. The Committee Chair consults with Issue submitters as needed. Those Issues fulfilling the criteria for acceptance are numbered and assigned to one of three Councils for consideration at the CFP Biennial ~~Conference~~ Mmeeting:

Council I	--	Laws and Regulations
Council II	--	Education, Certification and Administration
Council III	--	Science and Technology

3. Once an Issue is assigned to a Council, it may be given to a Committee to review in depth and develop a position for the Council to consider at the meeting. For a limited number of key Issues, Council Chairs may request a white paper be developed.

E. Issue Rejection Process

1. All Issues must be received in final form by the deadline date. If an Issue received prior to the deadline date does not meet the criteria set forth in IV. B**.**, the Issue Chair will make a reasonable attempt to contact the submitter with a brief explanation of the problem. Failure of the submitter to correct and/or resubmit the Issue prior to the deadline date will result in rejection of the Issue.

2. At least forty~~thirty~~ (40) days before the Conference meeting, the submitter of an Issue that does not meet the criteria for acceptance or is not in the jurisdiction of the Conference is notified with a copy to the Conference Chair of the reason(s) why the proposed Issue is not acceptable. A rejected Issue may be considered a "Special Issue" if accepted by the Board and submitted by the Board to the Council at the beginning of the CFP Biennial ~~Conference~~ M~~m~~eeting.

F. Numbering of Issues

Each Issue is given a number. The number shall reflect the year, Council assignment, and the sequence within that Council. For example, Issue 98-III-15 was submitted for the 1998 CFP Biennial Meeting, and is the fifteenth such issue assigned to Council III.

G. Presentation of the Issue to the Council

The submitter of each Issue, or the submitter's representative, is afforded the opportunity to verbally present the Issue to the Council as it is opened for discussion and to address questions that arise during its deliberation.

H. Supplemental Material to Issues

Supplemental reports, studies and other written materials required to explain an Issue should be submitted as an attachment to that Issue or as a link to an existing document on a publicly accessible website to ensure timely review by the

Councils. If that is not possible, written materials relating to an Issue may be made available to Council and Assembly members during CFP Biennial Meeting deliberations. Sufficient copies must be provided by the presenters for the Council members and provided in advance to the Council Chair for distribution. However, submitters may not expect that such materials will be read due to the press of business at the CFP Biennial Meeting. Therefore, providers may be asked to provide a brief oral summary of those materials during the appropriate Council or other meeting.

1. Conference Board members, Council members and Assembly Delegates will receive supplemental material that has been developed immediately before and during the CFP Biennial Meeting at no charge.
2. Late developing Conference committee updates shall be presented both orally and in writing.

I. Issues Packet

An Issues Packet shall be sent to all Conference members. The Issues Packet contains Issues arranged in the order assigned by the Issue Committee although the order may be rearranged prior to or during Council meetings based on a variety of considerations.

V. Councils

A. Meeting Arrangements

1. Council Chairs meet prior to the Issue deliberation to review and have a common understanding of uniform procedures to be followed during the Council meetings. This meeting is chaired by the Constitution and Bylaws/Procedures Committee Chair and the Parliamentarian will be present to answer any questions.

2. A meeting room is assigned to each of the Councils for the duration of the CFP Biennial~~Conference~~ M~~m~~eeting. Should Councils wish to meet at other times than scheduled, a notice must be posted as to when and where so all attendees are advised. In addition, the Executive Director must be notified of such a meeting. The Executive Director and the Chair of the Local Arrangements Committee shall assist in arranging a room.

3. Councils will post, in a conspicuous place, agendas that show the sequence in which the Issues will be discussed and will update the agenda as they dispense with each Issue. This allows a submitter or interested parties to move from Council to Council to present multiple Issues, if necessary.

4. If there are conflicts in agendas, i.e., where two or more Issues that were submitted by the same person are scheduled for discussion at the same time, the submitter should notify the Council Chairs as soon as a conflict is identified. The Council Chairs will make every effort to rearrange their agendas to accommodate presentation of the Issues by the submitter or the submitter's representative.

B. Council Member Application Process

New Council members and alternates are selected for the next CFP Biennial ~~Conference~~ M~~m~~eeting from applications submitted to the Executive Director. All selected Council members and alternates will receive notification of their appointment from the Council Chair.

C. Conducting Business

1. Rules

Before beginning Council deliberations, each Council Chair announces the respective rules to be followed, in addition to Robert's Rules of Order, reviews the agenda, schedules, limits of time for deliberation on each Issue by any individual, voting on Issues (i.e., acceptance, no action or referral) and any other pertinent information.

2. Referral of Issues to Another Council

If a Council decides by a simple majority vote that it is necessary to refer an Issue to another Council, the Council Chair immediately notifies the Issue Chair. The Council Vice-Chair works with the Issue Chair to ensure that the Issue and all supporting documentation and rationale for reassignment is successfully communicated and assigned to the new Council. Issue Chair reassigns the Issue and confirms that a notice has been posted on the agendas of all involved Councils. Sufficient copies of the reassigned Issue shall be provided to the new Council for its use in reviewing the Issue. A reassigned Issue is generally considered at the end of the Council agenda or can be grouped with like Issues.

3. Recorder

Each Council has a recorder pre-selected by the Conference Chair assigned for the purpose of noting significant information and recommendations generated in that Council. The recorder should be reasonably free of advocacy positions with the respective Council.

4. Participation in Other Council Meetings

Council members can leave their meeting to participate in other Council meetings for a particular Issue. Council Chairs should be told beforehand by their members if they are going to do this. Councils post an agenda of Issues along with action status to keep attendees informed and to facilitate scheduling for attendee. Council members are encouraged to participate in all deliberations in their assigned Council.

5. Council Deliberations and Voting Process

a. Councils deliberate Issues beginning with Issue 01. Should any Council member wish to change the order of discussion, the Chair requests a vote by the Council. If acceptable, the Chair tells the audience and posts a note on the door of the meeting room with the changes. Issues addressing similar subjects may be grouped under one Issue by consent of the Council members. A note describing the groupings is also posted on the door.

b. The Council Chair reads each Issue to the Council and entertains a motion and a second in order to bring the Issue to the floor for discussion. For discussion purposes, the Council Chair recognizes members of the Council first, the submitter and then those in the audience. Should members of the audience wish to be recognized by the Chair, they need to raise their hand, await recognition by the Chair, and then step forward to address the Council. The audience may come and go in an orderly fashion should they wish.

c. The following recommendations can be made by a Council:

· **ACCEPT AS WRITTEN**

Goes to Assembly of State Delegates as submitted.

· **ACCEPT AS AMENDED**

Goes to Assembly of State Delegates as amended.

· **NO ACTION**

Goes to the Assembly of State Delegates as submitted, with reason for "No Action."

In all cases the recommendation shall begin with the phrase "The Conference recommends…"

6. Council Reports

a. Upon conclusion of the Council meetings, each Council prepares a report. Each report will have two parts:

(1) Part I: Issues that were recommended "Accepted As Written" and Issues that were recommended "Accepted As Amended";

(2) Part II: Issues that were recommended as "No Action"

b. These reports are duplicated and distributed to the CFP Biennial Meeting ~~Conference~~ attendees before the Assembly of State Delegates session.

VI. Caucus/Consensus Building Meetings

Caucus and consensus building meetings are held at various times during the CFP Biennial ~~Conference~~ M~~m~~eeting for five groups: academia, consumers, local regulatory agencies, state regulatory agencies and industry. These meetings enable constituent groups to:

1. Select representatives from their respective groups to fill current or pending vacancies on the Conference Executive Board; and

2. Discuss proposed issues or issues that have been deliberated by the Councils.

VII. Assembly of Delegates

A. Role of the Assembly

The Assembly is to approve or reject recommendations from the three Councils, including amendments to the Constitution and Bylaws.

B. Workings of the Assembly

1. The Council Chairs present their reports to the Assembly in sequence beginning with Council I. Part I of each Council report is

presented first by each Council. After the Part I portion of the reports is completed the Part II portion follows.

2. Delegate voting options include "Yes," "No," or "Abstain."

   If a majority (simple or two-thirds as prescribed in the Constitution) of the voting Delegates vote "Yes" on Issues "accepted as submitted" or "accepted as amended" by the Council (contained in Part 1 of the Council Chair's report to the Assembly of State Delegates) the action recommended by the Council will be taken.

   If a simple majority of Delegates vote "No" on any Issues "accepted as submitted" or accepted as amended" by the Council (contained in Part 1 of the Council Chair's report to the Assembly of State Delegates) the Conference will take no action on the Issue.

   If a simple majority of the voting Delegates vote "Yes" on Issues on which the Council took no action (contained in Part 2 of the Council Chair's report to the Assembly of State Delegates) the Conference will take no action on the Issue.

   If a simple majority of the voting Delegates vote "No" on Issues on which the Council took no action (contained in Part 2 of the Council Chair's report to the Assembly of State Delegates) the Issue shall be referred to the Executive Board for consideration. The Executive Board will then determine the appropriate action to be taken.

3. The Delegates are asked to identify any Issues from the Council's report they wish to extract for separate, individual discussion.

4. Issues dealing with the Constitution and Bylaws and Procedures of the Conference are automatically extracted from the Council II report.

5. The Conference Chair asks for a motion to accept the Council report minus the extracted Issues. After the motion is made, the Conference Chair requests a second to the motion. The Council report, minus the extracted issues, is voted upon. Voting options are "Yes", "No", or "Abstain".

6. The Conference Chair asks for a motion to accept the Council recommendation for each extracted Issue. A second to the motion is requested for each extracted Issue.

7. Each extracted Issue before the Assembly can be discussed for clarification prior to a vote. Extracted Issues cannot be amended by the Assembly.

8. Any delegate may request the Conference Chair to announce the final vote totals on any Issue to the delegation and recorded in the Conference minutes.

VIII. Committees

A. Ad-Hoc Committees

1. Committees shall be created based on recommendations from Council and approved by the Delegates. Council Chairs shall submit for the Board approval the names of the Committee Chairs and membership of all the Committees assigned to the Council by the Executive Board meeting following the CFP Biennial Meeting.

B. Standing Committees

1. The following standing committees shall be established: the Audit Committee; Constitution and Bylaws/Procedures Committee, Issues Committee; Managers Training, Testing, and Certification Committee; Nominating Committee; Program Committee; Resolutions Committee; and Strategic Planning Committee.

C. Committee Membership

Whenever possible, depending upon the nature of the Issue, membership of the Committees should be made up of representatives from around the country and from regulatory, industry, consumers and academia.

D. Appointment of Members

1. The incoming Council Chairs appoint the Chairs of each Committee formed within their Council with the concurrence of the Conference Chair. The Conference Chair will confirm the appointment of the Committee Chair and then notify the person of their appointment. Once confirmed, the Committee Chair will select the remaining members of the Committee and submit them to the Conference Chair for final Board approval. Accepting a committee chair or member assignment requires a commitment of time and resources as described in the Constitution and Bylaws.

2. Federal participants (FDA/USDA/CDC) may appoint a member and an alternate for each Committee. The member participates in

discussion but does not vote. The alternate may act in the member's place if the member is unable to attend.

E. Committee Chair

Committee Chairs serve until the Committee charge is completed or until replaced, whichever occurs first. Under direction and guidance from the Council Chair, Committee Chairs shall develop a work plan and establish time frames to accomplish their work plan. A Committee Chair may appoint subcommittees in order to accomplish the work plan. The Conference Chair or the Chair's designee establishes a calendar for submission of interim and final Committee reports.

A Committee Chair's term shall be from appointment and last through the Executive Board Meeting following the next CFP Biennial Meeting.

F. Duties of Committee Members and the Chair

1. Committee members shall make every effort to attend meetings and participate in conference calls.

2. Committee members shall have the responsibility to notify the Committee Chair of their inability to attend a committee meeting or participate in a conference call at least fifteen days prior to the scheduled meeting or conference call.

3. Committee members shall have the responsibility to review for comment any standards, reports, recommendations, Issues, or other committee documents distributed within the time frames designated by the committee.

4. Committee members shall have the responsibility to complete work assignments within time frames designated by the committee or to notify the committee Chair or the Chair's designee of their inability to complete a work assignment.

5. A committee member who does not participate in two consecutive meetings and/or conference calls shall have their continued participation as committee members assessed by the committee Chair and evaluated by the committee. The committee member may be subject to removal from the committee. Removal of a committee member for failure to perform duties as specified above shall require the concurrence to of 2/3 of the voting members of the committee.

G. Term of the Committee

A Committee ceases to exist when its function has been completed and an Issue has been submitted and deliberated at the CFP Biennial ~~Conference~~ M~~m~~eeting unless it is a standing Committee, or the Council or Executive Board re-authorizes the Committee to continue to work on the Issue under consideration.

H. Committee Meetings

1. Committees may convene during the two years before the Conference meeting to complete discussions of the Issues assigned to them. The assignments are a result of previous Council recommendations that were passed by the Assembly of State Delegates. Committees can also convene just prior to the Conference meeting at the Conference meeting site.

2. If Committee members are unable to fulfill their obligation, they are to notify the Committee Chair immediately so that the Committee Chair may appoint a replacement. Members who are unable to attend a meeting may not send a substitute, but may forward any material for Committee consideration.

3. Committees may address new Issues, i.e., Issues submitted for the current year's meeting, which have been assigned to the Council, if the Council Chair and Vice-Chair deem it appropriate. The Conference Vice-Chair works with each Council Chair to ensure that Council Committees work on their assigned charges and report back to their respective Councils in a timely manner.

4. Before beginning committee meetings, each Committee Chair announces the respective rules to be followed, in addition to Robert's Rules of Order, reviews the agenda, and any other pertinent information. Only members of the committee can vote on items brought before the committee. A quorum must be participating to adopt a motion. A quorum is defined as a simple majority of committee members.

I. Committee Reports

1. Periodic Status Report

Council Chairs shall submit an interim status report of Committee activities to the Conference Chair no latter than thirty (30) days prior to each Executive Board meeting that does not coincide with a Biennial Meeting. The Conference Chair can send a report back to a Council Chair with a request that a committee work further on its report. Council Chairs shall be prepared to discuss the interim report(s) at each Executive Board meeting.

2. Final Report

Committees that are assigned to a Council and Standing Committees that are submitting an Issue shall provide a final report of their activities to the Council with a recommendation in the form of an Issue submitted for Conference deliberation. This shall be done ninety (90) days in advance of the Biennial Meeting as specified in Article II, Section 3, of the Constitution and Bylaws with the report attached to the pertinent Issue.

The Committee Chair or the Committee Chair's designee should be present when the Council meets during the Biennial Meeting to present and discuss the Committee's report.

J. Committee Sign-Up Sheets

At the Conference meeting, the Executive Director will post sign-up sheets for members interested in working on standing and ad hoc Committees.

IX. Conference Recommendations Relating to the FDA Food Code

Conference recommendations to State and local governments and others that pertain to retail food protection matters and that may therefore have relevance to the FDA Food Code are conveyed to the FDA in the following manner.

1. The Conference Chair will convey to the FDA and USDA any recommendations that relate to the Food Code within 45 days of the CFP Biennial ~~Conference~~ M~~m~~eeting.

2. The FDA and USDA will review and reconsider any material forwarded by the Conference. The FDA and USDA will respond in writing to the Conference Chair on each recommendation from the Conference. The FDA and USDA will make every effort to provide these written comments within 60 days of its receipt of the recommendations.

3. The FDA and USDA will be available to discuss any Issue with the Conference Executive Board in an effort to explore any concerns and identify mutually acceptable approaches for their resolution. The FDA and USDA will arrange to have appropriate staff available so that this discussion may occur at the Fall Board meeting following the CFP Biennial Meeting, unless by mutual agreement an earlier date is appropriate.

4. The FDA and USDA will provide a written update to the Conference Chair as a follow up on each recommendation no later

than 6 months prior to the next CFP Biennial Meeting~~Conference~~.

5. The responses from the FDA and USDA will be posted on the Conference's website as soon as possible.

Conference for Food Protection
2012 Issue Form

Internal Number: 116
Issue: 2012 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.

Title:
Merger and Conformance of CFP Governing Documents

Issue you would like the Conference to consider:
The Constitution and Bylaws/Procedures Committee is seeking to incorporate the *Constitution and Bylaws*, the *Conference Procedures*, the *Conference Biennial Meeting Manual*, position descriptions, Conference policies, etc., into a comprehensive "Conference for Food Protection Manual" that would be divided into multiple "chapters" including the documents listed above and any other relevant items, each as a separate chapter. The *Constitution and Bylaws* will remain as a stand-alone document, potentially as Chapter 1 of the manual, with each of the other complimentary Conference documents as parts of an all-inclusive handbook that can be indexed and cross-referenced. There are areas for improvement in each of these documents (chapters) in the conformance of terminology and language between documents. Also, combining the documents into one master manual will help guarantee that any updates or corrections are performed across the entire manual to ensure that documents match accordingly. The merged and cross-referenced document can be posted to the CFP website in a format similar to the FDA Food Code where each chapter, table of contents, index, etc. shows as an individual link that is part of the whole CFP Manual.

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 2012 - 2014 Constitution and Bylaws/Procedures Committee be charged to:

1. review the Conference for Food Protection governing documents (*Conference for Food Protection Constitution and Bylaws, Conference Procedures, Conference Biennial Meeting Manual, policies, position descriptions, etc.)* to facilitate a merger and conformance of these documents,
2. report back to the Executive Board on the progress of this charge, and
3. present an issue on this charge at the 2014 CFP Biennial Meeting.

Submitter Information:

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

Conference for Food Protection
2012 Issue Form

Internal Number: 112
Issue: 2012 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.

Title:
Definitions for Conference Constituencies

Issue you would like the Conference to consider:
The 2010 - 2012 Constitution and Bylaws/Procedures Committee has created definitions for each of the existing constituencies that represents the Conference for Food Protection membership. Current constituencies include: Regulatory - Local, State, District/Territory and Federal; Industry - Retail, Food Service, Processing and Vending; Academia; and Consumer. While each constituency is identified in the *Conference for Food Protection Constitution and Bylaws* by title, these constituencies do not currently have a clear definition for what comprises each.

Additionally, the Committee has sought to create definitions for several new constituencies that incorporate the expanding types of members who seek to be active participants in the Conference process. The largest majority of current members in the Conference for Food Protection are categorized as "other" because they do not fall within the existing Conference constituencies. New constituencies for consideration by the Conference include: Food Industry Support, Emeritus (retiree), and Student. The Vending Industry constituency has been expanded to include the Distribution Food Industry as a shared constituency titled 'Vending and Distribution Food Industry".

Creation of the new constituencies does not alter representation to the CFP Executive Board, Councils, or to the Conference Voting Delegates as currently prescribed in the *CFP Constitution and Bylaws*.

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...:
newly created language, noted below, relative to definitions for Conference constituencies, as developed by the Constitution and Bylaws/Procedures Committee, be incorporated into the *Conference for Food Protection Constitution and Bylaws* in Article III Registration and Membership, as a new Section 5 (all new language is in underline format).

Article III Registration and Membership

Section 5. Membership in the Conference is classified into constituencies that are representative of the key stakeholder groups which support the objectives of Article I and facilitate the requirements of Article IV. The Conference constituencies are defined as follows:

Subsection 1. Regulatory is comprised of those officers, agents or authorized representatives having authority over the regulation of food establishments, production, processing, vending, or distribution, or has oversight for prevention of foodborne illness in accordance with rule and/or law in their respective governmental jurisdiction. Sub-categories of this constituency include:

a. Local Regulator = government employee or agent representing a territorial division of local government with responsibility for regulation of food establishments, production, processing, vending or distribution, or has oversight for prevention of foodborne illness.

b. State Regulator = government employee or agent representing a territorial division of state government with responsibility for regulation of food establishments, production, processing, vending or distribution, or has oversight for prevention of foodborne illness.

c. Federal Regulator = government employee or agent representing a program or agency of the Federal Government with responsibility for regulation of food establishments, production, processing, vending or distribution, or has oversight for prevention of foodborne illness.

d. District/Territory Regulator = government employee or agent representing the U.S. District of Columbia or one of the six U.S. Territories with responsibility for regulation of food establishments, production, processing, vending or distribution, or has oversight for prevention of foodborne illness.

Subsection 2. Industry is comprised of those employees, agents or executives representing business entities that operate food establishment(s), production, processing, vending, or distribution; or, providers of an industry related service to such food operations; or, representatives of a professional organization or trade association that promotes, supports and/or markets to/for the food industry or its related services. Sub-categories of this constituency include:

a. Food Service Industry = employees, agents or executives representing business entities that operate food service establishments. Examples include, but are not limited to, restaurants of all sizes/types/styles of service, caterers, military food service, institutional and other health care food service, schools and university food service, common carrier food service (planes, trains, etc.), corporate food service operations, and government food service.

b. Retail Food Industry = employees, agents or executives representing business entities that operate retail food establishments. Examples include, but are not limited to, grocery stores, supermarkets, convenience stores, retail pharmacies, produce markets, roadside stands, department stores, warehouse sales clubs, seafood markets, retail bakeries, military base PX/groceries, and liquor stores.

c. Processing Food Industry = employees, agents or executives representing business entities that manufacture, process, package or label food items for wholesale sale. Examples include, but are not limited to, commercial food manufacturing, canning, packaging, commercial bakeries, commercial meat slaughter and processing, packing houses and distribution centers, farming and agricultural processing and packing operations, ice processing, and packing plants.

d. Vending and Distribution Food Industry = employees, agents or executives representing business entities that own and/or operate food companies that vend or distribute food either wholesale or retail. Examples include, but are not limited to, coffee and food vending service companies, service companies, commissaries, food supply chain operators, wholesale distributer, shipping lines, brokers, equipment manufacturers, and suppliers of products and services to operating service companies.

Subsection 3. Food Industry Support = employees, agents or executives representing business entities that provide direct or support services to food service establishments, retail food establishments, processing food operations, vending and distribution food operations. Examples include, but are not limited to, professional organizations, trade associations, pest control companies, auditing firms, standards associations, consultants, cleaning and sanitation management operations, training and/or testing companies or services, equipment and supply operations, software and technology, dieticians or dietary managers, media and legal representatives.

Subsection 4. Academia = academic professionals employed by a college or university involved in education or research involving food sciences, food operations, or food safety. Examples include, but are not limited to, professors, adjunct instructors, researchers, teaching assistants, and extension agents.

Subsection 5. Consumer = employees, agents or executives representing consumer advocacy organizations supporting food safety, food wholesomeness, allergen awareness, food policy matters and food standards and guidelines.

Subsection 6. Emeritus = members retired or honorably discharged from full-time work and no longer receiving compensation for work related to the Conference's mission. This constituency is designed for those professionals who, prior to retirement, were members of any Conference stake holder group in good standing of the Conference for Food Protection for at least three biennial cycles (6 years). Previous membership does not have to be in contiguous biennial cycles. An emeritus member may participate as an attendee/observer in all usual Conference functions such as attending the Biennial Meeting, including workshops, Council deliberations, Assembly of Delegates, and social functions. Emeritus members may serve as a member of a Council Committee, as a Council Committee Chair and participate and vote in constituency caucus meetings. The Executive Board may elect to assign an emeritus member to participate in other Conference related activities.

Subsection 7. Student = any student enrolled in a two-year, four-year, or graduate program in a college or university involving food sciences, food operations or food safety. A student member may participate as an attendee/observer in all usual Conference functions such as attending the Biennial Meeting, including workshops, Council deliberations, Assembly of Delegates, and social functions. Student members may serve as a member of a Council Committee. The Executive Board may elect to assign a student member to participate in other Conference related activities.

Submitter Information:

Name:	Lee M. Cornman, Chair		
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It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Conference for Food Protection
2012 Issue Form

Internal Number: 113
Issue: 2012 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.

Title:
Council Committee Size and Constituency

Issue you would like the Conference to consider:
The 2010 - 2012 Constitution and Bylaws/Procedures Committee has addressed recommendations from the 2010 Biennial Meeting as specified in Issue 2010 II-035. The Committee was charged with developing guidelines regarding committee structure, participant responsibilities, membership size, and constituency representation. To meet this charge, a new Article XV, Section 8, has been developed that clarifies committee size and constituency. Additionally, it is recommended that Section VIII, Paragraph D of the *CFP Conference Procedures* be moved into Article XIV, Section 1, of the *CFP Constitution and Bylaws* with minor revisions.

Language to amend the *CFP Constitutions and Bylaws* was developed to incorporate a minimum and maximum council committee size along with a balanced constituency [note: council committees (ad-hoc) are those established or re-created following every Biennial Meeting and report to a designated Council Chair]. This language provides for establishment of a manageable committee size to accommodate and achieve a voting quorum as well as incorporate active input and participation from other CFP member volunteers. The recommended amendment also provides a procedure structure for committee turnover between subsequent biennial meetings and for changes to members and/or constituencies between biennial meetings.

The recommendation to amend and move language from the *CFP Conference Procedures* into the *CFP Constitution and Bylaws* is also consistent with the charge specified in Issue 2010 II-035 and relevant to identification of committee membership. This language clarifies the appointment of committee chairs and committee members with Board approval and the appointment of Federal participants to each committee as a non-voting member.

Public Health Significance:
The Constitution and Bylaws/Procedure Committee shall submit recommendations to improve the Conference administrative functions through proposals to amend the *CFP Constitution and Bylaws* and *CFP Conference Procedures*.

Recommended Solution: The Conference recommends...:

1) that relevant sections in paragraph D. Appointment of Members, under Section VIII. Committees, in the *CFP Conference Procedures*, including the subsection on Federal agency participation, be moved to Section 1 of Article XIV Committees, in the *CFP Constitution and Bylaws*; and

2) that newly created language relative to Council Committee size and constituency be incorporated into the *CFP Constitution and Bylaws* in Article XV, as a new Section 8.

The recommended language changes are noted as follows (new language is underlined; language to be deleted is in strikethru format:

CFP Conference Procedures

VIII. Committees

A. thru C. No change.

~~D. Appointment of Members~~

~~1. The incoming Council Chairs appoint the Chairs of each Committee formed within their Council with the concurrence of the Conference Chair. The Conference Chair will confirm the appointment of the Committee Chair and then notify the person of their appointment. Once confirmed, the Committee Chair will select the remaining members of the Committee and submit them to the Conference Chair for final Board approval. Accepting a committee chair or member assignment requires a commitment of time and resources as described in the Constitution and Bylaws.~~

~~2. Federal participants (FDA/USDA/CDC) may appoint a member and an alternate for each Committee. The member participates in discussion but does not vote. The alternate may act in the member's place if the member is unable to attend~~.

E. thru J. No language change - renumbering only as paragraphs D through I.

CFP Constitution and Bylaws

Article XIV Committees

Section 1. All appointments to Conference Committees shall be made to provide a balance in representation of the stakeholders in the particular matter under consideration.

Subsection 1. The incoming Council Chairs appoint the Chairs of each Committee formed within their Council with the concurrence of the Conference Chair. The Conference Chair will confirm the appointment of the Committee Chair and then notify the person of their appointment. Once confirmed, the Committee Chair will select the remaining members of the Committee and submit them to the Conference Chair for final Board approval.

Subsection 2. Federal participants (FDA/USDA/CDC) may appoint a member and an alternate for each Committee. The member participates in discussion but does not vote. The alternate may act in the member's place if the member is unable to attend.

Section 2. thru 5. No change.

Article XV Duties of the Committees

Section 8. Council Committee Size and Constituency: Committee membership discussion is limited to Council committees only. Membership on Standing Committees or Executive Board Ad Hoc Committees is defined by the CFP Executive Board.

Subsection 1. Committee size.

Voting membership for council committees should be comprised of at least eleven (11) voting members with a maximum of no more than twenty-three (23) voting members.

a. Minimum size: Voting membership for a minimum size committee is the Chair, Vice Chair, two (2) representatives from state regulatory, two (2) representatives from local

regulatory, two (2) representatives from industry, one (1) from an academic institution, one (1) consumer representative, and one elective (1) representative which may be selected from any Conference constituency.

b. Maximum size: Voting membership for a maximum size committee is the Chair, Vice Chair, four (4) representatives from state regulatory, four (4) representatives from local regulatory, eight (8) representatives from industry, one (1) from an academic institution, one (1) consumer representative, and three elective (3) representatives that may be selected from any Conference constituency.

c. Any committee comprised of membership numbers between the minimum and maximum shall make every reasonable effort to maintain constituency balances.

Subsection 2. The Chair and Vice Chair of a council committee may be selected from any of the Conference constituencies as approved by the Council Chair and the Executive Board, provided each is from a different constituency. If a Committee Chair does not receive sufficient volunteers in the appropriate constituencies, they shall confer with the Council Chair to seek volunteers from the Conference membership making every reasonable effort to maintain constituency balances. The Committee Chair, in conference with the Council Chair and/or Executive Board, shall have the flexibility to fill vacancies in the voting membership with unbalanced constituency representation if deemed necessary to reach a minimum of 11 voting committee members. All proposed committee members must be approved by the Executive Board in accordance with Article XIII, Section 6, Subsection 4 of the Constitution and Bylaws.

Subsection 3. A maximum of 23 voting members are permitted on a council committee. All volunteers not selected for a voting position shall be offered an "at-large" non-voting position on the committee. There is no limit to the number of at-large non-voting members that may participate. At-large members will be included and allowed to participate in all committee functions, including but not limited to, meetings, conference calls, emails, deliberations, research and activities, but will not have an individual vote on committee actions. All voting members and at-large non-voting members shall be identified as such on the committee roster along with their respective constituency.

Subsection 4. In the event a council committee voting member departs such committee during a biennial cycle, an at-large member of the same constituency as the departing member shall be selected by the Council Chair to fill the vacancy, subject to approval by the Council Chair and Executive Board in accordance with Article XIII, Section 6, Subsection 4 of the Constitution and Bylaws. If a council committee voting member changes constituency during a biennial cycle, and there is no vacancy in that member's new constituency, the member will need to transition from service as a voting member on that committee and may continue to serve as an at-large non-voting member for the remainder of the biennial cycle. This transition will occur upon notification to the Committee Chair.

Subsection 5. The Chair of a council committee that continues over more than one biennial cycle shall assess the immediate previous committee membership to ensure at least 50% of the ongoing committee's voting membership are new members that did not serve as voting members on the immediate previous committee. This will ensure that an increased number of at-large members or others have an opportunity to participate as a voting member over time when there are a large number of volunteers.

Submitter Information:

Name: Lee M. Cornman, Chair
Organization: Constitution and Bylaws Committee
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City/State/Zip: Tallahassee, FL 32399
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It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Conference for Food Protection
2012 Issue Form

Internal Number: 080
Issue: 2012 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.

Title:
Limit Hand Hygiene Committee Size

Issue you would like the Conference to consider:
A separate issue addressed re-creation of the Hand Hygiene Committee. The 2010-2012 Hand Hygiene Committee believes that action on the complex topic of Hand Hygiene would be enhanced by limiting the committee size to facilitate involvement of all committee members on conference calls.

Public Health Significance:
The 2010-2012 Hand Hygiene Committee believes that progress towards its charge was impeded because of committee size. Interest in participating in the Committee was very high, with 50+ people volunteering to serve. The Committee divided into three sub-committees to address the charge, and attempted to use a steering committee to review progress made by the three groups. This multiplied the time commitment for steering committee members and sub-committee chairs who wished to participate in each of the sub-committees. Many committee members dropped out because of the extra time commitment, which hindered continuity. Additionally, the discussions in one committee would have benefited progress of other committees in making informed recommendations on specific situations where application of alternatives to handwashing may be appropriate to reduce public health risk.
The Committee recommends that a limited committee size will lead to a more coordinated work product for this complex topic. While the CFP conference call system can accommodate up to 25, scheduling a conference call for this number of people is problematic.

Recommended Solution: The Conference recommends...:
the size of the 2012-2014 Hand Hygiene Committee to be limited to less than 20 members (including advisors and chairs), to facilitate participation of the full committee on conference calls while maintaining adequate representation from relevant stakeholders.

Submitter Information:
Name: Mark Sampson, Co-Chair
Organization: 2010-2012 Hand Hygiene Committee

Address: Sterilox Food Safety, 162 Ash Way
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Conference for Food Protection
2012 Issue Form

Internal Number: 026
Issue: 2012 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.

Title:
Report - Issue Committee

Issue you would like the Conference to consider:
The Conference for Food Protection (CFP) Issue Committee requests acknowledgement of its final committee report and requests that the committee be assigned continuation charges to continue improving the Issue submission and review process.

Public Health Significance:
Clarification and improvement of the CFP Issue process will ensure that concerns brought forward from all stakeholders are given an equal opportunity for consideration and final approval.

Recommended Solution: The Conference recommends...:
1) 2012 Issue Committee Final Report (attached) be acknowledged along with the following supporting attachments:
a. Council I 2010 Final Issue Recommendations with Actions
b. Council II 2010 Final Issue Recommendations with Actions
c. Council III 2010 Final Issue Recommendations with Actions
d. Committee Submitted Issues - Review Process and Checklist
e. 2010-12 Issue Committee Roster
2) Issue Committee members be thanked for their service.
3) 2012-14 Issue Committee be assigned the following continuation charges with the requirement to report back to the 2014 Biennial Meeting:
a. Complete the charge from Issue 2010 II-30 to "Expand Archive and Posting Capabilities of CFP Approved Documents" on the Conference web site and develop a process / procedure to ensure posting of all:
i. Documents and attachments modified or edited after Issue packets are made available with reference to the original Issue number and attachment titles;
ii. Documents and attachments modified during and after Council deliberations at the Biennial Meetings; and
iii. Final version of conference approved guides, documents, and presentations in both PDF and the original editable format.

b. Work with the Constitution, Bylaws, and Procedures Committee to review, consolidate, and update CFP governing documents, guidelines, and instructions regarding:
i. Preparation, submission, and presentation of Issues, final committee reports, and Issue attachments.
ii. Roles and responsibilities for each biennium.
c. Review the *CFP Commercialism Policy* as it relates to Issue "attachments" (e.g., peer reviewed articles, industry sponsored studies, letters of recommendation, presentations).
d. Develop a "masthead, flag, nameplate, or style guide" to readily identify approved and posted documents as belonging to the Conference.

Submitter Information:

Name: Aggie Hale, Issue Co-Chair
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Attachments:

- "Council I 2010 Final Issue Recommendations"
- "Council II 2010 Final Issue Recommendations"
- "Council III 2010 Final Issue Recommendations"
- "Issue Review Checklist - Committee Issues"
- "Issues Committee Final Roster"
- "Issue Committee FINAL Report 2012"

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☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING

Issue: 2010 I-002 Title: Report – Plan Review Committee

Recommended Solution:

The Conference recommends re-creation of the committee to review and update the following Conference for Food Protection documents and present their finding at the 2012 CFP Biennial Meeting:

- Temporary Food Establishments
- Permanent Outdoor Cooking Operations

☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING

Issue: 2010 I-008 Title: Wild Harvested Mushrooms

Recommended Solution:

The Conference recommends that the Council consider forming a committee to continue discussion of this issue and that the following language and attachments for consideration to be placed on the CFP website as guidance listing steps that states can use to develop and implement a wild harvested mushroom program for their state. The charges will be:

- Develop guidelines to help regulators address the issue of wild mushrooms in food establishments
- Report back at the 2012 CFP.
- The name of the committee will be Wild Harvested Mushrooms Committee.

☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING

Issue: 2010 I-010 Title: USFDA Recall Policy Revision

Recommended Solution:

The Conference Recommends that a Recall Evaluation Committee be formed and work with FDA, USDA, and states on the following charge:

- Clarify the system of classification for recalls established by USDA and FDA.
- Create clarifying instructions and procedures that industry and consumers can easily understand and comply with.
- Recommend enforceable and reasonable time frames for execution of recall communications and actions.
- Clarify the information required to be included in supplier recall notifications.
- Recommend expectations for the notification of end-users, including restaurant and retail customers as well as school and institutional food service.
- Report back to the 2012 Biennial Meeting.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 I-011 Title: Signage Requirement on Reporting of Employee Health Conditions

Recommended Solution:

The Conference recommends that a letter be sent to the FDA recommending that Section 2-103.11 be amended.

Amend Section 2-103.11 Person in Charge by adding Paragraph (N) to read:

(N) " A verifiable system needs to be in place to communicate to employees the importance of employee health as described in, Subparagraphs 2-201.11 (A)(1), (2), (3), (4), and (5) to the permit holder, such as posting a sign, written agreement, or training related to reporting symptoms and diagnosis."

☒ **LETTER** ☐ CHARGES ☒ **CFP WEB POSTING**

Issue: 2010 I-015 **Title: Criticality Implementation & Education Committee – Criticality Training Slides**

Recommended Solution:

The Conference recommends

- acceptance of the PowerPoint presentation and speaker notes titled "Re-designation of Food Code Provisions" and place it in a downloadable format under the "Conference Developed Guidance and Documents" section of the Conference web site.
- that a letter be sent to FDA requesting the same PowerPoint presentation and speaker notes be made available through its web site.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 I-016 **Title: Criticality Implementation & Education Committee – Frequently Asked Questions**

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting that they:

- provide answers to the list of FAQs included in the attached document.
- have the FAQs and answers available for stakeholders on or before June 30, 2010 by posting on the FDA website.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 I-017 **Title: Criticality Implementation & Education Committee – Timely Correction of**

Violations

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting revision and/or addition to the following three sections in Chapter 8, Compliance and Enforcement in the FDA

See final Issue Recommended Solution for full details to include in letter

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☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 I-019 **Title: 4-501.114-Manual and Mechanical Warewashing Equipment Chemical Sanitation**

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting that Section 4-501-114 be revised as follows:

See final Issue Recommended Solution for full details to include in letter

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☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 I-021 **Title: 3-304.14 Wiping Cloths, Use Limitation**

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting written clarification in the Food Code or Annexes on how the FDA may recognize the appropriate use of dry cloths, including disposable towels, for wiping down counters and equipment.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 I-022 Title: Key Drop

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting the following changes to the Food Code:

that § 2.103.11 of the FDA Food Code be amended by adding a new ¶ 2.103.11 (F), and renumbering subsequent paragraphs in this Section appropriately, to specifically allow for the practice of key access deliveries by including the following language:

See final Issue Recommended Solution for full details to include in letter

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☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 I-024 Title: Management Responsibility Code Section 2-101.11

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting that the language in Food Code Section 2-101.11 (Responsibility and Assignment) be added with the following language and that additional changes to Chapter 2 be made as necessary to be consistent with this change.

Responsibility 2-101.11 Assignment*

(C) The PERMIT HOLDER through the certified food manager or person in charge (PIC) shall ensure that standard operating procedures that ensure compliance with the requirements of this Code are developed & implemented as specified under 8-201.12 (E) & (F);

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-021 Title: Food Protection Manager Certification

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting a change to the Food Code to require that at least one Person in Charge in each food establishment (exempting certain low risk establishments) be certified in food protection through a manager certification program that conforms to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs.

See final Issue Recommended Solution for full details to include in letter

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-002 Title: Amend "Outcome" Section of Program Standard No. 5

Recommended Solution:

The Conference recommends that a letter be written to FDA endorsing and recommending that the amendment below (indicated in underline format) be included to the appropriate Section of FDA's *Voluntary National Retail Food Regulatory Program Standards, Standard 5 - April 2009:*

See final Issue Recommended Solution for full details to include in letter

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☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING

Issue: 2010 II-003 Title: Report and Re-creation – Interdisciplinary FBI Committee

Recommended Solution:

The Conference recommends re-creation of the Foodborne Illness Training Committee with the following charges:

- continuing to track the progress of prominent disease training programs currently in development; and
- reporting back to the 2012 Biennial Meeting of the Conference for Food Protection.

☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING

Issue: 2010 II-005 Title: Re-create – Inspection Form Scoring Committee

Recommended Solution:

The Conference recommends re-creating the Inspection Form Scoring Committee during 2010-2012 to:

1. Continue working with academic researchers to:
   - investigate and determine the most effective Foodservice Establishment scoring system, based on the current identified risk factors and interventions identified in the FDA Food Code, and for use with the current FDA Food Establishment Inspection Form; including the possible development of a scoring system for the FDA Model Food Establishment Inspection Report Form.
   - determine the most effective way to communicate the Food Establishment Inspection scores to the public so they have access to information in advance of choosing where to dine or where to purchase food items; including the possible development of a method to post inspection scores so that the public has access to the information in advance of choosing where to dine and purchase food items.
   - identify funding sources to conduct research and provide a letter of support for funding already identified.
2. Report the committee's findings back to the Conference for Food Protection at the 2012 Biennial Meeting.

☐ LETTER ☐ CHARGES ☒ **CFP WEB POSTING**

Issue: 2010 II-006 Title: Report – Electronic Reporting Committee

Recommended Solution:

The Conference recommends that a more prominent link be provided on the CFP web site to the 2006-2008 Electronic Data Capture and Reporting Committee Survey.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-007 **Title: Re-create – Electronic Reporting Committee (title changed: Electronic Reporting)**

Recommended Solution:

The Conference recommends that the Conference Chair write a letter to the Food and Drug Administration (FDA) requesting that they develop a database management tool that will enable the analysis of future baseline survey data collected by regulatory agencies to assess and enhance the effectiveness of food safety programs and report back to the Conference for Food Protection.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-009 **Title: Allergen Management Course Addition to Appendix B-1, Standard 2**

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting:

- that upon its completion the FDA Allergen Management Course be reviewed by the re-created CFP Food Allergen Committee.

See final Issue Recommended Solution for full details to include in letter

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☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-010 **Title: Emergency Management Course Additions to Appendix B-1, Standard 2**

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting that Appendix, B-1, Standard 2 - Trained Regulatory Staff, FDA Draft Voluntary National Retail Food Regulatory Program Standards (2009) be revised to:

See final Issue Recommended Solution for full details to include in letter

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☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-011 **Title: Clarifying Language for Step 2, Standard 2 – Program Standards**

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting that Standard 2 - Trained Regulatory Staff, *FDA Voluntary National Retail Food Regulatory Program Standards (2009)* be revised as follows:

See final Issue Recommended Solution for full details to include in letter

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☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-012 **Title: Clarifying Definitions for Step 4, Standard 2 – Program Standards**

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting:

- that the terms "Trainer" and "Training Standard" as defined in the FDA Voluntary National Retail Food Program Standards (2009) be revised to reflect the language below.
- that Step 4, Standard 2 be revised to include clarification regarding the "Training Standard" requirements as presented below.

See final Issue Recommended Solution for full details to include in letter

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☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING

Issue: 2010 II-013 Title: Re-create – CFSRP Work Group

Recommended Solution:

The Conference recommends that a 2010-2012 Certification of Food Safety Regulation Professionals (CFSRP) Work Group be re-created to address the following charges:

1. Collaborate with the FDA Center for Food Safety and Applied Nutrition and the FDA Division of Human Resource Development to:

- Review 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.
- Review and revise, as needed, Standard 2 classroom curriculum, time frame for completion of Steps 1 through 4 for new hires or staff newly assigned to the regulatory retail food protection program.
- Determine if the CFP Field Training Manual and forms have completely addressed all recommendations received as part of the 2007 Assessment of Training Needs (ATN) pilot project.

2. Eliminate the potential redundancy of multiple verification tools (FDA *Retail Food Level I Performance Audit and FDA Procedures for Standardization and Certification of Retail Food Inspection / Training Officers*) utilized by FDA programs, work in collaboration with FDA's Center for Food Safety and Applied Nutrition, FDA's National Retail Food Team and the FDA's Division of Human Resource Development to:

- Conduct a pilot project over the next year using the FDA *Retail Food Level I Performance Audit* with a limited and selected number of jurisdictions. The FDA *Performance Audit* will be piloted for use during the two joint inspections conducted as part of the quality assurance component of *Standard 4 - Uniform Inspection Program.* An outline of the pilot project objectives, protocol, and projected timeline is included as Attachment A with this Issue. The CFP CFSRP work group will submit a report to the 2012 Biennial Meeting that documents the result of the pilot project and any recommendations for the use of verification tools as part of the FDA Program Standards*;* and,
- Conduct a joint assessment of FDA *Standardization Procedures* and FDA *Performance Audit* documents to determine if both verification tools are equally viable with distinct purposes and outcomes; and,
- Explore the feasibility of merging these existing verification tool documents and provide a plan for consolidation of such; and,
- Upon determination, assess the placement and administration of final verification tool(s) within the FDA *Program Standards* as appropriate, or separately as appropriate; and,
- With input and guidance from the CFSRP Work Group, FDA will determine if modifications to their draft FDA *Performance FDA Retail Food Level I Performance Audit* and/or *Standardization* documents are needed. Any modifications that would include changes to the Program Standards will be submitted as Issues by the CFP CFSRP Work Group to the 2012 Biennial Meeting.

3. Collaborate with FDA, other federal agencies, professional and industry associations to research what criteria is currently being used to assess the education and training qualifications of independent third party auditors that have been contracted to conduct institutional foodservice, restaurant, and retail food compliance inspections in lieu of a State/local/tribal regulatory retail food program. The re-created Work Group is to provide a report to the 2012 Biennial Meeting that:

- Assesses the number of jurisdictions and geographic areas where retail food compliance Inspections are conducted by independent third party auditors in lieu of a regulatory compliance program;
- Delineates the reasons jurisdictions have moved to a third party auditor inspection compliance program;

- Summarizes criteria used to select third party auditors for inspection compliance oversight responsibilities including, but not limited to, education and training qualifications;
- Assesses and determines appropriate training and standardization processes/protocols for third party auditors, and
- Identifies any agencies/organizations/working groups currently addressing education and training standards for third party auditors conducting retail food compliance inspections.

Based on the above research, the work group will provide a recommendation to the Conference as to what actions/initiatives, if any, need to be undertaken to provide a national structure for ensuring that third party auditors possess the necessary knowledge, skills, and abilities to conduct retail food program compliance inspections.

4. Evaluate and determine the best approaches to promoting awareness and implementation of the national training model contained in the CFP Field Training Manual and forms, Appendix B-2, Standard 2. The Work Group will:

- Research the use of websites, list serves, newsletters, testimonials, presentations, and training workshops, etc.
- Assess opportunities for enhancing the electronic versions of the CFP Field Training Manual and forms to minimize paperwork.

5. Report back to the 2012 Biennial Meeting its findings regarding the above charges.

☐ LETTER ☐ CHARGES ☒ **CFP WEB POSTING** ☒ **OTHER**

Issue: 2010 II-015 Title: FPMTTC Committee – Amend Training Language in Standards

Recommended Solution:

The Conference recommends revising the *Standards for Accreditation of Food Protection Manager Certification Programs,* Annex B, Section B 3, as noted below to clarify information available regarding food safety content to assist training program developers and evaluators.

Note: new language below is in underline format; language to be deleted is in strike through

See final Issue Recommended Solution for full details regarding edits

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☐ LETTER ☐ CHARGES ☒ **CFP WEB POSTING** ☒ **OTHER**

Issue: 2010 II-016 Title: FPMTTC Committee – Amend Section 5 of the Standards for Accreditation

Recommended Solution:

The Conference recommends revising the *Standards for Accreditation of Food Protection Manager Certification Programs,* Section 5 - *Food Safety Examination Administration* with substantial revisions as follows:

See final Issue Recommended Solution for full details regarding edits

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☐ LETTER ☐ CHARGES ☒ **CFP WEB POSTING** ☒ **OTHER**

Issue: 2010 II-017 Title: FPMTTC Committee – Remove "monitor" from Standards for Accreditation

Recommended Solution:

The Conference recommends removing the definition and use of the term "monitor" from the *Standards for Accreditation of Food Protection Manager Certification Programs* in the following sections*:*

See final Issue Recommended Solution for full details regarding edits

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☐ LETTER ☐ CHARGES ☒ **CFP WEB POSTING** ☒ **OTHER**

Issue: 2010 II-018 Title: FPMTTC Committee – Name Change

Recommended Solution:

The Conference recommends

- Changing the name of the CFP standing committee **from** "Managers Training, Testing and Certification Committee" (as listed in the *CFP Constitution and Bylaws*), and "Food Protection Manager Training, Testing and Certification Committee" (as listed in the *FPMTTC Committee Bylaws*) **to** "Food Protection Manager Certification Committee" in all CFP documents, including the *CFP Constitution and Bylaws 2008* in Article XIV Committees, Section 2. Subsection 4: Food Protection Managers Training, Testing and Certification Committee.
- Adding a new article to the *FPMTTC Committee Bylaws* specifying the full name of the committee and re-numbering all subsequent sections: Article I. Name. The Name of the Committee is Food Protection Manager Certification Committee.

The Conference further recommends that all other references in the CFP Constitution and Bylaws, FPMTTC Committee Bylaws, and information on the CFP Website be updated to reflect the new full committee name or the acronym FPMCC.
Refer to the FPMTTC Committee Report Issue attachment *Food Protection Manager Training, Testing, and Certification Committee Bylaws* for complete proposed revision.

☐ LETTER ☐ CHARGES ☒ **CFP WEB POSTING** ☒ **OTHER**
Issue: 2010 II-019 Title: FPMTTC Committee – Revise Bylaws
Recommended Solution:
The Conference recommends adopting the Committee Bylaw revisions as proposed by the Food Protection Manager Training, Testing and Certification Committee.

See final Issue Recommended Solution for full details regarding edits

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☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING
Issue: 2010 II-020 Title: New or Continuation Charges for the Renamed FPMTTC Committee
Recommended Solution:
The Conference recommends that the Food Protection Manager Certification Committee (FPMCC), a standing committee of the Conference be charged to:

- 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.
- request that ANSI and the Certification Providers will examine all options for resolving the exam security and independence issues as they pertain to trainers serving as test administrators and come to consensus with a suggested action plan as follows:
  - By April of 2011, a recommended solution to be reviewed by the ANSI / Certification providers workgroup
  - By June of 2011 the FPMCC, Certification Providers and ANSI have reached consensus on the recommended solutions
  - The draft recommendations will be submitted to the Executive Board for their review at the August 2011 Board meeting
  - Recommendations approved by the Executive Board will be submitted as an issue at the 2012 biennial meeting
- Pending Conference approval, the new requirements will be implemented no later than January of 2013.Investigate if the *Standards for Accreditation of Food Protection Manager Certification Programs* should create more alignment with ISO (International Standards Organization) 17024 and propose changes if needed.
- determine how Committee membership vacancies and change of membership representation are addressed in the Committee bylaws and propose changes if needed.
- report back to the Executive Board and the 2012 Biennial Meeting of the Conference for Food Protection.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-022 **Title: Report – Program Standards Committee**

Recommended Solution:

The Conference recommends that a letter be sent to the FDA recommending that:

- the FDA continue to send the Retail Resource Disk to all enrolled jurisdictions and that a hard copy be provided to enrolled jurisdictions only if requested.
- the following documents be made available on the FDA web site:
  - summary of Program Standards changes from 2007 and 2009
  - the two most current versions of the Program Standards (currently, 2007 and 2009)
  - all Supplemental Tools and Materials
  - the FDA Data Collection Manual

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-023 **Title: New Definition for Voluntary Retail Food Regulatory Program Standards**

Recommended Solution:

The Conference recommends that the Conference Chair send a letter to the FDA Commissioner requesting:

- that the Definitions in the Program Standards be amended to include designation in numerical order, and
- that the following definition be added:
  Self-Assessment Update **-** Comparison of one or more program elements against the Voluntary *National Retail Food Regulatory Program Standards* between the required 60-month, periodic Self-Assessments.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-024 **Title: Amendments to Program Standard No. 9 – Program Assessment**

Recommended Solution:

The Conference recommends that the Conference Chair send a letter to the FDA Commissioner requesting that Program Standard No. 9 be amended to read as specified in the attached document titled: *Proposed Amendments to Standard No. 9 - Program Assessment*.

See final Issue Recommended Solution for full details to include in letter

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☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-025 **Title: Financial Support for Voluntary Retail Food Regulatory Program Standards**

Recommended Solution:

The Conference recommends that the Conference Chair send a letter to the FDA Commissioner recommending that FDA enhance national food safety by providing multi-year funding through appropriate mechanisms to state, territorial, tribal, and local food safety agencies enrolled in the Voluntary National Retail Food Regulatory Program Standards to build the necessary infrastructure to assess, implement and audit program efforts to attain standards.

☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING
Issue: 2010 II-026 Title: Re-create – Program Standards Committee
Recommended Solution:
The Conference recommends re-creating the Program Standards Committee to work on the following charges:

1. Serve as a stakeholder group to provide input to an FDA internal working group which will be considering administrative functions such as:
   - Criteria for verification auditors
   - Recommending additional changes or improvements to the Program Standards
2. Formulate resolutions to issues brought before the committee.
3. Report back to Conference at the 2012 CFP Biennial Meeting.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING
Issue: 2010 II-027 Title: Change in Program Standard No. 6 and Appendix F, Compliance and Enforcement
Recommended Solution:
The Conference recommends that a letter be sent to the FDA requesting that the modified language proposed be incorporated into Standard 6 and Appendix F, Supplement to Standard 6 - Compliance and Enforcement of the Voluntary National Retail Food Regulatory Program Standards.

See final Issue Recommended Solution for full details to include in letter

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☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING
Issue: 2010 II-028 Title: Report – Constitution and Bylaws Committee
Recommended Solution:
The Conference further recommends that the Constitution and Bylaws/Procedures Committee continue their review of the provisions concerning definitions of membership categories, report back to the Executive Board, and submit, if deemed necessary, recommended changes as an issue at the 2012 Biennial Meeting.

☐ LETTER ☐ CHARGES ☒ **CFP WEB POSTING** ☒ **OTHER**
Issue: 2010 II-029 Title: Constitution – New Article Titled "Parliamentary Authority"
Recommended Solution:
The Conference recommends that a new Article, entitled Parliamentary Authority, be added to the Constitution and Bylaws and placed before the current Article XIX of the Constitution. The new Article would become Article XIX, the current Article XIX would become Article XX, and the current Article XX would become Article XXI.
Article XIX Parliamentary Authority
The rules of parliamentary procedure comprised in the current edition of Roberts Rules of Order, Newly Revised, shall govern all proceedings of the Conference and the Executive Board, subject to such special rules as have been or may be adopted.

☐ LETTER ☒ **CHARGES** ☒ **CFP WEB POSTING**

Issue: 2010 II-030 **Title: Expand Archive and Posting Capabilities of CFP Approved Documents**

Recommended Solution:

The Conference recommends expanding capabilities for archiving and posting documents on the Conference web site, and charging the Issue Committee with the development of a process and procedure to ensure posting of all:

a) documents and attachments modified or edited after the Issue packets are made available with reference to the original Issue number and attachment titles;
b) documents and attachments modified during and after Council deliberations at the Biennial Meetings; and
c) final version of conference approved guides, documents and presentations in both PDF and the original editable format.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 II-031 **Title: Coordination of the Two Current FDA Food Program Standards**

Recommended Solution:

The Conference recommends that a letter be sent to FDA asking them to work with appropriate interested parties to study the differences and similarities of both the Voluntary National Retail Food Regulatory Program Standards and the Manufactured Food Regulatory Program Standards and identify areas where harmonization can be achieved, and report back to the Conference.

☐ LETTER ☐ CHARGES ☒ **CFP WEB POSTING**

Issue: 2010 II-033 **Title: Barriers to Bare Hand Contact Training Materials**

Recommended Solution:

The Conference recommends approval of the following guidance documents (submitted as attachments to the Issue titled: *Report - Food Contact and Utensil Barrier Usage Committee)*:

1. Barrier to Bare Hand Contact Reference Document - English and Spanish
2. Barrier to Bare Hand Contact PowerPoint Presentation - English and Spanish

The Conference further recommends that these documents be posted to the CFP web site.

☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING

Issue: 2010 II-035 **Title: Limiting Committee Member Numbers (title changed: Committee Participation)**

Recommended Solution:

The Conference recommends the Constitution and Bylaws Committee develop guidelines regarding committee structure, participant responsibilities, membership size, and constituency representation and report back to the Executive Board no later than the August 2011 Executive Board Meeting with recommendations regarding proposed changes to policies and/or governing documents.

☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING

Issue: 2010 III-001 Title: Report and Re-creation – Food Allergen Committee

Recommended Solution:

The Conference recommends re-creation of the Food Allergen Committee to extend the reach of food allergy education, training and awareness as follows:

- Identify appropriate strategies to develop an FDA "endorsed" Allergen Management Course, including the review of course curriculum.
- Review the pending publication of FDA materials and guidance document(s) related to allergen management.
- Utilize the strengths of groups like FAAN and IFIC Foundation (in cooperation with the CFP Food Allergen Committee) to define and lead a health professional outreach activity such as a "food allergy resource page" of educational materials suitable for state/local regulatory officials, food managers, and food employees.
- Add a CDC representative to serve on the CFP Food Allergen Committee to help enhance our current public health perspectives and assist in the development and dissemination of a health professional outreach activity.
- Report back to the 2012 Biennial Meeting with the outcome of these charges.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 III-005 Title: On-Site Generation of Antimicrobial Pesticides

Recommended Solution:

The Conference recommends that a letter be sent to the FDA recommending changes to the Food Code as detailed in the attached "Food_Code_Recommendations_for_On-site_Generation_of_Antimicrobials" (extracted from Table 1 of the CFP 2008-10 Sanitizer Committee Final Report). Detailed rationales for the recommended changes are included in the table.

See final Issue Recommended Solution for full details to include in letter

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☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 III-006 Title: 4-501.19 Manual and Mechanical Warewashing Equipment, Wash Solution Temperature

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting that section 4-501.19 be revised to remove the minimum wash solution temperature and be classified as a Core C item by removing the "Pf" and substituting "C" at the end of the section as indicated below AND requests that the Annex 3 entry for this section be amended as stated below.

See final Issue Recommended Solution for full details to include in letter

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☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 III-007 Title: Reduced Minimum Temperatures for Mechanical Warewashing Equipment

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting the FDA Food Code be revised as follows:

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

See final Issue Recommended Solution for full details to include in letter

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☐ LETTER ☐ CHARGES ☒ **CFP WEB POSTING**

Issue: 2010 III-010 Title: Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail

Recommended Solution:

The Conference recommends approval of the new revised guidance document titled "Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail and Food Service Establishments" and that it be made available to interested stakeholders on CFP's web site.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 III-012 Title: Re-create – Hot Holding Committee

Recommended Solution:

The conference recommends that the Conference send a letter to FDA recommending that the issue of evaporative cooling and its relationship to pathogen growth during hot holding be investigated as a research priority.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 III-013 Title: Bare Hand Contact for RTE Ingredients that are Fully Cooked After Handling

Recommended Solution:

The Conference recommends that the Conference send a letter to FDA requesting that provisions to allow for use of Ready-to-Eat FOOD ingredients from containers that are used exclusively in food products which are subsequently fully cooked or reheated should be added to the Food Code.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 III-015 Title: Temperature of Water for Handwashing Sinks

Recommended Solution:

The Conference recommends that a letter be sent to the FDA recommending changes to the Food Code section 5-202.12 Handwashing Sink, Installation to read as follows:

5-202.12 Handwashing Sink, Installation.

(A) A handwashing sink shall be equipped to provide warm water at a temperature of 85oF (29.5oC) or above through a mixing valve or combination faucet.

☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING

Issue: 2010 III-016 Title: Sequential Application of Hand Antiseptic for Use in No-Water Situations

Recommended Solution:

The Conference recommends that a committee be formed to include appropriate stakeholders including Center for Food Safety and Applied Nutrition (CFSAN), CDC and Center for Drug Evaluation and Research (CDER) to address:

- the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses
- identify settings where alternatives to handwashing are appropriate. and
- report back to the 2012 Conference.

☐ LETTER ☒ **CHARGES** ☐ CFP WEB POSTING

Issue: 2010 III-018 Title: Updating ROP Criteria with regard to Cook Chill and Sous Vide

Recommended Solution:

The Conference recommends the formation of a new committee charged with the following:

- create a guidance document detailing the scientific evidence of ROP HACCP controls and preventive measures and provide implementation suggestions.
- recommend clarifications to the Food Code based on charge one.
- report back to the Conference in 2012.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 III-020 Title: 3-302.11 Packaged and Unpackaged Food – Separation

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting that Section 3-302.11 have (A)(1)(d) added as follows:

> 3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.
> (d) *Packaged raw Ground beef may be stored or displayed with or above other cuts of packaged raw beef*

and Annex 3 (Public Health Reasons/Administrative Guidelines) be amended.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 III-022 Title: Antimicrobial Treatments for Washing Fruits and Vegetables

Recommended Solution:

The Conference recommends that a letter be sent to the FDA recommending the following changes to the Food Code: Annex 3 §3-302.15 Washing Fruits and Vegetables.

See final Issue Recommended Solution for full details to include in letter

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☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 III-023 Title: Food Establishment Response Procedure to Vomiting and Diarrheal Contamination

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting modification of the 2009 Food Code to require that food establishments have access to a plan for responding to unexpected events that result in the discharge of vomitus or feces in any area other than a toilet.

☒ **LETTER** ☐ CHARGES ☐ CFP WEB POSTING

Issue: 2010 III-024 Title: Drying Agents

Recommended Solution:

The Conference recommends that a letter be sent to the FDA recommending the following changes to the Food Code,

> 7-204.14 Drying Agents, Criteria
> ***See final Issue Recommended Solution for full details to include in letter***

☐ LETTER ☐ CHARGES ☐ CFP WEB POSTING ☒ **OTHER**

DELEGATE ACTION: rejected

Issue: 2010 I-005 Title: Consumer Advisory for pinned/injected/tenderized meats: Food Code 3-603.11

Recommended Solution:

The Conference recommends no action.

Reason:

Food establishment operators may not be aware of what products have been tenderized because there is no requirement for labeling.

Issue Review Checklist – for Committee Submitted Issues

for the 2012 CFP Biennial Meeting

NOTE: a separate and less extensive checklist exists for independent (non-committee) issues

Timeline

November 2011

- ☐ Issue submission template and instructions available online by end of month

Friday, December 5, 2011

- ☐ **Deadline** for CFP committee chairs to submit final committee reports along with ALL prospective Issues and accompanying documents to their Council Chair for **preliminary review and approval**
  - **ALL CFP committee generated documents** MUST go through a formal **review** process PRIOR to online submittal; documents needing review include committee reports, Issues, and all attachments (see process and "Review Checklist" below)
  - Once approved by Council Chairs, all Issues and attachments MUST then be submitted via the online process prior to the posted deadline
  - **STANDING COMMITTEES:**
    - All Standing Committee reports and prospective Issues and accompanying documents are to be submitted to the Executive Director for review and approval.
    - For Standing Committee reports and Issues, the Executive Director will fulfill the same review functions as the Council Chair

Friday, January 6, 2012

- ☐ **Deadline for online Issue submittal** is 9:00 PM EST – this deadline applies to ALL Issues including CFP committee submitted Issues and independently submitted Issues
  - Once submitted online, the Issue Committee will conduct a final review and work with submitters and Council Chairs to clarify any questions or concerns
- ☐ Submittal of Issues in advance of the deadline is highly encouraged
- ☐ The only Issues that can be submitted AFTER the deadline must meet the *"Late Issue Submittal Policy"* *http://www.foodprotect.org/media/policy/Policy_CFP_Late_Issue_Submission.pdf*

Sunday, March 4, 2012

- ☐ Online Issue packets available

Preliminary Review – PRIOR to Online Submittal

Preliminary Review Process

- ☐ Preliminary Review:
  - All CFP committee generated documents are subject to a formal "offline" preliminary review process – Issues are NOT to be submitted online until the preliminary review has been conducted and approval granted by the respective Council Chair
  - During the preliminary review process, Council Chairs, Council Vice Chairs, and the Issue Chair(s) will serve as reviewers of CFP committee submitted documents
    - Council Chairs will forward documents submitted by the committee chairs to their respective Vice Chair and to the Issue Chair(s)
    - Council Chairs will serve as the primary contact with their respective committee chairs
    - Issue Chair(s) and Council Vice Chairs will forward any comments, questions, or concerns to the Council Chairs

- All reviewers will follow the "Review Checklist" (see below)
- When editing documents, "tracked changes" should be used whenever possible; once document review is complete, all track changes must be accepted or removed before submitting online

☐ Council Chairs will notify via email the Issue Chair(s) when the preliminary review process for each committee is complete and approval has been given for online submittal of Issues and accompanying documents; a copy of the final approved committee documents will be forwarded via email to the Issue Chair(s)

- Committee Issues are NOT to be submitted via the online submittal process until the preliminary review has been completed
  - Final review by the Issue Committee will NOT begin until approval is received from the Council Chair
- Preliminary review process MUST be completed far enough in advance to allow committee chairs to meet the online Issue submittal deadline
- Any changes made to a committee report, document, or Issue after the preliminary review process MUST be approved by the respective Council Chair

REVIEW CHECKLIST

A. SCOPE OF ISSUE

PLEASE NOTE: reviewing the "scope of issue" is the MOST critical aspect of the preliminary review. Limiting the scope AND clearly defining the intent of each Issue will facilitate a logical and sequential deliberation within Council. To facilitate the process, it is recommended to divide issues containing multiple actions or directives; single Issues containing multiple actions or directives are cumbersome to deliberate and may lead to confusing or contradictory recommended solutions. Once the online Issue submittal deadline has passed, the automated process does NOT allow the submittal of additional Issues; therefore, committee reports can NOT be divided into multiple Issues after the deadline has passed.

☐ The majority of CFP committees will submit more than one Issue…

- **First Committee Issue** – essentially a presentation of the committee report. The "Recommended Solution" of the first committee Issue contains **four (4) elements**:
  1. Statement to "acknowledge attached committee report" *(reports are NOT "accepted" or "approved" as this implies the entire content of the report has been debated and agreed upon by Council)*
     - ✓ Reports are to follow the approved Committee FINAL report format and include the following information: *(see Committee FINAL Report template)*
       - full list of committee charges from the previous Biennial Meeting (or as subsequently assigned by the Executive Board)
       - details of committee activities and recommendations
       - specific outcome(s) and disposition(s) for each assigned charge
       - specific direction regarding the future of the committee
       - new or continuation charges to be addressed during the upcoming biennium
       - list of all committee submitted Issues and attachments
       - list of committee members
  2. List of attachments (titles) for ALL committee generated "content documents" *(see description below regarding "content documents" vs. "supporting attachments")*

3. Specific direction regarding the future of the committee, such as:
   - ✓ Committee to be disbanded:
     - all charges previously assigned to committee have been completed
     - disbanded committees may NOT have continuation or new charges
   - ✓ Committee to be re-created, along with specifics regarding:
     - continuation charges (i.e., incomplete or ongoing charges from the previous Biennial Meeting)
     - requirement to "report back to the next Biennial Meeting"

   NOTE: newly created charges (not carried over from the previous Biennial Meeting) that the committee would like to address during the next biennium are best included in a subsequent stand-alone Issue, especially if it is anticipated that requesting the new charge(s) will result in debate within Council
   NOTE: if a decision to re-create a committee with continuation charges is dependent on the outcome of a subsequent Issue, the continuation charges and the report back requirement should be included in a subsequent stand-alone Issue and not included within the first committee Issue
   NOTE: standing committee final reports are required to be submitted as an Issue ONLY when council action is required (e.g., to approve or modify a CFP governing document or policy). By the designated deadline, all Standing Committees are required to submit their final committee report, prospective Issue(s), and any accompanying documents to the Executive Director for review and approval.
   NOTE: except for standing committees that report directly to the Executive Board, all CFP committees must be either disbanded or re-created each biennium
4. Thank you statement to committee members

- **Subsequent Committee Issue(s)** – the actual number or subsequent committee Issues will depend on the work completed by a committee. Committee generated documents, or specific elements of a committee report that need to be formally debated and approved, are to be submitted as subsequent stand-alone Issues; examples include:
  - Policy or guidance documents created by the committee
    - ✓ It is recommended that a separate Issue is submitted for each independent document
      EXCEPTION: large documents divided to meet attachment size restrictions should be presented within a single Issue
  - Committee recommendations regarding controversial or substantial changes to policy or practice
    EXCEPTION: non-substantive changes can be presented together as a single Issue (e.g., grammatical or editorial changes to existing approved documents)
  - New charges assigned to a re-created committee
    NOTE: the actual number of subsequent Issues submitted by a committee should be determined on a case-by-case basis depending on the complexity of the information to be presented; the Issue Chair(s) and Council Chairs can assist committee chairs in determining the best approach in submitting committee Issues.

B. CONTENT REVIEW – ISSUE and ATTACHMENTS

The goals of content review are to increase readability and understanding, and to minimize confusion during Council deliberation.

☐ General review includes…

- Verification that all sections of the Issue submission form are complete
- Spelling and grammar

- Content and clarity
- Document titles are in quotes or italics
- Narrative is gender non-specific
- Correct capitalization (e.g., committee names, Issue titles)
- Multiple page documents contain page numbers *("page __ of __" is the preferred format)*
- Correct use of organizational terminology and titles (e.g., "Conference," "Biennial Meeting," "Food Code" or "FDA Food Code")
- Correct use of strikethrough/underline format for changes to existing CFP documents, FDA Food Code, or other regulatory documents (i.e., underlining of "new or proposed" language with ~~"strikethrough"~~ for language to be deleted)
- Adherence to *"CFP Commercialism Policy" (i.e.,* Issues may NOT be commercial in nature) *http://www.foodprotect.org/media/policy/Policy_CFP_Commercialism.pdf*

☐ Issue Title…

- Limited to 75 characters
- Title uniquely describes purpose of Issue
  NOTE: Issue titles may be modified by the Issue Chair for clarification in the event of duplicate submittals
- Use of standardized "prefix" for CFP committee submitted Issue titles:
  - Report – _____ (insert committee name)
  - Re-Create – _____ (insert committee name)
  - Report and Re-Create – _____ (insert committee name)
    NOTE: this dual format is rarely used; see Issue Chair(s) for guidance

☐ Issue Description…

- Briefly describes the problem or concern to the retail food industry

☐ Public Health Significance…

- Describes impact this Issue will have on the industry
- Clearly stated and easily understood

☐ Recommended Solution…

> *NOTE: the "recommended solution" is the ONLY portion of the Issue that will appear in the Conference Proceedings; therefore, it needs to be as complete and as clearly written as possible.*

- Rationale of recommended solution must be sufficiently detailed to cover all aspects of the submission
- All recommendations made by a CFP committee must be extracted from the committee report and captured within the recommended solution section of the Issue submittal form
- Lists the exact titles of any subsequent committee Issue(s) and attachments *(recommend using a "cut-and-paste" of the title directly from the committee report)*
- When edits or modifications are proposed for an existing document (e.g., CFP governing document, FDA Food Code, other regulatory document), relevant sections are to be "cut-and-pasted" into the recommended solution using strikethrough/ underline format

- Acronyms must be spelled out when the term is first used
  EXCEPTIONS: FDA, USDA, CDC, EPA, CFP
- Any new or continuation charges assigned to a committee must be included within the recommended solution along with a requirement to "report back to the next Biennial Meeting"
- Direction(s) MUST be given to CFP regarding final disposition of the Issue, such as:
  - "a letter be sent to the FDA requesting…"
  - "modified language be incorporated into…"
  - "final guidelines to be posted on the CFP web site"
  - "a committee be created to study…"

☐ Attachments…

- There are two (2) different kinds of attachments:
  1. **"Content Documents"** – this is the body of work created by a committee that MUST be reviewed and approved via the Council deliberation process (e.g., guidelines, policy documents, suggested revisions to existing documents and regulatory codes)
     - ✓ Content documents should be "attached" only once to the first committee Issue along with the committee report
       - In subsequent committee Issues, the attachment should be referenced by the exact name of the attachment and the name of the Issue where the attachment can be found (for example: "See *Report – ABC Committee*, Attachment #1, titled: *XYZ"*)
  2. **"Supporting Attachment"** – this is information presented ONLY to assist in understanding the specific Issue (e.g., abstracts, articles, studies, reference material)
     - ✓ Large documents posted online (e.g., Food Code) are to be referenced only by the web address along with a notation of the specific page and/or section numbers; large publicly available documents are NOT to be attached in their entirety
- Attachment format:
  - All attachments MUST be in a format compatible with MS Word (.doc), as a PDF (portable document format)… or as a web address for existing documents
    - ✓ Content Attachments submitted as a PDF must be made available by the submitter in advance to the Council Scribe in a format compatible with MS Word (.doc) to facilitate editing during Council deliberations
  - Attachments should use a header or footer that includes both the document title and page numbers *("page __ of __" is the preferred format)*
  - Name of each attachment must be specific AND consistently referenced throughout all material submitted by the committee
  - Attachments over 2 megabytes (2 MB) must be divided into multiple smaller documents in a logical sequence
  - All Macros are to be removed from attached documents
- Council Chairs will work with committee chairs and the Issue Chair(s) to determine the best format and method of attaching documents to their Issues

- ☐ Submitter name…
  - CFP committee chair(s) is to be listed as the "submitter" (e.g., Jane Doe, Chair)
  - CFP committee name is to be listed as the "organization" (e.g., ABC Committee)

FINAL REVIEW – AFTER ONLINE SUBMITTAL

FINAL REVIEW PROCESS

- ☐ All CFP committee Issues MUST be approved by the respective Council Chair through the preliminary review process PRIOR to online submittal (see above)
- ☐ Once submitted online, the final review process for that Issue begins:
  - During the final review, the Issue Committee will serve as the primary contact with all Issue submitters via the online review process
  - CFP committee submitted Issues will be forwarded by the Issue Committee to Council Chairs for final review and approval via the online review process
- ☐ Revisions to an Issue after the submittal deadline will be limited to those requested by the Issue reviewers
  - Via the online Issue Management web site, the Issue submitter will receive edits and comments from the reviewers; the submitter can either:
    - "accept" the Issue (indicating it is ready for finalization)
    - submit another round of revisions (this part of the review process can go back-and-forth as many times as necessary until an Issue is ready to be finalized), or
    - "withdraw" the issue
- ☐ Once accepted and finalized, an Issue can no longer be edited until it is deliberated in Council.

FINAL REVIEW CHECKLIST

- ☐ Verify Council Chair approval of CFP committee submitted Issues
  - Any changes made to a committee report after the preliminary review process MUST be approved by the respective Council Chair
- ☐ Ensure that the final Issue meets CFP's Issue Acceptance *"Terms and Conditions"* as posted on the CFP web site
- ☐ Review all Issues and attachments using "Review Checklist" (noted above)
- ☐ Verify documents referenced in an Issue or in a committee report:
  - All attachments listed or referenced are actually "attached" to the appropriate Issue
  - All relevant attachment pages are included
  - All attached documents readily print and are in a readable format
  - All web address links are correct
- ☐ Issue Committee will conduct a final edit to standardize content of all Issues, for example:
  - Re-name multiple Issues with similar titles

- Ensure submitter's name and information follows a standardized format
  NOTE: the submitter's employer contact information is to be entered in the "submitter information" section at the bottom of the submittal form; it is NOT entered under "submitter name" at the top of the form
- Remove redundant or auto-generated wording from final Issue, for example:
  - Recommended Solution… deletion of the words "The Conference Recommends..." from the final submittal as this wording will be auto-generated in the final Issue packet

☐ Submitter will be notified via email when Issue has been accepted and finalized

Armatis	David	Industry -	Safe Foods First	135 Townsend Street, Suite 617	San Francisco CA		94107	(650) 274-8573	travelingchef@hotmail.com	
Bacon	Brenda	Industry - Retail Food Stores	Harris Tetter	701 Crestdale Road	Matthews	NC	28105	(704) 844-4443	bbacon@harristeeter.com	Council-I Vice Chair
Bhatt	Chirag	Industry	CHB Consulting	POBOX 680932	Houston	TX	77268	(281) 684-6883	chiragbhattTX@gmail.com	Council-II Chair
Casazza	Gene	Other - Restaurant Association	Jetro/Restaurant Depot	133-11 20th Avenue	College Point	NY	11356	(718) 412-4517	gcasazza@jetrord.com	
Cornman	Lee M.	Regulatory - State	Florida Dept of Agriculture and Consumer Services/Food Safety Division	3125 Conner Boulevard, MS C-18	Tallahassee	FL	32399-1650	(850) 245-5547	lee.cornman@freshfromflorida.com	
Elizondo	Marcel	Regulatory - Local	Austin/Travis Co Health and Human Services	15 Waller St	Austin	TX	78702	(512) 974-8068	marcel.elizondo@ci.austin.tx.us	
Everly	Vicki	Regulatory - Local	Santa Clara County Dept. of Environmental Health - Retired		San Jose	CA		(510) 501-0417	vicki.everly2@gmail.com	C'ee Co-Chair
Gaither	Marlene	Regulatory - Local	Coconino County (AZ) Health Department	2500 N. Fort Valley Road	Flagstaff	AZ	86001	(928) 527-8520	mgaither@coconino.az.gov	
Gifford	David	Regulatory - State	Washington State Dept. of Health							Council-III Vice Chair
Guzzle	Patrick	Regulatory - State	Idaho Department of Health and Welfare	450 West State Street, 4th Floor	Boise	ID	83720	(208) 334-5938	guzzlep@dhw.idaho.gov	Council-II Vice Chair
Hale	Aggie	Regulatory - State	Florida Dept. of Agriculture and Consumer Services	3125 Conner Boulevard, MS C-26	Tallahassee	FL	32399-1650	(850) 245-5549	aggie.hale@freshfromflorida.com	C'ee Co-Chair
Harris	Craig K.	Academia	Michigan State University	4564 Nakoma	Okemos	MI	48864	(517) 256-2234	harrisc@msu.edu	
Hazan	Stan	Other - Standards and Compliance	NSF International	789 Dixboro Road	Ann Arbor	MI	48105	(734) 769-5105	hazan@nsf.org	
Lewis	Glenda	Regulatory - Federal	Leader, Retail Food Protection Team	5100 Paint Branch Parkway	College Park	MD	20740	240-402-2150	glenda.lewis@fda.hhs.gov	
Linton	Richard	Academia	The Ohio State University	2015 Fyffe Rd.	Columbus	OH	43210	(614) 247 7881	linton.60@osu.edu	Council-III Chair
Marlow	Deborah	Regulatory - Local	Williamson County (TX) & Cities Health District	303 Main Street	Georgetown	TX	78626	(512) 943-3620	dmarlow@wcchd.org	Council-I Chair
Martin	Eric D.	Industry - Food Service	Margaritaville Enterprises, Inc.	6800 Lakewood Plaza Drive	Orlando	FL	32819	(407) 224-3216	emartin@margaritaville.com	

Committee Name:										
Moore	Eric	Industry - Food Service	Aramark	1717 Arch St.	Philadelphia	PA	19103	(215) 409-7343	moore-eric2@aramark.com	
Odom	Alan	Industry - Food Service	Compass Group	310 West Church St.	Benton	IL	62812	(618) 439-9753	alan.odom@compass-usa.com	
Patnoad	Martha	Academia	University of Rhode Island/Nutrition & Food Sciences	106 Ranger Hall, URI	Kingston	RI	02881	(401) 874-2960	mpatnoad@uri.edu	
Reid	Karen	Industry - Food Service	Walt Disney Parks and Resorts US	PO Box 10000,	Lake Buena Vista	FL	32830-1000	407-827-6971	karen.reid@disney.com	
Reinhard	Robert	Industry - Food Processing	Sara Lee Corporation	3500 Lacey Road	Downers Grove	IL	60515	(630) 598-8058	bob.reinhard@saralee.com	
Rosenwinkel	Kenneth	Industry - Retail Food Stores	Jewel-Osco/Supervalu	150 Pierce Road, Suite 200	Itasca	IL	60143	(630) 948-6787	ken.rosenwinkel@supervalu.com	
Sandford	Mary	Industry - Food Service	Burger King Corporation	5505 Blue Lagoon Drive	Miami	FL	33126	(305) 378-7917	msandford@whopper.com	
Starobin	Dr. Anna	Other - Sanitation Services	Ecolab	8300 Capital Drive	Greensboro	NC	27409	(336) 931-2185	anna.starobin@ecolab.com	
Weddig	Lisa	Industry - Food Processing	Better Seafood Board	7918 Jones Branch Dr., Suite 700	McLean	VA	22102	(703) 752-8886	lweddig@nfi.org	
Whiteside	Jayne	Other - Medical Services	Coastal Dialysis	55 Congress Avenue	Bath	ME	04530	(207) 443-7485	jelizwhiteside@yahoo.com	
Williams	Dee	Industry - Food Service	Jack in the Box Inc.	9330 Balboa Aevnue	San Diego	CA	92123	(858) 571-2550	dee.williams@jackinthebox.com	
Wright	Lisa	Other - CFP Administration	Conference for Food Protection	11080 Tondino Road	San Diego	CA	92131	(858) 536-8030	ewright1@san.rr.com	

Conference for Food Protection
2012 Issue Committee FINAL Report

COMMITTEE NAME: Issue Committee
COUNCIL: Standing Committee – Council II
DATE OF REPORT: December 28, 2011
SUBMITTED BY: Aggie Hale and Vicki Everly, Issue Co-Chairs

COMMITTEE CHARGE(s):

Constitutional Charge

Article XV Duties of the Committees

Section 1. The Issue Committee shall review all Issues submitted at least ninety (90) days before the Conference meeting. The Issue Committee shall assign for Council deliberation those Issues that have met the Issue acceptance criteria specified in the Conference Procedures Manual. Issue assignments shall be made in accordance with Article XIII, Section 1, Subsection 1; Section 2, Subsection 1; and Section 3, Subsection 1.

Charges Established by Issue

Issue 2010 II-30 "Expand Archive and Posting Capabilities of CFP Approved Documents"

The Conference recommends expanding capabilities for archiving and posting documents on the Conference web site, and charging the Issue Committee with the development of a process and procedure to ensure posting of all:

1. Documents and attachments modified or edited after the Issue packets are made available with reference to the original Issue number and attachment titles;
2. Documents and attachments modified during and after Council deliberations at the Biennial Meetings; and
3. Final version of conference approved guides, documents, and presentations in both PDF and the original editable format.

Charges Established by Executive Board

1. Clarify concerns regarding "final" committee reports, Issues, and attachments, including;
   a) Requirements for content and format.
   b) Instructions regarding the process for review and online submittal.
   c) Clarification of roles of Council Chair and Issue Chair in final approval.
   d) Clarification of when Standing Committee final reports need to be submitted as an Issue.
2. Revise, modify, or clarify Issue submittal criteria and review tools, including:
   a) Issue "rejection" process and procedure, including roles and responsibilities for committee-submitted documents and "independent" submittals.
   b) *CFP Commercialism Policy* as it relates to Issue "attachments" (e.g., peer reviewed articles, industry sponsored studies, letters of recommendation, presentations).
   c) Appropriate location of Issue "endorsements" (i.e., by an organization, agency, or individual) within the Issue submittal documentation.
   d) Final Issue submittal deadline (current deadline of 11:59 PM EST requires East Coast Council Chairs to be on "stand-by" until midnight).
3. Clarify concerns regarding "content attachments" (i.e., attachments reviewed and approved by council) that become Conference developed guides and documents, including:
   a) The review and approval process prior to Issue submission.
   b) Development of a "masthead, flag, nameplate, or style guide" to readily identify approved and posted documents as belonging to the Conference.
   c) Archive and posting of documents revised after Issue submittal (currently, the only version routinely archived is the original document attached to the submitted Issue even when the document is revised in council). (see "charges established by Issue" above)
4. Review and update CFP governing documents and position descriptions regarding the Issue process and responsibilities, including:
   a) Procedures and responsibilities for each biennium.
   b) Tools to facilitate tracking of charges to aid in review of committee reports and attachments.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS (with completion date noted):

1. *May 2010* – Developed a tool to facilitate tracking of committee charges between biennial meetings (see attached documents for each Council titled "*2010 Final Issue Recommendations with Actions*"); documents provided to Executive Director and Conference Chair in May 2010 and to the Executive Board in August 2010.

2. *July 2010* – In conjunction with the Executive Director, established Issue related deadline dates for the 2012 Biennial Meeting:
   - November 2011 – Issue Pre-Submission Form available online
   - Friday, December 5, 2011 – deadline for Committee Reports and prospective Issues to be submitted to Council Chairs for review
   - Friday, January 6, 2012 – Issue submission deadline (constitutionally mandated not less than 90 days before Biennial Meeting)
   - February 17, 2012 – Issue Committee deadline to finalize Council assignments
   - March 4, 2012 – Issue Packets made available by Director (constitutionally mandated at 40 days before Biennial Meeting)

3. *August 2011* – Received approval from Executive Board for a change in the final Issue submittal deadline time to 9:00 PM EST (previously set at 11:59 PM EST).

4. *August 2011* – Received approval from Executive Board for a modified review checklist to assist Council Chairs and the Issue Committee in the review of final committee reports and draft Issues (see attached document titled *"Committee Submitted Issues – Review Process and Checklist"*).
   - This comprehensive document was subsequently shortened into a separate checklist for independent (non-committee) submitted Issues by removing details specific to CFP committees; both checklists are available on the CFP web site as PDFs to assist Issue submitters.

5. *August 2011* – Executive Board approved language to clarify the appropriate location within an Issue for inclusion of "endorsements" (i.e., by an organization, agency, or individual). The following approved language was placed on the Issue submission web site for the 2012 Biennial Meeting:
   - *Endorsements of an Issue by an organization, agency, or individual are to be placed in the Issue Submission Form section titled "Issue you would like the Conference to Consider" or "Public Health Significance"; endorsements are not to be placed within the "Recommended Solution." Endorsement letters or copies of email communication may be submitted with an Issue as a supporting attachment.*

6. *August 2011* – Drafted modified language for Conference Procedures, Section IV, Conference Issues; language reviewed and approved by the Conference Executive Board at their August 2010 meeting and is presented at the 2012 Biennial Meeting as an Issue titled *"Procedures for Conference Issues – New Wording"* (all new wording underlined; there is no deleted language).

   a) Clarification of the requirement for the submittal of **Standing Committee** final reports and Issues.
   Conference Procedures, Section IV, Conference Issues:
   A. Issue Submission
      1. *The Executive Board shall approve an Issue Submission Form.*
      2. *Within the time specified in the Constitution and Bylaws, the Issue Submission Form shall be made available to Conference members and to other interested parties by 150 days prior to the Biennial Meeting.*
      3. *Issue submissions shall be made electronically through the internet. Issues may be submitted to the Executive Board only in the event of a late-breaking food safety Issue. Current instructions for submission and the form are available through the internet on the Conference web site or from the Executive Director.*
         a. *For the purpose of this Section a late-breaking food safety Issue is defined as an Issue that specifically relates to an event, practice or circumstance creating a situation requiring the immediate attention of the Conference that has occurred between the deadline of the Conference Issue submission deadline and the Biennial meeting.*
      4. *The deadline for Issues and their attachments is the date specified in the Constitution and Bylaws.*
         a. *Standing committee final reports are required to be submitted as an Issue ONLY when council action is required (e.g., to approve or modify a CFP governing document or policy). By the designated deadline, all Standing Committees are required to submit their final committee report, prospective Issue(s), and any accompanying documents to the Executive Director for review and approval.*

   b) Clarification of **Issue Acceptance Criteria** and the **Issue Rejection Process**:
   Conference Procedures, Section IV, Conference Issues:
   B. Issue Acceptance Criteria
      1. *In order for the Issue to be accepted by the Conference and considered for Council deliberation, all sections of the form must be completed. The Issue must be described completely, with its impact on retail distribution identified. The food protection or public health aspect of the Issue must be clearly stated to be easily understood. A suggested solution or rationale for the Issue must be sufficiently detailed to cover all aspects of the submission.*
         a. *Prior to finalization, all Issues are to be in a "finished form" (e.g., no annotations or unaccepted edits, all attachments present and complete). Issues that are not in this format may be rejected if the submitter*

fails to make requested revisions. Documents containing "track changes" or comments from reviewers cannot be accepted because they are, by definition, unfinished and incomplete; the Council will not know what wording to act upon.

b. *Issues will NOT be rejected based on content; the only reason for rejection will be non-compliance with the requirements for Issue acceptance.*

2. *When the recommended solution is to change the wording of a document, such as the Food Code or a Conference document, the portion of the document to be changed must be accurately identified, the change that is requested must be specified (e.g., actual language for replacement, addition, change or deletion), and the recommended language provided.*
3. *A late-breaking food safety Issue submitted after the deadline may be considered for assignment to a Council if it has first been presented to the Conference Executive Board for review and acceptance. The Conference Executive Board shall inform the Issue Committee Chair of its decision to accept or reject any Issue submitted after the Issue deadline.*

E. Issue Rejection Process

1. *All Issues must be received in final form by the deadline date. If an Issue received prior to the deadline date does not meet the criteria set forth in IV. B., the Issue Chair will make a reasonable attempt to contact the submitter with a brief explanation of the problem. Failure of the submitter to correct and/or resubmit the Issue prior to the deadline date will result in rejection of the Issue.*
   a. *Issue Chair will notify submitter in writing that Issue cannot be accepted as currently written and will be rejected if not submitted in a finished form.*
      1) *Notification to include: specific required changes, deadline date, reference to Issue acceptance Criteria, and a recommendation that Issue can be rewritten and referred to a committee if unable to finalize language.*
      2) *If Issue was submitted by a CFP committee, the respective Council Chair will also be notified; the Executive Director will be notified regarding Issues submitted by standing committees.*
      3) *If submitter is non-responsive, he/she will be notified a second time by the Issue Chair that Issue will be rejected if not submitted in a finished form.*
   b. *If no response is forthcoming from the submitter after the second notification, the Issue Chair will notify the Executive Director that the Issue is pending rejection.*
      1) *The Executive Director will evaluate the Issue Chair recommendation for rejection and agree or disagree based on the criteria spelled out in the Conference Procedures for Issue Acceptance; the Executive Director may elect to contact the submitter directly.*
         a) *If the Executive Director agrees with the Issue Chair decision to reject, he/she will forward the Issue to the Conference Chair and Vice Chair for their review.*
            - *The Conference Chair and/or Vice Chair may elect to contact the submitter directly to determine if he/she is willing to bring the Issue into compliance; thus, the submitter may have one last chance.*
            - *If the Conference Chair or Vice Chair do NOT choose to contact the submitter, the Issue will be rejected.*
            - *If the Conference Chair and Vice Chair disagree as to whether the Issue should be rejected, the matter will be referred to the Executive Board for resolution.*
         b) *If the Executive Director disagrees with the Issue Chair and determines the Issue (as written) meets the Issue acceptance requirements, he/she will send the Issue back to the Issue Chair with a written explanation; the Issue Chair may appeal such a finding to the Executive Board.*
2. *At least forty (40) days before the Conference meeting, the submitter of an Issue that does not meet the criteria for acceptance or is not in the jurisdiction of the Conference is notified by the Executive Director with a copy to the Conference Chair and the Issue Chair of the reason(s) why the proposed Issue is not acceptable. A rejected Issue may be considered a "Special Issue" if accepted by the Board and submitted by the Board to the Council at the beginning of the Conference meeting.*

7. *November - December 2011* – Updated instructions within the Issue Management Program (IMP) web site and worked with CFP Executive Assistant to conduct a beta test of the revised site.
8. *December 2011* – Worked with Council Chairs to review all CFP committee final reports, content attachments, and draft issues.
9. *January 2012 thru February 2012* – Completed constitutional charge for review and assignment of all Issues and attachments submitted for the 2012 Biennial Meeting.

REQUESTED ACTION:

The Issue Committee will be submitting two (2) Issues to the 2012 CFP Biennial Meeting:

1. Report – Issue Committee
   - Content attachment title: 2012 Issue Committee Final Report
   - Supporting attachment titles:
     - *Council I 2010 Final Issue Recommendations with Actions*
     - *Council II 2010 Final Issue Recommendations with Actions*
     - *Council III 2010 Final Issue Recommendations with Actions*
     - *Committee Submitted Issues – Review Process and Checklist*
     - *2010-12 Issue Committee Roster*
2. Procedures for Conference Issues – New Wording
   - No attachments to this Issue

The Issue Committee is a standing committee of the Conference for Food Protection and does <u>not</u> need to be re-created; it is, therefore, recommended that the following continuation charges be assigned to the 2012-14 Issue Committee with a requirement to report back at the 2014 Biennial Meeting:

1. Complete the charge from Issue 2010 II-30 to expand archive and posting capabilities of CFP approved documents on the Conference web site and develop a process / procedure to ensure posting of all:
   a. Documents and attachments modified or edited after Issue packets are made available with reference to the original Issue number and attachment titles;
   b. Documents and attachments modified during and after Council deliberations at the Biennial Meetings; and
   c. Final version of conference approved guides, documents, and presentations in both PDF and the original editable format.
2. Work with the Constitution, Bylaws, and Procedures Committee to review, consolidate, and update CFP governing documents, guidelines, and instructions regarding:
   a. Preparation, submission, and presentation of Issues, final committee reports, and Issue attachments.
   b. Roles and responsibilities for each biennium.
3. Review the *CFP Commercialism Policy* as it relates to Issue "attachments" (e.g., peer reviewed articles, industry sponsored studies, letters of recommendation, presentations).
4. Develop a "masthead, flag, nameplate, or style guide" to readily identify approved and posted documents as belonging to the Conference.

COMMITTEE MEMBER ROSTER:

- See attached PDF document titled *2010-12 Issue Committee Roster*.

Conference for Food Protection
2012 Issue Form

Internal Number: 027
Issue: 2012 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.

Title:
Procedures for Conference Issues - New Wording

Issue you would like the Conference to consider:
The Issue Committee seeks approval of language within the Conference Procedures to further clarify the Issue submission, acceptance, and rejection process.

Public Health Significance:
Clarification and improvement of the CFP Issue process will ensure that concerns brought forward from all stakeholders are given an equal opportunity for consideration and final approval.

Recommended Solution: The Conference recommends...:
adoption of the following new language in the Conference Procedures, Section IV, Conference Issues: (new wording underlined; there is no deleted language):
(NOTE: only relevant sections are included below... please refer to the full Conference Procedures document available at www.foodprotect.org)

A. Issue Submission

4. The deadline for Issues and their attachments is the date specified in the Constitution and Bylaws.

a. Standing committee final reports are required to be submitted as an Issue ONLY when council action is required (e.g., to approve or modify a CFP governing document or policy). By the designated deadline, all Standing Committees are required to submit their final committee report, prospective Issue(s), and any accompanying documents to the Executive Director for review and approval.

B. Issue Acceptance Criteria

1. In order for the Issue to be accepted by the Conference and considered for Council deliberation, all sections of the form must be completed. The Issue must be described completely, with its impact on retail distribution identified. The food protection or public health aspect of the Issue must be clearly stated to be easily understood. A suggested solution or rationale for the Issue must be sufficiently detailed to cover all aspects of the submission.

a. Prior to finalization, all Issues are to be in a "finished form" (e.g., no annotations or unaccepted edits, all attachments present and complete). Issues that are not in this format

may be rejected if the submitter fails to make requested revisions. Documents containing "track changes" or comments from reviewers cannot be accepted because they are, by definition, unfinished and incomplete; the Council will not know what wording to act upon.

b. Issues will NOT be rejected based on content; the only reason for rejection will be non-compliance with the requirements for Issue acceptance.

E. Issue Rejection Process

1. All Issues must be received in final form by the deadline date. If an Issue received prior to the deadline date does not meet the criteria set forth in IV. B., the Issue Chair will make a reasonable attempt to contact the submitter with a brief explanation of the problem. Failure of the submitter to correct and/or resubmit the Issue prior to the deadline date will result in rejection of the Issue.

a. Issue Chair will notify submitter in writing that Issue cannot be accepted as currently written and will be rejected if not submitted in a finished form.

1) Notification to include: specific required changes, deadline date, reference to Issue acceptance Criteria, and a recommendation that Issue can be rewritten and referred to a committee if unable to finalize language.

2) If Issue was submitted by a CFP committee, the respective Council Chair will also be notified; the Executive Director will be notified regarding Issues submitted by standing committees.

3) If submitter is non-responsive, he/she will be notified a second time by the Issue Chair that Issue will be rejected if not submitted in a finished form.

b. If no response is forthcoming from the submitter after the second notification, the Issue Chair will notify the Executive Director that the Issue is pending rejection.

1) The Executive Director will evaluate the Issue Chair recommendation for rejection and agree or disagree based on the criteria spelled out in the Conference Procedures for Issue Acceptance; the Executive Director may elect to contact the submitter directly.

a) If the Executive Director agrees with the Issue Chair decision to reject, he/she will forward the Issue to the Conference Chair and Vice Chair for their review.

- The Conference Chair and/or Vice Chair may elect to contact the submitter directly to determine if he/she is willing to bring the Issue into compliance; thus, the submitter may have one last chance.
- If the Conference Chair or Vice Chair do NOT choose to contact the submitter, the Issue will be rejected.
- If the Conference Chair and Vice Chair disagree as to whether the Issue should be rejected, the matter will be referred to the Executive Board for resolution.

b) If the Executive Director disagrees with the Issue Chair and determines the Issue (as written) meets the Issue acceptance requirements, he/she will send the Issue back to the Issue Chair with a written explanation; the Issue Chair may appeal such a finding to the Executive Board.

2. At least forty (40) days before the Conference meeting, the submitter of an Issue that does not meet the criteria for acceptance or is not in the jurisdiction of the Conference is notified by the Executive Director with a copy to the Conference Chair and the Issue Chair of the reason(s) why the proposed Issue is not acceptable. A rejected Issue may be considered a "Special Issue" if accepted by the Board and submitted by the Board to the Council at the beginning of the Conference meeting.

Submitter Information:

Name: Aggie Hale, Issue Co-Chair
Organization: Issue Committee
Address: FL Dept. of Agriculture3125 Conner Boulevard, MS C-26
City/State/Zip: Tallahassee, FL 32399-1650
Telephone: (850) 245-5549 Fax:
E-mail: aggie.hale@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
2012 Issue Form

Internal Number: 036
Issue: 2012 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.

Title:
Report- Interdisciplinary Foodborne Illness Training Committee

Issue you would like the Conference to consider:
The Conference for Food Protection (CFP) Interdisciplinary Foodborne Illness Training Committee (IFITC) seeks Council II's
1. Acknowledgement of its final committee report.
2. Thanking committee members for their work.

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 professionals in outbreak response can mitigate the effects of an outbreak.
Many states indicate utilizing some form of foodborne epi education programs, but there is great variability in training offerings. Training programs in outbreak investigation should have some consistency and a minimal level of proficiency to ensure rapid response and communication, amongst investigating parties.
The mere existence of programs does not guarantee efficacy of the training. Accreditation or voluntary standards can provide a level of quality assurance and/or consistency amongst foodborne illness training programs to ensure that professionals are comfortably prepared to investigate outbreaks, institute proper control measures, and correspond appropriately amongst the many other parties and jurisdictions involved.

Recommended Solution: The Conference recommends...:
to acknowledge the report and to thank the committee for its work.

Submitter Information:

Name: Anna Starobin, MD, CP-FS Co-Chair
Organization: Interdisciplinary Foodborne Illness Training Committee
Address: Ecolab8300 Capital Dr.
City/State/Zip: Greensboro, NC 27409
Telephone: 336 931 2185 Fax: 336 668 0744
E-mail: anna.starobin@ecolab.com

Attachments:

- "Interdisciplinary Foodborne Illness Training Committee Report"
- "Attachment A IFITC IFPTI Courses"
- "Attachment B IFITC CIFOR Courses"
- "Attachment C 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

COMMITTEE NAME: Interdisciplinary Foodborne Illness Training Committee

COUNCIL: II

DATE OF REPORT: 12/28/11

SUBMITTED BY: Anna Starobin, Co-Chair
Michéle Samarya-Timm, Co-Chair

COMMITTEE CHARGE(s):

1. Continue to track the progress of prominent disease training programs currently in development; and
2. Report back to the 2012 Biennial Meeting of the Conference for Food Protection.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

- The Interdisciplinary Foodborne Illness Training Committee (IFITC) created a regular schedule of monthly conference calls to accomplish the committee charges.
- Programs were identified and tracked (see IFITC Attachment A IFITC IFPTI Courses and Attachment B IFITC CIFOR Courses. A significant amount of time was spent clarifying the committee charge and ensuring the work being done stayed within these parameters.
- IFITC defined “prominent disease training programs” as accessible foodborne illness prevention/response education opportunities, of any length, offered at the state or national level.

The IFITC challenged members with the following action items:

1. Identify educational opportunities (trainings, courses, etc.) relevant to the committee charge.
2. Catalogue and compare existing foodborne illness training programs
3. Identify the target audience for existing foodborne illness training programs

IFITC identified The International Food Protection Training Institute (IFPTI) (www.IFPTI.org) as having a growing database of epidemiology–based trainings for foodborne disease response. IFITC sifted through IFPTI's course catalogue, and charted all entries that meet the definition of prominent disease training programs.

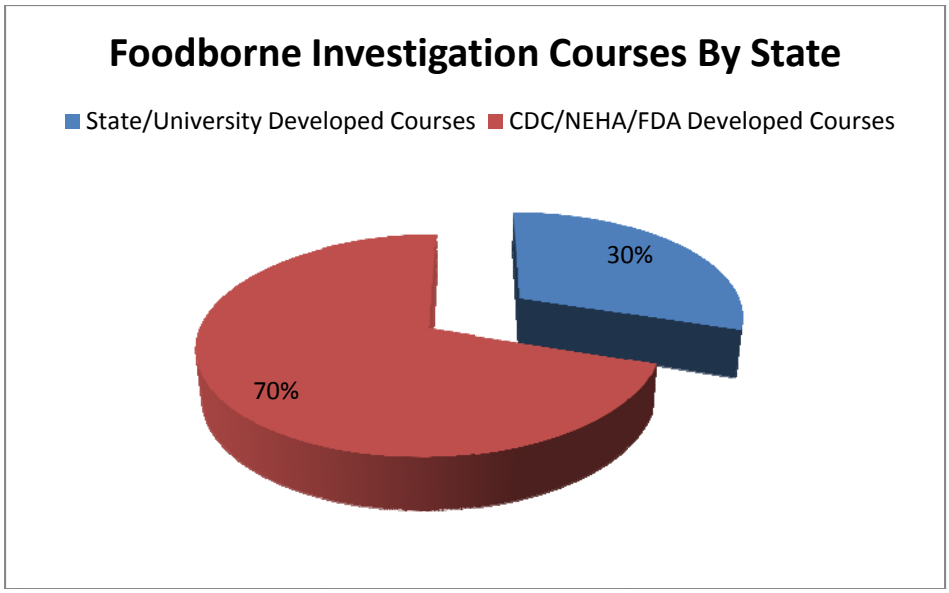
Individual states were contacted for information regarding their use of foodborne disease training programs. States which are using non-mainstream training programs were asked to describe the courses they use. Most of the states' training programs are not open to the public or are only available to a limited audience so they are not considered to meet this committee's definition of prominent courses.

IFITC also identified similar work by the Council to Improve Foodborne Outbreak Response (CIFOR). Prominent disease training programs from CIFOR's assessment were charted for reference.

Findings:

1. Nationally available training programs
   35 states (AK, AR, AZ, CA, CO, DE, FL, HI, ID, IL, IN, KY, LA, ME, MN, MS, MT, NC, ND, NE, NH, NJ, NV, OH, OK, PA, SC, SD, TN, TX, UT, VA, WA, WI, WY) utilize one or more of the following Foodborne Disease Investigation Training resources:
   - FDA ORA-U Foodborne Illness Investigations class
   - CDC/NEHA's Epi-Ready Foodborne Illness Response Strategies Team Training

2. State developed training programs
   15 states (AL, CT, GA, IA, KS, MA, MD, MI, MO, NM, NY, OR, RI, VA, WV) have developed state specific training materials independently or in conjunction with a University.



- IFITC created a chart identifying course parameters, cost, credits, applicability, etc. This information is in two attachments to this report.

Committee Recommendations:

1. To re-create the IFITC to continue to track the progress of prominent disease training program currently developed, identify essential educational content of foodborne disease outbreak training programs; establish evaluating and ranking criteria for identified courses; identify any gaps in foodborne disease outbreak training; consider if levels of foodborne disease outbreak training/retraining are needed;
2. Report back to the 2014 Biennial Meeting of the Conference for Food Protection.

COMMITTEE SUBMITTED ISSUES AND ATTACHMENTS:

- Issue # 1The Interdisciplinary Foodborne Illness Training Committee Final Report
- Issue # 2 Re-create the Interdisciplinary Foodborne Illness Training Committee
- Attachment A IFITC IFPTI Courses
- Attachment B IFITC CIFOR Courses
- Attachment C 2010-2012 Interdisciplinary Foodborne Illness Committee Roster

IFITC IFPTI Courses

Program Title	Course ID	IFPTI #	Publisher/ Agency	Format and Duration	Target Audience	Charge for The Program	Type of CEUs offered
Produce Farm Investigations	ER321	7.6.0002	FDA ORA-U	Classroom, field instruction	Inspectors and investigators	not listed	1.8 CEU
Epi-Ready for Response Teams	ER324	7.6.0003	FDA ORA-U	Classroom	FDA and State RRT team	not listed	1.8 CEU
Foodborne Illness Investigations	ER325	7.6.0004	FDA ORA-U	Classroom	Sanitarians, Inspectors, Lab, Epi, Nursing	not listed	1.9 CEU
Food & Feed Rapid Response Training	ER422	7.6.0008	FDA ORA-U	Workshop	FDA and State RRT team	not listed	not listed
Surveillance Investigations and Enforcement Methods	not listed	7.6.0277	U.S. Department of Agriculture	not listed	not listed	not listed	not listed
Enforcement, Investigations and Analysis	not listed	7.6.0281	USDA	Classroom	not listed	not listed	not listed
Epi-Ready Team Training	not listed	7.6.0313	NEHA	Classroom	Public and and privet sector health professionals	not listed	not listed

CFP Interdisciplinary Foodborne Illness Training Committee, 2010-2012

IFITC CIFOR Courses

Program Title	Publisher/ Agency	Format and Duration	Target Audience	Charge for The Program	Type of CEUs offered
Conducting Foodborne Illness Investigations	State of Massachusetts	Classroom 2 days on-site	EH, Epi, Lab	No	Unknown
FIRST - Field Investigator Response and Surveillance Training: Building Epi Surge Capacity in Disease Outbreaks	State of Florida	Self-Study on-line and Classroom 1 day on site	EH, Epi, Lab	No	Unknown
Food Emergency Response Investigation Training & Exercise	State of Illinois	Classroom 2 days on-site	EH, Epi, Lab	No	Unknown
Principles of Epidemiology	State of Missouri	Self-Study on-line and Classroom 2 days on-site	EH, Epi, Lab	No	Unknown
Field Epidemiology and outbreak Investigation	Winnebago County Rockford, IL	Classroom 2 days on-site	EH, Epi, Lab	No	Unknown
School Nurses Responding to the Challenges of Foodborne Illness	American Nurses Foundation	Classroom 2 – days on-site	School Nurses	No	Unknown
Epi-Ready	NEHA/CDC	Classroom 2 – days on –site Optional 3rd day – Food Defense and Train the trainer	EH, Epi, Lab, Nurses with team focus	Yes if attending at NEHA conference otherwise no if sponsored by CDC or State Agency	Unknown
Laboratory Investigation of Foodborne Illness	American Public Health Laboratories (APHL)	Classroom 4.5 days	Public Health Laboratorians	No	Unknown
State of Indiana	Environmental Outbreak Investigation	Classroom 2 days on-site	EH, Epi, Lab	No	Unknown
State of Virginia	Outbreak Investigation Training – Foodborne Module	2 days on-site	EH, Epi, Lab	No	Unknown
Food and Drug Administration	Foodborne Illness Investigation FD325	Classroom 2 ½ days on-site	EH, Epi, Lab	No	Unknown

Committee: Interdisciplinary FBI

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Wallace	Susan M.	Member	Academia	Johnson and Wales University	Providence	RI	(401) 598-1706	Susan.Wallace@jwu.edu
Armatis	David	Member	Industry - Food Service	Safe Foods First	San Francisco	CA	(650) 274-8573	travelingchef@hotmail.com
Mohyla	Paulo	Member	Industry - Food Service	McDonald's	Oak Brook	IL	(630) 623-7319	paulo.mohyla@us.mcd.com
Stevens-Grobbelaar	Becky	Member	Industry - Food Service	Yum! Brands, Inc.	Griffin	GA	(770) 228-8319	becky.stevens-grobbelaar@yum.com
Mitchell	Timothy	Member	Industry - Retail Food Stores	Publix Super Markets, Inc.	Lakeland	FL	(863) 688-1188	Tim.Mitchell@publix.com
Nicholson	Gina	Member	Industry - Retail Food Stores	The Kroger Company	Westerville	OH	(614) 898-3413	gina.nicholson@kroger.com
Baker	Rance	Member	Other - Association	National Environmental Health Association	Denver	CO	(303) 756-9090	rbaker@neha.org
Bugden	Elizabeth	Member	Other - Consulting Services	Bugden Solutions, Inc.	Manchester	NH	(603) 625-2606	bugdene@comcast.net
Starobin	Dr. Anna	Chair	Other - Sanitation Services	Ecolab	Greensboro	NC	(336) 931-2185	anna.starobin@ecolab.com
Nardone	Ernesto	Member	Other - Software Solutions	N2N Global	Longwood	FL	(407) 331-5158	enardone@us.n2nglobal.com
Sharp	Donald	Member	Non-Regulatory - Federal	USCDC	Atlanta	GA	(404) 639-2213	das8@cdc.gov
Lawrence	Michael David	Member	Regulatory - Local	Fairfax County Health Department	Fairfax	VA	(703) 246-8435	david.lawrence@fairfaxcounty.gov
Samarya-Timm	Michele	Co-Chair	Regulatory - Local	Somerset County Department of Health	Franklin Park	NJ	(732) 297-0750	SamaryaTimm@co.somerset.nj.us
Mack	James	Member	Regulatory - State	State of WI Dept of Health and Family Services	Madison	WI	(608) 266-8351	james.mack@wisconsin.gov
Williams	Janet	Consultant	Regulatory - Federal	FDA/CFSAN	College Park	MD	301-796-4534	Janet.Williams@fda.hhs.gov
Smith	Chris	Consultant Alternate	Regulatory - Federal	FDA	Atlanta	GA	404-253-1264	Chris.Smith@fda.hhs.gov
Barlow	Kristi	Consultant	Regulatory - Federal	USDA/FSIS	Washington	DC	202-690-7739	kristina.barlow@fsis.usda.gov

Conference for Food Protection
2012 Issue Form

Internal Number: 037
Issue: 2012 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.

Title:
Re-Create-Interdisciplinary Foodborne Illness Training Committee

Issue you would like the Conference to consider:
To continue tracking the progress of prominent disease training program (an accessible foodborne illness prevention/response education opportunities, of any length, offered at the state or national level). currently developed, identify essential educational content of foodborne disease outbreak training programs; evaluate and rank identified courses for relevance and content; identify any gaps in foodborne disease outbreak training; consider if levels of foodborne disease outbreak training/retraining are needed.

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 professionals in outbreak response can mitigate the effects of an outbreak.
Many states indicate utilizing some form of foodborne epidemiological education programs, but there is great variability in training offerings. Training programs in outbreak investigation should have some consistency and a minimal level of proficiency to ensure rapid response and communication, amongst investigating parties.
The mere existence of programs does not guarantee efficacy of the training. Accreditation or voluntary standards can provide a level of quality assurance and/or consistency amongst foodborne illness training programs to ensure that professionals are comfortably prepared to investigate outbreaks, institute proper control measures, and correspond appropriately amongst the many other parties and jurisdictions involved.

Recommended Solution: The Conference recommends...:
- that the Interdisciplinary Foodborne Illness Training Committee be re-created ; and
- Report back to the 2014 Biennial Meeting of the Conference for Food Protection.

Submitter Information:

Name: Anna Starobin, MD, CP-FS Co-Chair
Organization: Interdisciplinary Foodborne Illness Training Committee
Address: Ecolab8300 Capital Dr.
City/State/Zip: Greensboro, NC 27409

Telephone: 336 931 2185 Fax: 336 668 0744
E-mail: anna.starobin@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
2012 Issue Form

Internal Number: 078
Issue: 2012 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.

Title:
Report - Food Protection Managers Certification Committee (FPMCC)

Issue you would like the Conference to consider:
Please acknowledge the attached final report as submitted and thank the 2010-2012 Food Protection Manager Certification Committee (FPMCC) members for their effort in addressing the charges from the 2010 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*.
http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf

Recommended Solution: The Conference recommends...:
acknowledging the attached Food Protection Manager Certification Committee (FPMCC) report with attachments, and extending thanks to the Committee members for their work.

Submitter Information:

Name: Joyce Jensen, REHS, CP-FS, Committee Chair
Organization: Food Protection Manager Certification Committee
Address: 3140 N Street
City/State/Zip: Lincoln, NE 68510
Telephone: (402) 441-8033 Fax: (402) 441-6206
E-mail: jjensen@lincoln.ne.gov

Attachments:
- "FPMCC Final Report"
- "ANSI-Certification Providers Workgroup Report"
- "Proposed Standards Revision"
- "Proposed FPMCC Bylaws Revision"

- "FPMCC Roster"

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1Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: **Food Protection Manager Certification Committee**

COUNCIL (I, II, or III): **Council II**

DATE OF REPORT: **January 6, 2012**

SUBMITTED BY: **Joyce Jensen, REHS, CP-FS, Committee Chair**

COMMITTEE CHARGE(S):

Issue: 2010 II-020
The Conference recommends that the Food Protection Manager Certification Committee (FPMCC), a standing committee of the Conference be charged to:

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.

   - Request that ANSI and the Certification Providers will examine all options for resolving the exam security and independence issues as they pertain to trainers serving as test administrators and come to consensus with a suggested action plan as follows:
     - By April of 2011, a recommended solution to be reviewed by the ANSI / Certification providers workgroup;
     - By June of 2011 the FPMCC, Certification Providers and ANSI have reached consensus on the recommended solutions;
     - The draft recommendations will be submitted to the Executive Board for their review at the August 2011 Board meeting;
     - Recommendations approved by the Executive Board will be submitted as an issue at the 2012 biennial meeting; and
     - Pending Conference approval, the new requirements will be implemented no later than January of 2013.

2) Investigate if the *Standards for Accreditation of Food Protection Manager Certification Programs* should create more alignment with ISO (International Standards Organization) 17024 and propose changes if needed.

3) Determine how Committee membership vacancies and change of membership representation are addressed in the Committee bylaws and propose changes if needed.

4) Report back to the Executive Board and the 2012 Biennial Meeting of the Conference for Food Protection.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Meetings and Workgroup Assignments:

The FPMCC was charged with very important work to be completed by the 2012 CFP Biennial meeting. To accomplish those charges, each committee member was asked to participate on at least one workgroup. The FPMCC Chair Joyce Jensen and Vice-Chair Jeff Hawley selected workgroup chairs as follows:

Workgroup	Chair	Function
Logistics	Geoff Luebkemann	Arrange for meetings, conference calls, scribe assignments, and minutes
Communications	George Roughan	Prepare communication re: Standards, FAQ, and CFP webpage
Standards	Kate Piche	Maintain the Standards, and propose revisions
Bylaws	Vicki Every	Review and recommend revisions to FPMCC Bylaws
ANSI/Providers	Jeff Hawley	Examine all options for resolving the exam security and independence issues as charged by the 2010 CFP

The FPMCC held three face-to-face meetings: August 25-26, 2010 in Rosemont, IL; April 6-8, 2011 in Indianapolis, IN; and October 5-7, 2011 in Las Vegas, NV. In addition, a face-to-face ANSI/ Certification Provider Workgroup meeting was held December 13-15, 2010, in Orlando FL. A fourth FPMCC face-to-face meeting is scheduled on April 13, 2012, just prior to the 2012 CFP Biennial Meeting.

A new committee member orientation was presented just prior to our first face-to-face meeting on August 25, 2010. This orientation provided important information about the committee's history, the Standards (*Standards for Accreditation of Food Protection Manager Certification Programs)*, the terminology, and about ANSI and ACAC so new members are better prepared to participate in the committee meetings. This 2010 PowerPoint presentation is available on the CFP website.

FPMCC conference calls (or webinars) were held on: December 7, 2010; February 10, 2011; March 22, 2011; June 24, 2011; and November 16, 2011. An additional conference call is scheduled for early 2012 to review the Communication Workgroups recommendations for the CFP FPMC webpage. Changes to the webpage will be worked out with CFP Executive Director and Assistant. In addition, numerous workgroup conference calls were held in preparation for the FPMCC meetings/calls.

Exam Security per Issue: 2010 II-020 1) and 2):

Following the April 2010 CFP Biennial meeting, the FPMCC Chair and Vice Chair had the task to establish an ANSI-Certification Providers (ANSI-CP) Workgroup by June 2010 to begin the work on the charge to examine all options for resolving the exam security and independence issues as they pertain to trainers serving as test administrators, and come to consensus with a suggested action plan. The workgroup members agreed that John Marcello, with FDA's permission, should facilitate the problem resolution process to meet our committee charge.

The ANSI-CP Workgroup had monthly conference calls with homework assignments from the facilitator to clarify and quantify the exam security issues that were experienced by the certification providers or identified by ANSI. All data submitted were sanitized by the facilitator to allow for candid and accurate information being provided by all; it was necessary to understand the scope of the problem before addressing solutions. After much "homework" collecting, quantifying, and categorizing the security issues, the workgroup held a three day face-to-face meeting in December 2010 to complete the problem resolution process and establish the recommendations to be presented to the FPMCC.

The ANSI-CP Workgroup examined all of the exam security issues experienced by the certification providers. The workgroup established both short-term and long-term objectives for improving exam security. Recommendations were presented to address all of the short-term objectives for improvement of the entire testing process based on logistics, acceptability, cost, technology, and complexity. Recommended changes to the Standards were unanimously agreed on by the workgroup to address each of the security issues identified.

Exam Security Recommendations:

- **Exam Development** – Increase the exam form item bank from 600 to 1000.

- **Test Administrator/Proctor's Roles and Responsibilities -** Clearly delineate all Test Administrator/Proctor roles and responsibilities.

- **Training of Test Administrators/Proctors** - Require the certification organizations to provide a training program for Test Administrators/Proctors based on learning objectives that reflect their roles/responsibilities.

- **Verification of Test Administrators** - Require certification organizations to notify ANSI when Test Administrator/Proctor has been removed.

- **Exam Item Exposure** - Require certification organizations to have a system to track all examinations (exam books and/or answer sheets).

- **Exam Shipping and Handling** - Restructure Standards to include provisions that ensure security for all shipping and handling of exams by certification organizations and Test Administrators/Proctors.

- **Test Sites** - Require a private room accessible only to Test Administrators/Proctors and Examinees during test administration.

- **Certificates** - Require certification organizations to have a system to provide verification to the current validation of individual certificates.

- **Advertising Standards** - Test Administrator/Proctor cannot make statements or claims, nor have affiliation with any organization making statements or claims, such as guarantees of passing the exam.

- **Management Systems** - Include a new section to the Standards that contains requirements for the implementation of management systems that include document control, internal audits, and management review.

On March 22, 2011, the ANSI-CP Workgroup and John Marcello presented the Workgroup's process and recommendations to the FPMCC in a Webinar in preparation for the April 6-8, 2011, FPMCC meeting held in Indianapolis. Attached is the document "ANSI-Certification Providers Workgroup Report" that is a detailed summary report of the process the ANSI/Certification Providers Workgroup took to come to consensus on the recommendations.

At the April 2011 meeting the full FPMCC voted to accept the Workgroup's recommendations with just one opposing vote. The opposing concern was that while these recommendations increase exam security, they did not separate the roles of trainer and test administrator/proctor at this time. The FPMCC then began the specific work of incorporating the recommendations into the Standards. The recommended revision to the Standards, especially establishing the new Standard Section 9.0 - Management Systems, creates greater alignment with ISO (International Standards Organization) 17024 as identified in Issue: 2010 II-020.

As proposed in the FPMCC charges for 2014, the FPMCC will establish criteria and protocols to evaluate the effectiveness of the increased exam security resulting from these recommendations by December 2012. The results of the final evaluation of the exam security improvements will be presented to the 2016 CFP. At that time, the FPMCC will propose when and how FPMCC will move forward to meet the long-term objective to eliminate the inherent conflict of interest within the testing process and to meet all applicable nationally accepted personnel certification Standards based on the evaluation of exam security resulting from the implementation of the new Standards. This long-term objective will create alignment with International Standards Organization (ISO) 17024 per Issue: 2010 II-020.

These exam security recommendations resulted in the most substantial revision to the Standards since the Standards were adopted. Several of these recommendations have already been implemented by the certification organizations, who have reported a significant improvement in exam security as a result.

Using the FPMCC approved recommendations from the ANSI-CP Workgroup, the Standards Workgroup then drafted proposed revisions to address exam security and proposed additional clarifications to the Standards. This includes revisions to ensure terminology used was consistent

throughout the Standards and reorganization of the Standards to eliminate redundancy when possible.

A draft of the Standards revisions was presented to the CFP Executive Board at the August 30, 2011, meeting in Ann Arbor, Michigan. The Board asked questions and then voted to accept the report and recommendations presented by the FPMCC.

The FPMCC held a meeting in Las Vegas on October 5, 6, and 7, 2011, to refine the proposed revisions to the Standards to ensure clarity and consistency. A FPMCC conference call in November finalized the last of the wording changes made in a few areas.

The two FPMCC Issues submitted related to the *Standards for Accreditation of Food Protection Manager Certification Programs* have been separated into the substantive revisions related to exam security, and non-substantive cleanup revisions which include consistent terminology and a new numbering system. (See Issues titled "Standards - Strengthening Exam Security" and "Standards - Non-Substantive Revisions.")

Evaluating Effectiveness of Revised Standards on Exam Security

It is important to the FPMCC that the results of these revisions address the short term objectives as identified by the ANSI-CP Workgroup for: improving the entire testing process based on logistics, acceptability, cost, technology and complexity to enhance procedures and accountability of the test administrators, proctors and certification organizations; and to formalize a management system that creates systematic, continuous improvement process through document control, internal audits and management review.

The outcome of the proposed Standards revisions must then be evaluated to ensure that they are resulting in substantial improvement in exam security. The FPMCC is proposing a plan to work with ANSI to update the ANSI accreditation application to incorporate the final changes approved at the 2012 Biennial Meeting Standards, develop surveillance documents, establish an analysis framework and research plan for data collection and evaluation of improvement in exam security, complete a preliminary study to ensure that the evaluation tool works, and report to the 2014 Biennial Meeting.

Following the 2014 Biennial Meeting the FPMCC will then be prepared to complete an evaluation of the results of the 2012 Standards revision with a complete year of data from the certification organizations after implementation of the revised Standards. The FPMCC would then propose reporting back to the 2016 Biennial Meeting the results of the evaluation, and where the process is at relative to the long term objectives as identified by the ANSI-CP Workgroup for eliminating the inherent conflict of interest within the testing process and meeting all applicable nationally accepted certification standards.

The FPMCC understands that with improved surveillance and the implementation of the formal management systems (proposed new section of the Standards) there will be an initial increase of identified security breaches as compared to the information collected in 2010 by the ANSI-CP Workgroup. We recognize that this would not be reflecting an increase in actual security breaches, but rather a better system for identifying and reporting of these breaches.

To ensure that this evaluation work will be completed, the FPMCC has established the following work plan to be used for proposed FPMCC charges for both the 2012 and the 2014 Biennial Meetings of the Conference for Food Protection.

FPMCC Plan for Evaluation of the New Security Standards

April 2012 – Recommend to the CFP by approval of Continuing Charges to the FPMCC the formation of the Security Evaluation Workgroup for the purpose of starting the evaluation process by July 1, 2012.

June 30, 2012 - Establish an ad hoc workgroup (Security Evaluation Workgroup) for the purpose of:

1) Drafting ANSI revisions to the accreditation application,

2) Developing surveillance documents, and

3) Establishing an analysis framework and research plan for data collection and evaluation of improvement in exam security.

The FPMCC Chair will form the Security Evaluation Workgroup which will include:

- ANSI representative
- ANSI field research design (data) subject matter expert
- CFP ACAC representative
- One representative from each Certification Organization
- FPMCC Chair & Vice Chair
- One food industry representative
- One food regulatory representative

The Security Evaluation Workgroup will formulate a foundation for quantitative/qualitative analysis that addresses the long term goal to eliminate the inherent conflict of interest within the testing process by reducing undue trainer influence (when a trainer acts as a test administration/proctor) on exam administration and report its results of the analysis at the CFP 2014 Biennial Meeting.

July 2012 – The Security Evaluation Workgroup begins their work with a deadline to report findings to the FPMCC by December 1, 2012.

August 2012 – The FPMCC members are approved for the 2012-14 biennium.

October 2012 – The Security Evaluation Workgroup reports progress to full FPMCC meeting.

December 1, 2012 – The FPMCC receives, reviews, and approves the report of the Security Evaluation Workgroup.

June 30, 2013 – the deadline for full implementation of security Standards as approved at the 2012 Biennial Meeting.

J**une through October 2013** – The collection period of data compiled by ANSI for preliminary review and validation of the research plan, data collection instruments, and methods.

October or November 2013 – FPMCC meeting, prepare report for the 2014 Biennial Meeting.

December 2013 – FPMCC draft Final Report and proposed Issues submitted for the 2014 Biennial Meeting.

April 2014 - FPMCC reports findings and Issues to the 2014 CFP Biennial Meeting and recommends appropriate action.

June 30, 2014 – "New Security Standards" that are approved at the 2012 CFP Biennial Meeting become auditable with one year of data, to coincide with ANSI accreditation assessment period of the Certification Organizations.

Fall 2014 - FPMCC meeting; ANSI presents report to FPMCC on the quantitative/qualitative analysis findings on "New Security Standards" effectiveness.

Fall 2014 to Fall 2015 – FPMCC formulates recommendations.

December 2015/April 2016 - FPMCC reports findings and Issues to the 2016 CFP Biennial Meeting and recommends appropriate action.

FPMCC Bylaw Revisions (per Issue: 2010 II-020 3):

The Bylaws Workgroup drafted revisions to the FPMCC Bylaws based on the charge and CFP Executive Board input from the August 24, 2010 meeting in Rosemont, Illinois. The Bylaw workgroup was formed at the August 25-26, 2010, FPMCC meeting in Rosemont. Vicki Everly, Workgroup Chair, sought input from Ruth Hendy, the CFP Constitution and Bylaw/Procedures Chair, to address consistence with the CFP Bylaws when possible. The Bylaws Workgroup was tasked to explore the following areas in the FPMCC Bylaws and, if necessary, to make recommendations for language changes:

- Term limits and membership retention.
- Special rules (to replace existing "modified" Robert's Rules of Order language).
- Language Consistency – both within the FPMCC Bylaws and with the CFP Bylaws.
- Quorum language.
- Committee structure and voting (including workgroups and sub-committees).
- Removal of committee members for non-participation.
- Edit/revise "alternates" language.
- Edit to clarify "issue" terminology.
- Clarification of comments regarding adherence to CFP Bylaws and Robert's Rules of Order.

Proposed Bylaw revisions were presented and discussed at the April 8, 2011 FPMCC meeting in Indianapolis, and the October 5, 2011 meeting in Las Vegas.

The two FPMCC Issues submitted related to the *Food Protection Manager Certification Committee Bylaws* have been separated into:

a) the substantive revisions including the new language addressing membership from potential additional certification organizations, adding language to address alternate members and advisors to the committee; and
b) non-substantive changes which include consistent and accurate terminology and updating to current procedures.

Communication Workgroup:

It is a challenge to keep the information provided on the CFP web page up-to-date and current. The Communication Workgroup, with George Roughan as Chair, reviewed the CFP website. Concerns and broken links were identified, recommendations were provided, and many updates made as a result of their review. In addition, specific changes have been made to the Food Protection Manager Certification page.

The workgroup will continue to review and propose changes to update the webpage to keep it current and to make sure that the work of the FPMCC is available to all who want to keep up with the important work of the committee. Changes to the webpage will be approved by the FPMCC and then forwarded to the CFP Executive Assistant to post.

ANSI/ACAC:

At the August 25-26, 2010 FPMCC meeting, the committee discussed and provided input to the American National Standards Institute (ANSI) regarding proposed amendments to the Accreditation application based on the changes to the Standard approved at the 2010 CFP Biennial Meeting. The FPMCC voted unanimously to accept the changes in the application as amended, and voted unanimously to establish an implementation date of July 2011, the beginning of the next application cycle.

At the August 30, 2011 CFP Executive Board meeting, the Board accepted the FPMCC nomination of Joyce Jensen to serve as one of the two CFP designated ANSI-CFP Accreditation Committee (ACAC) members to begin after her tenure as FPMCC Chair ends at the 2012 CFP Biennial Meeting. Lee Cornman continues to serve as the other ACAC member representing CFP.

Acknowledgments:

The FPMCC would like to thank Dr. Roy Swift, Senior Director, Personnel Credentialing Accreditation Programs, with ANSI, for his work with the FPMCC. He has been a knowledgeable resource in personal certification, providing guidance that helped the FPMCC accomplish significant improvements to the Standards, especially over the past two years.

The FPMCC would like to thank John Marcello, Retail Food Specialist, FDA, for his facilitation of the ANSI-Certification Providers Workgroup. His organization skills and leadership through this process was outstanding. He helped the workgroup identify the problems and then led the group to find solutions that everyone could agree with.

The FPMCC would like to thank Dr. Cynthia Woodley, Vice President, Professional Testing Inc., for updating the orientation PowerPoint and presenting the new member orientation on August 25, 2010. Dr. Woodley was a long time member and past Chair of the FPMCC. This PowerPoint is available on the CFP website for anyone interested in the committee.

To assist with the logistics for the FPMCC meetings, a special thank you to:

- US Food Service for providing the meeting room for the August 25-26, 2010 FPMCC meeting in Rosemont, IL.
- Harris Teeter for hosting the December 7, 2010 conference call.
- National Registry for providing the meeting room and refreshments for the ANSI-Certification Providers workgroup December 14-16, 2010 in Orlando, FL.
- National Restaurant Association Solutions for hosting the February 10, 2011 FPMCC webinar/conference call.
- Prometric for hosting the March 22, 2011 webinar presented by John Marcello.
- The Florida Restaurant Association, the National Restaurant Association Solutions, and the National Registry for providing the meeting room and refreshments for the October 5-7, 2011 FPMCC meeting in Las Vegas, NV.

The Chair would like to recognize and thank the Vice-Chair Jeff Hawley, and the Workgroup Chairs: Kate Piche, Vicki Everly, George Roughan, and Geoff Luebkemann. They embraced their responsibility to accomplish a significant amount of the committee work during the past two years.

Last, but not least, the Chair would like to recognize and thank the 2010-2012 FPMCC members, and the organizations/agencies they represent, which allowed them to participate on the FPMCC. Without our involved, committed, and active members, we would not have been able to achieve as much as we have. As a result of respectful debate and discussion, a significant impact of the credibility of the Food Protection Manager Certification has been accomplished.

REQUESTED ACTION:

The Committee submits the following Issues to the 2012 CFP Biennial Meeting:

1) Report - FPMCC (Food Protection Manager Certification Committee Final Report)

2) Standards - Strengthening Exam Security (*Standards for Accreditation of Food Protection Manager Certification Programs* Security Revisions*)*

3) Standards - Non-Substantive Revisions *(Standards for Accreditation of Food Protection Manager Certification Programs* Non-Substantive Revisions*)*

4) FPMCC Bylaw Revision (*Food Protection Manager Certification Committee Bylaws* Revisions)

5) FPMCC Bylaw Non-Substantive Revisions (*Food Protection Manager Certification Committee Bylaws* Non-Substantive Revisions)

6) FPMCC - New and Continuation Charges

ATTACHMENTS:

1) *Standards for Accreditation of Food Protection Manager Certification Programs* (with revisions tracked in legislative format)

2) *Food Protection Manager Certification Committee Bylaws* (with revisions tracked in legislative format)

3) ANSI-Certification Providers Workgroup Report (process and recommendations for resolving concerns with Food Protection Manager exam security)

4) Food Protection Manager Certification Committee Member Roster

NEW OR CONTINUATION CHARGES:

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) Revise/Update the *Standards for Accreditation of Food Protection Manager Certification Programs* Preamble and Annexes.

3) Request approval of the formation of the Security Evaluation Workgroup by the FPMCC Chair for the purpose of starting the exam security evaluation process by July 1, 2012, with workgroup representation as follows:
   - ANSI representative,
   - ANSI field research design (data) subject matter expert
   - CFP ACAC representative
   - One representative from each Certification Organization
   - FPMCC Chair & Vice Chair
   - One food industry representative
   - One food regulatory representative

4) Evaluate the results of the Standards revisions as approved by the 2012 Biennial Meeting to ensure that they are resulting in substantial improvement in exam security. The FPMCC is proposing a plan to:
   - work with ANSI to update the ANSI accreditation application to incorporate the final Standards changes as approved at the 2012 Biennial Meeting,
   - develop surveillance documents,
   - establish an analysis framework and research plan for data collection and evaluation of improvement in exam security, and
   - complete a preliminary study to ensure that the evaluation tool works.

5) Report back to the Executive Board and the 2014 Biennial Meeting of the Conference for Food Protection.

ANSI-Certification Providers Workgroup Report

Process and Recommendations for Resolving Concerns with Food Protection Manager Exam Security

The following summary is based on the Webinar presentation to the FPMCC on March 22, 2011, identifying the process that the ASNI-Certifification Providers Workgroup completed, and the recommendations they presented to the FPMCC for the April 2011 Committee meeting. The FPMCC accepted the workgroup recommendations and developed draft Standard Revisions to address all of the recommendations.

ANSI/Certified Provider Workgroup Members

- John Marcello - Facilitator
- ANSI – Roy Swift
- ANSI-CFP Liaison – Lee Cornman
- CFP FPMCC – Jeff Hawley (Workgroup Chair), Joyce Jensen
- National Registry FSP – Larry Lynch
- NRA Solutions – Kate Piche
- Prometric – Ken Walters

Workgroup Meeting Structure

- ANSI/Certification Providers identified primary spokesperson for their organization
- Consensus building voting process used (thumbs up; sideways; down)
- Issue introduced for discussion must be:
  - Specific and Clear,
  - Contain Rationale, and
  - Focus is on one Issue at a Time
- Commitment to complete all sub group assignments within agreed upon time frames

Problem Solving Process

STEP 1 – Develop a Clear Problem Statement
STEP 2 – Analyze the Problem
STEP 3 – Generating Potential Solutions
STEP 4 – Selecting the Solution
STEP 5 – Implementing the Solution
STEP 6 – Evaluating the Solution

STEP 1 –Develop a Clear Problem Statement

- Each workgroup member developed a problem statement and provided specific examples
- Workgroup members ranked and prioritized the problem statements
- Certification Provider were then assigned the task of providing "Actual" documented complaints pertaining to the administration of their exams
- Most Common Incident Reported for Each of the "Problematic Areas"

- Documented complaints were them collated and organized into one comprehensive matrix
    - 6 Credibility / Training of Proctors: Suspected Cheating
    - 59 Handling / Shipping of Exam Packages: Missing exams / incomplete exam returns / past due exams / retired exams
    - 52 Location / Site Irregularities: Lost exams by carrier / inventory errors by test administrators
    - 6 Breach of Provider's T.A. Requirements: All candidates given same form of the exam

- After reviewing the complaint incident matrix, the workgroup added a 5th "problematic area" – Certification Provider's Quality Assurance Controls for Test Administration / Test Administrators:
    - ► Document Control
    - ► Internal Audits
    - ► Management Review

STEP 2 – Analyzing the Problem

- Workgroup conducted an assessment of how existing CFP Standards currently addressed the documented "problematic areas" and complaint incidents.
- Specific CFP Section numbers and provisions associated with each "problematic area" and complaint incident were added to the problem-solving matrix.
- Certification Providers identified quality assurance controls they had in place to address "problematic areas" and complaint incidences that are *in addition to* what is required in the CFP Standards.
- Provider's QA controls were added to the Problem-Solving Matrix.
- Certification Providers identified quality assurance controls they had in place to address "problematic areas" and complaint incidences that are *in addition to* what is required in the CFP Standards.
- Provider's QA controls were added to the Problem-Solving Matrix.

STEP 3 – Generating Potential Solutions

ANSI / Certification Providers reviewed the problem solving matrix and generated potential solutions / options for minimizing incidents related to document test administration and exam security.

- For each potential solution, ANSI / Certification Providers included rationale as to how the recommendation / option would enhance the test administration process for Food Protection Manager Certification.
- 52 Potential Solutions / Options were generated for the five "Problematic Areas"
    - ► Credibility & Training of TA's/Proctors (15 Solutions / Options)
    - ► Handing / Shipping of Exam Packages (10 Solutions / Options)
    - ► Location / Site Irregularities (10 Solutions / Options)
    - ► Breach of Provider's T.A. Requirements (9 Solutions / Options)
    - ► Providers QA Process / Management System (8 Solutions / Options)

STEP 4 – Selecting the Solution (Completed at the Orlando Face-to-Face meeting)

- Workgroup reviewed, combined, and ranked potential solutions.
- Every potential option or solution was considered.
- Potential Solutions were roughly assessed using one or more of the criteria included in Step 4.

Criteria used to Assess Solutions:

- **Control** – The extent to which the solution is within the control of the FPMCC and CFP
- **Appropriateness** - The degree to which the solution resolves the problem
- **Resource Requirements** - The extent which resources ($; people, etc.) are required for implement the solution
- **Return on Investment** - Cost-Benefit Analysis
- **Time** - Length of time it will take to resolve problem
- **Acceptability** - Degree to which people involved will accept the changes

Refined and Clarified Problem Statement/Charge:

"Examine all options for resolving the exam security and independence issues as they pertain to trainers serving as test administrators"

Refined and Clarified Overarching Workgroup Objective:

"Enhance the integrity of the entire testing process which included identification and analysis of root causes of security violations and recommended solutions"

Outline a Strategic Direction:

Identified Short-Term Objectives for improvement of the entire testing process based on logistics, acceptability, cost, technology, and complexity to:

► Enhance procedures & accountability of:
   a. Test Administrators,
   b. Proctors, and
   c. Certification Organizations.

► Formalize a management system that creates systematic, continuous improvement process through:
   a. Document Control,
   b. Internal Audits, and
   c. Management Review.

Identified Long-Term Objectives:

► Eliminate the inherent conflict of interest within the testing process.
► Meet all applicable nationally accepted personnel certification standards.

STEP 5 – Implementing the Solution

The FPMCC accepted the recommendations the ANSI-Certification Providers Workgroup presented. The workgroup provided a rough draft of proposed revisions to the Standards. The FPMCC felt it was important to make the Standard revisions clear and organized. The Standards Workgroup then worked on the details of fine tuning and

reorganizing the proposed revisions to Standard 5 and provided their recommendations to the FPMCC members in July. The draft recommendations will be submitted to the Executive Board in August 2011, for their review.

STEP 6 – Evaluating the Solution

Criteria and Protocol will be established to assess the effectiveness of the short-term solutions:

- Identify and standardize the assessment criteria
- Establish time frames for implementation and evaluation of short term objectives
- Determine who will conduct the effectiveness assessment
- Ensure short term objectives are providing the level of control consistent with the work group's long-term objectives

Workgroup Recommendations for Changes to Standards

Exam Development - On a quarterly basis have a minimum of 2 exam forms based on 1000 item bank (increased from 600).

Test Administrator/Proctor's Roles and Responsibilities - Standards must clearly delineate all Test Administrator/Proctor's roles and responsibilities.

Training of Test Administrators/Proctors - Require the certification organization to provide a training program for Test Administrator/Proctors based on learning objectives that reflect their roles/responsibilities.

Verification of Test Administrators - Require certification organization to notify ANSI when Test Administrator/Proctor has been removed.

Exam Item Exposure - Require the certification organization to have a system to track all examinations (exam books and/or answer sheets).

Exam Shipping and Handling - Restructure Standards to include provisions that ensure security for all shipping & handling of exams by the certification organization and Test Administrator/Proctors.

Test Sites - Require a private room accessible only to Test Administrator/Proctor and Examinees during test administration.

Certificates - Require the certification organization to have a system to provide verification to the current validation of individual certificates.

Advertising Standards – Test Administrator/Proctor cannot make statements or claims, or cannot have affiliation with any organization making statements or claims, such as guarantees of passing the exam.

Management Systems - Include a new section to the Standards that contains requirements for the implementation of management systems that include the following three components: Document Control; Internal Audits; and Management Review.

1. Document Control to include:
   - ► Lists of all documents pertaining to the certification program
   - ► Dates for documents approved for implementation by the certification organization
   - ► Who within the certification organization is responsible for the documents
   - ► Listing of individuals who have access to the documents

2. Internal Audits to include:
   - ► Identification of critical activities
   - ► Data to be collected and how often it is evaluated
   - ► How an audit should be conducted
   - ► Who can perform audits
   - ► How evaluation of critical activities is determined during the audits
   - ► Determine if any deficiencies have been found

3. Management review to include:
   - ► At a minimum, an annual review of the results from internal audits
   - ► A select management staff should comprise the committee that conducts the review
   - ► Committee reviews the results of audits to determine:
     - √ if corrective actions are needed
     - √ if preventive actions are needed
   - ► Determine effectiveness of corrective actions and preventive actions

In addition to the proposed changes to the Standards, the workgroup has requested the certification providers to collectively review their best practices / procedures and develop uniform, consistent test administration protocols for:

- ► Examination site conformity,
- ► Verbal instructions given to examinee at test site, and
- ► Classification of security breaches and/or infractions

Certification providers are assessing how they will deliver training programs to test administrators.

April ~~2010~~ 2012 (January 5, 2012 draft)

Conference for Food Protection

Standards for Accreditation of Food Protection Manager Certification Programs

As Amended ~~by~~ at the ~~2010~~ 2012 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. 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 have been developed after years of CFP's research into, and discussion about, Food Protection Manager *Certification* Programs.

All ~~*certifying*~~ *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. ~~*Certifying*~~ *Certification organizations* have as a primary purpose the evaluation of those individuals who wish to secure or maintain Food Protection Manager *Certification* in accordance with the criteria and standards established through the CFP. ~~*Certifying*~~ *Certification organizations* issue *certificates* to individuals who meet the required level of *competency*.

The CFP 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.

To earn *accreditation*, the *certification organization* ~~must~~ shall meet the following CFP standards and provide evidence of compliance through the documentation requested in

the application. In addition, the *certification organization* ~~must~~ shall agree to abide by *certification* policies and procedures which are specified by the CFP Food Protection Manager Certification Committee, hereinafter referred to as the FPMC Committee, approved by the CFP, and implemented by the *accrediting organization*.

The *accrediting organization* shall verify and monitor continuing compliance with the CFP standards through the entire *accreditation* period. The CFP FPMC Committee will work directly with the *accreditation organization* to enhance and maintain *certification* policies and procedures that meet the specific needs of Food Protection Managers while ensuring a valid, reliable and *legally defensible* evaluation of *certification* programs.

The American National Standards Institute (ANSI) was selected as the *accrediting organization* for the CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs and assumed its duties in January, 2003. The CFP FPMC Committee continues to work within the Conference structure to monitor the criteria and selection process for the organization serving as the accrediting body for Food Protection Manager *Certification* Programs.

The CFP strongly encourages regulatory authorities and other entities evaluating credentials for Food Protection Managers to recognize and endorse these standards and the accreditation process. The CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs provides the framework for universal acceptance of individuals who have obtained their credentials from an *accredited certification program*. In the U.S Food and Drug Administration's ~~Model~~ Food Code, hereinafter referred to as the FDA Food Code, Section 2-102.~~11~~ 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~~, as prescribed~~ in Section ~~Paragraph~~ 2-102.11~~(B)~~.

Modifications and Improvements

The FPMC Committee followed the Conference directive to use the 1996 conference working document, Standards for Training, Testing and *Certification* of Food Protection Managers, in the development of accreditation standards. Extensive revision of this document was presented to CFP's ~~2000, and 2002~~ 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* to enhance the integrity of the entire testing process, which includes identification and analysis of root causes of security violations and implement solutions.

The revision and reformatting of the document were made after a comprehensive FPMC Committee review of each section. ~~The~~ This revision of the *Standards for Accreditation of Food Protection Manager Certification Programs*:

1. adds and improves definitions that are more precise and more consistent with terminology and definitions used in the *psychometric* community and by accreditation organizations;
~~2. italicizes defined terms throughout the document;~~
~~3. eliminates ambiguities in the 1996 conference working document pertaining to test development and administration;~~
~~4. identifies *certification organization* responsibilities to candidates, the public and the *accrediting organization*;~~
~~5. adds computer-based test standards; and~~
~~6. clarifies demonstration of *continued proficiency*;~~
2. reorganizes *Standards* to eliminate duplication and align with purpose;
3. modifies or creates *Standards* to better address professional credibility and training of *test administrators/proctors*; handling of examination packages; shipping irregularities; location (site) irregularities; and breach of the *certification organization's test administrators/proctors* protocols and requirements;
4. uses "*test administrator/proctor*" in the *Standards* to indicate duties for both "*test administrator*" and "*proctor;*" and
5. adds a standard for management systems.

Annexes

The annexes located at the back of the document are NOT part of the standards, but provide information to guide those responsible for implementing or reviewing Food Protection Manager *Certification* Programs. Each of the annexes provides guidelines for specific responsibilities that impact the effective implementation of the Conference Standards for *Accreditation* of Food Protection Manager *Certification* Programs.

Annex A provides a "Code of Ethics" for *certification organization*s ~~and test providers~~ responsible for the design of the assessment tool used to measure ~~a candidate's~~ an examinee's *competency*. *Certification organization*s have a responsibility to ensure that the *certification* process is fair to the ~~candidates~~ examinees and protects their inherent rights.

Annex B provides some guidance to regulatory authorities that incorporate Food Protection Manager *Certification* as part of their requirements to obtain or retain a permit to operate. The CFP *Standards for Accreditation of Food Protection Manager Certification Programs* is designed to be a set of voluntary unifying national standards providing a mechanism for the universal acceptance of food protection managers who obtain their *certificate*s from an *accredited certification program*.

Over the past 25 years, many regulatory authorities have developed their own Food Protection Manager *Certification* Programs. This has resulted in a variety of standards for *certification* programs. The CFP national 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 as fulfilling their program requirements. Annex B provides additional guidance, developed through the CFP, for the implementation of these regulatory *certification* programs.

TABLE OF CONTENTS

(Note: Table of Contents Titles, terminology, and page numbers will be changed as needed to reflect the 2012 Biennial Meeting of CFP approved revisions to the Standards.)

SECTION 1.0 - DEFINITIONS

1.0 Definitions

1.1 **Accreditation** means that an *accrediting organization* has reviewed a Food Protection Manager *Certification* Program and has verified that it meets standards set by the CFP (a review of a ~~*certifying*~~ *certification organization* by an independent organization using specific criteria, to verify compliance with Food Protection Management *Certification* Program Standards).

1.2 **Accrediting organization** means an independent organization that determines whether a Food Protection Manager *Certification* Program meets the standards set by the CFP.

1.3 **Accredited certification program** means a Food Protection Manager *Certification* Program that has been evaluated and listed by an *accrediting organization* accepted by the CFP and has met the CFP standards for such programs.

~~a.~~ 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 ~~test~~ examination development and administration.

~~b.~~ 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 ~~test~~ questions on an ~~exam~~ 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 ~~*certifying*~~ *certification organization* that he/she has the knowledge, skills and abilities required to protect the public from foodborne illness. Duties of such persons include but are not necessarily limited to:

~~a.~~ A. responsibility for identifying hazards in the day-to-day operation of a *food establishment* that provides food for human consumption;

~~b.~~ B. development or implementation of specific policies, procedures or standards aimed at preventing foodborne illness;

~~c.~~ 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.~~ 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 ~~is~~ are being followed.

1.9 **Competency** means a defined combination of knowledge, skills, and abilities 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 ~~must~~ 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 ~~test~~ examination questions to determine the examinee's proficiency by selecting items 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 ~~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), 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.~~18~~19 Examination forms means alternate sets of ~~test~~ examination questions (with at least 25% alternate questions) to assess the same *competencies*, conforming to the same *examination specifications*.

1.~~19~~20 Examination specifications means the description of the specific content areas of an examination, stipulating the number or proportion of items for each area of *competency* and the level of complexity of those items. The specifications are based on the *job analysis* and its verification.

1.~~20~~ 21Examination version means ~~a test~~ an examination in which the exact set of items in an *examination form* is presented in another order, language, manner or medium.

1.22 Exposure Plan means the policies and procedures in place to ensure that examination items are not exposed to examinees or other people that may result in an examination item being memorized and/or shared.-

1.~~21~~23Food establishment

~~a.~~ A. Food establishment means an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption:

~~i.~~ 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

~~ii.~~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.~~ B. ~~Food establishment includes~~ including:

~~i.~~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

~~ii.~~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.~~ C. ~~Food establishment does not include~~ not including:

~~i.~~ 1) an establishment that offers only prepackaged foods that are not potentially hazardous;

~~ii.~~ 2) a produce stand that only offers whole, uncut fresh fruits and vegetables;

~~iii.~~ 3) a food processing plant;

~~iv.~~ 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 the food is prepared in a kitchen that is not subject to regulation and inspection by the *regulatory authority*;

~~v.~~ 5) an area where food that is prepared as specified in Subparagraph (c) (iv) of this definition is sold or offered for human consumption;

~~vi.~~ 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, 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 areas that the food is prepared in a kitchen that is not regulated and inspected by the *regulatory authority*; or

~~vii.~~ 7) a private home that receives catered or home-delivered food.

1.~~22~~24Food safety certification examination means an examination in food safety approved in accordance with the provisions of this program.

1.~~23~~25Instructor means an individual who teaches a course that includes *competencies* in prevention of foodborne illness.

1.26 Item means an examination question.

1.~~24~~27Item bank means all of the items that have been developed for the several forms of an examination. It includes all of the items available to create *examination forms*.

1.~~25~~28Item sequence means the presentation order of ~~test~~ examination items in an examination.

1.~~26~~29Job 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 necessary to carry out the tasks.

~~a.~~ A **Tasks** are the individual functions, whether mental or physical, necessary to carry out an aspect of a specific job.

~~b.~~ B. **Knowledge, skills, and abilities (KSAs)** include the information and other

attributes that the worker ~~must~~ shall possess in order to perform effectively and safely. They include information and understanding as well as learned behaviors and natural attributes.

1.~~27~~30Legal 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.~~28~~31Legally 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. ~~Candidates'~~ 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 ~~a candidate's~~ an examinee's knowledge, skills, and abilities required to protect the consumer from foodborne illness.

1.~~29~~32Overexposure means the relative frequency in which ~~a test~~ an examination item which is presented across all computerized tests has undermined the integrity of the ~~tests~~ examinations. Whether a test item is overexposed or not is based upon the type of ~~exam~~ examination test item (pictorial vs. written) and its frequency of use.

1.~~30~~33 Proctor means a person under the supervision of a *test administrator*, assisting by assuring that all aspects of an examination administration are being carried out with precision, with full attention to security and to the fair treatment of examinees. *Proctors* have the responsibility and ~~must~~ shall have the ability to observe examinee behaviors, accurately distribute and collect ~~test~~ examination materials, and assist the *test administrator* as assigned. They ~~must~~ shall have training or documented successful experience in monitoring procedures and ~~must~~ shall affirm in writing an agreement to maintain ~~test~~ examination security and to ~~assure~~ ensure that they have no conflict of interest. There must be at least one *proctor* for every 35 examinees. The *proctor* can also be a *test administrator*.

1. ~~31~~34Psychometric means scientific measurement or quantification of human qualities**,** traits, or behaviors.

1.~~32~~35Psychometrician means a professional with specific education and training in development and analysis of ~~tests~~ 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 ~~test~~ examination development and a minimum of two in statistical methods.

1.~~33~~36Regulatory authority means a government agency that has been duly formed under the laws of that jurisdiction to administer and enforce the law.

1. ~~34~~37Reliability means the degree of consistency with which ~~a test~~ an examination measures the attributes, characteristics or behaviors that it was designed to measure.

1. ~~35~~38Retail food industry means those sectors of commerce that operate *food establishments*.

1. ~~36~~39Test administrator means the individual at the test site who has the ultimate responsibility for conducting a *food safety certification examination*. ~~*Test administrators* must have training, documented successful experience, or a combination of experience and training in test administration and security procedures. They must provide written assurance of maintaining confidentiality of test contents and of adherence to standards and ethics of secure examination administration. Their responsibilities include but are not limited to:~~

~~a. verifying that the contents of the examination materials shipment matches the packing list,~~

~~b. assuring that the site conforms to requirements,~~

c. ~~training and supervising *proctors*,~~

~~d. assuring accurate identification of examinees,~~

~~e. adherence to all procedures and instructions in the examination administration manual,~~

~~f. maintaining security of test materials,~~

~~g. assuring compliance with procedures for handling any breaches of security that may occur,~~

~~h. proper handling of completed examinations,~~

~~i. confidentiality of candidate scores, and~~

~~j. such unspecified duties as may be required for safe and secure administration of the examination.~~

k. ~~of the examination.~~

The *test administrator* can also be a *proctor*.

1. ~~37~~40Test encryption and decoding means the security aspects of a computer examination to prevent the ~~test~~ 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. ~~38~~41Trainer, in this instance, means a professional with appropriate expertise who conducts a course in food safety for applicants for *certification* as Food Protection Managers.

1. ~~39~~42Validity means the extent to which ~~a test~~ an examination score or other type of assessment measures the attributes it was designed to measure. In this instance, does the ~~test~~ examination produce scores that can help determine if examinees are competent to protect the public from foodborne illness in a *food establishment*.

SECTION 2.0 – PURPOSE OF CERTIFICATION ORGANIZATIONS

2.0 Purpose of *Certification Organizations*

2.1 The *certification organization* shall have as a purpose the evaluation of those individuals who wish to secure or maintain Food Protection Manager *Certification* in accordance with the criteria and standards established through the CFP, and the issuance of *certificates* to individuals who meet the required level of *competency*.

2.2 A ~~*certifying*~~ *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 the *certification organization* have any conflict of interest with said *accrediting organization.*

SECTION 3.0 – STRUCTURE AND RESOURCES OF CERTIFICATION ORGANIZATIONS

3.0 Structure and Resources of *Certification Organizations*

3.1 **Structure of *certification organizations*.** The *certification organization* shall be incorporated as a *legal entity* (applies to the parent organization if the *certification organization* is a subsidiary of another organization).

3.2 A *certification organization* shall conform to all CFP standards for *accreditation* and demonstrate that the relationship between the *certification organization* and any related association, organization or agency ensures the independence of the *certification* program and its related functions.

3.3 If a *certification organization* provides both education and *certification*, the *certification organization* shall administratively and financially separate any education and *certification* functions that are specific to Food Protection Manager *Certification* to ensure that the *certification* program is not compromised. This may be satisfied if the governing structure documents to the *accrediting organization* the distinct separation of the two functions, confirming that no undue influence is exercised over either the education or the *certification* process by virtue of the structure within the association, organization, agency or another entity.

3.4 **Resources of *Certification Organizations*.** A *certification organization* shall conform to all CFP standards for *accreditation* and demonstrate

~~a.~~ A. the availability of financial resources to effectively and thoroughly conduct regular and ongoing *certification* program activities.

~~b.~~ 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

(Note; Subsection 4.17 has been modified, and Subsection 4.18 moved; the examination administration elements addressed by these subsections have been included in Section 5)

4.0 ***Food Safety Certification Examination*** **Development**

4.1 *Food safety certification examinations* administered by *accredited ~~certifying programs~~* ~~must~~ *certification organizations* shall comply fully with all criteria set by the CFP and ~~must~~ shall meet explicit and implicit standards to protect the public from foodborne illness. The *accredited certification organization* shall provide a *food safety certification examination* that:

A. conforms to all CFP Standards for Accreditation of Food Protection Manager Certification Programs;

B. has been developed from an *item bank* of at least 1000 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* ~~must~~ shall provide evidence that it meets the following professional requirements:

~~a.~~ A. ability to conduct or otherwise use a *legally defensible* and psychometrically valid *job analysis*;

~~b.~~ B. demonstrated experience in the development of psychometrically valid *competency examinations*;

~~c.~~ C. demonstrated capability to develop and implement thorough procedures for security of the *item bank,* printed, taped or computerized examinations, ~~exam~~ examination answer sheets, and ~~candidate~~ examinee scores;

~~d.~~ D. data handling capabilities commensurate with the requirements for effective processing, reporting, and archiving of ~~candidate~~ examinee *food safety certification examination* scores; and

~~e.~~ E. demonstrated evidence of an understanding of and willingness to abide by the principles of fairness and due process.

4.3 The *certification organization* ~~must~~ 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:

~~a.~~ A complete description of the scope and usage of the examination;

~~b.~~ B. *job analysis* task list, with knowledge, skills, and abilities (KSAs*);*

~~c.~~ C. *examination specifications*;

~~d.~~ D. the number of unduplicated items in the *item bank*;

~~e.~~ E. statistical performance of each item in the bank;

~~f.~~ F. number of *examination forms* and evidence of their *equivalence* to each other;

~~g.~~ G. description of method used to set passing score;

~~h.~~ H. copies of all logs, diaries, and personnel lists and descriptions kept as f required in the development process;

~~i.~~ I. summary statistics ~~(Section 4.16 Periodic Review)~~ for each *examination form*; and

~~j.~~ 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 ~~must~~ 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 ~~must~~ shall be sufficiently diverse as to avoid cultural bias and ensure fairness in content according to all federal requirements.

4.5 The *job analysis* ~~must~~ shall provide a complete description of the knowledge, skills, and abilities (KSAs) required to function competently in the occupation of *Certified Food Protection Manager*, with emphasis on those tasks most directly related to the *Certified Food Protection Manager's* role in the prevention of foodborne illness.

4.6 Detailed *food safety certification examination* specifications ~~must~~ shall be derived from a valid study of the *job analysis* tasks and their accompanying knowledge, skills, and abilities (KSAs) and ~~must~~ shall be appropriate to all aspects of the *retail food industry*. The *job analysis* ~~must~~ shall include consideration of scientific data concerning factors contributing to foodborne illness and its epidemiology. The *examination specifications*, consisting of percentage weights or number of items devoted to each content area, ~~must~~ shall be available to ~~candidates~~ examinees and to the public.

4.7 The *certification organization* or its contracted ~~test~~ examination provider ~~must~~ 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 ~~must~~ shall be provided to the *accrediting organization* on demand.

4.8 ~~*Certifying*~~ The *certification organizations* ~~are~~ is required to systematically evaluate practices in the *retail food industry* to ~~assure~~ 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, developed jointly by the American Psychological Association, American Educational Research Association and National Council for Measurement in Education, and on all appropriate federal requirements (for example, Americans with Disabilities Act). *Food safety certification examinations* ~~must~~ 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.

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*.

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4.11 The *food safety certification examination* ~~must~~ shall be based on psychometrically valid procedures to ~~assure~~ ensure the relative equivalence of scores from various *examination forms*. The ~~*certifying*~~ *certification organization* ~~must~~ shall provide evidence of such equivalence as public information.

4.12 When the *food safety certification examination* is administered in a medium other than the common pencil-and-paper format, evidence ~~must~~ shall be provided to ~~assure~~ 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* ~~must~~ shall be provided.

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 ~~must~~ shall provide evidence of content *equivalency* of the translated version with the original *examination form* and/or *item bank*. The developer ~~must~~ shall provide a detailed description of the translation method(s), including the rationale for selecting the translation method(s), and ~~must~~ 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 languages of both the original and the translated version of the *food safety certification examination.*

4.14 *Food safety certification examination* developers ~~must~~ 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 ~~test~~ examination items and of the full examination. Those materials ~~must~~ shall be provided to the *accrediting organization* on demand.

All examinations ~~must~~ shall be delivered and administered in a format that ensures the security of the examination (i.e. in a secured environment with a *test administrator*/*proctor*.) Un-proctored examinations are not acceptable regardless of the mode of administration.

4.15 Examination Development Security. The ~~*certifying*~~ *certification organization* will demonstrate that procedures are developed and implemented to ~~assure~~ ensure that individual items, *item banks, food safety certification examinations* presented in all media (printed, taped and computerized), test answer sheets and ~~candidate~~ 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. ~~and administration process beginning with examination and item development and including, but not limited to, transportation, administration, personnel, physical security, and disposition of secure materials.~~

4.16 Periodic Review. At least semiannually each ~~*certifying*~~ *certification organization* ~~must~~ 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 ~~exam~~ examination used) administered during the preceding six months, as well as other information that may be reasonably requested by the *accrediting organization*:

~~a.~~ A number of *food safety certification examinations* administered;
~~b.~~ B. mean;
~~c.~~ C. mode;
~~d.~~ D. standard deviation;
~~e.~~ E. range;
~~f.~~ F. *reliability* coefficient;
~~g.~~ G. number and percentage of ~~candidates~~ examinees passing the examination; and
~~h.~~ H. the statistics describing the performance of each item used on *food safety certification examinations* administered during the six-month period.

4.17 ~~Specific Procedures~~ Requirements for Examination Standardization.

~~**Administration.**~~ *Certification organizations* ~~must~~ shall specify conditions and procedures for administering all *food safety certification examinations* in a standard manner ~~in order~~ to ~~assure~~ ensure that all ~~candidates~~ examinees are provided with the opportunity to perform according to their level of ~~*competency*~~ ability and to ~~assure~~ ensure comparability of scores. *Examination Booklets* shall be of high quality printing to ensure ease of reading. ~~Procedures must include, but not be limited to:~~

a. ~~requirements for qualifications of *test administrators* and *proctors* and a suitable training program for each;~~
b. ~~a complete administration manual describing each step of the test administration process and the rationale for each;~~
c. ~~clear instructions for candidates both printed for distribution to candidates and read by the *test administrator*;~~

d. high quality printing of examination booklets to assure ease of reading,

e. specification of security procedures to assure lack of exposure of test items to unauthorized persons during testing and to prevent theft of examination items
or booklets,

f. clear criteria (with rationale) for physical facilities for examination administration,

g. clear criteria (with rationale) and procedures for adaptations necessary to accommodate qualified candidates with disabilities, and

h. clear criteria (with rationale) and procedures for adaptations necessary to accommodate qualified candidates with literacy limitations that may require a reader.

4.18 A *certification organization* must have a published, written policy regarding test-site interpretation of *food safety certification exams*. If a *certification organization* chooses to allow test-site interpretation of food safety exams when an exam is not available in the candidates' native language, the *certification organization* must have a published, formal application process available to all candidates. Procedures must include but not be limited to:

a. an application process for candidates that includes an evaluation and documentation component to determine the eligibility of the candidate for test-site interpretation,

a. an application process for interpreters that includes clear and precise qualifications that must include but not be limited to the following:

i. fluent in both languages,

ii. have a recognized skill in interpretation,

iii. trained in the principles of objective test administration,

iv. have no personal relationship with the candidate (may not be another candidate, may not be a relative or friend of the candidate and may not be a co-worker, employer, or an employee of the candidate),

v. may not be a *Certified Food Protection Manager* nor have any vested interest in Food Protection Manager certification or conflict of interest,

vi. provide references or other proof attesting to the interpreter's competencies and professional acumen, and

vii. agree in writing to maintain the security of the examination.

b. must be in a proctored environment where the interpreter and candidate are not a distraction to other candidates, and

c. must be in a proctored environment where the interpreter is not active as the *test administrator* or *proctor*.

SECTION 5 – FOOD SAFETY CERTIFICATION EXAMINATION ADMINISTRATION

(Note: Sections in Standard 5 have been revised and reorganized. They are in the proposed order with the original section number struck out.)

5.0 ***Food Safety Certification Examination*** **Administration.** All sections of these *Standards* apply to Computer Based Testing (CBT) Administration except Section 5.1.

~~**5.12**~~ **5.1 Security for** ***Examination Booklets.*** ~~**Packing, Shipping, and Storage of *Examination* Materials**~~.

~~Security of the *food safety certification examination* materials must be maintained in shipments to and from the examination administration site, and must include but not necessarily be limited, and are subject to the following requirements:~~

~~a. secure, tamper resistant packing is required for all materials in all phases of shipment; packing system must be designed to reveal any tampering or violation of the package's security;~~

A. Securing *examination booklets*

1) Each individual *examination booklet* shall be secured ~~in~~ 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* ~~the~~ 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.

~~b. shipping must be done by certifiable, traceable means so that its location can be determined at any given time; and~~

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.

~~c. the packing list must show the number of packages in the shipment and the exact contents of each.~~

D. Storage by *test administrator/proctor*

The package(s) of *examination booklet*s ~~must~~ shall be ~~placed in secure storage~~ secured at all times immediately upon delivery. ~~They must be kept in secure storage both before and after they are used.~~ 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) ~~assure~~ 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.

~~5.16~~ 5.2 Test Site Requirements.

Sites chosen for administering *food safety certification examination*s ~~must~~ shall conform to all legal requirements for safety, health, and accessibility for all qualified ~~candidates~~ examinees.

A. Additionally, the accommodations, lighting, space, comfort, and work space for taking the examination ~~must~~ shall reasonably allow ~~all candidates~~ examinees to perform at their highest level ~~of *competency*~~ of ability.

~~**5.17**~~ B. Requirements at each test site include, but are not limited to:

1) ~~a~~. accessibility in accordance with the requirements of the Americans with Disabilities Act, ~~must~~ shall be reasonably available for all qualified examinees, whether ~~it be the main site for an administration or in an alternative site meeting all other requirements of the main site~~ 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) ~~b.all sites must conform~~ conformity to all fire safety and occupancy ~~codes~~ requirements of the jurisdiction in which they are located;

3) ~~c.there must be~~ sufficient spacing between each examinee in the area in which the actual ~~testing~~ examination is conducted, or other appropriate and effective methods, to preclude any examinee from viewing another examinee's ~~test~~ examination;

4)~~d.~~ acoustics ~~must allow~~ allowing each examinee to hear instructions clearly, using an electronic audio system if necessary;

5) ~~e.~~lighting at each examinee's work space ~~must be~~ adequate for reading ~~fine print~~; ~~and~~

6) ~~f.~~ventilation and temperature ~~must be~~ 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.

~~4.18~~ 5.3A *certification organization* ~~must~~ shall have a published, written policy regarding test-site ~~interpretation~~ language translation of *food safety certification* ~~*exams*~~ *examinations*. If a *certification organization* ~~chooses to allow~~ allows test-site ~~interpretation~~ language translation of a *food safety certification* ~~*exams*~~ *examination* when an ~~exam~~ *examination version* is not available in the ~~candidates' native~~ examinees' requested language, the *certification organization* ~~must~~ shall have a published, formal application process available to all ~~candidates~~ potential examinees. Procedures ~~must~~ shall include but not be limited to:

~~a.~~ A. An application process for ~~candidates~~ potential examinees that includes an evaluation and documentation component to determine the eligibility of the ~~candidate~~ potential examinee for test-site ~~interpretation~~ language translation,

~~b.~~ B. An application process for ~~interpreters~~ translators that includes clear and precise qualifications that ~~must~~ shall include but not be limited to the following:

~~i.~~ 1) being fluent in both languages;

~~ii.~~ 2) have a recognized skill in ~~interpretation~~ language translation;

~~iii.~~ 3) trained in the principles of objective ~~test~~ examination administration;

~~iv.~~ 4) have no personal relationship with the ~~candidate~~ examinee (may not be another ~~candidate~~ examinee, may not be a relative or friend of the ~~candidate~~ examinee and may not be a co-worker, employer, or an employee of the ~~candidate~~ examinee);

~~v.~~ 5) ~~may~~ not ~~be~~ being a *Certified Food Protection Manager* nor ~~have~~ having any vested interest in Food Protection Manager certification or conflict of interest;

~~vi.~~ 6) provide references or other proof attesting to the ~~interpreter's~~ translator's competencies and professional acumen; and

~~vii.~~ 7) agree in writing to maintain the security of the examination.

~~c.~~ C. ~~must be in a~~ A proctored environment where the ~~interpreter~~ translator and ~~candidate~~ examinee are not a distraction to other ~~candidates~~ examinees, and

~~d.~~ D. ~~must be in a~~ A proctored environment where the ~~interpreter~~ translator is not active as the *test administrator* ~~or~~ / *proctor*.

~~5.19~~ 5.4 Scoring. ~~and Reporting Requirements.~~ ~~Completed answer sheets and test booklets (used and unused) must be shipped by the *test administrator* according to the *certification organization*'s written security procedures.~~

~~5.20~~ ~~Scoring will be done only by means authorized by the certification organization and approved by the accrediting organization.~~

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.

~~5.21~~ B. *Food safety certification examination* scores will not be released as being official until verified and approved by the c*ertification organization*.

~~5.22~~ C. Examinee scores will be confidential, available only to the examinee and to persons or organizations approved in writing by the examinee.

~~5.23~~ D. Score reports will be available to examinees in a time frame specified in the application, which will not ~~be later than~~ 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~~ ~~The *certification organization* shall ensure that all *test administrators* and *proctors* meet the competency requirements established by the *certification organization*, and comply with all requirements of the *certification organization*.~~

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.

~~**5.3**~~ **5.8** ***Instructor/Educator/Trainer*** **as** ***Test Administrator/Proctor*****.** ~~When an instructor/educator /trainer of food safety training administers, proctors or monitors a food safety certification examination from an accredited certification program, the *accredited certification organization* shall provide a food safety certification examination that:~~

~~a. conforms to all CFP standards,~~
~~b. has been developed from an item bank of at least 600 questions, and~~
~~c. minimally on a quarterly basis, is based on a new *examination form*.~~

~~The certifying organization must have a plan that demonstrates it has controlled for item and examination exposure. The exposure plan must take into account the number of times a test item and form/version is administered.~~

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. ~~**5.18 Examination Scheduling.**~~ Schedule examinations. *Food safety certification examination*s ~~must~~ 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 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 session;
2) report possible security breaches and examination administration irregularities in compliance with the *certification organization's* policies.

~~**5.13** *Test administrators* are responsible for the organization and administration of all examination site activities and procedures, and for the accurate identification of each examinee. They are also responsible for supervision of the activities of *proctors*. When the *instructor/educator/trainer* also serves in the role of *test administrator*, it is important that the individual clearly recognizes the difference in those two roles.~~

~~**5.14** *Proctors* shall work under the direction of the *test administrator*. They have the responsibility and must have the ability to observe examinee behaviors, accurately distribute and collect test materials, and assist the *test administrator* as assigned.~~

~~**5.15**~~ **5.10** The number of approved *proctors* assigned to a *test administrator* ~~must~~ shall be sufficient to allow each examinee to be observed and supervised to ~~assure~~ 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 examinees or fraction thereof.

5.11 Examination Security

~~**5.1**~~ **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 ~~must~~ shall be accomplished in a manner that ensures fairness to all ~~candidates~~ 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.

~~**5.2 Security of *Food Safety Certification Examination* Contents.** *Food safety certification examinations* must be presented in a manner that allows absolutely no one other than the examinees to see the contents of the booklet or alternative medium, both before, and after the examination is administered.~~

~~**5.9**~~ C. Where ~~special~~ reasonable accommodations ~~must~~ shall be made for otherwise qualified ~~candidates~~ examinees under provisions of the Americans with Disabilities Act, ~~arrangements must~~ 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 ~~candidate must~~ examinee shall be provided to the *certification organization*.

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~~5.10~~ 5.12 The *certification organization* ~~must~~ 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 ~~must~~ shall be specific procedures for handling and for reporting to the ~~*accrediting*~~ *certification organization*, any suspected or alleged:

1) cheating incidents;
2) lost or stolen ~~booklets~~ examination materials~~;~~
3) intentional or unintentional divulging of ~~test~~ examination items by examinees or ~~test~~ examination administration personnel; or
4) any other incidents perceived to have damaged the security of the examination or any of its individual items.

B. Corrective actions to guard against future security breaches ~~must~~ shall be established and implemented.

C. Documentation of corrective actions and their effectiveness ~~must~~ shall be made available to the ~~accreditation body~~ *accrediting organization*.

5.8 5.13 *Item* ~~&~~ and Examination Exposure. ~~The *certification organization* must demonstrate it has controlled for item and examination exposure. An exposure plan must take into account the number of times a test item and *examination form*/version is administered, that no *examination form* is retained for any test administration or by any *test administrator/proctor* for more than 90 days; and that at all times it can account for all copies of all used and unused *examination forms* before being returned to the *certification organization*.~~

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 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.

~~5.4 *Test Administrator/Proctor* Qualifications, Training and Duties~~.

5.14 *Certification Organization's* Responsibility to *Test Administrators/Proctors.*

A. The *certification organizations* ~~must~~ shall specify the responsibilities of ~~test administrators and of proctors~~ *test administrator/proctor*, set minimum criteria for approval of *test administrators* ~~and for~~ /*proctors*, and provide ~~suitable programs of~~ a training program to enable ~~persons~~ applicants to meet ~~those~~ the approval

criteria. Responsibilities, duties, qualifications and training of *test administrators* ~~and~~ */proctors* ~~must~~ shall be directed toward assuring standardized, secure examination administration and fair and equitable treatment of examinees. ~~Policies and procedures for taking corrective action(s) when any *test administrator* or *proctor* fails to meet job responsibilities must be implemented and documented.~~

~~5.5~~ B. The *certification organization* shall define and provide descriptions for the roles of *test administrators~~,~~ /proctors,* and *certification organization* personnel ~~that will clearly delineate~~ clearly indicating the responsibilities ~~of each~~ for these roles. The *certification organization* shall demonstrate how it ensures that all certification personnel, ~~including~~ *as well as test administrators* ~~and~~ */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.

~~5.7~~ 5.15 Test Administrator/Proctor Agreements. The *certification organization* shall enter into a formal agreement with the *test administrator/proctor* ~~and shall assess and monitor the performance of *test administrators* and *proctors* in accordance with all documented procedures and agreements.~~ The formal agreement shall at a minimum ~~include,~~ address:

A. provisions that relate to code of conduct;

B. conflicts of interest; and

C. ~~a statement of~~ 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~~s~~* 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.*

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).

~~5.11~~ 5.20 Examination Administration Manual.

The *certification organization* ~~must~~ 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* apply to Computer Based Testing (CBT) Administration except Section 5.1.

6.1 Computer-Based Test Development. *Examination specifications* for *computer-based testing* ~~must~~ 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 Items ~~must~~ shall be evaluated for suitability for computer delivery, be reviewed in the delivery medium, and be reviewed in the presentation delivery medium. Assumptions ~~must~~ shall not be made that items written for delivery via a paper/pencil medium are suitable for computer delivery nor should it be assumed that computer test items are suitable for paper/pencil delivery.

6.3 When *examination forms* are computer-generated, whether in *Computer-Adaptive Testing* (CAT) or in a simple linear *algorithm*, the *algorithm* for item selection and the number of items in the *item bank* from which the examination is generated shall ~~assure~~ ensure that the items are protected from *overexposure*. Item usage statistics ~~must~~ shall be provided for all available items in the pool.

6.4 *Computer-Based Testing* Administration. Where examination environments differ (for example, touch screen versus mouse) evidence ~~must~~ shall be provided to demonstrate equivalence of the examinees' scores.

6.5 Tutorials and/or practice tests ~~must~~ 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 ~~must~~ shall be demonstrated. Data ~~must~~ shall be gathered and continually analyzed to determine if scoring methods are comparable.

6.7 Evidence of security in the *computer-based testing* environment ~~must~~ 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 ~~must~~ shall be provided.

6.9 Policies and procedures regarding the recording and retention of the *item sequence* and item responses for each examinee ~~must~~ shall be developed and followed. Computer examinations using a unique sequence of items for each examinee ~~must~~ shall

record the information necessary to recreate the sequence of items and examinee responses on the computer examination.

6.10 Systems and procedures ~~must~~ shall be in place to address technical or operational problems in examination administration. For example, the examination delivery system ~~must~~ 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) ~~must~~ shall be developed.

6.11 Due Process. ~~Candidates must~~ Examinees shall be provided with any information relevant to *computer-based testing* that may affect their performance or score. Examples of such information might include but not be limited to: time available to respond to items; ability to change responses; and instructions relating to specific types of items.

SECTION 7.0 – CERTIFICATION ORGANIZATION RESPONSIBILITIES TO ~~CANDIDATES~~ EXAMINEES AND THE PUBLIC

7.0 A ~~C~~*certification* ~~O~~*organization's* Responsibilities to ~~Candidates~~ Examinees **and the Public.**

7.1 Responsibilities to Applicants for *Certification*. A ~~*certifying*~~ *certification organization* shall:

~~a.~~A. not discriminate among applicants 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.~~B. make available to all applicants information regarding formalized procedures for attainment of *certification* and provide evidence to the *accrediting organization* of the implementation of the policy;

~~c.~~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 organization of the implementation of the policy ~~(Section 4.17)~~;

~~d.~~D. provide evidence that competently proctored testing sites are readily accessible ~~(Section 5.4)~~;

~~e.~~ E. provide evidence of uniformly prompt reporting of *food safety certification examination* results to applicants ~~(Section 5.19, 5.9, 5.11 and 5.12)~~;

~~f.~~ F. provide evidence that applicants failing the *food safety certification examination* are given information on general areas of deficiency;

~~g.~~G. provide evidence that each applicant's *food safety certification examination* results are held confidential ~~(Sections 4.0 5.17 and 5.18)~~; and

~~h.~~H. have a formal policy on appeals procedures for applicants 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 ~~must~~ 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 years.

~~**7.3 Effective Date of *Certificate*** *Certificates* issued and electronic listing of *certificate* holders maintained by *accredited certification programs* shall identify the *food safety certification examination* form recognized by the *accrediting organization* and specify the date the examination was taken.~~

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*.

~~**7.4 Replacement or Duplicate *Certificate*.** Replacement or duplicate *certificates* issued through an *accredited certification program* shall carry the same effective date as the original, with an expiration worded in such a manner that indicates the *certification* will be valid for no more than five years.~~

7.5 Discipline of *Certificate* Holders and Applicants. 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 ~~must~~ 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* ~~must~~ shall have a published protocol for systematically investigating problems presented by users of the Program, including specific concerns about examination items, administration procedures, treatment of ~~candidates~~ 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 ORGANIZAION RESPONSIBILITIES TO THE ACCREDITING ORGANIZATION

8.0 ***Certification Organization*** **Responsibilities to the** ***Accrediting Organization*****.**

8.1 ~~*Certifying*~~ *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.~~A. ~~The~~ the name and complete ownership of the *legal entity*.

~~b.~~B. ~~The~~ the address, telephone/fax number(s) and other contact information of the *certification organization's* headquarters.

~~c.~~C. ~~The~~ 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.~~D. ~~Such~~ such fiscal information as may be needed to establish evidence of ability to carry out obligations under these standards.

8.2 **Summary Information.** A ~~*certifying*~~ *certification organization* shall:

~~a.~~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* ~~(Sections 4.3 and 4.4)~~;

~~b.~~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* ~~(Sections 4.3, 4.4 and 4.6)~~;

~~c.~~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 ~~(Section 4.9)~~;

~~d.~~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* ~~(Sections 4.8 and 4.16)~~;

~~e.~~E provide evidence that appropriate measures are taken to protect the security of all *food safety certification examination*s ~~(Sections 5.2 through and including 5.15)~~

~~f.~~ F publish a comprehensive summary or outline of the information, knowledge, or functions covered by the *food safety certification examination* ~~(Section 4.6)~~;

~~g.~~G make available general descriptive materials on the procedures used in examination construction and validation and the procedures of administration and reporting of results ~~(Section 4.7)~~; and

~~h.~~H compile at least semi-annually a summary of *certification* activities, including number of applicants, number tested, number passing, number failing, and number certified ~~(Sections 4.16)~~.

8.3 Responsibilities to the *Accrediting Organization*. The *certification organization* shall:

~~a.~~A. make available upon request to the *accrediting organization* copies of all publications related to the *certification* program,

~~b.~~B. advise the *accrediting organization* of any proposed changes in structure or activities of the ~~*certifying*~~ *certification organization*,

~~c.~~C. advise the *accrediting organization* of substantive change in *food safety certification examination* administration,

~~d.~~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.~~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.~~ F submit to the *accrediting organization* the report requirements information specified for the Food Protection Manager *Certification* Program, and

~~g.~~G be re-accredited by the *accrediting organization* at least every 5 years.

SECTION 9.0 – MANAGEMENT SYSTEMS

9.0 Each c*ertification* o*rganization* shall have a formal management system in place to facilitate continuous quality improvement and produce preventive and corrective actions.

9.1. **The management system** shall contain the following three components.

A. Document control to include:
   1) lists of all documents pertaining to the certification organization;
   2) dates for documents approved for implementation by the certification organization;
   3) the person(s) within the certification organization responsible for the documents; and
   4) listing of individuals who have access to the documents.

B. Internal audits to include:
   1) identification of critical activities;
   2) data collection process and evaluation schedule;
   3) audit methodology and evaluation process;
   4) the person(s) authorized to perform audits; and
   5) report audit findings and identify corrective action required.

C. A Management Review that includes:
   1) a documented annual review of internal audit results;
   2) a management group that conducts the review;
   3) a review of the audit results to determine corrective actions needed;
   4) a review of the audit results to determine preventive actions needed; and
   5) the effectiveness of corrective and preventive actions taken.

ANNEX A

Responsibilities of the Professionals Involved in the Credentialing Process for Certified Food Protection Managers

Accepted June 1997

Recognizing that the justification for regulating entrance to the occupation of *Certified Food Protection Manager* is to protect the safety and welfare of the public; and

recognizing that the responsibility and liability for overseeing the protection of safety and welfare of the public lies with those governmental jurisdictions at Federal, state and local levels having the power to set forth laws regulating entrance to and performance in occupations; and

recognizing that the rights of the public at large and of those members of that public who wish to enter an occupation ~~must~~ 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

recognizing that the *validity* of any credentialing process for *Certified Food Protection Manager*s 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 ~~assure~~ ensure that individuals have achieved mastery of the competencies;

therefore, professionals involved in the credentialing process for *Certified Food Protection Manager*s accept responsibilities based on those considerations.

Assessment tools will 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 ~~candidate~~ examinee scores.

Actual or potential conflicts of interest that might influence judgment or performance of examination developers, *test administrators ~~or~~ / proctors, ~~instructors/trainers/educators~~*, *instructors/educators/trainers* or other participants in the credentialing process will be disclosed.

Items for *competency* assessments will be selected to be a representative sample of the full spectrum of the competencies determined by the CFP and by federal guidelines to be

necessary to protect the public from foodborne illness, regardless of the training/education program undertaken by the applicants being tested.

Training/education will be based upon the full spectrum of the competencies agreed upon as being necessary to protect the public from foodborne illness, unbiased by any knowledge of the contents of the *competency* assessment for the credential.

Administration of the assessment instrument will be done with professional attention to security of the *food safety certification examination* to ~~assure~~ ensure current and continued *validity* of the examination and of the credential that is earned through its use.

Professionals and organizations will develop and implement full quality assurance procedures to ensure the accuracy of assessment decisions and the integrity of the entire credentialing process.

The rights of those who are assessed will be recognized and protected.

ANNEX B

Guidelines for Regulatory Authorities Implementing Food Protection Manager Certification Programs

B1. 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.

B2. A *Certified Food Protection Manager* is responsible for:

a. identifying hazards in the day-to-day operation of a *food establishment*;

b. developing or implementing specific policies, procedures or standards aimed at preventing foodborne illness;

c. coordinating training, supervising or directing food preparation activities and taking corrective action as needed to protect the health of the consumer; and

d. conducting in-house self-inspection of daily operations on a periodic basis to see that policies and procedures concerning food safety are being followed.

B3. **Qualifications for *Certification*.** To become a *Certified Food Protection Manager*, an individual ~~must~~ shall pass a *food safety certification examination* from an accredited ~~*certifying* program~~ *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.

B4. 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*.

NOTE: additional changes to Article and Section numbering may be necessary following final approval of proposed Bylaw changes.

Food Protection Manager Certification Committee Bylaws

Preamble

The Food Protection Manager Certification Committee, hereinafter referred to as the Committee, of the Conference for Food Protection, hereinafter referred to as the Conference, exists to carry out charges assigned via the Conference Issue process and from the Conference Executive Board, hereinafter referred to as the Board, relating to food protection manager training and certification ~~issues~~ and operates within the objectives stated in the Constitution and Bylaws of the Conference.

Article I. Name.

The Name of the Committee is Food Protection Manager Certification Committee.

Article II. Objectives.

Section 1. Systematically identify and address issues concerning Food Protection Manager Certification Programs.

Section 2. Adopt sound, uniform accreditation standards and procedures that are accepted by the Conference.

Section 3. Promote uniformity among all jurisdictions that subscribe to the principles of the Conference by obtaining their recognition and adoption of the Conference Standards for Accreditation of Food Protection Manager Certification Programs.

Section 4. Promote strategies to enhance equivalence among food protection manager certificates issued by certifying organizations.

Section 5. Establish and refine policies and standards to which certifying organizations shall conform.

Article III. Organization and Operation.

Section 1. The Committee is a standing committee within the Conference ~~and as such shall receive its charges from the Board~~.

Section 2. The Committee shall consider all ~~issues~~ Issues charged to the Committee ~~by the Board. The committee~~ and shall work to develop consensus. The Board may submit charges to the Committee at any time. The Committee is to deliberate the charges expeditiously, or within the time frame determined by the Board or the Committee Chair.

Section 3. The Committee shall use the protocol established in these Bylaws to address its charges ~~from the Board~~.

Section 4. All Committee recommendations shall be submitted as Issues to the Conference for deliberation. The Committee shall follow the protocol for Issue submission as established ~~in the Conference Bylaws~~ by the Conference.

Section 5. All ~~issues~~ Issues, intellectual properties, and/or inventions created by the Committee and approved by the ~~voting a~~ Assembly of ~~the Conference~~ Delegates become the property of the Conference.

Article TBD. Quorum

A quorum to conduct Committee meetings and conference calls shall be the presence or participation of one more than half of the filled Committee positions**.** A Committee quorum shall be considered a sufficient number for voting on issues under deliberation. The decisions resulting from a quorum vote shall be deemed representative of the Committee.

Article IV. Composition of Organizational Components and Eligibility Requirements for Serving in Official Capacities.

Section 1. The Committee shall be chaired by a Chair and Vice-Chair. Prior to each biennial Conference meeting, ~~T~~the incoming Chair and Vice-Chair shall be selected by the outgoing committee. The Chair, Vice-Chair and committee members ~~appointed by the Chair of Council II and~~ shall be approved by the Board.

~~Section 2. The Council II Chair shall select the Committee Chair and Vice-Chair.~~ The Chair and Vice-Chair shall not be selected from the same ~~group~~ constituency affiliation.

Section 2 ~~3~~. The Committee Chair and Vice-Chair shall serve until the conclusion of the next biennial Conference meeting. ~~At the conclusion of the conference meeting, the incoming Council II Chair will initiate the selection process for the Chair and Vice-Chair of the Committee.~~

Section 3 ~~4~~. The Committee Chair and Vice-Chair may serve consecutive terms with approval of the Board ~~at the discretion of the Council II Chair. The Council II Chair shall obtain recommendations from members of the Committee on qualified candidates~~.

Article V. Committee Structure and Representation.

Section 1. To be eligible to serve on the Committee as a voting member or non-voting alternate, individuals must commit in writing to active participation and be approved by the Conference Chair and the Board.

Section 2. The Committee Chair and Vice-Chair~~, and/or Council II Chair~~ will select committee members and alternates from the list of volunteers or recruit volunteers as appropriate to balance the committee as delineated ~~under Article IV. Committee Structure and Representation~~ in these Bylaws. In the event of a Committee vacancy with no designated alternate in that constituency, the Chair will first recruit from the remaining list of volunteers provided during the initial Committee selection process.

Section 3. The composition of the Committee is a balanced representation of industry, regulatory, academia, certification ~~providers~~ organizations, training providers, and consumers. The Committee membership representation shall consist of a maximum of ~~twenty-eight (28)~~ thirty (30) full ~~members~~ votes from the following constituencies ~~in addition to the Chair and Vice-Chair~~:

Subsection 1. Nine (9) representatives from regulatory agencies with food safety responsibilities:

a. Two (2) from State regulatory agencies;

b. Two (2) from local regulatory agencies;

c. Two (2) from federal government agencies;. ~~with retail food program responsibilities.~~

d. Three (3) "At Large" appointments;. ~~(*At Large representation – agencies with primary regulatory food safety responsibilities.)~~

Subsection 2. Nine (9) industry representatives:

a. Three (3) from the foodservice (restaurant) industry;

b. Three (3) from the retail food store industry; and

c. Three (3) "At Large" appointments. (*At large selections may include professional or trade organizations that directly represent the restaurant, retail food, institutional foodservice, and food vending segments of the industry, and whose mission incorporates a public health protection component.)

Subsection 3. ~~Three (3)~~ Five (5) total votes for certification ~~providers~~ organizations that are accredited by the Conference's accreditation process. All accredited certification organizations who volunteer will be given a voting position on the Committee; if more then five (5) organizations participate on the Committee, fractional but equal voting rights will be calculated as established in these Bylaws;

Subsection 4. Three (3) Food Protection Manager training providers;

Subsection 5. Two (2) representatives from academia, and

Subsection 6. Two (2) consumer/independent representatives/public members.

Section 4. Committee members will serve a two (2) year term, concurrent with the cycle of the biennial Conference meeting. Committee members are eligible to serve for consecutive terms contingent upon

~~Subsection 1. Indication of written interest to serve on the Committee.~~

~~Subsection 2. The availability of membership based on the representation requirements set forth in Article IV, Section 1.~~

~~Subsection 3. A~~an assessment by the Committee Chair and ~~Council II Chair,~~ Vice-Chair~~, and the incoming Chair of the Committee~~ to ensure a balance between members who have previously served on the Committee and new members.

Section 5. ~~In the event of a surplus or insufficient number of volunteers in a category, the Council II Chair may consult with the outgoing Committee Chair to identify potential candidates for appointment to the Committee.~~ Up to two (2) non-voting alternates will be included on the Committee roster each for industry, regulatory, academia, training providers, and consumers to best represent the category of each constituency. Each certification organization participating on the Committee may designate one (1) alternate from their own organization.

Section 6. The incoming Chair of the Committee shall make every effort to retain at least 50% of the Committee membership for a continuing term. This retention is recommended due to the complexity of issues, the need to retain continuity of Committee functions, and the short time frame between biennial Conference meetings.

Section 7. In the event a Committee member changes constituency during their term, the Chair may consider them for any open seat on the Committee which needs representation from their constituency or consider any open alternate position. If the Chair determines that there are no appropriate openings available, the Committee member will be asked to resign from the committee.

Article VI. Committee Organization, Operation, and Meetings

Section 1. The Committee shall receive its direction from the Board. The Board shall assign the Committee its charges as ~~ratified~~ approved during the biennial Conference meeting. The Board may assign additional charges to the Committee to ensure that the Conference Standards for Accreditation of Food Protection Manager Certification Programs and accreditation process are administered in a fair and responsible manner.

Section 2. The Committee shall meet at least annually and at the biennial Conference meeting. All Committee meetings are open to anyone to attend. In addition to

meetings, the Committee shall schedule conference calls, as deemed appropriate, for addressing issues under deliberation. In the event that sensitive, financial or proprietary information is under consideration by the Committee, the Chair shall have the option to conduct ~~a closed~~ an executive session until the confidential portion of the proceedings has been concluded.

~~Section 3. Committee meetings shall be conducted under the direction of the Chair. The Committee Chair shall call and preside at all meetings of the Committee.~~

~~Section 4. When the Committee Chair is absent, is unable to act, or refuses to act, the Vice-Chair shall perform the duties of the Committee Chair. When the Vice-Chair acts in place of the Chair, the Vice-Chair shall have all the powers and be subject to all restrictions upon the Committee Chair.~~

~~Section 5. A modified Robert's Rules of Order shall provide the framework for conducting Committee meetings and deliberations. The modification will allow some discussion between Committee members without having Chair recognition before entering into the dialogue. The Chair may at any time, request that Committee members be recognized before speaking to maintain an orderly process~~

~~Section 6. Guests and/or observers shall be recognized by a Committee member and/or the Chair before addressing the Committee.~~

Section 3 ~~7~~. In addition to the charges ~~and issues~~ received from the Board, Committee members may submit ~~issues~~ Issues and alternative recommendations to the Committee for discussion. Issues and recommendations introduced by Committee members shall be submitted using the Conference format.

- ~~State the problem or issue.~~
- ~~Discuss the key impacts of the issue on the accreditation process or Food Protection Manager Certification Programs.~~
- ~~Provide a recommended solution to the issue. All alternative positions to Committee issues must be presented with a clear recommended solution.~~

~~Section 8. The Committee Chair may designate ad hoc workgroups to conduct research, study proposals, develop procedures or recommendations related to complex issues and/or charges. Workgroups shall provide written reports and recommendations to the Committee for deliberation.~~ *(note – moved to Article VII, section 8)*

~~Section 9. A quorum to conduct Committee meetings and conference calls shall be the presence of one more than half of the filled Committee positions. A Committee quorum shall be considered a sufficient number for voting on issues under deliberations. The decisions resulting from a quorum vote shall be deemed representative of the Committee. In the event of a lack of a quorum, the Chair may vote to make up the quorum.~~ *(note – moved to New Article)*

~~Section 10. When a quorum of the Committee participates in a meeting or a conference call the Chair may call for a vote by the Committee on the motions before it.~~

Section 4 ~~11~~. Voting.

Subsection 1. A consensus building decision process will be used. When Committee members are asked to vote, each member will be able to express one of three positions.

- A thumb up indicates agreement with the issue on the floor
- A thumb sideways means the position on the floor is not the member's optimal solution, but they can accept the position
- A thumb down indicates that a member does not agree with the issue on the floor and would like an alternative recommendation considered.

The Committee Chair shall provide an opportunity for the dissenting member(s) to express the alternative position(s). After discussion of these alternative positions, the Chair will call for a final vote from the Committee.

Subsection 2. Except for certification organizations, all voting Committee members and alternates designated for that meeting shall have one (1) vote.

Subsection 3. All certification organizations accredited by the Conference's accreditation process participating on the Committee shall not to exceed a total of five (5) votes.

- If more than five (5) certification organizations volunteer to participate on the Committee, the five (5) votes allocated to certification organizations shall be fractionalized (evenly divided).
- The voting fraction shall be determined when the final committee membership is approved by the Board and shall remain in effect until the next biennial Conference meeting.
- Each certification organization shall be allowed no more than one (1) vote or one (1) voting fraction at any meeting.

~~Section 12~~ Subsection 4. The Vice-Chair may voice positions on issues~~. When the Committee Chair conducts a meeting, the Vice-Chair~~ and may vote on all matters before the Committee.

~~Section 13~~ Subsection 5. The Chair is a non-voting member of the Committee~~, with the following exceptions. In the event of a tie when the Committee Vice-Chair is not present and the process must go forward, the Chair may cast the deciding vote. The Chair may vote in the event a quorum is needed. I~~; however, in the event of a tie, the Chair may vote as the tie-breaker.

~~Section 14. The Chair may obtain affirmation from the Committee on some administrative items without proceeding through the formal motion, discussion and voting process defined in Robert's Rules of Order.~~

Section ~~1~~5. Committee funding. The Board may allocate funds to the Committee for its charges. These funds may be used to contract the services of outside experts to assist the Committee, attend meetings with potential accreditation entities, and other miscellaneous expenses that the Committee must incur, e.g., use of meeting rooms. Funding shall not be allocated to cover an individual Committee member's travel or per diem expenses to attend meetings ~~unless such expenditures are deemed essential to the completion of the Committee's charge. Expenditures to fund a Committee member's travel expenses must receive the concurrence of two-thirds (2/3) of the voting members of the Committee~~. Committee funding may be used only as directed by the Board.

Article VII. Duties of the Committee Chair

Section 1. The Chair and Vice Chair, with the approval of the Board ~~and the Council II Chair~~, shall select Committee members in accordance with ~~Article IV~~ these Bylaws.

Section 2. The Chair, with concurrence of two-thirds (2/3) of the voting members of the Committee may appoint non-voting Ex-Officio consultants and advisors to the Committee in accordance with ~~Article VIII~~ these Bylaws.

Section 3. The Chair shall preside at all meetings of the Committee, except as provided in ~~Article VII, Section 1~~ these Bylaws.

Section 4. The Chair shall coordinate the arrangement of meetings and conference calls and ensure that meeting dates and locations are posted in advance on the Conference web site.

Section 5. The Chair shall be responsible for distributing to Committee members and other meeting participants an agenda for the meeting or conference call. This agenda may be distributed by email, fax, mail, or other suitable means.

Section 6. The Chair may assign a Committee member, using a rotation basis or other appropriate means among all Committee members, to take minutes during designated meetings and conference calls.

Section 7. The Chair shall be responsible for distributing minutes of all Committee meetings or conference calls in a timely manner, usually within three weeks of the event.

~~Section 8. The Chair shall be responsible for preparing written or oral reports to the Board detailing the activities and expenditures of the Committee. The Chair shall be called upon to report at the biennial Conference meeting on the activities of the Committee.~~

Section 8. The Chair may designate ad hoc workgroups to conduct research, study proposals, and develop procedures or recommendations related to complex issues and/or

charges. Workgroups shall provide written reports and recommendations to the Committee for deliberation. *(note – moved from Article VI, section 8)*

~~Section 9. The Chair shall provide an annual written Committee budget report to Committee members and the Board.~~

Article VIII. Duties of the Committee Vice-Chair

Section 1. In the event the Chair is unable to perform the duties of the Chair, the Vice-Chair shall act as Chair.

Section 2. When acting as Chair, the Vice-Chair shall perform all the necessary duties for the Committee as outlined in ~~Article VI~~ these Bylaws.

Section 3. The Vice-Chair shall perform all duties assigned by the Chair.

Article IX. Duties of Committee Members / Alternates

~~Section 1. A Committee member's tenure shall be carried out in accordance with Article IV, Section 2.~~

Section 1 ~~2~~. Committee members shall have the responsibility to notify the Committee Chair of their inability to attend a meeting or participate on a conference call at least fifteen (15) days prior to the scheduled meeting or conference call. For any committee member that is unable to attend a scheduled meeting or conference call, an alternate will be assigned. Selection of the designated alternate will be agreed upon by the Committee Chair and the absent member and chosen to best represent the constituency of the absent member. ~~The member may submit in writing a designated representative in his/her place to the Chair.~~ This designated alternate may vote on issues before the committee only during the specified meeting or conference call.

Section 2 ~~3~~. Committee members ~~or designated representative~~ and alternates shall have the responsibility to review for comment standards, reports, recommendations, issues or other Committee documents distributed within the time frames designated by the Committee.

Section 3 ~~4~~. Committee members ~~or designated representative~~ and alternates shall have the responsibility to complete work assignments within time frames designated by the Committee.

Section 4 ~~5~~. Committee members ~~or designated representative~~ and alternates shall have the responsibility to notify the Committee Chair or the Chair's designee of their inability to complete a work assignment.

Section 5 ~~6~~. Committee members that do not participate ~~or provide a designated representative~~ for three (3) consecutive meetings and/or conference calls shall have their continued participation as Committee member assessed by the Committee Chair and evaluated by the Committee. The Committee member may be subject to being removed from their membership position. Removal of a Committee member for failure to perform duties as specified in ~~Article VIII~~ these Bylaws, shall require the concurrence of two-thirds (2/3) of the voting members of the Committee.

Article X. Committee Consultants and Advisors

Section 1. The Committee may contract the services of a consultant for issues beyond the scope of the Committee's expertise, if deemed necessary or if charged by the Board. The Committee Chair may identify a consultant or assign a consultant to an ad hoc workgroup with the approval of the full Committee.

Section 2. Contractual obligations for consultant services shall have the concurrence of two-thirds (2/3) of the voting members of the Committee and be approved by the Board.

Section 3. Committee consultants and Conference appointments to the Accreditation Committee shall serve as non-voting Ex-Officio members of the Committee.

~~Section 4. Funds for outside consultants shall come from the Committee budget, as determined by the Board.~~

Section 4. The Chair and Vice-Chair may invite, with approval from the Committee, advisors or subject matter experts to participate in meetings and conference calls, if it is determined that such individuals would provide additional information, insight, clarification, guidance or other assistance to the Committee, for a specified purpose. These advisors or subject matter experts will be non-voting guests in meetings and conference calls.

Article XI. Workgroups

Section 1. The Committee Chair may designate ad hoc workgroups to address the charges of the Board and complete the duties of the Committee.

Section 2. Each workgroup shall select a group leader who is responsible to report group activities to the Committee Chair and Vice-Chair.

Section 3. Workgroups shall report to the Committee Chair and Vice-Chair as determined by the Committee Chair. These reports shall also be disseminated to the full Committee.

Article XII. Committee Reports

Section 1. The Committee Chair shall be responsible for preparing written or oral reports to the Board detailing the activities and expenditures of the Committee. *(note – moved from Article VII, duties of the chair)* Written reports ~~submit a status report~~ of the Committee's activities shall be submitted ~~to the Council II Chair no later than thirty (30) days prior to the Board meetings~~ as required by the Conference procedures.

Section 2. The Committee Chair shall coordinate the development of a final report of the Committee activities to ~~the~~ Council II with recommended actions. The final report shall be done ~~in advance of the Conference meeting~~ as part of an Issue submission and~~. The submitted Issue containing the report~~ shall comply with all ~~the~~ Conference procedures ~~and time lines pertaining to the submission of Issues for deliberation~~.

Section 3. The Committee Chair, Vice-Chair, or ~~the Committee Chair's~~ designee as specified in writing to the ~~Chair of~~ Council II Chair, shall be in attendance when Council II meets during the Conference meeting to present and discuss the Committee's report and any ~~issues~~ Issues submitted by the Committee.

Article XIII. Amendments

The Food Protection Manager Certification Committee Bylaws may be altered, amended, or repealed by two-thirds (2/3) vote of the Committee and final concurrence from the Board. An ad hoc ~~task~~ workgroup chaired by the Vice Chair may be appointed by the Chair of the Committee to make recommendations to the Bylaws for consideration by the Board.

CFP Food Protection Manager Certification Committee Bylaws
Revised Bylaws approved 2010 ~~Conference~~ Biennial Meeting

Committee Name:
Food Protection Manager Certification Committee

First Name	Last Name	Company /Employer Name	City	State	Role
Julie	Albrecht	Univ of Nebraska/ Lincoln, Nutrition & Health Sciences Dept	Lincoln	NE	Member
Rose Mary	Ammons	Environmental Health Testing (National Registry)	Tampa	FL	Alternate
Anthony	Carotenuto	Navy and Marine Corps Public Health Center	Portsmouth	VA	Member
Lee	Cornman	FL Dept of Agriculture & Consumer Services	Tallahassee	FL	ACAC Representative
Larry	Edwards	FDA/ORA/Retail Food Specialist	Falls Church	VA	Alternate
Vicki	Everly	(Retired) Santa Clara Co Environmental Health		CA	Member
Ron	Grimes	NSF International	Ann Arbor	MI	Member
Patrick	Guzzle	Idaho Dept of Health and Welfare	Boise	ID	Member
Aggie	Hale	Fl. Dept. of Agriculture	Tallahassee	FL	Member
Jeffrey	Hawley	Harris Teeter, Inc.	Matthews	NC	Vice-Chair
Paul	Hineman	National Restaurant Association Solutions	Chicago	IL	Alternate
Lynn	Hodges	USDA-Office of Outreach, Education & Employee Training	Dallas	TX	Advisor
Christine	Hollenbeck	NEHA Entrepeneurial Zone	Denver	CO	Member
Keith	Jackson	Performance Food Group	Richmond	VA	Member
Joyce	Jensen	Lincoln-Lancaster Co. Health Dept	Lincoln	NE	Chair
Teresa	Lee	City of Rosenburg	Rosenburg	TX	Member
Geoff	Luebkemann	Florida Restaurant & Lodging Association	Tallahassee	FL	Member
Larry	Lynch	Environmental Health Testing (National Registry)	Orlando	FL	Member
Thomas	McMahan	Supervalu, Inc.	Boise	ID	Member
David	McSwane	Indiana University	Indianapolis	IN	Member
Cassandra	Mitchell	Fairfax County Health Department	Fairfax	VA	Member
Dianna	Pasley	Schnuck Markets, Inc.	St. Louis	MO	Member
Tara	Paster	Paster Training, Inc.	Pottstown	PA	Member
Kate	Piche'	National Restaurant Association Solutions	Chicago	IL	Member
Susan	Quam	Wisconsin Restaurant Association Education Foundation	Madison	WI	Member
Todd	Rossow	Publix Super Markets, Inc.	Lakeland	FL	Member
George	Roughan	TAP Series, LLC	Agoura Hills	CA	Member
Davene	Sarrocco-Smith	Lake County General Health District	Painesville	OH	Member
Roy	Swift	American National Standards Institute	Washington	DC	ANSI Representative
Bill	Vear	MindLeaders, Inc.	Dublin	OH	Member
Kenneth	Walters	Prometric	St. Paul	MN	Member
Patricia	Welch	Illinois Department of Public Health	Springfield	IL	Member
Brian	Wickman	Compass Group	Clyde Twp	MI	Member
Lauire	Williams	FDA/CFSAN/Office of Food Safety	College Park	MD	Advisor
Sharon	Wood	H-E-B Grocery Company	San Antonio	TX	Member

Conference for Food Protection
2012 Issue Form

Internal Number: 081
Issue: 2012 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.

Title:
Standards - Non-Substantive Revisions

Issue you would like the Conference to consider:
The FPMC Committee, in addition to making substantive revisions to address examination security *(see Issue titled: Standards - Strengthening Exam Security),* felt that the *Standards* needed additional revisions for consistency, clarity, and accuracy. In addition, a new numbering system is being proposed. These changes do not change any of the intent or current application of the *Standards* as they relate to the accreditation process. They do, however, make the Standards a better document.
Revisions include:

- Correctly referencing the Biennial meeting of the Conference for Food Protection
- Consistently referencing "certification organizations" which were sometimes referred to as "certifying organizations" or "certifying programs."
- Consistently referencing "test administrator/proctor" which was sometimes referred to as "test administrator and proctor" or "test administrator or proctor."
- Consistently referencing "examinee" which was sometimes referred to as "candidate."
- Consistently referencing "examination" which was sometimes referred to as "test" or "exam."
- Replacing the word "must" with "shall."
- Replacing the word "assure" with "ensure."
- Correcting typos and text errors.
- Correcting the section numbers of the FDA Food Code referenced in the preamble.
- Removing references to other sections of the Standards within the Standards.
- Revising the numbering scheme within the S*tandards*' Sections.

In addition, the *Standards* Table of Contents and page numbers will be revised as needed based on the revisions approved in April 2012.
As these are non-substantive revisions to the *Standards,* exact language changes can be found in the FPMCC Final Report attachment, *Standards for Accreditation of Food Protection Manager Certification Programs* with Committee proposed revisions.

Public Health Significance:

Food establishments have fewer critical risk factors according to the CDC as stated in the endorsement letter to the Conference (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*. http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf

Recommended Solution: The Conference recommends...:

approval of the non-substantive revisions to the *Standards for Accreditation of Food Protection Manger Certification* for improving consistency, clarity, and accuracy within the *Standards* and establishing a new numbering system.

Exact language changes are found in the FPMCC Final Report attachment, *Standards for Accreditation of Food Protection Manager Certification Programs* with Committee proposed revisions (January 5, 2012 draft).

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 079
Issue: 2012 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.

Title:
Standards - Strengthening Exam Security

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 significantly strengthen the examination security by modifying or creating standards to address the following recommendations from the FPMCC Workgroup.

- Exam Development - Increase the exam form item bank from 600 to 1000.
- Test Administrator/Proctor's Roles and Responsibilities - Clearly delineate all Test Administrator/Proctor roles and responsibilities.
- Training of Test Administrators/Proctors - Require the certification organizations to provide a training program for Test Administrators/Proctors based on learning objectives that reflect their roles/responsibilities.
- Verification of Test Administrators - Require certification organizations to notify ANSI when Test Administrator/Proctor has been removed.
- Exam Item Exposure - Require certification organizations to have a system to track all examinations (exam books and/or answer sheets).
- Exam Shipping and Handling - Restructure Standards to include provisions that ensure security for all shipping and handling of exams by certification organizations and Test Administrators/Proctors.
- Test Sites - Require a private room accessible only to Test Administrator/Proctor/Examinees during test administration.
- Certificates - Require certification organizations to have a system to provide verification to the current validation of individual certificates.
- Advertising Standards - Test Administrator/Proctor cannot make statements or claims, nor have affiliation with any organization making statements or claims such as guarantees of passing the exam.
- Management Systems - Include a new section to the Standards that contains requirements for the implementation of management systems that include document control, internal audits, and management review.

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*.
http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf

Recommended Solution: The Conference recommends...:
approval of revisions to the *Standards for Accreditation of Food Protection Manager Certification Programs* to address examination security and increase the credibility of the Food Protection Manager Certification.
All language and modifications are contained within attached document titled: "Recommended Solutions - Strengthening Exam Security" extracted from the document titled "*Standards for Accreditation of Food Protection Manager Certification Programs* with Committee Proposed Revisions" which is attached to the Issue titled "Report - FPMCC."
A summary of the changes include:
A. In the Preamble, revise the "Modifications and Improvements" section.
B. In *"*Section 1.0 - Definitions" - add specified definitions.
C. In *"*Section 4.0 - Food Safety Certification Examination Development" - revise Subsections 4.1 and 4.17 and move the components of 4.18 to Section 5.
D. In *"*Section 5.0 - Food Safety Certification Examination Administration" - reorganize, revise, replace, and add subsections as noted.
E. In *"*Section 7.0 - Certification Organization Responsibilities to Candidates and to the Public" - replace sections 7.3 and 7.4 with a new section.
F. Add a new "section 9.0 - Management Systems."
The Conference also recommends that the revised *Standards for Accreditation of Food Protection Manager Certification Programs* be posted to the CFP web site.

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Attachments:

- "Recommended Solutions - Strengthening Exam Security"

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.

The Conference recommends approval of the following revisions to the *Standards for Accreditation of Food Protection Manager Certification Programs* to address examination security and increase the credibility of the Food Protection Manager Certification (using underline format for new language and strikethrough for deleted language).

All language has been extracted from the document titled: "Draft of Revised Standards 12 9 2011" attached to the Issue titled: "Report - FPMCC."

A. In the *Standards* Preamble, revise the "Modifications and Improvements" section as follows:

The FPMC Committee followed the Conference directive to use the 1996 conference working document, Standards for Training, Testing and *Certification* of Food Protection Managers, in the development of accreditation standards. Extensive revision of this document was presented to CFP's ~~2000, and 2002~~ 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* to enhance the integrity of the entire testing process, which includes identification and analysis of root causes of security violations and implement solutions.

The revision and reformatting of the document were made after a comprehensive FPMC Committee review of each section. ~~The~~ This revision of the Standards for *Accreditation* of Food Protection Manager *Certification* Programs:

1. adds and improves definitions that are more precise and more consistent with terminology and definitions used in the *psychometric* community and by accreditation organizations;

~~2. italicizes defined terms throughout the document;~~

~~3. eliminates ambiguities in the 1996 conference working document pertaining to test development and administration;~~

4. ~~identifies *certification organization* responsibilities to candidates, the public and the *accrediting organization*;~~

~~5. adds computer-based test standards; and~~

6. ~~clarifies demonstration of *continued proficiency*;~~

2. modifies or creates *Standards* to better address professional credibility and training of test administrators/proctors; handling of examination packages; shipping irregularities; location (site) irregularities; and breach of the certification organization's test administrators/proctors protocols and requirements;

3. uses "*test administrator/proctor*" in the *Standards* to indicate duties for both "*test administrator*" and "*proctor;*" and

4. adds a standard for management systems.

B. In the *Standards* "Section 1.0 – Definitions" – add the following definitions:

1.18 Examination Booklet means the paper version of the *food safety certification examination*.

1.22 Exposure Plan means the policies and procedures in place to ensure that examination items are not exposed to examinees or other people that may result in an examination item being memorized and/or shared.

1.26 Item means an examination question.

C. In the *Standards* "Section 4.0 – Food Safety Certification Examination Development" – revise Subsections 4.1 and 4.17 and move the components of 4.18 to Section 5.

4.1 *Food safety certification examinations* administered by *accredited ~~certifying programs~~* ~~must~~ *certification organizations* shall comply fully with all criteria set by the CFP and ~~must~~ shall meet explicit and implicit standards to protect the public from foodborne illness. The *accredited certification organization* shall provide a *food safety certification examination* that:

A. conforms to all CFP Standards for Accreditation of Food Protection Manager Certification Programs;
B. has been developed from an *item bank* of at least 1000 questions; and
C. on a quarterly basis, is provided in at least two new *examination forms* in the English language.

4.17 ~~Specific Procedures~~ Requirements for Examination Standardization. ~~Administration.~~ *Certification organizations* ~~must~~ shall specify conditions and procedures for administering all *food safety certification examinations* in a standard manner ~~in order~~ to ~~assure~~ ensure that all ~~candidates~~ examinees are provided with the opportunity to perform according to their level of ~~*competency*~~ ability and to ~~assure~~ ensure comparability of scores. *Examination Booklets* shall be of high quality printing to ensure ease of reading. ~~Procedures must include, but not be limited to:~~

~~a. requirements for qualifications of *test administrators* and *proctors* and a suitable training program for each,~~
~~b. a complete administration manual describing each step of the test administration process and the rationale for each,~~
~~c. clear instructions for candidates both printed for distribution to candidates and read by the *test administrator*,~~
~~d. high quality printing of examination booklets to assure ease of reading,~~
~~e. specification of security procedures to assure lack of exposure of test items to unauthorized persons during testing and to prevent theft of examination items or booklets,~~
~~f. clear criteria (with rationale) for physical facilities for examination administration,~~
~~g. clear criteria (with rationale) and procedures for adaptations necessary to accommodate qualified candidates with disabilities, and~~

h. clear criteria (with rationale) and procedures for adaptations necessary to accommodate qualified candidates with literacy limitations that may require a reader.

4.18 A *certification organization* must have a published, written policy regarding test-site interpretation of *food safety certification exams*. If a *certification organization* chooses to allow test-site interpretation of food safety exams when an exam is not available in the candidates' native language, the *certification organization* must have a published, formal application process available to all candidates. Procedures must include but not be limited to:

a. an application process for candidates that includes an evaluation and documentation component to determine the eligibility of the candidate for test-site interpretation,

a. an application process for interpreters that includes clear and precise qualifications that must include but not be limited to the following:

i. fluent in both languages,

ii. have a recognized skill in interpretation,

iii. trained in the principles of objective test administration,

iv. have no personal relationship with the candidate (may not be another candidate, may not be a relative or friend of the candidate and may not be a co-worker, employer, or an employee of the candidate),

v. may not be a *Certified Food Protection Manager* nor have any vested interest in Food Protection Manager certification or conflict of interest,

vi. provide references or other proof attesting to the interpreter's competencies and professional acumen, and

vii. agree in writing to maintain the security of the examination.

b. must be in a proctored environment where the interpreter and candidate are not a distraction to other candidates, and

c. must be in a proctored environment where the interpreter is not active as the *test administrator* or *proctor*.

D. In the *Standards* "Section 5.0 – Food Safety Certification Examination Administration" – reorganize, revise, replace, and add subsections as follows:

5.0 *Food Safety Certification Examination* Administration. All sections of this Standard apply to Computer Based Technology (CBT) Administration except Section 5.1.

5.12 5.1 Security for *Examination Booklets.* Packing, Shipping, and Storage of *Examination* Materials.

Security of the *food safety certification examination* materials must be maintained in shipments to and from the examination administration site, and must include but not necessarily be limited, and are subject to the following requirements:

a. secure, tamper resistant packing is required for all materials in all phases of shipment; packing system must be designed to reveal any tampering or violation of the package's security;

A. Securing *examination booklets*

1) Each individual *examination booklet* shall be secured in 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* ~~the~~ 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.

~~b. shipping must be done by certifiable, traceable means so that its location can be determined at any given time; and~~

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.

~~c. the packing list must show the number of packages in the shipment and the exact contents of each.~~

D. Storage by *test administrator/proctor*

The package(s) of examination booklets ~~must~~ shall be ~~placed in secure storage~~ secured at all times immediately upon delivery. ~~They must be kept in secure storage both before and after they are used.~~ 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 back 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) ~~assure~~ 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.

~~5.16~~ 5.2 Test Site Requirements.

Sites chosen for administering *food safety certification examination*s ~~must~~ shall conform to all legal requirements for safety, health, and accessibility for all qualified ~~candidates~~ examinees.

A. Additionally, the accommodations, lighting, space, comfort, and work space for taking the examination ~~must~~ shall reasonably allow ~~all candidates~~ examinees to perform at their highest level ~~of *competency*~~ of ability.

~~**5.17**~~ B. Requirements at each test site include, but are not limited to:

1) ~~a~~. accessibility in accordance with the requirements of the Americans with Disabilities Act, ~~must~~ shall be reasonably available for all qualified examinees, whether the ~~exam~~ 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) ~~b.all sites must conform~~ conformity to all fire safety and occupancy requirements of the jurisdiction in which they are located;

3) ~~c.there must be~~ sufficient spacing between each examinee in the area in which the actual ~~testing~~ examination is conducted, or other appropriate and effective methods, to preclude any examinee from viewing another examinee's ~~test~~ examination;

4)~~d.~~ acoustics ~~must allow~~ allowing each examinee to hear instructions clearly, using an electronic audio system if necessary;

5) ~~e.~~lighting at each examinee's work space be adequate for reading fine print; ~~and~~

6) ~~f.~~ventilation and temperature ~~must be~~ 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.

~~4.18~~ 5.3A *certification organization* ~~must~~ shall have a published, written policy regarding test-site ~~interpretation~~ language translation of *food safety certification ~~exams~~ examinations*. If a *certification organization* ~~chooses to allow~~ allows test-site ~~interpretation~~ language translation of a *food safety certification ~~exams~~ examination* when an ~~exam~~ *examination version* is not available in the ~~candidates'~~ ~~native~~ examinees' requested language, the *certification organization* ~~must~~ shall have a published, formal application process available to all ~~candidates~~ potential examinees. Procedures ~~must~~ shall include but not be limited to:

~~a.~~ A. An application process for ~~candidates~~ potential examinees that includes an evaluation and documentation component to determine the eligibility of the ~~candidate~~ potential examinee for test-site ~~interpretation~~ language translation,

~~b.~~ B. An application process for interpreters that includes clear and precise qualifications that ~~must~~ shall include but not be limited to the following:

~~i.~~ 1) being fluent in both languages;

~~ii.~~ 2) have a recognized skill in ~~interpretation~~ language translation;
~~iii.~~ 3) trained in the principles of objective ~~test~~ examination administration;
~~iv.~~ 4) have no personal relationship with the ~~candidate~~ examinee (may not be another ~~candidate~~ examinee, may not be a relative or friend of the ~~candidate~~ examinee and may not be a co-worker, employer, or an employee of the ~~candidate~~ examinee);
~~v.~~ 5) ~~may~~ not ~~be~~ being a *Certified Food Protection Manager* nor ~~have~~ having any vested interest in Food Protection Manager certification or conflict of interest;

~~vi.~~ 6) provide references or other proof attesting to the ~~interpreter's~~ translator's competencies and professional acumen; and
~~vii.~~ 7) agree in writing to maintain the security of the examination.

~~c.~~ C. ~~must be in a~~ A proctored environment where the ~~interpreter~~ translator and ~~candidate~~ examinee are not a distraction to other ~~candidates~~ examinees, and

~~d.~~ D. ~~must be in a~~ A proctored environment where the ~~interpreter~~ translator is not active as the *test administrator* ~~or~~ / *proctor*.

~~5.19~~ 5.4 Scoring. ~~**and Reporting Requirements.** Completed answer sheets and test booklets (used and unused) must be shipped by the *test administrator* according to the *certification organization*'s written security procedures.~~

~~5.20~~ ~~Scoring will be done only by means authorized by the certification organization and approved by the accrediting organization.~~
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.

~~5.21~~ B. *Food safety certification examination* scores will not be released ~~and~~ as being official until verified and approved by the c*ertification organization*.

~~5.22~~ C. Examinee scores will be confidential, available only to the examinee and to persons or organizations approved in writing by the examinee.

~~5.23~~ D. Score reports will be available to examinees in a time frame specified in the application, which will not ~~be later than~~ 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 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** The *certification organization* shall ensure that all *test administrators* and *proctors* meet the competency requirements established by the *certification organization*, and comply with all requirements of the *certification organization*.~~

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.

~~**5.3**~~ **5.8** ~~**Instructor/Educator/**~~**Trainer as *Test Administrator*/*Proctor*.** ~~When an instructor/educator /trainer of food safety training administers, proctors or monitors a food safety certification examination from an accredited certification program, the *accredited certification organization* shall provide a food safety certification examination that:~~

~~a. conforms to all CFP standards,~~

~~b. has been developed from an item bank of at least 600 questions, and~~

~~c. minimally on a quarterly basis, is based on a new *examination form*.~~

~~The certifying organization must have a plan that demonstrates it has controlled for item and examination exposure. The exposure plan must take into account the number of times a test item and form/version is administered.~~

When a person acts as a *trainer* and a *test administrator/proctor*, that person relinquishes the role of *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. ~~**5.18 Examination Scheduling.**~~ Schedule examinations. *Food safety certification examinations* ~~must~~ 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.** Comply with the *certification organization*'s procedures for handling any breaches of exam security that may occur according to the certification organization's policies and rules.~~

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 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 booklets and answer sheets to *certification organization* or close computer based testing session;
2) report possible security breaches and examination administration irregularities in compliance with the *certification organization's* policies.

~~**5.13** *Test administrators* are responsible for the organization and administration of all examination site activities and procedures, and for the accurate identification of each examinee. They are also responsible for supervision of the activities of *proctors*. When the *instructor/educator/trainer* also serves in the role of *test administrator*, it is important that the individual clearly recognizes the difference in those two roles.~~

~~**5.14** *Proctors* shall work under the direction of the *test administrator*. They have the responsibility and must have the ability to observe examinee behaviors, accurately distribute and collect test materials, and assist the *test administrator* as assigned.~~

~~**5.15**~~ **5.10** The number of approved *proctors* assigned to a *test administrator* ~~must~~ shall be sufficient to allow each examinee to be observed and supervised to ~~assure~~ 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 examinees or fraction thereof.

5.11 Examination Security

~~**5.1**~~ **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 ~~must~~ shall be accomplished in a manner that ensures fairness to all ~~candidates~~ examinees.

~~**5.2**~~ 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.

~~**Security of *Food Safety Certification Examination* Contents.** *Food safety certification examinations* must shall be presented in a manner that allows absolutely no one other than the examinees to see the contents of the booklet or alternative medium, both before, during, and after the examination is administered. Only the examinee is allowed to break open the *examination* package or seals.~~

~~5.9~~ C. Where special legitimate accommodations ~~must~~ shall be made for otherwise qualified ~~candidates~~ examinees under provisions of the Americans with Disabilities Act, ~~arrangements must~~ 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 ~~candidate must~~ examinee shall be provided to the *certification organization*.

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~~5.10~~ **5.12** The *certification organization* ~~must~~ 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 ~~must~~ shall be specific procedures for handling and for reporting to the ~~*accrediting*~~ *certification organization*, any suspected or alleged:

1) cheating incidents;
2) lost or stolen ~~booklets~~ examination materials~~;~~
3) intentional or unintentional divulging of ~~test~~ examination items by examinees or ~~test~~ examination administration personnel; or
4) any other incidents perceived to have damaged the security of the examination or any of its individual items.

B. Corrective actions to guard against future security breaches ~~must~~ shall be established and implemented.

C. Documentation of corrective actions and their effectiveness ~~must~~ shall be made available to the ~~accreditation body~~ *accrediting organization*.

5.8 **5.13** ***Item* & and Examination Exposure.** ~~The *certification organization* must demonstrate it has controlled for item and examination exposure. An exposure plan must take into account the number of times a test item and *examination form*/version is administered, that no *examination form* is retained for any test administration or by any *test administrator/proctor* for more than 90 days; and that at all times it can account for all copies of all used and unused *examination forms* before being returned to the *certification organization*.~~

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 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.

5.4 ~~***Test Administrator/Proctor* Qualifications, Training and Duties.~~

5.14 ***Certification Organization's* Responsibility to *Test Administrators/Proctors.***

A. The *certification organization*~~s~~ ~~must~~ shall specify the responsibilities of ~~test administrators and of proctors~~ *test administrator/proctor*, set minimum criteria for approval of *test administrators* ~~and for~~ /*proctors*, and provide ~~suitable programs of~~ a training program to enable ~~persons~~ applicants to meet ~~those~~ the approval criteria. Responsibilities, duties, qualifications and training of *test administrators* ~~and~~ / *proctors* ~~must~~ shall be directed toward assuring standardized, secure

examination administration and fair and equitable treatment of examinees. ~~Policies and procedures for taking corrective action(s) when any *test administrator* or *proctor* fails to meet job responsibilities must be implemented and documented.~~

~~**5.5**~~ B. The *certification organization* shall define and provide descriptions for the roles of *test administrators~~,~~ /proctors,* and *certification organization* personnel ~~that will clearly delineate~~ clearly indicating the responsibilities ~~of each~~ for these roles. The *certification organization* shall demonstrate how it ensures that all certification personnel, ~~including~~ *as well as test administrators* ~~and~~ */ 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.

~~**5.7**~~ **5.15 Test Administrator/Proctor Agreements.** The *certification organization* shall enter into a formal agreement with the *test administrator/proctor* ~~and shall assess and monitor the performance of *test administrators* and *proctors* in accordance with all documented procedures and agreements.~~ The formal agreement shall at a minimum ~~include,~~ address:

A. provisions that relate to code of conduct;
B. conflicts of interest; and
C. ~~a statement of~~ 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~~s~~* 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. 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.*

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).

~~**5.11**~~ **5.20 Examination Administration Manual.**
The *certification organization* ~~must~~ 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 booklets;
   4) instructions on properly recording answers on answer sheets or online; and
   5) instructions on post-examination administration process.

E. In the *Standards "*Section 7.0 - Certification Organization Responsibilities to Candidates and to the Public" – replace sections 7.3 and 7.4 with one new section as follows:

~~**7.3 Effective Date of *Certificate*** *Certificates* issued and electronic listing of *certificate* holders maintained by *accredited certification programs* shall identify the *food safety certification examination* form recognized by the *accrediting organization* and specify the date the examination was taken.~~

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*.

~~**7.4 Replacement or Duplicate *Certificate*.** Replacement or duplicate *certificates* issued through an *accredited certification program* shall carry the same effective date as the original, with an expiration worded in such a manner that indicates the *certification* will be valid for no more than five years.~~

F. And add a new "section 9.0 – Management Systems" as follows:

9.0 Each certification organization shall have a formal management system in place to facilitate continuous quality improvement and produce preventive and corrective actions.

9.1. The management system shall contain the following three components.

A. Document control to include:
1) lists of all documents pertaining to the certification organization;
2) dates for documents approved for implementation by the certification organization;
3) the person(s) within the certification organization responsible for the documents; and
4) listing of individuals who have access to the documents.

B. Internal audits to include:
1) identification of critical activities;
2) data collection process and evaluation schedule;
3) audit methodology and evaluation process;
4) the person(s) authorized to perform audits; and
5) report audit findings and identify corrective action required.

C. A Management Review that includes:
1) a documented annual review of internal audit results;
2) a management group that conducts the review;
3) a review of the audit results to determine corrective actions needed;
4) a review of the audit results to determine preventive actions needed; and
5) the effectiveness of corrective and preventive actions taken.

Conference for Food Protection
2012 Issue Form

Internal Number: 084
Issue: 2012 II-015

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

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Title:
FPMCC Non-Substantive Bylaw Revisions

Issue you would like the Conference to consider:
The proposed non-substantive revisions to *the Food Protection Manager Certification Committee Bylaws* includes: clarification of terms and references for consistency and accuracy, and to eliminate duplication of Robert's Rules of Order which are adopted within the Bylaws.

Public Health Significance:
Food establishments have fewer critical risk factors according to the CDC as stated in the endorsement letter to the Conference (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*. http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf

Recommended Solution: The Conference recommends...:
approval of the non-substantive revisions to the *Food Protection Manager Certification Committee Bylaws*.
A summary of the proposed non-substantive revisions include:

- clarification of terms and references for consistency and accuracy, and
- elimination of language duplication with Robert's Rules of Order already adopted within the Bylaws.

Exact language changes are found in the FPMCC Final Report attachment, *Food Protection Manager Certification Committee Bylaws* with Committee proposed revisions (final draft revision Jan 2012).

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 082
Issue: 2012 II-016

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

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Title:
FPMCC Substantive Bylaw Revisions

Issue you would like the Conference to consider:
The proposed revision to *the Food Protection Manager Certification Committee Bylaws* includes:

- Membership and voting for all certification organizations.
- Addressing "alternate" and "advisor" membership.
- Addressing changes in constituency while serving on the committee as a representative of the constituency.

In anticipation of more than three certification organizations, it is important to revise the voting so that it is fair and consistent. The proposed wording, while limiting the number of votes, allows for every certification organization to be represented on the committee, regardless of how many certification organizations there are.

Public Health Significance:
Food establishments have fewer critical risk factors according to the CDC as stated in the endorsement letter to the Conference (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*. http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf

Recommended Solution: The Conference recommends...:
adopting the following Food Protection Manager Certification Committee (FPMCC) substantive Bylaw revisions to ensure a fair and consistent representation for all certification organizations. All new language is indicated in underline format; language to be deleted is in strike through.

Article V. Committee Structure and Representation.

Section 1. To be eligible to serve on the Committee as a voting member or non-voting alternate, individuals must commit in writing to active participation and be approved by the Conference Chair and the Board.

Section 2. The Committee Chair and Vice-Chair~~, and/or Council II Chair~~ will select committee members and alternates from the list of volunteers or recruit volunteers as appropriate to balance the committee as delineated ~~under Article IV. Committee Structure~~

~~and Representation~~ in these Bylaws. In the event of a Committee vacancy with no designated alternate in that constituency, the Chair will first recruit from the remaining list of volunteers provided during the initial Committee selection process.

Section 3. The composition of the Committee is a balanced representation of industry, regulatory, academia, certification ~~providers~~ organizations, training providers, and consumers. The Committee membership representation shall consist of a maximum of ~~twenty-eight (28)~~ thirty (30) full ~~members~~ votes from the following constituencies ~~in addition to the Chair and Vice-Chair~~:

Subsection 1. Nine (9) representatives from regulatory agencies with food safety responsibilities:

c. Two (2) from federal government agencies;. ~~with retail food program responsibilities.~~

d. Three (3) "At Large" appointments;. ~~(*At Large representation - agencies with primary regulatory food safety responsibilities.)~~

Subsection 3. ~~Three (3)~~ Five (5) total votes for certification ~~providers~~ organizations that are accredited by the Conference's accreditation process. All accredited certification organizations who volunteer will be given a voting position on the Committee; if more then five (5) organizations participate on the Committee, fractional but equal voting rights will be calculated as established in these Bylaws;

Section 4. Committee members will serve a two (2) year term, concurrent with the cycle of the biennial Conference meeting. Committee members are eligible to serve for consecutive terms contingent upon

~~Subsection 1. Indication of written interest to serve on the Committee.~~

~~Subsection 2. The availability of membership based on the representation requirements set forth in Article IV, Section 1.~~

~~Subsection 3. A~~an assessment by the Committee Chair and ~~Council II Chair,~~ Vice-Chair~~, and the incoming Chair of the Committee~~ to ensure a balance between members who have previously served on the Committee and new members.

Section 5. ~~In the event of a surplus or insufficient number of volunteers in a category, the Council II Chair may consult with the outgoing Committee Chair to identify potential candidates for appointment to the Committee.~~ Up to two (2) non-voting alternates will be included on the Committee roster each for industry, regulatory, academia, training providers, and consumers to best represent the category of each constituency. Each certification organization participating on the Committee may designate one (1) alternate from their own organization.

Section 7. In the event a Committee member changes constituency during their term, the Chair may consider them for any open seat on the Committee which needs representation from their constituency or consider any open alternate position. If the Chair determines that there are no appropriate openings available, the Committee member will be asked to resign from the committee.

Article VI. Committee Organization, Operation, and Meetings

Section ~~11~~ 4 Voting

Subsection 2. Except for certification organizations, all voting Committee members and alternates designated for that meeting shall have one (1) vote.

Subsection 3. All certification organizations accredited by the Conference's accreditation process participating on the Committee shall not exceed a total of five (5) votes.

• If more than five (5) certification organizations volunteer to participate on the Committee, the five (5) votes allocated to certification organizations shall be fractionalized (evenly divided).
• The voting fraction shall be determined when the final committee membership is approved by the Board and shall remain in effect until the next biennial Conference meeting.
• Each certification organization shall be allowed no more than one (1) vote or one (1) voting fraction at any meeting.

Article IX. Duties of Committee Members / Alternates

Section 1 ~~2~~. Committee members shall have the responsibility to notify the Committee Chair of their inability to attend a meeting or participate on a conference call at least fifteen (15) days prior to the scheduled meeting or conference call. For any committee member that is unable to attend a scheduled meeting or conference call, an alternate will be assigned. Selection of the designated alternate will be agreed upon by the Committee Chair and the absent member and chosen to best represent the constituency of the absent member. ~~The member may submit in writing a designated representative in his/her place to the Chair.~~ This designated alternate may vote on issues before the committee only during the specified meeting or conference call.

Section 2 ~~3~~. Committee members and alternates shall have the responsibility to review for comment standards, reports, recommendations, issues or other Committee documents distributed within the time frames designated by the Committee.

Section 3 ~~4~~. Committee members and alternates shall have the responsibility to complete work assignments within time frames designated by the Committee.

Section 4 ~~5~~. Committee members and alternates shall have the responsibility to notify the Committee Chair or the Chair's designee of their inability to complete a work assignment.

Article X. Committee Consultants and Advisors

Section 4. The Chair and Vice-Chair may invite, with approval from the Committee, advisors or subject matter experts to participate in meetings and conference calls, if it is determined that such individuals would provide additional information, insight, clarification, guidance or other assistance to the Committee, for a specified purpose. These advisors or subject matter experts will be non-voting guests in meetings and conference calls.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 085
Issue: 2012 II-017

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

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Title:
FPMCC - New and Continuation Charges

Issue you would like the Conference to consider:
The Food Protection Manager Certification Committee (FPMCC), a standing committee of the Conference, shall be charged to continue its work and has identified the following specific charges:

- 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.
- Revise/Update the *Standards for Accreditation of Food Protection Manager Certification Programs* Preamble and Annexes.
- Complete the pilot evaluation process, based on the initial impact of the revised *Standards,* to ensure that the evaluation tool will examine the components and outcomes of the additional examination security *Standards* as needed. The evaluation tool will then be used by the FPMCC in the 2014-2016 Biennium to determine if additional examination security requirements are needed to further insure credibility of the Food Protection Manager Certification Accreditation.

Public Health Significance:
Food establishments have fewer critical risk factors according to the CDC as stated in the endorsement letter to the Conference (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*. http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf

Recommended Solution: The Conference recommends...:
the following charges be assigned to the Food Protection Manager Certification Committee (FPMCC) for the 2012-2014 biennium:
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) Revise/Update as needed the *Standards for Accreditation of Food Protection Manager Certification Programs* Preamble and Annexes.
3) By July 1, 2012, the FPMCC Chair will request approval of the formation of a Security Evaluation Workgroup for the purpose of initiating the exam security evaluation process; workgroup representation will include:

- ANSI representative,
- ANSI field research design (data) subject matter expert,
- CFP ACAC representative,
- One representative from each Certification Organization,
- FPMCC Chair and Vice Chair,
- One food industry representative, and
- One food regulatory representative.

4) 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. The FPMCC is proposing a plan to:

- work with ANSI to update the ANSI accreditation application to incorporate the final Standards changes as approved at the 2012 Biennial Meeting,
- develop surveillance documents,
- establish an analysis framework and research plan for data collection and evaluation of improvement in exam security,
- complete a preliminary study to ensure that the evaluation tool works, and
- develop a timeline for continued improvement.

5) Report back to the Executive Board and the 2014 Biennial Meeting of the Conference for Food Protection.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 038
Issue: 2012 II-018

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

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Title:
Report - Program Standards Committee

Issue you would like the Conference to consider:
The Conference of Food Protection (CFP) Program Standards Committee (PSC) seeks Council II's acknowledgement of its committee report.

Public Health Significance:
The Voluntary National Retail Food Regulatory 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 in our continued goal of reducing foodborne illness risk factors and promoting active managerial control practices sustaining long term compliance. The PSC continues to work with the FDA internal working group and the FDA Clearinghouse Committee to clarify and address issues that arise with the Standards. Over the past two years, the PSC has worked with these FDA entities and the attached report outlines the progress and summary of their work.

Recommended Solution: The Conference recommends...:
Acknowledgement of the 2010-2012 Program Standards Committee Final Report and thanking the members for completed work.

Submitter Information:

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Attachments:
- "2010-2012 Program Standards Committee Final Report"
- "2010-2012 Program Standards Committee Roster"
- "Proposed Amendments to Standard No. 9 Program Assessment"
- "Standard No. 8 Assessment Workbook"

- "Standard No. 8 Assessment Workbook Instruction Guide"

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Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: **Program Standards Committee**

COUNCIL (I, II, or III): **II**

DATE OF REPORT: **11/15/11**

SUBMITTED BY: **Nicole Grisham**

COMMITTEE CHARGE(s):

Issue #: 2010 II-026

Charge: The Conference recommends re-creating the Program Standards Committee to work on the following charges:
1. Serve as a stakeholder group to provide input to an FDA internal working group which will be considering administrative functions such as:
    - Criteria for verification auditors
    - Recommending additional changes or improvements to the Program Standards
2. Formulate resolutions to issues brought before the committee.
3. Report back to Conference at the 2012 CFP Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The 2010-2012 Program Standards Committee (PSC) has met on a monthly basis by conference call to provide feedback to the FDA internal working group and to discuss additional changes and improvements to the Program Standards as identified in the committee charge.

Charge 1A – Criteria for verification auditors

Background:

FDA would like feedback on suggested criteria for verification auditors. Currently in Standard No. 9 it states that "an AUDITOR, as defined in the National Standards, shall complete the VERIFICATION AUDIT." An auditor is defined as "any authorized city, county, district, state, federal, tribal, or other third party person who has no responsibilities for the day-to-day operations of that jurisdiction and is charged with conducting a verification audit, which confirms the accuracy of the self-assessment." Additionally, a verification audit is defined as "a systematic, independent examination by an external party to confirm the accuracy of the self-assessment."

Committee work and discussion:

At the time the PSC commenced, a review of Standard No. 9 by the FDA internal working group and steering committee was underway. After discussing the scope of the work that the working group was focused on related to Standard No. 9, the PSC placed evaluating criteria for verification auditors and additional work on hold to avoid duplicating any efforts. The working group identified the need to separate the administrative sections of the Standard from the requirements of the Standard and desired the input of the PSC on these final documents as our direction. This separation was addressed partly to follow the format and logic of the other Standards and to provide better guidance to jurisdictions and auditors. Additionally, the separation allowed for a reevaluation of the components of Standard 9 which identified the possibility that a jurisdiction could conduct repeated Risk Factor Studies without ever implementing any activities designed to reduce the occurrence of foodborne illness risk factors and still meet Standard No. 9 by simply collecting the data. Thus, proposed language was added to the Standard to provide needed grammatical corrections, but more importantly, to ensure that enrolled jurisdictions develop a targeted intervention strategy or strategies designed to address the occurrence of the risk factors identified in their Risk Factor Study; identify procedures to ensure that these strategies are implemented; and evaluate the effectiveness of such strategies by subsequent Risk Factor Studies or other similar tools. The PSC received the draft of the proposed Standard No. 9 language with the administrative sections removed in October 2011 and provided feedback. This feedback was shared with the FDA internal working group in November 2011.

Currently, Standard No. 9 requires jurisdictions to conduct a Risk Factor Study and analysis of the resulting data to track trends over time related to the occurrence of risk factors. What is currently lacking is a requirement for jurisdictions to attempt to improve the compliance rates for the risk factors identified as having a high out of compliance rate in their Risk Factor Study. Although one of the objectives of the Program Standards is to track the results of regulatory efforts over time, as currently written, it is possible that a jurisdiction could conduct repeated Risk Factor Studies without ever implementing any activities designed to reduce the occurrence of foodborne illness risk factors and still meet Standard No. 9 by simply collecting the data.

The proposed additional language as submitted by the Program Standards Committee provides needed grammatical corrections, but more importantly, would ensure that enrolled jurisdictions develop a targeted intervention strategy or strategies designed to address the occurrence of the risk factors identified in their Risk Factor Study, that these strategies are implemented, and the effectiveness of each strategy is evaluated by subsequent Risk Factor Studies or other similar tools.

The proposed language does not require that interventions result in a reduction in the occurrence of the risk factors, simply that it is attempted and measured. It encourages innovative approaches by suggesting jurisdictions consider various types of interventions such as code changes, educational and training activities, enforcement and compliance strategies, etc. The purpose of the proposed intervention strategy is to attempt to effect improvement in reducing priority risk factor occurrences, between measurement intervals and to assess the strategy's effectiveness.

These proposed changes have been included as part of the amendments to Standard 9 as attached (submitted as Issue titled: Amendments to Program Standard No. 9 – Program Assessment).

The FDA internal working group and the PSC have discussed issues and the future work needed on the separation of the administrative pieces from Standard No. 9. Through these discussions, it was determined

that the FDA Center for Food Science and Applied Nutrition will consider submitting an issue to the CFP on the development of an administrative procedures document for the Standards. The PSC supports this concept and proposes the re-created PSC serves as a stakeholder group on the development of this administrative procedures document as part of the PSC charges listed under the submitted issue titled: Re-create Program Standards Committee. The following components of the potential issue from the FDA internal working group are acknowledged and supported by the PSC:

1. The CFP Program Standards Committee recommends that the Food and Drug Administration develop a document that describes the administrative processes it uses to:
   - enroll jurisdictions in the program standards;
   - measure the success of the jurisdictions in meeting the Voluntary Retail Food Regulatory Program Standards 1 through 9;
   - recognize jurisdictions that meet the Standards including how these jurisdictions are listed on the FDA website; and
   - address issues and resolve disputes concerning the results of non-conforming audits.

2. The CFP Program Standards Committee recommends the "active participant" portions of the current Standard 9 in the National Standards be moved to this administrative procedure document. This includes:
   - Self-Assessment
   - Verification Audit
   - Reporting Requirements for Self-Assessment and Verification Audit

3. The CFP Program Standards Committee recommends that the FDA internal working group utilizes this committee as a stakeholder group in the development of the recommended administrative procedures document.

Charge 1B - Recommending additional changes or improvements to the Program Standards

Background:

FDA requested general feedback on the use and implementation of the individual Standards and whether changes are needed to the requirements of one or more of the Standards. If the PSC believes that changes or improvements can be made to one or more of the Standards, please give a brief summary of the changes needed and the reason why.

Committee work and discussion:

The PSC reviewed the Standards and focused efforts on improving applications related to Standard No. 8. The current language of the Standard is felt to be unachievable for many jurisdictions. The PSC reviewed and discussed feedback and concerns expressed by the Standard No. 8 pilot audit conducted at Santa Clara County Department of Environmental Health as a primary baseline for a discussion starting point. The PSC members shared their respective agency's approach to assessing the inspection frequency of retail food establishments, program logistics, and method of determining the number of staff required to execute the program. Additionally, the PSC reviewed data and information from the *2009 FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types* since it was a validated study containing information related to our discussions. From these discussions, it was determined that the PSC would reevaluate the section of Standard No. 8 pertaining to Staffing Levels and the method for determining the number of full-time equivalent staff needed to properly execute a program.

The true intent of Standard No. 8 was discussed and the PSC focused on the section pertaining to Staffing Levels. This part of the Standard recommends "a staffing level of one full-time equivalent (FTE) devoted to food for every 280 – 320 inspections performed". While the PSC believes that this Standard as it applies to staffing level is unachievable for most jurisdictions and does not provide a realistic measurement that can be applied across various retail food regulatory programs across the nation, the majority agreed that if the PSC focused on a resource to assist in assessing the staffing level that valuable information pertaining to the challenges in meeting this Standard could be identified, which in the future could lead to a more attainable staffing level load. This would take additional research and quantitative validations which the PSC, due to limited time and resources, would not be able to adequately achieve. Thus the PSC agreed to focus on the development of a new resource to assist jurisdictions in assessing their staffing levels rather than addressing the current language in Standard No. 8 pertaining to staffing levels at this time. The developed tools are the most logical initial task, and language for staffing levels would be revisited and addressed as part of the PSC charges listed under the submitted issue titled: Re-create Program Standards Committee. The PSC chose to develop a new staffing level assessment resource in an Excel format through discussions and research on how our respective jurisdictions currently attempt to assess this part of the Standard, and revisiting the current guidance provided through the *2011 Self Assess and Audit Disk* for the Standards. The PSC developed the Excel resource to compliment the *Guide to Self Assess* for Standard No. 8.

Additionally, the PSC members utilized the draft Standard No. 8 Assessment Workbook to assess their staffing levels within their respective inspection programs and test the applicability of the new Excel resource. The PSC unanimously agreed that the new Excel resource greatly assisted in interpreting and applying the concepts in this section of the Standard. Through this testing application within the PSC, it was identified that an instruction guide would be a useful element to accompany the new Excel resource. The PSC developed the instruction guide for the new Excel resource to compliment the *Guide to Self Assess* for Standard No. 8 and recommends that both resource documents are made available to enrolled jurisdictions on the FDA web site and on upcoming versions of the *Self Assess and Audit Disk*.

Through the PSC's work, the PSC is recommending the addition of a new resource, Standard No. 8 Assessment Workbook and Instruction Guide (submitted as Issue titled: Standard No. 8 - Assessment Workbook and Instruction Guide).

Recommendation(s) for future charge:

The Program Standards Committee be re-created following the 2012 CFP Biennial Meeting with the following charges:

1. Serve as a stakeholder group to provide input to an FDA internal working group to:
    a. Collaborate on the development of an Administrative Procedures Document to support the Voluntary National Retail Food Regulatory Program Standards; and
    b. Recommend additional changes or improvements to the Program Standards.
2. Explore, assess, and reevaluate Staffing Levels language within Standard No. 8 and recommended any changes.
3. Formulate resolutions to issues brought before the committee and report back at the 2014 CFP Biennial Meeting.

REQUESTED ACTION:

The Program Standards Committee will submit four issues at the 2012 CFP Biennial Meeting based on the recommendation of the committee. These issues are titled:

1. Report - Program Standards Committee
2. Amendments to Standard No. 9 - Program Assessment
3. Standard No. 8 - Assessment Workbook and Instruction Guide
4. Re-Create - Program Standards Committee

Attachments:

- 2010-2012 Program Standards Committee Final Report
- 2010-2012 Program Standards Committee Roster
- Proposed Amendments to Standard No. 9
- Standard No. 8 - Assessment Workbook
- Standard No. 8 - Assessment Workbook Instruction Guide

COMMITTEE MEMBER ROSTER:

- *See attachment titled "2010-2012 Program Standards Committee Roster."*

Committee: Program Standards

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	Telephone	Email
Grisham	Nicole	Chair	Regulatory - state	CDPHE, CPD	Denver	CO	(303) 692-3626	nicole.grisham@state.co.us
Watts	Debbie	Co-Chair	Regulatory - Local	Tulsa Health Department	Tulsa	OK	(918) 595-4305	dwatts@tulsa-health.org
Collins	Linda	Consultant Alternate	Regulatory - Federal	FDA	Dallas	TX	(214) 253-4945	linda.collins@fda.hhs.gov
Ferguson	Sharon	Consultant	Regulatory - Federal	FDA	Seattle	WA	(206) 553-7001 x41	sharon.ferguson@fda.hhs.gov
Flynn	William	Member	Other - Sanitation Services	Everclean Services	Agoura Hills	CA	(877) 532-5326	bflynn@evercleanservices.com
Jensen	Joyce	Member	Regulatory - Local	Lincoln-Lancaster County Health Department	Lincoln	NE	(402) 441-8033	jjensen@lincoln.ne.gov
Finkenbinder	Dean	Member	Regulatory - State	Wyoming Department of Agriculture	Cheyenne	WY	(307) 777-6587	dean.finkenbinder@wyo.gov
Everly	Vicki	Member	Regulatory - Local	Santa Clara County Department of Environmental Health	San Jose	CA	(510) 501-0417	vicki.everly2@gmail.com
Read	David J.	Member	Regulatory - State	Minnesota Department of Agriculture	St. Paul	MN	(651) 201-6596	david.read@state.mn.us
Stryker	Kimberly	Member	Regulatory - State	State of AK Food Safety & Sanitation	Anchorage	AK	(907) 269-7628	kimberly.stryker@alaska.gov
Garcia	Kristin	Member	Regulatory - Local	Alexandria Health Department	Alexandria	VA	(703) 746-4971	kristin.garcia@vdh.virginia.gov
Taylor	Todd	Member	Other - Sanitation Services	Ecolab	Greensboro	NC	(919) 624-4849	todd.taylor@ecolab.com
Lawrence	Michael David	Member	Regulatory - Local	Fairfax County Health Department	Fairfax	VA	(703) 246-8435	david.lawrence@fairfaxcounty.gov
Hargrave	Cheryn	Member	Industry - Retail Food Stores	United Supermarkets	Lubbock	TX	(806) 928-0459	chargrave@unitedtexas.com
Eisenberg	Miriam	Member	Other - Sanitation Services	Ecolab	Lincolnshire	IL	(847) 597-9848	miriam.eisenberg@ecolab.com

Proposed Amendments to Standard No. 9 Program Assessment

STANDARD 9
PROGRAM ASSESSMENT

Table of Contents

STANDARD 9
PROGRAM ASSESSMENT

This Standard applies to the process used to measure the success of jurisdictions in meeting the *Voluntary National Retail Food Regulatory Program Standards 1 through 9* (hereafter referred to as the National Standards) and their progress in reducing the occurrence of foodborne illness risk factors. Additionally, it applies to the requirements for recognition by the Food and Drug Administration of those jurisdictions meeting the National Standards.

Requirement Summary

To be an active participant in the *Voluntary National Retail Food Regulatory Program Standards* and to be listed on the FDA Roll of Participating Jurisdictions, a jurisdiction must ~~assure~~ ensure that:

1. The program manager, or a designated representative, conducts an initial SELF-ASSESSMENT against the criteria in each of the nine (9) National Standards within 12 months following the date of enrollment and every 60 months thereafter; and,

2. The program manager, or a designated representative, requests a VERIFICATION AUDIT within 3 months following any SELF-ASSESSMENT in which one or more Standards is claimed as met. The VERIFICATION AUDIT is to be completed within 6 months of that SELF-ASSESSMENT; and,

3. Reporting, using the *FDA National Registry Report* and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Forms 3519 and 3520), will be completed and submitted to the appropriate FDA Regional Office within 30 days following a SELF-ASSESSMENT or a SELF-ASSESSMENT UPDATE and following any VERIFICATION AUDIT.

To achieve the criteria of Standard 9 and claim Standard 9 as met, a jurisdiction must ~~assure~~ ensure that:

1. 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; and,

2. An analysis is made of the data collected and a report on the outcomes and conclusions of the RISK FACTOR STUDY is written-

3. A targeted intervention strategy(s) designed to address the occurrence of the risk factors(s) identified in their RISK FACTOR STUDY is implemented and the effectiveness of such strategy(s) is evaluated by subsequent RISK FACTOR STUDIES or other similar tools.

Description of Requirement

To be an active participant in the National Standards and to be listed on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure that the following procedures for SELF-ASSESSMENTS, VERIFICATION AUDITS, and reporting are completed:

A. Self-Assessment

1. The program manager, or a designated representative, conducts an initial SELF-ASSESSMENT against the criteria in each of the nine (9) National Standards within 12 months of the date of enrollment and every 60 months thereafter.

   If it is determined that a Standard has been met, at that point the Appendix documents (hereinafter referred to as the worksheets) for that Standard(s) are to be completed in preparation of the VERIFICATION AUDIT.

   For any Standard(s) which are not met, it is recommended that any deficiencies in meeting the Standards criteria be identified in order to meet that Standard in the future. It is further recommended that priorities, action plans, and target dates be established to facilitate continuous improvement in the jurisdiction's program.

   The National Standards Edition to be used when completing the required 60-month SELF-ASSESSMENT is the most recent version of the *Voluntary National Retail Food Regulatory Program Standards* published on the FDA web site at http://www.fda.gov. Once at the FDA main web page, click on "Food," then "Food Safety," then "Retail Food Protection" and click on "Program Standards."

2. For any Standard a jurisdiction claims as met:

   a) The compliance status of the jurisdiction's program as measured against that Standard(s) is documented by completing the Appendix documents (worksheets) or documents containing equivalent summary information for that Standard; and,

   b). QUALITY RECORDS specified as requirements in each of the National Standards are established, identified, and maintained. The QUALITY RECORDS must be maintained in such a manner that an AUDITOR can be provided information necessary to verify that a

Standard's criteria have been met.

3. This complete SELF-ASSESSMENT cycle must be repeated at a minimum every 60 months. However, a jurisdiction may, and is encouraged to complete a SELF-ASSESSMENT UPDATE at any time during the 60-month interval to reflect the most current information on its program accomplishments as reflected by comparison against one or more of the individual Standards. A SELF-ASSESSMENT UPDATE can be made using the edition of the National Standards effective at its last required SELF-ASSESSMENT or a more recent edition of the National Standards, at the jurisdiction's discretion.

4. Following a SELF-ASSESSMENT UPDATE, a jurisdiction completes the worksheets or equivalent forms to document compliance with any additional National Standard(s) met since the last required SELF-ASSESSMENT, establishes the QUALITY RECORDS, and forwards the *FDA National Registry Report* and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Forms 3519 and 3520) to the appropriate FDA Regional Office within 30 days following a SELF-ASSESSMENT UPDATE.

B. Verification Audit

1. The program manager, or a designated representative, shall request a VERIFICATION AUDIT within three (3) months following any SELF-ASSESSMENT or SELF-ASSESSMENT UPDATE in which one or more Standard(s) is claimed as met. The VERIFICATION AUDIT is to be completed within six (6) months of that SELF-ASSESSMENT or SELF-ASSESSMENT UPDATE.

2. A complete SELF-ASSESSMENT of all Standards will be completed every 60 months after the initial SELF-ASSESSMENT. At each complete SELF-ASSESSMENT, a VERIFICATION AUDIT is to be conducted for any standard that is being claimed as met only if the Standard has been revised since the last VERIFICATION AUDIT.

3. An AUDITOR, as defined in the National Standards, shall complete the VERIFICATION AUDIT. VERIFICATION AUDITS confirm and report on the accuracy of a SELF-ASSESSMENT that claims one or more Standard(s) as met. During the VERIFICATION AUDIT, the auditor will:

   a) Review the QUALITY RECORDS and confirm that the SELF-ASSESSMENT accurately reflects the program's compliance status with each criterion for the version of the National Standards that was used when completing the SELF-ASSESSMENT or a SELF-ASSESSMENT UPDATE; and,

   b) Determine whether the QUALITY RECORDS specified as requirements in each of the National Standards have been established, identified, and maintained. If the quality records for a specific program element provide inadequate information upon which to make a determination of conformance with the Standard or to enable a VERIFICATION AUDIT, that Standard is not met.

C. Reporting Requirements for Self-Assessments and Verification Audits

1. Reporting, using the *FDA National Registry Report* and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Forms 3519 and 3520), shall be completed and submitted to the appropriate FDA Regional Office within 30 days following a SELF-ASSESSMENT or a SELF-ASSESSMENT UPDATE and following any VERIFICATION AUDIT.

2. Submission of the *FDA National Registry Report* and *Release Record and Agreement -Permission to Publish in National Registry* is required following each 60-month SELF-ASSESSMENT regardless of whether any Standard(s) are claimed as met.

3. If a jurisdiction wishes to complete a SELF-ASSESSMENT UPDATE with its most current program information, a new *FDA National Registry Report* (FDA Form 3519) and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Form 3520) must be submitted. Any report form submitted is marked to show attainment of all applicable Standards achieved at the time of submission. Dates showing current attainment for each Standard should be recorded on each submission in order to accurately reflect the program's history. Marking all applicable Standards with their most recent attainment dates ensures that accurate information is posted on the FDA List of Enrolled Jurisdictions.

4. The *FDA National Registry Report* (FDA Form 3519) and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Form 3520) is submitted following a VERIFICATION AUDIT. The date of the audit and the date of the version for the Standard that is being audited should be included on the report forms so that information may be added to the FDA List of Enrolled Jurisdictions.

ACHIEVING STANDARD 9

To achieve the criteria of Standard 9 and claim Standard 9 as met, a jurisdiction must ensure that:

A. A RISK FACTOR STUDY and report on the occurrence of foodborne illness risk factors is 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. A RISK FACTOR STUDY includes all facility types 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 five (5) years 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 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 there has been a net change in the occurrence of the risk factors.

The nine (9) facility types are:

- Institutions – 1) Hospitals; 2) Nursing Homes; 3) Elementary Schools (K-5)
- Restaurants – 4) Full Service; 5) Fast Food
- Retail Food Stores – 6) Delis; 7) Meat Departments; 8) Seafood Departments; 9) Produce Departments

(See the FDA's Data Collection Manual for additional information regarding facility types and help with Risk Factor Studies.)[LINK]

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 in Appendix J, 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. Refer to the Data Collection Manual to understand the statistical limitations and restrictions if using an inspection form or a data collection form different from the FDA data collection 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 (Survey) is implemented and the effectiveness is evaluated by subsequent Risk Factor Studies (Surveys) 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.

F. Achievement of Standard 9 is audited using the same procedures and reported using the *FDA National Registry Report* (FDA Form 3519) and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Form 3520) in the same manner as achievement of the other eight National Standards as detailed under **DESCRIPTION OF REQUIREMENTS** in this document for Self-Assessment, Verification Audit, and Reporting.

Outcome

The desired outcome of this Standard is to enable managers to measure their program against national criteria. The process identifies program elements that may require improvement or be deserving of recognition.

Documentation

The quality records required for this standard include:

1. The completed Appendices (worksheets) for each Standard and supporting records,
2. Survey reports on the occurrence of risk factors and *Food Code* interventions,
3. Documentation of performed interventions, actions or activities designed to improve the control of risk factors.
4. Verification audit reports,
5. FDA National Registry Report, FDA Form 3519, and
6. Affidavit of Permission to Publish, FDA Form 3520.

The Standard 9: Program Self-Assessment and Verification Audit Form, included as a file on this disk is designed to document the findings from the self-assessment and the verification audit process this Standard [LINK to print].

FTE CONVERSION FACTOR CALCULATIONS

Program Description and Supporting Information:

PRODUCTIVE ANNUAL FTE HOURS PER YEAR

Annual FTE Hours Per Year: Industry Standard		**2080**
	Agency Holiday Hours Per Year	
	Agency Vacation Leave Hours Per Year	
	Agency Sick Leave Hours Per Year	
	Agency Family-Personal Leave Hours Per Year	
Annual FTE Hours Per Year: Agency Staff		**2080**
	Productivity Adjustment	
	Personal Development Time	
Productive Annual FTE Hours Per Year (FTE Conversion Factor): Agency Staff		**2080**

Standard 8: Staffing Levels
FTE Data Supplement

Productive Annual FTE Hours Per Year (FTE Conversion Factor): Local Inspector		**2080**	
(POSITION CATEGORY) FOOD SAFETY INSPECTION HOURS			
Assignment/Activity	**% of Productive Annual Hours**	**Productive Annual Hours**	
		0	
		0	
		0	
		0	
		0	
		0	
		0	
		0	
FOOD SAFETY INSPECTION HOUR TOTAL		**0**	Position Description and Supporting Information:

(POSITION CATEGORY) FOOD SAFETY INSPECTION HOURS		
Assignment/Activity	**Productive Annual Hours**	
FOOD SAFETY INSPECTION HOUR TOTAL	**0**	Position Description and Supporting Information:

(POSITION CATEGORY) FOOD SAFETY INSPECTION HOURS		
Assignment/Activity	**Productive Annual Hours**	
FOOD SAFETY INSPECTION HOUR TOTAL	**0**	Position Description and Supporting Information:

Standard 8: Staffing Levels
FTE Data Supplement

Standard 8: Staffing Levels
FTE Data Supplement

Assignment/Activity
Routine Inspections

Re-inspections
Complaint Investigations
Outbreak Investigations
Compliance Follow-up Inspections
Risk assessment Reviews
Process Reviews
Variance Process Reviews
Foodborne Illness Complaint Response
Final Construction Inspections
Onsite Training
Temporary Event Inspections

Mobile Unit Inspections

Formal/Informal Hearings
Standardization Inspections

Position Category
FSIO
Trainer

Supervisor

Manager

Standard 8: Staffing Levels
FTE Data Supplement

Standard 8: Staffing Levels
FTE Data Supplement (Non-FS)

NON-FOOD SAFETY INSPECTION HOURS

(POSITION CATEGORY) NON-FOOD SAFETY INSPECTION HOURS	
As previously noted, the primary responsibility of the (POSITION CATEGORY) is to conduct food safety regulatory inspections in retail food establishments; however, (POSITION CATEGORY) are responsible for regulating other (non-food safety) areas of Environmental Health throughout the year. Position Description and Supporting Information:	

Non-Food Safety Assignment/Activity	**Activities Per Year**	**Hours Per Activity**	**Total Activity Hours**
			0
			0
			0
			0
			0
			0
Non-Food Safety Assignment/Activity Hour Total			0

Standard 8: Staffing Levels
FTE Data Supplement (Non-FS)

Type of Environmental Health Inspection

Administrative Conferences & Hearings (all)
Pool & Spa Inspections

Geothermal Well Inspections
Hotel Inspections
Marina Inspections
Personal Grooming Establishment Inspections

Wholesale food inspections
Dairy farm inspections
Milk plant inspections
Department of Corrections inspections
Tanning inspections
Body Art inspections
Hazardous waste inspections
Air quality inspections
Solid waste inspections
Land planning

Health fraud inspection
Consumer product safety inspection

Position Category
FSIO
Trainer
Supervisor
Manager

Standard 8: Staffing Levels
FTE Data Supplement Summary

FOOD SAFETY INSPECTION HOURS PER YEAR			
Position Category	**Food Safety Inspection Hours**	**Number of Employees**	**Position Category Food Safety Inspection Hour Total**
	0		0
	0		0
	0		0
Food Safety Inspection Hour Total			**0**
Non-Food Safety Inspection Hour Total			0
Annual Food Safety Inspection Hour Total			**0**
Total FTE Provided			**0.0**

Standard 8: Staffing Levels
FTE Data Supplement Summary

Position Category

FSIO
Trainer
Supervisor
Manager

FY2011 (July 1, 2010 - June 30, 2011) Inspection Data

NUMBER OF FOOD SAFETY INSPECTIONS

In accordance with Standard 8 Self-Assessment Guidance provided in the January 2011 version of the Program Standards and for the purposes of Standard 8, the types of services listed below under "inspection type" are included in the definition of an inspection.

Type of Food Safety Inspection	# of Food Safety Inspections
Total Annual Number of Food Safety Inspections	0

Type of Food Safety Inspection

Routine Inspections
Re-inspections
Complaint Investigations
Outbreak Investigations
Compliance Follow-up Inspections
Risk assessment Reviews
Process Reviews
Variance Process Reviews
Foodborne Illness Complaint Response
Final Construction Inspections
Onsite Training
Temporary Event Inspections
Mobile Unit Inspections

INSPECTION TO FTE RATIO	
Table Notes: In accordance with Standard 8 Self-Assessment Guidance provided in the January 2011 version of the Program Standards, the Inspection-to-FTE Ratio must fall between 280 and 320.	
Total Annual Number of Food Safety Inspections	0
Total FTE Provided	0.0
Inspection to FTE Ratio	**#DIV/0!**

AGENCY

Standard 8: Staffing Levels
Inspection to FTE Ratio

DATE

DEFINITIONS	
Food Safety Inspection Officer (FSIO)	This term describes the position category for the inspection staff in a food safety inspection program. In this workbook application, FSIO does not include trainers, supervisors, or managers. However, the agency is able to customize all position category titles to match their agency's terminology.
Productivity Adjustment	(x) hours per year per EHS as established by the (AGENCY). The Productivity Adjustment includes items listed in the Guide to Self Assess for Standard 8. These items include, but are not limited to administrative tasks (in-office paperwork and reports, phone calls, emails, Outlook calendar updates), inspection travel time, training time for the inspector, and required meetings. These factors may be defined by the AGENCY. Some jurisdictions may also exclude the time allotted for lunch and work breaks. Most jurisdictions of moderate size will have a personnel department, a human resource department, or a budgeting department that has calculated the average administrative overhead time for each position category or perhaps has established an FTE conversion factor. This may be some of the documentation that the jurisdiction supplies as source documentation.
Personal Development Time	(x) hours per year per EHS as established by the (AGENCY). The personal development time includes, but is not limited to continuing education, maintaining professional credentials, and required agency trainings and orientations.
Productive Annual FTE Hours Per Year (FTE Conversion Factor): Agency Staff	The Annual FTE Hours Per Year for Local Inspector less the productivity rate hours and personal development time hours.
Agency Holiday Hours Per Year	(x) hours per year per EHS as established by the (AGENCY).
Agency Vacation Leave Hours Per Year	(X) hours used in the FTE Data calculation represents an average of the hours of vacation leave earned among all EHS at (AGENCY). (Vacation leave hours earned amongst inspection staff may vary depending on years of service)
Agency Sick Leave Hours Per Year	(X) hours per year (use or lose) as established by (AGENCY)
Agency Family-Personal Leave Hours Per Year	(X) hours per year (use or lose) as established by (AGENCY)
Position Category	Only the personnel who have direct time for conducting inspections should be included in the position categories. Time for support and administrative personnel may not be included. Clerical support persons and administrators generally do not perform field work, and it is not appropriate to include portions of their time here. While they contribute to and are very important to the effective functioning of the “program,” they do not add to the inspection capacity. As an example, however, if a supervisor functions as a working supervisor, i.e., he/she performs some amount of inspectional work or conducts compliance follow-up inspections, conducts formal or informal hearings, etc., then that portion of time spent on field work should be counted as inspectional personnel time. The portion of their time spent preparing or reviewing reports and performing administrative tasks, however, should not be counted. The Standard requirement is intended to establish a workload ratio for personnel conducting field work directly related to the inspectional tasks.

2012

STANDARD 8 STAFFING LEVEL ASSESSMENT WORKBOOK; INSTRUCTION GUIDE

Table of Contents

Purpose: This information is being provided to assist with the application and use of the Standard 8 Staffing Level Assessment Workbook.

Overview: The *Standard 8 Staffing Level Assessment Workbook* was created with the intent of assisting enrolled jurisdictions in calculating their agency's Inspection to Full Time Equivalent (FTE) ratio. An agency enrolled in the *Voluntary National Retail Food Regulatory Program* Standards, will assess their program's staffing levels as part of *Standard 8, Program Support and Resources*. In addition to the contents of Standard 8, a *Self Assessment and Audit Disk* is provided to jurisdictions which contain a *Guide to Audit, Guide to Self Assess,* and *Self Assess and Audit Form.* While the *Guide to Self Assess* for Standard 8 provides additional direction and examples on assessing staffing levels, the *Standard 8 Staffing Level Assessment Workbook* provides the ability to enter information into an Excel format. The workbook allows a jurisdiction to customize the workbook to their needs while providing a structured framework for assessing staffing levels. Once staffing levels are assessed using the workbook, the data are easily accessible for analysis, maintenance, and revision. Each of these resources for Standard 8 supports each other and should be utilized as a combined resource rather than a stand alone application.

The format of the workbook was designed to maintain the staffing level information in a manner that could be easily edited and printed without inadvertently affecting formulas and calculations. Each worksheet within the workbook has the view set to *Page Layout* to maintain the visual aspect of how the information will print. When viewing a worksheet, the primary print sheet displays while the secondary print sheet is located to the right, the tertiary print sheet is below the primary print sheet, and the final print sheet is below the secondary print sheet. The information provided in the worksheets is limited to the primary and secondary print sheet; however, agencies may utilize the other print sheet areas for customized application information. As for references to the information in a worksheet throughout this instruction guide, the terms primary print sheet and secondary print sheet are used.

Several worksheets have drop selections for several cells on the primary print sheet which are populated from customized lists on the secondary print sheets. To maintain the functionality of this aspect on each worksheet, the location of the customized lists should not be altered. An agency may customize the references in the prepopulated lists by editing the information in each cell of the list directly. To view the drop selections for a particular cell on the primary print sheet simply select that cell by clicking in the cell and a down arrow appears to the right of the cell. Click on the down arrow to view the selections.

Additionally, several worksheets have tables for calculating activity time for Food Safety Inspection Officers (FSIOs). The workbook was designed for an agency to enter the information once for FSIOs versus entering information for each individual. Thus the approach to utilizing these tables is to enter values that are the best estimate or average for all FSIOs. The same would apply for the additional tables for trainers, supervisors, and managers if an agency has multiple positions in these categories. Given the nature of the calculations, utilizing the best estimate or average approach will give agencies a valuable measure. However, if an agency has a large number of staff, staff who is diversified in their program assignments, or other confounding factors, they have the ability to modify the worksheets or tables within the worksheet to fit their needs by copying and utilizing multiple worksheets, tables, or other applications provided. Since each worksheet applies a different logic and compensates for different elements, it is recommended an agency apply information to all of the worksheets before making any modifications to the workbook. It is possible that what is identified as a needed modification in one worksheet may be addressed in an application in another worksheet.

Finally, it is important to note that any modifications to the worksheets should occur on the primary print sheet and not the secondary print sheet to protect populated selections. Also important to note is that any modifications of tables may affect the populated calculations or selections. It is recommended that modifications to the workbook be evaluated and applied by the agency's personnel who are trained and have a high level of expertise in Excel applications. Having a master copy of the workbook to refer back to prior to making modifications is highly recommended. The intent of this workbook was to give a framework for staffing level assessment utilizing an Excel workbook and be able to be customized to fit any agency's needs.

Assessment Workbook Components and Guidance:

STEP 1: FTE Conversion Factor Worksheet:

Purpose: Determine Full-Time Equivalents (FTE): the number of productive hours contributed by one person working full-time for one year.

The *Guide to Self Assess* for Standard 8 gives us the following guidance pertaining to this worksheet:

Factors to Consider:

- If three people devote 1/3 of their productive time to food inspections for one year, that is one full-time equivalent devoted to food inspections. Organizations use a variety of formulas to arrive at the productive hours of one full-time employee. The number of productive hours that represent an FTE can range from 1100 to 1500 hours depending upon the average number of hours allotted for leave, training, and administrative time. For convenience sake, let us call the number of productive work hours the FTE conversion factor.

  Note: The FTE Conversion Factor is cell E13 on this worksheet. This FTE Conversion Factor is automatically applied on the FTE Data Supplement Sheet (cell C1).

- Let us look at what should and should not be included in the calculation to determine the total productive work hours for one individual or the FTE conversion factor. Assuming a forty-hour work week and fifty-two weeks in a year, there are 2080 total work hours available to a person in a year. However, not all of those hours will be spent in producing a work product. The following activities should not be included as part of the conversion factor:

  1. Holiday time,
  2. Vacation time,
  3. Sick leave time,
  4. Travel time to establishments,
  5. Training time for the inspector, or
  6. Time spent in the office completing paperwork or returning phone calls.

  Data Entry: Examples 1-3 above are represented by cells E6-E9 on this worksheet. If any of these options do not apply then a '0' should be entered into the cell. Cell E11, Productivity Adjustment, may be used to factor in travel time and office time. Additionally cell E12, Personal Development Time, may be used to factor in training time for the FSIO (See definition worksheet for explanations of Productivity Adjustment and Personal Development Time).

- Some jurisdictions may also exclude the time allotted for lunch and work breaks. Most jurisdictions of moderate size will have a personnel department, a human resource department, or a budgeting department that has calculated the average administrative overhead time for each position category or perhaps has established an FTE conversion factor. This may be some of the documentation that the jurisdiction supplies as source documentation.

  Note: If a jurisdiction wishes to factor in these elements, they may do so as part of the Productivity Adjustment, cell E11.

STEP 2: FTE Data Supplement Worksheet:

Purpose: Determine Food Safety Inspection Hours for each program position: the number of annual productive food safety inspection hours contributed by each position category working in the inspection program.

The *Guide to Self Assess* for Standard 8 gives us the following guidance pertaining to this worksheet:

- Only the time for personnel conducting inspections should be included in the ratio figure. Time for support and administrative personnel may not be included. Clerical support persons and administrators generally do not perform field work, and it is not appropriate to include portions of their time here. While they contribute to and are very important to the effective functioning of the "program," they do not add to the inspection capacity. As an example, however, if a supervisor functions as a working supervisor, i.e., he/she performs some amount of inspectional work or conducts compliance follow-up inspections, conducts formal or informal hearings, etc., then that portion of time spent on field work should be counted as inspectional personnel time. The portion of their time spent preparing or reviewing reports and performing administrative tasks, however, should not be counted. The Standard requirement is intended to establish a workload ratio for personnel conducting field work directly related to the inspectional tasks.

  Note: The FTE Conversion Factor is automatically populated from the previous sheet and is cell C1 on this worksheet.

  Data Entry:

  1. ***First an agency defines the various positions that contribute to the activities included in the staffing level assessment. An example of positions is provided on the secondary print sheet in cells I20-23. Each agency may customize these examples to reflect the position terminology within their agency. These cells populate selection items in cells A2, A14, and A22 on the primary print sheet.***

2. *Second an agency defines the various assignments/activities each position executes which would be included in the staffing level assessment. An example of assignments/activities is provided on the secondary print sheet in cells I2-16. These examples mirror those that are provided in the Standard 8 language. Each agency may customize these examples to reflect the position terminology within their agency. These cells populate selection items in cells A4-11, A16-19, and A24-26 in the primary print sheet.*

3. *Third the agency would select the positions and assignments utilizing the drop selections for the referenced cells above on the primary print sheet. The worksheet is formatted to select and enter activities for your primary inspection staff in the first table (i.e. inspectors) and various supporting staff in the tables below (i.e. trainers, supervisors, managers).*
    a. *Since FSIOs typically execute more activities and productive annual hours contributable to the staffing level assessment than other positions, the first table is reserved for this position category and allows for a variable calculation based on percent of work time contributable to an activity or productive annual hours.*
    b. *Since other food inspection program staff such as trainers, supervisors, and managers may also perform activities contributable to the staffing level assessment, additional tables are provided to allow for inclusion of productive annual hours for each activity.*

4. *Fourth the agency would enter the appropriate values for the first table (inspector position) in cells B4-B11 or C4-C11 based on the following:*
    a. *An agency may have FSIOs contribute a percentage of their time in the various activities in a program. For this application, an agency can enter the percentage contributable for each activity in cells B4-B11 in the primary print sheet. Once information for each cell is entered, the Productive Annual Hours for each activity will automatically be populated in the subsequent cell to the right. This is populated from that cell's established formula using the information from the percentage cell and the FTE Conversion Factor.*
    b. *An agency may not apply percentages for each activity and apply set hours for each activity. For this application, delete the formulas from cells C4-C11 and enter the total Productive Annual Hours for each activity. Please note that the formula for cell C12, Food Safety Inspection Hour Total, should not be deleted as this cell populates information in cell B3 on the FTE Data Supplement Summary worksheet.*

5. *Fifth the agency would enter the Productive Annual Hours for each activity in cells B/C16-B/C19 and B/C24-B/C26 in the subsequent tables. Cells B/C20 and B/C27 populate information in cells B4 and B5 on the FTE Data Supplement Summary worksheet.*

6. *This worksheet also allows for an agency to provide the position description and supporting information to the right of each table. This is useful for explaining agency specific terminology, activity specifics, position specifics, etc.*

STEP 3: FTE Data Supplement (Non-FS) Worksheet:

Purpose: Determine Non-Food Safety Inspection Hours for each program position: the number of annual non-food safety inspection hours contributed by each position category which should not be included in the staffing level assessment.

Note: The previous FTE Data Supplement worksheet utilizes the FTE Conversion Factor in the calculations for productive annual hours in the first table (FSIO category position). Since agencies may not have FSIOs who are 100% dedicated to the food inspection program, the percentage total in cells B4-B11 may not add up to 100% as a percentage of that position's time may apply to other programs. Thus the FTE Data Supplement (Non-FS) worksheet is provided to factor these non-food safety inspection hours out of the food safety inspection hours total, cell C12, calculated on the FTE Data Supplement worksheet.

Note: If FSIOs in a food inspection program have 100% of their FTE dedicated to activities contributable to the staffing level assessment, the FTE Data Supplement (Non-FS) worksheet does not have to be addressed or applied. This is also true for any trainer, supervisor, or manager positions factored in the spreadsheet as their activities were applied as hours not percentages in the FTE Data Supplement worksheet.

Note: If an agency finds that the applications in the FTE Data Supplement (Non-FS) worksheet are need for multiple positions, the table can be copied and modified to accommodate needs and multiple positions. The data validation logic which populates the Position Category, cell A/B/C2, and the Non-Food Safety Assignment/Activity, cells A9-A14, should carry through their logic as long as the tables are copied onto the same worksheet. However, the if multiple copies of this worksheet are applied, the calculation reference on the FTE Data Supplement Summary worksheet in cell D7 would have to be modified to include all additional copies of the FTE Data Supplement (Non-FS) worksheet.

Data Entry:

1. ***First an agency defines the various positions that contribute to the activities included in the staffing level assessment. An example of positions is provided on the secondary print sheet in cells H24-27. These should match the position descriptions utilized on previous worksheets. These cells populate selection items in cell A/B/C2 on the primary print sheet.***

2. ***Second an agency defines the various assignments/activities each position executes which would be included in the staffing level assessment. An example of assignments/activities is provided on the secondary print sheet in cells H2-19. Each agency may customize these examples to reflect the position terminology within their agency. These cells populate selection items in cells A9-14 in the primary print sheet.***

3. ***Third the agency would select the positions and assignments utilizing the drop selections for the referenced cells above on the primary print sheet.***

4. *Fourth the agency would enter the appropriate values for Activities Per Year, cells B9-B14, and Hours Per Year, cells C9-C14 for each assignment/activity. An agency may not have the need to enter the activities per year but rather apply a total hours per activity which represents hours spent on that activity over a year. For this application, an agency will enter a "1" for number of Activities Per Year and enter their hours per activity. Once all values are entered, the Total Activity Hours will be populated in cells D9-D14. These Total Activity Hours will populate the Non-Food Safety Assignment/Activity Hour Total in cell D15. Cell D15 populates information in cell D7 of the FTE Data Supplement Summary worksheet.*

5. *This worksheet also allows for an agency to provide supporting information and explanation in the cell under the position category in the table. This is useful for explaining agency specific terminology, activity specifics, position specifics, etc.*

STEP 4: FTE Data Supplement Summary Worksheet:

Purpose: Determine Food Safety Inspection Hours for all program positions: the number of annual food safety inspection hours contributed by all position categories which should not be included in the staffing level assessment.

Note: The previous FTE Data Supplement and FTE Data Supplement (Non-FS) worksheets populate cells B3-B5 and D7 in the FTE Data Supplement worksheet.

Data Entry:

1. *First an agency defines the various positions that contribute to the activities included in the staffing level assessment. An example of positions is provided on the secondary print sheet in cells H2-H5. These should match the position descriptions utilized on previous worksheets. These cells populate selection items in cell A3-A5 on the primary print sheet.*

2. *Second an agency enters the number of staff for each position category in cells C3-C5. Once all values are entered, the Position Category Food Safety Inspection Hour Total will populate in cells D3-D5. These will populate the Food Safety Inspection Hour Total in cell D6. Cell D8, Annual Food Safety Inspection Hour Total, populates utilizing the information from cells D6 and D7. Cell D9, Total FTE Provided populates utilizing the information from cell D8 and the FTE Conversion Factor, cell E13, of the FTE Conversion Factor worksheet. Cell D9, Total FTE Provided populates information in cell B4 of the Inspection to FTE Ratio worksheet.*

STEP 5: Inspection Data Worksheet:

Purpose: Determine the type and number of food safety inspection activities for the program: the type and number of annual food safety inspection activities contributing to the staffing level assessment as defined in Standard 8.

The *Guide to Self Assess* for Standard 8 gives us the following guidance pertaining to this worksheet:

Determine Number of Inspections:

- For the purposes of this standard, "inspections" are defined as routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews, foodborne illness complaint response, final construction inspections and other direct establishment contact time such as on-site training that is performed by the field inspection staff. If the same personnel who conduct inspections of the fixed-site establishments also conduct the inspections of temporary events and mobile units, then these inspection events should also be counted as "inspections" for purposes of calculating the workload ratio.

- Any calculation that uses only routine inspection counts would be suspect unless unusual circumstances exist or unusual justifications that can be provided. Special justifications or unusual circumstances must be evaluated on a case-by-case basis.

- Jurisdictions may have an automated or manual tracking system for counting the number of inspections/contacts or the number of hours spent on inspectional activities. If the system measures total hours only, then there would need to be estimates or formulas for the average inspection time in order to arrive at a number of inspections. A jurisdiction might also arrive at the number of inspections by calculating the number of permits in various categories and multiplying the number of permits by the number of required or average visits to each of those facilities categories.

- Whatever the form or format of the data collected, the jurisdiction must eventually arrive at an estimate of the number of on-site contacts made in a year.

Note: This worksheet is listed here in the steps of the process to keep with the flow of the worksheets and information which feeds into each other, however, this worksheet could be completed at any point in the process. An agency may find that completing this worksheet first helps to understand the data that should be included in previous worksheets.

Data Entry:

1. ***First an agency defines the various types of food safety inspections that contribute to the staffing level assessment as defined in Standard 8. An example of positions is provided on the secondary print sheet in cells D2-D14. These examples mirror those that are provided in the Standard 8 language and the Guide to Self Assess. These cells populate selection items in cell A4-A16 on the primary print sheet.***

2. ***Second an agency enters the number of food safety inspections in cells B4-B16. Once all values are entered, the Total Annual Number of Food Safety Inspections will populate in cell B17. This cell will populate the Total Annual Number of Food Safety Inspections in cell B3 on the Inspection to FTE Ratio worksheet.***

STEP 6: Inspection-FTE Ratio Worksheet:

Purpose: Determine the annual number of food safety inspection activities per FTE in the program: the number of annual food safety inspection activities per FTE dedicated to the program as defined in Standard 8.

Note: The tab for this worksheet is highlighted to indicate that the information needed to assess if an agency meets the staffing level requirement of Standard 8 is found on this worksheet. Information for this worksheet is populated from previous worksheets and provides the Inspection to FTE Ratio in cell B5. As noted in the Table Notes field on this worksheet, the Inspection to FTE Ratio should fall between 280 and 320 to meet the staffing level section of Standard 8. Values above 320 would indicate that the program is lacking adequate FTE to meet this part of the Standard.

ADDITIONAL INFORMATION: Definitions Worksheet:

Purpose: Provide definitions behind references and titles in the various worksheets: While this instruction guide provides detailed information on the steps and elements of the workbook applications, the definitions worksheet provides some common references for quick reference and to assist in accessible clarification when working with the workbook.

Conference for Food Protection
2012 Issue Form

Internal Number: 039
Issue: 2012 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.

Title:
Amendment to Standard 9 Program Assessment

Issue you would like the Conference to consider:
Amend Voluntary National Retail Food Regulatory Program Standards, Program Standard No. 9 to add an additional requirement to develop targeted intervention strategy(s) designed to address the occurrence of the risk factors identified in the jurisdiction's Risk Factor Study. And, those intervention strategies are implemented and the effectiveness of each strategy is evaluated by subsequent Risk Factor Studies or other similar tool. Additional grammatical corrections are also recommended.

Public Health Significance:
Currently, Standard No. 9 requires jurisdictions to conduct a Risk Factor Study and analysis of the resulting data to track trends over time related to the occurrence of risk factors. What is currently lacking is a requirement for jurisdictions to attempt to improve the compliance rates for the risk factors identified as having a high out of compliance rate in their Risk Factor Study. Although one of the objectives of the Program Standards is to track the results of regulatory efforts over time, as currently written, it is possible that a jurisdiction could conduct repeated Risk Factor Studies without ever implementing any activities designed to reduce the occurrence of foodborne illness risk factors and still meet Standard No. 9 by simply collecting the data.

The proposed additional language as submitted by the Program Standards Committee provides needed grammatical corrections, but more importantly, would ensure that enrolled jurisdictions develop a targeted intervention strategy or strategies designed to address the occurrence of the risk factors identified in their Risk Factor Study, that these strategies are implemented, and the effectiveness of each strategy is evaluated by subsequent Risk Factor Studies or other similar tools.

The proposed language does not require that interventions result in a reduction in the occurrence of the risk factors, simply that it is attempted and measured. It encourages innovative approaches by suggesting jurisdictions consider various types of interventions such as code changes, educational and training activities, enforcement and compliance strategies, etc. The purpose of the proposed intervention strategy is to attempt to effect improvement in reducing priority risk factor occurrences, between measurement intervals and to assess the strategy's effectiveness.

Recommended Solution: The Conference recommends...:
a letter be sent to the FDA requesting an amendment to the Voluntary National Retail Food Regulatory Program Standards, Standard 9 Program Assessment, to add requirements to ensure that enrolled jurisdictions develop a targeted intervention strategy or strategies designed to address the occurrence of the risk factors identified in their Risk Factor Study, that these strategies are implemented, and the effectiveness of each strategy is evaluated by subsequent Risk Factor Studies or other similar tools.

- The specific revisions to Standard 9 are amended to read as follows:

(NOTE: complete Standard 9 document with tracked changes is attached to Issue titled: Report - Program Standards Committee)

Requirement Summary, (pages 9-2 and 9-3):

To be an active participant in the *Voluntary National Retail Food Regulatory Program Standards* and to be listed on the FDA Roll of Participating Jurisdictions, a jurisdiction must ~~assure~~ ensure that:

To achieve the criteria of Standard 9 and claim Standard 9 as met, a jurisdiction must ~~assure~~ ensure that:

3. A targeted intervention strategy(s) designed to address the occurrence of the risk factors(s) identified in their Risk Factor Study is implemented and the effectiveness of such strategy(s) is evaluated by subsequent Risk Factor Studies or other similar tools.

Achieving Standard 9, (page 9-5 thru 9-7):

A. 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.

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 (Survey) is implemented and the effectiveness is evaluated by subsequent Risk Factor Studies (Surveys) 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.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 040
Issue: 2012 II-020

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

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Title:
Standard No. 8 Assessment Workbook and Instruction Guide

Issue you would like the Conference to consider:
The Conference for Food Protection (CFP) Program Standards Committee (PSC) is recommending that new resources developed by the PSC be approved and included on the *2011 Self Assess and Audit Disk* to compliment the *Guide to Self Assess* as a resource for assessing staffing levels as defined in Standard No. 8.

Public Health Significance:
The Voluntary National Retail Food Regulatory 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 in our continued goal of reducing foodborne illness risk factors and promoting active managerial control practices sustaining long term compliance. Standard No. 8 applies to Program Support and Resources which includes a section on assessing adequate staffing levels.
Standard No. 8 recommends "a staffing level of one full-time equivalent (FTE) devoted to food for every 280 - 320 inspections performed". While the committee believes that this Standard as it applies to staffing level is unachievable for most jurisdictions and does not provide a realistic measurement that can be applied across various retail food regulatory programs across the nation, the majority agreed that if the PSC focused on a resource to assist in assessing the staffing level that valuable information pertaining to the challenges in meeting this Standard could be identified, which in the future could lead to a more attainable staffing level load.
Over the past two years, the PSC developed a new staffing level assessment resource through discussions and research to compliment the *Guide to Self Assess* for Standard No. 8. The PSC also developed a supporting instruction guide and recommends it also be made available to enrolled jurisdictions.

Recommended Solution: The Conference recommends...:
1) Approval of the following documents (*included as attachments to the Issue titled: Report - Program Standards Committee)*:
- *Standard No. 8 - Assessment Workbook*
- *Standard No. 8 - Assessment Workbook Instruction Guide*

2) That a letter be sent to the FDA requesting that both resource documents be made available to enrolled jurisdictions on the FDA web site and on upcoming versions of the *Self Assess and Audit Disk*.

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Conference for Food Protection
2012 Issue Form

Internal Number: 041
Issue: 2012 II-021

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

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Title:
Re-create Program Standards Committee

Issue you would like the Conference to consider:
The Conference of Food Protection (CFP) Program Standards Committee (PSC) requests that the PSC be re-created to serve as a stakeholder group to provide input to the FDA internal working group and continued assessment of the Standards for recommending changes and improvements.

Public Health Significance:
The Voluntary National Retail Food Regulatory 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 in our continued goal of reducing foodborne illness risk factors and promoting active managerial control practices sustaining long term compliance.

Recommended Solution: The Conference recommends...:
The Program Standards Committee be re-created following the 2012 CFP Biennial Meeting with the following charges:

1. Serve as a stakeholder group to provide input to an FDA internal working group to:

a. Collaborate on the development of an Administrative Procedures Document to support the Voluntary National Retail Food Regulatory Program Standards; and

b. Recommend additional changes or improvements to the Program Standards.

2. Explore, assess, and reevaluate Staffing Levels language within Standard No. 8 and recommended any changes.

3. Formulate resolutions to issues brought before the committee and report back at the 2014 CFP Biennial Meeting.

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Conference for Food Protection
2012 Issue Form

Internal Number: 071
Issue: 2012 II-022

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

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Title:
Administrative Procedures for Retail Food Program Standards

Issue you would like the Conference to consider:
Jurisdictions that use the Voluntary National Retail Food Regulatory Program Standards would benefit from the availability of a document that describes the processes used by FDA to administer the Program Standards and the processes that FDA expects jurisdictions to follow to "enroll in" and "remain" an active participant. As an addendum to the Program Standards that is maintained by FDA, such a document would serve to consolidate items currently described in Program Standard No. 9 and elsewhere in supporting materials and on websites maintained by FDA.
Currently Standard No. 9 of the Voluntary National Retail Food Regulatory Program Standards contains many of the procedures that jurisdictions are expected to follow if they are to be considered "an active participant" in the Program Standards. Among other things, these procedures address the required frequency for completion of self-assessments and verification audits and how jurisdictions are expected to report progress to FDA for inclusion on FDA Listing of Enrolled Jurisdictions. FDA believes these broad "standards implementation" requirements should be moved from Standard No. 9 to the new addendum, so that Standard No. 9 requirements contain only requirements directly related to a jurisdiction's assessment of their own program.

Public Health Significance:
Currently Standard No. 9 requires jurisdictions to assess their programs by conducting a Risk Factor Study and analysis of the resulting data to track trends over time related to the occurrence of risk factors. The intent of this Standard is for enrolled jurisdictions to track and assess their program outcomes as demonstrated by the occurrence of foodborne illness risk factors over time and to develop and implement strategies to improve food safety in their jurisdiction.
In addition, Standard No. 9 includes administrative requirements related to the self-assessment and auditing of a program against the full set of Program Standards and establishes what must be reported to FDA in order for an agency to be recognized as an "active participant" in the Program Standards.
FDA believes such administrative requirements do not belong in a specific Program Standard and instead belong in an administrative procedures document that more fully

describes the roles and expectations of jurisdictions formally participating in the Program Standards and of FDA in administering the Program Standards. Having a separate procedures document that describes all that is required for active participation and recognition by FDA should make it easier for stakeholders to locate and understand all the procedures related to Program Standards participation. Further, having a separate administrative procedures document should provide FDA more flexibility to improve the ways it implements the Program Standards without changing a recognized Program Standard itself.

Among the items that FDA believes would be best moved to a separate administrative document are those currently in Program Standard No 9. related to:

- the frequency of self-assessments and audits;
- procedures for conducting self-assessments and audits;
- the qualifications of auditors; and
- the submission of forms to FDA for inclusion on the Listing of Enrolled Jurisdictions.

Also appropriate for inclusion in such a document are administrative procedures that are not contained in Standard No. 9 but that would address:

- Program Standards enrollment eligibility;
- Procedures for maintaining FDA's Listing of Enrolled Jurisdictions and other means of recognizing participating jurisdictions;
- Procedures for obtaining interpretations of Program Standards through FDA Program Standards Clearinghouse;
- Procedures for resolving disputes concerning the results of non-conforming verification audits.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that:

1. FDA develop and maintain an addendum to the Voluntary National Retail Food Regulatory Program Standards that describes the administrative processes used by FDA to implement the Program Standards and by jurisdictions that choose to be active participants in the Program Standards, and that the addendum address how, and with what frequency, to:
    - Enroll jurisdictions in the Program Standards;
    - Measure and report progress made by jurisdictions in assessing and auditing their programs for conformance with the Voluntary Retail Food Regulatory Program Standards 1 through 9 (including submission of specific forms);
    - Recognize those jurisdictions meeting the Standards, including how jurisdictions are listed on the FDA website;
    - Interpret the Standards and resolve disputes concerning the results of non-conforming audits; and
    - Otherwise successfully implement the Program Standards.
2. Upon availability of an administrative procedures document, FDA will amend Program Standard 9, as shown in Attachments A and B, to remove language that describes the administrative processes used by jurisdictions to demonstrate implementation of the Program Standards but that are not requirements for conformance with Program Standard 9-Program Assessment and to make necessary editorial changes, as needed;

3. During development of the administrative procedures document, FDA consult the CFP Program Standards Committee for input on its content and format and on the placement of such a document as an addendum to the Standards.

Submitter Information:

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Attachments:

- "Attachment A-EXAMPLE Proposed amendments to Standard 9 for Admin Procedures"
- "Attachment B-CLEAN COPY EXAMPLE Proposed amendments to Standard 9 - Admin"

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EXAMPLE of proposed text changes recommended for removal upon inclusion in Administrative Procedures Addendum.

STANDARD 9
PROGRAM ASSESSMENT

Table of Contents

Standard 9

Program Assessment

This Standard applies to the process used to measure the success of the enrolled jurisdiction's program in reducing the occurrence of foodborne illness risk factors to enhance food safety and public health in the community. ~~jurisdictions in meeting the *Voluntary National Retail Food Regulatory Program Standards 1 through 9* (hereafter referred to as the National Standards) and their progress in reducing the occurrence of foodborne illness risk factors. Additionally, it applies to the requirements for recognition by the Food and Drug Administration of those jurisdictions meeting the National Standards.~~

Requirement Summary

~~To be an active participant in the *Voluntary National Retail Food Regulatory Program Standards* and to be listed on the FDA Roll of Participating Jurisdictions, a jurisdiction~~ Program management must ensure ~~assure~~ that:

1. ~~The program manager, or a designated representative, conducts an initial SELF-ASSESSMENT against the criteria in each of the nine (9) National Standards within 12 months following the date of enrollment and every 60 months thereafter; and,~~
2. ~~The program manager, or a designated representative, requests a VERIFICATION AUDIT within 3 months following any SELF-ASSESSMENT in which one or more Standards is claimed as met. The VERIFICATION AUDIT is to be completed within 6 months of that SELF-ASSESSMENT; and,~~
3. ~~Reporting, using the *FDA National Registry Report* and *Release Record and Agreement - -Permission to Publish in National Registry* (FDA Forms 3519 and 3520), will be completed and submitted to the appropriate FDA Regional Office within 30 days following a SELF-ASSESSMENT or a SELF-ASSESSMENT update and following any VERIFICATION AUDIT.~~

~~To achieve the criteria of Standard 9 and claim Standard 9 as met, a jurisdiction must assure that:~~

~~2.~~ 1. 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 ~~risk factors~~; and,

~~3.~~ 2. An analysis is made of the data collected and a report on the outcomes and conclusions of the RISK FACTOR STUDY is written.

~~Description of Requirement~~

~~To be an active participant in the National Standards and to be listed on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure that the following procedures for SELF-ASSESSMENTS, VERIFICATION AUDITS, and reporting are completed:~~

~~**Self-Assessment:**~~

1. ~~The program manager, or a designated representative, conducts an initial SELF-ASSESSMENT against the criteria in each of the nine (9) National Standards within 12 months of the date of enrollment and every 60 months thereafter:~~

   ~~If it is determined that a Standard has been met, at that point the Appendix documents (hereinafter referred to as the worksheets) for that Standard(s) are to be completed in preparation of the VERIFICATION AUDIT.~~

   ~~For any Standard(s) which are not met, it is recommended that any deficiencies in meeting the Standards criteria be identified in order to meet that Standard in the future. It is further recommended that priorities, action plans, and target dates be established to facilitate continuous improvement in the jurisdiction's program.~~

   ~~The National Standards Edition to be used when completing the required 60-month SELF-ASSESSMENT is the most recent version of the *Voluntary National Retail Food Regulatory Program Standards* published on the FDA web site at http://www.fda.gov[1]. Once at the FDA main web page, click on "Food," then "Food Safety," then "Retail Food Protection" and click on "Program Standards."~~

2. ~~For any Standard a jurisdiction claims as met:~~
   a. ~~The compliance status of the jurisdiction's program as measured against that Standard(s) is documented by completing the Appendix documents (worksheets) or documents containing equivalent summary information for that Standard; and,~~
   b. ~~QUALITY RECORDS specified as requirements in each of the National Standards are established, identified, and maintained. The QUALITY RECORDS must be maintained in such a manner that an AUDITOR can be provided information necessary to verify that a Standard's criteria have been met.~~
3. ~~This complete SELF-ASSESSMENT cycle must be repeated at a minimum every 60 months. However, a jurisdiction may, and is encouraged to complete a SELF-ASSESSMENT at any time during the 60-month interval to reflect the most current information on its program accomplishments as reflected by comparison against one or more of the individual Standards. A SELF-ASSESSMENT can be made using the edition of the National Standards effective at its last required SELF-ASSESSMENT or a more recent edition of the National Standards, at the jurisdiction's discretion.~~
4. ~~Following a SELF-ASSESSMENT UPDATE, a jurisdiction completes the worksheets or equivalent forms to document compliance with any additional National Standard(s) met since the last required SELF-ASSESSMENT, establishes the QUALITY RECORDS, and forwards the *FDA National Registry Report and Release Record*~~

and Agreement -Permission to Publish in National Registry (FDA Forms 3519 and 3520) to the appropriate FDA Regional Office within 30 days following a SELF-ASSESSMENT update.

B. **Verification Audit**

1. The program manager, or a designated representative, shall request a VERIFICATION AUDIT within three (3) months following any SELF-ASSESSMENT or SELF-ASSESSMENT in which one or more Standard(s) is claimed as met. The VERIFICATION AUDIT is to be completed within six (6) months of that SELF-ASSESSMENT or SELF-ASSESSMENT UPDATE.
2. A complete SELF-ASSESSMENTof all Standards will be completed every 60 months after the initial SELF-ASSESSMENT. At each complete SELF-ASSESSMENT, a VERIFICATION AUDIT is to be conducted for any standard that is being claimed as met only if the Standard has been revised since the last VERIFICATION AUDIT.
3. An AUDITOR, as defined in the National Standards, shall complete the VERIFICATION AUDIT. VERIFICATION AUDITS confirm and report on the accuracy of a SELF-ASSESSMENT that claims one or more Standard(s) as met. During the VERIFICATION AUDIT, the auditor will:
    a. Review the QUALITY RECORDS and confirm that the SELF-ASSESSMENT ASSESSMENT accurately reflects the program's compliance status with each criterion for the version of the National Standards that was used when completing the SELF-ASSESSMENT or a SELF-ASSESSMENT UPDATE; and,
    b. Determine whether the QUALITY RECORDS specified as requirements in each of the National Standards have been established, identified, and maintained. If the quality records for a specific program element provide inadequate information upon which to make a determination of conformance with the Standard or to enable a VERIFICATION AUDIT, that Standard is not met.

C. **Reporting Requirements for SELF-ASSESSMENTS and VERIFICATION AUDITS**

1. Reporting, using the *FDA National Registry Report* and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Forms 3519 and 3520), shall be completed and submitted to the appropriate FDA Regional Office within 30 days following a SELF-ASSESSMENT or a SELF-ASSESSMENT update and following any VERIFICATION AUDIT.
2. Submission of the *FDA National Registry Report and Release Record and Agreement -Permission to Publish in National Registry* is required following each 60-month SELF-ASSESSMENT regardless of whether any Standard(s) are claimed as met.
3. If a jurisdiction wishes to complete a SELF-ASSESSMENT UPDATEwith its most current program information, a new *FDA National Registry Report* (FDA Form 3519) and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Form 3520) must be submitted. Any report form submitted is marked to show attainment of all applicable Standards achieved at the time of submission. Dates showing current attainment for each Standard should be recorded on each submission in order to accurately reflect the program's history. Marking all

~~applicable Standards with their most recent attainment dates ensures that accurate information is posted on the FDA List of Enrolled Jurisdictions.~~

4. ~~The *FDA National Registry Report* (FDA Form 3519) and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Form 3520) is submitted following a VERIFICATION AUDIT. The date of the audit and the date of the version for the Standard that is being audited should be included on the report forms so that information may be added to the FDA List of Enrolled Jurisdictions.~~

Description of Requirement

Achieving Standard 9

To achieve the criteria of Standard 9 and claim Standard 9 as met, a jurisdiction must ensure ~~assure~~ that:

A. A RISK FACTOR STUDY and report on the occurrence of the five (5) foodborne illness risk factors is 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. ~~A~~ The RISK FACTOR STUDY includes all facility types 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 ~~five (5) years~~ 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 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 there has been a net change in the occurrence of the risk factors.

   The nine (9) facility types are:

   - Institutions – 1) Hospitals; 2) Nursing Homes; 3) Elementary Schools (K-5)

- Restaurants – 4) Full Service; 5) Fast Food
- Retail Food Stores – 6) Delis; 7) Meat Departments; 8) Seafood Departments; 9) Produce Departments

(See the FDA's Data Collection Manual for additional information regarding facility types and help with Risk Factor Studies.)

B. A jurisdiction may use routine inspection data or may ~~conduct~~ use a separate data methodology ~~collection~~ in completing a RISK FACTOR STUDY. A data collection instrument similar to the FDA Model Data Collection Form in the FDA Data Collection Manual ~~in Appendix J~~, 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. ~~Refer to the Data Collection Manual to understand the statistical limitations and restrictions if using an inspection form or a data collection form different from the FDA data collection 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. Refer to the Data Collection manual to understand the statistical limitations and restrictions if using an inspection form or a data collection form different from the FDA data collection instrument.

C. ~~Achievement of Standard 9 is audited using the same procedures and reported using the *FDA National Registry Report* (FDA Form 3519) and *Release Record and Agreement - Permission to Publish in National Registry* (FDA Form 3520) in the same manner as achievement of the other eight National Standards as detailed under **DESCRIPTION OF REQUIREMENTS** in this document for Self-Assessment, Verification Audit, and Reporting.~~

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. ~~The completed Appendices (worksheets) for each Standard and supporting records,~~
2. Survey reports on the occurrence of risk factors and *Food Code* interventions;
3. Survey collection tools or inspection sheets used for data collection; and
4. Documentation that each facility type regulated is surveyed during the 60-month survey cycle.
5. ~~Verification audit reports,~~
6. ~~FDA National Registry Report, FDA Form 3519, and~~
7. ~~Affidavit of Permission to Publish, FDA Form 3520.~~

~~The Standard 9: Program Self-Assessment and Verification Audit Form, included as a file on this disk is designed to document the findings from the self-assessment and the verification audit process this Standard~~.

CLEAN COPY EXAMPLE Proposed amendments to Program Standard 9 recommended for removal upon inclusion in an Administrative Procedures Addendum.

STANDARD 9
PROGRAM ASSESSMENT

Table of Contents

CLEAN COPY EXAMPLE Proposed amendments to Program Standard 9 recommended for removal upon inclusion in an Administrative Procedures Addendum.

Standard 9

Program Assessment

This Standard applies to the process used to measure the success of the enrolled 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. 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; and,

2. An analysis is made of the data collected and a report on the outcomes and conclusions of the RISK FACTOR STUDY is written.

Description of Requirement

Achieving Standard 9

To achieve the criteria of Standard 9 and claim Standard 9 as met, a jurisdiction must ensure that:

A. A RISK FACTOR STUDY and report on the occurrence of the five (5) foodborne illness risk factors is 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 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 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 there has been a net change in the occurrence of the risk factors.

The nine (9) facility types are:

- Institutions – 1) Hospitals; 2) Nursing Homes; 3) Elementary Schools (K-5)
- Restaurants – 4) Full Service; 5) Fast Food
- Retail Food Stores – 6) Delis; 7) Meat Departments; 8) Seafood Departments; 9) Produce Departments

(See the FDA's Data Collection Manual for additional information regarding facility types and help with Risk Factor Studies.)

B. A jurisdiction may use routine inspection data or may use a separate data methodology in completing a RISK FACTOR STUDY. A data collection instrument similar to the FDA Model Data Collection Form in the FDA Data Collection Manual, 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. Refer to the Data Collection manual to understand the statistical limitations and restrictions if using an inspection form or a data collection form different from the FDA data collection instrument.

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 *Food Code* interventions;
2. Survey collection tools or inspection sheets used for data collection; and
3. Documentation that each facility type regulated is surveyed during the 60-month survey cycle.

Conference for Food Protection
2012 Issue Form

Internal Number: 046
Issue: 2012 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.

Title:
Report - CFSRP Part A - Certification of Food Safety Regulation Prof.

Issue you would like the Conference to consider:
The CFP Certification of Food Safety Regulation Professionals (CFSRP) Work Group seeks the Conference's acknowledgement of its Work Group Report Part A.
(NOTE: CFSRP Part B of the Work Group report is submitted in a separate Issue titled: Report - CFSRP Part B - Uniform Inspection Program Audit Pilot Project).

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 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:

- Maintain and update this national training model;
- Explore additional training and/or assessment needs for regulatory retail food programs; and
- Build consensus among all retail food safety stakeholders.

Recommended Solution: The Conference recommends...:
acknowledgement of the Conference for Food Protection, Certification of Food Safety Regulation Professionals - Work Group Report Part A and the following attachments.

- 2012 CFP CFSRP Committee Final Report
- CFP CFSRP Committee Roster
- Assessment of Training Needs Survey Summary
- Third Party Auditor Survey Results
- IFPTI Curriculum Framework

The Conference also recommends thanking all the 2010-2012 CFSRP members, and the organizations/agencies they represent, which allowed them to actively participate on the Work Group.

Submitter Information:

Name: Susan Kendrick, Co-Chair
Organization: Certification of Food Safety Regulation Professionals Work Group
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Attachments:

- "CFP CFSRP Committee Roster"
- "Assessment of Training Needs Survey Summary"
- "Third Party Auditor Survey Results"
- "IFPTI Curriculum Framework"
- "CFSRP Final Report 2012"

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.

2012 Committee Lists for Program Booklet

First Name	Last Name	Company /Employer Name	City	State	Role (Chair, Co-Chair, Vice Chair)
Rance	Baker	National Environmental Health Association	Denver	CO	Member
Angela	Benton	Jetro/Restaurant Depot	College Point	NY	Member
Martin	Bucknavage	Penn State University	State College	PA	Member
Lee M.	Cornman	Florida Dept of Agriculture and Consumer Services/Food Safety Division	Tallahassee	FL	Member
Catherine	Cummins	Virginia Department of Health	Radford	VA	Member
Vicki	Everly	Retired - Local Regulatory	San Jose	CA	Member
Michael	Gentry	Alaska Dept of Environmental Conservation	Anchorage	AK	Member
Christopher	Gordon	Virginia Department of Health	Richmond	VA	Alt Member
Ron	**Grimes**	NSF International	Ann Arbor	MI	**Vice-Chair**
Joe	Hainline	Jefferson County Health Department	Hillsboro	MO	Member
Cheryn	Hargrave	United Supermarkets	Lubbock	TX	Member
Ruth N.	Hendy	Texas Department of State Health Services	Austin	TX	Member
DeBrena	Hilton	Tulsa Health Department	Tulsa	OK	Member
Christina N.	Johnson	Publix Super Markets, Inc.	Boynton Beach	FL	Member
Susan	**Kendrick**	Oregon Department of Agriculture	Salem	OR	**Chair**
Dr. David	McSwane	Indiana University	Indianapolis	IN	Member
Stephanie	Mohn	Marsh Supermarkets	Indianapolis	IN	Member
Michelle	Motsinger	Colorado Department of Public Health & Environment	Denver	CO	Member
Angela	Nardone	N2N Global	Longwood	FL	Member
Duane	O'Donnelll	Business Environmental Resource Center	McClellan	CA	Member
Melvin	Pascall	Ohio State University	Columbus	OH	Member
David J.	Read	Minnesota Department of Agriculture	St. Paul	MN	Member
Michael	Roberson	Publix Super Markets, Inc.	Lakeland	FL	Alt Member
Amy	Roedl	National Restaurant Association Solutions	Chicago	IL	Member
Michele	Samarya-Timm	Somerset County Department of Health	Franklin Park	NJ	Member
Zia	Siddiqi	Orkin Commercial Services	Atlanta	GA	Member
Joyce	Theard	Saint Louis County Department of Health	Clayton	MO	Member
Debbie	Watts	Tulsa Health Department	Tulsa	OK	Alt Member
John	Marcello	FDA	Tempe	AZ	Advisor
Jim	Fear	FDA	Rockville	MD	Advisor

Alternates - each of these members has another representative from their company, jurisdiction or association and agreed to act as an alternate.

Assessment of Training Needs

1. What is the NAME of your agency?

	Response Count
	16
answered question	**16**
skipped question	**1**

2. Do you represent:

		Response Percent	Response Count
Federal		0.0%	0
State		**52.9%**	**9**
Local County		35.3%	6
Local City		11.8%	2
Tribal		0.0%	0
		answered question	**17**
		skipped question	**0**

3. What is the population living within your Jurisdiction?

		Response Percent	Response Count
less than 25,000		0.0%	0
25,000 to 49,9999		5.9%	1
50,000 to 99,9999		0.0%	0
100,000 to 249,999		17.6%	3
250,000 to 499,999		5.9%	1
500,000 or above		**70.6%**	**12**
		answered question	**17**
		skipped question	**0**

4. What is your Jurisdiction's total number of retail food and food service establishments under permit?

		Response Percent	Response Count
less than 100		0.0%	0
101 to 500		11.8%	2
501 to 1,000		0.0%	0
1,001 to 3,000		17.6%	3
3,001 to 6,000		23.5%	4
6,001 or above		**47.1%**	**8**
		answered question	**17**
		skipped question	**0**

5. How many Food Safety Inspection Officers (FSIO's) are employed by your Jurisdiction FULL TIME (i.e., 100%) in the retail food and food service programs?

	Response Percent	Response Count
less than 4	**29.4%**	**5**
4 to 8	23.5%	4
9 to 12	5.9%	1
13 to 20	11.8%	2
21 to 30	5.9%	1
31 or more	23.5%	4
	answered question	**17**
	skipped question	**0**

6. How many Food Safety Inspection Officers (FSIO's) are employed by your Jurisdiction with responsibilities in other food protection or environmental health program areas in addition to their retail food and food service protection duties?

	Response Percent	Response Count
less than 4	23.5%	4
4 to 8	23.5%	4
9 to 12	0.0%	0
13 to 20	5.9%	1
21 to 30	17.6%	3
31 or more	**29.4%**	**5**
	answered question	**17**
	skipped question	**0**

7. If your Food Safety Inspection Officers (FSIO's) have responsibilities in other food protection or environmental health program areas, on average, how much of their annual work plan is dedicated to the retail food and food service protection programs?

	Response Percent	Response Count
less than 10%	5.9%	1
10% to 29%	5.9%	1
30% to 49%	23.5%	4
50% to 69%	23.5%	4
70% to 89%	**35.3%**	**6**
90% or more	5.9%	1
	answered question	**17**
	skipped question	**0**

8. Is your jurisdiction still ENROLLED in the FDA Voluntary National Retail Food Regulatory Program Standards?

	Response Percent	Response Count
Yes	**100.0%**	**17**
No	0.0%	0
	answered question	**17**
	skipped question	**0**

9. If enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards, has your Jurisdiction MET all the Standard 2-Trained Regulatory Staff criteria?

	Response Percent	Response Count
Yes	23.5%	4
No	**70.6%**	**12**
Not applicable	5.9%	1
	answered question	**17**
	skipped question	**0**

10. What is the minimum level of education a FSIO MUST have to be considered for employment by your Jurisdiction in the retail food protection program?

	Response Percent	Response Count
High School Graduate	0.0%	0
Associate's degree	5.9%	1
Bachelor's degree	**94.1%**	**16**
	Other (please specify)	3
	answered question	**17**
	skipped question	**0**

11. Are FSIO's in your Jurisdiction REQUIRED to complete at least 30 semester hours of science as part of their academic degree PRIOR TO employment or assignment to the retail food protection program?

	Response Percent	Response Count
Yes	**70.6%**	**12**
No	29.4%	5
	answered question	**17**
	skipped question	**0**

12. Identify which Credential(s) the FSIOs in your Jurisdiction are REQUIRED to hold? (Check all that apply)

	Response Percent	Response Count
REHS/RS issued by NEHA	11.8%	2
REHS/RS issued by State Registration Board	**47.1%**	**8**
CFSP issued by NEHA	17.6%	3
Not applicable	41.2%	7
	Other (please specify)	5
	answered question	**17**
	skipped question	**0**

13. As a part of your agency's training program, have your FSIO's utilized any of the following types of education or trainings (check all that apply):

	Response Percent	Response Count
FDA sponsored food safety CLASSROOM courses	82.4%	14
WEB-BASED (distant learning courses) such as those offered through FDA ORA U	**100.0%**	**17**
In-house (provided by your jurisdiction) CLASSROOM courses	70.6%	12
Food safety courses provided by trade or professional organizations such as IFPTI	58.8%	10
An ANSI-CFP accredited Food Protection Manager Certification Course	41.2%	7
Other – Please describe in box provided below.	11.8%	2
	Other	4
	answered question	**17**
	skipped question	**0**

14. For each educational or training opportunity listed below, rate their effectiveness in preparing your FSIO's for their current job responsibilities.

	Highly Effective	Effective	Not Effective	Response Count
FDA sponsored food safety CLASSROOM courses	**66.7% (8)**	33.3% (4)	0.0% (0)	12
WEB-BASED (distant learning courses) such as those offered through FDA ORA U	23.1% (3)	**69.2% (9)**	7.7% (1)	13
In-house (provided by your jurisdiction) CLASSROOM courses	**50.0% (5)**	**50.0% (5)**	0.0% (0)	10
Food safety courses provided by trade or professional organizations such as IFPTI	**54.5% (6)**	45.5% (5)	0.0% (0)	11
An ANSI-CFP accredited Food Protection Manager Certification Course	11.1% (1)	**77.8% (7)**	11.1% (1)	9
Other	**50.0% (2)**	25.0% (1)	25.0% (1)	4
			Other (please specify)	4
			answered question	**17**
			skipped question	**0**

15. If your FSIO's have taken an FDA sponsored food safety CLASSROOM course(s), please provide a rating for each of the following statements:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	N/A	Rating Average	Response Count
The objectives of the training course(s) were provided and understood prior to training	35.3% (6)	**58.8% (10)**	0.0% (0)	0.0% (0)	0.0% (0)	5.9% (1)	1.63	17
The training course(s) encouraged exchange of information and expression of ideas successfully	**47.1% (8)**	41.2% (7)	5.9% (1)	0.0% (0)	0.0% (0)	5.9% (1)	1.56	17
The training course(s) covered the topics FSIO's needed to learn about	41.2% (7)	**52.9% (9)**	0.0% (0)	0.0% (0)	0.0% (0)	5.9% (1)	1.56	17
The content of the training course (s) was relevant to FSIO's assigned job duties	41.2% (7)	**47.1% (8)**	5.9% (1)	0.0% (0)	0.0% (0)	5.9% (1)	1.63	17
The objectives of the training course(s) were achieved	35.3% (6)	**58.8% (10)**	0.0% (0)	0.0% (0)	0.0% (0)	5.9% (1)	1.63	17
The language used in the training course(s) was easy to understand	41.2% (7)	**52.9% (9)**	0.0% (0)	0.0% (0)	0.0% (0)	5.9% (1)	1.56	17
Enough time was devoted to each training session	41.2% (7)	**47.1% (8)**	5.9% (1)	0.0% (0)	0.0% (0)	5.9% (1)	1.63	17
						answered question		**17**
						skipped question		**0**

16. If your FSIO's have taken a WEB-BASED (distant learning courses) such as those offered through FDA ORA U, please provide a rating for each of the following statements:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	N/A	Rating Average	Respons Count
The objectives of the training course(s) were provided and understood prior to training	35.3% (6)	**58.8% (10)**	5.9% (1)	0.0% (0)	0.0% (0)	0.0% (0)	1.71	1
The training course(s) encouraged exchange of information and expression of ideas successfully	12.5% (2)	12.5% (2)	**31.3% (5)**	18.8% (3)	18.8% (3)	6.3% (1)	3.20	1
The training course(s) covered the topics FSIO's needed to learn about	29.4% (5)	**58.8% (10)**	11.8% (2)	0.0% (0)	0.0% (0)	0.0% (0)	1.82	1
The content of the training course (s) was relevant to job duties assigned to FSIO's	31.3% (5)	**50.0% (8)**	18.8% (3)	0.0% (0)	0.0% (0)	0.0% (0)	1.88	1
The objectives of the training course(s) were achieved	23.5% (4)	**58.8% (10)**	17.6% (3)	0.0% (0)	0.0% (0)	0.0% (0)	1.94	1
The language used in the training course(s) was easy to understand	29.4% (5)	**52.9% (9)**	17.6% (3)	0.0% (0)	0.0% (0)	0.0% (0)	1.88	1
Enough time was devoted to each training session	35.3% (6)	**41.2% (7)**	11.8% (2)	0.0% (0)	0.0% (0)	11.8% (2)	1.73	1
						answered question		**1**
						skipped question		

17. If your FSIO's have taken in-house (provided by your jurisdiction) CLASSROOM courses, please provide a rating for each of the following statements:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	N/A	Rating Average	Response Count
The objectives of the training course(s) were provided and understood prior to training	23.1% (3)	**69.2% (9)**	0.0% (0)	7.7% (1)	0.0% (0)	0.0% (0)	1.92	13
The training course(s) encouraged exchange of information and expression of ideas successfully	**53.8% (7)**	46.2% (6)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	1.46	13
The training course(s) covered the topics FSIO's needed to learn about	**53.8% (7)**	46.2% (6)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	1.46	13
The content of the training course (s) was relevant to FSIO's assigned job duties	**69.2% (9)**	30.8% (4)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	1.31	13
The objectives of the training course(s) were achieved	7.7% (1)	**84.6% (11)**	7.7% (1)	0.0% (0)	0.0% (0)	0.0% (0)	2.00	13
The language used in the training course(s) was easy to understand	23.1% (3)	**76.9% (10)**	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	1.77	13
Enough time was devoted to each training session	7.7% (1)	**53.8% (7)**	38.5% (5)	0.0% (0)	0.0% (0)	0.0% (0)	2.31	13
						answered question		**13**
						skipped question		**4**

18. If your FSIO's have taken food safety courses provided by trade or professional organizations such as IFPTI, please provide a rating for each of the following statements:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	N/A	Rating Average	Respons Count
The objectives of the training course(s) were provided and understood prior to training	20.0% (3)	**46.7% (7)**	0.0% (0)	0.0% (0)	0.0% (0)	33.3% (5)	1.70	1
The training course(s) encouraged exchange of information and expression of ideas successfully	**40.0% (6)**	26.7% (4)	0.0% (0)	0.0% (0)	0.0% (0)	33.3% (5)	1.40	1
The training course(s) covered the topics FSIO's needed to learn about	20.0% (3)	**46.7% (7)**	0.0% (0)	0.0% (0)	0.0% (0)	33.3% (5)	1.70	1
The content of the training course (s) was relevant to FSIO's assigned job duties	**33.3% (5)**	26.7% (4)	6.7% (1)	0.0% (0)	0.0% (0)	**33.3% (5)**	1.60	1
The objectives of the training course(s) were achieved	26.7% (4)	**40.0% (6)**	0.0% (0)	0.0% (0)	0.0% (0)	33.3% (5)	1.60	1
The language used in the training course(s) was easy to understand	26.7% (4)	**40.0% (6)**	0.0% (0)	0.0% (0)	0.0% (0)	33.3% (5)	1.60	1
Enough time was devoted to each training session	26.7% (4)	**40.0% (6)**	0.0% (0)	0.0% (0)	0.0% (0)	33.3% (5)	1.60	1
						answered question		**1**
						skipped question		

19. If your FSIO's have taken an ANSI-CFP accredited Food Protection Manager Certification Course, please provide a rating for each of the following statements:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	N/A	Rating Average	Respons Count
The objectives of the training course(s) were provided and understood prior to training	0.0% (0)	**50.0% (6)**	0.0% (0)	8.3% (1)	0.0% (0)	41.7% (5)	2.29	1
The training course(s) encouraged exchange of information and expression of ideas successfully	8.3% (1)	**41.7% (5)**	0.0% (0)	8.3% (1)	0.0% (0)	**41.7% (5)**	2.14	1
The training course(s) covered the topics FSIO's needed to learn about	0.0% (0)	33.3% (4)	8.3% (1)	16.7% (2)	0.0% (0)	**41.7% (5)**	2.71	1
The content of the training course (s) was relevant to FSIO's assigned job duties	0.0% (0)	**41.7% (5)**	8.3% (1)	8.3% (1)	0.0% (0)	**41.7% (5)**	2.43	1
The objectives of the training course(s) were achieved	8.3% (1)	**41.7% (5)**	0.0% (0)	8.3% (1)	0.0% (0)	**41.7% (5)**	2.14	1
The language used in the training course(s) was easy to understand	8.3% (1)	**41.7% (5)**	0.0% (0)	8.3% (1)	0.0% (0)	**41.7% (5)**	2.14	1
Enough time was devoted to each training session	0.0% (0)	33.3% (4)	16.7% (2)	8.3% (1)	0.0% (0)	**41.7% (5)**	2.57	1
						answered question		**1**
						skipped question		

20. If your FSIO's have taken FDA sponsored food safety CLASSROOM course(s), how can improvements be made?

	Response Percent	Response Count
Clarify objectives	18.2%	2
Provide better information before the course	**36.4%**	**4**
Update content	27.3%	3
Make more interactive	18.2%	2
Reduce content	9.1%	1
Increase content	9.1%	1
Make more difficult	18.2%	2
Make less difficult	0.0%	0
Improve assessment at end of training	9.1%	1
Add video	27.3%	3
Other (please specify)		3
answered question		**11**
skipped question		**6**

21. If your FSIO's have taken WEB-BASED (distant learning courses) such as those offered through FDA ORA U, how can improvements be made?

	Response Percent	Response Count
Clarify objectives	9.1%	1
Provide better information before the course	0.0%	0
Update content	45.5%	5
Make more interactive	**63.6%**	**7**
Reduce content	0.0%	0
Increase content	9.1%	1
Make more difficult	27.3%	3
Make less difficult	0.0%	0
Improve assessment at end of training	0.0%	0
Add video	9.1%	1
	Other (please specify)	3
	answered question	**11**
	skipped question	**6**

22. If your FSIO's have taken, in-house (provided by your jurisdiction) CLASSROOM courses, how can improvements be made?

	Response Percent	Response Count
Clarify objectives	36.4%	4
Provide better information before the course	27.3%	3
Update content	**54.5%**	**6**
Make more interactive	27.3%	3
Reduce content	0.0%	0
Increase content	9.1%	1
Make more difficult	0.0%	0
Make less difficult	0.0%	0
Improve assessment at end of training	36.4%	4
Add video	0.0%	0
	Other (please specify)	2
	answered question	**11**
	skipped question	**6**

23. If your FSIO's have taken an ANSI-CFP accredited Food Protection Manager Certification Course, how can improvements be made?

	Response Percent	Response Count
Clarify objectives	0.0%	0
Provide better information before the course	25.0%	1
Update content	0.0%	0
Make more interactive	0.0%	0
Reduce content	0.0%	0
Increase content	25.0%	1
Make more difficult	**50.0%**	**2**
Make less difficult	0.0%	0
Improve assessment at end of training	0.0%	0
Add video	0.0%	0
	Other (please specify)	2
	answered question	**4**
	skipped question	**13**

24. If your FSIO's have taken food safety courses provided by trade or professional organizations such as IFPTI, how can improvements be made?

	Response Percent	Response Count
Clarify objectives	0.0%	0
Provide better information before the course	0.0%	0
Update content	**80.0%**	**4**
Make more interactive	20.0%	1
Reduce content	0.0%	0
Increase content	0.0%	0
Make more difficult	60.0%	3
Make less difficult	0.0%	0
Improve assessment at end of training	40.0%	2
Add video	0.0%	0
	Other (please specify)	0
	answered question	**5**
	skipped question	**12**

25. Of the available education and training courses that are currently available, what are some of the gaps you have identified?

	Response Count
	14
	answered question	**14**
	skipped question	**3**

26. Are there any additional training needs you have identified?

	Response Count
	9
answered question	9
skipped question	8

Page 2, Q1. What is the NAME of your agency?		
1	Public Health - Seattle & King County	Nov 1, 2011 3:08 PM
2	Consumer Health Services Wyoming Dept. of Agriculture	Oct 31, 2011 4:50 PM
3	Olmsted County Public Health Services	Oct 28, 2011 5:26 AM
4	Kansas Department of Agriculture	Oct 26, 2011 6:27 AM
5	City of Lubbock	Oct 25, 2011 10:55 AM
6	Florida Department of Agriculture and Consumer Services	Sep 19, 2011 1:00 PM
7	Fairfax County Health Department	Sep 19, 2011 12:21 PM
8	MN Dept of Ag	Sep 15, 2011 1:48 PM
9	Oregon Department of Agriculture	Sep 13, 2011 11:39 AM
10	Tacoma Pierce County Health Department	Sep 12, 2011 4:52 PM
11	Indiana State Dept. of Health	Sep 12, 2011 11:50 AM
12	Whatcom County Health Department	Sep 9, 2011 5:35 PM
13	Maricopa County Environmental Services	Sep 6, 2011 10:28 AM
14	Town of Danvers, MA; Board of Health	Sep 6, 2011 5:30 AM
15	Texas Department State Health Services	Sep 2, 2011 12:56 PM
16	MA Department of Public Health, Bureau of Environmental Health, Food Protection Program	Sep 2, 2011 12:35 PM

Page 4, Q10. What is the minimum level of education a FSIO MUST have to be considered for employment by your Jurisdiction in the retail food protection program?		
1	Bachelor's or relevent experience	Oct 26, 2011 6:29 AM
2	high school if experience can count per yr of degree requirement	Sep 19, 2011 1:04 PM
3	Additional college level science is required: 30 Semester hours or 45 quarter hours.	Sep 9, 2011 5:39 PM

Page 4, Q12. Identify which Credential(s) the FSIOs in your Jurisdiction are REQUIRED to hold? (Check all that apply)		
1	cfpm	Sep 19, 2011 1:04 PM
2	Food Protection Manager Certification	Sep 19, 2011 12:22 PM
3	No-entry level, Yes-Technical Leads	Sep 12, 2011 5:00 PM
4	RS/REHS is preferred and FSIOs receive premium pay to compensate for RS/REHS.	Sep 9, 2011 5:39 PM
5	Certified Food Protection Manager	Sep 2, 2011 12:39 PM

Page 5, Q13. As a part of your agency's training program, have your FSIO's utilized any of the following types of education or trainings (check all that apply):		
1	Washington State Dept of Health sponsored food safety courses	Nov 1, 2011 3:14 PM
2	State Sponsored New Inspector Training	Sep 12, 2011 5:05 PM
3	Washington State Department of Health and the Washington State Environmental Health Association have provided face to face training for FSIOs. Our FDA retail specialists have provided assistance with field training and standardization. Some staff have taken on-line courses through NEHA.	Sep 9, 2011 5:48 PM
4	MHOA and MEHA sponsored conferences	Sep 2, 2011 12:51 PM

Page 5, Q14. For each educational or training opportunity listed below, rate their effectiveness in preparing your FSIO's for their current job responsibilities.		
1	WSDOH courses	Nov 1, 2011 3:14 PM
2	State Sponsored New Inspector Training	Sep 12, 2011 5:05 PM
3	The survey tool aoppears to malfunction here. It will not allow me to check more than one item as highly effective. In additiona to the answers above, I have found our in-house training (with the help of our retail specialists) highly effective.	Sep 9, 2011 5:48 PM
4	MHOA and MEHA sponsored conferences	Sep 2, 2011 12:51 PM

Page 6, Q20. If your FSIO's have taken FDA sponsored food safety CLASSROOM course(s), how can improvements be made?		
1	provide more content about risk-based assessments and how to assess Active Managerial Control with a focus on how to communicate with opertors to foster long-term effective management of FBI risk factors	Oct 28, 2011 5:53 AM
2	Offer more training locations	Oct 25, 2011 10:59 AM
3	sometimes time is spent on info not relevant to course	Sep 19, 2011 1:30 PM

Page 6, Q21. If your FSIO's have taken WEB-BASED (distant learning courses) such as those offered through FDA ORA U, how can improvements be made?		
1	technical difficulties with the web-site have created challenges on a regular basis. It would also be helpful to have assessment results (test scores) and progress/status reports e-mailed to the FSIO's supervisor or trainer to provide an opportunity to review and discuss with FSIO periodically.	Oct 28, 2011 5:53 AM
2	Separate courses to focus on different roles. Some course content is not relevant to job duties. Example-pasteurization is important for individuals with role in processing, but is not seen at retail level. Interesting but not relevant. With limited time courses more focused for various professional roles/duties at federal, state, and local, processing, retail, etc. would make some of the courses more relevant.	Sep 12, 2011 5:13 PM
3	Still waiting for some courses to be developed!	Sep 9, 2011 5:51 PM

Page 6, Q22. If your FSIO's have taken, in-house (provided by your jurisdiction) CLASSROOM courses, how can improvements be made?		
1	I create the training and get lots of advise on how to make it better - most of which is beyond the scope of my skills!	Nov 1, 2011 3:18 PM
2	working on that now	Sep 19, 2011 1:30 PM

Page 6, Q23. If your FSIO's have taken an ANSI-CFP accredited Food Protection Manager Certification Course, how can improvements be made?		
1	there may be value in development of a course/cirricullum aimed solely at inspectors so that the class can be more focused on the role of the FSIO versus the role of the certified food manager	Oct 28, 2011 5:53 AM
2	onlly take exam and not a course	Sep 19, 2011 1:30 PM

Page 6, Q25. Of the available education and training courses that are currently available, what are some of the gaps you have identified?		
1	Budget and time constraints to get more staff to classes. We need to have a more formal way to share information from courses The more practical and take away ready the information is the better.	Nov 1, 2011 3:18 PM
2	There is a disconnect from what is taught in the classroom versus what happens during actual food preparation. Videos should be from the inspector's point of view	Oct 31, 2011 5:00 PM
3	FDA training is very good, but not offered often, so it is a waiting game for new staff. We have to send them when it's offered versus when it is best to send them. We also have to travel and make lodging accomodations to attend FDA training. The Food Manager Certification courses are good but are primarily aimed at food managers. There is no solid source of training regarding how to conduct risk-based assessments and assessing Active Managerial Control except from learning from experienced staff....classroom or other support for this would be helpful.	Oct 28, 2011 5:53 AM
4	Practicing communication skills and conflict management. Practicing testimony.	Oct 26, 2011 6:33 AM
5	We need training that is closer to our city.	Oct 25, 2011 10:59 AM
6	more communication training especially with oral cultures	Sep 19, 2011 1:30 PM
7	1) Maintaining the risk-based focus of training 2) Food industry perspective 3) Ability to apply new information/procedures to "real-time" regulatory activities	Sep 19, 2011 12:36 PM
8	It is difficult to get all staff to classroom trainings due to limited space and availability.	Sep 13, 2011 12:02 PM
9	Availability of live in-person training.	Sep 12, 2011 11:57 AM
10	problem solving in stressful situations. Tools to de-escalate angry operators. Recall response.	Sep 9, 2011 5:51 PM
11	More information on the background of the code, a class on how to read and use the code	Sep 6, 2011 10:33 AM
12	Its voluntary - no standardized inspections in MA due to the varying level of skill among all the inspectors in the 351 separate jurisdictions!	Sep 6, 2011 5:36 AM
13	Too much time elapses between revisions and updates are made to the training materials	Sep 2, 2011 1:02 PM
14	Lenght of classroom courses and travel restrictions.	Sep 2, 2011 12:53 PM

Page 6, Q26. Are there any additional training needs you have identified?		
1	We will be doing some serious acessment in 2012 that may shed light on training needs.	Nov 1, 2011 3:18 PM
2	Love the small series about how to do an inspection, prepare for doing an inspection. Need more training on how to document inspections.	Oct 31, 2011 5:00 PM
3	jurisdictions that regulate both retail and manufacturing could benefit by a course that points out the common food safety components involved and the major differences	Sep 19, 2011 1:30 PM
4	1) Compliance & enforcement activities 2) Understanding and applying the guidance information outlined in the FDA Food Code	Sep 19, 2011 12:36 PM
5	We need to formalize our training on plan review for retail. We also need to provide our staff with more training on special processes that fall under a variance and/or HACCP.	Sep 13, 2011 12:02 PM
6	There is much more out there than just retail and we need more training for manufactured foods, LACF, etc.	Sep 12, 2011 11:57 AM
7	See above.	Sep 9, 2011 5:51 PM
8	Nothing beats ride-a-longs in the field with expereinced inspectors	Sep 6, 2011 10:33 AM
9	No	Sep 2, 2011 1:02 PM

Third Party Auditors Survey Questions

State	#1	#2	#3	#4	Completed by	Email	Telephone
Alabama							
Alaska							
Arizona							
Arkansas	N	Arkansas does not have local jurisdictions.	N/A	N	Teresa Bullock	teresa.bullock@arkansas.gov	501-661-2171
California							
Colorado							
Connecticut	N	Soma may hire individuals as consultants to perform inspections of regulated food establishments, but they are persons who are certified (per CT Regulations) by the CT Dept. of Public Health to conduct such inspections	N/A	N	Tracey Weeks	tracey.weeks@ct.gov	860-509-7297
Deleware							
Florida	No. All food safety regulatory authority is preempted to the state.	N	N/A	There has been no discussion for authorizing third party audits.	Lee M.. Cornman	lee.cornman@freshfromflorida.com	850-245-5595
Georgia							
Hawaii							
Idaho	N	N	N/A	N	Patrick Guzzle	guzzlep@dhw.idaho.gov	208-334-5936
Illinois							
Indiana	No, but it does not prohibit it either.	None that I am aware of.	N/A	Yes, we are looking at recognizing legitimate 3rd party audits such as AIB, SQF, Silliker, etc., to offset the inspection load in our manufactured foods program to allow us to spend more time on problem and high risk facilities	Scott Gilliam	sgilliam@isdh.in.gov	317-233-7467
Iowa							
Kansas	N	Not to my knowledge	N/A	No, but we do have authority to authorize third party inspections on lodging facilities.	Steve Moris	steve.moris@kda.ks.gov	785-296-5600
Kentucky	N	N	N/A	N	Pamela Hendren	pamelam.hendren@ky.gov	502-564-7181
Louisiana							

Third Party Auditors Survey Questions

Maine	There are 4 municipalities within Maine that have state delegated authority to inspect eating establishments. There are no third party audits.	N	N/A	N	Lisa Brown	lisa.brown@maine.gov	207-287-5691
Maryland							
Massachusetts							
Michigan	Y	Yes, may LHD's utilize 3rd party consultants. Some are individuals (Retired LHD Staff) & some are univeristies (MSU, U of M, Wayne State).	Carmen Merz, cmerz@ingham.org, 517-887-4312	BLANK	Tom Tederington	tederingtont@michigan.gov	517-335-7092
Minnesota	N	None that I am aware of. A few local health agencies contract with a neighboring local health agency to provide inspection service for restaurant and food service. Restaurant and food service inspections are under the jurisdiction of the MN Dept of Health. They delegate their inspection authority to a number of local health agencies and will allow a local health agency to contract with another local health agency for inspection services. The MN Dept of Agriculture inspects retail food stores such as bakeries, convenience and grocery stores. The MDA delegates retail inspection authority to a small number of local health agencies but does not allow the agency to contract with another local health agency to conduct inspections	N/A	Not that I am aware of.	David Read	david.read@state.mn.us	651-201-6596
Mississippi	N	N	N/A	N	John Luke	john.luke@msdh.state.ms.us	601-576-7689
Missouri							
Montana	N	N	N/A	N	Christine Cox	ccox@mt.gov	406-444-2089
Nebraska	N	N	N/A	N	George Hanssen	george.hanssen@nebraska.gov	402-471-3422

Third Party Auditors Survey Questions

Nevada							
New Hampshire							
New Jersey	N	N	N/A	N	Mary Lou Falco	marylou.falco@doh.state.nj.us	609-826-4935
New Mexico							
New York							
North Carolina							
North Dakota	N	N	N/A	BLANK	Kenan Bullinger	kbulling@nd.gov	701-328-1292
Ohio							
Oklahoma							
Oregon	N	N	N/A	N	Dave Martin	david.c.martin@state.or.us	971-673-0450
Pennsylvania							
Puerto Rico							
Rhode Island							
South Carolina							
South Dakota							
Tennessee	N	N	N/A	Not at this time.	Lori LeMaster	lori.lemaster@tn.gov	615-741-8531
Texas	Y	Yes, at least 10.	Lisa Pomeroy, Bureau Veritas, lisa.pomeroy@us.bureauveritas.com, 800-907-7199	BLANK	Ruth Hendy	ruth.hendy@dshs.state.tx.us	512-834-6753
Utah							
Vermont							
Virginia	N	N	N/A	BLANK	Chris Gordon	christopher.gordon@vdh.virginia.gov	804-864-7417
Washington							
West Virginia	N	N	N/A	N	Linda Whaley	Linda.k.whaley@wv.gov	304-356-4283
Wisconsin	N	Not that we are aware of.	N/A	None whatsoever	James Mack	james.mack@wisconsin.gov	608-266-8351
Wyoming							
Total Responses	18						

Survey Questions ***1*** ***2*** ***3*** ***4***

Third Party Auditors Survey Questions

Does your state provide the legislative authority to state and local government agencies to contract independent third party auditing firms to conduct institutional foodservice, restaurant, and retail food	Are there any local jurisdictions within your state that are currently contracting with independent third party auditing firms to conduct institutional foodservice, restaurant, and retail food compliance inspections in lieu of State/local/tribal regulatory retail food programs?	If so, please provide a contact name, email address, and office telephone number where more information can be obtained from those jurisdictions.	If state and local jurisdictions are currently conducting regulatory inspections only, is any consideration being given to authorizing third party audits of retail food establishments in the future?

International Food Protection Training Institute
Curriculum Framework
For An
Integrated Food Safety System

DRAFT

Certificate and CEU Issuance (IACET/ANSI)

Professional Level Program Certificates

Leadership (Leadership) L4 - 4000

Advocacy | Budget | Change Management | Continuity of Operations | Human Resource Management | Legislative Affairs | Policy Making | Public Relations | Resource Leveraging | Risk Analysis (Management & Communication) | Stakeholder Support

Technical Specialist: (Master) L3 - 3000

Animal Drugs | BSE Investigations | Medicated Feed | Non-Medicated Feed | Rendering Plants | Shellfish | Tissue Residue | Acidified Foods | Aseptic Processes | Biotechnology and Nanotechnology | Dietary Supplements | Economic Adulteration | Infant Formula | Juice HACCP | Low Acid Canned Food | Medical Foods | Pasteurization | Seafood HACCP | Web Site Reviews | Specialized Process | Standardization

Unprocessed Concentration | Electives | Manufactured Concentration | Electives | Retail Concentration | Electives

Audit | Food Defense Vulnerability Assessment (Carver Plus Shock, etc) | Food Emergency Response (ICS) | Risk Analysis

Electives: Research Design | Statistical Analysis

Instructor Development | Executive Program | Leadership Program

Professional Level Program Certificates

Aquaculture | Dairy | Food Animals (Eggs) | Produce (Sprouts, Leafy Green Vegetables) | Shellfish | Additives | Animal Food Processing | Commodity-Specific | Feed | Food | Milk or Milk Products | Meat & Poultry | Packaging | Seafood/ Shellfish | Active Managerial Control | Catering | Cottage Foods | Food Preparations Techniques | Food Service | Grocery | Plan Review | Retail HACCP/ Variance | Vending, Temp, Other

Unprocessed Concentration | Electives | Manufactured Concentration (labeling. etc) | Electives | Retail Concentration (labeling, etc.) | Electives

Good Agricultural Practices (GAPs) | Allergens | Food Processing & Preservation | Food Salvage & Disposal | Formula Review | Imports | Ingredients & Additives

Journey Level: (Application) L2 - 2000 (Applied Inspection Techniques)

Communication Skills | Epidemiology, Foodborne Illness Investigation & Response | Food Defense | Food Emergencies (ICS) | Food Safety Programs | (HACCP, GMPs, GAPs, GWPs, SSOPs, Personal Health and Hygiene, Sanitary Design and Construction) | Food Transportation | Investigation, Sampling Techniques, & Laboratory Methodology | Law | Professional (soft) Skills (EG time management, etc) | Risk Analysis (Management, Assessment, & Communication) | Science & Technology | Traceability & Recalls

Fellowship in Food Protection | Annual Updates | Emerging Issues

Integrated Food Safety System

Professional Level Program Certificates

Entry Level: (Knowledge) L1 - 1000

Unprocessed Foundations | Manufactured Foundations | Feed Only | Retail Foundations

Allergens (ORAU) | **Labeling** (ORAU) Manufactured & Feed | Food Defense Awareness (ORAU) | Environmental Health Safety (ORAU) | Inspections, Compliance & Enforcement (ORAU) | Sampling (ORAU)

Integrated Food Safety System Orientation

Jurisdiction

Employee Safety

Communication Skills | Epidemiology (Not in Feed) | HACCP | Microbiology (not in Feed) | Prevailing Statutes, Regulations & Ordinances | Public Health Principles

(ORA-U Level I - Feed, Milk & Local, Shellfish, Standard 2: Manufactured, Retail)

Vertically Integrated National Curriculum (Secondary Education - Higher Education - Career Spanning Professional Development)

Higher Education Food Protection Curriculum

Secondary Education (high school) Curriculum Focus

Certificate and CEU Issuance (IACET/ANSI)

Program Certificates

Leadership (Leadership) L4 - 4000

Technical Specialist: (Master) L3 - 3000

Journey Level: (Application) L2 - 2000 (Applied Inspection Techniques)

Epidemiology | Food Regulatory | Information Technology | Homeland Security | Laboratory | Veterinary

Entry Level: (Knowledge) L1 - 1000

Vertically Integrated National Curriculum (Secondary Education -

Higher Education Food Protection Curriculum

Secondary Education (high school) Curriculum Focus

1Conference for Food Protection
Committee Report

COMMITTEE NAME: Certification of Food Safety Regulation Professionals Committee

COUNCIL (I, II, or III): II

DATE OF REPORT: December 05, 2011

SUBMITTED BY: Susan Kendrick, Committee Co-Chair; Ron Grimes Co-Chair

COMMITTEE CHARGES:

1. Collaborate with the FDA Center for Food Safety and Applied Nutrition and the FDA Division of Human Resource Development to:

- Review 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.
- Review and revise, as needed, Standard 2 classroom curriculum, time frame for completion of Steps 1 through 4 for new hires or staff newly assigned to the regulatory retail food protection program.
- Determine if the CFP Field Training Manual and forms have completely addressed all recommendations received as part of the 2007 Assessment of Training Needs (ATN) pilot project.

2. Eliminate the potential redundancy of multiple verification tools (FDA Retail Food Level I Performance Audit and FDA Procedures for Standardization and Certification of Retail Food Inspection / Training Officers) utilized by FDA programs, work in collaboration with FDA's Center for Food Safety and Applied Nutrition, FDA's National Retail Food Team and the FDA's Division of Human Resource Development to:

- Conduct a pilot project over the next year using the FDA Retail Food Level I Performance Audit with a limited and selected number of jurisdictions. The FDA Performance Audit will be piloted for use during the two joint inspections conducted as part of the quality assurance component of Standard 4 - Uniform Inspection Program. An outline of the pilot project objectives, protocol, and projected timeline is included as Attachment A with this Issue. The CFP CFSRP work group will submit a report to the 2012 Biennial Meeting that documents the result of the pilot project and any recommendations for the use of verification tools as part of the FDA Program Standards; and,
- Conduct a joint assessment of FDA Standardization Procedures and FDA Performance Audit documents to determine if both verification tools are equally viable with distinct purposes and outcomes; and,
- Explore the feasibility of merging these existing verification tool documents and provide a plan for consolidation of such; and,

- Upon determination, assess the placement and administration of final verification tool(s) within the FDA Program Standards as appropriate, or separately as appropriate; and, with input and guidance from the CFSRP Work Group, FDA will determine if modifications to their draft FDA Performance FDA Retail Food Level I Performance Audit and/or Standardization documents are needed. Any modifications that would include changes to the Program Standards will be submitted as Issues by the CFP CFSRP Work Group to the 2012 Biennial Meeting.

3. Collaborate with FDA, other federal agencies, professional and industry associations to research what criteria is currently being used to assess the education and training qualifications of independent third party auditors that have been contracted to conduct institutional foodservice, restaurant, and retail food compliance inspections in lieu of a State/local/tribal regulatory retail food program. The re-created Work Group is to provide a report to the 2012 Biennial Meeting that:

- Assesses the number of jurisdictions and geographic areas where retail food compliance Inspections are conducted by independent third party auditors in lieu of a regulatory compliance program;
- Delineates the reasons jurisdictions have moved to a third party auditor inspection compliance program;
- Summarizes criteria used to select third party auditors for inspection compliance oversight responsibilities including, but not limited to, education and training qualifications;
- Assesses and determines appropriate training and standardization processes/protocols for third party auditors, and
- Identifies any agencies/organizations/working groups currently addressing education and training standards for third party auditors conducting retail food compliance inspections.

Based on the above research, the work group will provide a recommendation to the Conference as to what actions/initiatives, if any, need to be undertaken to provide a national structure for ensuring that third party auditors possess the necessary knowledge, skills, and abilities to conduct retail food program compliance inspections.

4. Evaluate and determine the best approaches to promoting awareness and implementation of the national training model contained in the CFP Field Training Manual and forms, Appendix B 2, Standard 2 the Work Group will:

- Research the use of websites, list serves, newsletters, testimonials, presentations, and training workshops, etc.
- Assess opportunities for enhancing the electronic versions of the CFP Field Training Manual and forms to minimize paperwork.

5. Report back to the 2012 Biennial Meeting its findings regarding the above charges

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Meetings and Workgroup Assignments:
The CFSRP Work Group was charged with a great deal of significant work to be completed by the 2012 CFP Biennial meeting. In order for the Work group as a whole to accomplish these charges, the workgroup was divided into smaller sub-workgroups centering on individual committee charges. Each committee member was asked to participate on at least one sub-workgroup. The CFSRP Co-Chair Susan Kendrick and Co-Chair Ron Grimes selected sub-workgroup chairs as follows:

Workgroup	(Co) Leaders	Function
Subgroup 1	Dave Read and Michelle Motsinger	Work with FDA CFSAN on training, evaluation, and/or certification of FSIOs
Subgroup 2	Lee Cornman and John Marcello	Conduct and evaluate FDA Program Performance Audit
Subgroup 3	Christina Johnson and Ruth Hendy	Research criteria used to assess qualifications third party auditors
Subgroup 4	Michelle Samarya-Timm	Determine the best approaches to promoting CFP Field Training Manual

The CFSRP held all meetings by conference calls in an effort to ease travel restrictions that were placed on the individual committee members. The dates of the conference calls were: September 23, 2010; December 3, 2010; February 8, 2011; April 26, 2011; June 22, 2011; August 18, 2011; October 3, 2011; October 31, 2011; and November 30, 2011.

Due to the complexity of the charges and information presented, the CFSRP Work Group final report is presented in two parts:

Part A – All committee charges and activities except for the pilot project noted in Part B.
Part B – Uniform Inspection Program Audit Pilot Project.

Charge 1: Collaborate with the FDA Center for Food Safety and Applied Nutrition and the FDA Division of Human Resource Development.

- The FDA's Food Protection Plan, the President's Food Safety Working Group, and the recent passage of the Food Safety Modernization Act are major drivers for the development of the Integrated Food Safety System to ensure food safety in a cohesive and comprehensive manner. Collaboration and coordination of federal, state, tribal, and local food safety program efforts is essential for implementation of this system. One important step toward integration is the adoption of the Retail Food Regulatory Program Standards and the Manufactured Food Regulatory Program Standards by food safety regulatory agencies to promote uniformity and the use of best practices in their regulatory programs.

The Conference for Food Protection has a role in assisting retail food programs to develop the capacity and infrastructure for an integrated approach.

- The CFSRP Workgroup has members participating on the Partnership for Food Protection (PFP) Training and Certification Workgroup (TCWG). The workgroup was formed in 2008 as an outcome of the FDA/ 50 State Gateway to Food Protection meeting held in St Louis, MO. The committee's charges were to:
    - Establish competencies and certification for all disciplines.
        1. Short-term deliverable: Perform a job analysis for (all governmental jobs and stakeholders) inspectors involved in food and feed protection (prevention, intervention, and response). Identify current competency assessments and credentials. Develop a set of core competencies. Develop a framework for credentialing that could be taken back to associations and agencies to share.
        2. Long-term deliverable: To expand to include other disciplines, experienced staff, and stakeholders involved in food and feed protection.
    - Establish a national training center.
        1. Short-term deliverable: Assess and review training currently available for all disciplines involved in food and feed protection (prevention, intervention, and response) and identify any gaps. Use this information to assess whether Kellogg Foundation International Food Protection Training Institute (IFPTI) proposal fits needs and goals identified by the work group.
        2. Long-term deliverable: To put together a comprehensive course catalog.
- The PFP TCWG has worked diligently on these charges since inception. For additional detail, see the links to the 2008 50 State Meeting Report, the 2010 50 State Meeting Report, the 2010 PFP TCWG report, and the 2010 Food Safety Training and Certification Vision for Federal, State, Local, Territorial, and Tribal Regulators.
  Link directly to the 50 State Meeting Reports:
  http://www.fda.gov/ForFederalStateandLocalOfficials/Meetings/50-StateMeeting/default.htm
  Link directly to the Vision:
  http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/Meetings/UCM274679.pdf
  Link directly to the training work group final report:
  http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/Meetings/UCM274677.pdf
- The TCWG developed a plan to conduct Retail Food Safety Specialist Job Task Analysis (JTA) for food inspection positions that FDA has initiated through a contract and has completed a number of JTA's for federal staff conducting specific food safety inspections. This work can be used by state and local entities

to compare to their own inspection activities to verify similar activities and identify differences or gaps that may exist between federal, state, and local food inspection activities.

- The TCWG also endorsed the IFPTI as a training institute to deliver food safety training to federal, state, and local food safety staff. Additionally, the IFPTI has inventoried food safety training available around the country into a course catalog currently available on their website at www.ifpti.org. The IFPTI established a Curriculum Development Team that included members of the CFSRP and the PFP TCWG to design a competency based framework to identify and develop food safety curriculum addressing four professional levels (entry, journey, technical, and leadership) for training people at different stages of their career. The IFPTI Curriculum Framework is attached to this report.
- As a result of the ongoing work of the Partnership for Food Protection Training and Certification Workgroup, the CFSRP workgroup decided **not** to recommend revisions to Retail Food Regulatory Program Standard 2 until more information is available from the Retail Food Safety Specialist Job Task Analysis for state and local food safety regulatory professionals.
- Once the Retail Food Safety Specialist Job Task Analysis is complete, the information can be used to review the Standard 2 curriculum to identify any gaps and recommendations for change and has been included as a continuation charge – See Issue titled: Re-create CFSRP Work Group.
- A follow-up survey to the CFSRP 2008 Assessment of Training Needs Pilot Project was conducted (see attached *Assessment of Training Needs Survey Summary*).
    - The original pilot project participants were re-surveyed to identify and assess existing training and gaps in training for food safety inspection officers (FSIO's).
    - The survey was completed by 16 of the 30 original pilot project participants and 53% of respondents represented State agencies while 35% represented local county agencies, and 12% represented local city agencies.
- A majority of respondents require a Bachelors Degree (94%) as the minimum level of education an FSIO must have to be considered for employment with their agency, and 70% require at least 30 semester hours of science as a part of their academic degree prior to employment or assignment to the retail food protection program.
- As a part of their agency's training program, a large majority of respondents had utilized FDA sponsored food safety classroom courses (82.4%) and FDA web-based learning such as ORA-U (100%). Additionally, many also provided in-house classroom courses (71%) and over half were utilizing IFPTI as a mechanism for training (59%).
- Feedback on course delivery, effectiveness, content, and objectives were very favorable for all of the above-mentioned training methods.
    - Respondents did offer suggestions for improvement including:
        1. Providing better information before the course,
        2. Updating content,
        3. Adding video as a training method,
        4. Making courses more interactive, and more difficult.

- Feedback from respondents also indicated there was a gap in training and that some topics were not currently being addressed in trainings, including:
    1. Communication,
    2. Problem solving,
    3. Conflict management, and
    4. Actual application of learned knowledge and skills in a classroom environment.

- The 2010-2012 CFP CFSRP Work Group is recommending that a new charge be assigned to a re-created CRFSP Work Group to collaborate with the FDA Center for Food Safety and Applied Nutrition, the FDA Division of Human Resource Development, and the Partnership for Food Protection Training and Certification Workgroup (PFP TCWG) to:
    - 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.
    - When completed, use the Retail Food Safety Specialist Job Task Analysis being developed under the umbrella of the PFP TCWG to review and revise the Standard 2 curriculum to 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.
    - Determine if the CFP Field Training Manual and forms need to be revised based on the findings of the PFP TCWG and the Retail Food Safety Specialist Job Task Analysis.

Charge 2: Eliminate the potential redundancy of multiple verification tools (FDA Retail Food Level I Performance Audit and FDA Procedures for Standardization and Certification of Retail Food Inspection / Training Officers) utilized by FDA programs, and work in collaboration with FDA's Center for Food Safety and Applied Nutrition, FDA's National Retail Food Team, and the FDA's Division of Human Resource Development.

- Developed a uniform inspection program audit pilot project jurisdiction feedback on the audit process and forms.
- Seventeen jurisdictions enrolled in the pilot study. Fourteen of those completed the pilot and returned the forms (6 State, 7 County, 1 City jurisdiction).
- Results of the feedback from the Standardization/Certification of Retail Food Safety Inspection Officers Pilot Project was statistically analyzed and categorized.
- The Pilot Project is presented under separate cover as an Issue document titled: Report – CFSRP Part B – Uniform Inspection Program Audit Pilot Project.
- Participating jurisdictions have indicated that both the FDA Standardization Procedures and FDA Performance Audit documents are valuable verification

tools but rather than merging the two documents, they would prefer to have the training tool as an Appendix to Standard 4.

- The Conference recommends that a letter be sent to FDA requesting that they:

1. Work in collaboration with the Program Standards Committee to revise Standard 4, Uniform Inspection Program, to address the pilot project comments and to assess the criteria in Standard 4 to make it more program focused rather than focused on the individual.

2. Review for potential revisions to the Standard 4 Uniform Inspection Program criteria and field inspection review process, the following recommendations contained in the CFP CFSRP Uniform Inspection Program Audit Pilot Project Report.
   - 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.

   - 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.

   - The presentation of the 10 Program Elements contained in 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.

   - 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.

   - 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.

   - 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.

- The field inspection assessment conducted as part of Standard 4 seems to take an all or nothing approach. Item 1 for example 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.

- 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.

- 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.

3. Obtain input and feedback from the CFP Program Standards Committee to assist FDA in the review of the recommendations contained in the CFP CFSRP pilot project report.

Charge 3: Collaborate with FDA, other federal agencies, and professional and industry associations to research what criteria is currently being used to assess the education and training qualifications of independent third party auditors that have been contracted to conduct institutional foodservice, restaurant, and retail food compliance inspections in lieu of a State/local/tribal regulatory retail food program.

- Explored option of obtaining third party audit information from NEHA surveys, but these did not provide any information relevant to the work of this committee.
- Decided to survey States to see where Third Party Audits could/were being utilized to offset regulatory inspections.
- Developed a short four question survey (see attached *Third Party Auditor Survey Summary*).
- Discussed how contract inspectors might be standardized.
- The 2010 CFP delegates were sent a survey but only 36% responded.
- A follow-up email to the non-responsive states was conducted.
- The results of the survey revealed mixed results of the 18 respondents:
    - Only two states indicated that there are third party auditors performing inspections in their states.
    - One State indicated authority to authorize third party inspections of lodging facilities but they were not aware of any current situations.

- One State indicated "consultants" certified to conduct inspections by the State Dept of Public Health could be utilized.
- One State is considering recognizing third party audits for manufactured foods.

- The 2010-2012 CFP CFSRP Work Group is recommending that new charges be assigned to a re-created CFSRP Work Group to:
  - Collaborate with FDA, other federal agencies, and professional and industry associations to evaluate the results of the Retail Food Safety Specialist Job Task Analysis being developed under the umbrella of the PFP TCWG to:
    1. Assess and determine appropriate training and standardization processes/protocols for third party auditors.
    2. Identify any agencies/organizations/working groups currently addressing education and training standards for third party auditors conducting retail food compliance inspections.
    3. Provide a recommendation to the Conference as to what actions/initiatives, if any, need to be undertaken to provide a national structure for ensuring that third party auditors possess the necessary knowledge, skills, and abilities to conduct retail food program compliance inspections.

Charge 4: Evaluate and determine the best approaches to promoting awareness and implementation of the national training model contained in the CFP Field Training Manual and forms, Appendix B 2, Standard 2.

- The 2010-2012 CFP CFSRP Work Group recommends that the FDA serve as the appropriate authority to implement and promote the CFP Field Training Manual. The Work Group has identified the following items to provide assistance to the FDA in their promotional activities:
  - CDC's Environmental Public Health Performance Standards toolkit, which was created in partnership with National Association of County and City Health Officials (NACCHO), was reviewed and determined to be a valuable model for promotion and implementation of the CFP Field Training Manual.
  - Case studies of jurisdictions that use the CFP Field Training Manual would be a valuable resource in a toolkit provided by FDA to jurisdictions that are working to include the Field Training Manual in their program.
  - Application forms for available financial incentives would be an asset in a toolkit provided by FDA as financial assistance would promote implementation of the Field Training Manual in jurisdictions that are not currently using the Manual.
  - The toolkit should also include references of agencies and subject matter experts to contact for implementation questions.

The Conference recommends that a 2012-2014 Certification of Food Safety Regulation Professionals Work Group be re-created to address the charges listed above.

REQUESTED ACTION:

The Committee submits the following Issues and attachments to the 2012 CFP Biennial Meeting:

1) Issue #1: CFSRP Part A – Work Group Report
   Recommending acceptance of CFP CFSRP Work Group Report
   Attachments to this Issue includes:
   - 2012 CFP-CFSRP Committee Final Report (content attachment to be reviewed and acknowledged by Council II)
   - CFSRP Work Group Roster (supporting attachment)
   - IFPTI Curriculum Framework (supporting attachment)
   - Assessment of Training Needs Survey Summary (supporting attachment)
   - Third Party Auditor Survey Results (supporting attachment)
2) Issue #2: CFSRP Part B – Uniform Inspection Program Audit Pilot Project
   Recommending acceptance of CFP CFSRP Uniform Inspection Program Audit Pilot Project
   Attachments relevant to this Issue include:
   - Uniform Inspection Program Audit Pilot Project Report (content attachment to be reviewed and acknowledged by Council II)
   - Guide to Uniform Inspection Program Audit, Worksheet, and Reference Guide (supporting attachment)

3) Issue #3: Recommendations from Uniform Inspection Program Audit Pilot Project
   Attachments relevant to this Issue include:
   - The *Uniform Inspection Program Audit Pilot Project Report*, submitted as an attachment to the Issue titled: "CFSRP Part B – Uniform Inspection Program Audit Pilot Project."

4) Issue #4: Recommendations for Promoting the Field Training Manual

5) Issue #5: Re-create Certification of Food Safety Regulation Professionals Work Group

ATTACHMENTS:

- IFPTI Curriculum Framework
- Assessment of Training Needs Survey Summary
- The Uniform Inspection Program Audit Pilot Project Report
- Guide to Uniform Inspection Program Audit, Worksheet, and Reference Guide
- Third Party Auditor Survey Results
- CFSRP Work Group Roster

COMMITTEE MEMBER ROSTER:

- See attached: CFP CFSRP Work Group Member Roster (pdf)

Conference for Food Protection
2012 Issue Form

Internal Number: 049
Issue: 2012 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.

Title:
Report - CFSRP Part B - Uniform Inspection Program Audit Pilot Project

Issue you would like the Conference to consider:
The CFP Certification of Food Safety Regulation Professionals (CFSRP) Work Group seeks the Conference's acknowledgement of Part B of its report summarizing the data and feedback received from the 14 State and local jurisdictions that participated in the Uniform Inspection Program Audit Pilot Project.
(NOTE: Part A of the Work Group report is submitted in a separate Issue titled:
Report - CFSRP Part A - Certification of Food Safety Regulation Professionals Work Group)

Public Health Significance:
The 2010 Conference charged the CFSRP Work Group with coordinating a pilot project that assessed 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. 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.
The CFP *Guide to the Uniform Inspection Program Audit, Audit Worksheet*, and *Audit Reference Guide* used for the pilot study are available on the CFP web link:
http://foodprotect.org/about/news/?id=cfp-cfsrp-pilot-project-announcement
The pilot project report summarizes the feedback from the participating jurisdictions who:

- Determined the strengths and weaknesses of the *Uniform Inspection Program Audit* process, *Audit Worksheet*, instructions, and guidance documents.
- Provided assessments on the ease of use of the documents.
- Determined the length of time and resource commitment necessary to complete the audit process.
- Reviewed the 10 inspection program areas and competencies that comprise the Standard 4 criteria for omissions, additions, and items deemed to be not applicable. (A detailed description of the 10 inspection areas and competencies is contained in the *Audit Reference Guide* available on the CFP web link noted above.)

- Assessed the appropriateness of including the *Uniform Inspection Program Audit* process and *Audit Worksheet* as a model template for Standard 4.

The *Uniform Inspection Program Audit Pilot Project Report* is included with this Issue as an Attachment.

Recommended Solution: The Conference recommends...:

acknowledgement of the Certification of Food Safety Regulation Professionals - Work Group's Report Part B, the summary and findings in the attached *Uniform Inspection Program Audit Pilot Project Report*.

The Conference further recommends that an expression of thanks be extended to the 14 State and local jurisdictions (listed in the report Acknowledgements) for their invaluable contributions.

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Attachments:

- "Guide to Uniform Inspection Program Audit, Worksheet, and Reference Guide"
- "Uniform Inspection Program Audit Pilot Project Report 12-01-11"

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.

Guide to the Uniform Inspection Program Audit, Audit Worksheet, and Audit Reference Guide

Guide to the Uniform Inspection Program Audit
http://foodprotect.org/about/news/?id=cfp-cfsrp-pilot-project-announcement

Audit Worksheet Form
http://foodprotect.org/about/news/?id=cfp-cfsrp-pilot-project-announcement

Audit Reference Guide
http://foodprotect.org/about/news/?id=cfp-cfsrp-pilot-project-announcement

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

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CONFERENCE FOR FOOD PROTECTION

CERTIFICATION OF FOOD SAFETY REGULATION PROFESSIONALS WORK GROUP

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Vicki Everly, Retired – Local Regulatory

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Susan Kendrick, Co-Chair, Oregon Department of Agriculture

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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

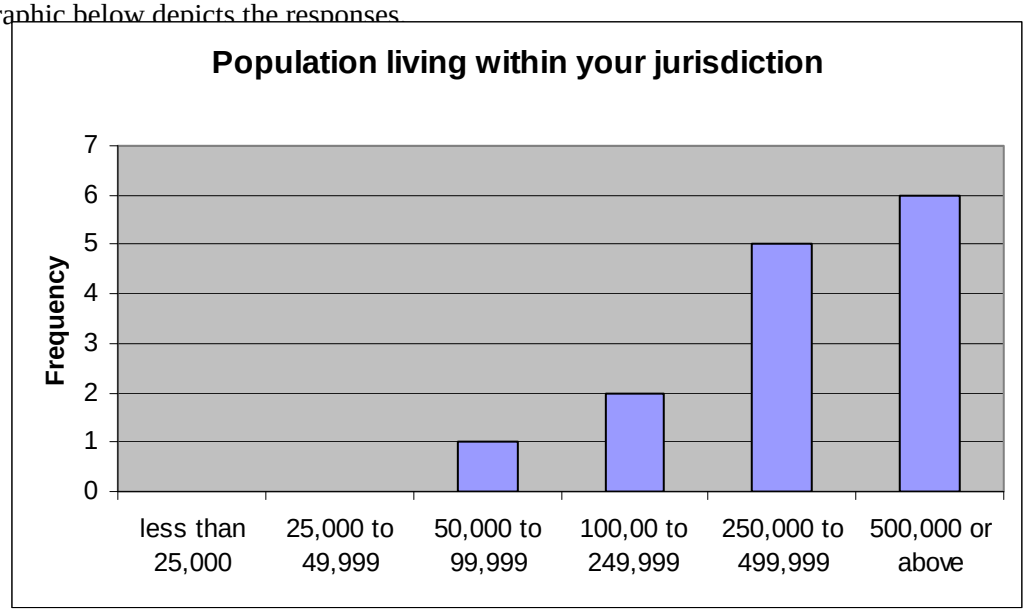
Uniform Inspection Program - Jurisdiction Audit Feedback Form – The survey instrument used during the pilot project to collect data and feedback from jurisdictions on the uniform inspection program audit process and forms. Terms in the narrative of the report pertaining to "survey"; "survey instrument"; 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)**

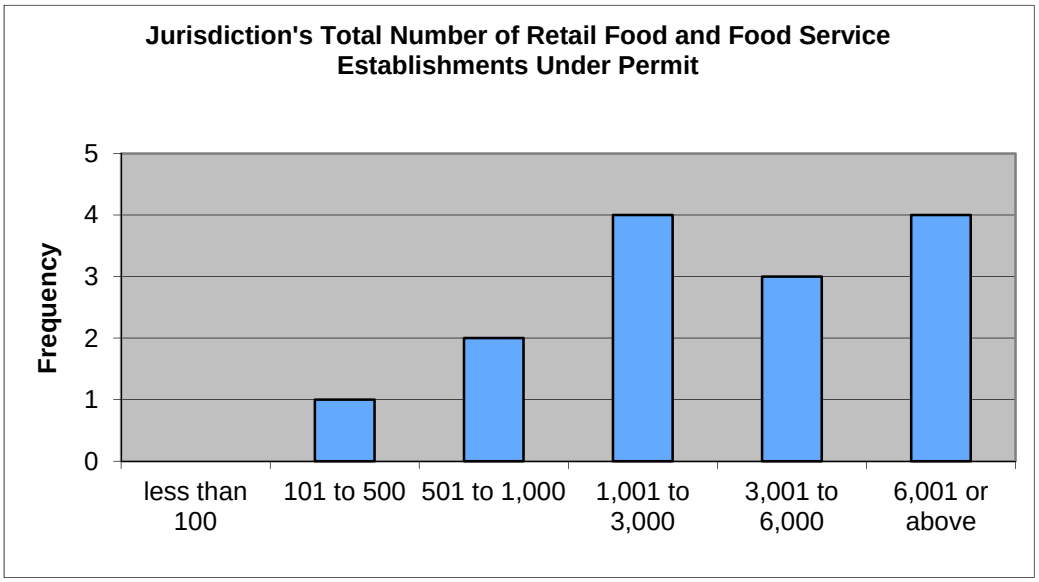
A total of 14 jurisdictions participated in the Audit Pilot Project. The population in these jurisdictions ranged from one jurisdiction with a population of 50,000 to 99,999 to 11 jurisdictions with populations of 250,000 or higher. Of the jurisdictions responding, 43% had population sizes of 500,000 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)**

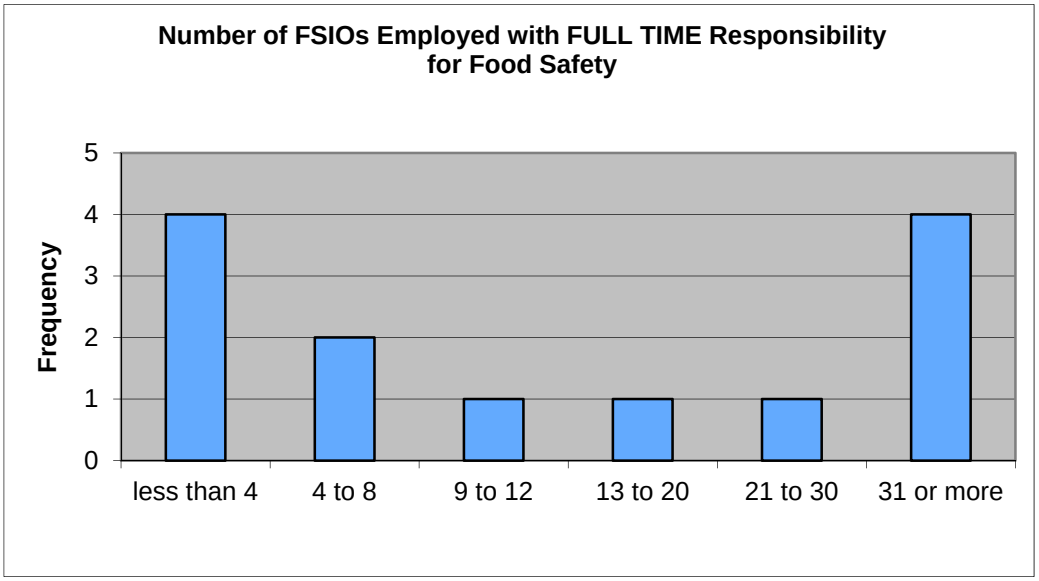
Of the 14 jurisdictions responding, no jurisdictions had less than 100 foodservice establishments under permit, while seven reported 3,001 or more such establishments. Fifty-nine percent (59%) of the jurisdictions reported having 3,001 or more establishments under permit. Twenty-nine percent (29%) of 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)**

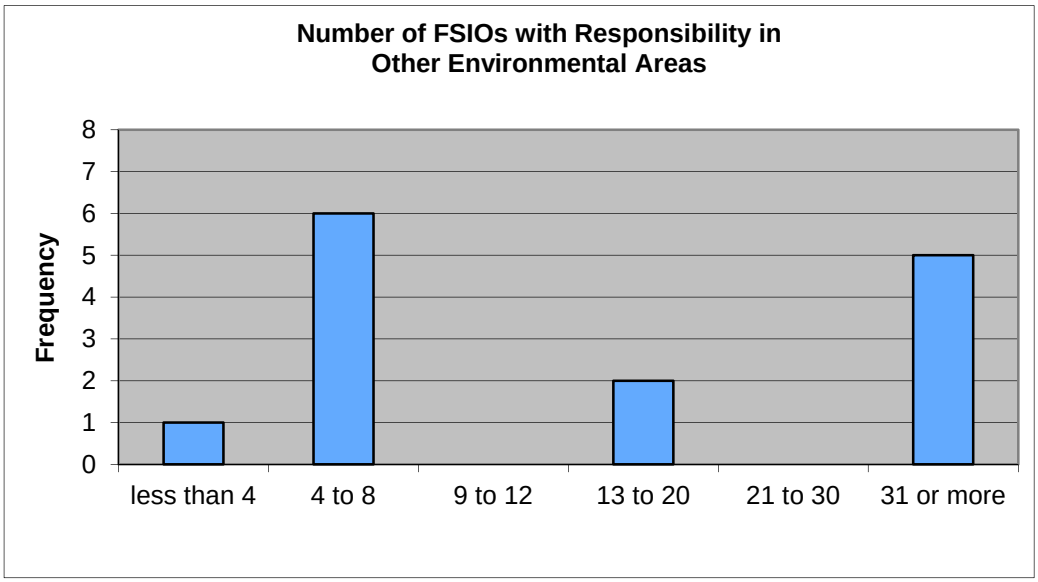
Of the 13 jurisdictions responding, four (31%) reported having less than 4 full-time FSIOs while four (31%) reported having 31 or more full-time FSIOs. The median number of responding jurisdictions was 9 to 12 full-time FSIOs. The chart below depicts the responses.



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)

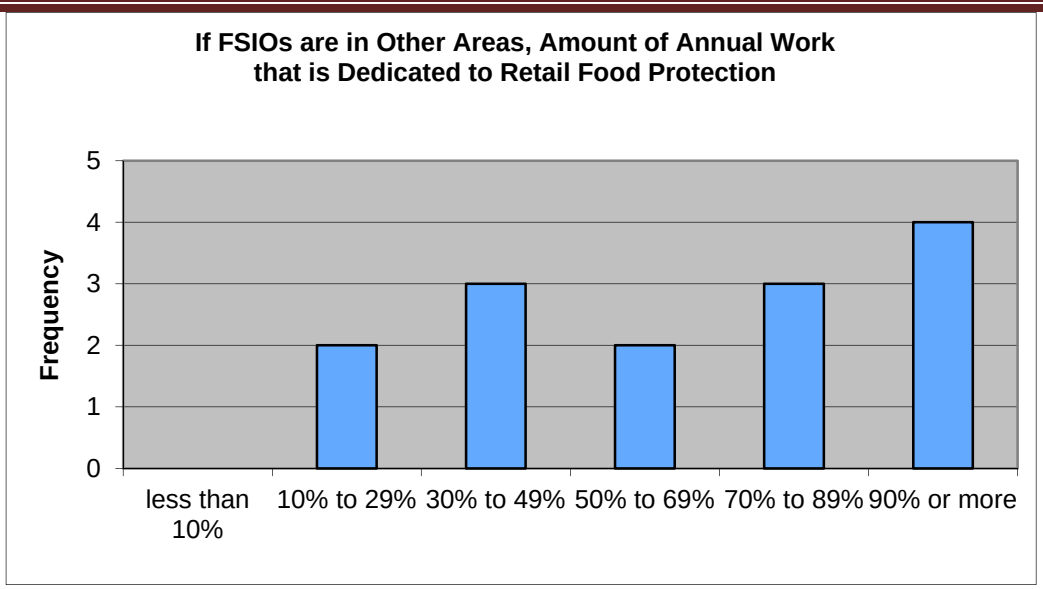
Of the 14 jurisdictions responding, the number of FSIOs with responsibilities in other environmental health program areas in addition to their retail food protection duties ranged from one jurisdiction with less than 4 FSIOs with alternate assignments to five jurisdictions (36%) having 31 or more FSIOS 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)**

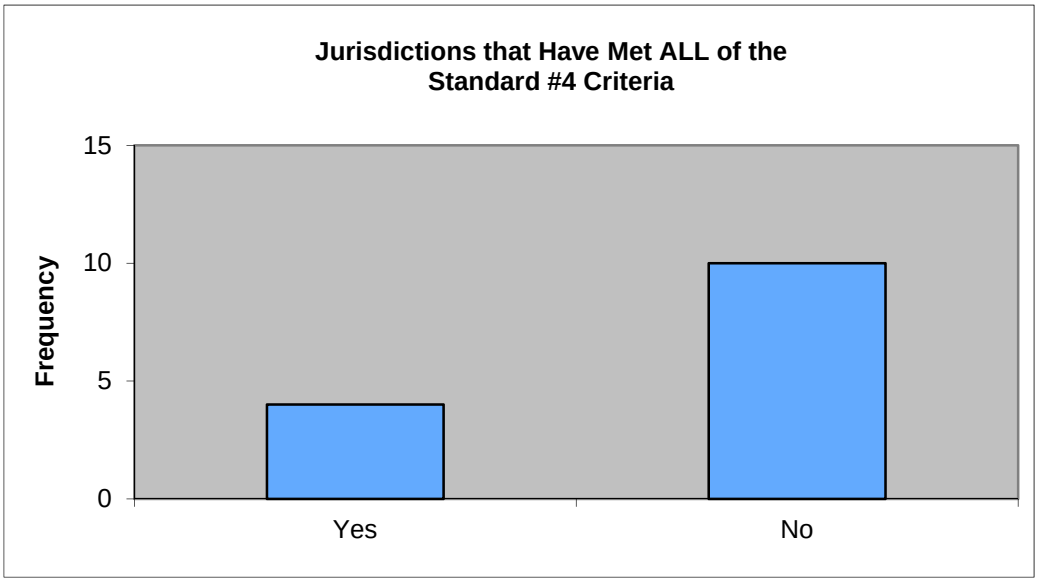
- We are moving from a Field Training Plan program developed in-house to a customized version of the CFP Field Training Plan. Mostly we are using a customized version.
- We have written policies and procedures for staff to follow while conducting inspections.

- 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:

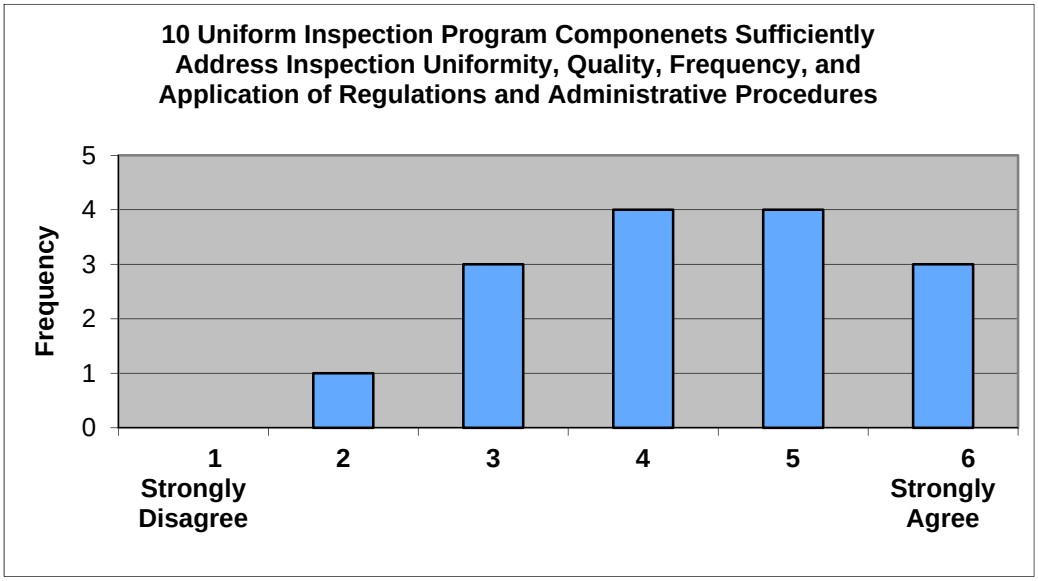
- Add 2009 FDA Food Code as a reference document

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.

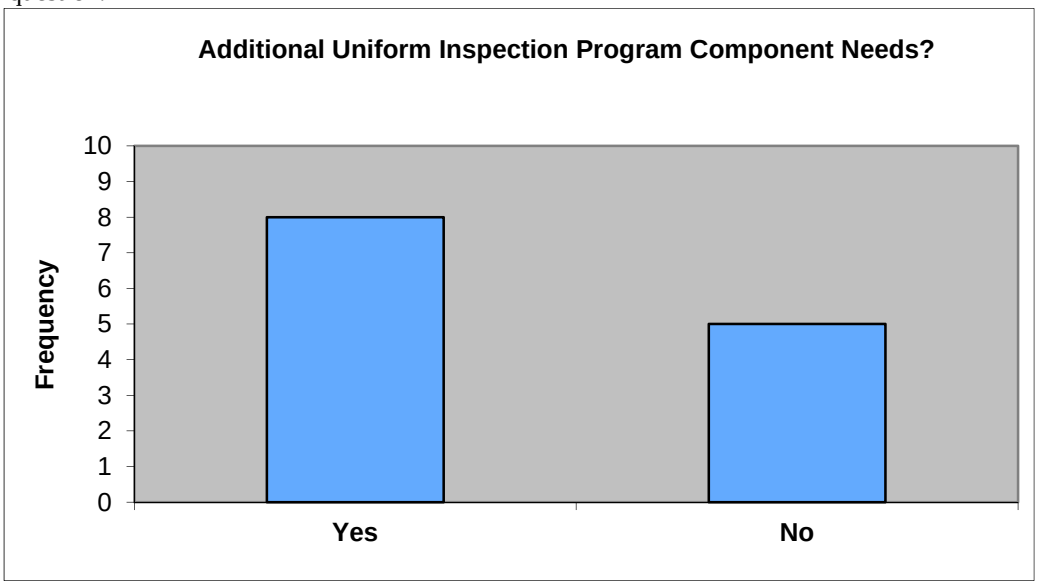
Both YES and NO – the minimum of two file reviews and joint inspection are appropriate

- 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.

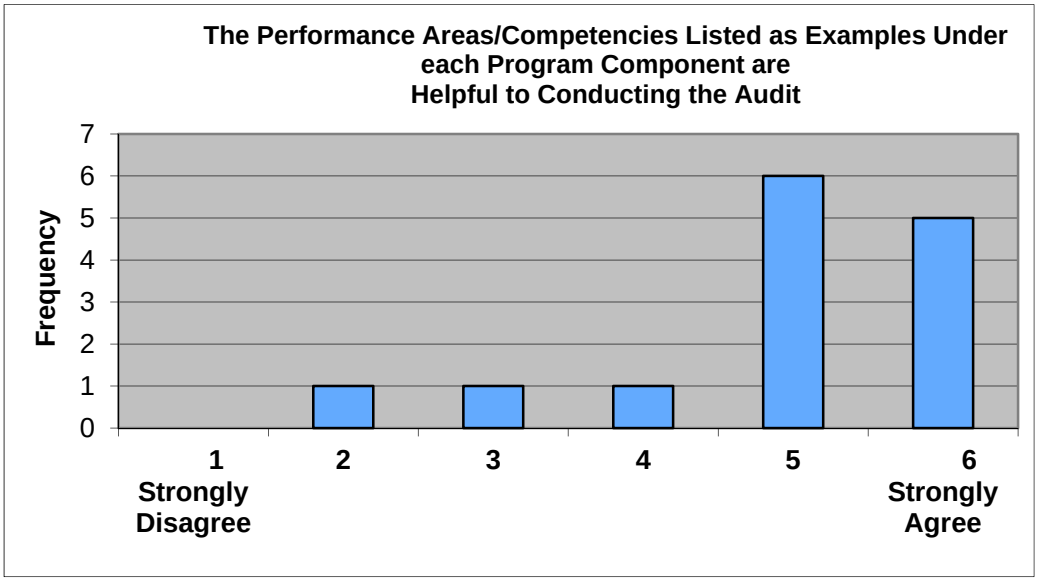
ITEM 10

- 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.

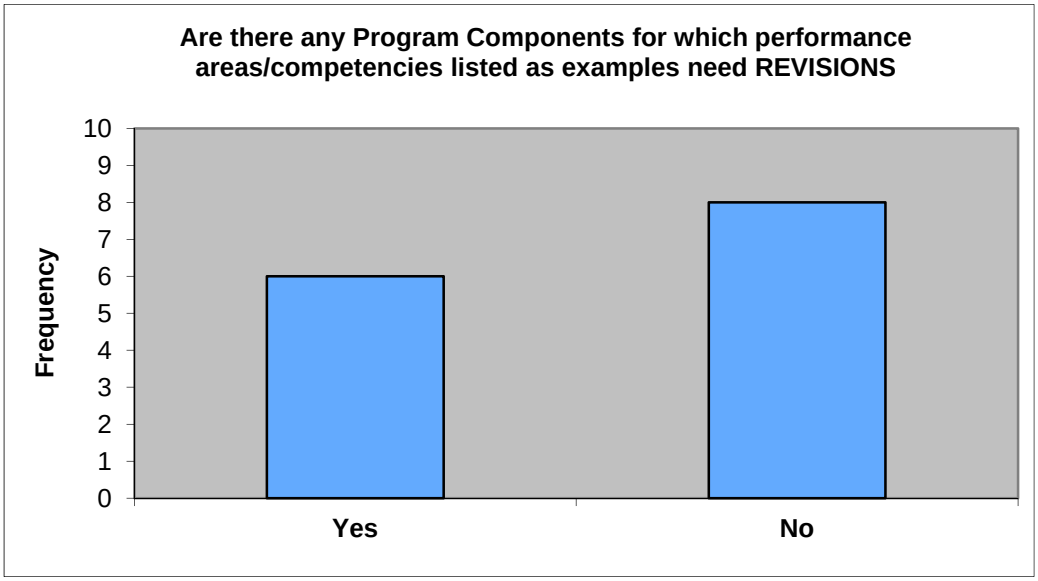
- We felt this guide was very useful in navigating through the program.
- Yes, we like the detailed examples given.
- Item #1 is the most difficult one to assess and rate for our department. We currently have 27 Risk Factors and 27 Good Retail Practices. If the FSIO consistently misses one of these does 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?

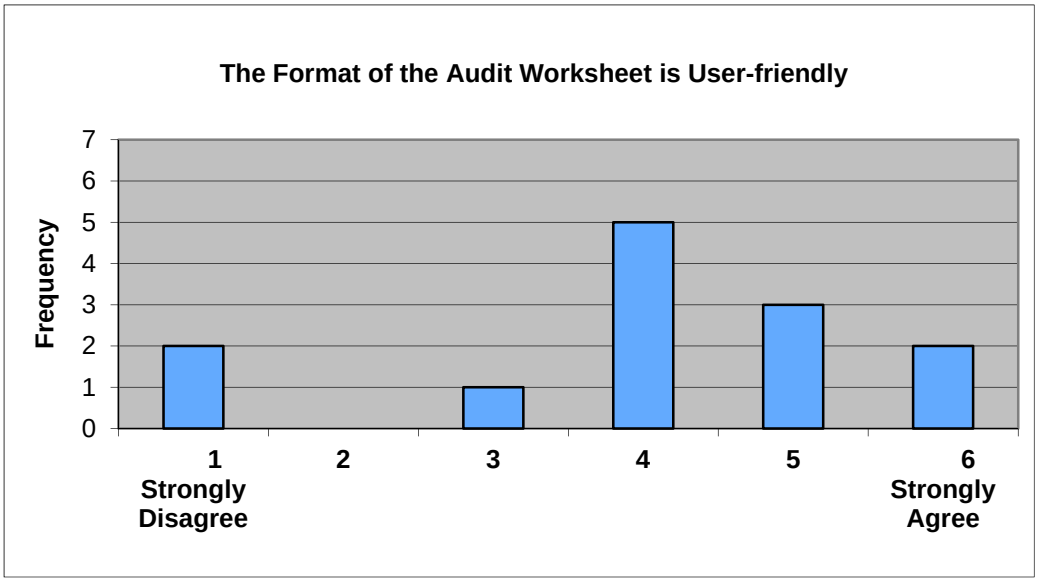
Section IV – Audit Worksheet – Format Evaluation

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?

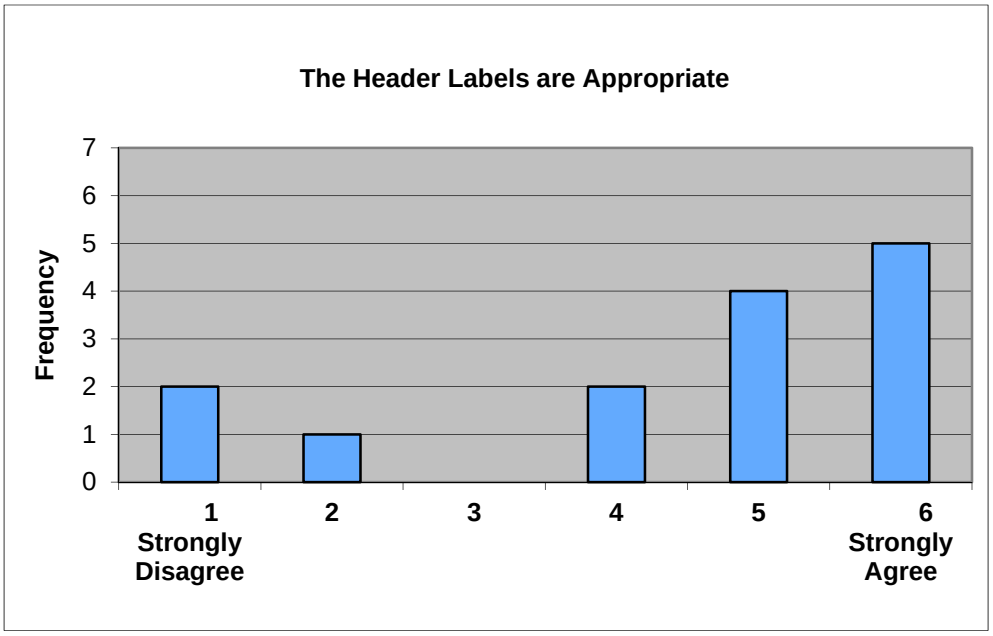
- Try to get complete audit worksheet on one page.
- The flow could be improved by having it match the workflow in the Field Training worksheet. For those program areas/competencies listed in the Audit Reference Guide that have additional reference observations in the Field Training Reference Document, 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:



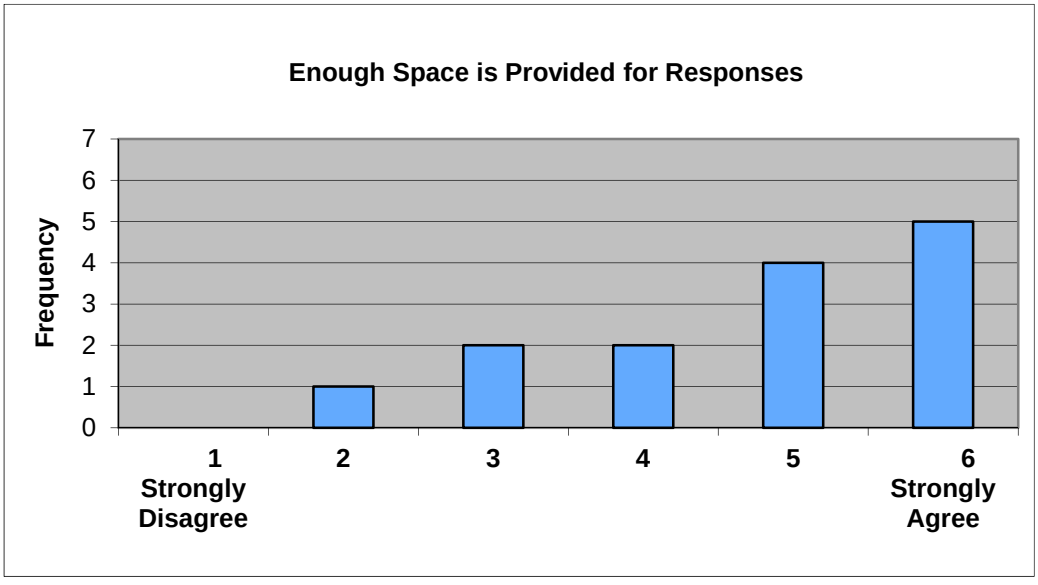
What improvements would you recommend?

- 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.

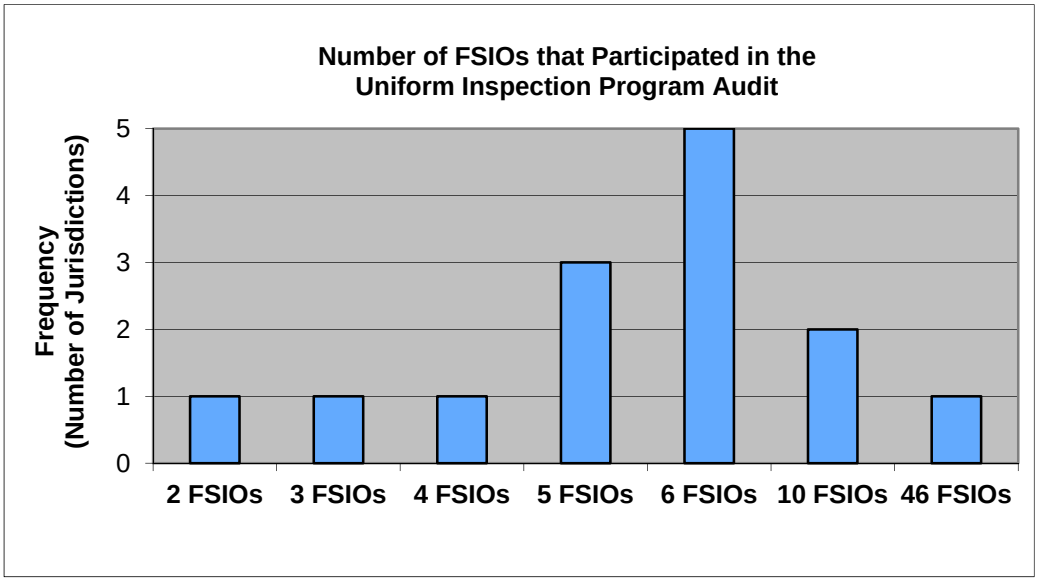
- A date should be established for completing the required re-training. When re-training has been completed a date should be designated for a follow-up audit.
- Adding a column with a timeframe on when the specific improvement will need to be completed.

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

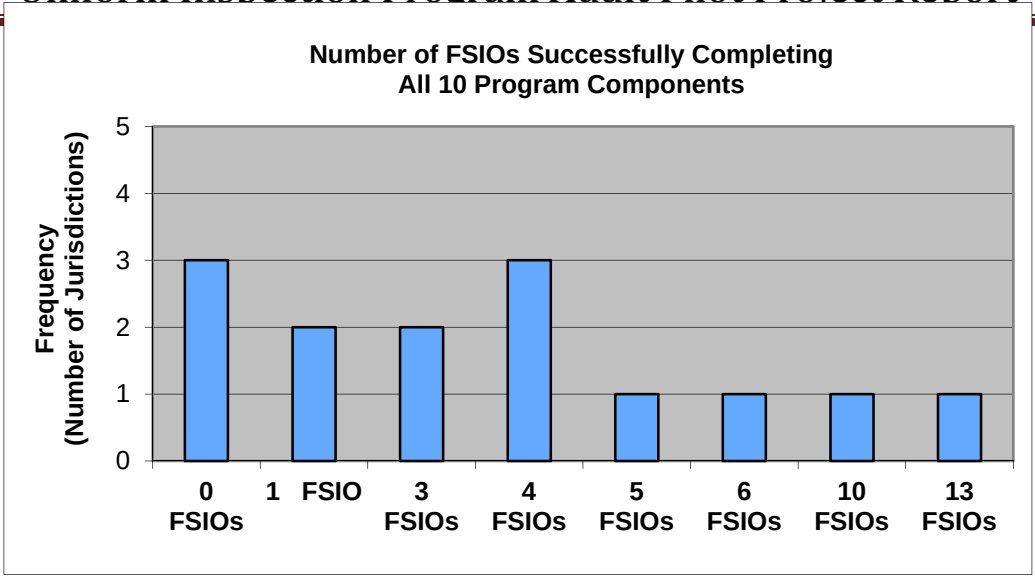
A total of 76 FSIOs participated in the Uniform Inspection Program Audit Pilot Project. The number of FSIO's from each individual jurisdiction ranged from one jurisdiction that had two FSIO participating to one jurisdiction that had 46 FSIOs participating. More jurisdictions (5) had six FSIOs participating 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

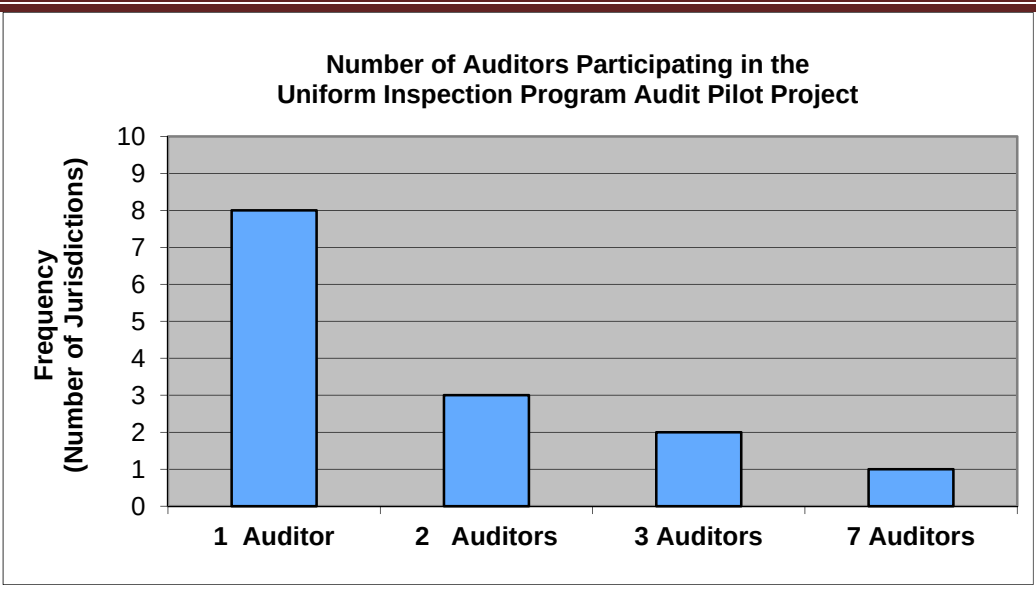
*** Total exceeds 14 because two jurisdictions listed more than one answer**

- 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)**

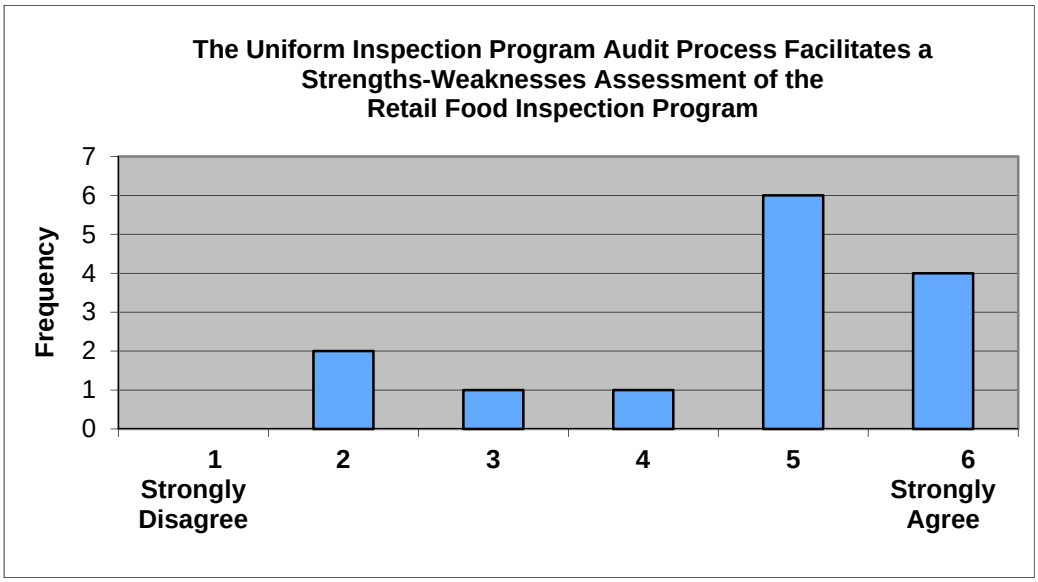
If differences were noted, provide specific examples?

(*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?

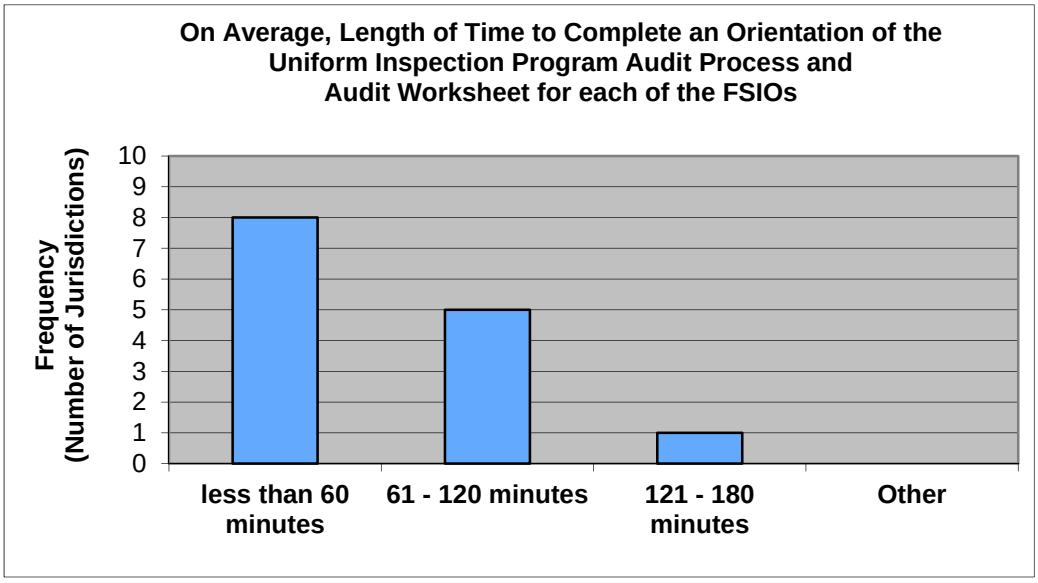
- Shorten length of all forms, if possible.
- It is a very useful tool. The area of concern for me, for one is doing enough audits to get representative samples to determine what change need to done. I feel that many FSIO feel that the ATN process is a pass or fail, even when they are repeatedly told 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.

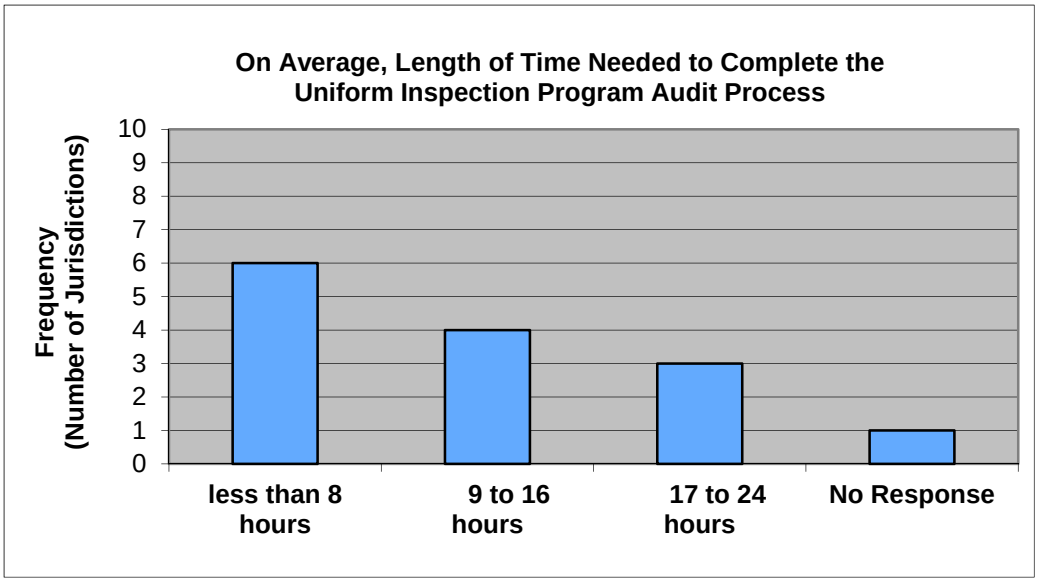
Average time it took to complete an on-site joint field-training inspection					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	less than 60 minutes	0	0.0	0.0	0.0
	61 - 120 minutes	5	35.7	35.7	35.7
	121 - 180 minutes	7	50.0	50.0	85.7
	Other (see below*)	2	14.3	14.3	100.0
	*4 hours – (1)				
	*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	

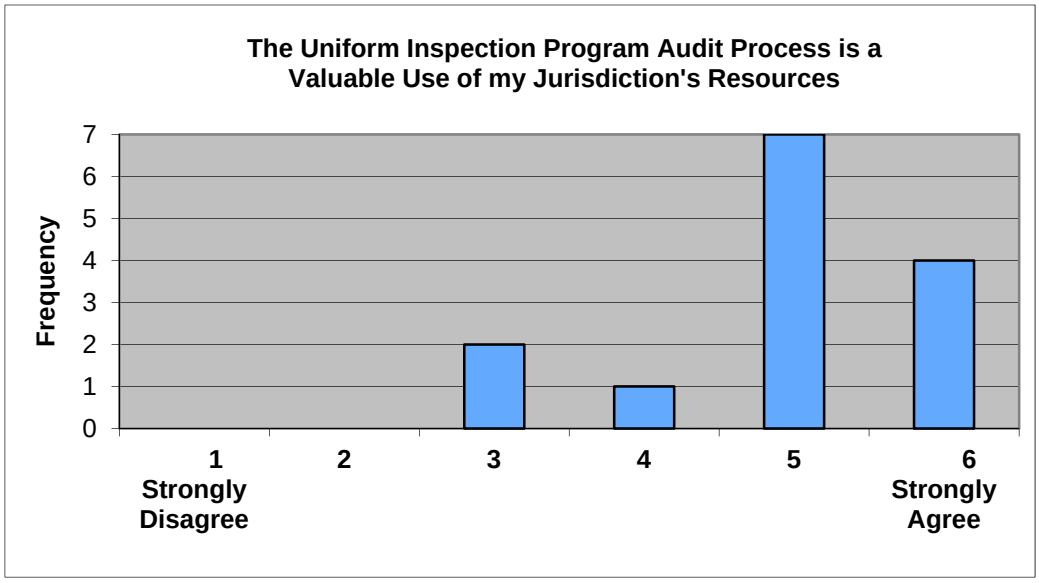
The graphic below depicts the response from the previous page pertaining to the average time needed to complete the audit process with FSIOs.



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?

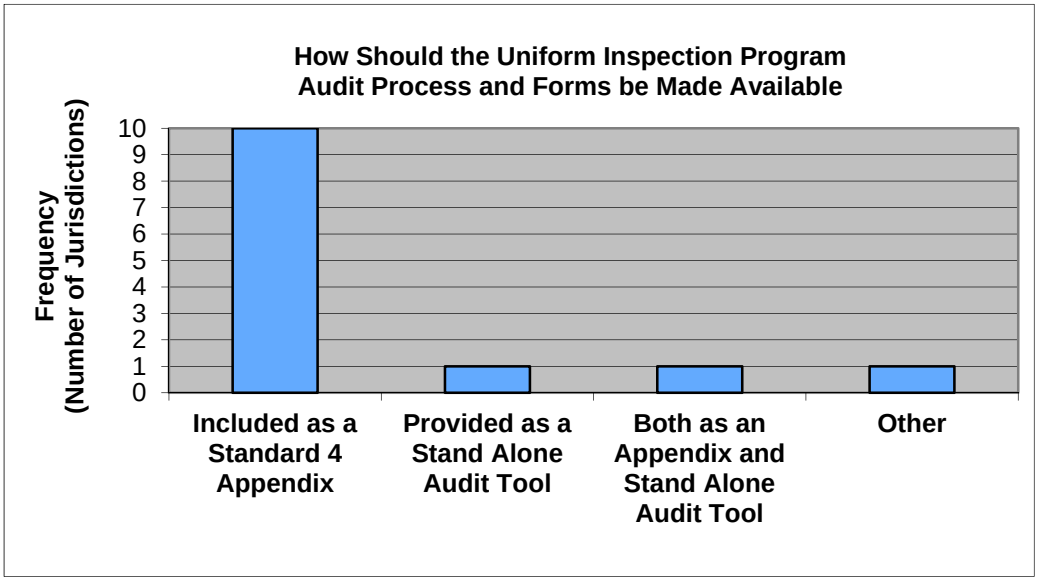
- Time consuming , but in the end gave us a very good understanding of the "big picture" of our program.
- The program is very useful. Even with the limited number of FSIO's audits we were able to find some areas in the inspection program that may need reviewed or beefed up in our training program.
- 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
2012 Issue Form

Internal Number: 051
Issue: 2012 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.

Title:
Recommendations from Uniform Inspection Program Audit Pilot Project

Issue you would like the Conference to consider:
Based on a review of the findings and feedback from the *Uniform Inspection Program Audit Pilot Project* (conducted July 2010 through June 2011), the CFP Certification of Food Safety Regulation Professionals Work Group has identified specific criteria contained in the Voluntary National Retail Food Regulatory Program Standards, Standard 4 - *Uniform Inspection Program* criteria that should be reviewed and revised, as necessary, to facilitate the implementation of quality assurance assessments within regulatory retail food protection programs. The CFSRP Work Group is recommending that the FDA, with input from the CFP Program Standard Committee, review the pilot project recommendations impacting Standard 4 - *Uniform Inspection Program*, to determine if the suggested revisions to the criteria are appropriate and in keeping with the intent and scope of the FDA *Voluntary National Retail Food Regulatory Program Standards.*

The Work Group's ***Uniform Inspection Program Audit Pilot Project Report was submitted*** as an attachment to the Issue titled: Report - CFSRP Part B - Uniform Inspection Program Audit Pilot Project.

Public Health Significance:
Standard 4 applies to a regulatory 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 a review of each Food Safety Inspection Officer's (FSIO) work be made during at least two joint inspections, with a corresponding file review of at least the three most recent inspection reports. These quality assurance assessments provide important feedback that will assist the regulatory jurisdiction in identifying existing strengths and potential areas for improvement within their existing retail food training program or administrative policies.

The *Uniform Inspection Program Audit Pilot Project* provided an opportunity to garner important feedback from a limited number of jurisdictions enrolled in the FDA *Voluntary National Retail Food Regulatory Program Standards* on the practical application of the criteria contained in Standard 4. The subsequent pilot project report contains a number of recommendations for enhancing the effectiveness of the Standard that 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 to include qualifications for an individual charged with assessing the performance of field staff 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.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that they:
1. Work in collaboration with the Program Standards Committee to revise Standard 4, Uniform Inspection Program, to address the pilot project comments and to assess the criteria in Standard 4 to make it more program focused rather than focused on the individual.
2. Review for potential revisions to the Standard 4 Uniform Inspection Program criteria and field inspection review process, the following recommendations contained in the CFP CFSRP Uniform Inspection Program Audit Pilot Project Report.

- Revise the Guide to Conducting a Uniform Inspection Program Audit. Some changes that should be considered include:
  a) 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;
  b) Clarifying the process for selecting the establishments that are to be used for the file and field review;
  c) Clarifying the parameters for what is to be included as part of the establishment file review;
  d) Providing expanded guidance on the auditor's qualifications, role, and responsibilities.
- Align the 10 Program Elements contained in Standard 4 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.
- Present the 10 Program Elements contained in the Standard 4 criteria, the Guide to Conducting a Uniform Inspection Program Audit, and Audit Worksheet in a linear format to reflect a logical sequence to the inspection process.

- Incorporate the information contained in the Audit Reference Guide into the Guide to Conducting a Uniform Inspection Audit to eliminate the need for multiple documents.
- Ensure consistency in the weighting/assessing of each of the 10 Program Elements. 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.
- Design the audit process and worksheet to allow jurisdictions the flexibility for assessing inspection Program Elements that are specific to their retail food protection program. 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.
- Re-evaluate the assessment protocol for Performance Elements and provide better guidance as to what constitutes an effective performance measurement. The field inspection assessment conducted as part of Standard 4 seems to take an all or nothing approach. Item 1 for example 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.
- Provide defined performance measurements that are quantifiable within the Program Elements contained in Standard 4. Some of the Program Elements are very subjective in nature and do not contain definitive performance measurements, such as producing legible reports.
- Include a comment section within the Audit Worksheet 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.

3. Obtain input and feedback from the CFP Program Standards Committee to assist FDA in the review of the recommendations contained in the CFP CFSRP pilot project report.

Reference:

The *Uniform Inspection Program Audit Pilot Project Report* was submitted as an attachment to the Issue titled: Report - CFSRP Part B - Uniform Inspection Program Audit Pilot Project.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 052
Issue: 2012 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.

Title:
Re-create Certification of Food Safety Regulation Professionals Work Group

Issue you would like the Conference to consider:
The CFP Certification of Food Safety Regulation Professionals (CFSRP) Work Group has identified specific initiatives pertaining to the training and professional development of regulatory retail food safety inspection officers that require continued Conference deliberation. A 2012-2014 CFP Certification of Food Safety Regulations Professional (CFSRP) Work Group should be created by the Conference to continue the work on these initiatives.

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 model training plan and log, field training worksheets, and joint field training process presented in the CFP *Field Training Manual for Regulatory Retail Food Safety Inspection Officers (Field Training Manual)*, approved at the 2008 Biennial Meeting are only a part of a professional development continuum that is needed to ensure regulatory retail food safety professionals have the knowledge and skills to effectively conduct inspections of retail food stores, restaurants, and/or institutional foodservice facility types.
The 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:

- Maintain and update this national training model;
- Explore additional training and/or assessment needs for regulatory retail food programs; and
- Build consensus among all retail food safety stakeholders.

Recommended Solution: The Conference recommends...:
that a re-created 2012-2014 Certification of Food Safety Regulation Professionals (CFSRP) Work Group be charged with the following:

Charge 1: Collaborate with the FDA Center for Food Safety and Applied Nutrition, the FDA Division of Human Resource Development, and the Partnership for Food Protection Training and Certification Workgroup (PFP TCWG) to:

- 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.
- When completed, use the Retail Food Safety Specialist Job Task Analysis being developed under the umbrella of the PFP TCWG to review and revise the Standard 2 curriculum to 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.
- Determine if the CFP Field Training Manual and forms need to be revised based on the findings of the PFP TCWG and the Retail Food Safety Specialist Job Task Analysis.

Charge 2: Collaborate with FDA, other federal agencies, and professional and industry associations to evaluate the results of the Retail Food Safety Specialist Job Task Analysis being developed under the umbrella of the PFP TCWG to:

- Assess and determine appropriate training and standardization processes/protocols for third party auditors.
- Identify any agencies/organizations/working groups currently addressing education and training standards for third party auditors conducting retail food compliance inspections.
- Provide a recommendation to the Conference as to what actions/initiatives, if any, need to be undertaken to provide a national structure for ensuring that third party auditors possess the necessary knowledge, skills, and abilities to conduct retail food program compliance inspections.

Charge 3: Work in collaboration with the FDA to:

- Revise Standard 4 Uniform Inspection Program to address comments contained in the 2012 Work Group's pilot project report.
- Assess and re-evaluate the criteria in Standard 4 to make it more "program focused" rather than focused on the individual.

Charge 4: Report back the Work Group's findings and outcomes to the 2014 Biennial Meeting of the Conference for Food Protection.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 016
Issue: 2012 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.

Title:
Recommendations for Promoting the Field Training Manual

Issue you would like the Conference to consider:
An evaluation of the best approaches to promoting awareness and implementation of the national training model contained in the CFP Field Training Manual and forms, Appendix B 2, Standard 2, was conducted by the CFP Certification of Food Safety Regulation Professionals Work Group. The CFSRP Work Group has identified that FDA is the most appropriate authority to promote and implement the Field Training manual and the Work Group has specific recommendations to be presented to FDA in a letter from the Conference.

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 model training plan and log, field training worksheets, and joint field training process presented in the CFP *Field Training Manual for Regulatory Retail Food Safety Inspection Officers (Field Training Manual)*, approved at the 2008 CFP Biennial Meeting are an important part of a professional development continuum that is needed to ensure regulatory retail food safety professionals have the knowledge and skills to effectively conduct inspections of retail food stores, restaurants, and/or institutional foodservice facility types.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA recommending that the FDA actively promote implementation and use of the *Field Training Manual for Regulatory Retail Food Safety Inspection Officers (Field Training Manual).* The following items are offered to provide assistance to the FDA in their promotional activities:

- CDC's Environmental Public Health Performance Standards toolkit, which was created in partnership with National Association of County and City Health Officials (NACCHO), was reviewed and determined to be a valuable model for promotion and implementation of the CFP Field Training Manual.

- Case studies of jurisdictions that use the CFP Field Training Manual would be a valuable resource in a toolkit provided by FDA to jurisdictions that are working to include the Field Training Manual in their program.
- Application forms for available financial incentives would be an asset in a toolkit provided by FDA as financial assistance would promote implementation of the Field Training Manual in jurisdictions that are not currently using the Manual.
- The toolkit should also include references of agencies and subject matter experts to contact for implementation questions.

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Conference for Food Protection
2012 Issue Form

Internal Number: 086
Issue: 2012 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.

Title:
CIFOR Foodborne Illness Outbreak Response Guidelines for Industry

Issue you would like the Conference to consider:
Currently there is no national tool or guidance available directed to the retail industry to assist in preparation for, or in response to a foodborne illness outbreak.

The multi-stakeholder Council to Improve Foodborne Outbreak Response (CIFOR) was established to develop model programs and processes to facilitate the investigation and control of foodborne illness outbreaks. This model was not intended to replace existing procedural manuals found at the local, state and federal agencies but rather to improve the coordination and performance at all levels of government involved in foodborne illness outbreaks. However, the initial voluntary guidelines lacked a defined role for industry during foodborne illness outbreaks.

Recently, the CIFOR Industry Workgroup, composed of representatives from FDA, CDC, state and local health departments, industry and trade associations, completed the Foodborne Illness Response Guidelines for the Food Industry (CIFOR Guidelines for Industry) which was developed as voluntary guidance for managers of food establishments (Industry) to help outline, clarify, and explain Industry's recommended role in a foodborne illness outbreak investigation. The Guidelines provide industry with step-by-step guidance that includes preparation, detection, investigation, control, and follow-up. The Guidelines also provide key information to assist Industry in understanding what to expect when first notified of potential illnesses and provides tools to help guide industry through the investigation process.

Familiarity with the CIFOR Guidelines and Tools will aid regulators, health officials, and industry in responding to an outbreak situation. The CIFOR Guidelines and tools should be included in both the FDA Food Code and Voluntary National Retail Food Regulatory Program Standards for the regulatory community and also made widely available to food service and retail operators.

Public Health Significance:
The CIFOR protocol for investigating foodborne illnesses provides guidance and direction for the regulatory and regulated communities. During a foodborne illness outbreak, time is of the essence in order to identify the offending food product and to remove it from the

market place. To facilitate and ensure correct information is obtained in a timely fashion, a consistent approach to investigating foodborne illness outbreaks is crucial.

By using these *CIFOR Guidelines* and Tools, Industry can take an active and educated role in the outbreak response and investigation, reducing the impact to the public and their business. A fully coordinated investigation can then proceed more quickly and accurately, yielding more dependable results that are in the interest of public health while limiting impact to the involved industry.

The benefits of having a uniform approach include:

1. The *CIFOR Guidelines* are a Best Practices document.
2. Investigation training is simplified by having everyone training to the same requirements and investigation protocols.
3. Industry can be better prepared to supply critical information supporting an investigation and provide better control measures when a multijurisdictional outbreak occurs.
4. As stated in the *CIFOR Guidelines* Preface'...it (*CIFOR Guidelines*) is not intended to replace existing procedure manuals. Agencies and individuals should use the *Guidelines* to compare existing procedures, fill gaps in and update site-specific procedures, create procedures where they do not exist, and train program staff.
5. Even though every outbreak has its own path to completion, a systematic approach, as provided by CIFOR, will help ensure that a thorough and timely investigation is completed.
6. CIFOR addresses the complexity of multijurisdictional investigations and seeks to improve communication and coordination at all levels of government and industry.
7. There has been developmental buy-in to the CIFOR Guidelines by all the affected stakeholders (CDC, FDA, state and local health agencies as well as industry).

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:

1. Addition of the final, approved (currently in draft form per CDC) *CIFOR Guidelines* and Tools to the Food Code, Annex 2 (References), Part 3 (Supporting Documents); and
2. Inclusion of the final, approved *CIFOR Guidelines* and tools as a reference into the FDA Program Standard Number 5, *Foodborne Illness Investigation and Response.* This would be in addition to Standard 5's reference to the International Association of Food Protection's *Procedure to Investigate a Foodborne Illness.*
3. Exploration of other channels of distribution for the CIFOR Guidelines.

CIFOR documents will be available here: http://www.cifor.us/.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 103
Issue: 2012 II-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.

Title:
CIFOR Foodborne Illness Response Guidelines for the Food Industry

Issue you would like the Conference to consider:
The Council to Improve Foodborne Outbreak Response (CIFOR) *Foodborne Illness Response Guidelines for the Food Industry* was developed as *voluntary* guidance for managers of Food Establishments ("Industry") to help outline, clarify, and explain Industry's recommended role in a foodborne illness outbreak investigation. It provides a step-by-step approach that Industry can take, including preparation, detection, investigation, control, and follow-up. The *Guideline* also describes key information to assist Industry in understanding what to expect when first notified of potential illnesses and provides Tools to help guide Industry through the process.
The Guideline and its tools provide valuable information for industry and the regulatory community in the event of a foodborne disease outbreak. It should be made widely available to stakeholders through publication as part of the FDA Food Code. Once officially adopted by CIFOR, the Guideline and tools will be available at www.cifor.us.

Public Health Significance:
By using this Guideline and Tools, Industry can take an active and educated role in the outbreak response and investigation, reducing the impact to the public and their business. A fully coordinated investigation can then move more quickly and accurately, yielding dependable results that are in the interest of public health while limiting impact to Industry.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code:

1. following its publication, the addition of the CIFOR Foodborne Illness Response Guidelines for the Food Industry to the FDA Food Code, Annex 2 (References), Part 3 (Supporting Documents).
2. following its publication, the addition of the CIFOR Foodborne Illness Response Guidelines for the Food Industry as a reference in FDA's Voluntary National Retail Food Regulatory Program Standard #5: Foodborne Illness and Defense Preparedness and Response.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 020
Issue: 2012 II-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.

Title:
Transition of the CFP Standard to the ISO/IEC 17024 Standard

Issue you would like the Conference to consider:
The Conference should consider adopting the International Standard "ISO/IEC 17024: Conformity Assessment - General Requirements for Bodies Operating Certification of Persons" developed by the International Organization for Accreditation in lieu of the "Conference for Food Protection Standards for the Accreditation of Food Protection Manager Certification Programs" over a multi-year transition period. The Conference should task the Food Manager Certification Committee with developing a plan to transition from the Conference standard to the ISO standard.

The Conference would still maintain control over the accreditation process associated with the Conference's accreditation. The American National Standards Institute (ANSI) would evaluate applicant certification bodies against ISO/IEC 17024 and determine if the requirements have been met and would accredited the organization against the ISO standard. The Conference would still have to accept ANSI's recommendations before an organization would be deemed to be accredited by the Conference. ANSI cannot accredit a certification body for the Conference. Only the Conference can award conference accreditation unless the Conference designates ANSI to do this for them.

Attached to this issue are three files that should be reviewed. The first is the application for accreditation. This file is attached because it contains the language of the ISO/IEC 17024 standard. Because the standard is a copyrighted standard, it is not allowed to be placed in this issue for presentation to the entire conference. However the text of the standard does appear in the application so the conference may review the clauses of the standard by reviewing the application. The second file that is attached is a background paper that describes the issue in further detail. Finally the third file is a letter from the American National Standards Institute attesting to the comparability of the two standards.

Public Health Significance:
The safety of food in the United States is dependent upon Food Managers who understand and implement basic food safety concepts. The Conference has established a standard and an accreditation process against that standard to ensure that Food Manager Certification Programs attesting to the knowledge and skills of Food Managers are valid, reliable and legally defensible. Over time, this standard must be updated and maintained

by experts familiar in standards language and standards development. A volunteer pool of food experts may not have the necessary knowledge to adequately maintain the standard.
The United States government (including the Department of Defense, Food and Drug Administration, and Department of Energy) have identified an international standard (ISO/IEC 17024) and accreditation against this standard by the American National Standards Institute (ANSI). They have selected ISO/IEC 17024 standard as the standard of choice for providing evidence that a personnel certification program is valid, reliable and legally defensible. ISO/IEC 17024 is maintained by an international organization, the International Organization for Standardization (ISO) on a regular basis and has world-wide acceptance. By using this standard in lieu of the Conference standard, the public can be assured that Food Manager Certification Programs are recognized against the very best standard by the very best accrediting body.

Recommended Solution: The Conference recommends...:
adoption of "ISO/IEC 17024 Conformity Assessment: General requirements for bodies operating certification of persons" to replace the "Conference for Food Protection Standard for the Accreditation of Food Protection Manager Certification Program" over a multi-year transition period. This adoption simply means a swapping of one standard (the Conference Standard) for another equivalent standard (the ISO Standard).
The Conference also recommends that the Food Protection Manager Certification Committee be tasked with:

- developing a multi-year process to gradually transition to the new ISO standard. The transition should occur in stages allowing sufficient time for all accredited certification bodies to meet the new standard and in guidance with the American National Standards Institute (ANSI).
- revising the Committee governing documents to reflect the transition of the Conference standard to the ISO standard, to reflect any additional requirements above the ISO standards that the conference would want to require for Conference Accreditation, and to reflect the conference maintaining control over the Conference accreditation process.

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Attachments:

- "ANSI Application for Accreditation (contains the 17024 standard language)"
- "Background Information for Issue"
- "ANSI Letter Stating Equivalence of ISO standard to CFP standard"

Date Issued: 2009-05-01 PUBLIC FORM **PCAC-FR-504**
Approved by: Lane Hallenbeck (2009-05-01) Revision: 2

Application for ANSI Accreditation Under ANSI/ISO/IEC 17024

INTRODUCTION TO ANSI PERSONNEL CERTIFICATION ACCREDITATION PROGRAM

Over the past decade, technology has improved the flow of information and provided the world with a tremendous financial market expansion. While this had led to the growth of a more inclusive global economy, the expansion of our world through data exchange has also provided us with challenges. Some of these challenges include the security of information over the Internet, government trade agreements being changed to accommodate the electronic transfer of knowledge, and a world wide industry skill shortage due to lack people trained in this new world of work.

These factors have forced the growth of a rapid transfer of knowledge through education and training. It is important for the consumer to know whether they are receiving a quality knowledge product. To that end, products are regulated and standardized for the protection of the public. Organizations such as ANSI, the International Organization for Standardization (ISO), and the International Electrotechnical Commission (IEC) develop standards, which protect the integrity of a product or service. Organizations apply for and obtain a stamp of approval only after going through a rigorous quality review of not only their product or service, but also their organization as a whole based on globally accepted standards.

Over the past two years, ISO/IEC committees made up of over 22 countries have been developing a standard, ISO/IEC/FDIS 17024, which addresses the general requirements for bodies operating certification schemes for persons. This standard shows how the world can exchange quality programs through the standardization of skills and knowledge, which lead to a certification of a person. ISO/IEC/FDIS 17024 requirements set the standard for all countries' personnel certification programs, through rigorous requirements using quality objectives.

Overview of Draft International Standard of ISO/IEC/FDIS 17024 Standard for bodies operating certification of persons

ISO/IEC/FDIS 17024 specifies requirements which ensure that certification bodies operating certification systems for persons operate the certification of persons in a consistent, comparable, and reliable manner. The standard is broken up into fourteen clauses. Each clause has several sub-components. The clauses are as follows:

Certification body	Organizational structure
Development and maintenance	Management system
Outsourcing	Records
Confidentiality	Personnel requirements
Examiners	Application
Evaluation	Decision on certification
Surveillance and re-certification	Use of certificates and logos

Since its inception in 1918, ANSI has been creating the benchmark of excellence in U.S. voluntary standardization and conformity assessment systems. ANSI is responsible for the integrity of this audit process. Organizations applying for accreditation understand that throughout the process of compliance they will be treated according to ANSI's cornerstone principles of openness, consensus, due process, and balance.

ANSI is the sole United States representative and dues-paying member of the two major non-treaty international standards organizations, ISO and IEC. ANSI possesses the in-depth knowledge of the global standards arena and is in the unique position of creating the first personnel certification accreditation program for U.S. organizations.

By completing this application, you will have begun the first step to compliance with this international standard. In addition you will receive a quality review, tailored for your organization, using your input.

All application questions must be submitted in writing or via e-mail.

Applications and questions should be directed to:

American National Standards Institute (ANSI)
Attn: Dr. Roy Swift
Senior Director, Personnel Credentialing Accreditation Programs
1899 L Street, NW
11th Floor
Washington, DC 20036
Rswift@ansi.org

All applications will be the sole property of ANSI.

GENERAL INFORMATION FOR SUBMISSION

Process

To facilitate the process of review, please submit one application for each review. One application will be acceptable for a multiple scheme (certification construct/credential) review. Please review each question carefully and when appropriate, respond to questions separately for each individual scheme. Be consistent in your responses, Clause 4.3.2, Item B Scheme 1, Scheme 2 etc. Fill out the application completely. You may attach supporting documentation that further clarifies your answer. Applications must be in 11 or 12-point font size. Submit three copies of the application and supporting documentation.

Application Overview

The application is divided into two sections.

Part 1 is an organizational questionnaire.

Part 2 is a questionnaire based on the ANSI/ISO/IEC 17024 standard. This portion is divided by clauses. Attachments may be added to supplement your answer. Documentation attached may assist in several clause areas. When using an attachment to supplement an answer, note the attachment number on the question. Every attachment must have a cover sheet stating the relevant clause, responding question and where the answer/explanation can be found in the document.

Sample	**Attachment A**	**Policy Manual**	
	Clause 4.2.4	Question A	Reference found on Page 3, paragraphs 5-10
	Clause 4.4.3	Question C	Section (b) Reference Page 20, paragraphs 1-3

Multiple Schemes

Again, when submitting the application for a multiple scheme review, you will need to clarify your relative answers as individual schemes. Be consistent in your responses, Scheme 1, Scheme 2 etc.

Accreditation Assessment

After applications are received, a ten (10) day review period begins. At this time, ANSI will determine whether the material submitted is complete. If necessary, applicants may be asked to provide additional information for clarification. Requested information must be received within ninety (90) days of request. When it is determined that the application is complete, assessors will be assigned to your organization. You will be advised of the assessors' names and given five (5) days to accept or provide information relating to conflict of interest regarding the assessor(s). Assessors will be assigned to your organization from your acceptance of them until the final determination of compliance.

Accepted assessors will review your application and determine an audit plan. The audit plan will be submitted to you for review and comment. Once the plan is agreed upon, an on-site audit will ensue. Your organization will be evaluated using the attached requirements. Please review attachments for all requirements and be ready to supply applicable documentation to the assessors as requested. The length of the audit will depend on the size of the organization and programs being reviewed.

Fees

Application fee	$3000.00
On-site audit and preparation	$1250.00 per day, each assessor, plus expenses. Includes: Review of documentation and preparation, on-site audit, oral report at end of audit, written report with commendations, opportunities for improvement, and non-conformity statements.
Corrective actions	<u>All non-conforming items must be corrected before organization is approved for accreditation.</u> Organizations will be given statements describing the rationale for every non-conforming item. You will discuss and determine a timeline with assessors to correct the non-conforming items. Fees associated with reviewing corrective actions are billed at $1,250 per day or fraction thereafter.

Annexes

A Application Milestones
B Documentation that may assist you in completing application
C Declaration Statement (<u>this must be returned with application</u>)
D Definitions of terminology common to ISO/IEC/DIS standards

APPLICATION FOR ANSI ACCREDITATION

Part 1: Applicant Information

Date:

Certification Body:

Address:

City, State, Zip:

Contact Person:

Title:

E-Mail: Phone:

Fax: Web Site:

1. What is the legal structure of your organization?

☐ Corporate Entity (Not Tax Exempt)
☐ Corporate Entity (Tax Exempt)
☐ Part of Parent Organization (includes wholly owned subsidiary)
☐ Other Please specify:

2. How long has your organization been in existence?

3. How long has your organization been offering personnel certification?

4. How many active certificates are in your database?

☐ 50-100
☐ 101-500
☐ 501-1000
☐ 1001-3000
☐ 3001-5000
☐ 5001-10,000
☐ 10,001-50,000
☐ 50,001-100,000
☐ 100,001 and up

5. How many applications are received each year?

☐ 0-500
☐ 501-1000
☐ 1001-3000
☐ 3001-5000
☐ 5001-10,000
☐ 10,001-20,000
☐ 20,001 and up

6. How many applicants are tested each year?

☐ 0-500
☐ 501-1000
☐ 1001-3000
☐ 3001-5000
☐ 5001-10,000
☐ 10,001-20,000
☐ 20,001 and up

7. How many tests are administered each year?
☐ 0-500
☐ 501-1000
☐ 1001-3000
☐ 3001-5000
☐ 5001-10,000
☐ 10,001-20,000
☐ 20,001 and up

8. How many applicants are certified each year?
☐ 0-500
☐ 501-1000
☐ 1001-3000
☐ 3001-5000
☐ 5001-10,000
☐ 10,001-20,000
☐ 20,001 and up

9. Is your program open to international applicants who are trained/educated outside the United States?
☐ Yes ☐ No

10. If yes, does your organization have any reciprocity agreements in place?
☐ Yes ☐ No

If yes, please explain.

11. Is your certification program necessary for personnel to obtain employment in your industry?
☐ Yes ☐ No

If yes, please explain why.

12. Does your organization outsource components of your personnel certification program?
☐ Yes ☐ No

If yes, what is outsourced?

Questions related to certification scheme

13. List the certification schemes within the scope for which you are applying for accreditation.
Name(s)

14. How are your candidates assessed? Check all that apply:
☐ Written paper and pencil examination
☐ Oral examination
☐ Combination of written and oral examinations
☐ Performance based (directly observed)
☐ Portfolio (representative sample of work)
☐ Computer based testing
☐ Computer adaptive testing
☐ Other Please specify:

15. Where is your assessment given? Check all that apply.
☐ Industry setting
☐ Commercial Testing center
☐ Educational Institution
☐ Other Please specify:

16. How often is the examination given, if applicable?
☐ on demand
☐ one time per year
☐ two times per year
☐ three times per year
☐ four times per year
☐ greater than four times per year

Part 2: Compliance with Requirements of ANSI/ISO/IEC 17024

4 Requirements for certification bodies

4.1 Certification body

4.1.1 The policies and procedures of the certification body and their administration shall be related to the criteria in which certification is sought, shall be fair and equitable among all candidates, and shall comply with all applicable regulations and statutory requirements. The certification body shall not use procedures to impede or inhibit access by applicants and candidates, except as provided for in this International Standard.

Clause 4.1.1

Using your policies and procedures, describe how your certification body ensures fair and equitable treatment of candidates throughout all phases of your certification program.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

List laws and regulations applicable to your certification body in the certification process.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.1.2 The certification body shall define policies and procedures for granting, maintaining, renewing, expanding and reducing the scope of the desired certification, and suspending or withdrawing the certification.

Clause 4.1.2

Describe your certification body's policies and procedures for granting, maintaining, and renewing an individual's certificate.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe your certification body's policies and procedures for suspending or withdrawing an individual's certificate.

Name of supporting Document:
Attachment numbers(s):

Page/paragraph:

Describe and cite the policies and procedures whereby your organization would expand or reduce the scope of its certification scheme(s).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.1.3 The certification body shall confine its requirements, evaluation and decision on certification to those matters specifically related to the scope of the desired certification.

Clause 4.1.3

Define the scope and parameters of your certification scheme(s). Provide relevant portions of your published documents.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2 Organizational structure

4.2.1 The certification body shall be structured so as to give confidence to interested parties in its competence, impartiality and integrity. In particular, the certification body:

a) shall be independent and impartial in relation to its applicants, candidates and certified persons, including their employers and their customers, and shall take all possible steps to assure ethical operations;

b) shall be responsible for its decisions relating to the granting, maintaining, renewing, expanding and reducing the scope, or suspending and withdrawing the certification;

c) shall identify the management [group(s) or person(s)] which shall have overall responsibility for
1) evaluation, certification and surveillance as defined in this International Standard, the applicable competence standards and other relevant documents,
2) the formulation of policies relating to the operation of the certification body, with regard to certification of persons
3) decisions on certification,
4) the implementation of its policies and procedures,
5) the finances of the certification body, and
6) the delegation of authority to any committees or individuals to undertake defined activities on its behalf;

d) shall have documents establishing it as a legal entity or part of a legal entity.

Application for ANSI Accreditation Under ANSI/ISO/IEC 17024

Clause 4.2.1

Describe and provide documentation of how your certification body is independent and impartial.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe your ethics policy for staff, consultants, and volunteers.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Provide a description or chart of your organization's structure and the responsibilities of each component.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe how the components of your organization relate to each other and how decisions are made.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Identify your body's management and describe their qualifications.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe the financial controls in place to ensure the independence of the certification body.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Provide documentation establishing your organization as a legal entity or part of a legal entity.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.2 The certification body shall have a documented structure which safeguards impartiality, including provisions to assure the impartiality of the operations of the certification body. This structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification system, without any particular interest predominating.

Clause 4.2.2

Demonstrate how the structure provides for balancing stakeholder interests without any particular interest predominating.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe how changes in the organizational structure are made and approved by the certification body. Cite any policies and procedures used to implement these changes.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.3 The certification body shall appoint a scheme committee, which shall be responsible for the development and maintenance of the certification scheme for each type of certification being considered. The scheme committee shall fairly and equitably represent the interests of all parties significantly concerned with the certification scheme, without any particular interest predominating. Where a certification scheme is developed by organizations other than the certification body, the respective developer of the scheme shall adhere to the same principles.

Clause 4.2.3

a) Describe the structure and functions of your scheme committee and the qualifications of its members. (Refer to definition of scheme committee in ISO/IEC FDIS 17024)

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe the structure and functions of other advisory bodies in relation to the scheme committee.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Describe relationships, functions, and qualifications of any technical support for the scheme committee.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.4 The certification body
a) shall have the financial resources necessary for the operation of a certification system and to cover associated liabilities,

b) shall have policies and procedures that distinguish between the certification of persons and any other activities, and
c) shall assure that the activities of bodies related to it do not compromise the confidentiality and impartiality of its certification.

Clause 4.2.4

a) List and describe the sources of funds used for the operation of your certification system and associated liabilities.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Attach current and the previous three-year audited financial statements. Indicate the level of funding of all activities.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) What activities other than certification services does your certification body conduct? Explain how your certification body distinguishes these activities from certification services.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

d) Explain how your policies and procedures maintain confidentiality, objectivity, and impartiality of the certification with respect to your relationships with other bodies.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.5 The certification body shall not offer or provide training, or aid others in the preparation of such services, unless it demonstrates how training is independent of the evaluation and certification of persons to ensure that confidentiality and impartiality are not compromised.

Clause 4.2.5

If the certification body provides or aids others in the preparation of training services, demonstrate how training is independent of the evaluation and certification of persons to ensure that confidentiality and impartiality are not compromised.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe the training and how it relates to the certification process.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.6 The certification body shall define policies and procedures (e.g. code of conduct) for the resolution of appeals and complaints received from applicants, candidates, certified persons and their employers, and other parties about the certification process and criteria, as well as policies and procedures for the performance of certified persons. These policies and procedures shall ensure that appeals and complaints are resolved independently, in an unbiased manner.

Clause 4.2.6

Describe the process for appeals and complaints. Using examples of resolved issues over the past three years, describe how the policies and procedures were applied in an unbiased manner.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Provide written policies and procedures for appeals and complaints.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Provide policies and procedures that define the performance of certified persons (e.g. codes of conduct/ethics).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.7 The certification body shall employ or contract enough people with the necessary education, training, technical knowledge and experience to perform certification functions relating to the type, range and volume of work performed, under a responsible management.

Clause 4.2.7

a) Identify any certification functions for which your organization contracts and document how they are monitored. Show the job responsibilities and qualifications of contractors' personnel.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Identify personnel with functions related to the certification. Show their job responsibilities, qualifications, and ways of monitoring performance.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Provide justification that the number of people employed and contracted is adequate.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3 Development and maintenance of a certification scheme

4.3.1 The certification body shall define the methods and mechanisms to be used to evaluate the competence of candidates, and shall establish appropriate policies and procedures for the initial development and continued maintenance of these methods and mechanisms.

Clause 4.3.1

a) Describe methods and mechanisms used to evaluate candidates.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe the policies and procedures for continually evaluating and updating the methods and mechanisms used to evaluate the competence of candidates.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3.2 The certification body shall define a process for the development and maintenance of certification schemes that includes the review and validation of the scheme by the scheme committee.

Clause 4.3.2

a) Describe the development of the certification process for specific scheme(s).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) How is(are) each scheme(s) reviewed and updated as needed?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3.3 The certification body shall, where applicable, give due notice to representatives of the scheme committee of any changes in its requirements for certification. The certification body shall take into account the views expressed by the scheme committee before deciding on the precise form and effective date of the changes. Following decision on, and publication of, the changed requirements, the certification body shall, where applicable, inform the interested parties and the certified persons appropriately. The certification body shall verify that each certified person complies with the changed requirements within such a period of time as is reasonable for the certification body in consultation with the scheme committee.

Clause 4.3.3

How does the certification body notify the scheme committee of proposed changes in requirements for certification?
How does the certification body take scheme committee views into account?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

What are the policies and procedures for making a change to a scheme?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

How are stakeholders notified of a change in certification requirements?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

How does the certification body ensure compliance with the change?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3.4 The criteria against which the competence of a person is evaluated shall be those defined by the certification body in accordance with this International Standard and other relevant documents. If explanation is required as to the application of these documents to a specific certification scheme, it shall be developed by experts, endorsed by the scheme committee, and published by the certification body.

Clause 4.3.4

What documents did your certification body use in developing the criteria against which the competency of a person is evaluated?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

How did experts in your field contribute to the development of the criteria for competence? What are the qualifications of the experts?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3.5 Certification shall not be restricted on the grounds of undue financial or other limiting conditions, such as membership of an association or group. Successful completion of an approved training course may be a requirement of a certification scheme, but recognition/approval of training courses by the certification body shall not compromise impartiality, or reduce the demands of the evaluation and certification requirements.

Clause 4.3.5

Describe the rationale upon which certification requirements are based and the data supporting the rationale. Justify fees and requirements.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe how any recognition/approval of training programs relates to how certification decisions are made.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3.6 The certification body shall evaluate the methods for examination of candidates. Examinations shall be fair, valid and reliable. Appropriate methodology and procedures (such as collecting and maintaining statistical data) shall be defined to reaffirm, at least annually, the fairness, validity, reliability and general performance of each examination and all identified deficiencies corrected.

Clause 4.3.6

Describe the procedures to evaluate the examinations. Include content reviews, psychometric analyses, cut score studies and other methodology applied to evaluate the instruments/procedures used to determine certification.

Name of supporting Document:
Attachment numbers(s):

Page/paragraph:

Describe any validity, reliability, adverse impact or other studies conducted regarding your examination(s).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Cite the standards that you use to develop the criteria against which you evaluate your examination processes, procedures and instrument(s).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.4 Management system

4.4.1 The certification body shall operate a management system which is documented and covers all the requirements of this International Standard, and ensures the effective application of these requirements.

Clause 4.4.1

Provide documentation of your management system and indicate how it ensures the effective application of the requirements of ISO/IEC/FDIS 17024. (Cite responses to other sections of this application as needed).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.4.2 The certification body shall ensure that a) a management system is established and maintained in accordance with this International Standard, and b) its management system is understood and implemented at all levels of the organization.

Clause 4.4.2

Describe how your certification body established and how it maintains its management system.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

How does your organization ensure that your management system is understood and implemented on all levels of the organization?

Name of supporting Document:
Attachment numbers(s):

Page/paragraph:

4.4.3 The certification body shall have document control and internal audit and management review systems in place, including provisions for continual improvement, corrective and preventive actions.

Clause 4.4.3

a) Provide documentation of your document control procedures.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Provide documentation of your internal audit and management review systems, including continuous improvement processes and procedures for taking corrective and preventive action.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.5 Subcontracting

4.5.1 When a certification body decides to subcontract work related to certification (e.g. examination) to an external body or person, a properly documented agreement covering the arrangement, including confidentiality and prevention of a conflict of interest, shall be drawn up. The decision on certification shall not be subcontracted.

Clause 4.5.1

a) Show documentation of the agreement and a detailed description of all certification-related work that is contracted to individuals and/or organizations.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Attach samples of your confidentiality and conflict of interest statements and agreements.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Provide documentation that the organization does not contract for decisions on certification.

Name of supporting Document:
Attachment numbers(s):

Page/paragraph:

4.5.2 The certification body
a) shall take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, renewing, expanding and reducing the scope, and suspending or withdrawing certification;
b) shall ensure that the subcontractor is competent and complies with the applicable provisions of this International Standard and is not involved, either directly or through their employer, with training or the maintenance of the certification of persons in such a way that confidentiality and impartiality could be compromised, and
c) shall maintain a list of its subcontractors, and assess and monitor their performance in accordance with documented procedures.

Clause 4.5.2

a) Describe how your certification body monitors work for which it contracts. Include processes and procedures that ensure that corrective actions are taken when needed.

   Name of supporting Document:
   Attachment numbers(s):
   Page/paragraph:

b) Describe how your certification body determines that its contractor(s) is(are) competent to perform their work for the organization.

   Name of supporting Document:
   Attachment numbers(s):
   Page/paragraph:

c) Describe how your certification body ensures that its contractor(s) are not involved with the training or maintenance of the certification in such a way that confidentiality and impartiality could be compromised.

   Name of supporting Document:
   Attachment numbers(s):
   Page/paragraph:

d) Describe your organization assesses and monitors the work of its contractor(s).

   Name of supporting Document:
   Attachment numbers(s):
   Page/paragraph:

4.6 Records

4.6.1 The certification body shall maintain a record system appropriate to its particular circumstances and to comply with regulations, including a means to confirm the status of a certified person. The records shall demonstrate that the

certification process has been effectively fulfilled, particularly with respect to application forms, evaluation reports, surveillance activities and other documents relating to granting, maintaining, renewing, expanding and reducing the scope, and suspending or withdrawing certification.

Clause 4.6.1

a) Describe in detail your certification record system and demonstrate how it meets the requirement of the standard.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.6.2 The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and the confidentiality of the information. The records shall be kept for an appropriate period of time to demonstrate continued confidence for at least one full certification cycle, or as required by recognition arrangements, contractual, legal or other obligations.

Clause 4.6.2

a) Describe how your organization's certification records are managed and show how these procedures meet the requirements of the standard.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Give the rationale for how long your certification records are maintained.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.7 Confidentiality

The certification body shall, through legally enforceable commitments, keep confidential all information obtained in the process of its activities. These commitments shall cover all individuals working within the body, including committee members, and external bodies or individuals acting on its behalf. Such information shall not be disclosed to an unauthorized party without the written consent of the organization or individual from whom the information was obtained, except where the law requires such information to be disclosed. When the certification body is required by law to release such information, the organization or individual concerned shall be informed beforehand of what information will be provided.

a) Provide your confidentiality policies and documentation of your procedures for maintaining confidentiality of all information obtained through certification activities. (Refer to responses given in other sections of this application as needed.)

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) If applicable, provide evidence of a denial for a request for information.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.8 Security

All examinations and related items shall be maintained in a secure environment by the certification body, or its subcontractors, to protect the confidentiality of these items throughout their useful life.

a) Describe in detail the policies and procedures by which you and your contractor(s) protect the security and confidentiality of examinations and related items.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5 Requirements for certification body personnel

5.1.1 The certification process shall define the competence requirements for employed or contracted persons involved in the certification process.

Clause 5.1.1

a) List the personnel, including contract personnel directly involved in the certification process. Identify their qualifications for performing their assigned tasks.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe and cite the process for approving the required qualifications of personnel or contractor positions/individuals.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5.1.2 The certification body shall require its employed or contracted persons to sign a document by which they commit themselves to comply with the rules defined by the certification body, including those relating to confidentiality and those relating to independence from commercial and other interests, and from any prior and/or present link with the persons to be examined that would compromise impartiality.

Clause 5.1.2

a) Attach samples of confidentiality forms/agreements/declaration statements used by personnel and volunteers that declare they are committed to the certification bodies' rules. (Refer to other responses to this application as appropriate.)

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe and cite the policies and procedures associated with these forms.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5.1.3 Clearly documented instructions shall be available to the employed or contracted persons describing their duties and responsibilities. These instructions shall be kept up to date. All personnel involved in any aspect of certification activities shall possess appropriate education, experience and technical expertise which satisfies defined competence criteria for the tasks identified. They shall be trained for their specific responsibilities and made aware of the significance of the certification offered.

Clause 5.1.3

a) Provide descriptions of personnel (employed or contracted) duties and responsibilities. List and describe all training and orientation programs and the personnel who have attended.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5.1.4 The certification body shall establish and maintain current documentation on the relevant qualification, training and experience of each individual. The information shall be accessible to the individual(s) concerned and shall include the following:
a) name and address;
b) organization affiliation and position held;
c) education and professional status;
d) experience and training in the relevant;
e) their specific responsibilities and obligations within the certification body;
f) performance appraisals;
g) date of most recent updating of records.

Clause 5.1.4

a) How, where, and by whom are personnel records maintained?

Name of supporting Document:

Attachment numbers(s):
Page/paragraph:

b) What type of information is placed in personnel files? Provide an example of any standard forms utilized for all personnel.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5.2 Requirements for examiners

5.2.1 Examiners shall meet the requirements of the certification body based upon applicable competence standards and other relevant documents. The selection process shall ensure that examiners assigned to an examination or part of an examination at least
a) are familiar with the relevant certification scheme,
b) have a thorough knowledge of the relevant examination methods and examination documents,
c) have appropriate competence in the field to be examined,
d) are fluent both in writing and orally in the language of examination, and
e) are free from any interest so that they can make impartial and non-discriminatory judgments (assessments).

Clause 5.2.1

a) Describe and cite the selection criteria, qualifications, and responsibilities of examiners. (This would include scorers for performance/product assessment.)

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) How are examiners selected and trained, and how is their performance monitored, evaluated, and adjusted as needed?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5.2.2 If an examiner has a potential conflict of interest in the examination of a candidate, the certification body shall undertake measures to ensure that confidentiality and impartiality of the examination is not compromised (see 4.2.5). These measures shall be recorded.

Clause 5.2.2

If a trainer/instructor is(was) used in the evaluation process, present the the rationale and justification for this practice.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Provide evidence that objectivity and impartiality is(was) maintained under these circumstances.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6 Certification process

6.1.1 The certification body shall provide on request a current detailed description of the certification process, appropriate to each certification scheme (including fees), and the documents containing the requirements for certification, the applicants' rights, and the duties of a certified person which includes a code of conduct, if applicable (see 6.6.2).

Clause 6.1.1

a) Provide a sample of the descriptive documentation that is given to candidates.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.1.2 The certification body shall require the completion of an application, signed by the applicant seeking certification, which includes
a) the scope of the desired certification,
b) a statement that the person agrees to comply with the requirements for certification and to supply any information needed for the evaluation,
c) details of relevant qualifications, confirmed and supported by evidence, and
d) general information on the applicant, for example name, address and other information required to identify the person.

Clause 6.1.2

a) Describe the application process. Attach a sample application.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Provide a rationale for information requested on the application.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) If an electronic signature is accepted, how is the signature verified?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

d) What policies and procedures are in place to verify application information?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.2 Evaluation

6.2.1 The certification body shall review the application to confirm that
a) the certification body has the capability to deliver the requested certification,
b) the certification body is aware of and can, within reason, accommodate any special needs of applicants, such as language and/or disabilities, and
c) the applicant has the required education, experience and training specified by the scheme.

Clause 6.2.1

a) Identify what documents are required from candidates, how applications are reviewed, and how documentation submitted and statements made by applicants are verified.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Provide documentation of your policy and procedures for determining and providing accommodations for candidates who indicate that they have special needs.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) How does the certification body address language issues indicated by applicants? (This includes exams given in foreign languages as well as disability-related language issues.)

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

d) What are the qualifications of the individuals who review applications? How is the performance of their functions monitored, evaluated, and corrected if needed?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.2.2 The certification body shall examine competence, based on the requirements of the scheme, by written, oral, practical, observational or other means.

Clause 6.2.2

a) Describe how relevant knowledge, skills, and abilities are examined in the certification process.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe studies performed to ensure that all appropriate competence criteria are objectively and systematically evaluated?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.2.3 Examinations shall be planned and structured in a manner which ensures that all scheme requirements are objectively and systematically verified, with sufficient documented evidence produced to confirm the competence of the candidate.

Clause 6.2.3

a) What method(s) is(are) used to evaluate specific knowledge, skills, and abilities?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) For each scheme, provide a rationale for specific assessment mechanism(s) used.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.2.4 The certification body shall adopt reporting procedures that ensure the performance and results of the evaluation are documented in an appropriate and comprehensible manner, including the performance and results of examinations.

Clause 6.2.4

Describe how examination results are recorded.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe how examination results are reported and maintained.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe any regulations or requirements for reporting results outside your organization, how you comply with them, and how you maintain confidentiality of individual results in accordance with your policies.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.3 Decision on certification

6.3.1 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. Those who make the certification decision shall not have participated in the examination or training of the candidate.

Clause 6.3.1

a) Describe the process by which certification decisions are reached.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) What body makes the decision on certification?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Describe the policies and procedures in place to prevent an error regarding the decision of certification of a candidate.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.3.2 The certification body shall provide a certificate to all certified persons. The certification body shall maintain sole ownership of the certificates. The certificate may take the form of a letter, card or other medium, signed or authorized by a responsible officer of the certification body.

Clause 6.3.2 (*See Clause 6.3.3 for requirements*)

Provide a model of the certificate, letter, card, or other medium issued to all successful candidates notifying them of their certification.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe how your certification body protects the integrity of its certification from unauthorized use.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.3.3 These certificates shall contain, as a minimum, the following information:
a) the name of the certified person and a unique certification number;
b) the name of the certification body;
c) a reference to the competence standard or other relevant documents, including issue, on which the certification is based;
d) the scope of the certification, including validity conditions and limitations;
e) the effective date of certification and date of expiry.

Clause 6.3.3 (See 6.3.2)

6.4 Surveillance and recertification procedure

6.4.1 The certification body shall define a pro-active surveillance process to monitor certificants' compliance with relevant provisions of the certification scheme.

Clause 6.4.1

a) Describe the surveillance methods used to monitor certificate holders.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) How is it determined that certificate holders are compliant with current certification requirements?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.4.2 The certification body shall have procedures and conditions for the maintenance of certification in accordance with the certification scheme. These conditions, including the frequency and content of surveillance activities, shall be endorsed

by the scheme committee. The conditions shall be adequate to ensure that there is impartial evaluation to confirm the continuing competence of the certified person.

Clause 6.4.2

a) How often does the committee charged with surveillance review their procedures?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) What surveillance techniques are used to ensure impartiality in the evaluation of certified persons?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.5 Recertification

6.5.1 The certification body shall define recertification requirements according to the competence standard and other relevant documents, to ensure that the certified person continues to comply with the current certification requirements.

6.5.2 The certification body shall have procedures and conditions for the maintenance of certification in accordance with the certification scheme. These conditions, including the frequency and content of recertification activities, shall be endorsed by the scheme committee. The conditions shall be adequate to ensure that there is impartial evaluation to confirm the continuing competence of the certified person.

Clauses 6.5.1 and 6.5.2

a) Describe recertification requirements.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe the recertification program and how it is implemented. Include documentation of how there is impartial evaluation to confirm the continuing competence of the certificant.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.6 Use of certificates and logos/marks

6.6.1 A certification body that provides a certification mark or logo shall document the conditions for use and shall appropriately manage the rights for usage and representation.

Clause 6.6.1

a) Describe the use of the certification mark. Attach the certification mark and describe its use.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) How is the certification mark protected from misuse?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.6.2 The certification body shall require that a certified person sign an agreement
a) to comply with the relevant provisions of the certification scheme,
b) to make claims regarding certification only with respect to the scope for which certification has been granted,
c) not to use the certification in such a manner as to bring the certification body into disrepute, and not to make any statement regarding the certification which the certification body may consider misleading or unauthorized,
d) to discontinue the use of all claims to certification that contains any reference to the certification body or certification upon suspension or withdrawal of certification, and to return any certificates issued by the certification body, and
e) not to use the certificate in a misleading manner.

Clause 6.6.2

a) Provide a copy of the agreement that includes all of the elements in clause 6.5.2.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.6.3 Inappropriate references to the certification or misleading use of certificates and marks or logos in publications, catalogues, etc. shall be addressed with corrective measures, such as the suspension or withdrawal of certification, publication of the infraction and, if appropriate, additional legal action.

Clause 6.6.3

Describe how any inappropriate references to certification and its corresponding marks have been addressed.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Annex A: Personnel Certification Accreditation — Application Milestones

Application	**Date**
___Received application materials	_____
___Reviewed materials, if necessary send questions to ANSI	_____
___Sent in application and fee	_____
___Received acknowledgement from ANSI	_____
Ten-day review period begins.	
___Received assessor names	_____
___Sent back response card accepting/declining assessor(s)	_____
Once assessors are approved by organization, they will conduct a paper review of application.	
___Quality evaluations complete	_____
___Information requested, (90) days to resubmit without further fees	_____
___90 day deadline	_____
___Audit plan determined by assessors, sent to organization for approval and discussion.	_____
___Audit plan accepted.	_____

On-site Audit

___Assessors arrive	_____
___Audit conducted	_____
___Oral and summary report received	_____
___Written report received	_____

Non-conforming item(s)

___Plan drawn up with assessors for correction	_____
___Corrective actions approved	_____
___All non-conformities corrective actions approved	_____
___Corrective actions taken and sent in for review	_____
___Acknowledgment received	_____

___Non-conformities accepted as corrected _____

OR

___Further corrective action required _____

___Accreditation awarded _____

Annex B: List of possible documents to assist you in filling out application materials

1. Accommodations Policy & Procedures
2. Annual Report
3. Audits
4. Board Minutes
5. Bylaws
6. Candidate Handbook
7. Certification Handbook
8. Committee Minutes
9. Confidentiality Agreements
10. Contracts
11. Disclaimer Statement
12. Ethics Policy
13. Financial Statements and Audits
14. Insurance
15. Job Descriptions
16. Job/practice Analysis
17. Management Manual
18. Mission Statement
19. Personnel

Attachment C: Declaration Statement

Applicant agrees to meet the following conditions:

1. Applicant shall provide ANSI with all information requested for the process of assessing competency of a personnel certification body;
2. Applicant agrees to pay all fees charged for assessment of competence; including all subsequent fees once competence is recognized;
3. Applicant is familiar with the requirements for assessment of competency for personnel certification bodies;
4. The certification body can demonstrate it:
   - Is an independent third-party as a certifier of services provided to individuals;
   - Is a legal entity or part of a legal entity; and
   - Has a clearly defined scope of certification.

ANSI requires each applicant to adhere to the following:

a) make all necessary arrangements for the conduct of assessments, including provisions for examining documentation, and access to records (including internal assessment reports) and personnel for the purpose of surveillance, re-assessment and resolution of complaints;
b) make claims only regarding activities defined in the scope of the accreditation granted;
c) not use the accreditation in such a manner as to bring the Personnel Certification Accreditation Program into disrepute and not make any statement regarding the accreditation which Personnel Certification Accreditation Program may consider misleading or unauthorized;
d) upon withdrawal of the Personnel Certification Accreditation Program accreditation, discontinue use of all advertising material which references the Personnel Certification Accreditation Program accreditation and return all accreditation documents including the certificate to ANSI;
e) not allow the Personnel Certification Accreditation Program accreditation to imply that a person's competencies are approved by the Personnel Certification Accreditation Program;
f) ensure that no Personnel Certification Accreditation Program document, logo, or report nor any part thereof is used in a misleading manner; and
g) comply with Personnel Certification Accreditation Program requirements when referencing the status of Personnel Certification Accreditation Program accreditation in communication media such as documents, brochures, or advertising.

I accept the conditions aforementioned and attach said completed application for accreditation review by the American National Standards Institute.

Please sign below.

_____	_____	_____
Name	Approving Authority Title	Date

Attachment D: Terms and Definitions

Certification Scheme: Certification scheme (body of knowledge) relating to a specific certification of an occupation, specialty, role, or skill.

Certification System: Management system for carrying out certification process.

Examiner: An individual who actually evaluates a candidate or the candidate's performance or product (not a proctor.)

Internal Audit: An evaluation conducted by an individual within the organization.

Surveillance: Surveillance is a process by which certificants are monitored to determine whether the certification body should initiate any action to suspend or revoke the certification.

Acronyms

ANSI American National Standards Institute

ISO International Organization for Standardization

IEC International Electrotechnical Commission

ANSI/ISO/IEC 17024:2003, General requirements for bodies operating certification of persons. This international standard specifies requirements which ensure that certification bodies operating certification schemes for persons operate in a consistent, comparable, and reliable manner.[1]

PCAC Personnel Certification Accreditation Committee

[1] ANSI/ISO/IEC 17024, page v

Attachment A – Issue Background

When the Conference for Food Protection (CFP) adopted the CFP Standards for the Accreditation of Food Protection Manager Certification Programs, there were no suitable existing standards in place. The Conference explored other standards available at the time including the National Commission for Certifying Agencies (NCCAs) Standards for the Accreditation of Certification Programs but found none of them to be acceptable for use by the Conference. Therefore, the Conference developed its own standard.

Once a standard has been developed, it must be maintained on an ongoing basis. This requires a dedicated group of individuals and standards experts who not only understand the history of the standard in question, but also the standards development and maintenance process. The Food Manager Certification Committee has admirably stepped up to maintain the standard but with a limited number of committee participants experienced in standards development and/or a good understanding of the history of the standard, the conference would be better served by the use of a professional and world-wide accepted standard developed and maintained by an international standards organization.

Since the Conference developed its standard, an International Standard developed by the International Organization for Standardization (ISO) has been developed. This standard, ISO/IEC 17024 – Conformity Assessment: General Requirements for Bodies Operating Certification of Persons, has the power of a worldwide accepted standards development organization (ISO) behind it. Additionally, because it is an international standard, it has worldwide acceptance. Organizations such as the Global Food Safety Initiative (GFSI) are referencing this standard as a normative document in the development of their own standards for the competence of auditors.

ISO/IEC 17024 is not only maintained by an international group of standard experts and adopted by governments in countries all over the world, it is even being adopted by U.S. governmental agencies. The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Department of Human Resource Development (DHRD) is currently developing training and professional certification for a range of occupational positions. FDA has contracted for the development of personnel certification programs that will meet or exceed the requirements of ISO/IEC 17024 and that will be accreditable by the American National Standards Institute (ANSI) against ISO/IEC 17024. Additionally, other U.S. Governmental agencies (Department of Defense, Department of Labor, and Department of Energy) have officially recognized ANSI and ISO/IEC 17024 as the one accrediting body and personnel certification standard, by which it judges the quality and validity of all personnel certification programs.

ISO/IEC 17024 is sufficiently similar to the CFP Standards for accreditation of food protection manager programs in content, to substitute one for the other. Organizations meeting the CFP standard would have little difficulty meeting the ISO/IEC 17024 standard. And personnel certification organizations accredited against the ISO/IEC 17024 standard would not only find their programs accepted in the United States, but would potentially find them accepted world-wide. These programs would have the ability to join the Multi-Lateral Agreement (MLA) being developed by the International Accreditation Forum (IAF) for mutual recognition by Accrediting Bodies in all countries party to the MLA. For example, a Food Protection Manager accredited by ANSI against ISO/IEC 17024, could find acceptance in the United Kingdom by the ANSI partner in the United Kingdom, the United Kingdom Accreditation Service (UKAS).

World-wide acceptance is going to become the requirement of the future. U.S. only based accreditation will eventually be phased out as governments work towards the transportability of foods, supplies and people. More and more governments, including the U.S. Government are going to work towards international standards and international accreditation against those standards.

Adoption of ISO/IEC 17024 in lieu of the CFP standard will turn maintenance of the standard over to a professional standards organization and will allow the conference to concentrate on issues within its expertise. It will also move the conference towards a world-accepted standard and the use of a standard that the United States government is already in the process of adopting. End users of manager certification (managers, regulators, employers, the public) can all be confident that the world's best standard for personnel certification programs is being applied and the world's best accrediting body (ANSI) is accrediting those certification programs against that standard.

ANSI serves as the accrediting body for both standards. The transition of accreditation from the CFP standard to the ISO standard could be accomplished very easily due to the fact that ANSI is the accreditor of both standards. The Conference would maintain control by specifying the conditions under which the ISO standard would be accepted in lieu of the CFP standard. The conference would always have the right to revert back to its own standard at some future point should it determine the ISO standard is no longer in the best interest of the food industry.

Because only one of the providers has been accredited by ANSI against both requirements, this submitter is aware that a generous timeline should be adopted to allow all interested organizations to become accredited by ANSI against ISO/IEC 17024. Therefore, the Conference Food Manager Certification Committee should be tasked with developing a transition plan that slowly transitions from the CFP standard to the ISO standard.

One suggestion is to offer a 6 year transition plan similar to what is described below:

Immediately – CFP recognizes ISO/IEC 17024 as equivalent to the CFP Standard for Accreditation of Food Protection Manager Certification Programs. Thus Certification Bodies accredited by ANSI against ISO/IEC 17024 are immediately granted accreditation by ANSI against the CFP standard without undergoing a separate and additional accreditation audit.

Years 1-2 – ANSI continues to accredit Certification Bodies to the CFP standard and the conference continues to maintain the standard. ANSI conducts workshops to interested CFP accredited certification bodies and other interested parties on the similarities of the two standards and any additional requirements that might need to be met to become accredited under ISO/IEC 17024. ANSI begins accrediting Certification Bodies against ISO/IEC 17024. Those Certification Bodies accredited, are immediately deemed to meet CFP and no longer need to submit separate application for CFP accreditation.

Years 2-4 – Food Protection Manager Certification Bodies apply for and achieve accreditation by ANSI against ISO/IEC 17024. ANSI continues to maintain both programs.

Year 5-6 – ANSI phases out accreditation against the CFP standard. Any Certification Body not accredited by ANSI against ISO/IEC 17024 will cease to be accredited by ANSI at the end of the term of their accreditation.

ANSI
American National Standards Institute

January 24, 2012

To Whom It May Concern:

I have been requested by Dr. Cynthia Woodley to make a statement about the comparability of the Conference for Food Protection: Standards for Accreditation of Food Protection Manager Certification Programs and ANSI/ISO/IEC 17024 Conformity Assessment – General requirements for bodies operating certification of persons.

As the purveyor of accreditation service for both standards, our professional staff believe the Standards are similar and ANSI/ISO/IEC 17024 is equal or higher than the CFP Standards for Accreditation of Food Protection Manager Certification Program.

Lane Hallenbeck
Vice President
Accreditation Services

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Conference for Food Protection
2012 Issue Form

Internal Number: 087
Issue: 2012 II-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.

Title:
Adoption of ISO/IEC 17024 Standard for Personnel Certification Programs

Issue you would like the Conference to consider:
The Conference should consider adopting ISO/IEC 17024 - Conformity Assessment: General Requirements for Bodies Operating Certification of Persons as a Standard that is equivalent to the Conference for Food Protection Standard for Accreditation of Food Protection Manager Certification Program.
The American National Standard has deemed the two standards to be equivalent. Based on the equivalence of the standards, the Conference should consider accepting Certification Organizations who are accredited to ISO/IEC 17024 by the American National Standards Institute as also meeting the Conference's Standard.
Attached to this issue are three files that should be reviewed in consideration of this issue. The first is the application for accreditation. This file is attached because it contains the language of the ISO/IEC 17024 standard. Because the standard is a copyrighted standard, it is not allowed to be placed in this issue for presentation to the entire conference. However the text of the standard does appear in the application so the conference may review the clauses of the standard by reviewing the application. The second file that is attached is a letter from the American National Standards Institute attesting to the comparability of the two standards. The third file attached is the language from the introduction of ISO/IEC 17024 that describes the purpose of the standard to illustrate that the standard has the same purpose as the Conference's standard (a standard of best practice for certification programs).

Public Health Significance:
The safety of food in the United States is dependent upon Food Managers who understand and implement basic food safety concepts. The Conference has established a standard and an accreditation process against that standard to ensure that Food Manager Certification Programs attesting to the knowledge and skills of Food Managers are valid, reliable and legally defensible. When the Conference standard was developed, no equivalent standard was available for use by the Conference. Since that time, the International Organization for Standardization (ISO) has developed a standard that is not only equivalent, but is of higher quality than the Conference standard. This standard is ISO/IEC 17024 - Conformity Assessment - General Requirements for bodies operating

certification of persons and certification bodies are accredited by the American National Standards Institute (ANSI) against this standard. Certification Organizations seeking accreditation by ANSI against ISO/IEC 17024 must also submit for accreditation by ANSI against the Conference Standard. This results in a duplication of effort. ANSI must send out auditors to audit the same Certification Organization Food Manager program against two similar standards and the Certification Organization must pay twice. This results in an increase cost to the industry. If costs to verify the knowledge of Food Managers increase, the risk to the public is that Food Managers will not seek certification.

Recommended Solution: The Conference recommends...:
adoption of ISO/IEC 17024 "Conformity Assessment: General Requirements for Bodies Operating Certification of Persons" as an equivalent standard to the "Conference for Food Protection Standard for the Accreditation of Food Protection Manager Certification Program" and grant immediate reciprocal accreditation acceptance of a certification organization accredited by the American National Standards Institute (ANSI) against ISO/IEC 17024 as meeting the Conference standard. Thus an organization achieving accreditation by ANSI against ISO/IEC 17024 would also simultaneously receive accreditation against the Conference Standard.

Submitter Information:

Name:	Cynthia D. Woodley		
Organization:	Professional Testing Inc.		
Address:	7680 Universal Blvd. Suite 300		
City/State/Zip:	Orlando, FL 32819		
Telephone:	407-264-2993 / 407-620-3645	Fax:	407-264-2855
E-mail:	cdwoodley@proftesting.com		

Attachments:

- "ANSI Application for Accreditation (contains 17024 language)"
- "ANSI Letter Stating Equivalence of the ISO Standard to the CFP Standard"
- "Introduction to ISO/IEC 17024 Which describes the Purpose of the Standard"

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.

Date Issued: 2009-05-01 PUBLIC FORM **PCAC-FR-504**
Approved by: Lane Hallenbeck (2009-05-01) Revision: 2

Application for ANSI Accreditation Under ANSI/ISO/IEC 17024

INTRODUCTION TO ANSI PERSONNEL CERTIFICATION ACCREDITATION PROGRAM

Over the past decade, technology has improved the flow of information and provided the world with a tremendous financial market expansion. While this had led to the growth of a more inclusive global economy, the expansion of our world through data exchange has also provided us with challenges. Some of these challenges include the security of information over the Internet, government trade agreements being changed to accommodate the electronic transfer of knowledge, and a world wide industry skill shortage due to lack people trained in this new world of work.

These factors have forced the growth of a rapid transfer of knowledge through education and training. It is important for the consumer to know whether they are receiving a quality knowledge product. To that end, products are regulated and standardized for the protection of the public. Organizations such as ANSI, the International Organization for Standardization (ISO), and the International Electrotechnical Commission (IEC) develop standards, which protect the integrity of a product or service. Organizations apply for and obtain a stamp of approval only after going through a rigorous quality review of not only their product or service, but also their organization as a whole based on globally accepted standards.

Over the past two years, ISO/IEC committees made up of over 22 countries have been developing a standard, ISO/IEC/FDIS 17024, which addresses the general requirements for bodies operating certification schemes for persons. This standard shows how the world can exchange quality programs through the standardization of skills and knowledge, which lead to a certification of a person. ISO/IEC/FDIS 17024 requirements set the standard for all countries' personnel certification programs, through rigorous requirements using quality objectives.

Overview of Draft International Standard of ISO/IEC/FDIS 17024 Standard for bodies operating certification of persons

ISO/IEC/FDIS 17024 specifies requirements which ensure that certification bodies operating certification systems for persons operate the certification of persons in a consistent, comparable, and reliable manner. The standard is broken up into fourteen clauses. Each clause has several sub-components. The clauses are as follows:

Certification body	Organizational structure
Development and maintenance	Management system
Outsourcing	Records
Confidentiality	Personnel requirements
Examiners	Application
Evaluation	Decision on certification
Surveillance and re-certification	Use of certificates and logos

Since its inception in 1918, ANSI has been creating the benchmark of excellence in U.S. voluntary standardization and conformity assessment systems. ANSI is responsible for the integrity of this audit process. Organizations applying for accreditation understand that throughout the process of compliance they will be treated according to ANSI's cornerstone principles of openness, consensus, due process, and balance.

ANSI is the sole United States representative and dues-paying member of the two major non-treaty international standards organizations, ISO and IEC. ANSI possesses the in-depth knowledge of the global standards arena and is in the unique position of creating the first personnel certification accreditation program for U.S. organizations.

By completing this application, you will have begun the first step to compliance with this international standard. In addition you will receive a quality review, tailored for your organization, using your input.

All application questions must be submitted in writing or via e-mail.

Applications and questions should be directed to:

American National Standards Institute (ANSI)
Attn: Dr. Roy Swift
Senior Director, Personnel Credentialing Accreditation Programs
1899 L Street, NW
11th Floor
Washington, DC 20036
Rswift@ansi.org

All applications will be the sole property of ANSI.

GENERAL INFORMATION FOR SUBMISSION

Process

To facilitate the process of review, please submit one application for each review. One application will be acceptable for a multiple scheme (certification construct/credential) review. Please review each question carefully and when appropriate, respond to questions separately for each individual scheme. Be consistent in your responses, Clause 4.3.2, Item B Scheme 1, Scheme 2 etc. Fill out the application completely. You may attach supporting documentation that further clarifies your answer. Applications must be in 11 or 12-point font size. Submit three copies of the application and supporting documentation.

Application Overview

The application is divided into two sections.

Part 1 is an organizational questionnaire.

Part 2 is a questionnaire based on the ANSI/ISO/IEC 17024 standard. This portion is divided by clauses. Attachments may be added to supplement your answer. Documentation attached may assist in several clause areas. When using an attachment to supplement an answer, note the attachment number on the question. Every attachment must have a cover sheet stating the relevant clause, responding question and where the answer/explanation can be found in the document.

Sample	**Attachment A**	**Policy Manual**	
	Clause 4.2.4	Question A	Reference found on Page 3, paragraphs 5-10
	Clause 4.4.3	Question C	Section (b) Reference Page 20, paragraphs 1-3

Multiple Schemes

Again, when submitting the application for a multiple scheme review, you will need to clarify your relative answers as individual schemes. Be consistent in your responses, Scheme 1, Scheme 2 etc.

Accreditation Assessment

After applications are received, a ten (10) day review period begins. At this time, ANSI will determine whether the material submitted is complete. If necessary, applicants may be asked to provide additional information for clarification. Requested information must be received within ninety (90) days of request. When it is determined that the application is complete, assessors will be assigned to your organization. You will be advised of the assessors' names and given five (5) days to accept or provide information relating to conflict of interest regarding the assessor(s). Assessors will be assigned to your organization from your acceptance of them until the final determination of compliance.

Accepted assessors will review your application and determine an audit plan. The audit plan will be submitted to you for review and comment. Once the plan is agreed upon, an on-site audit will ensue. Your organization will be evaluated using the attached requirements. Please review attachments for all requirements and be ready to supply applicable documentation to the assessors as requested. The length of the audit will depend on the size of the organization and programs being reviewed.

Fees

Application fee	$3000.00
On-site audit and preparation	$1250.00 per day, each assessor, plus expenses. Includes: Review of documentation and preparation, on-site audit, oral report at end of audit, written report with commendations, opportunities for improvement, and non-conformity statements.
Corrective actions	All non-conforming items must be corrected before organization is approved for accreditation. Organizations will be given statements describing the rationale for every non-conforming item. You will discuss and determine a timeline with assessors to correct the non-conforming items. Fees associated with reviewing corrective actions are billed at $1,250 per day or fraction thereafter.

Annexes

A Application Milestones
B Documentation that may assist you in completing application
C Declaration Statement (this must be returned with application)
D Definitions of terminology common to ISO/IEC/DIS standards

APPLICATION FOR ANSI ACCREDITATION

Part 1: Applicant Information

Date:

Certification Body:

Address:

City, State, Zip:

Contact Person:

Title:

E-Mail: Phone:

Fax: Web Site:

1. What is the legal structure of your organization?

☐ Corporate Entity (Not Tax Exempt)
☐ Corporate Entity (Tax Exempt)
☐ Part of Parent Organization (includes wholly owned subsidiary)
☐ Other Please specify:

2. How long has your organization been in existence?

3. How long has your organization been offering personnel certification?

4. How many active certificates are in your database?

☐ 50-100
☐ 101-500
☐ 501-1000
☐ 1001-3000
☐ 3001-5000
☐ 5001-10,000
☐ 10,001-50,000
☐ 50,001-100,000
☐ 100,001 and up

5. How many applications are received each year?

☐ 0-500
☐ 501-1000
☐ 1001-3000
☐ 3001-5000
☐ 5001-10,000
☐ 10,001-20,000
☐ 20,001 and up

6. How many applicants are tested each year?

☐ 0-500
☐ 501-1000
☐ 1001-3000
☐ 3001-5000
☐ 5001-10,000
☐ 10,001-20,000
☐ 20,001 and up

7. How many tests are administered each year?
☐ 0-500
☐ 501-1000
☐ 1001-3000
☐ 3001-5000
☐ 5001-10,000
☐ 10,001-20,000
☐ 20,001 and up

8. How many applicants are certified each year?
☐ 0-500
☐ 501-1000
☐ 1001-3000
☐ 3001-5000
☐ 5001-10,000
☐ 10,001-20,000
☐ 20,001 and up

9. Is your program open to international applicants who are trained/educated outside the United States?
☐ Yes ☐ No

10. If yes, does your organization have any reciprocity agreements in place?
☐ Yes ☐ No

If yes, please explain.

11. Is your certification program necessary for personnel to obtain employment in your industry?
☐ Yes ☐ No

If yes, please explain why.

12. Does your organization outsource components of your personnel certification program?
☐ Yes ☐ No

If yes, what is outsourced?

Questions related to certification scheme

13. List the certification schemes within the scope for which you are applying for accreditation.
Name(s)

14. How are your candidates assessed? Check all that apply:
☐ Written paper and pencil examination
☐ Oral examination
☐ Combination of written and oral examinations
☐ Performance based (directly observed)
☐ Portfolio (representative sample of work)
☐ Computer based testing
☐ Computer adaptive testing
☐ Other Please specify:

15. Where is your assessment given? Check all that apply.
☐ Industry setting
☐ Commercial Testing center
☐ Educational Institution
☐ Other Please specify:

16. How often is the examination given, if applicable?
☐ on demand
☐ one time per year
☐ two times per year
☐ three times per year
☐ four times per year
☐ greater than four times per year

Part 2: Compliance with Requirements of ANSI/ISO/IEC 17024

4 Requirements for certification bodies

4.1 Certification body

4.1.1 The policies and procedures of the certification body and their administration shall be related to the criteria in which certification is sought, shall be fair and equitable among all candidates, and shall comply with all applicable regulations and statutory requirements. The certification body shall not use procedures to impede or inhibit access by applicants and candidates, except as provided for in this International Standard.

Clause 4.1.1

Using your policies and procedures, describe how your certification body ensures fair and equitable treatment of candidates throughout all phases of your certification program.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

List laws and regulations applicable to your certification body in the certification process.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.1.2 The certification body shall define policies and procedures for granting, maintaining, renewing, expanding and reducing the scope of the desired certification, and suspending or withdrawing the certification.

Clause 4.1.2

Describe your certification body's policies and procedures for granting, maintaining, and renewing an individual's certificate.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe your certification body's policies and procedures for suspending or withdrawing an individual's certificate.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe and cite the policies and procedures whereby your organization would expand or reduce the scope of its certification scheme(s).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.1.3 The certification body shall confine its requirements, evaluation and decision on certification to those matters specifically related to the scope of the desired certification.

Clause 4.1.3

Define the scope and parameters of your certification scheme(s). Provide relevant portions of your published documents.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2 Organizational structure

4.2.1 The certification body shall be structured so as to give confidence to interested parties in its competence, impartiality and integrity. In particular, the certification body:

a) shall be independent and impartial in relation to its applicants, candidates and certified persons, including their employers and their customers, and shall take all possible steps to assure ethical operations;

b) shall be responsible for its decisions relating to the granting, maintaining, renewing, expanding and reducing the scope, or suspending and withdrawing the certification;

c) shall identify the management [group(s) or person(s)] which shall have overall responsibility for
1) evaluation, certification and surveillance as defined in this International Standard, the applicable competence standards and other relevant documents,
2) the formulation of policies relating to the operation of the certification body, with regard to certification of persons
3) decisions on certification,
4) the implementation of its policies and procedures,
5) the finances of the certification body, and
6) the delegation of authority to any committees or individuals to undertake defined activities on its behalf;

d) shall have documents establishing it as a legal entity or part of a legal entity.

Clause 4.2.1

Describe and provide documentation of how your certification body is independent and impartial.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe your ethics policy for staff, consultants, and volunteers.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Provide a description or chart of your organization's structure and the responsibilities of each component.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe how the components of your organization relate to each other and how decisions are made.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Identify your body's management and describe their qualifications.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe the financial controls in place to ensure the independence of the certification body.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Provide documentation establishing your organization as a legal entity or part of a legal entity.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.2 The certification body shall have a documented structure which safeguards impartiality, including provisions to assure the impartiality of the operations of the certification body. This structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification system, without any particular interest predominating.

Clause 4.2.2

Demonstrate how the structure provides for balancing stakeholder interests without any particular interest predominating.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe how changes in the organizational structure are made and approved by the certification body. Cite any policies and procedures used to implement these changes.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.3 The certification body shall appoint a scheme committee, which shall be responsible for the development and maintenance of the certification scheme for each type of certification being considered. The scheme committee shall fairly and equitably represent the interests of all parties significantly concerned with the certification scheme, without any particular interest predominating. Where a certification scheme is developed by organizations other than the certification body, the respective developer of the scheme shall adhere to the same principles.

Clause 4.2.3

a) Describe the structure and functions of your scheme committee and the qualifications of its members. (Refer to definition of scheme committee in ISO/IEC FDIS 17024)

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe the structure and functions of other advisory bodies in relation to the scheme committee.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Describe relationships, functions, and qualifications of any technical support for the scheme committee.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.4 The certification body
a) shall have the financial resources necessary for the operation of a certification system and to cover associated liabilities,
b) shall have policies and procedures that distinguish between the certification of persons and any other activities, and
c) shall assure that the activities of bodies related to it do not compromise the confidentiality and impartiality of its certification.

Clause 4.2.4

a) List and describe the sources of funds used for the operation of your certification system and associated liabilities.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Attach current and the previous three-year audited financial statements. Indicate the level of funding of all activities.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) What activities other than certification services does your certification body conduct? Explain how your certification body distinguishes these activities from certification services.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

d) Explain how your policies and procedures maintain confidentiality, objectivity, and impartiality of the certification with respect to your relationships with other bodies.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.5 The certification body shall not offer or provide training, or aid others in the preparation of such services, unless it demonstrates how training is independent of the evaluation and certification of persons to ensure that confidentiality and impartiality are not compromised.

Clause 4.2.5

If the certification body provides or aids others in the preparation of training services, demonstrate how training is independent of the evaluation and certification of persons to ensure that confidentiality and impartiality are not compromised.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe the training and how it relates to the certification process.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.6 The certification body shall define policies and procedures (e.g. code of conduct) for the resolution of appeals and complaints received from applicants, candidates, certified persons and their employers, and other parties about the certification process and criteria, as well as policies and procedures for the performance of certified persons. These policies and procedures shall ensure that appeals and complaints are resolved independently, in an unbiased manner.

Clause 4.2.6

Describe the process for appeals and complaints. Using examples of resolved issues over the past three years, describe how the policies and procedures were applied in an unbiased manner.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Provide written policies and procedures for appeals and complaints.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Provide policies and procedures that define the performance of certified persons (e.g. codes of conduct/ethics).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.2.7 The certification body shall employ or contract enough people with the necessary education, training, technical knowledge and experience to perform certification functions relating to the type, range and volume of work performed, under a responsible management.

Clause 4.2.7

a) Identify any certification functions for which your organization contracts and document how they are monitored. Show the job responsibilities and qualifications of contractors' personnel.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Identify personnel with functions related to the certification. Show their job responsibilities, qualifications, and ways of monitoring performance.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Provide justification that the number of people employed and contracted is adequate.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3 Development and maintenance of a certification scheme

4.3.1 The certification body shall define the methods and mechanisms to be used to evaluate the competence of candidates, and shall establish appropriate policies and procedures for the initial development and continued maintenance of these methods and mechanisms.

Clause 4.3.1

a) Describe methods and mechanisms used to evaluate candidates.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe the policies and procedures for continually evaluating and updating the methods and mechanisms used to evaluate the competence of candidates.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3.2 The certification body shall define a process for the development and maintenance of certification schemes that includes the review and validation of the scheme by the scheme committee.

Clause 4.3.2

a) Describe the development of the certification process for specific scheme(s).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) How is(are) each scheme(s) reviewed and updated as needed?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3.3 The certification body shall, where applicable, give due notice to representatives of the scheme committee of any changes in its requirements for certification. The certification body shall take into account the views expressed by the scheme committee before deciding on the precise form and effective date of the changes. Following decision on, and

publication of, the changed requirements, the certification body shall, where applicable, inform the interested parties and the certified persons appropriately. The certification body shall verify that each certified person complies with the changed requirements within such a period of time as is reasonable for the certification body in consultation with the scheme committee.

Clause 4.3.3

How does the certification body notify the scheme committee of proposed changes in requirements for certification? How does the certification body take scheme committee views into account?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

What are the policies and procedures for making a change to a scheme?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

How are stakeholders notified of a change in certification requirements?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

How does the certification body ensure compliance with the change?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3.4 The criteria against which the competence of a person is evaluated shall be those defined by the certification body in accordance with this International Standard and other relevant documents. If explanation is required as to the application of these documents to a specific certification scheme, it shall be developed by experts, endorsed by the scheme committee, and published by the certification body.

Clause 4.3.4

What documents did your certification body use in developing the criteria against which the competency of a person is evaluated?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

How did experts in your field contribute to the development of the criteria for competence? What are the qualifications of the experts?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3.5 Certification shall not be restricted on the grounds of undue financial or other limiting conditions, such as membership of an association or group. Successful completion of an approved training course may be a requirement of a certification scheme, but recognition/approval of training courses by the certification body shall not compromise impartiality, or reduce the demands of the evaluation and certification requirements.

Clause 4.3.5

Describe the rationale upon which certification requirements are based and the data supporting the rationale. Justify fees and requirements.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe how any recognition/approval of training programs relates to how certification decisions are made.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.3.6 The certification body shall evaluate the methods for examination of candidates. Examinations shall be fair, valid and reliable. Appropriate methodology and procedures (such as collecting and maintaining statistical data) shall be defined to reaffirm, at least annually, the fairness, validity, reliability and general performance of each examination and all identified deficiencies corrected.

Clause 4.3.6

Describe the procedures to evaluate the examinations. Include content reviews, psychometric analyses, cut score studies and other methodology applied to evaluate the instruments/procedures used to determine certification.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe any validity, reliability, adverse impact or other studies conducted regarding your examination(s).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Cite the standards that you use to develop the criteria against which you evaluate your examination processes, procedures and instrument(s).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.4 Management system

4.4.1 The certification body shall operate a management system which is documented and covers all the requirements of this International Standard, and ensures the effective application of these requirements.

Clause 4.4.1

Provide documentation of your management system and indicate how it ensures the effective application of the requirements of ISO/IEC/FDIS 17024. (Cite responses to other sections of this application as needed).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.4.2 The certification body shall ensure that a) a management system is established and maintained in accordance with this International Standard, and b) its management system is understood and implemented at all levels of the organization.

Clause 4.4.2

Describe how your certification body established and how it maintains its management system.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

How does your organization ensure that your management system is understood and implemented on all levels of the organization?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.4.3 The certification body shall have document control and internal audit and management review systems in place, including provisions for continual improvement, corrective and preventive actions.

Clause 4.4.3

a) Provide documentation of your document control procedures.

Name of supporting Document:
Attachment numbers(s):

Page/paragraph:

b) Provide documentation of your internal audit and management review systems, including continuous improvement processes and procedures for taking corrective and preventive action.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.5 Subcontracting

4.5.1 When a certification body decides to subcontract work related to certification (e.g. examination) to an external body or person, a properly documented agreement covering the arrangement, including confidentiality and prevention of a conflict of interest, shall be drawn up. The decision on certification shall not be subcontracted.

Clause 4.5.1

a) Show documentation of the agreement and a detailed description of all certification-related work that is contracted to individuals and/or organizations.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Attach samples of your confidentiality and conflict of interest statements and agreements.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Provide documentation that the organization does not contract for decisions on certification.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.5.2 The certification body
a) shall take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, renewing, expanding and reducing the scope, and suspending or withdrawing certification;
b) shall ensure that the subcontractor is competent and complies with the applicable provisions of this International Standard and is not involved, either directly or through their employer, with training or the maintenance of the certification of persons in such a way that confidentiality and impartiality could be compromised, and
c) shall maintain a list of its subcontractors, and assess and monitor their performance in accordance with documented procedures.

Clause 4.5.2

a) Describe how your certification body monitors work for which it contracts. Include processes and procedures that ensure that corrective actions are taken when needed.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe how your certification body determines that its contractor(s) is(are) competent to perform their work for the organization.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Describe how your certification body ensures that its contractor(s) are not involved with the training or maintenance of the certification in such a way that confidentiality and impartiality could be compromised.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

d) Describe your organization assesses and monitors the work of its contractor(s).

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.6 Records

4.6.1 The certification body shall maintain a record system appropriate to its particular circumstances and to comply with regulations, including a means to confirm the status of a certified person. The records shall demonstrate that the certification process has been effectively fulfilled, particularly with respect to application forms, evaluation reports, surveillance activities and other documents relating to granting, maintaining, renewing, expanding and reducing the scope, and suspending or withdrawing certification.

Clause 4.6.1

a) Describe in detail your certification record system and demonstrate how it meets the requirement of the standard.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.6.2 The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and the confidentiality of the information. The records shall be kept for an appropriate period of time to demonstrate continued confidence for at least one full certification cycle, or as required by recognition arrangements, contractual, legal or other obligations.

Clause 4.6.2

a) Describe how your organization's certification records are managed and show how these procedures meet the requirements of the standard.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Give the rationale for how long your certification records are maintained.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.7 Confidentiality

The certification body shall, through legally enforceable commitments, keep confidential all information obtained in the process of its activities. These commitments shall cover all individuals working within the body, including committee members, and external bodies or individuals acting on its behalf. Such information shall not be disclosed to an unauthorized party without the written consent of the organization or individual from whom the information was obtained, except where the law requires such information to be disclosed. When the certification body is required by law to release such information, the organization or individual concerned shall be informed beforehand of what information will be provided.

a) Provide your confidentiality policies and documentation of your procedures for maintaining confidentiality of all information obtained through certification activities. (Refer to responses given in other sections of this application as needed.)

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) If applicable, provide evidence of a denial for a request for information.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

4.8 Security

All examinations and related items shall be maintained in a secure environment by the certification body, or its subcontractors, to protect the confidentiality of these items throughout their useful life.

a) Describe in detail the policies and procedures by which you and your contractor(s) protect the security and confidentiality of examinations and related items.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5 Requirements for certification body personnel

5.1.1 The certification process shall define the competence requirements for employed or contracted persons involved in the certification process.

Clause 5.1.1

a) List the personnel, including contract personnel directly involved in the certification process. Identify their qualifications for performing their assigned tasks.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe and cite the process for approving the required qualifications of personnel or contractor positions/individuals.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5.1.2 The certification body shall require its employed or contracted persons to sign a document by which they commit themselves to comply with the rules defined by the certification body, including those relating to confidentiality and those relating to independence from commercial and other interests, and from any prior and/or present link with the persons to be examined that would compromise impartiality.

Clause 5.1.2

a) Attach samples of confidentiality forms/agreements/declaration statements used by personnel and volunteers that declare they are committed to the certification bodies' rules. (Refer to other responses to this application as appropriate.)

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe and cite the policies and procedures associated with these forms.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5.1.3 Clearly documented instructions shall be available to the employed or contracted persons describing their duties and responsibilities. These instructions shall be kept up to date. All personnel involved in any aspect of certification activities shall possess appropriate education, experience and technical expertise which satisfies defined competence criteria for the tasks identified. They shall be trained for their specific responsibilities and made aware of the significance of the certification offered.

Clause 5.1.3

a) Provide descriptions of personnel (employed or contracted) duties and responsibilities. List and describe all training and orientation programs and the personnel who have attended.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5.1.4 The certification body shall establish and maintain current documentation on the relevant qualification, training and experience of each individual. The information shall be accessible to the individual(s) concerned and shall include the following:
a) name and address;
b) organization affiliation and position held;
c) education and professional status;
d) experience and training in the relevant;
e) their specific responsibilities and obligations within the certification body;
f) performance appraisals;
g) date of most recent updating of records.

Clause 5.1.4

a) How, where, and by whom are personnel records maintained?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) What type of information is placed in personnel files? Provide an example of any standard forms utilized for all personnel.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5.2 Requirements for examiners

5.2.1 Examiners shall meet the requirements of the certification body based upon applicable competence standards and other relevant documents. The selection process shall ensure that examiners assigned to an examination or part of an examination at least
a) are familiar with the relevant certification scheme,
b) have a thorough knowledge of the relevant examination methods and examination documents,

c) have appropriate competence in the field to be examined,
d) are fluent both in writing and orally in the language of examination, and
e) are free from any interest so that they can make impartial and non-discriminatory judgments (assessments).

Clause 5.2.1

a) Describe and cite the selection criteria, qualifications, and responsibilities of examiners. (This would include scorers for performance/product assessment.)

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) How are examiners selected and trained, and how is their performance monitored, evaluated, and adjusted as needed?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

5.2.2 If an examiner has a potential conflict of interest in the examination of a candidate, the certification body shall undertake measures to ensure that confidentiality and impartiality of the examination is not compromised (see 4.2.5). These measures shall be recorded.

Clause 5.2.2

If a trainer/instructor is(was) used in the evaluation process, present the the rationale and justification for this practice.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Provide evidence that objectivity and impartiality is(was) maintained under these circumstances.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6 Certification process

6.1.1 The certification body shall provide on request a current detailed description of the certification process, appropriate to each certification scheme (including fees), and the documents containing the requirements for certification, the applicants' rights, and the duties of a certified person which includes a code of conduct, if applicable (see 6.6.2).

Clause 6.1.1

a) Provide a sample of the descriptive documentation that is given to candidates.

Name of supporting Document:

Attachment numbers(s):
Page/paragraph:

6.1.2 The certification body shall require the completion of an application, signed by the applicant seeking certification, which includes
a) the scope of the desired certification,
b) a statement that the person agrees to comply with the requirements for certification and to supply any information needed for the evaluation,
c) details of relevant qualifications, confirmed and supported by evidence, and
d) general information on the applicant, for example name, address and other information required to identify the person.

Clause 6.1.2

a) Describe the application process. Attach a sample application.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Provide a rationale for information requested on the application.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) If an electronic signature is accepted, how is the signature verified?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

d) What policies and procedures are in place to verify application information?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.2 Evaluation

6.2.1 The certification body shall review the application to confirm that
a) the certification body has the capability to deliver the requested certification,
b) the certification body is aware of and can, within reason, accommodate any special needs of applicants, such as language and/or disabilities, and
c) the applicant has the required education, experience and training specified by the scheme.

Clause 6.2.1

a) Identify what documents are required from candidates, how applications are reviewed, and how documentation submitted and statements made by applicants are verified.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Provide documentation of your policy and procedures for determining and providing accommodations for candidates who indicate that they have special needs.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) How does the certification body address language issues indicated by applicants? (This includes exams given in foreign languages as well as disability-related language issues.)

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

d) What are the qualifications of the individuals who review applications? How is the performance of their functions monitored, evaluated, and corrected if needed?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.2.2 The certification body shall examine competence, based on the requirements of the scheme, by written, oral, practical, observational or other means.

Clause 6.2.2

a) Describe how relevant knowledge, skills, and abilities are examined in the certification process.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe studies performed to ensure that all appropriate competence criteria are objectively and systematically evaluated?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.2.3 Examinations shall be planned and structured in a manner which ensures that all scheme requirements are objectively and systematically verified, with sufficient documented evidence produced to confirm the competence of the candidate.

Clause 6.2.3

a) What method(s) is(are) used to evaluate specific knowledge, skills, and abilities?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) For each scheme, provide a rationale for specific assessment mechanism(s) used.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.2.4 The certification body shall adopt reporting procedures that ensure the performance and results of the evaluation are documented in an appropriate and comprehensible manner, including the performance and results of examinations.

Clause 6.2.4

Describe how examination results are recorded.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe how examination results are reported and maintained.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe any regulations or requirements for reporting results outside your organization, how you comply with them, and how you maintain confidentiality of individual results in accordance with your policies.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.3 Decision on certification

6.3.1 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. Those who make the certification decision shall not have participated in the examination or training of the candidate.

Clause 6.3.1

a) Describe the process by which certification decisions are reached.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) What body makes the decision on certification?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

c) Describe the policies and procedures in place to prevent an error regarding the decision of certification of a candidate.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.3.2 The certification body shall provide a certificate to all certified persons. The certification body shall maintain sole ownership of the certificates. The certificate may take the form of a letter, card or other medium, signed or authorized by a responsible officer of the certification body.

Clause 6.3.2 (*See Clause 6.3.3 for requirements*)

Provide a model of the certificate, letter, card, or other medium issued to all successful candidates notifying them of their certification.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Describe how your certification body protects the integrity of its certification from unauthorized use.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.3.3 These certificates shall contain, as a minimum, the following information:
a) the name of the certified person and a unique certification number;
b) the name of the certification body;
c) a reference to the competence standard or other relevant documents, including issue, on which the certification is based;
d) the scope of the certification, including validity conditions and limitations;
e) the effective date of certification and date of expiry.

Clause 6.3.3 (See 6.3.2)

6.4 Surveillance and recertification procedure

6.4.1 The certification body shall define a pro-active surveillance process to monitor certificants' compliance with relevant provisions of the certification scheme.

Clause 6.4.1

a) Describe the surveillance methods used to monitor certificate holders.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) How is it determined that certificate holders are compliant with current certification requirements?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.4.2 The certification body shall have procedures and conditions for the maintenance of certification in accordance with the certification scheme. These conditions, including the frequency and content of surveillance activities, shall be endorsed by the scheme committee. The conditions shall be adequate to ensure that there is impartial evaluation to confirm the continuing competence of the certified person.

Clause 6.4.2

a) How often does the committee charged with surveillance review their procedures?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) What surveillance techniques are used to ensure impartiality in the evaluation of certified persons?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.5 Recertification

6.5.1 The certification body shall define recertification requirements according to the competence standard and other relevant documents, to ensure that the certified person continues to comply with the current certification requirements.

6.5.2 The certification body shall have procedures and conditions for the maintenance of certification in accordance with the certification scheme. These conditions, including the frequency and content of recertification activities, shall be endorsed by the scheme committee. The conditions shall be adequate to ensure that there is impartial evaluation to confirm the continuing competence of the certified person.

Clauses 6.5.1 and 6.5.2

a) Describe recertification requirements.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) Describe the recertification program and how it is implemented. Include documentation of how there is impartial evaluation to confirm the continuing competence of the certificant.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.6 Use of certificates and logos/marks

6.6.1 A certification body that provides a certification mark or logo shall document the conditions for use and shall appropriately manage the rights for usage and representation.

Clause 6.6.1

a) Describe the use of the certification mark. Attach the certification mark and describe its use.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

b) How is the certification mark protected from misuse?

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.6.2 The certification body shall require that a certified person sign an agreement
a) to comply with the relevant provisions of the certification scheme,
b) to make claims regarding certification only with respect to the scope for which certification has been granted,
c) not to use the certification in such a manner as to bring the certification body into disrepute, and not to make any statement regarding the certification which the certification body may consider misleading or unauthorized,
d) to discontinue the use of all claims to certification that contains any reference to the certification body or certification upon suspension or withdrawal of certification, and to return any certificates issued by the certification body, and
e) not to use the certificate in a misleading manner.

Clause 6.6.2

a) Provide a copy of the agreement that includes all of the elements in clause 6.5.2.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

6.6.3 Inappropriate references to the certification or misleading use of certificates and marks or logos in publications, catalogues, etc. shall be addressed with corrective measures, such as the suspension or withdrawal of certification, publication of the infraction and, if appropriate, additional legal action.

Clause 6.6.3

Describe how any inappropriate references to certification and its corresponding marks have been addressed.

Name of supporting Document:
Attachment numbers(s):
Page/paragraph:

Annex A: Personnel Certification Accreditation — Application Milestones

Application	**Date**
___Received application materials	_____
___Reviewed materials, if necessary send questions to ANSI	_____
___Sent in application and fee	_____
___Received acknowledgement from ANSI	_____
Ten-day review period begins.	
___Received assessor names	_____
___Sent back response card accepting/declining assessor(s)	_____
Once assessors are approved by organization, they will conduct a paper review of application.	
___Quality evaluations complete	_____
___Information requested, (90) days to resubmit without further fees	_____
___90 day deadline	_____
___Audit plan determined by assessors, sent to organization for approval and discussion.	_____
___Audit plan accepted.	_____

On-site Audit

___Assessors arrive	_____
___Audit conducted	_____
___Oral and summary report received	_____
___Written report received	_____

Non-conforming item(s)

___Plan drawn up with assessors for correction	_____
___Corrective actions approved	_____
___All non-conformities corrective actions approved	_____
___Corrective actions taken and sent in for review	_____
___Acknowledgment received	_____
___Non-conformities accepted as corrected	_____

OR

___Further corrective action required _____

___Accreditation awarded _____

Annex B: List of possible documents to assist you in filling out application materials

1. Accommodations Policy & Procedures
2. Annual Report
3. Audits
4. Board Minutes
5. Bylaws
6. Candidate Handbook
7. Certification Handbook
8. Committee Minutes
9. Confidentiality Agreements
10. Contracts
11. Disclaimer Statement
12. Ethics Policy
13. Financial Statements and Audits
14. Insurance
15. Job Descriptions
16. Job/practice Analysis
17. Management Manual
18. Mission Statement
19. Personnel

Attachment C: Declaration Statement

Applicant agrees to meet the following conditions:

1. Applicant shall provide ANSI with all information requested for the process of assessing competency of a personnel certification body;
2. Applicant agrees to pay all fees charged for assessment of competence; including all subsequent fees once competence is recognized;
3. Applicant is familiar with the requirements for assessment of competency for personnel certification bodies;
4. The certification body can demonstrate it:
   - Is an independent third-party as a certifier of services provided to individuals;
   - Is a legal entity or part of a legal entity; and
   - Has a clearly defined scope of certification.

ANSI requires each applicant to adhere to the following:

a) make all necessary arrangements for the conduct of assessments, including provisions for examining documentation, and access to records (including internal assessment reports) and personnel for the purpose of surveillance, re-assessment and resolution of complaints;
b) make claims only regarding activities defined in the scope of the accreditation granted;
c) not use the accreditation in such a manner as to bring the Personnel Certification Accreditation Program into disrepute and not make any statement regarding the accreditation which Personnel Certification Accreditation Program may consider misleading or unauthorized;
d) upon withdrawal of the Personnel Certification Accreditation Program accreditation, discontinue use of all advertising material which references the Personnel Certification Accreditation Program accreditation and return all accreditation documents including the certificate to ANSI;
e) not allow the Personnel Certification Accreditation Program accreditation to imply that a person's competencies are approved by the Personnel Certification Accreditation Program;
f) ensure that no Personnel Certification Accreditation Program document, logo, or report nor any part thereof is used in a misleading manner; and
g) comply with Personnel Certification Accreditation Program requirements when referencing the status of Personnel Certification Accreditation Program accreditation in communication media such as documents, brochures, or advertising.

I accept the conditions aforementioned and attach said completed application for accreditation review by the American National Standards Institute.

Please sign below.

_____	_____	_____
Name	Approving Authority Title	Date

Attachment D: Terms and Definitions

Certification Scheme: Certification scheme (body of knowledge) relating to a specific certification of an occupation, specialty, role, or skill.

Certification System: Management system for carrying out certification process.

Examiner: An individual who actually evaluates a candidate or the candidate's performance or product (not a proctor.)

Internal Audit: An evaluation conducted by an individual within the organization.

Surveillance: Surveillance is a process by which certificants are monitored to determine whether the certification body should initiate any action to suspend or revoke the certification.

Acronyms

ANSI American National Standards Institute

ISO International Organization for Standardization

IEC International Electrotechnical Commission

ANSI/ISO/IEC 17024:2003, General requirements for bodies operating certification of persons. This international standard specifies requirements which ensure that certification bodies operating certification schemes for persons operate in a consistent, comparable, and reliable manner.[1]

PCAC Personnel Certification Accreditation Committee

[1] ANSI/ISO/IEC 17024, page v

ANSI
American National Standards Institute

January 24, 2012

To Whom It May Concern:

I have been requested by Dr. Cynthia Woodley to make a statement about the comparability of the Conference for Food Protection: Standards for Accreditation of Food Protection Manager Certification Programs and ANSI/ISO/IEC 17024 Conformity Assessment – General requirements for bodies operating certification of persons.

As the purveyor of accreditation service for both standards, our professional staff believe the Standards are similar and ANSI/ISO/IEC 17024 is equal or higher than the CFP Standards for Accreditation of Food Protection Manager Certification Program.

Lane Hallenbeck
Vice President
Accreditation Services

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Introduction

ISO/IEC 17024 has been drawn up with the objective of achieving and promoting a globally accepted benchmark for organizations operating certification of persons. Certification of persons is one means of providing assurance that the certified person meets the requirements of the certification scheme. Confidence in the respective certification schemes is achieved by means of a globally accepted process of assessment, subsequent surveillance and periodic re-assessments of the competence of certified persons.

However, it is necessary to distinguish between situations where certification schemes for persons are justified and situations where other forms of qualification are more appropriate. The development of new certification schemes for persons, in response to the ever increasing velocity of technological innovation and growing specialization of personnel, may compensate for variations in education and training and thus facilitate the global job market. Alternatives to certification may still be necessary in positions where public services, official or governmental operations are concerned.

In contrast to other types of conformity assessment bodies, such as management system certification/ registration bodies, one of the characteristic functions of the personnel certification body is to conduct an examination, which uses objective criteria for competence and scoring. While it is recognized that such an examination, if well planned and structured by the certification body, can substantially serve to ensure impartiality of operations and reduce the risk of a conflict of interest, alternative requirements have been included in ISO/IEC 17024.

In either case, ISO/IEC should be the basis for the recognition of the certification bodies and their certification schemes, in order to facilitate their acceptance at the national and international levels. Only the harmonization of the system for developing and maintaining certification schemes for persons can establish the environment for mutual recognition and the global exchange of personnel.

ISO/IEC 17024 specifies requirements which ensure that certification bodies operating certification schemes for persons operate in a consistent, comparable and reliable manner. The requirements in this International Standard are to be considered as general requirements for bodies operating certification schemes for persons and therefore may have to be supplemented in response to additional demonstrated market need/desire (i.e. improvement of the profession) or specific government requirements (i.e. protection of the public).

Conference for Food Protection
2012 Issue Form

Internal Number: 022
Issue: 2012 II-032

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

All information above the line is for conference use only.

Title:
Inspection Form Scoring Committee

Issue you would like the Conference to consider:
This Issue is submitted on behalf of the Conference so that Council II may deliberate and recommend what action(s) to take with respect to the Inspection Form Scoring Committee. The Committee submitted a draft committee report (see attached) to the Council II Chair but did not submit a final report or Issues for the 2012 Biennial Meeting.

Public Health Significance:
The Inspection Form Scoring Committee has worked for several years to develop a uniform system for the evaluation of food establishments with respect to food safety. Such a system would be of benefit to the retail food industry, regulators, and consumers for risk communication and risk management.

Recommended Solution: The Conference recommends...:
that the attached Inspection Form Scoring Committee report be acknowledged and the Committee members be thanked for their work.
The Conference also recommends that the Council II debate the future of the Inspection Form Scoring Committee and determine whether this committee is to be:
a) disbanded (as recommended in the attached report), or
b) re-created for the next biennium with specified new charges or with contination charges from the 2010 Biennial Meeting, and with a requirement to report back to the 2014 CFP Biennial Meeting.
Respectfully, a "no action" or "accept as submitted" recommendation are not valid options for this Issue.

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Attachments:

- "Inspection Form Scoring Committee Final Report"
- "Content Attachment #1"
- "Supporting Attachment 1"
- "Inspection Form Scoring Committee Roster final"

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Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: Inspection Form Scoring Committee

COUNCIL (I, II, or III): II

DATE OF REPORT: 12/15/2011

SUBMITTED BY: Bill Flynn, Margaret Binkley

COMMITTEE CHARGE(s):

The CFP recommends that a committee be formed and charged with the following:

- Conduct academic research to:
    - Investigate and determine the most effective Foodservice Establishment scoring system that is based on the current identified risk factors and interventions identified in the FDA Food Code for use with the current FDA Food Establishment Inspection Form.
    - Determine the most effective way to communicate the Food Establishment Inspection scores to the public so they have access to the information in advance of choosing where to dine and purchase food items.
- Work with academic researchers to identify funding sources to conduct their research and provide a letter of support for funding identified.
- Report the committee's finding back to the conference at the 2012 Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Initial interest in the 2010-2012 Inspection Form Scoring Committee was relatively high, with 30+ people volunteering to participate in the committee processes. An initial questionnaire was sent to all participants to gather answers to various assumptions developed from past Committees that related to the Charge. Comments were requested as well as other information that was felt the Committee should pursue. Initial questions/concerns formed by the Committee were:

- Is our objective as the Committee to reduce foodborne illness? Increase restaurant compliance? Or getting the word out to the public?
- Can the knowledge of scores allow for the public to make better decisions about restaurant selection or reduce food-borne illness? Or both?

Survey results included an over-whelming majority who agreed that a form that is intuitive to both the public and inspector is the most important charge of the committee.

There were six assumptions given where the Committee was asked to rate the need to address this assumption. These assumptions were:

1) "The health jurisdictions program includes inspector and industry training"-There was an overwhelming support of this assumption with 88% agreeing this was needed. Comments were: "Standardization is critical to the success of any inspection/grading

program" and "Standardization for health jurisdictions-the inspection staff must be trained on CDC risk factors so grades will be consistent, accurate, and meaningful.

2) "The scoring system is easy for the health inspector, the public and industry to understand"- there was a 100% support that this assumption was needed. Comments included: "There should be standardization of scoring/grading systems. Few of the systems are "apples to apples" so this is hard for industry and the general public to understand the differences" and "Must be risk-based and supported by science".

3) "The inspector's performance is standardized on an ongoing basis"-Again, 88% felt this was needed. Comments included "Standardization of the program and scoring would go a long way in standardizing an inspector's performance".

4) "The jurisdiction is using a risk-based food code that requires effective control of CDC risk factors"-Over 80% of the committee felt this was needed. Comments were "YES!" and "Systems that result in low scores because floors, walls, and ceilings aren't clean don't provide the best help to citizens looking for a safe place to dine".

5) "The health department regularly evaluates their inspection program results using a consistent and effective methodology"-Here 75% felt that this assumption was somewhat needed. Comments included "Not unimportant, but not as critical once a good system is in place. It is more critical to ensure consistency among staff at that point".

6) "The public receives the sanitation scores in a way that allows them to make informed decisions about where they would like to eat"-75% felt this was needed. Comments included "Public education on what a grade/score represents is an important component of a successful program" and "Message must emphasize and include that some minimum level/score of food establishment means it's safe for consumers".

It was felt that to be able to address the charge, it would be valuable to divide the group into three teams and assign specific duties to each. The teams decided on were:

1. Information Gathers

- Gather form and scoring examples from local health department jurisdictions.
- Identify commonalities to keep the number of systems measured minimal.
- Obtain local jurisdictions/state surveys and gather information from the public to clarify the understanding of the system.

2. Practitioner

- Conduct health department-like, non-regulatory inspections using different forms to determine if it works for inspectors.
- Determine if inspectors find this easy to use in real life inspection scenarios.

3. Results Team

- Academia will take information; provide its meaningfulness and conclusions.
- Provide adequate scientific literature regarding public and inspector sentiment and understanding of current scoring methods.

Charge 1

Although information was gathered from 500 health inspection reports from 75 jurisdictions across the country, the data was not able to be analyzed prior to the processing of this report. If the committee is to continue, the data can be used for processing at that time. In the process of gathering the data, it was found that many health departments were against any type of scoring method. Some of the auditors that participated in the study asked to no longer participate because their departments don't believe in scoring. They believe the message of food safety and training is most impactful when scores are not involved.

A number of studies have been conducted relating to the posting of health inspection scores by a variety of methods and the public's perception of these scores. (See Supporting Attachment #1.)

Although there have been many studies completed on health inspection scores from various angles, there is still more research that could be conducted to answer the charge of this Committee. Some of the problems with present research is the fact that there are many different scoring methods used by city/county/state inspectors including: a percentage out of 100; a letter grade of A,B,C; pass/fail; or a color-coded sign posted in the window of a restaurant. Until some type of standardization can be developed to make comparisons between all of the scoring systems, no concise results can be reported. It has been found by the Committee that problems also lie in the fact that retail establishments (grocery stores) unlike restaurants tend to have many separate departments that receive multiple scores and can score poorly in some areas which would not represent the "true" score of the grocery store. It was also found that many health department s were against any type of scoring method. Other comments were:

1. Believe the inspection form speaks for itself. Grading systems of any kind are going to result in an over simplification of a complex set of data.
2. The best way to judge a location is review the full inspection report.
3. Grades in most areas turn into a self-enforcement tool, which is fine if this is what is wanted.

Charge 2

In 2010 our original researcher from Loma Linda University withdrew their committed resources due to a downturn in the economy. Subsequent interviews with potential researchers from University of Minnesota School of Public Health, Kansas State University, and North Carolina State University determined that the committee charge was broad enough that it would be advantageous for multiple researchers to work together.

The original goal of developing a grant application for the National Institute of Food and Agriculture (NIFA) Integrated Research, Education, and Extension Competitive Grants Program – National Integrated Food Safety Initiative was abandoned due to researcher turnover in 2011. Instead of the grant the committee sourced volunteer research from Dr. Barbara Almanza from Purdue, Dr. Margaret Binkley from Ohio State University, and private industry consultants. The outcomes have been promising. (See Content Attachment #1.)

REQUESTED ACTION:

The Inspection Form Scoring Committee believes that the continuation of this Committee may not be to the benefit of the Conference for Food Protection.

The Inspection Form Scoring committee recommends the conference:

- Issue 1 – Acknowledge the work by members of the committees and thank the members for their time trying to meet the committee charge.
- Issue 2 – Disband the committee - the charge was determined to be too broad; there is no effective way to show that a Foodservice Establishment scoring system can assist the public in making an informed decision on where to eat without adequate funding.

CONTENT ATTACHMENT #1

Draft CFP Scoring Committee Study Plan

I. Scoring Committee Working Assumptions: Scoring can have a positive impact on public health by reducing the risk factors associated with foodborne disease if:
   - The committee can raise approximately $75,000 in resources to modify a web-based database.
   - The health jurisdictions program includes inspector and industry training.
   - The scoring system is easy for the health inspector, the public and regulated industry to understand.
   - The inspector's performance is standardized on an ongoing basis.
   - The jurisdiction is using a risk based food code that required effective control of CDC risk factors.
   - The health department regularly evaluates their inspection program results using a consistent and effective methodology.
   - The public receives the health inspection report scores in a way that allows them to make an informed decision about where they would like to eat.
   - Restaurants, grocery stores, institutional kitchens, etc. need to be evaluated differently.

II. Information Gatherers Objectives:
   - Collect inspection reports of jurisdictions that score inspection reports from random health jurisdictions using public disclosure systems or freedom of information act.
   - Organize a list of conveniently accessed health jurisdiction reports.
   - Organize health department scoring systems based on the size of a jurisdiction.
   - Source a web-based database to house health inspection data and scoring normalization.

III. Practitioners Objectives:
   - Utilizing actual health jurisdiction forms, conduct standardized inspections using the five most common health jurisdiction scoring formats.
   - Using the latest version of CFP inspection report form, conduct standardized inspections using a normalized scoring technique based on percent of 100.

IV. Researcher Objectives:
   - Conduct literature review/ research to identify communication techniques that consumers, regulators, and the industry can mutually understand.
   - Develop consumer and industry survey instruments and work with CSPI and NRA on conducting surveys to targeted populations.
   - Analyze the results of the survey instrument and write a research paper with findings, recommendations, and conclusions.

V. Scoring Committee Accomplishments:
   - A web-based database has been created to gather, report, and analyze the committee's information. The cost was absorbed through private donations, fundraisers, and volunteer programmers from graduate students.
   - 75 unique health jurisdiction forms have been gathered for analysis.
   - A list of conveniently accessed health jurisdiction reports has been organized on the database.

- The list of health department scoring systems organized by the size of a jurisdiction is 75% complete.
- The database has been program to normalize scores on percent of 100 as test. Once researchers determine the most successful method of reporting scores, that system will be utilized to normalize health jurisdiction scores.
- Approximately 100 standardized inspections have been gathered ready to compare the scoring results of 5 different health jurisdiction inspections forms.

VI. Scoring Committee Challenges:

- Creating and programming the database consumed many hours and most of the committee resources.
- Information gathering, in a non-web based environment, allowed for inefficiencies when gathering the results from random locations across the country.
- Gathering the information while maintaining anonymity for the subject restaurants, could compromise the ability to report results.

SUPPORTING ATTACHMENT #1

References of studies that have been conducted relating to the posting of health inspection scores by a variety of methods and the public's perception of these scores.

- Worsford (2005). This study examined the public's perceptions of hygiene standards in eating places and their interest in having consumer information on the premises. They found that people who eat out regularly claimed that the standard of food hygiene of food premises was important to them when deciding where to dine. Consumers believed they have the right to know the results of a hygiene inspection and most would some type of reliable system so they may better judge hygiene standards of restaurants. About half of the respondents felt it was somewhat difficult for them to find needed information on inspection standards.

Respondents preferred the use of "stars" so they could better judge hygiene standards

- Simon et al (2005). This study examined the impact on grading cards on foodborne illness hospitalizations in Los Angeles County. The grading system was introduced in January 1998. After data were adjusted, it was found that restaurant hygiene grading program was associated with a 13.1 percent decrease in the number of foodborne-disease hospitalizations in Los Angeles County and was sustained over the next two years (1999–2000). It was felt that the posting of these hygiene grading cards was an effective intervention for reducing the number of foodborne diseases.
- Almanza et al (2002). This study examined the debate concerning the fact if publishing the results of health inspections in the media would influence the public's decision to dine out in specific restaurants. Health inspection scores were examined and analyzed both before and after the publication of restaurants scores. The results showed that overall, inspection scores increased and the number of consumer complaints decreased.
- Choi et al (2011). This study examined the impact of inspection score information on consumer behavior by asking consumers to decide on the selection of restaurants based on health inspection scores. The study found that the more violations a restaurant had, the more likely the consumer decided to select another restaurant to dine.
- Henson et al (2006).This paper explores the ways in which consumers assess the safety of food in restaurants. The study examined how consumers base their assessment of food safety in restaurants using a range of visible. Restaurant health inspection reports were one of the assessments that were used and found to vary among the group of consumers.
- Boehnke (2000). This study used a worldwide survey, that the US was the only country that had a disclosure systems or posted letter grade systems to make public the inspection status of the restaurant. They found the systems of disclosure and letter grading varied greatly and included the use of websites to make public restaurant inspection information.

They also found that the information and purposes of the websites ranged widely from being disciplinary to being supportive with both the industry and the public as users.

- Thompson (2005). This study examined, among other items, the levels of standardization in the inspection activities in the city of Toronto as well as information. What was found was that inspections are being conducted in a more consistent manner across the city and the owners feel that the inspectors tend to be fair and impartial. They also feel that disclosure of inspection results have the opportunity to offer an incentive to the operators to comply better with the regulations.
- Dundes (2001). This study examined how college students and health professionals interpreted health inspection scores. The sample was asked how they interpreted either a score (a percentage

was used) or a sign (a letter grade) that represented the results of a health inspection. It was found that the public does not have a clear understanding of the meaning of posted health inspection scores.

- Jones et al (2008).This study specifically examined the public knowledge and attitudes regarding public health inspections of restaurants. Respondents were asked how many times a year restaurants were inspected and more than half felt it should be 12 times. The study found there were many areas of misunderstanding by the public in regards to restaurant inspections.

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Committee Name:

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Committee Name:

Conference for Food Protection
2012 Issue Form

Internal Number: 044
Issue: 2012 II-033

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

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Title:
Electronic Reporting for Health Inspections

Issue you would like the Conference to consider:
The issue of electronic reporting for health inspections has been a topic at several meetings of the Conference for Food Protection. It is clear that the increased availability and visibility to health inspection results helps foodservice establishment management and regulators work together to ensure food safety. We urge that substantive progress be made toward this objective.

In 2010, the CFP Electronic Reporting Committee (Issue 2010 II-007) submitted the following statement that was adopted by the Conference:

"The Conference recommends that the Conference Chair write a letter to the Food and Drug Administration (FDA) requesting that they develop a database management tool that will enable the analysis of future baseline survey data collected by regulatory agencies to assess and enhance the effectiveness of food safety programs and report back to the Conference for Food Protection."

We urge that FDA develop a database management tool that will enable the entry and analysis of inspection results, and allow access by establishment owners and operators in order to enhance the effectiveness of food safety programs.

Public Health Significance:
It is important that there be visibility to the results of food safety efforts at retail food establishments. The ability to access health inspection information will support clarity in application of health code regulations and in compliance activities. The result is improved food safety performance for the consumer and better protection of the public health.

Recommended Solution: The Conference recommends...:
a letter be sent to FDA requesting that FDA develop a database management tool that will enable the entry and analysis of inspection results, and allow access by establishment owners and operators in order to enhance the effectiveness of food safety programs.

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Conference for Food Protection
2012 Issue Form

Internal Number: 094
Issue: 2012 II-034

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

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Title:
Harmonized Food Code and Electronic Reporting for Health Inspections

Issue you would like the Conference to consider:
The National Council of Chain Restaurants includes 32 chain restaurant companies with representation throughout the United States. Current health inspections use a variety of formats, scoring methods, and electronic or paper recording of inspection reports, depending on jurisdiction. This variety leads to inconsistency in inspections making comparison of restaurant performance problematic across national chains. Harmonization and electronic reporting in a single report format would create searchable and downloadable databases for use in improving restaurant performance and enhancing the effectiveness of food-safety programs.
Universal adoption of the FDA Food Code in its entirety by state and local health departments would greatly facilitate the harmonization of uniform inspection tools and compliance reporting throughout the United States. Varying Food Code regulations hamper chain restaurants from developing consistent training materials, performance metrics, and corrective actions to health report violations. This makes regulatory compliance for national chains complex, time-consuming, and resource intensive. It also results in varying programs of food-safety protection. We acknowledge that a stated goal of FDA's Retail Food Safety Initiative is the universal adoption of the Food Code and we support FDA, state and local health authorities in achieving this goal.

Public Health Significance:
A harmonized approach to Health Inspection data collection, warehousing and availability would do the following:

- Allow uniformity on the application and reporting of health-code regulations and compliance activities across the US.
- Facilitate corporate/business owner awareness of inspection results, engaging restaurant leadership in the remediation of critical violations, inspection failures, and any other urgent inspection outcomes.
- Allow industry to perform ongoing analytics of violation trends across federal, state and local jurisdictions so that resources can be better allocated to reduce targeted violations, improve public health, and manage poor-performing restaurants.

- Facilitate cross agency/jurisdictional data sharing for state and national benchmarking studies and become a data resource for academia, industry, consumers, and the media.

Recommended Solution: The Conference recommends...:
That a letter be sent to FDA recommending:

- The FDA develop an electronic database for state and local health inspection reports that uses consistent violation categories/types and scoring methodology for health inspection reporting.
- That this database should be accessible by corporate/business owners, consumers, reporters, and academia for the purpose of better compliance reporting and data analysis to improve public health protection and better manage restaurant performance.

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Conference for Food Protection
2012 Issue Form

Internal Number: 088
Issue: 2012 II-035

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

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Title:
Standardized Data Collection and Electronic Reporting of Inspections

Issue you would like the Conference to consider:
Current health department food establishment inspection forms use a variety of formats, scoring approaches and records that can be stored electronically or on paper. Food establishment inspection data would be most effective if collected and stored in a standardized format that is readable and searchable across multiple technology platforms. Standardized data collection formats could help reduce a significant barrier to sharing of inspection data.

Public Health Significance:
A standardized approach to Inspection data collection, warehousing, and access could:

- Facilitate cross agency/jurisdictional data sharing for state and national Baseline (Risk Factor) Studies, and be a data resource for academia and industry partners.
- Allow the development of third party web and mobile applications which can provide controlled access of inspection results to consumers, regulators, industry and media.
- Allow corporate/business owner awareness of inspection results and trends, engaging food establishment management in the remediation of critical violations, repeat violations, inspection failure, and any other urgent inspection outcomes.
- Allow industry to perform ongoing analytics of inspection findings so that resources can be optimally allocated to reduce violations, better manage poor performing food establishments, and improve public health.
- Reduce time and resources needed by regulatory agencies to comply with inspection data requests from media, consumers and others.

Recommended Solution: The Conference recommends...:
that a committee be created to study how health department inspection data can be collected more uniformly through the use of standardized formats to enhance public health. Utilizing Food Code Annex 7, Form 3-A (Food Establishment Inspection Form) and Guide 3-B (Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices) as the starting point, the committee is charged to consider:

- Uniform violation categories / types, by utilizing the FDA inspection form,

- Consistent scoring methodology, and
- Development of a centralized electronic database with controlled access.

The committee will report on its findings, along with implementation recommendations at the 2014 CFP Biennial Meeting.

These activities should be undertaken with the intent of eventually creating a national database to warehouse inspection data from contributing states, local jurisdictions and other sources.

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Conference for Food Protection
2012 Issue Form

Internal Number: 003
Issue: 2012 II-036

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

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Title:
Risk-Based Inspection Form-Marking

Issue you would like the Conference to consider:
REMOVE THE RESTRICTION FROM THE AUDIT MANUAL THAT THE FORM NOT BE PRE-POPULATED WITH ITEMS MARKED "IN"

Public Health Significance:
THE RECOMMENDED RISK-BASED INSPECTION FORM CONTAINS "IN/ OUT / NA / AND NO" CATEGORIES FOR 54 GROUPS OF VIOLATIONS. USE OF THIS FORM IS NECESSARY TO MEET AT LEAST 3 SEPARATE Retail Food Regulatory Program STANDARDS. REQUIRING EACH OF THE 54 GROUPS TO EACH BE MARKED EVERY INSPECTION IS REQUIRED TO ELIMINATE ALLEGED POTENTIAL BIAS THAT MAY BE PRESENT IF THE FORM IS PRE-POPULATED WITH ITEMS MARKED "IN".
REASONS THIS REQUIREMENT SHOULD BE ELIMINATED INCLUDE:

- THERE IS NO STATISTICALLY VALID RESEARCH THAT SHOWS SUCH BIAS WOULD OCCUR. FORCING INDIVIDUALS TO ROUTINELY MARK 50+ ITEMS ON A FORM EACH INSPECTION WOULD JUST AS LIKELY PROMOTE "DRY LAB" BEHAVIOR TO JUST GET THROUGH THE FORM AND INCREASE GENERAL HUMAN ERROR. LETTING PROFESSIONALS JUST MARK THE ITEMS THAT HAVE MEANING FOR THAT INSPECTION (OUT,NA/NO) WOULD BE FAR MORE MEANINGFUL.
- THE CONSISTENT APPROACH OF CFP HAS BEEN TO STATE OUTCOMES, NOT TO PRESCRIBE SPECIFIC SOLUTIONS. THIS ALLOWS INDUSTRY TO USE AN IMPLEMENTATION SYSTEM THAT MEETS THEIR NEEDS AND FLEX THAT SYSTEM TO UTILIZE CURRENT TECHNOLOGY AND TRAINING METHODS. THAT SAME PHILOSOPHY SHOULD BE USED FOR THE REGULATORY AGENCIES. QUALITY CONTROL SYSTEM SPECIFICS OVER THE INSPECTION WRITING PROCESS SHOULD BE DETERMINED BY EACH AGENCY. FOR EXAMPLE, WITH THE INSPECTION FORM, QUALITY CONTROL CAN BE MAINTAINED THROUGH INITIAL AND ONGOING TRAINING WITH A STANDARDIZED TRAINER, SUPERVISORY REVIEW, REPORTS OF MARKING PATTERNS USED BY STAFF IF THE FORM IS MAINTAINED IN AN ELECTRONIC DATABASE, ETC.

- RESOURCE STRAPPED STATE AND LOCAL AGENCIES CANNOT AFFORD THE EXTRA TIME NEEDED TO ROUTINELY MARK "IN" ON A FORM OVER 50 TIMES PER INSPECTION. FOR EXAMPLE AT AN EXTRA 5 MINUTES PER INSPECTION TO MARK EACH OF THE ITEMS "IN", USE OF THIS FORM STATEWIDE IN MICHIGAN WOULD CAUSE A 5.4 FTE STAFF REDUCTION IN TIME (101,682 INSPECTIONS X 5 MINUTES= 508,410 MINUTES/60=8474 HOURS/1550 HOURS/FTE=5.4 FTE'S). THIS REPRESENTS A 2.2% REDUCTION IN STAFFING STATEWIDE.
- INFLEXIBLE, COMMAND AND CONTROL REQUIREMENTS SUCH AS THIS WILL BE A DETERRENT TO AGENCIES ENROLLING AND OR WORKING TO PROGRESS TO MEET THE STANDARDS.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting removal of the Audit Manual restriction that the risk-based retail inspections form fields not be pre-populated as "in."

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Attachments:
- "Michigan's form-fillable retail risk-based form"

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FI-237 (Rev 7-09)

Michigan Food Establishment Evaluation Report

Page _____ of _____

Agency Name	Agency Address

Establishment Name	Address	City	License #

Person in Charge	Inspection Type	Risk Category
	Routine	X

FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS

Check (√) designated compliance status (IN, OUT, NO, NA) for each numbered item

IN=in compliance **OUT**=not in compliance **NO**=not observed **NA**=not applicable

Mark "X" in appropriate box for COS and/or R

COS=corrected on-site during inspection **R**=repeat violation

Compliance Status						COS	R
	IN	OUT	NA	NO			
Demonstration of Knowledge							
1	✔				Person in charge present, demonstrates knowledge, and performs duties		
Employee Health							
2	✔				Management awareness; policy present		
3	✔				Proper use of reporting, restriction & exclusion		
Good Hygienic Practices							
4	✔				Proper eating, tasting, drinking, or tobacco use		
5	✔				No discharge from eyes, nose, and mouth		
Preventing Contamination by Hands							
6	✔				Hands clean & properly washed		
7	✔				No bare hand contact with RTE foods or approved alternate method properly followed		
8	✔				Adequate handwashing facilities supplied & accessible		
Approved Source							
9	✔				Food obtained from approved source		
10	✔				Food received at proper temperature		
11	✔				Food in good condition, safe, & unadulterated		
12	✔				Required records available: shellstock tags, parasite destruction		
Protection from Contamination							
13	✔				Food separated & protected		
14	✔				Food-contact surfaces: cleaned & sanitized		
15	✔				Proper disposition of returned, previously served, reconditioned, & unsafe food		

Compliance Status						COS	R
	IN	OUT	NA	NO			
Potentially Hazardous Food Time/Temperature							
16	✔				Proper cooking time & temperatures		
17	✔				Proper reheating procedures for hot holding		
18	✔				Proper cooling time & temperatures		
19	✔				Proper hot holding temperatures		
20	✔				Proper cold holding temperatures		
21	✔				Proper date marking & disposition		
22	✔				Time as a public health control: procedures & record		
Consumer Advisory							
23	✔				Consumer advisory provided for raw or undercooked foods		
Highly Susceptible Populations							
24	✔				Pasteurized foods used; prohibited foods not offered		
Chemical							
25	✔				Food additives: approved & properly used		
26	✔				Toxic substances properly identified, stored, & used		
Conformance with Approved Procedures							
27	✔				Compliance with variance, specialized process, & HACCP plan		

Risk factors are improper practices or procedures identified as the most common contributing factors of foodborne illness or injury. Public Health Interventions are control measures to prevent foodborne illness or injury.

GOOD RETAIL PRACTICES

Good Retail Practices are preventative measures to control the addition of pathogens, chemicals, and physical objects into foods.

Compliance Status						COS	R
	IN	OUT	NA	NO			
Safe Food and Water							
28	✔				Pasteurized eggs used where required		
29	✔				Water & ice from approved source		
30	✔				Variance obtained for specialized processing method		
Food Temperature Control							
31	✔				Proper cooling methods used Adequate equipment for temperature control		
32	✔				Plant food properly cooked for hot holding		
33	✔				Approved thawing methods used		
34	✔				Thermometers provided & accurate		
Food Identification							
35	✔				Food properly labeled; original container		
Prevention of Food Contamination							
36	✔				Insects, rodents, animals absent		
37	✔				Contam. prevented during food prep., storage, display		
38	✔				Personal cleanliness		
39	✔				Wiping cloths: properly used & stored		
40	✔				Washing fruits & vegetables		

Compliance Status						COS	R
	IN	OUT	NA	NO			
Proper Use of Utensils							
41	✔				In-use utensils properly stored		
42	✔				Utensils, equip. & linens: stored, dried, handled		
43	✔				Single-use & single-serve articles: stored & used		
44	✔				Gloves properly used		
Utensils, Equipment and Vending							
45	✔				Food & non-food contact surfaces cleanable, properly designed, constructed & used		
46	✔				Warewashing- installed, maintained & used; test strips		
47	✔				Non-food contact surfaces clean		
Physical Facilities							
48	✔				Hot & cold water available, adequate pressure		
49	✔				Plumbing installed; proper backflow devices		
50	✔				Sewage & waste water properly disposed		
51	✔				Toilet facilities: constructed, supplied, clean		
52	✔				Garbage/refuse properly disposed; fac. maintained		
53	✔				Physical facilities installed, maintained & clean		
54	✔				Adeq. ventilation & lighting; designated areas used		

Person in Charge (Signature)	Inspector (Signature)	Date

As required by Act 92, Public Acts of 2000, as amended

Conference for Food Protection
2012 Issue Form

Internal Number: 005
Issue: 2012 II-037

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

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Title:
HACCP Training

Issue you would like the Conference to consider:
The 2009 FDA Food Code allows establishments to obtain variances to the Code and under certain circumstances requires those establishments to submit Hazard Analysis Critical Control Point (HACCP) plans to the regulatory authority.
The preface to the 2009 Code states "Retail processors may be given the same opportunity as federally-regulated establishments to use innovative techniques in the production of safe foods. Retail establishments may apply to the regulatory authority for a variance to use a specific federal food safety performance standard for a product or a process in lieu of compliance with otherwise applicable specifications in the Food Code. However, to show compliance with the federal performance standard, the retail processor must, like a federally inspected establishment, show that processing controls are in place to ensure that the standard is being met. Thus, a request for a variance based on a federal performance standard must be supported by a validated HACCP plan with record-keeping and documented verification being made available to the regulatory authority."
However, in establishments that operate under federally mandated HACCP plans, the regulations that require the HACCP plan also require TRAINING. Retail establishments, operating under the food code, may attempt to submit a HACCP plan as part of a variance application; however, the Food Code contains no specific HACCP training requirement.
The current language in Section 2-102.11 of the Food Code, dealing with the Person in Charge (PIC) being able to demonstrate application of the HACCP principles, simply is not sufficient to prepare an individual to perform a hazard analysis, prepare a HACCP plan, or successfully implement a HACCP program.

Public Health Significance:
The Food Code allows regulatory authorities to grant variances to the Code and then requires the establishment to operate in a HACCP environment. The production of safe food cannot be assured if the operator does not understand the program.
The fact that a variance has been required shows that the process being used has more risk (because it would not be allowed without the special permission of a variance). When the HACCP plan is improperly followed, unsafe food may be the result.

Taking the logical step of requiring the operator to be trained in the food safety system that is being used at the establishment will help mitigate the risk of foodborne illness due to system failure.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the agency to:

- Establish a HACCP Curriculum based on the 7 principles of Hazard Analysis and Critical Control Point principles developed by the National Advisory Committee on Microbiological Criteria for Foods. ***or***
- Designate a national organization to establish the above curriculum, and
- amend the 2009 Food Code (as modified by the Supplement issued in 2011) as follows (new language shown with underline):

Section 2-102.30 Persons engaged in HACCP Plan Development and Application
A person responsible for developing a hazard analysis and HACCP plan and reviewing the HACCP records, must have successfully completed training in the application of HACCP principles.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 070
Issue: 2012 II-038

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

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Title:
Support and Funding for Consumer Participation at the CFP

Issue you would like the Conference to consider:
The Conference for Food Protection plays an integral role in the development of the FDA Food Code. The cooperation and input of various stakeholders - including consumer, industry, and regulatory representatives - is crucial to the development of the Food Code, an important public health guidance document. Currently, consumer participation in the Conference is anemic, in part because of the financial cost of attending the Biennial Meeting. Consumer advocates represent customers at Food Code-regulated establishments and victims of foodborne illness, all of whom have an important stake in the decisions that are made at the Biennial Meeting. It is well-recognized that the input of these stakeholders is crucial to the development of sound public health policy, yet the current makeup of the Biennial Meeting does not reflect that contribution. Financial barriers to consumer participation must be recognized and mitigated. Without adequate consumer participation, both the credibility and the substance of the Food Code suffer.

Public Health Significance:
Consumer organizations can provide critical insight into consumer attitudes, beliefs, and interests, and are active participants in public policy and regulatory matters before federal, state, and local governments, and have made a significant impact in improving food safety.

Recommended Solution: The Conference recommends...:
That the Executive Board of the Conference for Food Protection, consider, approve, and manage a program to provide double-blind participant scholarships (created from industry and regulatory sources) to provide funding for consumer participants at CFP. A subcommittee of the Executive Board should be created to administer scholarships, with an organizing document that places paramount importance on increasing consumer representation to CFP. A minimum number of scholarships should be created for the next Biennial Meeting, with a goal toward increasing consumer participation each cycle. Scholarships should be adequate to cover the cost of transportation to and from the meeting, conference registration fees, lodging, and meals. Consumer representatives should be required to submit relevant 501-C3 status documentation, a statement of the

primary sources of organizational funding, and a mission statement to be eligible for a scholarship.

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Conference for Food Protection
2012 Issue Form

Internal Number: 072
Issue: 2012 III-001

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

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Title:
Report - Hand Hygiene Committee

Issue you would like the Conference to consider:
At the 2010 Conference for Food Protection Biennial Meeting, the Hand Hygiene Committee was formed and charged "to address:

1. the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses,
2. identify settings where alternatives to handwashing are appropriate,
3. recommend studies that should be completed to get research questions answered for when scientific literature is not available, and
4. report back to the 2012 Conference."

The 2010-2012 Hand Hygiene Committee is submitting four issues to the 2012 Conference for Food Protection:

1. Report - Hand Hygiene Committee
2. Disseminate the 2010-2012 Hand Hygiene Committee Report
3. Re-Create - Hand Hygiene Committee
4. Limit Hand Hygiene Committee Size

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.

Recommended Solution: The Conference recommends...:

- acknowledgement of the 2010-12 Hand Hygiene Committee report, and
- thanking the 2010-2012 Hand Hygiene Committee for its work addressing scientific, regulatory and behavioral considerations related to efficacy and risk reduction strategies of alternative hand hygiene regimes compared to handwashing.

The future of the Hand Hygiene Committee is submitted as a separate Issue.

Submitter Information:

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Attachments:

- "2010-12 Hand Hygiene Committee Final Report"
- "Scientific Regulatory and Behavioral Considerations of Hand Hygiene Regimes"
- "2010-12 Hand Hygiene Committee Roster"

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Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: 2010-2012 Hand Hygiene Committee

COUNCIL (I, II, or III): III

DATE OF REPORT: January 23, 2012

SUBMITTED BY: Committee Co-Chairs Katherine MJ Swanson and Mark Sampson

COMMITTEE CHARGE(s):

The Conference recommends that a committee be formed to include appropriate stakeholders including Center for Food Safety and Applied Nutrition (CFSAN), CDC and Center for Drug Evaluation and Research (CDER) to address:

1. the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses,
2. identify settings where alternatives to handwashing are appropriate,
3. recommend studies that should be completed to get research questions answered for when scientific literature is not available [added by the CFP Board]

and report back to the 2012 Conference.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Sub-committee Structure and Approach

Interest in participating in the 2010-2012 Hand Hygiene Committee was very high, with 50+ people volunteering to serve. The Committee, therefore divided into three sub-committees to address the charge. The complexities of the science, behavioral and regulatory considerations involved with hand hygiene products suggested that an educational report for CFP membership could be beneficial to clarify the multiple elements of the subject. The committee, therefore focused its work on creating such a report and each sub-committee addressed specific topics related to the charge.

- Science of hand hygiene – Co-chairs Don Schaffner and Dale Grinsted
  - Identify the hazards associated with hand hygiene-related food safety issues including bacteria, viruses, allergens and others if appropriate
  - Briefly review the pros and cons of methods used to evaluate effectiveness of hand hygiene solutions (*in vivo* versus *in vitro*)
  - Summarize the available science on the efficacy of hand hygiene approaches at removing hazards and reducing risk, including handwashing and other approaches
- Regulatory status of hand hygiene products for food handlers – Co-chairs Mark Sampson and Catherine Adams Hutt
  - Provide a fact-based summary of current regulatory requirements for hand hygiene products, the regulatory jurisdiction and antimicrobial claims that are allowed by the regulatory authority to form a common understanding for the committee and CFP members.
  - Attempts to change existing federal regulatory requirements outside of the Food Code were out of scope.
- Behavioral aspects of hand hygiene – Chair Michele Samarya-Timm
  - Identify compliance issues and behavioral aspects of hand hygiene
  - Identify potential public health benefit of improved hand hygiene compliance using different approaches
  - Address Charge #2 related to settings where alternatives to handwashing may apply

All sub-committees were asked to recommend research to answer unresolved questions. The work products of these groups were combined and reviewed with the full committee to build consensus on this final report to address the charges.

CDER and CFSAN FDA committee consultants requested that the following statement be used to clarify the FDA's involvement with the Committee:

> "FDA supports the Conference for Food Protection (CFP) process; however, there are some instances within this committee (and subcommittees) that discussion on certain topics can lead to a conflict of interest for FDA. When the CFP Hand Hygiene Committee (and its subcommittees) addresses issues relating to efficacy, uses and corresponding efficacy data, methods, standards, effectiveness and what constitutes an acceptable drug applied to human skin (hand antiseptic), FDA CDER and CFSAN can not engage fully in all committee discussions due to a conflict of interest with the regulatory process already in place through FDA CDER."

Executive Summary

Addressing the effectiveness of hand hygiene strategies is a complex issue involving scientific, regulatory and behavioral considerations. In the United States, several vegetative bacterial pathogens or their toxins are associated with foodborne illness outbreaks where inappropriate application of hand hygiene regimens were noted; however, norovirus is by far the pathogen reported most frequently in these outbreaks (CDC 2006). A majority of these reported norovirus-associated foodborne outbreaks also involve food that was handled by ill individuals (CDC 2006). Many of these outbreaks may not have occurred if ill food handlers were effectively excluded from the establishment. Because of the low median infectious dose for norovirus and certain other agents (e.g., Shigella, Hepatitis A), it is questionable whether even effective hand hygiene regimens would be capable of preventing transfer of highly infectious pathogens when food is handled by symptomatic people.

Effectiveness of any hand hygiene regimen involves many factors, including the hand hygiene product type (e.g., soap, hand antiseptic), amount applied, method of application, duration of application and pathogen of concern. Norovirus is more resistant to chemical agents used in hand hygiene products than vegetative bacteria. While bacterial spores are also more resistant than vegetative bacteria, sporeformers of foodborne illness concern must be in their vegetative state and grow in the food to a high level to present a food safety risk. Thus inactivation of spores is not a major concern for hand hygiene in a food handler setting.

Handcare products that make antimicrobial claims are regulated as drugs in the US. Currently there are no antimicrobial hand hygiene products for food handler applications in the US with FDA-approved claims for antiviral effectiveness, thus there is no ready mechanism for an establishment to choose a hand antiseptic product that may be effective against foodborne viral pathogens when used according to label instructions. The antiviral profile of several commercially available products has been assessed in peer-reviewed literature (e.g., Park et al., 2010; Liu et al., 2011), demonstrating that some products can achieve significant reductions.

Behavioral issues related to hand hygiene involve both use of proper procedure and commitment to perform the task, thus there is a need to understand human factors in order to remove barriers and enhance hand hygiene compliance. Some laboratory studies suggest that application of some form of hand hygiene is better than doing nothing at all; however, this has not been evaluated in the context of a risk assessment that evaluated human variation in application of hand hygiene regimes. At least one regulatory jurisdiction allows the use of alternatives to handwashing, such as a two step hand cleanser-sanitizer protocol, in certain settings where water is limited. Behavioral and risk assessment research that evaluates the magnitude of risk reduction achieved by varying forms of hand hygiene actions (i.e., nothing, rinsing, hand sanitizing, washing, or washing and brushing) would be useful to move from an all-or-nothing approach in every situation, to one recognizing that different procedures may be suitable for different situations.

In conclusion, the Committee was unable to identify specific situations where application of alternatives to handwashing is appropriate. However, the Committee believes that its approach of considering scientific, regulatory and behavioral factors creates the ground work necessary that such recommendations would be

possible in the future. Thus the Committee recommends continuation of this work and is submitting an issue to re-create the Hand Hygiene Committee.

Charge 1 – Address the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses

Introduction

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. In this report, hand hygiene products available to reduce the risk of spreading infectious agents are categorized as:

- handwashing agents (plain soaps or antimicrobial soaps)
- hand wipes (plain and antiseptic) and
- hand antiseptics (antiseptic waterless agents)

Handwashing with plain soap suspends microorganisms and mechanically removes them by rinsing with water. Plain bar soap, foam and liquid preparations are comprised of detergents with surfactant (surface-active agents), which increase the cleaning properties of water and gives the product the ability to remove soil from surfaces, such as human skin. Microbial reduction using plain soap is due to the physical removal of foreign material or microorganisms, not a biocidal effect.

An *antimicrobial soap* combines the cleaning action of plain soap (i.e., physical removal of foreign material) with antiseptic agents that kill microorganisms. The antimicrobial agents used in antimicrobial soaps (e.g., chloroxylenol, quaternary ammonium compounds, chlorhexidine gluconate, iodine/iodophors and triclosan) have an immediate effect that reduces the number of microflora on skin and in certain cases may exhibit residual or sustained activity that continues to reduce the number of microbial flora after the handwash is complete. The effectiveness of these agents is primarily directed toward vegetative bacteria.

Antimicrobial wipes are towelettes or paper towels that are saturated with an antimicrobial solution that has been shown to reduce the numbers of microorganisms on skin. The antimicrobial ingredient is typically isopropyl or ethyl alcohol and/or a quaternary ammonium compound. There are also some specialized products with other antimicrobial ingredients.

Hand antiseptics (also called hand sanitizers) are waterless agents with antiseptic properties that decrease the number of microorganisms present. For the purposes of this paper, hand antiseptics do not require the use of water. Alcohol-based hand antiseptics are the most common type and typically contain ethanol or isopropanol and may contain n-propanol or a combination of these agents. Hand antiseptics are typically not designed as hand cleansers and thus are usually intended to be used on visibly clean hands as a single application. However, most hand antiseptics contain emollients, emulsifiers and water, all of which can act as cleaning agents when assisted by hand-to-hand rubbing and physical removal with a paper towel, in a manner similar to a hand wipe.

Foodborne pathogens associated with hand hygiene-related outbreaks

To address the charge, the committee first identified the foodborne pathogens relevant to hand hygiene interventions. The CDC (2009) provides a list of infectious diseases that are transmitted through handling the food supply, which is summarized in Table 1 below and in Annex 3 Section 2-201.11 of the 2009 Food Code. Two categories are identified – 1) those pathogens that are *often* transmitted by food when handled by an infected person and 2) those pathogens that are *occasionally* transmitted thorough handling by an infected worker but usually transmitted by contamination at the source or in food processing or by non-foodborne routes. Those "often" involving infected workers include pathogens with low infective dose (e.g., the viruses, *Salmonella* Typhi and *Shigella*) and those that are shed in high numbers when an active infection exists (e.g., the viruses, *Staphylococcus aureus* and *Streptococcus pyogenes*). The 2009 Food Code Sections 2-201.12 and 2-201.13 specify exclusion or restriction of food workers from a food establishment when certain diagnoses or symptoms listed in Table 1 exist. Annex 3 of the Food Code (2009, page 337) specifically notes that "exclusion of food employees exhibiting or reporting diarrhea symptoms is an essential

intervention in controlling the transmission of norovirus from infected food employees' hands to RTE food items." This recognizes that even thorough hand hygiene may not be sufficient to prevent transmission of disease when food is handled by symptomatic food handlers.

Table 1 CDC listing of infectious and communicable diseases transmitted through handling the food supply

Category	Agent	Modes of transmission	Symptoms that indicate infection that could be transmitted to others through food
Pathogens *often* transmitted by food contaminated by infected persons who handle food	Viruses - Norovirus - Hepatitis A virus - Sapovirus Bacteria - *Salmonella* Typhi - *Shigella* species - *Staphylococcus aureus* - *Streptococcus pyogenes*	• Failure of food handlers to: - wash hands, - wear clean gloves, or - use clean utensils • Also transmitted person to person	• Diarrhea • Vomiting • Open skin sores, boils • Fever • Dark urine • Jaundice
Pathogens *occasionally* transmitted by food contaminated by infected persons who handle food, but *usually* transmitted by contamination at the source or in food processing or by non-foodborne routes	Bacteria - *Campylobacter jejuni* - Enterohemorrhagic *E. coli* - Enterotoxigenic *E. coli* - Non-typhoidal *Salmonella* - *Vibrio cholera* - *Yersinia enterocolitica* Parasites - *Cryptosporidium* species - *Entamoeba histolytica* - *Giardia intestinalis* - *Taenia solium*	• Usually intrinsically contaminated or cross-contaminated during processing or preparation • Occasionally transmitted by infected food handler with acute diarrhea • Bacterial pathogens often require multiplication in the food before they will cause disease	• Acute diarrheal illness
Adapted from: CDC 2009. Federal Register November 23, 2009, 74(224):61151			

CDC (2006) also published foodborne illness contributing factors that were reported for outbreaks occurring from 1998-2002. In that time period, of the 3072 outbreaks for which contributing factors were reported, 25% identified bare-hand contact, 20% identified infected persons and 6% identified gloved-hand contact as factors contributing to these outbreaks. Table 2 summarizes the CDC (2006) data by etiology for foodborne illness outbreaks reported as being associated with hand contact (with or without gloves) or handling by an infected person as a contributing factor. Norovirus was the dominant etiology for outbreaks involving these contributing factors, and bacterial etiologies were reported for 40% of the bare-hand contact outbreaks, 35% of gloved-hand outbreaks and 35% of infected person outbreaks involved bacterial agents. Only one parasite (*Giardia intestinalis*) and no chemicals were reported to be associated with hand hygiene related outbreaks in this time period.

It cannot be determined from these data how many outbreaks "involving infected persons or carrier" included symptomatic food handlers, for which handwashing may not be adequate to prevent spread of illness as previously discussed. It is interesting to note that for each of the pathogens listed by CDC as "*often* transmitted through food contaminated by infected persons" (see Table 1), the number of outbreaks reported to be handled by an infected person was frequently much greater than the number involving bare-hand contact. Conversely, for "pathogens *occasionally* transmitted by food contaminated by an infected handler," the number of outbreaks associated with bare-hand contact was higher than the number associated with infected persons handling food.

Vegetative bacterial pathogens are generally more easily inactivated by chemical agents used in antimicrobial hand care products than the viruses and parasites of foodborne illness concern. While bacterial spores are also more resistant than vegetative bacteria, sporeformers of foodborne illness concern must be in their vegetative state and grow in the food to a high level to present a food safety risk. Thus inactivation of spores is not a major concern for hand hygiene in a food handler setting.

This analysis suggests that norovirus is the most common pathogen associated with hand hygiene-related foodborne illness outbreaks. Thus, when addressing "the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing," norovirus should be considered.

Table 2 Hand contact contributing factors reported for foodborne illness outbreaks 1998-2002 in the United States

Etiology		Bare-hand contact n (% of confirmed)		Gloved-hand contact n (% of confirmed)		Infected person or carrier n (% of confirmed)	
Bacterial	Non-typhoidal *Salmonella*	37	(15)	4	(7)	64	(18)
	Staphylococcus aureus	17	(7)	5	(9)	30	(9)
	Shigella	12	(5)	3	(5)	16	(5)
	Escherichia coli	12	(5)	1	(2)	6	(2)
	Clostridium perfringens	8	(3)	2	(4)	2	(1)
	Campylobacter	5	(2)	2	(4)	1	(<1)
	Vibrio parahaemolyticus	2	(1)	1	(2)	1	(<1)
	Bacillus cereus	1	(<1)	1	(2)	1	(<1)
	Streptococcus	0	(0)	0	(0)	1	(<1)
	Total Bacterial	*94*	*(40)*	*19*	*(35)*	*122*	*(35)*
Viral	Norovirus	129	(54)	30	(55)	202	(58)
	Hepatitis A	13	(5)	4	(7)	16	(5)
	Total Viral	*142*	*(59)*	*34*	*(62)*	*218*	*(62)*
Parasitic	*Giardia intestinalis*	1	(<1)	0	(0)	2	(1)
Multiple etiologies		2	(1)	1	(2)	7	(2)
Total confirmed etiology		239	-	55	-	349	-
Unknown etiology		526	-	132	-	251	-

Adapted from: CDC 2006. MMWR 55(SS10):1-34.

Methods used to evaluate effectiveness of hand hygiene solutions (in vivo versus in vitro)

(per previous discussion, FDA was not able to comment on this section)

Ideally, well-controlled and statistically valid epidemiological outcome studies would be available to determine the relative effectiveness of hand hygiene products and regimens. Unfortunately, these types of studies are very rare and pose fundamental design and execution challenges. As a result, the primary methods used to evaluate effectiveness of hand hygiene products are laboratory-based, including *in vivo* (using living subjects) and *in vitro* (not using living subjects) testing, and to a limited extent risk modeling.

The type of test used to evaluate the effectiveness of hand hygiene solutions can have a significant impact on the results generated. Because of this, it is important to understand how a test was conducted when attempting to compare the effectiveness of hand hygiene solutions and it is difficult to compare the results from one study to another. It is important to note that, the most common pathogen associated with transmission of foodborne illness via hands, human norovirus, cannot be cultured in the laboratory. Murine norovirus and feline calicivirus have been used as surrogates to estimate reductions in infectivity, but the scientific debate on the "best" surrogate continues because the mode of inactivation for different antimicrobial agents varies (e.g., Cannon et al. 2006; Park et al. 2010). Currently, human norovirus results can be studied using polymerase chain reaction (PCR) technology, which reflects destruction of ribonucleic acid (RNA) as an indirect measure of loss of infectivity. However, it is possible for a virus to lose infectivity without destruction of RNA.

While standardized methods (e.g., ASTM, EN standards) exist for both *in vivo* and *in vitro* tests, methods used in the literature vary widely in their procedures and approach. This section provides a brief overview of the different types of tests used and the variation that can occur. It is not the intent of this report to recommend any specific type of test.

In vivo tests

In vivo tests evaluate performance of hand hygiene measures using the hands of human test subjects. Many different *in vivo* tests using a wide variety of methodologies have been used to evaluate the performance of hand hygiene measures. Key differences include use of an inoculum, handwash technique and sampling method.

Use of an inoculum: In some cases the area being washed is inoculated with a marker organism (e.g., *E. coli*, *Staphylococcus aureus* or *Serratia marcescens*). Although *Serratia* is not commonly found on hands, its red pigment makes it easy to distinguish from background flora when conducting tests. *Serratia* is referred to as a "transient" hand microbe because it is only present for a short time on the hands, typically on the surface of skin. This is in contrast to "resident" hand microbes that are almost always present on hands, sometimes deep in the skin tissue. The use of a marker organism like *Serratia* can help to evaluate the performance of the handwash process on transient rather than resident flora, and to standardize the starting concentration of microorganisms on the skin of the test subjects.

In some *in vivo* tests, no inoculum is used. The level and nature of microorganisms present on human skin varies from person to person and over time for a given individual. These factors must be taken into account when interpreting these test results. Montville and Schaffner (2011) found that choice of the specific marker organism makes little difference, but that the choice between marker organisms and resident flora has a substantial impact on the results. According to their analysis, this appears to be primarily due to a difference in starting concentration. Quantifying differences is easier when starting with a uniformly high concentration because it helps to keep endpoint numbers above the level of detection.

Handwash technique: Standardized *in vivo* tests use a prescribed handwash method, but not all studies in the literature use standardized test methods. Some allow the test subject to wash their own hands and others have a technician conduct the wash. This can influence the variation observed in procedures practiced by human subjects. More variation is typically observed when each subject performs the hand hygiene procedure.

Sampling method: There are many ways to enumerate the organisms remaining on the skin after washing. For example, in the *glove juice test*, the test subject dons disposable gloves, a sampling fluid is added to the gloves, the subject's hands are massaged and the microbes in the sampling fluid in the glove are enumerated. Other sampling techniques include collecting wash fluid into basins and enumerating organisms in the collected fluid, rubbing fingertips in Petri dishes containing a sampling fluid, placing a cylinder on the skin, adding a sampling fluid to cylinder and scrubbing the skin using a sterile swab, or simply pressing the finger tips to an agar plate.

The large inherent variability with any *in vivo* test coupled with differences in enumeration methodology leads to one of the major disadvantages of *in vivo* testing – conflicting, inconsistent and often non-comparable results. The variability also contributes to another disadvantage – cost. Multiple subjects are needed to estimate variability and it is not uncommon for a single test on a single subject to cost in excess of a thousand dollars. The variability of *in vivo* testing often requires high numbers of test subjects to statistically demonstrate differences, thus studies can be quite expensive. Use of pathogens for *in vivo* testing presents ethical issues that must be carefully considered.

Despite the disadvantages associated with *in vivo* hand hygiene efficacy testing, an advantage is that *in vivo* testing may provide information on how effectively a hand hygiene procedure will reduce microbial levels on hands in actual use. However, *in vivo* tests described do not prove that a tested hand hygiene procedure will actually prevent or reduce illness in the real world. At best, it provides a surrogate endpoint for the hand hygiene procedure's ability to prevent or reduce the risk of disease. Clinical trials to evaluate prevention of disease are rarely, if ever, performed.

In vitro tests

In vitro studies do not involve human or animal test subjects. The most common type of *in vitro* test for hand hygiene studies is the suspension or *time-kill test*. In these studies, the test microorganism is suspended in a solution containing the test product. After a specified exposure time, an aliquot of solution is removed, the antimicrobial activity is typically neutralized and any surviving microorganisms are determined. As with *in vivo* tests, many variables must be considered for *in vitro* testing, including product and test organism concentrations, types of organisms, the presence and concentration of interfering substances such as soil or hard water, the use of different temperatures, different neutralizer systems and various exposure times. Typically, greater reductions are observed for *in vitro* tests than for *in vivo* tests because of the direct exposure of the microorganism to the antimicrobial agent. Even seemingly trivial variations in test procedures, such as growing the inoculum on solid versus liquid media or the number of times the test cultures have been transferred, can affect the results. As with *in vivo* testing, this can make comparison of results between different studies difficult.

An advantage of *in vitro* tests is that they are relatively easy and inexpensive to do. This makes it easier to study more organisms and to collect sufficient replicates in a reproducible manner to demonstrate statistical significance even when the data are variable. The largest drawback of *in vitro* testing is that they are further removed from the clinical endpoint than *in vivo* tests. Just as an *in vivo* test is not a perfect predictor of a clinical endpoint, so an *in vitro* test is not a perfect predictor for an *in vivo* result.

The Hand Hygiene Committee summarized advantages and disadvantages of *in vivo* and *in vitro* efficacy testing in Table 3. Both types rely on enumeration of viable microbial targets to measure the extent of reduction after a treatment, which is possible for many pathogens involved in foodborne illness transmitted via hands, but currently not human norovirus.

Table 3 Advantages and disadvantages of *in vivo* and *in vitro* tests to demonstrate efficacy of hand hygiene solutions.

Test method	Advantages	Disadvantages
In vivo (uses human subjects)	• Closer to clinical endpoints • May demonstrate impact of full hand hygiene procedure (i.e., rinsing, friction, duration)	• Significant person-to-person variation • Expensive and difficult to conduct • Concerns with human exposure to certain pathogens
In vitro (does not use human subjects)	• Typically less variable than *in vivo* methods • Can study more organisms in a controlled manner • Less expensive	• Further removed from clinical endpoints

Summarize the available science on the efficacy of hand hygiene approaches at removing hazards and reducing risk, including handwashing and other approaches

(per previous discussion, FDA was not able to comment on this section)

As discussed above, the wide variety of test methods used to study hand hygiene procedures makes it very difficult to compare the efficacy of handwashing to alternative hand hygiene regimes. Recent peer-reviewed papers summarize much of the available science on this topic. Todd et al. (2010a) provide an extensive review of nearly 250 publications addressing the impact of washing and drying of hands to reduce microbial contamination. Montville and Schaffner (2011) looked more specifically at a quantitative comparison of antimicrobial versus non-antimicrobial hand soaps and evaluated the impact of methodological differences in the extent of reduction achieved. Both of these reviews reported that many factors influence the efficacy of handwashing, including the type and volume of soap used, friction, and duration of washing. Some of the findings of these reviews include:

- Using <1mL portion of hand soap appeared to be less effective than using 1ml or more.
- Vigorous washing is an important factor in that it removes or loosens microorganisms with mechanical action.
- On average, use of antimicrobial soaps results in fewer microorganisms on hands.
- Todd et al. (2010a) found that duration of handwashing is an important factor and duration of at least 15 seconds is needed. They concluded that while washing up to 30 seconds may provide somewhat greater

microbial removal from hands, this further reduction may not be meaningful as it involves removing resident microorganisms that are not generally associated with transmission of foodborne illness. Various studies have indicated that the average wash duration by the general public and food handlers is about 10 seconds, in spite of the 15 second recommendations.

- Frequency of handwashing is also an important factor. Several studies suggest that while most individuals (>85%-95%) self-report washing hands after using the bathroom, observational studies indicated that the frequency (particularly among men) was considerably lower (ca. 70%). In food settings the frequency of handwashing at appropriate times may be as low as 30% during peak business hours. However, training and specific interventions could increase that to over 50%.
- Temperature has relatively little impact on the efficacy of handwashing. Temperatures that are too high (over 110°F) increase the risk of skin damage and reduce handwashing compliance.
- Drying, particularly using towels, removes ca. 90% of the organisms that remain after washing. Removal of microorganisms by air dryers is more questionable. Moreover, the time needed to dry hands with many air drying systems is often longer than towel drying, so hands often remain wet for people who do not wait. Wet hands have been shown to harbor and transfer organisms more easily than dry hands. There is also some concern that the airflow from certain air driers may be a source of contamination.

Todd et al. (2010b) provides a recent comprehensive, peer review of waterless hand antiseptics relevant to food handlers, including 150 references. They found that product type, concentration, volume and contact time influenced results. They concluded that "alcohol-based antiseptics should be combined with regular handwashing schedules and should not replace handwashing and drying or the use of fingernail brushes." In regard to wiping methods, they indicated that food handlers may ignore some of the steps in two or three stage procedures, thus they did not recommend such procedures in general. However, they also stated that "because [two or three stage] wipe methods tested have been more effective than soap and water, they should be considered feasible, practical hand hygiene interventions for remote food service situations or where water availability is limited."

The effectiveness of hand antiseptics against human norovirus was questioned by Todd et al. (2010b) based on the available literature at the time of their review. However, Park et al. (2010) compared the effectiveness of seven hand antiseptics against murine norovirus (MNV) and feline calicivirus (FCV) as potential surrogates for human norovirus. One ethanol-based and one triclosan-based hand antiseptic reduced both MNV and FCV by >2.6 and $\geq$ 3.4 logs, respectively, using *in vitro* infectivity test methods. Four products demonstrated effectiveness against either MNV or FCV. The chlorhexidine product was not effective against either virus. Thus effectiveness varied among the different hand antiseptics. Liu et al. (2011) studied inactivation of human norovirus using the *in vivo* finger pad test, reporting log reductions of RNA from 0.10 to 3.74 for six commercially available hand antiseptic products. This study also illustrated the large variation that can be observed among hand antiseptic products. These two studies did not include a measure of the reduction that could be achieved with handwashing treatments. Further, some of the products studied may not have "Food Code" compliant ingredients.

A number of *in vivo* studies have included handwashing and hand antiseptics in the same investigation. Some of these studies concluded that hand antiseptics were ineffective at reducing microbial levels on hands while others suggested that they are effective in either reducing numbers or reducing transfer of infection. Two examples of studies that concluded hand antiseptics were ineffective include the following.

- Courtenay et al. (2005) compared washing with soap and water, rinsing with either warm or cool water, and ethanol-based hand antiseptics for reducing *E. coli* on hands. The soap and water washing demonstrated >2.6 log reduction, which was significantly greater than solely rinsing with warm water (2.2 log reduction), rinsing with cool water (1.5 log reduction) or ethanol-based hand antiseptic (0.2-0.7 log reduction).
- Lin et al. (2003) studied the effect of six handwashing techniques on *E. coli* and FCV levels inoculated under natural and artificial fingernails. Washing techniques included use of tap water alone, soap and water, antimicrobial soap, hand antiseptic, soap plus hand antiseptic, and soap plus nailbrush. Only reductions in counts under the fingernails were reported. For *E. coli,* no significant difference was noted between any of the washing techniques except washing with soap using a nailbrush. The nailbrush technique reduced the *E. coli* population approximately 2.5 – 3 logs while other techniques reduced the population 1 – 2 logs. For FCV, soap with nailbrush washing also significantly reduced the population greater than 2 logs for both nail

types. The hand antiseptic treatment resulted in a significantly lower reduction of FCV for both nail types (<1 log) than other treatments. Interestingly, there was no significant difference between log reductions of either *E. coli* or FCV from finger nails when tap water alone was compared to any of the handwashing methods using soap without a nail brush.

Conversely, a number of studies concluded that the use of hand antiseptics reduced organisms on hands the same or better than washing alone. For example:

- Brown et al. (2007) evaluated reductions of microbial counts on uninoculated hands following washing with plain soap, antimicrobial soap or use of an alcohol-based hand antiseptic. Fingers were touched to agar plates before and after treatment, and qualitative assessment of the number of bacteria present was determined. The alcohol-based hand antiseptic reduced the relative counts significantly more than the plain or antimicrobial soap treatments.
- Schaffner and Schaffner (2007) determined the effectiveness of an alcohol-based hand antiseptic on hands contaminated with a nonpathogenic surrogate for *E. coli* O157:H7, where the source of the contamination was frozen hamburger patties. The effectiveness of the hand antiseptic was similar to that for handwashing and glove use previously reported. The person-to-person microbial reduction variability from hand antiseptic use is similar to published data for glove use and was less variable than published data on handwashing effectiveness.
- Paulson (1999) studied the reduction of *Serratia marcescens* for hand hygiene regimens including plain lotion soap, antimicrobial lotion soap, alcohol-based hand antiseptic, and combinations of these using the glove juice method. The alcohol treatment alone or in combination with handwashing, reduced the population almost 4 logs. The soap treatments alone provided a 2 – 3 log reduction in *Serratia* counts and there was no statistically significant difference between antimicrobial and plain soap treatments, although the antimicrobial treatment was consistently higher. A combined treatment was recommended.
- Michaels et al. (2003) studied the impact of varying volumes of alcohol-based hand antiseptic on reducing inoculated transient microflora from previously washed hands, as well as the impact of the hand antiseptics on reducing levels of transient flora from under finger nails. Levels of hand antiseptic at 3mL or 6mL resulted in a significant reduction of transient flora over washing alone, while lower levels did not. Consistent with the results reported by Lin et al. (2003), washing hands with a nail brush was required for significant reductions under fingernails.
- Restaino and Wind (1990) reviewed literature available at the time and reported that appropriate alcohol preparations were more effective in reducing microbial counts that handwashing alone. They also commented on the need to use products that are non-irritating to the skin.

It is clear from the studies summarized that there is a large amount of variability between and within studies with behavioral aspects frequently compounding interpretations of data. Montville and Schaffner (2011) concluded that "The inherent variability in handwashing seen in the published literature underscores the importance of using a sufficiently large sample size to detect difference when they occur."

Few studies have attempted to assess the effect of hand antiseptics from a risk reduction perspective. Bidawid et al. (2004) studied the transfer of feline calicivirus (FCV) from fingertips to a variety of surfaces. Finger pads were contaminated with FCV, allowed to dry, and then touched to various surfaces to evaluate the percent of transfer. Results (see Figure 1) demonstrated that treating hands with water, soap and water, or alcohol significantly reduced the percentage transferred, with less than 1% transferred following handwashing or a water rinse, ca. 1-3% transferred after treatment with alcohol, and 13-48% transfer if no hand hygiene intervention was used. While alcohol treatments were not as effective as soap and water or water alone, all of these hand hygiene interventions were significantly more effective than no hand hygiene treatment at all.

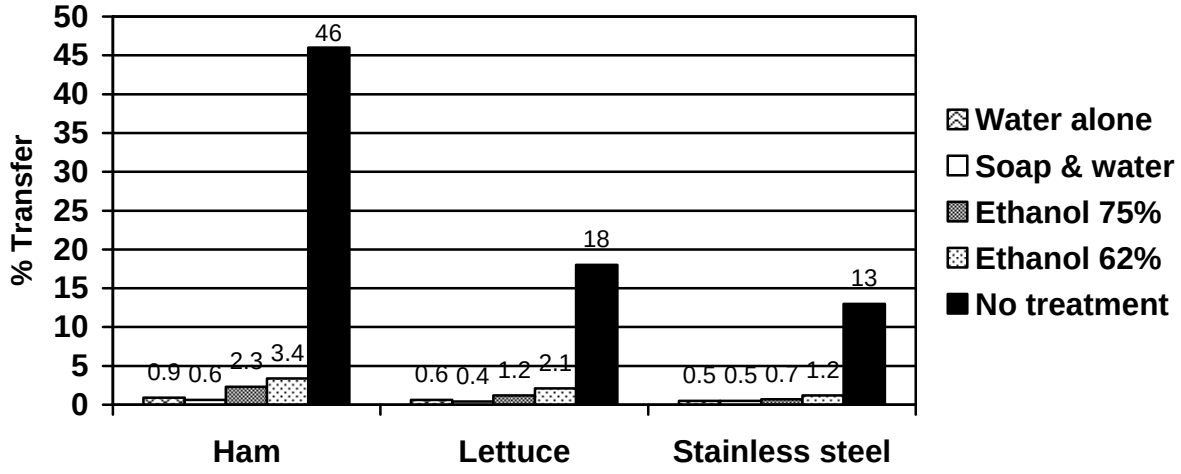

Figure 1 Feline calicivirus transfer from inoculated finger pads to ham, lettuce and stainless steel surfaces after treatment with various hand hygiene regimens. Adapted from Bidawid et al. (2004)

Regulatory requirements related to efficacy of hand hygiene products

This section is intended to provide a brief overview of the regulatory requirements related to the efficacy of hand hygiene products. It is not intended to be a comprehensive, complete discussion of the regulatory approval process. It represents the Hand Hygiene Committee's best understanding of the process, and FDA was not able to comment on this section. Those seeking additional information about FDA's position on the appropriate uses of hand antiseptics in food establishments are directed to Annex 3 of the FDA Food Code.

Approval process

Hand antiseptics that meet specific criteria described in Section 2-301.16 of the 2009 Food Code may be applied "only to hands that are cleaned as specified under Section 2-301.12" in retail and foodservice establishments. Annex 3 – Section 2-301.16 of the 2009 Food Code explains that hand antiseptics are drug products that must comply with FDA CDER regulations, and provides more information on where approved products are listed as well as other requirements not related to the effectiveness of the products against foodborne pathogens.

As drugs, hand antiseptics must be demonstrated to be safe and effective. This can be accomplished by one of two means:

1. The hand antiseptic may be approval by FDA under a new drug application (NDA). Drugs approved through this route are listed in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book" (FDA 2011).

2. The hand antiseptic may have an active ingredient identified by FDA (1994) in the Tentative Final Monograph (TFM) for Health-Care Antiseptic Drug Products for OTC Human Use in the handwash category, be listed with FDA as a drug, and comply with other relevant drug requirements.

The TFM specifies the active ingredients that can be contained within handwash products, as well as labeling, product testing and other general requirements. The *in vitro* and *in vivo* testing provisions in the TFM are well detailed and list specific organisms that products can make claims against. There is also a clinical study requirement depending on the final claim. The TFM antimicrobial spectrum tests determine the efficacy of products using Minimum Inhibitory Concentration (MIC) and time kill tests against 25 laboratory strains and 25 fresh clinical isolates included in a specific list of vegetative bacteria and the yeast *Candida*. Time-kill tests are also required using "standard ATCC strains identified for the MIC tests. The TFM also requires an *in vivo* handwash assay using *Serratia* as the test organism. There are currently no virus tests listed on the TFM and therefore antiviral hand hygiene claims are not available through the TFM, despite the fact that as noted above, norovirus is by far the pathogen reported most frequently in outbreaks where inappropriate application of hand hygiene regimens were noted.

For hand antiseptics, the TFM classifies alcohol 60–95% and povidone iodine 5–10% as Category 1 – Generally Recognized as Safe and Effective. Many potential active ingredients for hand antiseptics including triclosan, triclocarban, benzalkonium chloride, benzethonium chloride and parachlorometaxylenol, are classified in Category III, requiring more data for final determination on safety and efficacy. Pending a Final Monograph, products based upon ingredients classified as Category III can be marketed provided they meet the performance testing requirements of the TFM. Premarket approval through the New Drug Application (NDA) process is required for products that contain active ingredients not listed in the TFM.

FDA Guidance on Hand Antiseptics

While the CDC recommends alcohol-based hand gels as a suitable alternative to handwashing for health care personnel *"if hands are not visibly soiled*" (CDC 2002), FDA (2003) clarified that this recommendation is not applicable to food establishments. This exclusion is based on the differences in controlling common nosocomial pathogens in health care settings and common foodborne pathogens in retail and foodservice settings. FDA (2003) also highlights that the pathogens most commonly transmitted by hands in health care settings differ from those in retail and food service settings, and the types and levels of soil on the hands of health care workers differ from foodservice/retail workers.

The FDA (2003) factsheet concluded:

> "Proper handwashing, as described in the Food Code continues to serve as a vital and necessary public health practice in retail and food service. Using alcohol gel in place of handwashing in retail and food service does not adequately reduce important foodborne pathogens on foodworkers' hands. Concern about the practice of using alcohol-based hand gels in place of handwashing with soap and water in a retail or food service setting can be summarized into the following points:
>
> - "Alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain nonenveloped (nonlipophilic) viruses; and
> - "Ingredients used in alcohol-based hand gels for retail or food service must be approved food additives, and approved under the FDA monograph or as a New Drug Application (NDA); and
> - "Retail food and food service work involves high potential for wet hands and hands contaminated with proteinaceous material. Scientific research questions the efficacy of alcohol on moist hands and hands contaminated with proteinaceous material."

It is important to note that even in health care settings, alcohol-based hand gels are to be used as an alternative to handwashing "only if hands are not visibly soiled" (CDC 2002).

State and Local Jurisdictions

At least one regulatory jurisdiction allows the use of alternatives to Food Code compliant handwashing in specific situations where water is limited. For example, hand sanitizers are required after handwashing with non-potable water on Colorado River rafting trips (National Park Service 2011), and a two step hand cleanser-sanitizer protocol was approved by the Southern Nevada Health District when water is not available and only pre-packaged foods are used (Jim Mann, personal communication).Research on the impact of adoption of alternative procedures on hand hygiene compliance or public health outcomes would be useful to further inform the discussion on alternatives to handwashing. Such studies have been conducted in health care and home settings by academic, medical, public health and industry researchers (e.g., Hilburn et al. 2003, Sandora et al. 2005), but not in food handling settings.

Regulatory Status Summary

In summary, hand care products with antimicrobial claims are considered to be drugs, thus approval and registration are under the regulatory jurisdiction of FDA's Center for Drug Evaluation and Research. Antiviral hand hygiene claims are not available through the Tentative Final Monograph and to date no US antimicrobial hand care product with virucidal claims for food handler application has been approved through the New Drug Application (NDA) process. As a drug, antimicrobial hand care products should be used following label instructions. FDA's Center for Food Safety and Applied Nutrition provides guidance through the *Food Code* on when and where hand hygiene practices should be applied.

Identify compliance issues and behavioral aspects of hand hygiene

As previously discussed, many factors such as time, temperature, friction, product volume, product type, etc., influence the effectiveness of hand hygiene regimes. At the same time, motivating food workers to apply proper hand hygiene procedures at the right time is an important food safety need. Thus, procedures are important for effective hand hygiene. Operators make their final choice of protocols based on the requirements in the Food Code guidance and their risks, based on their customer mix, menu, facilities and system control. There is no one-size-fits-all protocol for the wide range of food service and retail establishment practices that exist. Procedures should be selected to assure their minimum cleanliness levels are maintained.

The Committee identified barriers to proper handwashing behaviors by discussing the question "*If hand hygiene (hand antiseptic) was allowed in place of handwashing, would there be a significant increase in desired behaviors, either for use: 1) in place of handwashing or 2) in addition to handwashing?"*

For this exercise, the Committee considered only behaviors and *not* necessarily effectiveness. The Committee discussed which factors encourage or discourage desired handwashing behaviors for both traditional soap and water wash, and use of approved hand antiseptic. Information reported in Tables 4-6 is based on expertise of the Behavior Sub-committee of the CFP Hand Hygiene Committee, with review by the full committee. No quantitative or qualitative data were reviewed during the sub-committee's discussion.

Table 4 What encourages / discourages desired behaviors regarding ***how*** to perform hand hygiene?
(Note: effectiveness of the application is not considered in this comparison)

Potential barriers	Handwashing	Hand antiseptic or alternative
Water temperature	Too hot or cold discourages Just right encourages	Not applicable
Type of product (Like or dislike scent, feel, etc.)	How well does it lather? Does it cause dry hands or maintain skin health? Does it sting?	Does it make hands sticky? Does it cause dry skin or maintain skin health? Does it sting?
Towel vs. hand dryer	Slow drier discourages Empty or malfunctioning towel dispensing discourages	Drier not applicable. Towel may be needed (wipes or two-step procedure), thus availability or malfunctioning situations are similar.
Urgency / pressure / motivation	Must go to sink to perform	Can be applied "on the go" for a one step process
Proximity of product and equipment, ease of reaching	Need sink (plumbing), soap, drying equipment	Portable or easy installation in multiple locations. Potentially closer to work station.
Training (need to know how, when and why)	Applies equally. Potentially more material available on procedure.	Applies equally
Supplies available and working	Applies equally	Applies equally
Laziness	Applies equally	Applies equally
Ease – automated vs. manual. Method of dispensing	Automatic options may encourage or discourage. Must be functioning	Automated dispensing quicker when functioning. Must be functioning.
Time	Takes too long (perception)	Fewer steps for single application
Double handwashing	Takes too long	Applicable to two-step process
Policy – management commitment and enforcement	Applies equally	Applies equally
Job aids – detailed instructions	Applies equally	Applies equally
Hand hygiene signs	Applies equally	Applies equally
Behavior modeled by co-workers and management	Can motivate or de-motivate	Can motivate or de-motivate
Requirement for employment	Applies to both	Applies to both
Existence of regulations	Encourages policy, not employees	Currently hinders adoption
Visible / type of soil	Adjust to soil type	Appropriate for visibly clean hands only. May be unpleasant on heavily soiled hands
Pleasant experience	Applies equally	Applies equally

Factors that may either encourage or discourage *how* handwashing or hand antiseptic behaviors performed are listed in Table 4. Many of the barriers apply equally to how hand hygiene is performed for either handwashing or hand antiseptic use. Perceived speed of application for use of single step hand antiseptic applications may remove a potential barrier that exists for handwashing. Hand antiseptics may also remove barriers associated with proximity to the supplies need to perform the task. While the issue of training applies equally to both types of hand hygiene, it was noted that much emphasis has been placed on the proper handwashing technique. This may vary for different hand antiseptic applications and may be less obvious (e.g., single application versus two-step process; need to fully cover fingers, finger tips and nail area).

Factors that may either encourage or discourage *when* desired handwashing or hand antiseptic behaviors are appropriate are listed in Table 5. Again, many potential barriers apply equally to both hand hygiene regimens. The perceived need is an area where differences exist. Some workers wash their hands when they are heavily soiled from a self-protection standpoint. Conversely, single step hand antiseptics are typically designed to be used on visibly clean hands; therefore the visual cue of hands looking dirty does not apply. The sub-committee thought that there were opportunities to reduce confusion on when to wash hands or use hand antiseptics, for example when used with gloves (see the section on when alternatives may be appropriate).

Table 5 What encourages / discourages desired behaviors regarding *when* to perform hand hygiene?
(Note: effectiveness of the application is not considered in this comparison)

Potential barriers	Handwashing	Hand antiseptic or alternative
Perceived need	Wash when hands look or feel dirty. Workers wash to protect themselves (e.g., after clearing a messy table)	Perceived need for single step may change because this should be done on clean hands. Likely the same for a two step process
Touch points / requirements (too many)	Applies equally	Applies equally
Policy– management commitment and enforcement	Applies equally	Applies equally
Training – urgency	Applies equally	Applies equally
Focus on the why	Applies equally	Applies equally
Clarifying specifics in Food Code / misinterpretations	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements and interpretation of regulations
In concert with glove use / confusion with glove use	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements
Clarifying examples	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements
Motivation	Applies equally	Applies equally
Proximity / ease	Need sink (plumbing), soap, drying equipment	Portable or easy installation in multiple locations. Potentially closer to work.
When need to wash – settings / relevance	When they look or feel dirty	Apply to visibly clean hands
Requirement to stay employed	Applies equally	Applies equally
Visibility of kitchen	Depends on customers – are they more interested in the food / techniques or hygiene?	Less time away from food prep
Pleasant experience (some products make hands feel and/or smell good)	Applies equally	Applies equally
Hand antiseptic is a second barrier	May be tempted to skip washing	May do it more often if it is quicker

Factors that may either encourage or discourage regarding why to perform hand hygiene are listed in Table 6. Communication of the reasons why hand hygiene should be performed is very important for employee acceptance

and increases the likelihood that proper hand hygiene will be performed. Most of the factors that can encourage hand hygiene behaviors apply equally to both washing and antiseptic use. However, explaining why there are different considerations for when hand antiseptics are appropriate, may cause confusion and thus create a barrier to compliance. This type of communication must be planned carefully.

Table 6 What encourages / discourages desired behaviors regarding *why* to perform hand hygiene?
(Note: effectiveness of the application is not considered in this comparison)

Potential barriers	Handwashing	Hand antiseptic or alternative
Buy-in / encouragement	Handwashing is a recognized foundation for food safety and healthy living.	Explaining the differences of when handwashing is appropriate versus when alternatives are appropriate may complicate the message and confuse the "Why"
Expected practice / culture of hand hygiene	Applies equally	Applies equally
Not a lot of training tools; print training vs. activity based	Applies equally	Applies equally
Trainer effectiveness	Applies equally	Applies equally
Oral vs. written	Applies equally	Applies equally
Proximity	Getting staff to the sink	Getting to the product
Lack of motivation	Applies equally	Applies equally
Expectation of customers	Visibility of kitchen	Visibility of kitchen
Pleasant experience	Applies equally	Applies equally
Location / availability of supplies	Applies equally	Applies equally, but may be easier to have sanitizer available in some locations
Equipment working correctly	Applies equally	Applies equally

Identify potential public health benefit of improved hand hygiene compliance using different approaches

Several studies have evaluated the use of alcohol-based hand sanitizers in reducing infection rates in a variety of settings, including schools, day care settings, hospitals and long term care facilities. Two examples described below to illustrate the type of information that can be gained.

- Hilburn et al. (2003) studied use of alcohol-based hand sanitizers in acute care facilities and reported a 36.1% decrease in infection rates when alcohol-based products were used. Key factors cited to contribute to this improvement included enhanced effectiveness against causative agents and increased hand care compliance because products were easy to use and gentle to the skin, which removes a barrier for hand hygiene application. The CFP Hand Hygiene Committee notes that these results may not be immediately transferable to food handling settings because the agents, and likely the hand sanitizer products, differ. However, research on compliance in foodservice settings may be beneficial to determine if a similar improvement is noted.
- Sandora et al (2005) studied use of alcohol-based hand sanitizer coupled with hand hygiene education with children enrolled in 26 child care centers. They monitored transfer of secondary illness to people in the home. The CFP Hand Hygiene Committee recognizes that the primary mode of transmission in this study is person-to-person and that the pathogens involved may not necessarily be foodborne pathogens. However, the secondary illnesses were significantly lower for families with alcohol-based hand sanitizers in the home compared to control families.

While the Hilburn et al. (2003) "clinical end point" data demonstrate a benefit from hand sanitizers in clinical settings, the study was confounded with many other factors such as training, other interventions and increased handwashing. Therefore it is difficult to determine the effect of the hand sanitizers alone. Respiratory illness and gastroenteritis are seasonal events that occur with some frequency in institutional type settings. Foodborne illness outbreaks are less frequent thus conducting these types of studies specifically for food handing considerations will be problematic.

Charge 2 – Identify settings where alternatives to handwashing are appropriate

The Committee considered the information above and practical aspects of preparing, holding and serving food in its consideration of identifying settings where alternatives to handwashing are appropriate. From a practical and behavioral matter, the Committee thought it useful to clarify situations when and where alternatives to handwashing, such as hand antiseptics are not the best option. These include:

- Anywhere there is a properly functioning hand sink
- After toilet use
- At the start of a shift
- After lunch break
- Between handling raw and RTE foods
- After sneezing into hands
- If person has cuts, skin infections
- When hands look or feel soiled

The Committee also recognized that there are situations where alternatives to handwashing may be appropriate as a risk reduction strategy. For example, when hands are not visibly soiled hand antiseptics may *potentially* be an option:

- Between glove use
- After touching hair
- After coughing / sneezing / drinking
- In areas where there is environmentally no water
- In water outages / boil water situations
- During temporary events
- In farm stands
- For mobile vendors

The Committee recognized that there are water-short situations where the specific dual step hand cleanser-sanitizer protocol (Edmonds 2010) may be a potential alternative to water/soap handwashing as a risk reduction strategy. Some may question if providing an alternative may drive operators to use hand-antiseptics in place of traditional handwashing. The product costs of alcohol washing versus water washing will strongly favor traditional handwashing where running potable water is conveniently available.

The committee was unable to make specific recommendations. However, given time and integration of scientific and behavioral considerations, specific recommendations may be possible using a risk management approach.

Charge #3 – Recommend studies that should be completed to get research questions answered for when scientific literature is not available

Much of the research conducted on hand hygiene is done in areas other than food-related settings. There is a need for such studies to be conducted to inform decision making. Potential questions that could be addressed through research include:

- If hand antiseptic use was allowed in lieu of soap and water handwashing, would there be a significant increase in desired behaviors and would this reduce foodborne illness?
- Does providing options (soap and water vs. alternative hand hygiene methods) in foodservice or retail settings increase real-world compliance? If so, what is the public health benefit?
- Can studies on hand hygiene behaviors in hospitals be extrapolated to foodservice environments?
- What handwashing / hand hygiene options increase frequency of use?
- Why are food handlers not washing their hands?
- What is the range of temperatures that are considered to be comfortable for handwashing?
- Can new risk assessment and risk management models be applied to hand hygiene in food services settings to quantify the changes in risk when different interventions are applied?
- Can case-control epidemiological studies be conducted to compare hand hygiene related foodborne illness outbreaks in regulatory jurisdictions that allow the use of alternatives to handwashing, to those that do not?
- What is the clinical endpoint effect of various hand hygiene practices in a food setting?

Data supported answers to the above questions would help inform decision making on proposing alternatives to handwashing in certain situations to protect public health.

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Recommendation(s) for future charge:

The CFP Hand Hygiene Committee recommends the following:

1. Acknowledgement of the 2010-12 Hand Hygiene Committee report.
2. Thanking the 2010-2012 Hand Hygiene Committee for its work addressing scientific, regulatory and behavioral considerations related to efficacy and risk reduction strategies of alternative hand hygiene regimes compared to handwashing.
3. Submission of *Scientific, Regulatory and Behavioral Considerations of Hand Hygiene Regimes* to a peer reviewed journal, with the 2010-2012 Hand Hygiene Committee listed as a co-author.
4. Posting *Scientific, Regulatory and Behavioral Considerations of Hand Hygiene Regimes*, if published, on the CFP website as an educational tool that illustrates the interaction of scientific, regulatory and behavioral considerations related to alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses.
5. Re-creation of the Hand Hygiene Committee to more closely examine the current Food Code requirements for when employees are required to wash their hands using soap and running water. If credible information suggests that one or more of the situations under which food employees are currently required to wash their hands does not result in meaningful risk reduction, work with FDA to explore whether those mandates could be modified, either in the Code itself or by recognizing when it is appropriate to waive the requirement (e.g., other approaches to hand hygiene are available and practiced).
6. The re-created Committee uses the report of the 2010-2012 Committee as a reference, illustrating the interactions of scientific, regulatory and behavioral considerations related to alternative hand hygiene regimes compared to handwashing. The committee should characterize what recent research tells us about:
    - the extent to which the current minimum requirements for how and when employees are to wash their hands are effective in rendering food employees hands free of various soils, as well as, any pathogens of concern;
    - what other regimens for cleansing employees hands, if any, may deliver outcomes that are similar to or better than handwashing so as to suggest that they could be included as acceptable methods for rendering hands free of soil and pathogens.
7. The size of the Hand Hygiene Committee to be limited to less than 20 members (including advisors and chairs), to facilitate participation of the full committee on conference calls while maintaining adequate representation from relevant stakeholders. This will lead to a more coordinated work product since there would be continuity of thought. While the CFP conference call system can accommodate up to 25, scheduling a conference call for this number of people is problematic.
8. The committee report back its findings to the 2014 Biennial Meeting.

REQUESTED ACTION:

The Hand Hygiene committee will submit four (4) issues at the 2012 Conference based on the recommendations of the committee. The issues are:

- Report – 2010-2012 Hand Hygiene Committee
- Disseminate the 2010-2012 Hand Hygiene Committee Report
- Re-create – Hand Hygiene Committee
- Limit Hand Hygiene Committee Size

Attachments

1. *2010-12 Hand Hygiene Committee Final Report*
2. *Scientific Regulatory and Behavioral Considerations of Hand Hygiene Regimes*
3. *2010-2012 Hand Hygiene Committee Roster*

COMMITTEE MEMBER ROSTER:

The committee roster is attached. The Co-chairs wish to thank these active committee members for their expertise and dedication to addressing this complex issue.

Respectfully submitted by,

Katherine MJ Swanson and Mark Sampson, Co-chairs for the 2010-2012 Hand Hygiene Committee

Scientific, Regulatory and Behavioral Considerations of Hand Hygiene

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ABSTRACT

Addressing the effectiveness of hand hygiene strategies involves scientific, regulatory and behavioral considerations. In the United States, norovirus is the pathogen reported most frequently in outbreaks associated with lapses in hand hygiene; however several bacterial pathogens have also been implicated. Effectiveness of any hand hygiene regimen involves many factors, including the product type (e.g., soap, hand antiseptic), amount applied, application method, duration and pathogen of concern. Handcare products making antimicrobial claims are regulated as drugs in the United States. Through 2011, no antimicrobial hand hygiene products for food handler applications have FDA-approved claims for antiviral effectiveness. However, the antiviral profile of several commercially available products has been assessed in peer-reviewed literature, demonstrating that some products can achieve significant reductions. Hand hygiene behavioral issues involve use of proper procedure and a commitment to perform the task, thus understanding human factors is important to enhance hand hygiene compliance. Behavioral and risk assessment research that evaluates the magnitude of risk reduction achieved by varying forms of hand hygiene actions (i.e., nothing, rinsing, hand sanitizing, washing, or washing and brushing) would be useful to move from an all-or-nothing approach in every situation, to one recognizing that different procedures may be suitable for different situations.

INTRODUCTION

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. In this report, hand hygiene products available to reduce the risk of spreading infectious agents are categorized as:

- handwashing agents (plain soaps or antimicrobial soaps)
- hand wipes (plain and antiseptic) and
- hand antiseptics (antiseptic waterless agents)

Handwashing with plain soap suspends microorganisms and mechanically removes them by rinsing with water. Plain bar soap, foam and liquid preparations are comprised of detergents with surfactant (surface-active agents), which increase the cleaning properties of water and gives the product the ability to remove soil from surfaces, such as human skin. Microbial reduction using plain soap is due to the physical removal of foreign material or microorganisms, not a biocidal effect.

An *antimicrobial soap* combines the cleaning action of plain soap (i.e., physical removal of foreign material) with antiseptic agents that kill microorganisms. The antimicrobial agents used in antimicrobial soaps (e.g., chloroxylenol, quaternary ammonium compounds, chlorhexidine gluconate, iodine/iodophors and triclosan) have an immediate effect that reduces the number of microflora on skin and in certain cases may exhibit residual or sustained activity that continues to reduce the number of microbial flora after the handwash is complete. The effectiveness of these agents is primarily directed toward vegetative bacteria.

Antimicrobial wipes are towelettes or paper towels that are saturated with an antimicrobial solution that has been shown to reduce the numbers of microorganisms on skin. The antimicrobial ingredient is typically isopropyl or ethyl alcohol and/or a quaternary ammonium compound. There are also some specialized products with other antimicrobial ingredients.

Hand antiseptics (also called hand sanitizers) are waterless agents with antiseptic properties that decrease the number of microorganisms present. For the purposes of this paper, hand antiseptics do not require the use of water. Alcohol-based hand antiseptics are the most common type and typically contain

ethanol or isopropanol and may contain n-propanol or a combination of these agents. Hand antiseptics are typically not designed as hand cleansers and thus are usually intended to be used on visibly clean hands as a single application. However, most hand antiseptics contain emollients, emulsifiers and water, all of which can act as cleaning agents when assisted by hand-to-hand rubbing and physical removal with a paper towel, in a manner similar to a hand wipe.

FOODBORNE PATHOGENS ASSOCIATED WITH HAND HYGIENE-RELATED OUTBREAKS

The CDC (*6*) provides a list of infectious diseases that are transmitted through handling the food supply, which is summarized in Table 1 and in Annex 3 Section 2-201.11 of the 2009 Food Code. Two categories are identified – 1) those pathogens that are *often* transmitted by food when handled by an infected person and 2) those pathogens that are *occasionally* transmitted thorough handling by an infected worker but usually transmitted by contamination at the source or in food processing or by non-foodborne routes. Those "often" involving infected workers include pathogens with low infective dose (e.g., the viruses, *Salmonella* Typhi and *Shigella*) and those that are shed in high numbers when an active infection exists (e.g., the viruses, *Staphylococcus aureus* and *Streptococcus pyogenes*). The 2009 Food Code Sections 2-201.12 and 2-201.13 specify exclusion or restriction of food workers from a food establishment when certain diagnoses or symptoms listed in Table 1 exist. Annex 3 of the 2009 Food Code (page 337) specifically notes that "exclusion of food employees exhibiting or reporting diarrhea symptoms is an essential intervention in controlling the transmission of norovirus from infected food employees' hands to RTE food items." This recognizes that even thorough hand hygiene may not be sufficient to prevent transmission of disease when food is handled by symptomatic food handlers.

CDC (*5*) also published foodborne illness contributing factors that were reported for outbreaks occurring from 1998-2002. In that time period, of the 3072 outbreaks for which contributing factors were reported, 25% identified bare-hand contact, 20% identified infected persons and 6% identified gloved-hand contact as factors contributing to these outbreaks. Table 2 summarizes the CDC (*5*) data by etiology for foodborne illness outbreaks reported as being associated with hand contact (with or without gloves) or handling by an infected person as a contributing factor. Norovirus was the dominant etiology for outbreaks involving these contributing factors, and bacterial etiologies were reported for 40% of the bare-

hand contact outbreaks, 35% of gloved-hand outbreaks and 35% of infected person outbreaks involved bacterial agents. Only one parasite (*Giardia intestinalis*) and no chemicals were reported to be associated with hand hygiene related outbreaks in this time period.

It cannot be determined from these data how many outbreaks "involving infected persons or carrier" included symptomatic food handlers, for which handwashing may not be adequate to prevent spread of illness as previously discussed. It is interesting to note that for each of the pathogens listed by CDC as "*often* transmitted through food contaminated by infected persons" (see Table 1), the number of outbreaks reported to be handled by an infected person was frequently much greater than the number involving bare-hand contact. Conversely, for "pathogens *occasionally* transmitted by food contaminated by an infected handler," the number of outbreaks associated with bare-hand contact was higher than the number associated with infected persons handling food.

Vegetative bacterial pathogens are generally more easily inactivated by chemical agents used in antimicrobial hand care products than the viruses and parasites of foodborne illness concern. While bacterial spores are also more resistant than vegetative bacteria, sporeformers of foodborne illness concern must be in their vegetative state and grow in the food to a high level to present a food safety risk. Thus inactivation of spores is not a major concern for hand hygiene in a food handler setting.

This analysis suggests that norovirus is the most common pathogen associated with hand hygiene-related foodborne illness outbreaks. Thus when addressing "the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing," norovirus should be considered.

METHODS TO EVALUATE EFFECTIVENESS OF HAND HYGIENE SOLUTIONS

Ideally, well-controlled and statistically valid epidemiological outcome studies would be available to determine the relative effectiveness of hand hygiene products and regimens. Unfortunately, these types of studies are very rare and pose fundamental design and execution challenges. As a result, the primary methods used to evaluate effectiveness of hand hygiene products are laboratory-based, including *in vivo* (using living subjects) and *in vitro* (not using living subjects) testing, and to a limited extent risk modeling.

The type of test used to evaluate the effectiveness of hand hygiene solutions can have a significant impact on the results generated. Because of this, it is important to understand how a test was conducted when attempting to compare the effectiveness of hand hygiene solutions and it is difficult to compare the results from one study to another. It is important to note that, the most common pathogen associated with transmission of foodborne illness via hands, human norovirus, cannot be cultured in the laboratory. Murine norovirus and feline calicivirus have been used as surrogates to estimate reductions in infectivity, but the scientific debate on the "best" surrogate continues because the mode of inactivation for different antimicrobial agents varies (e.g., *3*, *18*). Currently, human norovirus results can be studied using polymerase chain reaction (PCR) technology, which reflects destruction of ribonucleic acid (RNA) as an indirect measure of loss of infectivity. However, it is possible for a virus to lose infectivity without destruction of RNA.

While standardized methods (e.g., ASTM, EN standards) exist for both *in vivo* and *in vitro* tests, methods used in the literature vary widely in their procedures and approach. This section provides a brief overview of the different types of tests used and the variation that can occur. It is not the intent of this report to recommend any specific type of test.

***In vivo* tests**

In vivo tests evaluate performance of hand hygiene measures using the hands of human test subjects. Many different *in vivo* tests, using a wide variety of methodologies, have been used to evaluate the performance of hand hygiene measures. Key differences include use of an inoculum, handwash technique and sampling method.

Use of an inoculum. In some cases the area being washed is inoculated with a marker organism (e.g., *E. coli*, *Staphylococcus aureus* or *Serratia marcescens*). Although *Serratia* is not commonly found on hands, its red pigment makes it easy to distinguish from background flora when conducting tests. *Serratia* is referred to as a "transient" hand microbe because it is only present for a short time on the hands, typically on the surface of skin. This is in contrast to "resident" hand microbes that are almost always present on hands, sometimes deep in the skin tissue. The use of a marker organism like *Serratia* can help to evaluate the performance of the handwash process on transient rather than resident flora, and to standardize the starting concentration of microorganisms on the skin of the test subjects.

In some *in vivo* tests, no inoculum is used. The level and nature of microorganisms present on human skin varies from person to person and over time for a given individual. These factors must be taken into account when interpreting these test results. Montville and Schaffner (*16*) found that choice of the specific marker organism makes little difference, but that the choice between marker organisms and resident flora has a substantial impact on the results. According to their analysis, this appears to be primarily due to a difference in starting concentration. Quantifying differences is easier when starting with a uniformly high concentration because it helps to keep endpoint numbers above the level of detection.

Handwash technique. Standardized *in vivo* tests use a prescribed handwash method, but not all studies in the literature use standardized test methods. Some allow the test subject to wash their own hands and others have a technician conduct the wash. This can influence the variation observed in procedures practiced by human subjects. More variation is typically observed when each subject performs the hand hygiene procedure.

Sampling method. There are many ways to enumerate the organisms remaining on the skin after washing. For example, in the *glove juice test*, the test subject dons disposable gloves, a sampling fluid is added to the gloves, the subject's hands are massaged and the microbes in the sampling fluid in the glove are enumerated. Other sampling techniques include collecting wash fluid into basins and enumerating organisms in the collected fluid, rubbing fingertips in Petri dishes containing a sampling fluid, placing a cylinder on the skin, adding a sampling fluid to cylinder and scrubbing the skin using a sterile swab, or simply pressing the finger tips to an agar plate.

The large inherent variability with any *in vivo* test coupled with differences in enumeration methodology leads to one of the major disadvantages of *in vivo* testing – conflicting, inconsistent and often non-comparable results. The variability also contributes to another disadvantage – cost. Multiple subjects are needed to estimate variability and it is not uncommon for a single test on a single subject to cost in excess of a thousand dollars. The variability of *in vivo* testing often requires high numbers of test subjects to statistically demonstrate differences, thus studies can be quite expensive. Use of pathogens for *in vivo* testing presents ethical issues that must be carefully considered.

Despite the disadvantages associated with *in vivo* hand hygiene efficacy testing, an advantage is that *in vivo* testing may provide information on how effectively a hand hygiene procedure will reduce

microbial levels on hands in actual use. However, *in vivo* tests described do not prove that a tested hand hygiene procedure will actually prevent or reduce illness in the real world. At best, it provides a surrogate endpoint for the hand hygiene procedure's ability to prevent or reduce the risk of disease. Clinical trials to evaluate prevention of disease are rarely, if ever, performed.

In vitro tests

In vitro studies do not involve human or animal test subjects. The most common type of *in vitro* test for hand hygiene products is the suspension or "time-kill" test. In these studies, the test microorganism is suspended in a solution containing the test product. After a specified exposure time, an aliquot of solution is removed, the antimicrobial activity is typically neutralized and any surviving microorganisms are determined. As with *in vivo* tests, many variables must be considered for *in vitro* testing, including product and test organism concentrations, types of organisms, the presence and concentration of interfering substances such as soil or hard water, the use of different temperatures, different neutralizer systems and various exposure times. Typically, greater reductions are observed for *in vitro* tests than for *in vivo* tests because of the direct exposure of the microorganism to the antimicrobial agent. Even seemingly trivial variations in test procedures, such as growing the inoculum on solid versus liquid media or the number of times the test cultures have been transferred, can affect the results. As with *in vivo* testing, this can make comparison of results between different studies difficult.

An advantage of *in vitro* tests is that they are relatively easy and inexpensive to do. This makes it easier to study more organisms and to collect sufficient replicates in a reproducible manner to demonstrate statistical significance even when the data are variable. The largest drawback of *in vitro* testing is that they are further removed from the clinical endpoint than *in vivo* tests. Just as an *in vivo* test is not a perfect predictor of a clinical endpoint, so an *in vitro* test is not a perfect predictor for an *in vivo* result.

The CFP 2010-2012 Hand Hygiene Committee summarized advantages and disadvantages of *in vivo* and *in vitro* efficacy testing in Table 3. Both types rely on enumeration of viable microbial targets to measure the extent of reduction after a treatment, which is possible for many pathogens involved in foodborne illness transmitted via hands, but currently not human norovirus.

EFFICACY OF HAND HYGIENE APPROACHES AT REMOVING PATHOGENS AND REDUCING RISK

As discussed above, the wide variety of test methods used to study hand hygiene procedures makes it very difficult to compare the efficacy of handwashing to alternative hand hygiene regimes. Recent peer-reviewed papers summarize much of the available science on this topic. Todd et al. (*23*) provide an extensive review of nearly 250 publications addressing the impact of washing and drying of hands to reduce microbial contamination. Montville and Schaffner (*15*) looked more specifically at a quantitative comparison of antimicrobial versus non-antimicrobial hand soaps and evaluated the impact of methodological differences in the extent of reduction achieved. Both of these reviews reported that many factors influence the efficacy of handwashing, including the type and volume of soap used, friction, and duration of washing. Some of the findings of these reviews include:

- Using <1mL portion of hand soap appeared to be less effective than using 1ml or more.
- Vigorous washing is an important factor in that it removes or loosens microorganisms with mechanical action.
- On average, use of antimicrobial soaps results in fewer microorganisms on hands.
- Todd et al. (*23*) found that duration of handwashing is an important factor and duration of at least 15 seconds is needed. They concluded that while washing up to 30 seconds may provide somewhat greater microbial removal from hands, this further reduction may not be meaningful as it involves removing resident microorganisms that are not generally associated with transmission of foodborne illness. Various studies have indicated that the average wash duration by the general public and food handlers is about 10 seconds, in spite of the 15 second recommendations.
- Frequency of handwashing is also an important factor. Several studies suggest that while most individuals (>85%-95%) self-report washing hands after using the bathroom, observational studies indicated that the frequency (particularly among men) was considerably lower (ca. 70%). In food settings the frequency of handwashing at appropriate times may be as low as 30% during peak business hours. However, training and specific interventions could increase that to over 50%.
- Temperature has relatively little impact on the efficacy of handwashing. Temperatures that are too high (over 110°F) increase the risk of skin damage and reduce handwashing compliance.

- Drying, particularly using towels, removes ca. 90% of the organisms that remain after washing. Removal of microorganisms by air dryers is more questionable. Moreover, the time needed to dry hands with many air drying systems is often longer than towel drying, so hands often remain wet for people who do not wait. Wet hands have been shown to harbor and transfer organisms more easily than dry hands. There is also some concern that the airflow from certain air driers may be a source of contamination.

Todd et al. (*24*) provides a recent comprehensive, peer review of waterless hand antiseptics relevant to food handlers, including 150 references. They found that product type, concentration, volume and contact time influenced results. They concluded that "alcohol-based antiseptics should be combined with regular handwashing schedules and should not replace handwashing and drying or the use of fingernail brushes." In regard to wiping methods, they indicated that food handlers may ignore some of the steps in two or three stage procedures, thus they did not recommend such procedures in general. However, they also stated that "because [two or three stage] wipe methods tested have been more effective than soap and water, they should be considered feasible, practical hand hygiene interventions for remote food service situations or where water availability is limited."

The effectiveness of hand antiseptics against human norovirus was questioned by Todd et al. (*24*) based on the available literature at the time of their review. However, Park et al. (*18*) compared the effectiveness of seven hand antiseptics against murine norovirus (MNV) and feline calicivirus (FCV) as potential surrogates for human norovirus. One ethanol-based and one triclosan-based hand antiseptic reduced both MNV and FCV by >2.6 and $\geq$ 3.4 logs, respectively, using *in vitro* infectivity test methods. Four products demonstrated effectiveness against either MNV or FCV. The chlorhexidine product was not effective against either virus. Thus effectiveness varied among the different hand antiseptics. Liu et al. (*14*) studied inactivation of human norovirus using the *in vivo* finger pad test, reporting log reductions of RNA from 0.10 to 3.74 for six commercially available hand antiseptic products. This study also illustrated the large variation that can be observed among hand antiseptic products. These two studies did not include a measure of the reduction that could be achieved with handwashing treatments. Further, some of the products studied may not have "Food Code" compliant ingredients.

A number of *in vivo* studies have included handwashing and hand antiseptics in the same investigation. Some of these studies concluded that hand antiseptics were ineffective at reducing microbial levels on hands while others suggested that they are effective in either reducing numbers or reducing transfer of infection. Two examples of studies that concluded hand antiseptics were ineffective include the following.

- Courtenay et al. (*7*) compared washing with soap and water, rinsing with either warm or cool water, and ethanol-based hand antiseptics for reducing *E. coli* on hands. The soap and water washing demonstrated >2.6 log reduction, which was significantly greater than solely rinsing with warm water (2.2 log reduction), rinsing with cool water (1.5 log reduction) or ethanol-based hand antiseptic (0.2-0.7 log reduction).
- Lin et al. (*13*) studied the effect of six handwashing techniques on *E. coli* and FCV levels inoculated under natural and artificial fingernails. Washing techniques included use of tap water alone, soap and water, antimicrobial soap, hand antiseptic, soap plus hand antiseptic, and soap plus nailbrush. Only reductions in counts under the fingernails were reported. For *E. coli,* no significant difference was noted between any of the washing techniques except washing with soap using a nailbrush. The nailbrush technique reduced the *E. coli* population approximately 2.5 – 3 logs while other techniques reduced the population 1 – 2 logs. For FCV, soap with nailbrush washing also significantly reduced the population greater than 2 logs for both nail types. The hand antiseptic treatment resulted in a significantly lower reduction of FCV for both nail types (<1 log) than other treatments. Interestingly, there was no significant difference between log reductions of either *E. coli* or FCV from finger nails when tap water alone was compared to any of the handwashing methods using soap without a nail brush.

Conversely, a number of studies concluded that the use of hand antiseptics reduced organisms on hands the same or better than washing alone. For example:

- Brown et al. (*2*) evaluated reductions of microbial counts on uninoculated hands following washing with plain soap, antimicrobial soap or use of an alcohol-based hand antiseptic. Fingers were touched to agar plates before and after treatment, and qualitative assessment of the number of

bacteria present was determined. The alcohol-based hand antiseptic reduced the relative counts significantly more than the plain or antimicrobial soap treatments.

- Schaffner and Schaffner (*22*) determined the effectiveness of an alcohol-based hand antiseptic on hands contaminated with a nonpathogenic surrogate for *E. coli* O157:H7, where the source of the contamination was frozen hamburger patties. The effectiveness of the hand antiseptic was similar to that for handwashing and glove use previously reported. The person-to-person microbial reduction variability from hand antiseptic use is similar to published data for glove use and was less variable than published data on handwashing effectiveness.
- Paulson (*19*) studied the reduction of *Serratia marcescens* for hand hygiene regimens including plain lotion soap, antimicrobial lotion soap, alcohol-based hand antiseptic, and combinations of these using the glove juice method. The alcohol treatment alone or in combination with handwashing, reduced the population almost 4 logs. The soap treatments alone provided a 2 – 3 log reduction in *Serratia* counts and there was no statistically significant difference between antimicrobial and plain soap treatments, although the antimicrobial treatment was consistently higher. A combined treatment was recommended.
- Michaels et al. (*15*) studied the impact of varying volumes of alcohol-based hand antiseptic on reducing inoculated transient microflora from previously washed hands, as well as the impact of the hand antiseptics on reducing levels of transient flora from under finger nails. Levels of hand antiseptic at 3mL or 6mL resulted in a significant reduction of transient flora over washing alone, while lower levels did not. Consistent with the results reported by Lin et al. (*13*), washing hands with a nail brush was required for significant reductions under fingernails.
- Restaino and Wind (*20*) reviewed literature available at the time and reported that appropriate alcohol preparations were more effective in reducing microbial counts that handwashing alone. They also commented on the need to use products that are non-irritating to the skin.

It is clear from the studies summarized that there is a large amount of variability between and within studies with behavioral aspects frequently compounding interpretations of data. Montville and Schaffner (*16*) concluded that “The inherent variability in handwashing seen in the published literature

underscores the importance of using a sufficiently large sample size to detect difference when they occur."

Few studies have attempted to assess the effect of hand antiseptics from a risk reduction perspective. Bidawid et al. (*1*) studied the transfer of feline calicivirus (FCV) from fingertips to a variety of surfaces. Finger pads were contaminated with FCV, allowed to dry, and then touched to various surfaces to evaluate the percent of transfer. Results (see Figure 1) demonstrated that treating hands with water, soap and water, or alcohol significantly reduced the percentage transferred, with less than 1% transferred following handwashing or a water rinse, ca. 1-3% transferred after treatment with alcohol, and 13-48% transfer if no hand hygiene intervention was used. While alcohol treatments were not as effective as soap and water or water alone, all of these hand hygiene interventions were significantly more effective than no hand hygiene treatment at all.

REGULATORY REQUIREMENTS RELATED TO EFFICACY OF HAND HYGIENE PRODUCTS

Approval process

Hand antiseptics that meet specific criteria described in Section 2-301.16 of the 2009 Food Code may be applied "only to hands that are cleaned as specified under Section 2-301.12" in retail and foodservice establishments. Annex 3 – Section 2-301.16 of the 2009 Food Code explains that hand antiseptics are drug products that must comply with FDA Center for Drug Evaluation and Research (CDER) regulations, and provides more information on where approved products are listed as well as other requirements not related to the effectiveness of the products against foodborne pathogens.

As drugs, hand antiseptics must be demonstrated to be safe and effective. This can be accomplished by one of two means:

1. The hand antiseptic may be approval by FDA under a new drug application (NDA). Drugs approved through this route are listed in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book" (*11*).
2. The hand antiseptic may have an active ingredient identified by FDA (*9*) in the Tentative Final Monograph (TFM) for Health-Care Antiseptic Drug Products for OTC Human Use in the

handwash category, be listed with FDA as a drug, and comply with other relevant drug requirements.

The TFM specifies the active ingredients that can be contained within handwash products, as well as labeling, product testing and other general requirements. The *in vitro* and *in vivo* testing provisions in the TFM are well detailed and list specific organisms that products can make claims against. There is also a clinical study requirement depending on the final claim. The TFM antimicrobial spectrum tests determine the efficacy of products using Minimum Inhibitory Concentration (MIC) against 25 laboratory strains and 25 fresh clinical isolates included in a specific list of vegetative bacteria and the yeast *Candida*. Time kill tests are also required using "standard ATCC strains identified for the MIC tests. The TFM also requires an *in vivo* handwash assay using *Serratia* as the test organism. There are currently no virus tests listed on the TFM and therefore antiviral hand hygiene claims are not available through the TFM, despite the fact that as noted above, norovirus is by far the pathogen reported most frequently in outbreaks where inappropriate application of hand hygiene regimens were noted.

For hand antiseptics, the TFM classifies alcohol 60–95% and povidone iodine 5–10% as Category 1 – Generally Recognized as Safe and Effective. Many potential active ingredients for hand antiseptics including triclosan, triclocarban, benzalkonium chloride, benzethonium chloride and parachlorometaxylenol, are classified in Category III, requiring more data for final determination on safety and efficacy. Pending a Final Monograph, products based upon ingredients classified as Category III can be marketed provided they meet the performance testing requirements of the TFM. Premarket approval through the New Drug Application (NDA) process is required for products that contain active ingredients not listed in the TFM.

FDA guidance on hand antiseptics

While the CDC recommends alcohol-based hand gels as a suitable alternative to handwashing for health care personnel "*if hands are not visibly soiled*" (*4*), FDA (*10*) clarified that this recommendation is not applicable to food establishments. This exclusion is based on the differences in controlling common nosocomial pathogens in health care settings and common foodborne pathogens in retail and foodservice settings. FDA (*10*) also highlights that the pathogens most commonly transmitted by hands in health care

settings differ from those in retail and food service settings, and the types and levels of soil on the hands of health care workers differ from foodservice/retail workers. The FDA (*10*) factsheet concluded:

> "Proper handwashing, as described in the Food Code continues to serve as a vital and necessary public health practice in retail and food service. Using alcohol gel in place of handwashing in retail and food service does not adequately reduce important foodborne pathogens on foodworkers' hands. Concern about the practice of using alcohol-based hand gels in place of handwashing with soap and water in a retail or food service setting can be summarized into the following points:
>
> - "Alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain nonenveloped (nonlipophilic) viruses; and
> - "Ingredients used in alcohol-based hand gels for retail or food service must be approved food additives, and approved under the FDA monograph or as a New Drug Application (NDA); and
> - "Retail food and food service work involves high potential for wet hands and hands contaminated with proteinaceous material. Scientific research questions the efficacy of alcohol on moist hands and hands contaminated with proteinaceous material."

It is important to note that even in health care settings, alcohol-based hand gels are to be used as an alternative to handwashing "only if hands are not visibly soiled" according to CDC (*4*).

State and local jurisdictions

At least one regulatory jurisdiction allows the use of alternatives to Food Code compliant handwashing in certain settings where water is limited (*17*). It is important to understand the specific situations where such alternatives are allowed. Research on the impact of adoption of alternative procedures on hand hygiene compliance and potentially case control studies to investigate public health outcomes of such programs would be useful to further inform the discussion on alternatives to handwashing.

Regulatory status summary

Hand care products with antimicrobial claims are considered to be drugs, thus approval and registration are under the regulatory jurisdiction of FDA's Center for Drug Evaluation and Research. Antiviral hand hygiene claims are not available through the Tentative Final Monograph and to date no US

antimicrobial hand care product with virucidal claims for food handler application has been approved through the New Drug Application (NDA) process. As a drug, antimicrobial hand care products should be used following label instructions. FDA's Center for Food Safety and Applied Nutrition provides guidance through the *Food Code* on when and where hand hygiene practices should be applied.

COMPLIANCE ISSUES AND BEHAVIORAL ASPECTS OF HAND HYGIENE

As previously discussed, many factors such as time, temperature, friction, product volume, product type, etc., influence the effectiveness of hand hygiene regimes. At the same time, motivating food workers to apply proper hand hygiene procedures at the right time is an important food safety need. Thus, procedures are important for effective hand hygiene. Operators make their final choice of protocols based on the requirements in the Food Code guidance and their risks, based on their customer mix, menu, facilities and system control. There is no one-size-fits-all protocol for the wide range of food service and retail establishment practices that exist. Procedures should be selected to assure their minimum cleanliness levels are maintained.

The Committee identified barriers to proper handwashing behaviors by discussing the question "If hand hygiene (hand antiseptic) was allowed in place of handwashing, would there be a significant increase in desired behaviors, either for use: 1) in place of handwashing or 2) in addition to handwashing?"

For this exercise, the Committee considered only behaviors and *not* necessarily effectiveness. The Committee discussed which factors encourage or discourage desired handwashing behaviors for both traditional soap and water wash, and use of approved hand antiseptic. Information reported in Tables 4-6 is based on expertise of the Behavior Sub-committee of the CFP Hand Hygiene Committee, with review by the full committee. No quantitative or qualitative data were reviewed during the Sub-committee's discussion.

Factors that may either encourage or discourage *how* handwashing or hand antiseptic behaviors performed are listed in Table 4. Many of the barriers apply equally to how hand hygiene is performed for either handwashing or hand antiseptic use. Perceived speed of application for use of single step hand antiseptic applications may remove a potential barrier that exists for handwashing. Hand antiseptics may

also remove barriers associated with proximity to the supplies need to perform the task. While the issue of training applies equally to both types of hand hygiene, it was noted that much emphasis has been placed on the proper handwashing technique. This may vary for different hand antiseptic applications and may be less obvious (e.g., single application versus two-step process; need to fully cover fingers, finger tips and nail area).

Factors that may either encourage or discourage *when* desired handwashing or hand antiseptic behaviors are appropriate are listed in Table 5. Again, many potential barriers apply equally to both hand hygiene regimens. The perceived need is an area where differences exist. Some workers wash their hands when they are heavily soiled from a self-protection standpoint. Conversely, single step hand antiseptics are typically designed to be used on visibly clean hands; therefore the visual cue of hands looking dirty does not apply. The sub-committee thought that there were opportunities to reduce confusion on when to wash hands or use hand antiseptics, for example when used with gloves (see the section on when alternatives may be appropriate).

Factors that may either encourage or discourage regarding *why* to perform hand hygiene are listed in Table 6. Communication of the reasons why hand hygiene should be performed is very important for employee acceptance and increases the likelihood that proper hand hygiene will be performed. Most of the factors that can encourage hand hygiene behaviors apply equally to both washing and antiseptic use. However, explaining why there are different considerations for when hand antiseptics are appropriate, may cause confusion and thus create a barrier to compliance. This type of communication must be planned carefully.

PUBLIC HEALTH BENEFIT OF IMPROVED HAND HYGIENE COMPLIANCE

Several studies have evaluated the use of alcohol-based hand sanitizers in reducing infection rates in a variety of settings, including schools, day care settings, hospitals and long term care facilities. Two examples described below to illustrate the type of information that can be gained.

- Hilburn et al. (*12*) studied use of alcohol-based hand sanitizers in acute care facilities and reported a 36.1% decrease in infection rates when alcohol-based products were used. Key factors cited to contribute to this improvement included enhanced effectiveness against causative agents and

increased hand care compliance because products were easy to use and gentle to the skin, which removes a barrier for hand hygiene application. The CFP Hand Hygiene Committee notes that these results may not be immediately transferable to food handling settings because the agents, and likely the hand sanitizer products, differ. However, research on compliance in foodservice settings may be beneficial to determine if a similar improvement is noted.

- Sandora et al. (*21*) studied use of alcohol-based hand sanitizer coupled with hand hygiene education with children enrolled in 26 child care centers. They monitored transfer of secondary illness to people in the home. The CFP Hand Hygiene Committee recognizes that the primary mode of transmission in this study is person-to-person and that the pathogens involved may not necessarily be foodborne pathogens. However, the secondary illnesses were significantly lower for families with alcohol-based hand sanitizers in the home compared to control families.

While the Hilburn et al. (*12*) "clinical end point" data demonstrate a benefit from hand sanitizers in clinical settings, the study was confounded with many other factors such as training, other interventions and increased handwashing. Therefore it is difficult to determine the effect of the hand sanitizers alone. Respiratory illness and gastroenteritis are seasonal events that occur with some frequency in institutional type settings. Foodborne illness outbreaks are less frequent thus conducting these types of studies specifically for food handing considerations will be problematic.

Settings where alternatives to handwashing may be appropriate

The Committee considered the information above and practical aspects of preparing, holding and serving food in its consideration of identifying settings where alternatives to handwashing are appropriate. From a practical and behavioral matter, the Committee thought it useful to clarify situations when and where alternatives to handwashing, such as hand antiseptics are not the best option. These include:

- Anywhere there is a properly functioning hand sink
- After toilet use
- At the start of a shift
- After lunch break
- Between handling raw and RTE foods
- After sneezing into hands

- If person has cuts, skin infections
- When hands look or feel soiled

The Committee also recognized that there are situations where alternatives to handwashing may be appropriate as a risk reduction strategy. For example, when hands are not visibly soiled hand antiseptics may *potentially* be an option:

- Between glove use
- After touching hair
- After coughing / sneezing / drinking
- In areas where there is environmentally no water
- In water outages / boil water situations
- During temporary events
- In farm stands
- For mobile vendors

The Committee recognized that there are water-short situations where the specific dual step hand cleanser-sanitizer protocol (*8*) may be a potential alternative to water/soap handwashing as a risk reduction strategy. Some may question if providing an alternative may drive operators to use hand-antiseptics in place of traditional handwashing. The product costs of alcohol washing versus water washing will strongly favor traditional handwashing where running potable water is conveniently available. The committee was unable to make specific recommendations. However, given time and integration of scientific and behavioral considerations, specific recommendations may be possible using a risk management approach.

RESEARCH NEEDS

Much of the research conducted on hand hygiene is done in areas other than food-related settings. There is a need for such studies to be conducted to inform decision making. Potential questions that could be addressed through research include:

- If hand antiseptic use was allowed in lieu of soap and water handwashing, would there be a significant increase in desired behaviors and would this reduce foodborne illness?

- Does providing options (soap and water vs. alternative hand hygiene methods) in foodservice or retail settings increase real-world compliance? If so, what is the public health benefit?
- Can studies on hand hygiene behaviors in hospitals be extrapolated to foodservice environments?
- What handwashing / hand hygiene options increase frequency of use?
- Why are food handlers not washing their hands?
- What is the range of temperatures that are considered to be comfortable for handwashing?
- Can new risk assessment and risk management models be applied to hand hygiene in food services settings to quantify the changes in risk when different interventions are applied?
- Can case-control epidemiological studies be conducted to study hand hygiene related foodborne illness outbreaks comparing regulatory jurisdictions allow the use of alternatives to handwashing, to those that do not?
- What is the clinical endpoint effect of various hand hygiene practices in a food setting?

Data supported answers to the above questions would help inform decision making on proposing alternatives to handwashing in certain situations to protect public health.

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599 **Table 1** CDC* listing of infectious and communicable diseases transmitted through handling the food

600 supply

Category	Agent	Modes of transmission	Symptoms that indicate infection that could be transmitted to others through food
Pathogens *often* transmitted by food contaminated by infected persons who handle food	Viruses - Norovirus - Hepatitis A virus - Sapovirus Bacteria - *Salmonella* Typhi - *Shigella* species - *Staphylococcus aureus* - *Streptococcus pyogenes*	• Failure of food handlers to: - wash hands, - wear clean gloves, or - use clean utensils • Also transmitted person to person	• Diarrhea • Vomiting • Open skin sores, boils • Fever • Dark urine • Jaundice
Pathogens *occasionally* transmitted by food contaminated by infected persons who handle food, but *usually* transmitted by contamination at the source or in food processing or by non-foodborne routes	Bacteria - *Campylobacter jejuni* - Enterohemorrhagic *E. coli* - Enterotoxigenic *E. coli* - Non-typhoidal *Salmonella* - *Vibrio cholera* - *Yersinia enterocolitica* Parasites - *Cryptosporidium* species - *Entamoeba histolytica* - *Giardia intestinalis* - *Taenia solium*	• Usually intrinsically contaminated or cross-contaminated during processing or preparation • Occasionally transmitted by infected food handler with acute diarrhea • Bacterial pathogens often require multiplication in the food before they will cause disease	• Acute diarrheal illness

601 *Adapted from: CDC (*5)*

602 **Table 2** Hand contact contributing factors reported for foodborne illness outbreaks 1998-2002 in the

603 United States*

Etiology		Bare-hand contact n (% of confirmed)		Gloved-hand contact n (% of confirmed)		Infected person or carrier n (% of confirmed)	
Bacterial	Non-typhoidal *Salmonella*	37	(15)	4	(7)	64	(18)
	Staphylococcus aureus	17	(7)	5	(9)	30	(9)
	Shigella	12	(5)	3	(5)	16	(5)
	Escherichia coli	12	(5)	1	(2)	6	(2)
	Clostridium perfringens	8	(3)	2	(4)	2	(1)
	Campylobacter	5	(2)	2	(4)	1	(<1)
	Vibrio parahaemolyticus	2	(1)	1	(2)	1	(<1)
	Bacillus cereus	1	(<1)	1	(2)	1	(<1)
	Streptococcus	0	(0)	0	(0)	1	(<1)
	Total Bacterial	***94***	***(40)***	***19***	***(35)***	***122***	***(35)***
Viral	Norovirus	129	(54)	30	(55)	202	(58)
	Hepatitis A	13	(5)	4	(7)	16	(5)
	Total Viral	***142***	***(59)***	***34***	***(62)***	***218***	***(62)***
Parasitic	*Giardia intestinalis*	1	(<1)	0	(0)	2	(1)
Multiple etiologies		2	(1)	1	(2)	7	(2)
Total confirmed etiology		**239**	**-**	**55**	**-**	**349**	**-**
Unknown etiology		**526**	**-**	**132**	**-**	**251**	**-**

*Adapted from: CDC (*4*)

604

605 **Table 3** Advantages and disadvantages of *in vivo* and *in vitro* tests to demonstrate efficacy of hand
606 hygiene solutions.

Test method	Advantages	Disadvantages
In vivo (uses human subjects)	• Closer to clinical endpoints • May demonstrate impact of full hand hygiene procedure (i.e., rinsing, friction, duration)	• Significant person-to-person variation • Expensive and difficult to conduct • Concerns with human exposure to certain pathogens
In vitro (does not use human subjects)	• Typically less variable than *in vivo* methods • Can study more organisms in a controlled manner • Less expensive	• Further removed from clinical endpoints

607

608 **Table 4** What encourages / discourages desired behaviors regarding ***how*** to perform hand hygiene?

609 (Note: effectiveness of the application is not considered in this comparison)

Potential barriers	**Handwashing**	**Hand antiseptic or alternative**
Water temperature	Too hot or cold discourages Just right encourages	Not applicable
Type of product (Like or dislike scent, feel etc.)	How well does it lather? Does it cause dry hands or maintain skin health? Does it sting?	Does it make hands sticky? Does it cause dry skin or maintain skin health? Does it sting?
Towel vs. hand dryer	Slow drier discourages Empty or malfunctioning towel dispensing discourages	Drier not applicable. Towel may be needed (wipes or two-step procedure), thus availability or malfunctioning situations are similar.
Urgency / pressure / motivation	Must go to sink to perform	Can be applied “on the go” for a one step process
Proximity of product and equipment, ease of reaching	Need sink (plumbing), soap, drying equipment	Portable or easy installation in multiple locations. Potentially closer to work station.
Training (need to know how, when and why)	Applies equally. Potentially more material available on procedure.	Applies equally
Supplies available and working	Applies equally	Applies equally
Laziness	Applies equally	Applies equally
Ease – automated vs. manual. Method of dispensing	Automatic options may encourage or discourage. Must be functioning	Automated dispensing quicker when functioning. Must be functioning.
Time	Takes too long (perception)	Fewer steps for single application
Double handwashing	Takes too long	Applicable to two-step process
Policy – management commitment and enforcement	Applies equally	Applies equally
Job aids – detailed instructions	Applies equally	Applies equally
Hand hygiene signs	Applies equally	Applies equally
Behavior modeled by co-workers and management	Can motivate or de-motivate	Can motivate or de-motivate
Requirement for employment	Applies to both	Applies to both
Existence of regulations	Encourages policy, not employees	Currently hinders adoption
Visible / type of soil	Adjust to soil type	Appropriate for visibly clean hands only. May be unpleasant on heavily soiled hands
Pleasant experience	Applies equally	Applies equally

610

611 **Table 5** What encourages / discourages desired behaviors regarding ***when*** to perform hand hygiene?

612 (Note: effectiveness of the application is not considered in this comparison)

Potential barriers	**Handwashing**	**Hand antiseptic or alternative**
Perceived need	Wash when hands look or feel dirty. Workers wash to protect themselves (e.g., after clearing a messy table)	Perceived need for single step may change because this should be done on clean hands. Likely the same for a two step process
Touch points / requirements (too many)	Applies equally	Applies equally
Policy– management commitment and enforcement	Applies equally	Applies equally
Training – urgency	Applies equally	Applies equally
Focus on the why	Applies equally	Applies equally
Clarifying specifics in Food Code / misinterpretations	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements and interpretation of regulations
In concert with glove use / confusion with glove use	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements
Clarifying examples	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements
Motivation	Applies equally	Applies equally
Proximity / ease	Need sink (plumbing), soap, drying equipment	Portable or easy installation in multiple locations. Potentially closer to work.
When need to wash – settings / relevance	When they look or feel dirty	Apply to visibly clean hands
Requirement to stay employed	Applies equally	Applies equally
Visibility of kitchen	Depends on customers – are they more interested in the food techniques or hygiene?	Less time away from food prep
Pleasant experience (some products make hands feel and / or smell good)	Applies equally	Applies equally
Hand antiseptic is a second barrier	May be tempted to skip washing	May do it more often if it is quicker

613

614 **Table 6** What encourages / discourages desired behaviors regarding ***why*** to perform hand hygiene?

615 (Note: effectiveness of the application is not considered in this comparison)

Potential barriers	**Handwashing**	**Hand antiseptic or alternative**
Buy-in / encouragement	Handwashing is a recognized foundation for food safety and healthy living.	Explaining the differences of when handwashing is appropriate versus when alternatives are appropriate may complicate the message and confuse the "Why"
Expected practice / culture of hand hygiene	Applies equally	Applies equally
Not a lot of training tools; print training vs. activity based	Applies equally	Applies equally
Trainer effectiveness	Applies equally	Applies equally
Oral vs. written	Applies equally	Applies equally
Proximity	Getting staff to the sink	Getting to the product
Lack of motivation	Applies equally	Applies equally
Expectation of customers	Visibility of kitchen	Visibility of kitchen
Pleasant experience	Applies equally	Applies equally
Location / availability of supplies	Applies equally	Applies equally, but may be easier to have sanitizer available in some locations
Equipment working correctly	Applies equally	Applies equally

616

617 **Figure 1** Feline calicivirus transfer from inoculated finger pads to ham, lettuce and stainless steel

618 surfaces after treatment with various hand hygiene regimens. Adapted from Bidawid et al. (*1*)

619

Committee Name: 2010-12 CFP Hand Hygine Committee

1-Dec-11

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Conference for Food Protection
2012 Issue Form

Internal Number: 075
Issue: 2012 III-002

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

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Title:
Disseminate the Outcome of 2010-2012 Hand Hygiene Committee

Issue you would like the Conference to consider:
The 2010-2012 Hand Hygiene Committee submits "Scientific, Regulatory and Behavioral Considerations of Hand Hygiene Regimes." This was extracted from the 2010-2012 Hand Hygiene Committee Report, modified and formatted for publication in a peer reviewed journal and for potential posting on the CFP website after publication. Authors include Chairs and Co-chairs of the 2010-2012 Hand Hygiene Sub-committees, and the acknowledgement section recognizes committee members.

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.

Effective decision-making on appropriate approaches for removal or reduction of potential pathogens from hands involves consideration of the scientific aspects on what can be achieved, regulatory aspects of approaches that are approved for use, and behavioral aspects of approaches that will be implemented by food handlers. Concise information on each of these elements is not currently available in one document, thus broad dissemination of such information would enable all stake holders to make better informed decisions on hand hygiene approaches, as well as identifying areas where research is needed.

The 2010-2012 Hand Hygiene Committee also believes that listing the Committee as a co-author would make a broader audience aware of the collaborative nature of the work of the Conference for Food Protection, potentially recruiting more food safety professionals to become involved in CFP work to enhance public health.

Recommended Solution: The Conference recommends...:
Approval of the document generated by the Committee titled: *Scientific Regulatory and Behavioral Considerations of Hand Hygiene Regimes,* and*:*

- Submission to a peer reviewed journal, with the 2010-2012 Hand Hygiene Committee listed as a co-author, to make a broader audience aware of the collaborative nature of the work of the Conference for Food Protection.
- Posting the document on the CFP website as an educational tool that illustrates the interaction of scientific, regulatory and behavioral considerations related to alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses. When and if the document is accepted in a peer reviewed journal, request to replace the current document with the peer reviewed version.

Attachments:

See *Report* - (document attached to Issue titled: ***Report - Hand Hygiene Committee***, as Attachment #2)

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Conference for Food Protection
2012 Issue Form

Internal Number: 007
Issue: 2012 III-003

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

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Title:
Clarification of Section 3-301.11(D) Preventing Contamination from Hands.

Issue you would like the Conference to consider:
Allow an exception for bare hand contact with ready-to-eat foods immediately before the food is heated as a sole ingredient to a temperature of at least 63°C (145°F). Also, change the current exception for bare hand contact with ready-to-eat food as the ready-to-eat food is being added to another ready-to-eat food to require a kill step temperature of 63°C (145°F).

Public Health Significance:
The 20011 Supplement to the 2009 FDA Food Code added language with the specific intent to allow pizza operators to have bare hand contact with ready-to-eat (RTE) pizza toppings placed on a pizza prior to cooking. Commercially prepared pizzas are heat treated to approximately 165°F -170°F - which is at or slightly above minimum cook temperatures required in paragraphs 3-401.11(A)-(B) or section 3-401.12.

When this additional language was added, there was no intention to create an additional minimum time/temperature cooking parameter or alter the minimum time/temperature parameters for cooking raw animal foods. However, since the Food Code only addressed heat treatment of RTE food in two situations - cooking plant food for hot holding and reheating food for hot holding - the creation of an additional time/temperature cooking parameter to address the added risk of bare hand contact with RTE foods not added to raw animal foods was unavoidable.

If there is scientific importance that makes it necessary to heat RTE ingredients touched by bare hands to 165°F, then all RTE ingredients touched by bare hands should be heated to this same temperature. Otherwise, the RTE ingredients added to food that is not a raw animal product should only be required to be heated to the lowest minimum time/temperature cooking requirement present in paragraph 3-401.11(A)(1) (145°F for 15 seconds).

Additionally, heat treatment of RTE foods that have had bare hand contact are only addressed when the RTE food is added as an ingredient - not when it is simply touched prior to heating on its own (e.g., a washed raw potato placed on a baking sheet). This is an oversight that should be addressed. Allowing bare hand contact with RTE foods heated only immediately prior to heating will ensure the touched food item will not mistakenly be

included in some other menu item that is not subsequently heat treated. Also, restricting the bare hand contact to immediately before heating will reduce the likelihood of the production of Staphylococcus aureau enterotoins due to bare hand contact.
Annex 3 - 3-401.13 and 3-301.11 suggest that RTE foods cooked to the minimum time/temperature required by the Food Code, in combination with proper handwashing and adherence to employee health requirements, provides an adequate means of interrupting disease transmission - whether added as an ingredient or heated alone. There is no indication that bare hand contact with RTE food that will not be added to raw animal food poses a greater risk and therefore requires a higher level of heat treatment than RTE foods added to raw animal foods.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 3-301.11(D), be amended as follows (new language shown with underline):
(D) *Paragraph (B) of this section does not apply to a food employee that contacts exposed, ready-to-eat food with bare hands:*
(1) Immediately prior to heating the ready-to-eat food to a temperature of at least 63ºC (145ºF) if heated as a sole ingredient; or
(2) At the time the ready-to-eat food is being added as an ingredient to a food that:
(a) C*ontains a raw animal food and is to be cooked in the food establishment to heat all parts of the food to the minimum temperatures specified in ¶3-401.11(A)-(B) or §3-401.12; or*
(b) Does not contain a raw animal food but is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 63ºC (145ºF).

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Conference for Food Protection
2012 Issue Form

Internal Number: 101
Issue: 2012 III-004

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

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Title:
Double glove use or glove changing in relation to handwashing

Issue you would like the Conference to consider:
The conditions under which double gloving or glove changing without handwashing would be allowed/acceptable to ensure proper food handling.
Due to current wording and/or interpretations of the 2009 FDA Food Code, the determination has been verbally made that double gloving is allowed even between raw food handling and ready to eat food handling, with handwashing only required when glove in direct contact with hand is removed. (Note: This verbal interpretation was offered by FDA staff members and State of Wisconsin Department of Agriculture, Trade and Consumer Protection (retail establishment regulations) at a HACCP related training opportunity in 2010.)
Confusion regarding proper procedure for double gloving is based on two factors -- the inclusion of single use glove (a type of utensil in the Food Code definitions) and ambiguity in the "When to Wash" procedures in Food Code Section 2-301.14. Currently, 2-301.14 states "before putting on gloves" and "after engaging in other activities that contaminate the hands", but does not specifically state handwashing is required between each new pair of gloves.
There are two established scenarios where a food employee can change gloves without handwashing:

- Working with same type of food product (e.g., ready to eat product, then another ready to eat product) -- For example, making a cold cut sandwich then donning new glove to make a chef salad
- Working with multiple foods, but handling them in an order that will prevent cross contamination based on proper cook temperatures (e.g., moving from ready to eat product to raw product) -- For example, making a lettuce salad with a glove on, then donning new glove to work with raw beef. Handwashing would not be required whether or not an additional glove was used or original glove removed.

However, during inspections at several national franchises in the past several years, the following scenario has been observed:
Step 1: Employee wears glove when making a ready to eat chef salad
Step 2: Employee then uses same glove, or another glove on top of the first glove, to handle raw meat (burger, for example)

Step 3: Employee immediately goes back to handling ready to eat food (assembles burger items-bun, condiments, lettuce, cooked foods, etc) and has done one of the following:

- If only one glove was worn for step 1 and 2, employee removes glove and dons a new glove WITHOUT HANDWASHING
- If glove worn in Step 1, then additional top glove put on for Step 2, employee removes top glove only. Bottom original glove remains on and employee continues ready to eat food handling WITHOUT HANDWASHING

Many believe that at Step 3, all glove(s) are to be removed and hands are to be washed prior to resuming ready to eat food handling. Without specific Food Code clarification, unfortunately, the issue is susceptible to misinterpretation.

It has been explained that the additional glove is a utensil, that if you put on and take off the glove "properly" there's no risk, etc. In these situations, in Wisconsin, establishments are told to seek a variance for this type of procedure.

Is there a risk from improper glove changing and lack of handwashing in the situations noted above? Are we assuming too much if we believe that gloves are impermeable without the potential for "leak contamination"? Are we also allowing a risk during removal and redonning of gloves if handwashing is not done after possible contamination (dirty surfaces, raw food handling, etc.) According to the attached article from Food Safety Magazine, the frequency at which gloves are breached during in-use procedures was 56% of vinyl and 19% of NRL leaked post-procedure (see highlighted areas in attached article).

Public Health Significance:

Improper glove use and improper handwashing contribute to contamination of food. Because of this, cross contamination from hands from primarily fecal-oral pathogens and cross contamination from foodborne pathogens (including those with low infective doses such as Enteropathogenic E. Coli*, Campylobacter jejuni, Staphylococcus aureus, Shigella,* and others based on high risk population susceptibility) remains viable during improper food handling.

Recommended Solution: The Conference recommends...:

That the following charges be assigned to a re-created Hand Hygiene Committee:

- Determine if/when double gloving procedures would be acceptable without handwashing. If so, what would those acceptable procedures be?
- What glove criteria or standards would need to be met for a glove to be considered a utensil and not require handwashing?
- The findings of the committee to be used to recommend FDA Food Code language modifications regarding glove procedures and handwashing and that these findings be presented at the 2014 Biennial Meeting.

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Attachments:

- "CFP Issue Attachment - Clean Operations"

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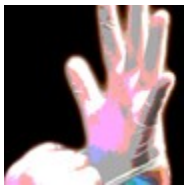
http://www.foodsafetymagazine.com/article.asp?id=1498&sub=sub1



CLEAN OPERATION
Understanding the Glove Risk Paradigm: Part II

By Barry Michaels

August/September 2004

Click here to read Understanding the Glove Risk Paradigm: Part I

Gloves in and of themselves are not a panacea, but rather it is their proper selection and use that can help reduce risks associated with commercial food handling. Gloves are meant to protect the product and the worker. If the gloves are torn or punctured, worn without being changed or sanitized, and the worker's hands were not washed before donning, then risk is amplified rather than reduced.

The objective of this two-part article is to help food safety managers make educated decisions with regard to glove selection in critical food environments. Due to the variability of food types, handling configurations and risks associated with each facility and finished product, no specific recommendations can be made. Hazard Analysis and Critical Control Points (HACCP) principles must guide management committees in making responsible risk-based decisions that effectively deal with assorted microbial food hazards.

As discussed in Part I of this article, the current risk landscape is littered with glove tips and drips from punctured gloves.[1] It is no accident that glove parts end up in food. The stresses, strains, sharp corners, constant flexing and snags encountered in food processing require more physical strength and elasticity than commonly used glove materials provide. When inappropriate materials are used in food processing or service environments it becomes apparent that they are operating outside of their functional envelopes, and hence, breaks, punctures and leaks lead to contaminated food product. Studies in the health care field have shown that 50% of the time, glove wearers fail to notice glove punctures.[2] In many cases these are accidents just waiting to happen. When a puncture occurs, thousands of bacteria or virus particles can rapidly drip out of the breach.[3] When selecting gloves, important features to review are: break and abrasion resistance, durability, elasticity and resilience, tactile sensitivity and heat dissipation. The following review will delve into the pros and cons of the various glove types used in the food environment. The data and descriptions provided deal with the most commonly available glove products on the market. As in any general review, there will be exceptions due to proprietary processes and not all glove types could be explored in the space allotted.

Glove Types Detailed

Polyethylene (PE) copolymer gloves are generally the least expensive of all glove types. They are available in high-, medium- and low-density forms, which influence various physical properties. Typically loose fitting with a "one-size-fits-all" claim, dexterity is lower than that of any other glove type. While some could argue that the loose fit allows venting of the hand, PE gloves tear quite easily and are not suitable for use around high heat.[4] The heat welded seams on PE gloves are a typical failure region. A Conference for Food Protection issue submitted in 2004 sought U.S. Food and Drug Administration (FDA) Food Code status for "short task" PE food-handling gloves. This submission characterized PE gloves for use during periods of a few seconds up to two or three minutes. PE gloves are available with built-in antimicrobial compounds; however, it is doubtful that this feature is of value for a glove whose useful life is extremely limited.

Vinyl (polyvinyl chloride), otherwise known as PVC gloves, are considered by some as an acceptable alternative to latex, providing snug fit capabilities and some degree of dexterity. They are more resistant to ozone and oil than natural rubber latex (NRL) and can be worn around heat sources without risk of melting.[4-6] Testing of vinyl has revealed that in some cases they begin leaking as soon as they are donned with stretch or snag on nail edges.[5] Electron photomicrographs in Figure 1 show how such punctures are created when the glove is stretched. Although vinyl provides better resistance to oils than NRL, its short usable life limits its utility in food applications.[9] Due to poor durability, lack of tensile strength and susceptibility to alcohol breakdown, they have been described by some in the healthcare field as "infection control nightmares."[7-8,10]

Nitrile (carboxylated butadiene-acrylonitrile) gloves were also developed as a replacement for latex. Like vinyl, they are less elastic than NRL but are significantly more durable.[10-11] They feature good physical properties and provide the wearer with good dexterity. Nitrile gloves are resistant to many chemicals but like other glove types are sensitive to alcohol degradation. They have been found to be sensitive to ozone degradation and the elastomers can be somewhat brittle, possessing a higher modulus and greater stiffness than NRL.[11-12] While they are abrasion- and puncture-resistant, once breached, they tear easily resulting in breaks where their varied colors help to identify glove pieces that may end up in food (Figure 1).[1,10] Nitrile gloves can be purchased at a moderate cost.

Natural Rubber Latex (NRL) is the most commonly available and often among the least expensive of the comfortable, tight-fitting elastic glove types. They offer good dexterity, a snug fit, good tactile sensitivity and can withstand high heat. For these reasons, NRL gloves were considered the gold standard in gloves for many years.[12-13] The downside of the material is that many people are now either allergic to latex or to the chemical additives used in the glove making process.[14] Latex particles and other chemicals can slough off into food product when the

chlorinated glove surface breaks, as shown in Figure 1. NRL gloves will deteriorate over time by exposure to oxygen, ozone or ultraviolet light and are degraded by oils and solvents such as alcohol.[10,12]

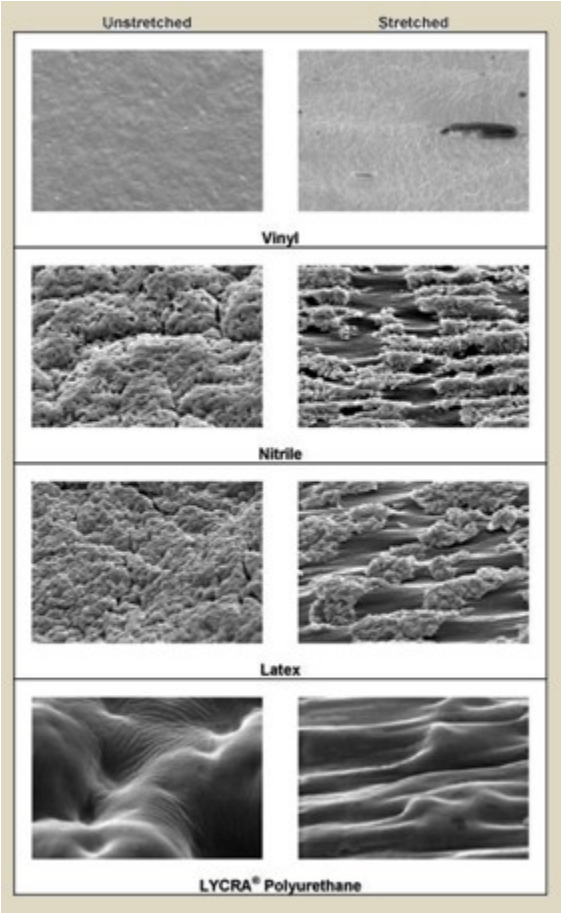


Figure 1. Scanning electron microscope image of glove surfaces shown at 2000X magnification of glove types under unstretched and stretched conditions.

Polyurethane (PU) gloves are free of chemical additives other than the pure polymer itself, consisting of polymeric methylene diphenyldiisocyanate. These glove types are head and shoulders above the rest with regard to high tensile strength and durability (Figure 1). The newer formulations have elongation at break comparable to NRL, making them very comfortable to wear.[15-16] PU gloves formulated with LYCRA polyester are resistant to abrasion, oils and to alcohol deterioration and provide reusability through in situ cleaning and sanitizing.[17-18] PU gloves dramatically reduce the chances of Type I and Type IV allergic reactions, as well as irritation dermatitis by not containing latex proteins, accelerants, plasticizers or sulfur vulcanizing agents common to all other glove types in one form or another.[16]

Glove Comparison and Selection Tips

Table 1 summarizes key pieces of information relevant to glove performance for the main glove types used in the food industry. This table is a collection of data from several dozen articles published in various scientific and medical journals concerning glove test results and characteristics. Perhaps the most striking information provided by this chart is the frequency at which gloves are breached during in-use procedures where 56% of vinyl and 19% of NRL leaked post-procedure.

	New Leaks – Water*	Failure Rate Bacteria*	Failure Rate Virus*	Failure Rate Virus Post 70% Ethanol*	Leaks After In-Use Procedure*	Overall Composite Chemical Durability**	Chemical Durability –Oils, Greases, Organics**	Contact Dermatitis Reports*	Typical Tensile Strengths Mega Pascals (MPa)	Elongation at Break (%)
Study Number (n=)	(12)	(3)	(10)	(1)	(19)	(10)	(10)	(16)		
Polyethylene (PE)	41	40	65	94	83	5	10	<1	5-28	250-425
Vinyl (PVC)	8	48	20	56	56	15	20	<1	11-15	250-450
Nitrile	7	NA	22	NA	5	35	40	<1	23-27	380-580
Latex (NRL)	10	7	15	1	19	20	10	6	26-28	750-850
Polyurethane (PU)	1.5	NA	<1	NA	<1	35	40	<1	42-43	760-810

*Scale percent (%) average having defect
**Composite durability with acid, bases, oxidizing agents, solvents and/or oils/greases, organics/organic based solvents.
(Scale: 5=Not Recommended, 10=Poor, 20=Fair, 30=Good, 40=Excellent)
NA= No Data Available

Table 1. Glove status when new and durability with use or after being sanitized.

Table 2 summarizes and supplements information on glove types provided in this article. No one glove solves every food application but as strength and durability increases, so does reduction of risk profile.[19] Mindful of puncture potential, supply issues and waste with certain glove types, some food safety managers are switching to or evaluating reusable polyurethane gloves that can be cleaned and sanitized on the fly. Ultimately, safety managers should match glove to worker and determine effectiveness through in-use performance evaluations. Mana-gers should know and understand the performance characteristics of the gloves being used relative to the specific hazards associated with food and process type.

Material	Plastic (Poly)	Vinyl	Nitrile	Natural Rubber Latex	Polyurethane
Composition/ Source	Polyethylene	Polyvinyl chloride (plasticized)	Acrylonitrile & butadiene	Cis 1.4 Polyisoprene *Hevea brasiliensis*	Diphenylmethane diisocyanate elastomers
Strength & Durability	Very poor, weakest of all glove types, easily breaks in use	Poor, weak, breaks easily & punctures easily in use	Good, possesses some puncture resistance	Good, strong & durable	Very durable with excellent puncture, tear & abrasion resistance
Puncture Resistance	Punctures easily when stressed, low tensile strength	Low tensile, punctures easily during use	Has puncture resistant properties	Strong, has some puncture resistant qualities	Has superior level of puncture resistance; higher overall performance
Tear Resistance	Very poor	Poor	Poor	Good	Very good
Chemical Barrier Properties	Extremely poor protection, soluble in some solvents, including alcohols	Limited barrier protection; easily permeated by organic solvents, oils & alcohol	Resists most solvents better than NRL or neoprene, sensitive to alcohols & ketones	Good protection from most caustics and detergents; soluble to solvents such as alcohols	Exhibits excellent resistance to ozone, oxidizers, fuel, oil & solvents as well as alcohols & sanitizers
Strength Deterioration O_2, O_3 & UV Light	Yes	No	Yes	Yes	No
Elasticity	Dexterity, very compromised	Dexterity compromised	Less than latex, over time tends to cramp wearer's hand If tight	Elasticity is apparent due to elastic quality rubber	Elasticity closest to latex/polyisoprene very high memory in newer formulations
Softness	Fair	Fair	Good	Very good	Very good
Fit & Comfort	Very limited fit & feel (baggy)	Loose cuff, fit limited (baggy)	Tighter fit, users often choose a larger size compromising dexterity	Very good comfortable fit due to its elasticity	Good comfort &fit; has latex-like qualities
Allergenicity	Contains no latex protein but contact dermatitis reported from additives	Contains no proteins but some curing agents, chemical ingredients & plasticizers	Contains no proteins but contains accelerators and other chemicals	Contains protein & chemical allergens, low powder is preferred	Contains no latex proteins & no chemical accelerators, lowest levels of extractables
Use	Short task, single use	Single-use	Single-use	Single-use	Multi-use glove
Wear Life	<5 min.	15-30 min.	< 1 hour	1-2 hours	< 2 days
Cost Per Use	Very low	Low	Moderate	Low	Moderate
Advantages	Low cost, lightweight & mild chemical resistance	Low cost, no protein allergens, resists acids, alkalis, fats & resists aging	Moderate cost, good physical properties & dexterity	Good elasticity & dexterity, low cost, good physical properties & memory	Extremely strong with superior puncture resistance, it exhibits excellent tear and abrasion resistance
Disadvantages	Only for short-duration tasks, limited fit, feel & strength, dangerous around high heat	Moderate flexibility limited fit & feel, punctures & fatigues quickly, contains irritating chemicals, plasticizers can leach, often poor quality	Limited fit, feel & flexibility, slow memory, possible finger fatigue, contains sensitizing chemicals	Not good for use with oils, greases, organics; large quality variations contains allergens & sensitizers	Can be slippery; food soils easily removed from gloves, properties are formula and process dependent

Table 2. Comparison guide for glove types used in food processing/service facilities.

1. Consider Working Load and Tensile Strength. Safe working loads for common glove materials are often exceeded many times per hour in modern food plant environments. Work with your glove supplier to specify the physical integrity that you require of these products. For example, the physical integrity of the glove used in meat processing over the course of a few hours needs to be very high compared to the deli counter, where the glove might be disposed of immediately after one use.

• Tensile strength is a good determinant of puncture and tear resistance. If running a high abrasion manufacturing process, stronger more durable gloves are dictated.

• Glove selection will depend on how long workers will be required to wear gloves for efficient operation. For example, latex research shows that barrier breakdown is in direct relationship with time worn.[20] In other words, for most glove types, risk of food contamination is directly proportional to time in-use.

2. Check for Allergic Reaction Potential and Insure Skin Health. Hand health is extremely important, therefore low- or no-allergen gloves are recommended.

• Look for low protein latex gloves to reduce allergy potential.

• Nitrile gloves are an alternative to latex, but contain many of the same chemical additives in latex gloves, minus the protein.

• If upon changing glove types, similar skin problems remain in some individuals, it is a sign that the problem was not solved and this may involve antioxidants, accelerators or other sensitizing chemical additives.

• Food handlers should carefully specify the chemical integrity required to the glove manufacturer.

3. Size Gloves Properly and Consider Ease of Donning and Comfort of Fit. With gloves, size matters.

• Tight gloves can restrict dexterity, cause discomfort and hand fatigue.

• Loose gloves that don't have the requisite stretchiness represent a safety hazard to users and also can result in unnecessary fatigue.

• Cumbersome, loose-fitting gloves increase the risk of microbial contamination and transfer.

• Prevent excessive sweating by choosing a glove that allows heat dissipation versus gloves that do not. Cool wearing gloves reduce skin problems and discomfort while increasing worker efficiency.

• Glove flexibility and stretch are important determinants of comfort during use.

4. Ensure Proper Hand Washing and Glove-Changing Protocols. As noted, even the process of changing gloves is fraught with hazards, because many glove materials cause excess moisture build-up, causing difficult to disinfect contamination from the nail region to spread all over the hand.[21-22]

• Wash hands before and after wearing, so that the new glove or contact surface touched by those hands does not become contaminated before and during donning.

• To properly change gloves, each glove should be grasped in turn at the top of each cuff in a manner peeling the glove inside out.

• Unless it is a multi-use glove, which can be cleaned and sanitized repeatedly, single-use gloves must be discarded after the task is completed.

5. The Choice of Powder Free is an Important One. Powder was originally used to make donning easier with wet or dry hands and as a release agent to remove gloves from molds. This powder can aerosol latex allergens to a point at which they could be inhaled. Use of powders has been replaced by a chlorination step. This chlorination aids in the donning process, but also presents potential risk of skin irritation potential and food contamination.

6. Single-Use and Multi-Use Gloves are Mutually Exclusive.

• Single-use gloves must be discarded when soiled and cannot be reused.

• Multi-use gloves should be washed or sanitized regularly and by reusing them, gain economic, environmental and

efficacy advantages.

• Multi-use gloves can be cleaned and sanitized many times more effectively than the human hand, in a sense taking hand hygiene to a higher level of efficacy and risk reduction.

Studies have shown that when gloves are worn beyond their design and structural limits, it is not a matter of whether a puncture, rip or tear will occur, but rather at what point in the process and how much product contamination will result. This may cause only minor discomfort on the part of the consumer, consumer affairs personnel and quality control manager, but it also could lead to something worse. It is the food safety manager's job to eliminate foreseeable risks, building resilience and redundancy into a facility's food safety system. If inferior gloves are used, made of materials that are not up to the job required, used incorrectly or under a flawed standard operating procedure, the inevitable result is amplification of risk.[7-8,19]

It may only be a matter of time before the piper gets paid. While a glove break in and of itself might be considered an upper warning limit, the fact is that the process is out-of-control at the point of leakage. If there is one thing we have learned from analyzing accidents, it is that we can't slack off when running critical systems.[23] System complexity places high demands on a manager's capacity to gather information and design effective strategies.[24] When analyzing catastrophes and how they happen, James Chiles writes, "Usually we can get through our days making many errors but never have to pay the bill."[25] Obviously, these are days in which everyone, including the company at risk, skate happily on. But on really bad days, sometimes through multiple-failure chains of circumstances, things can (no pun intended) get out of hand. We must be aware of potential flaws in our food safety machinery—the human hand and our hand surrogates, the gloves—because under certain circumstances, little errors can cause big problems. Gloves used in food environments should be chosen based on their physical properties. It is key that barrier performance, durability, comfort of fit, tactile sensitivity, dermal compatibility and cost-effectiveness fit the task at hand.[19] ♦

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Conference for Food Protection
2012 Issue Form

Internal Number: 012
Issue: 2012 III-005

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

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Title:
Clarify when handwashing is required before donning/changing gloves

Issue you would like the Conference to consider:
Employees are required to wash their hands whenever there is a risk of cross-contamination of Ready-to-eat (RTE) foods or clean food contact surfaces/equipment. Section 2-301.14 (H) of the 2009 Food Code states that hands need to be washed "before donning gloves for working with FOOD."

The intent in the Food Code is to minimize the risk of cross-contamination of RTE foods; however, gloves may be worn for other reasons than handling RTE food and they may be changed more frequently than is necessary to prevent cross-contamination. In these situations, the need to wash hands before donning/changing gloves is not consistent with the intent of the Food Code nor does it impact public health.

Section 2-301.14 (F) of the 2009 Food Code states that hands should be washed "as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks." [Bold inserted] However, Section 2-301.14 (H) states that hands should be washed "Before donning gloves for working with food." This has been misinterpreted to mean that hands must be washed every time gloves are changed even when performing the same task.

Section 2-301.14 should allow employees to change gloves without having to wash their hands when they are: (1) performing the same task without increased risk of cross-contamination and (2) when handling raw food and not increasing the risk of cross-contamination with RTE foods or clean food contact surfaces.

Public Health Significance:
2009 Food Code Section 2-301.14 (*When to Wash)* states that food employees must wash their hands before food preparation and at other times as listed in subsections A-H, including before donning gloves. As per Annex 3 - *Public Health Reasons / Administrative Guidelines - Chapter 2, Management and Personnel,* "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." Clearly the intent is to minimize the risk of cross-contamination of ready to eat foods and food contact services.

There are many situations when an employee's activity has not changed yet gloves are changed. For example, a store policy may require that an employee change gloves

between the preparation of each customer's sandwich, even though the gloves are not contaminated and there is no increased risk of cross-contamination. However, based on Section 2-301.14, if the employee does not wash their hands between the glove changes, this would result in a critical violation although there is no public health risk. As per Section 2-301.14 (F), gloves should be changed "as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks." In the example above, the employee is not changing tasks and therefore changing gloves is optional as company policy or as consumer preference dictates, but there is not a public health basis for doing so.

The wording in Section 2-301.14 (H) states that hands should be washed "Before donning gloves for working with food." This has sometimes been interpreted to mean that hands must be washed every time gloves are changed, even if the activity has not changed or if there has been no contamination of the gloves or hands.

Furthermore, requiring that hands are washed before every glove change, even when an employee is repeating the same task, may actually serve as a deterrent to wearing or changing gloves. When employees can quickly change gloves without the additional step of handwashing when performing the same task, they are more likely to change gloves more frequently.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), ¶ 2-301.14 (H), be amended to clarify the situations when hands shall be washed before donning gloves for working with food as follows (new language shown with underline):

(H) Before initially donning gloves for working with food,[P] and when changing tasks; [P]

AND the following language be added at the end of Annex 3, - Public Health Reasons / Administrative Guidelines - Chapter 2, Management and Personnel 2-301.14 *When to Wash:*

"Employees must wash their hands after any activity which may result in contamination of the hands. "When gloves are used to handle food, hands should be washed prior to donning gloves. If there is no change in the task being performed and there are no activities which could potentially result in cross contamination, then hands do not have to be washed between each change of gloves when performing the same task."

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Conference for Food Protection
2012 Issue Form

Internal Number: 076
Issue: 2012 III-006

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

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Title:
Re-create - Hand Hygiene Committee

Issue you would like the Conference to consider:
Re-creation of the Hand Hygiene Committee to more closely examine the current "Food Code" requirements for when employees are required to wash their hands using soap and running water, and potentially identify alternative approaches, where appropriate.

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. The 2010-2012 Hand Hygiene Committee believes that the necessary ground work was established during its deliberations to make informed recommendations on specific situations where application of alternatives to handwashing may be appropriate to reduce public health risk.

Recommended Solution: The Conference recommends...:
1. Re-creation of the Hand Hygiene Committee to:
   - More closely examine the current Food Code requirements for when employees are required to wash their hands using soap and running water.
   - If credible research suggests that one or more of the situations under which food employees are currently required to wash their hands does not result in meaningful risk reduction, work with FDA to explore whether those mandates could be modified, either in the Code itself or by recognizing when it is appropriate to waive the requirement (e.g., other approaches to hand hygiene are available and practiced).

2. The re-created committee uses the report of the 2010-2012 committee as a reference, illustrating the interactions of scientific, regulatory and behavioral considerations related to alternative hand hygiene regimes compared to handwashing. The committee should characterize what recent research tells us about:
   - the extent to which the current minimum requirements for how and when employees are to wash their hands are effective in rendering food employees hands free of various soils, as well as, any pathogens of concern;

- what other regimens for cleansing employees hands, if any, may deliver outcomes that are similar to or better than handwashing so as to suggest that they could be included as acceptable methods for rendering hands free of soil and pathogens.

3. The committee report back its findings to the 2014 Biennial Meeting.

Attachments:

See *Report - Hand Hygiene Committee*, Attachment #1 titled *2010-2012 Hand Hygiene Committee Final Report*

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Conference for Food Protection
2012 Issue Form

Internal Number: 050
Issue: 2012 III-007

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

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Title:
Rationale for 100 degree F. hot water at hand sink.

Issue you would like the Conference to consider:
There is currently no scientific research that shows hand washing is more effective at removing pathogens when warm water is used as compared to cold water usage. The FDA Food Code currently requires 100º F water at the hand sink. At the 2010 CFP Biennial Meeting, the Conference recommended changing the water temp at hand sinks to 85º F; however, this was not adopted when FDA issued the Supplement to the 2009 Food Code. Is there research or a scientific basis for requiring 100º F water at the hand sink? If not, will the FDA sponsor, support or encourage research to validate the best handwashing water temperature?

Public Health Significance:
Proper handwashing is one of the three pillars for preventing foodborne illness transmitted by food handlers. The objective of water temperature needs to focus on what will encourage and promote more routine and frequent handwashing. Currently, we justify the water temperature requirement based mostly on soft science:

1. Warm water is more conducive to encourage employee hand washing;
2. Warm water is more effective at removing soils in the food environment;
3. ASTM standards require 100-108º F water for testing soap formulation's efficacy.

Is there any research available to justify 100º F water at hand sinks? In fact, the only research we are currently aware of shows just the opposite. Research by Michaels and Paulsen (attached) came to the conclusion that, "*The initial experiment involved testing with bland non-antimicrobial soap at 5 temperatures from 4.4°C (40°F) to 49°C (120°F). Independent of soil or bacterial type (resident or transient) there was no significant difference in efficacy attributed to water temperature.*"

Studies designed to determine the best temperature for handwashing could put to rest the current confusion and debates as to what water temperature should be available at a handsink for hand washing.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that they support and/or fund scientific research that would justify the appropriate water temperature for handwashing at a hand sink.

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Attachments:

- "Handwashing Water Temperature Effects on the Reduction of Resident and ..."

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Dairy, Food and Environmental Sanitation, Vol. 21, No. 12, Pages 997-1007

Handwashing Water Temperature Effects on the Reduction of Resident and Transient (*Serratia marcescens*) Flora when Using Bland Soap

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ABSTRACT

For many years, sanitarians have specified that hands be washed using warm or hot water to reduce cross-contamination risks, with various authors indicating temperatures between 38°C and 48.9°C. However, it has been suggested that these temperatures may contribute to skin damage when frequent handwashing is necessitated (in health care and food service). This study evaluates the bacterial reduction efficacy of water temperature during normal handwashing. The hands of two groups of four experimental subjects were soiled with sterile or contaminated substances (tryptic soy broth and hamburger meat). Uninoculated menstruum was used to study the effects of treatment temperatures on resident microflora reduction, while *Serratia marcescens*-inoculated menstruum was used to study treatment effects on transient microorganism reduction. Following contamination with appropriate media, one hand was immediately sampled to obtain baseline (control) data, using the "glove-juice" technique for microorganism recovery. Hands were then moistened with water at the assigned temperature (4.4°C, 12.8°C, 21.1°C, 35°C or 48.9°C), washed 15 s with bland soap, and rinsed 10 seconds at the same temperature as was used before; and the opposing hand was then sampled. Results indicate that water temperature has no effect on transient or resident bacterial reduction during normal handwashing when bland soap is used.

A peer-reviewed article.

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TABLE 1. Year 2000 Conference for Food Protection water temperature issues

Issue #	Submitter	Requested change from 110°F (43°C) minimum	Reasons given for change requested
2000-I-23	L. Wisniewski (Select Concepts)	"Warm Water"	1. Hand discomfort decreases frequency
2000-I-24	M. Scarborough (GA Dept. of Human Resources, Div. Publ. Health)	37.7°C (100°F)	1. No science (110°F vs. 100°F) 2. Plumbing code @100°F max. (safety concerns)
2000-I-25	J. Budd (Healthminder/ Sloan Valve Co.)	35°C (95°F)	1. No scientific basis 2. Max. soap efficacy at 35°C 3. Hand comfort 4. Hot water discourages hand washing
2000-I-26	E. Rabotoski (WI Conference Food Protection)	"Tempered" 85°F (29.5°C) to 110°F (43°C)	1. Hand discomfort 2. Possible scalding
2000-I-27	B. Adler (MN Dept. of Health)	Impose temp. range 110°F (43°C) to 130°F (54.4°C)	1. Need upper limit or subject to OSHA 2. Food workers don't wash 25 s so cannot scald
2000-I-28	F. Reimers (H.E.B. Grocery Co.)	"Tempered" to warm	1. No science 2. Max. soap efficacy 3. 110°F risks injury 4. Waste water as wait for temp. at 110°F

INTRODUCTION

A critical and thorough evaluation of a simple handwashing reveals numerous variables that must be considered to achieve maximum or appropriate degerming of the hands and fingernail regions. Numerous studies have explored topics such as type of soap (e.g., antibacterial vs. plain, liquid vs. bar), amount of soap and handwashing technique, nailbrush or sanitizer use, drying technique (e.g., cloth vs. paper towels, paper towels vs. air-drying), and application of hand sanitizers (post-wash liquids). Although studies indicate that these variables are crucial in achieving effective removal of transient bacteria from the hands under controlled testing conditions, testing to determine specific guidelines for water temperatures and flow rates is rarely mentioned in the scientific literature. Many of the currently employed handwashing practices may be based on untested traditions that could actually result in compromised skin health. With so many variables involved in such a "simple" procedure, it would make sense to explore and maximize all possible aspects of the process while minimizing negative collateral. This is especially important because many observations of food service workers have revealed what are considered poor habits in handwashing techniques. Studies indicate that handwashing compliance drops considerably without supervision and monitoring, or in situations where skin damage occurs. This further amplifies the need to strengthen knowledge of all variables that might improve or weaken daily handwashing prac-

TABLE 2. A comparison of resident flora and transient flora studies

	Resident flora	Transient flora
Test Laboratory	BioScience Laboratories	Silliker Research Laboratories
Location	Bozeman, MT	South Holland, IL
Study Director	D. Paulson J. Budd	V. Gangar
		M. Arenas
Test Subjects	Paid Volunteers	Laboratory Workers
No. Test Subjects	4 (3 Females, 1 Male)	4 (1 Female, 3 Male)
Test subjects age (range)	26 – 56	24 – 25
Test temperatures (°C)	4.4, 12.8, 21.1, 35, 48.9	4.4, 12.8, 21.1, 35, 48.9
Test temperatures (°F)	40, 55, 70, 95, 120	40, 55, 70, 95, 120
Test soil		
Tryptic soy broth (TSB)	1.0 ml (0.5 ml/hand)	1.0 (ml/hand)
ϒ - irradiated ground beef (GB)	3.0 grams (1.5 g/)	3.0 grams
Microbial inoculum	None	*S. marcescens*
No. test days/soil/	1	2
Temperature/ Subject		
Total data points/temperature	8	16
Mean baseline count Log_{10}		
TSB	6.05	6.91
GB	6.40	7.21
Amount of time massaged with TSB and GB	45 seconds	2 minutes
Amount of time TSB and GB air-dried	2 minutes	1 minute
Amount of soap used for handwashing	3 ml	3 ml

tices throughout the food and health care industries.

Two types of flora, transient and resident, exist on the hands. The transient flora are generally removed fairly easily. They do not have adhesion characteristics that hold them to the skin's surface *(8)* and are somewhat suppressed by secretions and competitive exclusion by normal resident flora. Resident flora are removed more slowly. Because of co-evolution, resident flora have adapted to conditions on the skin surface that cause rapid die-off of most transients. Invaginations such as the nail fold, hair follicles and sebum-producing sebaceous glands support a rich resident flora. Transient flora may consist of pathogens, spoilage bacteria or harmless environmental species. Under certain conditions transient flora can change status and become permanent residents. Resident flora as a rule are not pathogenic types. Frequent or prolonged exposure of the skin to microbial contamination in soils, skin damage or fissures provide portals of entry to deeper tissue and may result in the presence of many pathogenic bacteria among the resident species *(11,27)*.

Removal of viable bacteria, dirt and grease from the skin is accomplished by friction and surfactant action, which lowers surface tension. Alkaline detergent solutions remove bacteria from skin more efficiently than acid or neutral so-

lutions do *(20)*, forming the basis for skin sampling solutions used in this study *(37)*.

Added to the aforementioned studies are the many references to warm or hot water use for handwashing from the Internet or popular press. These references are meant to provide information to food workers or consumers. Questions need to be answered regarding water temperature guidelines with respect to handwashing: Do soaps perform better depending on the water temperature for handwashing? Does hot water help cleanse the hands better than cool or plain tap water? What are the physiological changes of the skin when different temperature/soap combinations are used? Does water temperature make a significant difference in reducing the numbers of transient and/or resident bacteria on the hands?

The effective water temperature used for washing and rinsing hands has been under debate recently at the Year 2000 Conference for Food Protection. Six issues were brought before Council I with regard to FDA Food Code hand washing water temperature specifications. The 1999 Food Code (*36*) requires sinks used for handwashing to be equipped so as to be "capable of providing water of at least 43°C (110°F), accomplished through use of a mixing valve or a combination faucet." An outline summarizing the issues brought forth by the various submitters at the Year 2000 Conference, including requested changes and reasons given for those changes, is provided in Table 1.

All but one of the issue submissions requested temperature decreases with the intent of improving hand comfort, as the discomfort associated with higher temperatures results in decreases in hand washing frequency or compliance (I-23, I-25). Several submitters note a lack of scientific information on the subject (I-24, I-25, I-28). There is concern that a minimum handwashing temperature of 43°C (110°F) in addition to causing discomfort (I-23, I-26), will result in injury or scalding (I-28, I-24, I-26) and may even be in conflict with local plumbing codes (I-24). Two submitters point out that soaps currently available target maximum effectiveness at around 35°C (95°F) (I-25, I-28). Two submitters requested that the minimum temperature of 43°C (110°F) be changed to warm water (I-23, I-28) or that it be tempered to a range of 29.5°C (85°F) to 43°C (110°F). And finally, one submission (I-27) sought to place an upper temperature limit of 54.4°C (130°F), for fear that these regulations would be subject to OSHA scrutiny and criticism without a limit. Interestingly, it was noted in this submission, through reference to the Consumer Product Safety Commission, that second-or third-degree burns have been shown to occur in the elderly at temperatures not much over 43°C (110°F). Council I and the General assembly of voting delegates passed a recommendation to lower the Food Code water temperature minimum to 29.5°C (85° F).

The universe of food handling situations requiring effective personal hygiene runs from temporary handwash stations set up in produce fields to advanced state-of-the art kitchens used to produce extended-shelf-life ready-to-eat foods sold at retail. In many of these situations, it is difficult to provide water meeting strict temperature ranges. Further, it is difficult to manage and monitor food handlers to insure that the 43°C (110°F) temperature minimum is maintained during all handwashing activities. When subject to regulatory inspections, violations are given to food industry entities based on Food Code specifications. Therefore, in the interest of possibly increasing handwashing compliance or efficacy and clarifying the importance of this issue to enforcement authorities, handwashing studies were undertaken.

In a literature search for effect of water temperature on hygienic efficiency, only two experimental studies shed light on this issue. Both of these involved hand sampling studies, in which the objective was to remove and enumerate as many bacteria on the hands as possible, either as normal or transient flora. In hand scrubbing experiments, Price *(27)* found that at temperatures from 24°C (75.2°F) to 56°C (132.8°F) there was no difference in de-germing rate. Because he scrubbed hands with a brush for a specific period of time, each in turn in a series of sterile wash basins, he might have been capable of seeing differences upon counting the flora in each basin. After conducting over 80 experiments in a 9-year period, Price concluded that the largest variable in determining the rate of removal of bacteria from the hands was the vigorousness of scrubbing. Other factors, such as soap used or water temperature, were less important. In later hand sampling experiments implementing the glove juice method for recovery of microorganisms, no differences in isolation rates were seen at either 6°C (42.8°F) or 23°C (73.4°F) *(12)*. Although this information is inconclusive and does not answer questions concerning bacterial loads suspended in a confounding soil, they tend to indicate that there may not be a very great difference in efficacy over a range of temperatures from 6°C (42.8°F) to 56°C (132.8°F).

Various menstruum have been used for handwashing efficacy studies. For studies involving transient flora, the most often used soil is tryptic soy broth (TSB). Microorganisms exhibit good survivability, with even distribution of contaminating microorganisms into skin cracks, creases and invaginations being possible. Ground beef probably represents the most appropriate menstruum because of concern for risks of *E. coli* O157:H7 infection, but is only occasionally used *(30, 31)*. Numerous cases of foodborne illness have been tied to poor personal hygiene after ground beef preparation.

On the basis of all the information gained from the literature search and analysis, experiments

were performed to determine if there was a superior temperature or range of temperatures for removal of bacterial contamination from hands during handwashing. This involved contaminating hands with marker bacteria and washing hands with soap and water, followed by counting resident and transient (marker) bacteria. Because it was realized that both the use of antimicrobial soap and drying with paper towels would confound and alter the effects of water temperature washing and rinsing, bland soap was used and hands were not dried with paper towels.

MATERIALS AND METHODS

This study was performed at BioScience Laboratories (for resident bacteria) and Silliker Research and Laboratory Services (for transient bacteria). Table 2 provides a comparison of methods used for testing in the two laboratories.

A stable pigmented strain of *Serratia marcescens* (SLR 1421) was used to simulate transient hand contamination. This organism is used frequently used in hand disinfection studies *(5, 22, 23, 24, 28)*.

Tryptic soy agar (TSA) and tryptone glucose yeast (TGY) agar spread plates, deionized water, sterile stripping fluid, Butterfield's phosphate buffer solution, phosphate buffer with 0.1% Triton X-100, TSB with 1% Tween and 0.3% lecithin, sterile latex-free surgical gloves, alcohol, and Ivory® liquid soap (non-antimicrobial) were used.

Subjects rinsed both hands under running tap water at the designated temperature, and shook off any excess. Three ml of Liquid Ivory® Soap was dispensed into the subjects' cupped hands and rubbed over all surfaces, including the lower third of forearms, making sure not to lose any soap. After complete soap dispersal, a small amount of tap water was added, and subjects lathered their hands and forearms vigorously for 15 s. Subjects then rinsed their hands and forearms for 10 s under running tap water maintained at a flow rate of 7.6 liters/min (2 gallons/min) at the designated temperature, after which they shook the hands two times to remove excess moisture. While still wet, the subjects' hands were gloved for sampling using the Glove Juice technique.

Glove juice sampling procedure

The effectiveness of bacterial reductions from the hands was evaluated using the glove juice recovery method as described in ASTM test methods (*4*). Following the prescribed wash and rinse procedure, sterile, powder-free latex gloves were donned. Seventy-five ml of Sterile Stripping Fluid (aqueous phosphate buffer with 0.1% Triton) were instilled into the glove, the wrists were secured, and attendants massaged the hands through the gloves in a uniform manner for 60 s. Aliquots of the glove juice were removed and serially diluted in Butterfield's Phosphate Buffer solution containing 1.0% Tween 80 and 0.3% Lecithin as product neutralizers.

Enumeration

For normal (resident) bacteria, duplicate spiral plates were prepared from appropriate dilutions using TSA with product neutralizers. The plates were incubated at 30°C ± 2°C (86°F ± 2°F) for 48 h. Colonies were counted and the data recorded using the CASBA™ 4 plate-counting system.

For transient (*Serratia marcescens*) bacteria, Samples were spread on TGY agar following appropriate dilutions, and incubated at 35°C (95°F) for 24 to 48 h. Any pink colonies observed were considered to be *S. marcescens*, while the others were considered to be normal flora. The number of bacteria were tabulated using the following formula:

$$B = A[\sum x/n]^{10\text{-}D}$$

Where:

B = estimated number of microorganisms

A = portion volume = 75 ml (phosphate buffer added to glove)

$\sum x/n$ = average CFU per plate for each dilution level

D = dilution level

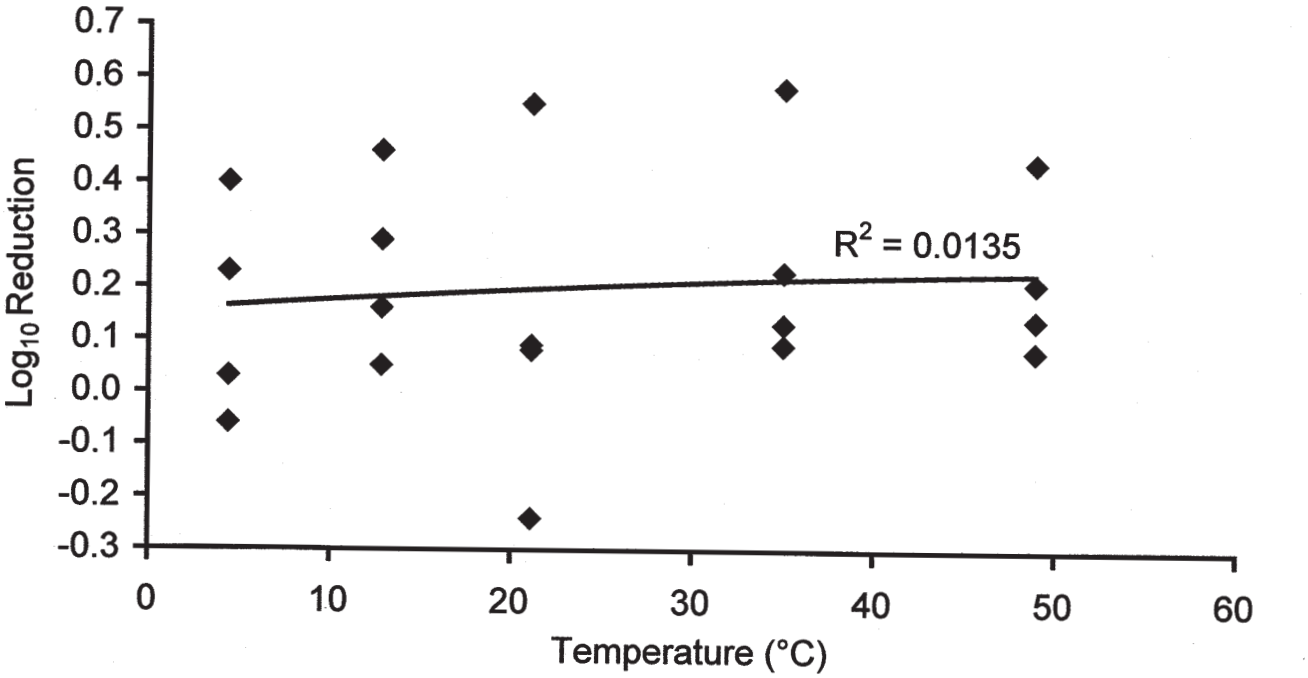
Subjects for normal (resident) flora experiment

The constant exposure of microbiology laboratory technicians to sanitizers and the necessity of disinfection provides the potential for high variability in the resident or "normal" flora and physiological condition of their hands and forearms. Working daily with various microorganisms that are not considered part of the normal (resident) skin flora (including agents used in their testing and evaluation) increases the susceptibility of these individuals to infection and skin damage. For this reason, volunteers were used to get a more accurate picture of the effects of water washing temperature on resident flora.

Between the ages of twenty-six and fifty-six four healthy subjects were selected, three females and one male. All subjects' hands and forearms were free from clinically evident dermatosis, injuries, open wounds, hangnails, or any other disorder that could compromise the subject and the study. Participation was restricted to individuals not currently using any topical or systemic antimicrobials, steroids, or other medication known to affect the resident microbial flora of the skin.

The "pre-test period, seven days prior to the testing portion of the study, was designed to generate optimum levels of resident flora for testing purposes. During this period, subjects were instructed to avoid using medicated soaps, lotions, deodorants and shampoos, as well as skin contact with solvents, detergents, acids and bases, or other

Figure 1. Handwashing efficacy (log_{10} reduction) for resident flora in TSB and selected water washing and rinsing temperature



products known to affect the microbial population of the skin. Avoidance of UV tanning beds and swimming or bathing in biocide-treated pools or hot tubs was mandatory. During this period, subjects were supplied with a personal hygiene kit, containing non-medicated soap, shampoo, deodorant, lotion, and rubber gloves to be worn when contact with antimicrobials, solvents, detergents, acids, or bases could not be avoided. For subjects' safety, leaving the lab once the testing began was prohibited.

Testing period of normal (resident) flora

Each subject was utilized for approximately one-half hour every other day of the test period, excluding weekends and holidays (a total of ten test days per subject). Subjects were instructed to avoid washing their hands for two hours prior to testing, and fingernails were trimmed to a free-edge of less than 1 mm if not already done. All jewelry was removed from the hands and arms prior to washing.

Testing of normal (resident) flora with TSB

On each of the five test days, subjects had 1.0 ml (0.5 ml per hand) of TSB placed into their cupped hands in ten aliquots of approximately 0.1 ml. The broth was distributed evenly over both hands, not reaching above the wrists, by gentle continuous massage for 45 s. After a timed two-minute air dry, the non-dominant hand of each subject was sampled for baseline using the Glove Juice Sampling technique. Subjects washed their hands as previously described, and the other hand was then sampled using the Glove-Juice technique. These procedures were repeated each day, with the non-dominant hand being used for baseline sampling for each subject on each test day. The water temperature for the handwashes on each test day was adjusted for subjects to wash at a different temperature. Test days one through five were performed at the following water temperatures, respectively: 4.4°C (40°F), 12.8°C (55°F), 21.1°C (70°F), 35°C (95°F), and 48.9°C (120°F).

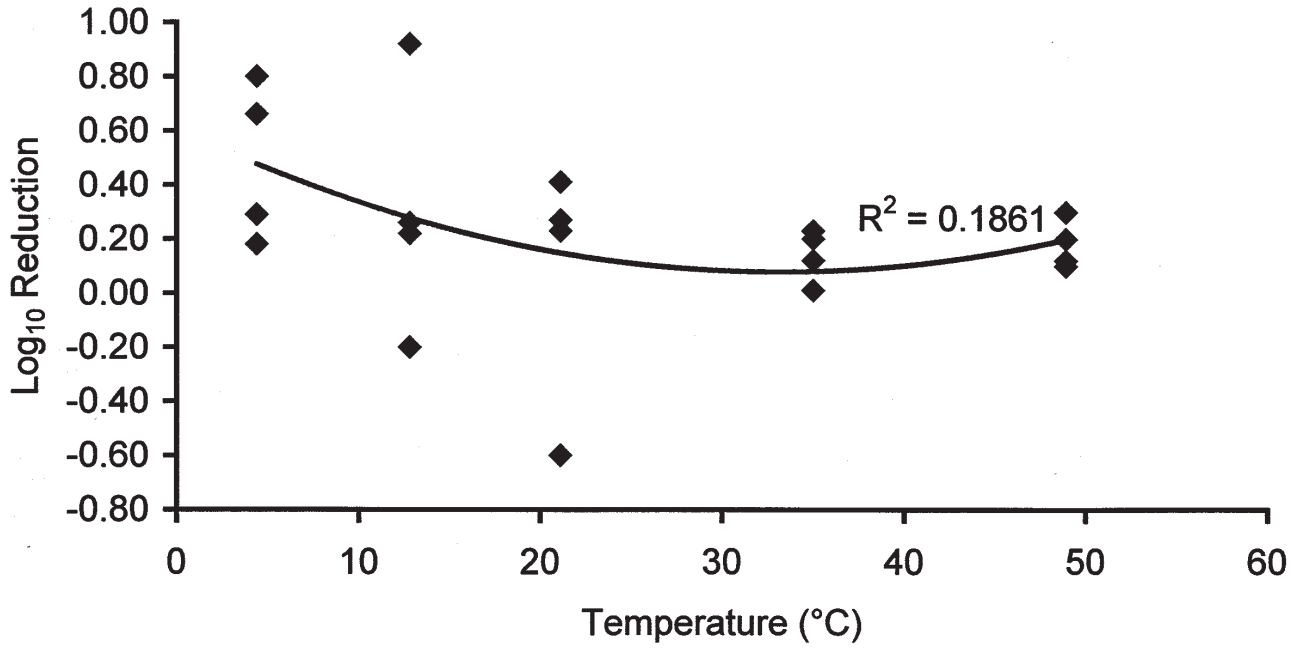
Testing of normal (resident) flora with ground beef

On each of five test days, subjects handled and smeared three grams of gamma-irradiated hamburger meat on their hands for two minutes. After a timed two-minute air dry, the non-dominant hand of each subject was sampled for baseline using the glove juice sampling technique. Subjects washed their hands as previously described, and the other hand was then sampled using the glove-juice technique. These procedures were repeated each day, with the non-dominant hand being used for baseline sampling for each subject on each test day. Wash and rinse temperatures were each day identical to those used for the resident flora with TSB testing.

Testing of transient flora with TSB and gamma-irradiated ground beef

Four laboratory workers, one female and three males, twenty-four to twenty-five years of age, were chosen for this experiment. Testing was performed over a four-week

Figure 2. Handwashing efficacy (log_{10} reduction) for resident flora in ground beef at selected water washing and rinsing temperatures



period in order to alternate left and right hands for baseline readings for each temperature and inoculum. Testing procedures for the ground beef were identical to testing for normal (resident) flora, with the addition of 1×10^8 *S. marcescens*. Testing with TSB was similar to the tests for transient flora, with the following exceptions: the addition of 1×10^8 *S. marcescens*, a two-minute massage period of broth into the hands, and a one-minute drying period. Subjects washed their hands as previously described, with the opposing hand being used for baseline on alternate days. Hands were washed as previously described, and the glove juice technique was utilized for recovery.

Methods of analysis of normal (resident) and transient bacteria

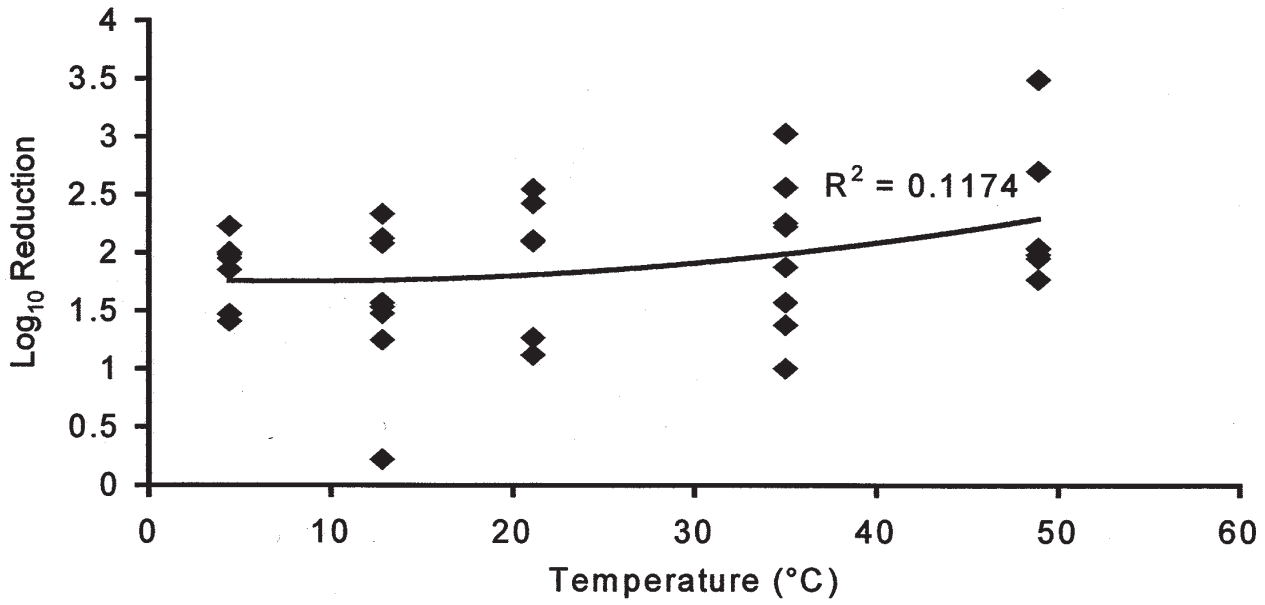
The plate count data collected from this study were evaluated using MiniTab® statistical computer software. Prior to performing a statistical analysis, exploratory data analysis was performed. Stem-leaf ordering, letter value displays, and box plots were generated. Geometric mean colony counts were obtained and log or % reductions in transient and normal flora were determined from these values through comparisons to baseline counts. The experiments were analyzed for significance using statistical ANOVA software. A series of two-sample Student *t*-tests were conducted using the 0.05 significance level for Type 1 (α) error and corrected for multiple comparisons on means.

RESULTS AND DISCUSSION

Because a number of submitters at the Conference for Food Protection brought forward the issue of skin injury and possible scalding at temperature above 43°C (110°F), a review of pertinent literature was undertaken to determine if facts support lowering of the temperature for reasons other than efficacy. The Consumer Product Safety Commission has noted that residential water heater thermostat settings should be set at 49°C (120°F) to reduce the risk of the majority of tap water scald injuries. Although the majority of scalding incidents in the home occur in children under the age of five and in the elderly, third-degree burns are known to result from a 2 s exposure to 66°C (150°F), 6 s at 60°C (140°F) and 30 s at 54.4°C (130°F) *(35)*. As we age, our skin becomes thinner, losing suppleness. This fact is important, as many seniors are now actively involved in the food industry. Due to the elder risk particularly, some have recommended that water be delivered from the tap at even lower temperatures, of less than 43°C (110°F) *(33)*.

The activity of soaps, friction, and rinsing become crucial because the temperatures recommended in handwashing water alone would not provide thermal destruction of pathogenic microorganisms. Relevant to the discomfort issue (brought forward as issues I-23 and I-26) is a study involving dishwashing soaps. In that study, participants could withstand only water temperatures of 43°C, 45°C, and 49°C (110°F, 113°F and 120°F), with tolerance levels related to discomfort peaking at one minute *(9)*. Even though this is considerably longer than the 10 to 25 s exposure period that would result from hand-wash-

Figure 3. Handwashing efficacy (log_{10} reduction) for transient flora (*S. marcescens*) in ground beef at selected water washing and rinsing temperatures



ing, it is indicative of the fact that temperatures from 43°C to 49°C (110° to 120°F) are at the discomfort threshold.

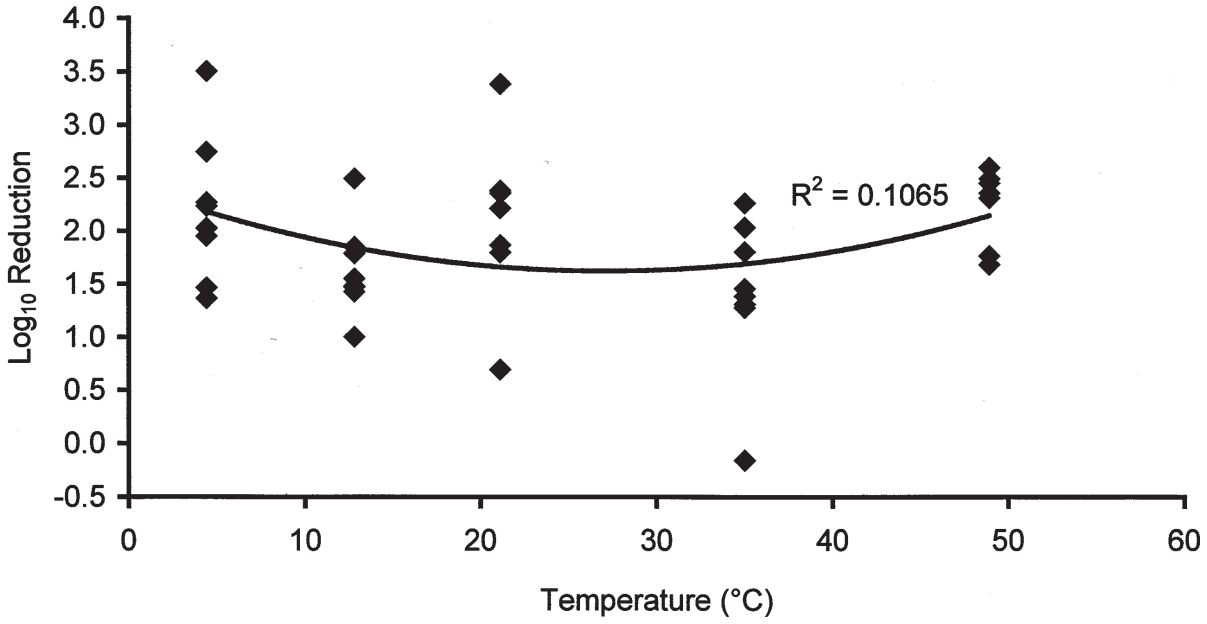
Appropriate handwashing duration (15 seconds) for this study was determined through review of various governmental agency recommendations and previous handwashing study observations (*1, 3, 10, 36*). Suggested lathering times by specific agencies are: the 1999 FDA Food Code (20 seconds) (*36*), the American Society for Testing and Materials (ASTM) (15 seconds) (*3*), The Association for Professionals in Infection Control and Epidemiology (APIC) (minimum of 10 seconds) (*10*), and The American Society for Microbiology (ASM) (a 10 to 15 s vigorous scrub) (*1*). Several studies support a washing duration of at least 10 seconds, with sufficient transient removal efficiency achieved by 30 seconds. A study by Stiles and Sheena *(32)* involving workers in a meat processing facility determined that a wash of 8 to 10 s was too short for adequate soil removal from the hands. A study by Ojajarvi *(21)* compared a 15 s and a two-minute wash, with the latter providing only an additional 3% transient bacterial reduction. Two observational studies were reviewed in the health care and food service industries to determine average durations in the real world. A study of nurses *(34)* revealed an average wash time of 21 s, while a survey of restaurant employees *(4)* showed that the average duration was 20 s.

After experiments were completed, log_{10} reductions of each individual handwashing were calculated by subtracting counts obtained after handwashing from baseline data. Statistical analysis using ANOVA, was performed, with no statistical difference seen between any set of handwashing and rinsing temperatures for normal (resident) or transient flora with either of the two contaminating soils. Figures 1 and 2 show log_{10} reduction results for the range of temperatures used in these experiments for normal (resident) flora soiled with TSB and with gamma irradiated ground beef, respectively. Four data points are provided at each temperature and soil. Two log_{10} reduction data points for both TSB and ground beef appear as negative for transient flora. Polynomial regression analysis was performed to display potential trends even though no statistical significance could be shown. In respect to normal (resident) flora, although rising temperature reduction efficacy seemed to increase slightly with TSB inocula, a slight decrease in efficacy was seen with ground beef. Resident TSB and ground beef R^2 values of 0.0135 and 0.1861, respectively, provide evidence of the lack of a relationship between the two variables.

Figures 3 and 4 show log_{10} reduction results for transient flora in TSB and gamma irradiated ground beef, respectively, at temperatures tested. Only one negative log_{10} reduction figure was observed. While polynomial regression showed a slight increase in efficacy with increasing temperature for ground beef inoculum, both high 48.9°C (120°F) and low 4.4°C (40°F) temperatures tended to have higher log_{10} reductions than the mid temperatures tested. Again, TSB and ground beef R^2 values of 0.1065 and 0.1174, respectively, provide evidence of a lack of relationship between the two variables.

The geometric mean log_{10} reduction for all transient flora experiments involving both TSB and ground beef inocula was 1.9,

Figure 4. Handwashing efficacy (log_{10} reduction) for transient flora (*S. marcescens*) in TSB at selected water washing and rinsing temperatures



whereas the resident flora log_{10} reduction was 0.2 for both menstruum. These log_{10} reduction figures are in agreement with results from other similarly performed studies of both resident *(6, 19)* and transient flora *(2, 7, 26)*.

A comparison of log_{10} reduction variability (as seen in Fig. 1-4) was reviewed for trends that could indicate increased or decreased variability with certain temperatures under specific inoculum conditions. Coefficient of variation values for each temperature group for both resident and transient flora as well as both menstruum were determined by obtaining the ratio of the standard deviations of each group to the mean log_{10} reductions. Figure 5 shows the coefficient of variation (expressed in percent) for each testing condition. Coefficients of variation are fairly consistent for transient flora, with resident flora data exhibiting a great deal of variation. Overall, there appeared to be a slightly lower variation in log_{10} reduction figures for the 48.9°C (120°F) temperature over the 35° C (95°F) group. Variability data from the 4.4°C (40°F) and 12.8°C (55°F) groups were similarly low, with variability for temperature ranges peaking at 21.1°C (70°F). Subjects freely commented that the water at a temperature of 4.4°C (40°F) was uncomfortable. In issues brought before the CFP, temperatures at or above 43°C (110°F) were argued to be uncomfortable. Taken together with the variability noted, it suggests that participants more consistently wash their hands when water temperatures are between 35°C (95°F) and 48.9°C (120°F).

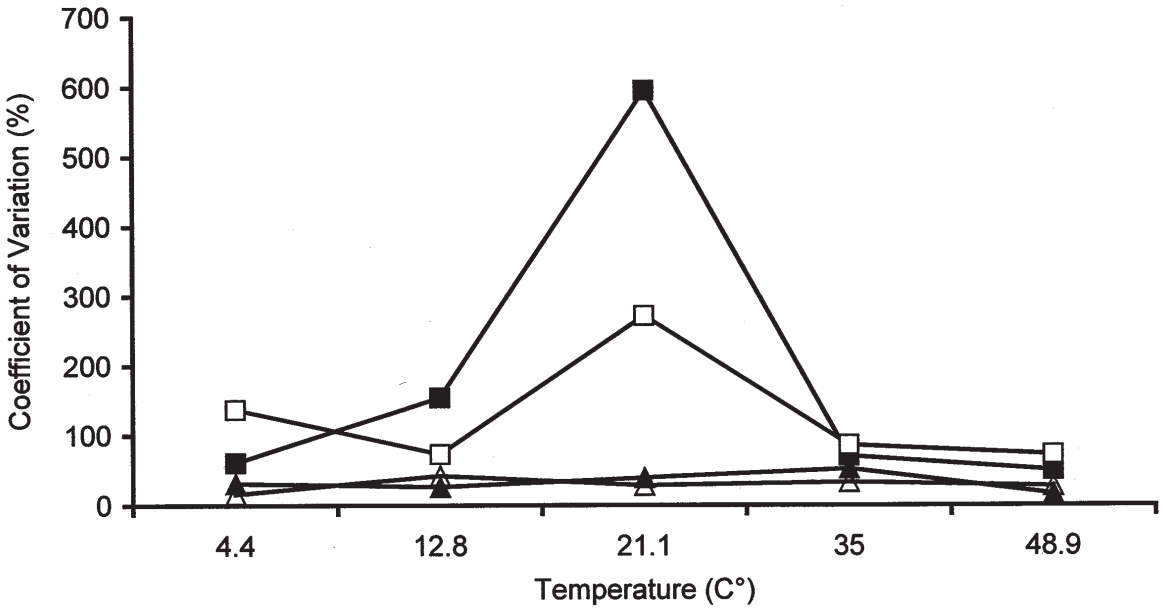
Friction has been identified as a key element in removing microbial contaminants from hands *(11, 27)*. Friction applied during the hand drying process is instrumental in finishing the process. Removal of transient flora appears to be even more friction dependent than removal of resident flora. Surfactant and antimicrobial compounds in soap are responsible for lifting soil and killing microorganisms suspended in the soil. When bland soap is used to wash hands, handwashing efficacy appears to be dependent on the effects of surfactant action of the soap along with friction applied during the washing and rinsing process. Rinsing also provides the necessary removal by dilution. To facilitate appropriate rinsing of the hands, some personal hygiene consultants have suggested the practice of using thicker, higher-viscosity soaps in larger doses, which would require a longer, more vigorous rinsing routine.

Price *(27)*, upon noticing that in his scrubbing experiments water temperature had little effect at de-germing of the skin, commented that water applied to the skin at a given temperature quickly reaches equilibrium with normal skin surface temperature unless hands are totally immersed.

Skin oils derived from sebum are liquid in the sebaceous gland and solidify on the skin surface. Beef tallow melts in the range of 35°C to 40°C (95°F to 104°F), while lard or butterfat are liquefied at temperatures around 30°C (86°F) *(15)*. If handwashing efficacy for both resident and transient floras embedded in both natural and artificially applied fats depended on thermal melting, then log_{10} reduction figures should have been greatest at the highest temperature and least at temperatures that cause these fats to congeal.

Fats such as tallow or lard are distinguished from oils in that oils are liquids at room temperature.

Figure 5. Coefficient of variation values (%) for handwashing $\log_{10}$ reduction of resident and transient flora with TSB and ground beef soils. Resident flora ground beef -■-, resident flora TSB -□-, transient flora TSB -▲-, transient flora ground beef -△-



Hand soap formulations are designed to lift soil through their foaming action, dispersing and solubilizing organic soils using detergent surfactants. Primary micelles are present, having hydrophilic and hydrophobic groups attached to the ends of the surfactant monomer. Soaps with multiple surfactants form mixed micelles, which increases efficiency with various soil mixtures. In water and organic soil mixtures, these form complex micelle structures around hydrocarbon moieties (encapsulation), resulting in microemulsions. Thus, the soap provides a "bridge" between the oily droplet and water, permitting the soapy water to "wash away" greasy material.

Price *(27)* described the contradictory aspect of soap, which tends to reduce surface friction. Soaps of his day were not the more developed formulas now available and used in this experiment. In the experiments described here, a 3-ml aliquot of bland soap was used to remove a total of one gram of TSB or three grams of ground beef. Use of lower quantities of soap would obviously provide lower surfactant effectiveness. The quantity of soap used for handwashing has the ability to affect handwashing efficacy, as shown by Larson *(14)*. Several studies *(13, 16, 17, 18, 19, 21, 25, 29, 31)* have used soap amounts in the range of 2.5 to 5.0 ml in their handwashing protocol. The higher levels are considered excessive, except in hospital infection control. Many food service operations set soap dispensers at 1 ml per pump, and employees often times use multiple pumps. As the experiments described here utilized 1.5 grams ground beef menstruum per hand, 3 ml of soap was chosen to represent an amount found to be significantly effective in an earlier study *(14)*. In that study, it was determined that 3-ml of soap provided greater bacterial reductions than did 1 ml for a liquid, nonantimicrobial soap. Observations of soap usage by health care employees in the hospital setting were also performed, as nine different departments, from labor and delivery to psychology, determined average soap use to be around 2.18 ml per incidence, compared to 3.5 by the general population *(14)*.

Surfactants in soap have surface tension lowering capabilities. The vigorous rubbing action of hands creates a rapid formation of surfaces and changing pressure gradients, which develop and increase micelle formation. The combined action of soap, friction and dilution appears to outweigh any advantage that temperature might have in the liquefying of fats, which would normally occur in the range of 30°C to 40°C (86°F to 104°F).

Many antimicrobials are inactivated by the presence of organic soils or soaps. Several writers have suggested that these antimicrobial ingredients present in soaps are not in contact with microorganisms long enough to provide sufficient antimicrobial action. Of the commonly used antimicrobial ingredients employed in soap products, only iodophors have been shown to exhibit temperature-dependent antimicrobial effects due to temperature-dependent dissociation constants for PVP and iodine present in the formulation. For these reasons, even if antimicrobial agents were present in soap, it is doubtful that water temperature would have a significant effect on overall hygienic efficiency. It should also be noted that under real-life conditions, hands would be dried (usually with paper towels) and that further bacterial reductions in the range of 1 $\log_{10}$ are seen, reducing any slight difference in efficacy with antimicrobial soaps.

ACKNOWLEDGMENTS

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Conference for Food Protection
2012 Issue Form

Internal Number: 098
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Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
Addressing Nontyphoidal Salmonella in the FDA Food Code

Issue you would like the Conference to consider:
Amend the 2009 FDA Food Code to add nontyphoidal *Salmonella* as one of the reportable illnesses for action by the Person in Charge, add Code language to address employee health controls for the exclusion and restriction of nontyphoidal *Salmonella,* and remove exclusion and restriction language in all applicable Code Sections.

Public Health Significance:
Nontyphoidal *Salmonella* (NTS) *enterica* serotypes are among the most common and important foodborne pathogens. NTS are estimated to cause more than one million domestically acquired foodborne illnesses in the United States each year (Scallan et. al. 2011), and are the leading cause of hospitalizations and deaths due to foodborne illness in the United States (Barton-Behravesh et al. 2011, CDC 2011). Whereas reductions in incidence have been achieved for many other foodborne pathogens in recent years, no significant change in incidence of NTS infections has occurred since the start of FoodNet surveillance during 1996-1998 (CDC 2011). Therefore, further interventions are needed to reduce the incidence of NTS infections.

Commercial food establishments are an important setting for the transmission of NTS, both in the form of recognized foodborne disease outbreaks as well as sporadic infections. During 1998 to 2002, the 585 *Salmonella enterica* outbreaks reported to the Centers for Disease Control and Prevention accounted for 49% of all bacterial outbreaks (Lynch et al. 2006). Fifty-three percent of *Salmonella* outbreaks occurred in commercial food establishments, the most common setting for *Salmonella* outbreaks (Lynch et al. 2006). Outbreaks of salmonellosis at commercial food establishments frequently involve direct transmission to patrons from fresh produce or undercooked foods of animal origin, or cross contamination from these foods. However, numerous NTS outbreak investigations have implicated food workers as the source of the outbreak or strongly suggested transmission from food workers (Ethelberg et al. 2004; Greig et al. 2007; Hedberg et. al. 1991; Hedican et al. 2009; Hundy and Cameron 2002; Khuri-Bulos et al. 1994; Maguire et al. 2000; Medus et al. 2006; Todd et al 2007a, 2007b).

In a study of restaurant-associated salmonellosis outbreaks in Minnesota published by Medus et al. (2006), the importance of infected food workers as a source of contamination

in the outbreaks was supported by several observations. First, a specific food vehicle was statistically implicated or suspected in a low proportion of the restaurant outbreaks (39%), which suggests that the specific food items or food handling errors were not the primary causes for these outbreaks. Second, food workers infected with NTS were identified in the majority (83%) of the outbreak investigations. Overall, 12% of the food workers tested positive for NTS. Infected food workers who reported a history of illness shed NTS in the stool for a median of 1 month. The authors concluded that regardless of the original source of a *Salmonella* outbreak in a restaurant (e.g., raw meat or eggs), the initial source of a salmonellosis outbreak, food workers frequently serve as reservoirs for NTS and contribute to transmission to patrons. Thus, assessment of food worker history, i.e. symptoms and exposures, stool samples and exclusion or restriction of infected food workers from the food establishment are essential for controlling restaurant-associated outbreaks of salmonellosis.

In a study of food workers with salmonellosis who were detected through routine surveillance (Medus et al. 2010), 2.2% of identified culture-confirmed *Salmonella* cases were food workers, and identification of these cases were critical to the identification of numerous outbreaks. The authors concluded that the rapid identification and follow-up of food workers among reported cases of salmonellosis is important to the early detection and control of outbreaks in restaurant settings. Importantly, even hostesses, servers, bartenders, and others who theoretically have limited food preparation duties can serve as sentinels of transmission within the restaurant. The authors also stated that food workers should be considered an important source of *Salmonella* transmission, and those identified through surveillance should raise a high index of suspicion of a possible outbreak at their place of work. Food service managers need to be alert to *Salmonella*-like illnesses among food workers to facilitate prevention and control efforts, including exclusion of infected food workers or restriction of their duties.

The Food and Drug Administration's Food Code does not currently exclude or restrict food workers with a NTS infection (US FDA 2009). Restriction of food workers infected with NTS after resolution of symptoms is not a national standard. However, because of the prolonged duration of shedding of NTS, evidence that food workers have been the source of foodborne outbreaks, evidence that food workers work while ill (Green et al. 2005), and evidence of inadequate hand hygiene practices (Green et al. 2006; US FDA 2004), exclusion or restriction of infected food worker duties is a reasonable public health measure. At a minimum, potential for transmission and how to prevent it should be discussed with the food worker and their manager.

The biology of NTS and the epidemiology of salmonellosis are complex; food workers may be an underappreciated part of that complexity. In order to decrease the incidence of NTS infections in the United States, commercial food establishments should also be targets for more focused prevention measures, and prevention and control efforts should consider food workers as an important source of NTS transmission.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:

1. Include illness due to nontyphoidal *Salmonella* (NTS) as an illness that upon diagnosis by a health practitioner:

- Requires food employees to report the diagnosis and any symptoms associated with NTS to the Person in Charge;
- Prompts the Person in Charge to exclude a food employee with symptoms and a diagnosis of NTS until asymptomatic for at least 24 hours; and
- Prompts the Person in Charge to restrict a NTS-diagnosed food employee whose symptoms have resolved for at least 30 days from the date of onset of those symptoms;

2. Develop language in the appropriate sections of Food Code, Chapter 2 that addresses the conditions for exclusion and restriction and reinstatement following exclusion and restriction as stated above.

3. Add language to the public health reasons in Annex 3 contained in Attachment A titled, "Addressing Nontyphoidal Salmonella in the FDA Food Code (new language has been underlined), including associated changes in the Part 2-2 Employee Health Tables (not shown).

Submitter Information:

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Attachments:

- "Attachment A: Proposed changes to Food Code Annex 3, Public Health Reason"
- "Attachment B: Addressing NT Salmonella.Article1"
- "Attachment C: Addressing NT Salmonella.Article2.Abstract"
- "Attachment D: Addressing NT Salmonella - References"

Amend Annex 3, Public Health Reasons and Administrative Guidelines in Part 2-2, Employee Health, and its related subparts and Tables including Subpart 2-201, Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201, Section 2-201.12, Exclusions and Restrictions, and Section 2-201.13, Removal of Exclusions and Restrictions, to read as follows:

Add information about nontyphoidal *Salmonella* to read:

Nontyphoidal *Salmonella* (NTS) *enterica* serotypes are among the most common and important foodborne pathogens. NTS are estimated to cause more than one million domestically acquired foodborne illnesses in the United States each year (Scallan et. al. 2011), and are the leading cause of hospitalizations and deaths due to foodborne illness in the United States (Barton-Behravesh et al. 2011, CDC 2011). Whereas reductions in incidence have been achieved for many other foodborne pathogens in recent years, no significant change in incidence of NTS infections has occurred since the start of FoodNet surveillance during 1996–1998 (CDC 2011). Therefore, further interventions are needed to reduce the incidence of NTS infections.

Commercial food establishments are an important setting for the transmission of NTS, both in the form of recognized foodborne disease outbreaks as well as sporadic infections. During 1998 to 2002, the 585 *Salmonella enterica* outbreaks reported to the Centers for Disease Control and Prevention accounted for 49% of all bacterial outbreaks (Lynch et al. 2006). Fifty-three percent of *Salmonella* outbreaks occurred in commercial food establishments, the most common setting for *Salmonella* outbreaks (Lynch et al. 2006). Outbreaks of salmonellosis at commercial food establishments frequently involve direct transmission to patrons from fresh produce or undercooked foods of animal origin, or cross contamination from these foods. However, numerous NTS outbreak investigations have implicated food workers as the source of the outbreak or strongly suggested transmission from food workers (Ethelberg et al. 2004; Greig et al. 2007; Hedberg et. al. 1991; Hedican et al. 2009; Hundy and Cameron 2002; Khuri-Bulos et al. 1994; Maguire et al. 2000; Medus et al. 2006; Todd et al 2007a, 2007b).

In a study of restaurant-associated salmonellosis outbreaks in Minnesota published by Medus et al. (2006), the importance of infected food workers as a source of contamination in the outbreaks was supported by several observations. First, a specific food vehicle was statistically implicated or suspected in a low proportion of the restaurant outbreaks (39%), which suggests that the specific food items or food handling errors were not the primary causes for these outbreaks. Second, food workers infected with NTS were identified in the majority (83%) of the outbreak investigations. Overall, 12% of the food workers tested positive for NTS. Infected food workers who reported a history of illness shed NTS in the stool for a median of 1 month. The authors concluded that regardless of the original source of a *Salmonella* outbreak in a restaurant (e.g., raw meat or eggs), the initial source of a salmonellosis outbreak, food workers frequently serve as reservoirs for NTS and contribute to transmission to patrons. Thus, assessment of food worker history, i.e. symptoms and exposures, stool samples and exclusion

or restriction of infected food workers from the food establishment are essential for controlling restaurant-associated outbreaks of salmonellosis.

In a study of food workers with salmonellosis who were detected through routine surveillance (Medus et al. 2010), 2.2% of identified culture-confirmed *Salmonella* cases were food workers, and identification of these cases were critical to the identification of numerous outbreaks. The authors concluded that the rapid identification and follow-up of food workers among reported cases of salmonellosis is important to the early detection and control of outbreaks in restaurant settings. Importantly, even hostesses, servers, bartenders, and others who theoretically have limited food preparation duties can serve as sentinels of transmission within the restaurant. The authors also stated that food workers should be considered an important source of *Salmonella* transmission, and those identified through surveillance should raise a high index of suspicion of a possible outbreak at their place of work. Food service managers need to be alert to *Salmonella*-like illnesses among food workers to facilitate prevention and control efforts, including exclusion of infected food workers or restriction of their duties.

The Food and Drug Administration's Food Code does not currently exclude or restrict food workers with a NTS infection (US FDA 2009). Restriction of food workers infected with NTS after resolution of symptoms is not a national standard. However, because of the prolonged duration of shedding of NTS, evidence that food workers have been the source of foodborne outbreaks, evidence that food workers work while ill (Green et al. 2005), and evidence of inadequate hand hygiene practices (Green et al. 2006; US FDA 2004), exclusion or restriction of infected food worker duties is a reasonable public health measure. At a minimum, potential for transmission and how to prevent it should be discussed with the food worker and their manager.

The role of infected food handlers in nontyphoidal salmonellosis outbreaks in establishments serving highly susceptible populations has not been examined. Such events are much less frequent than those in establishments not serving highly susceptible populations. For example, from 1998-2011 to date, only 29 nontyphoidal salmonellosis outbreaks were reported to CDC that occurred in nursing home facilities, compared with 731 outbreaks in restaurants or delis. There are many highly susceptible persons in the general population who eat in regular, non-institutionalized settings. A more restrictive exclusion criteria for establishments serving highly susceptible populations is not warranted at this time.

The biology of NTS and the epidemiology of salmonellosis are complex; food workers may be an underappreciated part of that complexity. In order to decrease the incidence of NTS infections in the United States, commercial food establishments should also be targets for more focused prevention measures, and prevention and control efforts should consider food workers as an important source of NTS transmission.

NONTYPHOIDAL *SALMONELLA*

General Description:

Nontyphoidal *Salmonella enterica* (NTS) are bacteria that cause a diarrheal illness called salmonellosis. NTS are among the most common and important causes of enteric disease. An estimated 1.2 million cases occur annually in the United States; of these, approximately 42,000 are culture-confirmed cases reported to the Centers for Disease Control and Prevention.

Salmonella lives in the intestines of animals or humans. It can be found in water, food, soil, or surfaces that have been contaminated with the feces of infected animals or humans. People can become infected with *Salmonella* by:

- Eating foods contaminated with the bacteria. Contaminated foods are often of animal origin, such as beef, poultry, unpasteurized milk, or eggs. Fruits and vegetables may also be contaminated. Any food can be contaminated by an infected food handler.
- Contacting farm animals or pets (including reptiles, amphibians, chicks, and ducklings), animal feces, or animal environments.
- Touching contaminated surfaces or objects and then touching ones mouth or putting a contaminated object into ones mouth.
- Drinking contaminated water.

The majority of infections are thought to be acquired through consumption of contaminated food.

Incubation Period:
Symptoms often begin 12 to 72 hours after being exposed to the bacteria, although it can take up to a week or more for symptoms to develop in some people.

Symptoms and Complications:
Symptoms of salmonellosis include diarrhea, abdominal cramps, and fever. The illness usually lasts 4 to 7 days. Persons with NTS infections usually recover without treatment. However, in approximately 20% of persons, the illness is so severe that hospitalization is required. In these patients the NTS infection may spread from the intestine to the blood stream, and then to other body sites and can cause death unless the person is treated promptly with antibiotics. An estimated 400 fatal cases of salmonellosis occur each year. A small number of persons experience long-term consequences from NTS infections, such as arthritis that can last for months or years.

Antibiotic treatment for salmonellosis is generally not indicated for typical intestinal illness. Antibiotics typically do not shorten the duration of illness or eliminate the carrier state. However, antibiotic treatment is recommended for persons who develop invasive (extraintestinal) infections, infants under 2 months of age, the elderly, or those who have certain underlying medical conditions that predispose them to invasive infection.

Infectivity:
The minimum infectious dose of NTS for humans is generally described as 100 to 1,000 organisms. However, doses of fewer than 10 organisms have caused illness in multiple outbreaks. Persistence of NTS in the stool after the acute phase of illness is a well described consequence of NTS infections. This persistence is often referred to as a temporary carrier state, and the term "shedding" is used to describe the excretion of *Salmonella* in the stool.

Studies have consistently shown that the median duration of shedding in the stool to be 4 to 5 weeks after onset of acute gastroenteritis. Persons who have been exposed to NTS but who never develop symptoms can also be temporary carriers of NTS; these persons shed NTS for a

shorter period of time than persons who experienced illness. Carriers of NTS are known to shed the bacteria in the stool intermittently. Treatment with antimicrobials does not eradicate NTS from stool and may actually prolong the duration of shedding.

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Salmonella Outbreaks in Restaurants in Minnesota, 1995 through 2003: Evaluation of the Role of Infected Foodworkers

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ABSTRACT

The 23 restaurant-associated salmonellosis outbreaks that occurred in Minnesota from 1995 through 2003 were reviewed to characterize the role of infected foodworkers. The median duration of the outbreaks was 21 days (range, 1 to 517 days). The median number of culture-confirmed patron cases per outbreak was seven (range, 1 to 36 cases). The median incubation for patron cases ranged from 9 h to 5.9 days. A specific food vehicle was implicated in four outbreaks and suspected in five. *Salmonella* of the same serotype and pulsed-field gel electrophoresis subtype as that found in patrons was recovered from foodworkers in 19 outbreaks. Overall, 12% (129 of 1,033) of foodworkers tested positive for *Salmonella.* Sixty-four (53%) of 121 *Salmonella*-positive foodworkers reported not having had a recent gastrointestinal illness. Overall, the median duration of *Salmonella* shedding was 16 days. Among foodworkers who reported gastrointestinal illness, the median shedding duration was 30 days as compared with 3 days for asymptomatic foodworkers. Positive environmental samples were recovered in 4 (33%) of 12 outbreaks. No specific food vehicle was identified in any outbreaks associated with *Salmonella*-positive environmental samples. The median duration of outbreaks with positive environmental samples (187 days) was significantly longer than the median duration of outbreaks with negative environmental results (26 days, $P = 0.03$). A higher proportion of *Salmonella*-positive foodworkers (22 versus 8%) was identified in outbreaks with positive environmental samples. *Salmonella* outbreaks in restaurants are frequently prolonged yet produce a small number of confirmed patron cases. Prolonged outbreak durations suggest a persistent reservoir of contamination. Infected foodworkers likely serve as an important source for *Salmonella* transmission. Therefore, assessment of foodworker infection is essential for controlling restaurant outbreaks.

Nontyphoidal salmonellae are important foodborne pathogens that cause an estimated 1.4 million illnesses and more than 15,000 hospitalizations in the United States each year *(41).* From 1993 to 1997, *Salmonella enterica* was the most common foodborne outbreak etiology reported to the Centers for Disease Control and Prevention, accounting for 357 outbreaks; 137 (38%) of those outbreaks occurred in commercial food establishments (restaurants, delicatessens or cafeterias) *(36).*

Salmonella can be shed in the stool of infected persons for weeks after infection. A literature review conducted 20 years ago revealed that 50% of persons with *Salmonella* infections stopped shedding the organism by 5 weeks, and 90% of adults were culture negative 9 weeks after infection *(8).* In a study in Sweden, the median duration of shedding was 35 days in symptomatic infected travelers and 38 days in asymptomatic infected travelers *(24).*

The infectious dose of nontyphoidal *Salmonella* for humans is generally described as 10^2 to 10^3 organisms *(6, 34).* However, doses of 10 to 20 organisms *(12, 25)* and even fewer than 10 organisms *(11, 13, 16, 18, 21)* have caused illness. Several outbreak investigations have provided evidence of an inverse relationship between dose and incubation of illness, with low doses resulting in longer incubation periods *(15, 17, 31, 32).* Attack rates are also dependent on dose, with low doses resulting in lower attack rates *(15, 21).*

The number of *Salmonella* organisms shed in the stool decreases over time; however, one study revealed counts higher than 10^3 (range, 5×10^4 to 4×10^6) organisms per gram of feces in 5 of 10 specimens from persons tested 20 to 25 days after illness and counts higher than 10^2 (range, 10^2 to 2×10^5) organisms per gram of feces in 5 of 7 specimens from persons tested 27 to 33 days after initial diagnosis *(38).* In the same study, fingertip contamination after defecation was demonstrated. Handwashing was sufficient to remove the contamination from the fingertips of eight of nine study participants. The stool of the participant whose hands remained contaminated after handwashing had a *Salmonella* count of 6×10^3 organisms per gram of feces 15 days after illness *(38).* In an earlier study in which fingers were artificially inoculated with *Salmonella,* the pathogen was recovered after a 15-s handwashing bout at 10 min postinoculation *(37).*

The low infectious dose, prolonged shedding, and contamination of fingertips support the possibility that infected foodworkers can contaminate food and transmit *Salmonel-*

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la. However, the magnitude of the role of infected foodworkers in *Salmonella* outbreaks in commercial food establishments is uncertain. There is a prevalent paradigm that the contribution of foodworker *Salmonella* infection in transmission to patrons is negligible *(8, 12)*; however, this paradigm is based on a decades-old interpretation of available data. Since that time, numerous outbreak investigations have clearly implicated foodworkers or suggested foodworker transmission of *Salmonella (7, 14, 15, 19, 23, 26, 30).*

To further characterize the potential role of infected foodworkers in transmission of *Salmonella* to patrons during restaurant outbreaks, we evaluated all salmonellosis outbreaks in restaurants in Minnesota from 1995 through 2003, including the shedding of *Salmonella* in the stools of infected foodworkers associated with those outbreaks.

MATERIALS AND METHODS

Outbreak investigation records and summary reports of all confirmed foodborne salmonellosis outbreaks in restaurants in Minnesota from 1995 through 2003 were reviewed. An outbreak was defined as two or more cases of salmonellosis associated with the same *Salmonella* serotype and pulsed-field gel electrophoresis (PFGE) subtype with a common exposure, regardless of whether the cases involved patrons or foodworkers. The number of infected patrons identified for each outbreak was determined. The duration of an outbreak was defined as the number of days with documented transmission to patrons. Incubation time was calculated as the number of hours between the reported meal date and time and the date and time of illness onset for confirmed patron cases and in some outbreaks suspected patron cases. If meal time or onset time was not available, incubation time was calculated in days.

All employees of the outbreak restaurants regardless of specific duties (foodworkers) were required to submit stool specimens for *Salmonella* testing. Stool samples from foodworkers associated with 19 outbreaks were sent to the Minnesota Department of Health Public Health Laboratory (MDH PHL) for testing, and samples from three outbreaks were tested by the City of Minneapolis Public Health Laboratory as part of the investigation. *Salmonella* isolates from specimens tested at the City of Minneapolis were sent to the MDH PHL for confirmation and serotyping. *Salmonella* isolates from outbreak cases detected through routine surveillance were serotyped at the MDH PHL and subtyped by PFGE using previously described standardized methods *(5). Salmonella* isolates from some or all foodworkers in each outbreak also were subtyped by PFGE. Environmental samples collected by public health staff involved in the investigation were tested at the City of Minneapolis in two outbreaks and at the MDH PHL in six outbreaks. Environmental isolates were serotyped and subtyped by PFGE at the MDH PHL. In four outbreaks, environmental sampling was conducted by private commercial laboratories hired by the implicated restaurant. Isolates from three of these outbreaks were confirmed, serotyped, and subtyped by PFGE at the MDH PHL. Isolates from the fourth outbreak were not forwarded to the MDH PHL.

For most outbreak investigations, two consecutive negative *Salmonella* cultures collected at least 24 h apart were required of each foodworker; only one negative culture was required during three outbreak investigations. All foodworkers who tested positive for *Salmonella* were required to continue to submit stool samples until two or more consecutive specimens collected at least 24 h apart tested negative for *Salmonella.* Attempts were made to interview all foodworkers about their history of gastrointestinal symptoms (including specific symptoms and date of illness onset) and job responsibilities using a standard questionnaire at the time of the investigation. A foodworker was classified as having a history of gastrointestinal illness when any compatible symptoms were reported within 1 month of the earliest known meal date associated with a salmonellosis case or during the investigation, even when symptoms were mild (e.g., any nausea, any cramps, or any diarrhea) or could have been explained by a chronic condition.

The total number of foodworkers interviewed and tested for each outbreak was ascertained. Laboratory records of foodworkers who tested positive for *Salmonella* were reviewed to document the dates of specimen collection of the first positive, last positive, first negative, and second negative specimens. If specimen collection date was unavailable, date of specimen receipt at the PHL was used as a proxy for the specimen collection date. Interview records were reviewed to ascertain whether the foodworker reported a history of gastrointestinal illness symptoms and to ascertain the date of symptom onset.

Duration of *Salmonella* shedding in the stool was defined as the number of days from symptom onset until the collection date of the last positive stool specimen. For reportedly asymptomatic foodworkers and foodworkers who did not recall the onset date, shedding was calculated from the collection date of the first positive specimen to the collection date of the last positive specimen. Shedding in foodworkers who stopped submitting stool samples before they had any negative results was calculated using the date of the last positive sample submitted. To more directly compare symptomatic and asymptomatic infections, shedding was also calculated in symptomatic foodworkers from the collection date of the first positive specimen after the start of the investigation to the collection date of the last positive specimen. The Wilcoxon two-sample test was used to compare the median durations of *Salmonella* shedding in the stool of symptomatic and asymptomatic foodworkers and to compare the median duration of outbreaks in restaurants with *Salmonella*-positive and -negative environmental sample results.

Descriptive and summary statistics were generated using SAS 9.1 and SAS Enterprise Guide 2.0 (SAS Institute, Cary, N.C.).

RESULTS

Outbreak and restaurant characteristics. From 1995 through 2003, 39 confirmed foodborne outbreaks of *Salmonella* infection were identified in Minnesota. Of these, 23 outbreaks occurred in restaurants (range, one to four per year). *Salmonella enterica* serotypes associated with restaurant outbreaks included Typhimurium (seven outbreaks), Heidelberg (five), Enteritidis (four), Braenderup (three), Newport (three), and Montevideo (one) (Table 1). Two restaurants had two outbreaks each (Table 1; outbreaks 10 and 22 and outbreaks 11 and 21). A single restaurant chain accounted for five outbreaks (nos. 6, 7, 8, 12, and 17) in different locations. Eighteen of the 23 restaurants were table service restaurants (outbreaks 1, 3, 4, 6 through 14, 16, 17, and 20 through 23), 3 were buffets (outbreaks 2, 18, and 19), 1 was a cafeteria-style restaurant (outbreak 5), and one was a nonchain soup, salad, and sandwich restaurant (outbreak 15). Eleven of the 23 outbreaks occurred in restaurants that serve breakfast all day (outbreaks 1, 6, 7, 8,

TABLE 1. *Descriptive data for outbreaks of salmonellosis in restaurants in Minnesota, 1995 through 2003*

Outbreak no.	*Salmonella* serotype	Vehicle	Outbreak dates	Positive environmental samples	Outbreak duration (days)[a]	No. of confirmed infected patrons	Incubation time[b]		
							Median (days)	Shortest (h)	Longest (days)
1	Typhimurium	Unknown	May 95–Aug 95	No	92	33	3.0	24.0	13.0
2	Typhimurium	Unknown	Jul 95–Aug 95	None taken	20	8	2.8	24.0	4.0
3	Typhimurium	Salad	Aug 95–Sept 95	None taken	21	9	2.0	9.0	8.9
4	Typhimurium	Unknown	Jan 96–Jun 96	None taken	167	5	1.0	24.0	8.0
5	Newport	Chicken pasta salad suspected	Jul 97–Dec 97	No	147	20	2.5	24.0	11.0
6	Braenderup	Unknown	July 97–Oct 97	Yes	99	4	1.9	12.0	10.8
7	Braenderup	Unknown	Oct 97–Jul 98	Yes	274	3	4.5	48.0	7.0
8	Braenderup	Unknown	Oct 97–Mar 99	Yes	517	7	5.9	23.0	7.4
9	Heidelberg	Unknown	Jun 98	None taken	1	1	3.6		
10	Heidelberg	Unknown	May 99	No	4	3	1.2	8.0	2.0
11	Montevideo	Unknown	Jun 99	No	1	1	10.0		
12	Heidelberg	Unknown	Jun 99–Jul 99	Yes	53	25	1.5	11.0	8.0
13	Typhimurium	Unknown	Aug 99	No	1	3	5.0		
14	Heidelberg	Meatloaf or eggs suspected	Apr 00–Jun 00	No	37	5	0.4	1.5	4.3
15	Typhimurium	Ground turkey suspected	Apr 00–May 00	None taken	5	4	5.0	96.0	6.0
16	Enteritidis	Eggs suspected	Sep 00	No	25	10	0.9	8.0	5.9
17	Enteritidis	Eggs	Jun 01–Jul 01	No	27	12	2.3	1.0	3.3
18	Newport	Unknown	Aug 01	None taken	11	9	2.0	24.0	6.0
19	Enteritidis	Chicken suspected	Apr 02	None taken	4	2	3.5	72.0	4.0
20	Newport	Unknown	Jul 02	None taken	7	5	2.3	13.0	7.7
21	Typhimurium	Unknown	Nov 02	None taken	14	14	3.4	37.0	11.9
22	Heidelberg	Eggs or pancakes	Sep 03	None taken	25	36	3.8	12.0	11.0
23	Enteritidis	French toast or eggs	Oct 03–Nov 03	None taken	21	20	3.4	19.0	7.3

[a] Documented length of transmission to patrons.
[b] Confirmed and probable case information may have been included in the calculations of incubation time.

10, 12, 14, 16, 17, 21, and 23), and 2 outbreaks occurred at a restaurant with an extensive breakfast menu (outbreaks 11 and 21). Six outbreaks occurred in restaurants serving ethnic foods: Chinese (outbreaks 2, 18, and 19), Italian (outbreaks 5 and 9), and Indian (outbreak 13).

The median duration of the restaurant outbreaks was 21 days, ranging from 1 day in outbreaks where only one patron case was identified to 517 days. Transmission to patrons occurred for more than 10 days in 70% of the restaurant outbreaks, for more than 1 month in 35%, and for more than 3 months in 21%. The two outbreaks with only one patron case were investigated when surveillance revealed culture-confirmed infections with the same serotype and PFGE subtype of *Salmonella* in a patron and a foodworker. Additional infected foodworkers were subsequently identified in the investigations of those outbreaks.

A vehicle was statistically implicated in four (17%) of the outbreaks (Table 1). In five additional outbreaks (22%), a vehicle was suspected but not statistically confirmed. During the study time period, there were 16 foodborne outbreaks of salmonellosis in settings in Minnesota other than a restaurant. In 14 (88%) of those outbreaks, a specific vehicle was implicated. Of those 16 outbreaks, 11 occurred at events (e.g., wedding receptions, banquets, and graduation or other parties) or in institutional settings; for these 11 outbreaks, a vehicle was identified in 10 (91%). The remaining five outbreaks were associated with commercial food products consumed in a variety of settings; for these outbreaks, a vehicle was confirmed in four and was strongly suspected in one.

Patron cases. The median number of culture-confirmed patron cases identified per restaurant outbreak was 7 (range, 1 to 36) (Table 1). With the exception of the two outbreaks (nos. 9 and 11) in which a single infected patron was identified and two other outbreaks (nos. 5 and 15), *Salmonella* isolates recovered from all patrons were indistinguishable by PFGE. In one outbreak (no. 5), two subtypes (different by six bands) of *Salmonella* Newport were isolated from patrons. In another outbreak (no. 15), two subtypes of *Salmonella* Typhimurium that differed by nine bands were isolated from patron cases.

The median incubation time for patrons for each outbreak ranged from 9 h to 5.9 days (excluding outbreaks 9, 11, and 13, in which incubation time was known for only one person). The range of incubations was also recorded for each outbreak. The shortest documented incubation was 1.5 h, and the longest was 13 days.

Foodworker illness and shedding of *Salmonella* in stools. In 22 of the 23 restaurant outbreaks, foodworkers

TABLE 2. *Number of foodworkers tested and number for whom an illness history was obtained in restaurant-associated outbreaks of salmonellosis in Minnesota, 1995 through 2003*

Outbreak no.[a]	Total no. of foodworkers tested	No. (%) of foodworkers with *Salmonella*:				
		With outbreak serotype	With any serotype	For whom symptom status was obtained	With history of gastrointestinal illness	Reportedly asymptomatic
1	60	13 (22)	13 (22)	12 (92)	7 (58)	5 (42)
2	14	1 (7)	1 (7)	0		
3	63	16 (25)	16 (25)	15 (94)	10 (67)	5 (33)
4	31	3 (10)	5 (16)	4 (80)	1 (25)	3 (75)
5	237	4 (2)	4 (2)	4 (100)	1 (25)	3 (75)
6	68	3 (4)	3 (4)	3 (100)	0	3 (100)
7	0					
8	41	10 (24)	10 (24)	8 (80)	1 (13)	7 (88)
9	117	2 (2)	3 (3)	1 (33)	1 (100)	0
10	12	2 (17)	2 (17)	2 (100)	1 (50)	1 (50)
11	39	9 (23)	9 (23)	9 (100)	5 (56)	4 (44)
12	74	26 (35)	27 (36)	27 (100)	11 (41)	16 (59)
13	7	0	0			
14	12	3 (25)	3 (25)	3 (100)	0	3 (100)
15	14	2 (14)	2 (14)	2 (100)	2 (100)	0
16	25	2 (8)	2 (8)	2 (100)	0	2 (100)
17	72	2 (3)	3 (4)	3 (100)	2 (67)	1 (33)
18	17	0	0			
19	10	0	0			
20	24	5 (21)	5 (21)	5 (100)	4 (80)	1 (20)
21	44	10 (23)	10 (23)	10 (100)	6 (60)	4 (40)
22	23	4 (17)	4 (17)	4 (100)	1 (25)	3 (75)
23	29	7 (24)	7 (24)	7 (100)	4 (57)	3 (43)
Total	1,033	124 (12)	129 (12)	121 (94)	57 (47)	64 (53)

[a] See Table 1.

were interviewed about their history of gastrointestinal illness and submitted stool specimens for *Salmonella* testing as part of the investigation. In 18 of 22 outbreaks, all foodworkers were required to submit stool samples until two consecutive specimens collected at least 24 h apart tested negative for *Salmonella.* In three outbreaks (nos. 9, 14, and 20), all foodworkers were required to submit one stool sample, but those whose samples were positive for *Salmonella* were required to continue submitting specimens until two consecutive specimens tested negative for *Salmonella.* In one of those three outbreaks (no. 20), workers who reported a history of gastrointestinal illness were also required to submit two stool samples for testing, even if the first was negative for *Salmonella.* In one outbreak (no. 1), all workers were required to submit specimens until three consecutive specimens were negative.

Salmonella-positive foodworkers were identified in 19 (83%) of 22 outbreaks. *Salmonella* of the same serotype as the patron isolates was recovered from foodworker specimens in all 19 outbreaks. Of 1,033 foodworkers tested overall, 129 (12%) submitted at least one stool sample that was positive for *Salmonella.* One hundred twenty-four of the 129 foodworkers were positive for the outbreak serotype (Table 2). For eight foodworkers in 4 of 17 outbreaks (nos. 1, 12, 16, and 21) the first specimen was negative for *Salmonella* but the second, which was collected 1 to 7 days later, was positive. Four foodworkers stopped submitting stool samples before any of their specimens tested negative. Thirty-five (7%) of 499 foodworkers tested in 14 outbreaks reported a history of recent gastrointestinal symptoms but two consecutive stools samples were negative for *Salmonella.*

Salmonella of the same PFGE subtype as the patron isolates was isolated from foodworker stool samples in all outbreaks with *Salmonella*-positive foodworkers. In addition, *Salmonella* Newport of a subtype that differed by more than 10 bands was recovered from one foodworker in one outbreak (no. 5), and two different subtypes of *Salmonella* Typhimurium (the outbreak subtype and a subtype that was nine bands different) were recovered from a stool sample of one *Salmonella*-positive foodworker in another outbreak (no. 15). Two different subtypes of *Salmonella* Heidelberg (the outbreak subtype and a subtype that was one band different) were recovered from the stool of one foodworker in one outbreak (no. 12). *Salmonella* subtypes that differed by only one band from the patron isolates were recovered from one foodworker in two additional outbreaks (nos. 11 and 20).

Illness history was obtained for 121 of the 129 foodworkers that tested positive for *Salmonella,* and 64 (53%) of these 121 foodworkers reported not having a history of recent gastrointestinal illness symptoms.

The proportion of *Salmonella*-positive foodworkers ranged from 0 to 36% per outbreak (median, 16%). Among

TABLE 3. *Median shedding period for* Salmonella *serotypes in stool samples of foodworkers in restaurant-associated salmonellosis outbreaks in Minnesota, 1995 through 2003*

Salmonella serotype	No. of workers	Median (range) shedding period (days)[a]
All	129	16 (1, 280)
Typhimurium	45	17 (1, 280)
Heidelberg	37	5 (1, 127)
Braenderup	13	3 (1, 74)
Enteritidis	12	25 (1, 114)
Newport	10	23 (5, 58)
Montevideo	9	27 (1, 87)
Oranienberg	1	1
Somatic C2	1	17
Unknown	1	1

[a] Shedding period was calculated from the date of illness onset in symptomatic foodworkers and from the collection date of the first positive sample for asymptomatic foodworkers.

those who tested positive and for whom an illness history was obtained, the proportion that reported no history of recent gastrointestinal illness ranged from 0 to 100% per outbreak (median, 44%) (Table 2).

The median duration of shedding regardless of illness history ($n = 129$) was 16 days (range, 1 to 280 days), and this value varied by serotype. Among serotypes associated with multiple cases, the median duration of shedding ranged from 3 days for *Salmonella* Braenderup to 27 days for *Salmonella* Montevideo (Table 3).

Among *Salmonella*-positive foodworkers who reported gastrointestinal illness ($n = 57$), the median duration of shedding was 30 days (range, 2 to 280 days) (Fig. 1A). Among asymptomatic foodworkers ($n = 64$), the median duration of shedding was 3 days (range, 3 to 97 days) (Fig. 1B). To more directly compare shedding in the two groups, the shedding period was recalculated in symptomatic foodworkers from the collection date of the first *Salmonella*-positive specimen after the start of the investigation to the collection date of the last *Salmonella*-positive specimen for both groups. The median duration of shedding from the first positive specimen was 13 days among symptomatic foodworkers and 3 days among asymptomatic foodworkers ($P = 0.004$).

The date of illness onset was available for at least one foodworker in 15 of the 19 outbreaks with positive foodworkers (Table 2). In 13 of these 15 outbreaks (nos. 1, 3, 4, 5, 8, 9, 11, 12, 15, 17, 18, 21, and 23), foodworkers reported illness onset before at least one patron's illness onset. In four outbreaks (nos. 9, 11, 15, and 21), at least one foodworker reported illness onset before the onset of the earliest patron illness. In 8 of 15 outbreaks (nos. 2, 5, 8, 9, 12, 15, 21, and 23), at least one foodworker had illness onset before the median patron illness onset point. In six outbreaks (nos. 5, 9, 12, 15, 21, and 23), the median foodworker illness onset date was before the median patron illness onset date.

Environmental sampling. Environmental sampling was conducted in 12 outbreak restaurants, and positive environmental samples were recovered in 4 (33%) of these restaurants. In three outbreaks, *Salmonella* of the outbreak serotype and PFGE subtype was recovered from (i) a cold holding area behind the cook's line and a cutting board (outbreak 6), (ii) egg grill grease traps, cake grill grease traps, and cutting boards (outbreaks 7 and 8), (iii) grill stands (outbreak 8), and (iv) the dishwasher area and employee break room (outbreak 7). In one outbreak, *Salmonella* was recovered from a grill grease trap and the side surface of a water cooler (outbreak 12), but isolates were not serotyped or subtyped by PFGE.

A vehicle was not identified in any of the outbreaks with *Salmonella*-positive environmental samples; in these outbreaks, the median duration of transmission was 187 days, and 22% of the workers tested positive for *Salmonella.* Conversely, a specific vehicle was implicated or suspected in four (50%) of the eight outbreaks in which *Salmonella* was not recovered from the environment; in these outbreaks, duration of transmission was shorter (median, 26 days; $P = 0.03$), and only 8% of the workers tested positive for *Salmonella* (Table 4).

Previously unrecognized outbreak. During the review of surveillance cases, a previously unrecognized *Salmonella* Enteritidis outbreak associated with a single restaurant in 1997 was identified. The six cases were caused by *Salmonella* Enteritidis with an indistinguishable PFGE pattern. The four infected patrons and two infected foodworkers from the restaurant were interviewed as part of routine surveillance. Their illness onset dates and patron meal dates ranged from June through September 1997.

DISCUSSION

The results of this study indicate that salmonellosis outbreaks in restaurants are usually not simple point source events caused by ingestion of one particular contaminated food item; rather, they are complex events that may last for several weeks or months. Despite the long duration, in many outbreaks only a small number of patron cases were identified. Nine of the outbreaks in the study period included 5 or fewer culture-confirmed patron cases, and fewer than 10 cases were identified in four of the five outbreaks with the longest duration. The identified cases likely represented only a small proportion of those who actually become ill. An estimated 38.6 salmonellosis cases occur for each culture-confirmed case *(41)*. Therefore, even a few confirmed cases can signal a much larger problem.

The importance of infected foodworkers as a source of contamination in these outbreaks is supported by several observations. First, a specific food vehicle was statistically implicated or suspected in a low proportion of the restaurant outbreaks (39%), which suggests that the specific food items or food handling errors were not the primary causes for these outbreaks.

Second, foodworkers infected with *Salmonella* were identified in the majority (83%) of the outbreak investigations. Overall, 12% of the foodworkers tested positive for

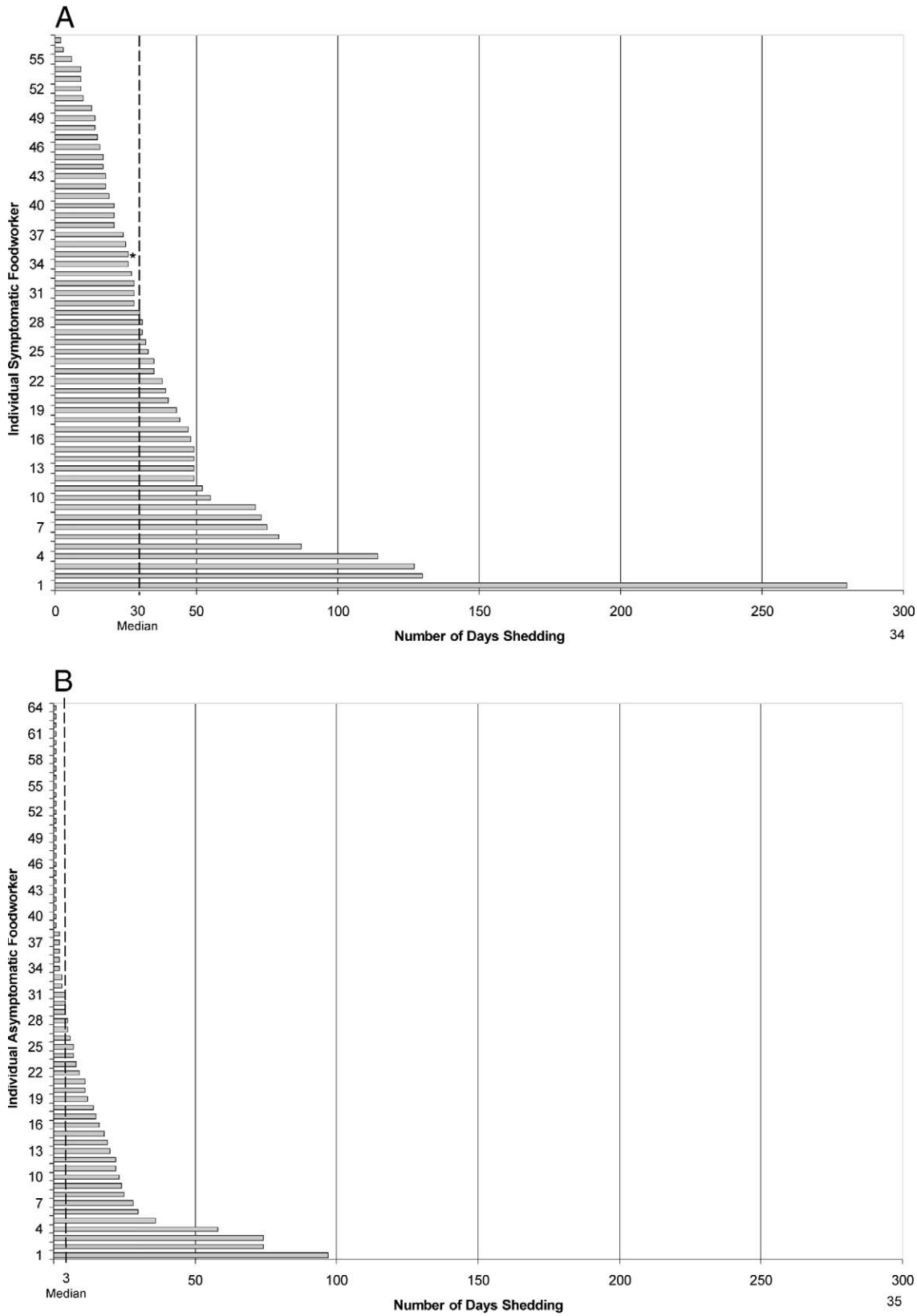

FIGURE 1. *Shedding in (A) symptomatic (*n = *57) and (B) asymptomatic (*n = *64) foodworkers tested during restaurant-associated outbreaks of salmonellosis in Minnesota, 1995 through 2003. * When infected individual did not recall the date of onset, shedding was calculated as the time between collection of the first* Salmonella*-positive stool sample and collection of the last positive specimen.*

TABLE 4. *Characteristics of restaurant-associated outbreaks of salmonellosis in Minnesota, 1995 through 2003, separated by results of environmental sampling*

Salmonella status of environmental samples	No. of outbreaks	No. (%) of outbreaks in which a vehicle was identified	No. (%) of *Salmonella*-positive foodworkers	Median duration of outbreaks (days)[a]
Positive	4	0	40/183 (22)	186
Negative	8	4 (50)	35/464 (8)	26

[a] Documented period of transmission to patrons.

Salmonella. Among these employees, half reported no history of recent gastrointestinal illness. Infected foodworkers who reported a history of illness shed *Salmonella* in the stool for a median of 1 month. Even though it is impossible to ascertain when asymptomatic persons became infected, the duration of shedding differed significantly in symptomatic and asymptomatic infected workers when shedding was compared based on the start of testing. Because these data were collected during outbreak investigations, it is not known how many of the *Salmonella*-positive foodworkers sought antibiotic treatment as a result of testing during the investigation. Foodworkers with a history of gastrointestinal illness may have preferentially sought treatment after finding out that they were infected with *Salmonella,* and because antibiotic treatment may prolong the duration of shedding *(2, 33, 35, 42),* these foodworkers shed *Salmonella* in the stool for longer than did their asymptomatic peers. Alternatively, some of the foodworkers that tested negative after antibiotic treatment that was not disclosed to the outbreak investigators may have continued to shed the pathogen because their infection was not truly eradicated and their negative status was only temporary *(10).*

Third, illness incubation in many patrons was longer than the 12 h to 3 days *(3, 4)* believed to be characteristic of *Salmonella* infections. In 43% of the outbreaks, the median incubation period was longer than 3 days. The long incubation periods and relatively small number of cases identified in these outbreaks suggest that the infectious dose was low, as would be expected if infected foodworkers were an important source of contamination in restaurants. A restaurant-associated outbreak of *Salmonella* Typhimurium infection in Denmark in 2003 that was traced to an asymptomatic infected foodworker had the same pattern of long incubation period and low infection rate *(15).* Long incubation and low infection rates were also attributed to low levels of contamination of dessert buns in an outbreak of *Salmonella* Enteritidis infection among school children in Japan in 2001 *(31).*

Although handwashing should be sufficient to remove *Salmonella* contamination from fingers, most people, even those in professions where hand hygiene is critical, do not adequately wash their hands *(1, 9, 40).* Thus, infected foodworkers likely act as a reservoir of *Salmonella* and contaminate foods at high enough levels to transmit illness to some patrons.

The prolonged outbreak durations documented in this study indicate either continual reintroduction of contaminated food or a persistent reservoir of contamination. Both the persistence of the outbreak strains identified by PFGE and the difficulty in implicating a specific vehicle strongly suggest that a reservoir of contamination within the restaurant is more likely than reintroduction of a single contaminated food over time. Infected foodworkers, environmental contamination, or both could serve as sources of contamination of different foods with a low inoculum of *Salmonella* over a period of weeks to months. In these investigations, *Salmonella* was recovered from food contact areas such as cutting boards and grill grease traps and from areas that did not come into direct contact with foods, such as an employee break room and a water cooler. These findings suggest that foodworkers' hands can contaminate surfaces. In contrast with the high proportion of outbreaks in which infected foodworkers were identified, in only 33% of the outbreaks evaluated for environmental contamination was *Salmonella* recovered from the environment.

Eating outside the home has consistently been a risk factor for sporadic *Salmonella* infections. A case-control study of salmonellosis conducted in 1996 and 1997 revealed that eating eggs outside the home was a risk factor for *Salmonella* Heidelberg infections *(20)* and that eating runny eggs outside the home and eating chicken outside the home were risk factors for *Salmonella* Enteritidis infections *(27).* More than half of the outbreaks in the present study occurred in restaurants that serve breakfast all day or have extensive breakfast menus and therefore use a large number of eggs. Therefore, eggs were considered the likely vehicle through which *Salmonella* entered the restaurant in many of our outbreaks, with subsequent transmission to patrons facilitated by infected foodworkers and environmental contamination. Outbreaks with low infection rates and long duration may represent the midpoint in a continuum ranging from transmission to a single patron resulting in a sporadic case of illness to the easily identified outbreak with a large number of cases in a short period of time *(22, 28, 29, 39).* Without use of real-time PFGE subtyping in conjunction with routine interviewing of all affected individuals, many of these outbreaks would have escaped detection. Our identification of a previously undetected outbreak during the review of records for this study illustrates that outbreaks with few cases over a prolonged period of time are easy to miss, even when real-time PFGE is used in conjunction with interviews.

Outbreaks of *Salmonella* infection in restaurants are complex events involving multiple factors that can be evaluated using a systems-based approach to correlate outbreak presentations with food safety system failures: (i) consumption of undercooked foods of animal origin (FAO) can be a direct source of illness for patrons; (ii) uncooked FAO can be a source for cross-contamination of ready-to-eat (RTE) foods; (iii) FAO can contaminate the environment, leading to sporadic or persistent contamination of RTE foods over time; (iv) foodworkers can become infected through contact with FAO or with environments contaminated by FAO or by consumption of contaminated foods; (v) infected foodworkers can contaminate the environment,

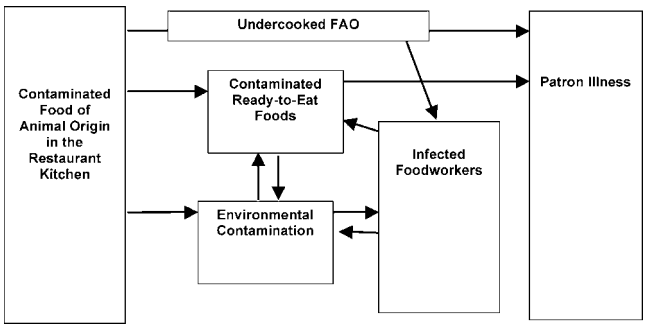

FIGURE 2. *Outbreaks of salmonellosis in restaurants are complex events with multiple pathways leading to transmission to patrons.*

which in turn can result in contamination of RTE foods; and (vi) RTE foods can become contaminated when prepared by infected foodworkers (Fig. 2). The complexity of these potential food safety system failures makes it difficult to ascertain the original source of the organism (food versus foodworker).

Regardless of the initial source of the outbreak, our results demonstrate that foodworkers frequently serve as reservoirs for *Salmonella* and contribute to transmission to patrons. Thus, assessment of foodworker infection by obtaining an illness history and testing stool samples and exclusion of infected foodworkers from the food establishment are essential for controlling restaurant-associated outbreaks of salmonellosis.

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ATTACHMENT C: Addressing NT Salmonella – Article 2 Abstract

Medus, C., K. E. Smith, J. B. Bender, F. Leano, and C. W. Hedberg. 2010. *Salmonella* infections in food workers identified through Routine Public Health Surveillance in Minnesota: Impact on Outbreak Recognition. J. Food Prot. 73:2053-2058.

"ABSTRACT

The frequency of *Salmonella*-infected food workers identified through routine surveillance from 1997 to 2004 in Minnesota was determined in order to evaluate the impact of surveillance on the detection of outbreaks in restaurants and to quantify the duration of *Salmonella* shedding in stool. Of 4,976 culture-confirmed *Salmonella* cases reported to the Minnesota Department of Health, 110 (2.2%) were identified as food workers; this was less than one-half the number expected based on the incidence of *Salmonella* in the general population. Twenty food workers (18%) were associated with outbreaks. Twelve were involved in nine independent outbreaks at the restaurants where they worked. The identification of the index food worker in six of these outbreaks was critical to the initiation of outbreak investigations that revealed much larger problems. Among food workers who submitted specimens until at least one negative result was obtained (n ~ 69), the median duration of shedding was 22 days (range, 1 to 359 days). Among the four most common serotypes (Enteritidis, Typhimurium, Heidelberg, and Newport) the median duration of shedding was significantly longer for Salmonella Newport (80 days; P ~ 0.02) and for *Salmonella* Enteritidis (32 days; P ~ 0.04) than for *Salmonella* Heidelberg (8 days). Food workers should be considered an important source of *Salmonella* transmission, and those identified through surveillance should raise a high index of suspicion of a possible outbreak at their place of work. Food service managers need to be alert to *Salmonella*-like illnesses among food workers to facilitate prevention and control efforts, including exclusion of infected food workers or restriction of their duties."

Submitter's Note: Full article exceeded CFP file limit. Abstract submitted in lieu of full article.

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Conference for Food Protection
2012 Issue Form

Internal Number: 043
Issue: 2012 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.

Title:
Report - ROP Committee (ROP 1)

Issue you would like the Conference to consider:
At the 2010 Conference for Food Protection, two issues regarding reduced oxygen packaging resulted in the formation of a CFP committee. That committee was charged with:
1.) create a guidance document detailing the scientific evidence of ROP HACCP controls and preventive measures and provide implementation suggestions
2.) recommend clarifications to the Food Code based on charge one
3.) report back to the Conference in 2012
The Reduced Oxygen Packaging (ROP) Committee requests acknowledgement of their final report including attachments, acknowledgement of the committee members for their hard work, and requests disbanding the committee.

Public Health Significance:
ROP offers unique advantages and opportunities for the food industry but also raises several microbiological and potential foodborne illness concerns. Products packaged using ROP may be produced safely if proper scientifically validated controls are in effect. Updates and clarifications of Food Code requirements and public health reasons are essential to ensure proper safeguards and to avoid unproductive confusion for inspectors and operators.

Recommended Solution: The Conference recommends...:
acknowledgment of the 2010-12 Reduced Oxygen Packaging Committee Report, with thanks to the members of the Committee for completing their task, and disbanding the committee.

Submitter Information:

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Attachments:

- "Committee Roster"
- "Report - ROP Committee -new"
- "Supporting information -new"

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.

2012 Committee Lists for Program Booklet

Committee Name: Reduced Oxygen Packaging

Last Name	First Name	Position (Chair/Member)	Constituency	Company /Employer Name	City	State	Position (Chair/Member)
Grinstead	Dale	Co-chair	Industry	Johnson Diversey	Sturtevant	WI	Co-chair
Nummer	Brian A.	Co-chair	Academia	Utah State University	Logan	UT	Co-chair
Blade	William Henry	Member	Regulatory	Rhode Island Department of Health	Providence	RI	Member
Dreesman	Kevin	Member	Regulatory	Illinois Department of Health	Springfield	IL	Member
Fletcher	Jessica	Member	Regulatory	Mohegan Tribe	Uncasville	CT	Member
Goldberg	Dan	Member	Industry	Walt Disney Parks and Resorts US	Lake Buena Vista	FL	Member
Gordon	Christopher	Member	Regulatory	Virginia Department of Health	Richmond	VA	Member
Graham	Joe	Member	Regulatory	Washington State Department of Health	Olympia	WA	Member
Kenney	Stetphen	Member	Industry	Darden Restaurants	Orlando	FL	Member
McGuffey	Charles E.	Member	Industry	7-Eleven, Inc.	Dallas	TX	Member
Ortiz	Joel	Member	Industry	Whole Foods Market	Austin	TX	Member
Parker	Richard	Member	Industry	HEB	San Antonio	TX	Member
Payton	Larry	Member	Industry	Tokyo Gardens Sushi	Houston	TX	Member
Schaffner	Donald	Member	Academia	Rutgers University	New Brunswick	NJ	Member
Schwartz	Thomas L.	Member	Industry	International Flight Services Association	Burke	VA	Member
Snyder	Oscar Peter	Member	Industry	Hospitality Institute of Tech and Mgmt	St Paul	MN	Member
Yamnik	Dale	Member	Industry	Yum! Brands, Inc.	Castle Rock	CO	Member
Scott	Jenny	Member	Regulatory (non voting)	USFDA	Washington	DC	Member
Moore	Veronica	Member	Regulatory (non voting)	USFDA	Washington	DC	Member

Conference for Food Protection
FINAL Committee Report

Committee: Reduced Oxygen Packaging 2010-2012

Council: III

Date of report: December 14, 2011

Submitted by: Brian Nummer and Dale Grinstead, Co-Chairs

Committee Charge:

The Conference recommends the formation of a new committee that is charged with the following:

1.) Create a guidance document detailing the scientific evidence of ROP HACCP controls and preventive measures and provide implementation suggestions.

2.) Recommend clarifications to the Food Code based on charge one.

3.) Report back to the Conference in 2012.

Committee Activities and Recommendations:
The committee has met approximately monthly from October 2010 until December 2011 via phone conference and email. The following is a summary of actions on charges:

1.) Create a guidance document detailing the scientific evidence of ROP HACCP controls and preventive measures and provide implementation suggestions.

The committee has extensively discussed preventative measures for the reduced oxygen packaging (ROP) hazards C. *botulinum* and L. *monocytogenes*. The Committee has decided to amend and update the Annex 6 public health reasons of the Food Code rather than create its own guide from scratch (Issue submitted: Updates to Annex 3 Public Health Reasons and References Annexes). Individual issues regarding hazard preventative measures or measures to improve the ROP portions of the Food Code were presented to the CFP ROP Committee along with the scientific rationale for safety. All issues presented were approved as amended by the CFP ROP Committee. Individual issues were then used to craft suggested changes to the Food Code (see below).

2.) Recommend clarifications to the Food Code based on charge one.

Issue outputs were submitted to 2012 CFP as follows:

- Definitions for Reduced Oxygen Packaging
- Sous Vide - Cook Chill Time and Temperature Changes
- Sous Vide and Cook Chill pH and Temperature
- Requirement to submit a HACCP plan to the regulatory authority
- Updates to Annex 3 Public Health Reasons and References Annexes

3.) Report back to the Conference in 2012.

This document serves as the 2012 Conference for Food Protection report. The committee report and five issues relating to this work will be submitted to council III as documented above.

Requested Board (or other) actions

Acknowledge this final committee report, acknowledge the hard work of the committee members, and dissolve this committee.

Recommendation(s) for future charge

To disband the committee because all charges have been completed.

This final report and the committee member roster are respectfully submitted by Brian A Nummer and Dale Grinstead, co-chairs of the 2010 – 2012 CFP Reduced Oxygen Packaging Committee.

ROP Committee Supporting Documents

Appendix 1 – Table 1: Summary of code and Annex changes proposed by 2009-2012 ROP committee and the rationale for each change.

Appendix 2 -Table 2: References summarizing growth limitation of psychrotrophic *Clostridium botulinum.* 1 page

Appendix 3 - Table 3: References summarizing growth limitation of *Listeria monocytogenes* 2 pages

Appendix 4- Committee summary of time to toxin formation of C. *botulinum* in foods with attached reference article (Skinner-Larkin paper reviews extensive research done by FDA scientists regarding time to toxin formation of C. *botulinum* in foods).

Appendix 5 – Email from FDA CFSAN clarifying when HACCP plans must be submitted.

Appendix 6 - Committee issue voting summary with individual members suggested edits.

Table 1: Summary of code and Annex changes proposed by 2009-2012 ROP committee and the rationale for each change.

Table 1A. Section 1-201.10 changes

Food Code	Recommended Changes	Rationale
1-201.10 (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	No recommended changes	
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:	No recommended changes	
1-201.10 (2) Reduced oxygen packaging includes:	No recommended changes	
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;	No recommended changes	
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;	No recommended changes	
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, no respiring FOOD, and impermeable PACKAGING material;	No recommended changes	
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 psychotropic pathogens; or	No recommended changes	
e) Sous vide PACKAGING, in which raw or partially cooked FOOD is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.	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.	Adding the vacuum packaging language brings this in line with the accepted understanding of sous vide and with the process outlined in Annex 6 2 (B) 4b

New	1-201.10 (3) Reduced Oxygen Packaging does not include: a) Placing product in a bag and sealing it immediately prior to or after cooking, cooling or reheating the product as long as the product is: i. Labeled with the time and date the product is placed in the bag; Pf ii. Removed from the bag within 48 hours of the time product is placed in the bag; P	Short term storage of food products held in cold storage at temperatures of 41o F or below in oxygen barrier bags for less than 48 hours does not allow sufficient time for the production of Clostridium botulinum nor the rapid and progressive growth of Listeria monocytogenes. The current code allows up to 48 hours to cool product from 41o F to 34o F for reduced oxygen packaging. As long as product is stored below 41o F no regulatory action would be taken on this product until the product reached the end of the 48 hour time period. The 48 hour time frame is validated by numerous studies reviewed by the CFP's ROP committee. The Skinner-Larkin model for pathogen growth (see Annex 2 for references) shows that the 48 hour time frame is a conservative estimate and C. botulinum and L. monocytogenes would take far longer to produce toxin or grow to dangerous levels.

Table 1B. Section 3-502.11 changes

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:	No recommended changes	
A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement;	No recommended changes	
B) Curing FOOD;	No recommended changes	
C) Using FOOD ADDITIVES or adding components such as vinegar:	(C) Using FOOD ADDITIVES or adding components such as vinegar**, except as specified in 3-502.12 (D)(2)(e)(iii)**:[Pf]	This change will allow ROP processes to add an acidifying agent to reduce pH to below 5.0 so that product may be held at below 41° F for up to 30 days. Research has shown that this yields an acceptable method with a built in safety margin to allow ROP processes without the need for going through the variance process.
1) As a method of FOOD preservation rather than as a method of flavor enhancement, or	No recommended changes	
2) To render a FOOD so that it is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL OF SAFETY FOOD);	No recommended changes	
D) Packaging FOOD using a REDUCED OXYGEN PACKAGING method except where the growth of and toxin formation by Clostridium botulinum and the growth of Listeria monocytogenes are controlled as specified under § 3-502.12;	No recommended changes	
E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store or display shellfish that are offered for human consumption;	No recommended changes	
F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT;	No recommended changes	
G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; or	No recommended changes	
H) Sprouting seeds or beans.	No recommended changes	

Table 1C. Section 3-502.12 changes

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria	No recommended changes	
***Clostridium botulinum and Listeria monocytogenes* Controls**	No recommended changes	
A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (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.	No recommended changes	
B) A FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that:	No recommended changes	
1) Identifies the FOOD to be PACKAGED;	No recommended changes	
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:	No recommended changes	
(a) Has an AW of 0.91 or less,	No recommended changes	
(b) Has a PH of 4.6 or less,	No recommended changes	
(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, or	No recommended changes	
(d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables;	No recommended changes	
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:	No recommended changes	
(a) Maintain the FOOD at 5oC (41oF) or below, and	No recommended changes	
(b) Discard the FOOD if within 14 calendar days of its PACKAGING it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption;	No recommended changes	
4) Limits the refrigerated shelf life to no more than 14 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;	No recommended changes	
5) Includes operational procedures that:	No recommended changes	
(a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under ¶ 3-301.11(B),	No recommended changes	
(b) Identify a designated work area and the method by which:	No recommended changes	

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, and	No recommended changes	
(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, and	No recommended changes	
(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; and	No recommended changes	
NEW	**(d) If pH is used as a barrier to growth of *Clostridium botulinum* and *Listeria monocytogenes* such as in 3-502.12 (D)(2)(e)(iii), delineate equilibrium pH measurement, instrument calibration, and recordkeeping procedures.**	Monitoring of pH as a control for pathogens C. botulinum and L. monocytogenes is important to the safety of the product to ensure that the proper food product pH is consistently maintained.
6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:	No recommended changes	
(a) Concepts required for a safe operation,	No recommended changes	
(b) EQUIPMENT and facilities, and	No recommended changes	
(c) Procedures specified under Subparagraph (B)(5) of this section and 8-201.14(D).	No recommended changes	
NEW	**(7) Is provided to the regulatory authority prior to implementation.**	The consequences of an ill conceived plan to conduct ROP operations in a food establishment can be serious; and since many food establishments are only inspected by their regulatory authority once or twice a year; requiring notification of the regulatory authority by the food establishment is a prudent requirement. This will allow the regulatory authority to be made immediately aware of the food establishment's intention to conduct ROP operations and will also give the regulatory authority the option to review the plan to ensure that the requirements of 3-502.12 are being followed. Prior approval is not recommended to facilitate a food establishment initiating operations without a lengthy review process. Furthermore, the Food Code is quite specific in its requirements to conduct this operation safely.
Fish		
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.	No recommended changes	

Cook-Chill or Sous Vide		
D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT that PACKAGES FOOD using a cook-chill or sous vide process shall:	(D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT that PACKAGES **POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD)** FOOD using a cook-chill or sous vide process shall:	This change limits the following paragraphs of this section to only potentially hazardous foods (time / temperature controlled for safety foods). If a food is non-PHF (non-TCS) it will not support the growth of pathogens and therefore should not be subject to either variance or ROP provisions of the code.
1) Implement a HACCP PLAN that contains the information as specified under 8-201.14(D);	No recommended changes	
2) Ensure the FOOD is:	No recommended changes	
(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,	No recommended changes	
(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under § 3-401.11,	(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under § 3-401.11 **(A-B)**, P	This change limits items which can be packaged using Sous Vide or Cook Chill technologies to only those foods which are fully cooked. Undercooked, partially cooked or raw foods cannot be safely prepared using sous vide or cook chill technologies therefore these paragraphs are eliminated and only the paragraphs that provide appropriate thermal lethality are included in this reference, i.e. 3-401.11 (A) & (B).
(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4,	No recommended changes	
(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),	No recommended changes	
(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and subsequently:	(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3- 501.14 and ~~subsequently~~: P	Word not needed based on changes below
(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;	No recommended changes	
(ii) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours, at which time the FOOD must be consumed or discarded;	(ii) ~~*Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then*~~ *held at 5°C (41°F) or less for no more than* ~~*72 hours*~~ **7 days**, *at which time the FOOD must be consumed or discarded*; P	This change is driven by data which shows that there is no growth of Clostridium botulinum during the first seven days of storage at 41° F or less. Data supporting this change is based upon research by Skinner and Larkin and more information can be found in the Committee's report. Additionally, Listeria monocytogenes growth is prevented since this pathogen would have been eliminated through the cook step during the sous vide or cook chill

		process. All other pathogen growth is controlled by storage at temperatures at or below 41° F.
(iii) *Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from PACKAGING, at which time the food must be consumed or discarded*; or	~~(iii) Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from PACKAGING, at which time the food must be consumed or discarded;~~ P ~~or~~ **(iii) Has an equilibrium pH of 5.0 or less, verified by a properly calibrated digital pH meter, and held at 5°C (41°F) or less until consumed or discarded within 30 days after the date of PACKAGING;** P **or**	Original text not needed in light of the changes to 3-502.12 (D) (2) (e) (ii) above. The new language is based upon research which shows that C. botulinum and L. monocytogenes cannot grow if a food has a pH below 5.0 and a temperature below 41° F. The growth of L. monocytogenes and other pathogens are also controlled by the same factors as listed for 3-502.12 (D) (2) (e) (ii).
(iv) Held frozen with no shelf life restriction while frozen until consumed or used.	No recommended changes	
(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,	No recommended changes	
(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, and	No recommended changes	
(h) Labeled with the product name and the date PACKAGED;Pf and	No recommended changes	
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:	No recommended changes	
(a) Make such records available to the REGULATORY AUTHORITY upon request, and	No recommended changes	
(b) Hold such records for at least 6 months; and	No recommended changes	
4) Implement written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section.	No recommended changes	
Cheese	No recommended changes	
E) A FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:	No recommended changes	
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;	No recommended changes	
2) Have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and as specified under (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;	No recommended changes	

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	No recommended changes	
4) Discards the REDUCED OXYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.	No recommended changes	
8-201.13 When a HACCP Plan is Required		
A) Before engaging in an activity that requires a HACCP PLAN, a PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY for approval a properly prepared HACCP PLAN as specified under § 8-201.14 and the relevant provisions of this Code if:	No recommended changes	
1) Submission of a HACCP PLAN is required according to LAW;	No recommended changes	
2) A VARIANCE is required as specified under Subparagraph 3-401.11(D)(4), § 3-502.11, or 4-204.110(B);	No recommended changes	
3) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE based on a plan submittal specified under § 8-201.12, an inspectional finding, or a VARIANCE request.	No recommended changes	
B) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN as specified under § 3-502.12.	(B) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN **which is provided to the regulatory authority prior to implementation** as specified under § 3-502.12.	The consequences of an ill conceived plan to conduct ROP operations in a food establishment can be serious; and since many food establishments are only inspected by their regulatory authority once or twice a year; requiring notification of the regulatory authority by the food establishment is a prudent requirement. This will allow the regulatory authority to be made immediately aware of the food establishment’s intention to conduct ROP operations and will also give the regulatory authority the option to review the plan to ensure that the requirements of 3-502.12 are being followed.
C) Before engaging in an activity that requires a HACCP PLAN, a PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY for approval a properly prepared HACCP PLAN as specified under § 8-201.14 and the relevant provisions of this Code if:	No recommended changes	
4) Submission of a HACCP PLAN is required according to LAW;	No recommended changes	
5) A VARIANCE is required as specified under Subparagraph 3-401.11(D)(4), § 3-502.11, or 4-204.110(B);	No recommended changes	
6) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE based on a plan submittal specified under § 8-201.12, an inspectional finding, or a VARIANCE request.	No recommended changes	
D) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN as specified under § 3-502.12.	No recommended changes	

Table 1D. Annex changes

3-502.11 Variance Requirement (From Food Code Annex 3)		
Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.	No recommended changes	
The concept of variances may be new to some regulatory authorities. Some jurisdictions may not have a formal process to respond to industry requests for variances, although informal allowances may have been allowed in specific situations. Recognizing the opportunity to use the variance process may require additional rulemaking, or at least policy development, at the jurisdictional level. Rulemaking can be used to outline the procedures for a variance request, including the information required in section 8-103.11. In addition, the rulemaking process can address the regulatory authority's responsibility to consider an industry's variance application and an appeals process in case a variance is not given due consideration or is denied. The Conference for Food Protection Variance Committee recommended that regulatory agencies adopt a variance review process. General guidance regarding administrative procedures is given below.	No recommended changes	
Regulatory authorities considering implementing variances have encountered issues relating to their authority or technical, scientific ability to evaluate or validate a variance request. From any variance request there may emerge a set of complex issues and scientific competencies beyond the ability of the regulatory authority to validate. The Conference for Food Protection Variance Committee recommended that rulemaking should reflect a multi-level matrix of regulatory agencies ranging from local regulatory authorities through FDA and reflected that recommendation in the following flow chart. The regulatory authority is encouraged to seek input and guidance from authoritative sources such as processing authorities, professional associations, or academia. Within the Variance Committee's model, the process for seeking FDA advice begins with the Regional Food Specialists.	No recommended changes	
Except for the Interstate Travel Program, FDA generally does not directly regulate retail and food service establishments, including entertaining variances for that segment of the industry. FDA is still exploring processes for handling variances on a national basis such as those received from national chain businesses. In conjunction with the 2000 CFP Variance Committee, FDA will continue to explore ways to provide assistance and guidance to regulators regarding access to scientific and technical resources in order to make science-based decisions regarding variances.	No recommended changes	
FDA recommends that regulatory authorities develop a written administrative	No recommended changes	

process that is consistent with, and addresses the information contained in, Food Code sections 8-103.10, 8-103.11, and 8-103.12, and follow a process consistent with the recommendations of the CFP Variance Committee as shown in its flow chart.		
Model Administrative Procedures for Regulators to Address Variances:		
A) Designate an agency team and assign a leader to address variance requests.	No recommended changes	
B) Establish an agency review process leading to approval or denial of variance applications. For food safety issues, include recommendations for consulting with food processing authorities, food scientists, academia, professional organizations, other government agencies including the FDA Regional Food Specialist, or other experts external to the agency.	No recommended changes	
C) Set reasonable timelines for decision making. Determine if the variance application addresses an intrastate or interstate issue.	No recommended changes	
a) For variances that have interstate or national implications, especially those that address food safety, regulators are urged to contact and work closely with their FDA Regional Food Specialist to determine if a national policy related to the issue exists. Regulators are encouraged to be consistent with national policies, guidelines, or opinions.	No recommended changes	
b) For variances that address intrastate issues, regulators are also encouraged to determine if other State or national guidance exists, and to stay consistent with it.	No recommended changes	
D) Make the agency's decision. Inform the applicant.	No recommended changes	
a) If the variance request is approved, determine the starting date and document all special provisions with which the applicant must comply.	No recommended changes	
b) If the variance request is denied, inform the applicant as to the reasons for the denial, the applicant's right to appeal, and the appeal process.	No recommended changes	
5) Inform other interested parties, including the FDA Regional Food Specialist.	No recommended changes	
a) For variances having interstate or national implications, especially those that address food safety, regulators are urged to inform their FDA Regional Food Specialist so that FDA is aware of, and can appropriately disseminate the information regarding food safety variances that may affect food establishments in other jurisdictions, such as national chains.	No recommended changes	
b) For variances that address intrastate issues, regulators are encouraged to share the information as if it were an interstate issue.	No recommended changes	
6) Document all agency actions and decisions in the facility's file. Consider including documentation of special variance provisions on the establishment's permit to operate.	No recommended changes	
7) If the variance is approved, inform the inspector assigned to that facility and train the inspector on the variance provisions, including the implementation of the industry's HACCP plan, if required.	No recommended changes	

8) Establish procedures to periodically review the status of the variance, determine if it successfully accomplishes its public health objective, and ensure that a health hazard or nuisance does not result from its implementation.	No recommended changes	
9) Establish written procedures for withdrawing approval of the variance if it is not successful.	No recommended changes	
3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria. (From Food Code Annex 3)		
Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). 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.	No recommended changes	
This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging material that readily allow the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 cm2/m3/24 hours or greater. A reduced oxygen atmosphere will result with an Oxygen Transmission rate of 10-100. The process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.	This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging material that readily allows the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 **cc/m^2** ~~cm^2/m^3~~/24 hours or greater. A reduced oxygen atmosphere will **often** result with an Oxygen Transmission rate of 10-100. The process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.	Corrects inaccurate description of OTR to that found in the US FDA Fisheries HACCP Guide.
NEW	**If packaging material OTR is to be used as a barrier to *C. botulinum* growth and an exemption from ROP HACCP requirements in sections 3-502.11 and 3-502.12 the operator must provide scientific evidence to the regulatory authority that the packaging, under it's intended use, maintains an oxygen atmosphere for the duration of the refrigerated shelf life. At the time of this writing, only one packaging product possesses an OTR greater than 10,000 cc/m2/24h with scientific evidence acceptable to the FDA that it maintains an**	Suggested text clarifies 10 K bag exclusion. Would require variance for all uses other than that approved by FDA Seafood HACCP Guidance for raw seafoods.

	aerobic atmosphere when shrink packaging raw seafood with no inclusions (marinades, oils, etc). The packaging allows oxygen to pass permitting resident bacteria to spoil the seafood before the toxin of *C. botulinum* could develop.	
Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic **C. botulinum** and **L. monocytogenes** are able to multiply well below 5°C (41°F). For this reason, **C. botulinum** and **L. monocytogenes** become the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.	Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic **C. botulinum** and **L. monocytogenes** are able to multiply **slowly** ~~well~~ below 5°C (41°F). For this reason, **C. botulinum** and **L. monocytogenes** become the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as	Clarifies current text so that it does not suggest that C. botulinum or L. monocytogenes grow quickly at refrigeration temperatures.
When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of **C. botulinum** and **L. monocytogenes** without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control **C. botulinum** and **L. monocytogenes** when used in conjunction with a food storage temperature of 5°C (41°F) or less. They include aw of 0.91 or less; pH of 4.6 or less; cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or high levels of competing microorganisms. **C. botulinum** will not produce toxin below an aw of 0.91. Nitrite, used in meat and poultry curing, inhibits the outgrowth of **C. botulinum** spores. Most foodborne pathogens do not compete well with other microorganisms, therefore foods that have a high level of spoilage organisms or lactic acid bacteria can safely be packaged using ROP. Other intrinsic or extrinsic factors can also control the growth and/or toxin production of **C. botulinum** and **L. monocytogenes**.	No recommended changes	
New	**Non-potentially hazardous food (non-time/temperature control for safety food) as defined by interaction tables A and B (section 1-201.10) contain pH and Aw intrinsic factors that prevent the growth of both *C. botulinum* and *L. monocytogenes*. Therefore these foods are exempt from the reduced oxygen packaging HACCP requirements of 3-502.11 or 3-502.12 provided they are as received and not modified in the operation and labeled as non-potentially hazardous foods.**	Adds text to clarify non-PHF exclusion from ROP HACCP 3-502.11 or 3-502.12 as proposed above.

Naturally fermented cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all of the following: a lower pH, production of organic acids, and natural antibiotics or bacteriocins such as nisin by lactic acid bacteria, salt (NaCl) added during processing, low moisture content, added preservatives, and live competing cultures. Very few outbreaks have occurred that were associated with cheese. The few outbreaks of foodborne illness associated with cheeses or cheese products could be traced in large part to temperature abuse with storage at uncontrolled ambient air temperatures. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of **L. monocytogenes** under modified atmosphere conditions.	No recommended changes	
When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary barriers such as aw, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of **C. botulinum** and **L. monocytogenes**. Non-proteolytic C. botulinum spores are able to germinate and produce toxin at temperatures down to 3ºC (38ºF). Therefore, to control for toxin production by C. botulinum, an anaerobe, ROP foods must be held at 3ºC (38ºF) or less. Listeria monocytogenes is able to grow, although very slowly, at temperatures down to - 1ºC (30ºF). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential.	When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary barriers such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of ***C. botulinum*** and ***L. monocytogenes***. Non-proteolytic ***C. botulinum*** spores are able to germinate and produce toxin at temperatures down to 3°C (38°F). Therefore, to control for toxin production by ***C. botulinum***, an anaerobe, ROP foods must be held at 3°C (38°F) or less. ***Listeria monocytogenes*** is able to grow, although very slowly, at temperatures down to - 1°C (30°F). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any	Added text to clarify need to obtain a variance for low temperature cooking processes, e.g. sous vide.

	surviving pathogens is essential. **Cooking at low temperatures below that stated in 3-401.11 (A-C) may not destroy vegetative cells and may in fact become an incubation temperature for some pathogens. Any use of these low cooking temperatures combined with ROP packaging must be approved via the variance process.**	
Four separate options are provided in (D)(2)(e). These time-temperature combinations will provide equivalent food safety protection without need for a variance. The first is cooling the bagged product to 1ºC (34ºF) and holding for up to 30 days after the product is sealed in the bag. The second is cooling bagged product to 1ºC (34ºF), removing product to a different refrigeration unit and holding at any temperature up to 5ºC (41ºF) for up to 72 hours with the total storage time not to exceed 30 days. This situation is often encountered when a central kitchen prepares and stores the bagged product at 1ºC (34ºF) then transports it to a satellite kitchen under their control where it can be held at 5ºC (41ºF) or less. The third option is cooling to 3ºC (38ºF) and holding for no more than 72 hours from packaging. The fourth option can be used without a restricted shelf life while the bagged product is held frozen until thawed to be consumed or used in another preparation.	Four separate options are provided in (D)(2)(e). These time-temperature combinations will provide equivalent food safety protection without need for a variance. The first is cooling the bagged product to 1°C (34°F) and holding for up to 30 days after the product is sealed in the bag. The second is cooling bagged product to **5°C (41°F),** ~~1°C (34°F), removing product to a different refrigeration unit~~ and holding at any temperature up to 5°C (41°F) for up to **7 days** ~~72 hours with the total storage time not to exceed 30 days. This situation is often encountered when a central kitchen prepares and stores the bagged product at 1°C (34°F) then transports it to a satellite kitchen under their control where it can be held at 5°C (41°F) or less~~. The third option **relies on a secondary barrier, pH. When the pH is at or below 5.0 *C. botulinum* and *L. monocytogenes* cannot grow at 5°C (41°F). Therefore, 30 days storage is permitted. Note that when using pH as a barrier, a pH measurement, calibration and recordkeeping SOPs are required.** ~~is cooling to 3°C (38°F) and holding for no more than 72 hours from packaging.~~ The fourth option can be used without a restricted shelf life while the bagged product is held frozen until thawed to be consumed or used in another preparation.	Changes this section to accommodate the proposed changes made to 3-502.12 (D)(2)(e) and 3-502.12 (D)(2)(e)(iii). Reference to central and satellite kitchens deleted because It appeared extraneous.
Since there are no other controlling factors for **C. botulinum** and **L. monocytogenes** in a cook-chill or sous vide packaging system, temperature control must be continuously monitored electronically and visually examined twice daily to verify that refrigeration temperatures are adequate. New technology makes it relatively easy to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook chill and sous vide products at 1°C (34°F) or 3ºC (38ºF) or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if	Since there **may not be** ~~are no~~ other controlling factors for ***C. botulinum*** and ***L. monocytogenes*** in a cook-chill or sous vide packaging system, temperature control must be continuously monitored electronically and visually examined twice daily to verify that refrigeration temperatures are adequate. New technology makes it relatively easy to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook chill and sous vide	Corrected text acknowledges that there may be other controlling factors. The 38°F option has been deleted in the recommended changes to 3-502.12 (D)(2)(e)(iii).

temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures which can be displayed using computer software.	products at 1°C (34°F) or **5°C (41°F)** ~~3°C (38°F)~~ or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures which can be displayed using computer software.	
Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.	No recommended changes	
Time is also a factor that must be considered in ROP. The 14 day “use by” date is required label information for VP, MAP, and CAP products and cannot exceed the manufacturer’s “sell by” or “use by” date. This is considered a safe time period because two barriers to growth are required to be present. When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 34°F or less with an option of 3ºC (38ºF) for up to 72 hours after packaging with stringent temperature monitoring and recording requirements. These criteria allow both institutional-sized cook chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook chill and sous vide processes.	Time is also a factor that must be considered in ROP. **Processes that use ROP packaging for storage less than 48h do not pose a hazard for pathogen growth when refrigerated at 5°C (41°F) or less and are exempt from the HACCP requirement of sections 3-502.11 and 3-502.12. Examples are sous vide cooking provided a proper cooking temperature is used according to 3-401.11 (A-C) followed by immediate service and enhanced cooling of foods using ROP bags. The main factors in this exemption are that the food must be date marked and consumed or removed from packaging after 48h.** The 14 day "use by" date is required label information for VP, MAP, and CAP products and cannot exceed the manufacturer's "sell by" or "use by" date. This is considered a safe time period because two barriers to growth are required to be present. When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process **or inhibiting their growth**, preventing recontamination, and then refrigerating at 34°F or less ~~with an option of 3°C (38°F) for up to 72 hours after packaging with stringent temperature monitoring and recording requirements~~. **The 7 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 5°C (41°F) or less.** These criteria allow both institutional-sized cook chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast	Clarifies that some uses of ROP “bags” do not pose a risk especially those uses within a 48h time frame. Secondly, clarifies time factors in the safety of ROp based on extensive studies by Dr’s Skinner and Larkin of the US FDA. The Skinner-Larkin data indicates that it would take 9 days at 41°F to pose a potential risk for *C. botulinum* toxin production at the earliest. The 7 days shelf life was determined to match the current date-marking for *L. monocytogenes* and provide an extra 2 day margin of error in *C. botulinum* toxin production at 41°F. J Food Prot. 1998 Sep;61(9):1154-60. Conservative prediction of time to Clostridium botulinum toxin formation for use with time-temperature indicators to ensure the safety of foods. Skinner GE, Larkin JW. Dr. Skinner is still with the FDA and joined the committee on two calls. He validated that the science, cited above, was still accurate and up to date.

	chillers to safely use cook chill and sous vide processes.	
The extended shelf life for vacuum packaged hard and semisoft cheeses is based on many intrinsic factors in these cheeses plus the normal refrigeration temperature of 41°F or less to maintain safety.	No recommended changes	
A Hazard Analysis Critical Control Point (HACCP) plan is essential when using ROP processing procedures. ***C. botulinum*** and ***L. monocytogenes*** are potential hazards which must be controlled in most foods unless the food is a low acid canned food produced under 21 CFR Part 108 or 113 or an acidified food produced under 21 CFR 114. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used.	No recommended changes	
When a food establishment intends to use ROP technology but does not use one of the secondary barriers defined in section 3-502.12 (a single barrier of 34°F combined with the criteria specified in paragraph 3-502.12(D), or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), the operator must submit an application for a variance under section 3-502.11 providing evidence that the ROP methodology intended for use is safe.	When a food establishment intends to use ROP technology but does not use one of the secondary barriers defined in section 3-502.12 (a single barrier of 34°F combined with the criteria specified in paragraph 3-502.12(D), or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), the operator must submit an application for a variance under section 3-502.11 providing evidence that the ROP methodology intended for use is safe. **It is highly recommended that the operator and/or the regulatory authority consult a process authority to validate the scientific evidence the ROP methodology intended for use is safe.**	This change is recommended to help assure that adequate ROP methodologies are used.
Unfrozen raw fish and other seafood are specifically excluded from ROP because of these products' natural association with ***C. botulinum*** type E which grows at or above 3oC (37-38oF). Fish and seafood that are frozen before, during and after the ROP packaging process are allowed.	Unfrozen raw fish and other seafood are specifically excluded from ROP **without a variance** because of these products' natural association with ***C. botulinum*** type E which grows at or above 3°C (37-38°F). Fish and seafood that are frozen before, during and after the ROP packaging process are allowed.	Corrects text that implies ROP of non-frozen fish with a variance is not permitted.

Annex 6 2 (B) Definitions: 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:	No recommended changes	
1) Cook-chill is a process that uses a plastic bag filled with hot cooked food from which air has been expelled and which is closed with a plastic or metal crimp.	Cook-chill is a process that uses a**n** ~~plastic~~ **impermeable** bag filled with hot cooked food and from which air has been expelled ~~and which is closed with a plastic or metal crimp.~~ **and are then sealed or crimped closed.** .	Alignment with definitions in 1-201.10
2) Controlled Atmosphere Packaging (CAP) is an active system which continuously maintains the desired atmosphere within a package throughout the shelf-life of a product by the use of agents to bind or scavenge oxygen or a sachet containing compounds to emit a gas. CAP is defined as packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere.	No recommended changes	
3) Modified Atmosphere Packaging (MAP) is a process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action. MAP is defined as packaging of a product in an atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air, which normally contains 78.08% nitrogen, 20.96% oxygen, 0.03% carbon dioxide.	No recommended changes	
4) Sous Vide is a specialized process of ROP for ingredients that require refrigeration or frozen storage (PHF/TCS food) until the package is thoroughly heated immediately before service. The sous vide process is a pasteurization/cooking step that reduces bacterial load but is not sufficient to make the food shelf-stable. The process involves the following steps:	No recommended changes	
a) Preparation of the raw materials (this step may include grilling or broiling for color of some or all ingredients):	No recommended changes	
b) Packaging of the product immediately before cooking, application of vacuum, and sealing of the package;	No recommended changes	
c) Pasteurization/cooking of the product using required time/temperature parameters;	No recommended changes	
d) Rapid and monitored cooling of the product at or below 3ºC (38ºF) or 1ºC (34ºF) or frozen; and	No recommended changes	
e) Reheating of the packages 74ºC (165ºF) for hot holding or to any temperature for immediate service before opening and service.	No recommended changes	
5) Vacuum Packaging reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.	Vacuum Packaging reduces the amount of air from a package and hermetically seals the package so that a ~~near-perfect~~ vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.	The phrase near-perfect is vague and non quantifiable.

Appendix 2 -Table 2: References summarizing growth limitation of psychrotrophic *Clostridium botulinum.* 1 page

CFP ROP Committee 2011 - Growth limitation of psychrotrophic *Clostridium botulinum*

Author	Year	Reference	Aw	pH	WPS	Comments
Peck	1997	Trends in Food Science and Technology 8:186-192	≤ 0.97	≤ 5.0	≥ 3.5%	Review article
Graham and Peck	1997	Letters in Applied Microbiology 24:95-100			≥ 4.5%	Detected growth at 4.5% salt in 2 weeks at 8°C and 4% salt in 11 weeks at 5°C.
FDA	2001	Fish and Fisheries Product Hazards and Controls Guidance Chap 13	≤ 0.97	≤ 5.0	≥ 5.0%	Simply cites growth limits.
ECFF	2006	Recommendations for the Production of Prepackaged Chilled Foods	≤ 0.97	≤ 5.0		European Chilled Foods Federation (ECFF)
Peck et al	2008	Trends in Food Science & Technology 19: 207-216	≤ 0.97	≤ 5.0	≥ 3.5%	Updated review article.
Peck	2006	Clostridium botulinum and the safety of minimally heated chilled foods: an emerging issue? Journal of Applied Microbiology, 101, 556-570.	≤ 0.97	≤ 5.0	≥ 5.0%	Peck also cites the ECFF data for WPS at 3.5%. No explanation is provided as to the difference.
Lund & Peck	2000	Lund, B.M. and Peck, M.W. (2000) Clostridium botulinum. In The Microbiological Safety and Quality of Food ed. Lund, B.M., Baird-Parker, T.C. and Gould, G.W. pp. 1057–1109. Gaithersburg: Aspen	≤ 0.94*			*The minimum water activity permitting growth is 0.97 and 0.94 with NaCl and glycerol, respectively, as humectants. Other salts and sugars studied were 0.97.
Lindstrom et al	2006	International Journal of Food Microbiology 108 (2006) 92 – 104.	≤ 0.97	≤ 5.0	≥ 5.0%	Hazard and control of group II (non-proteolytic) *Clostridium botulinum* in modern food processing
MW Peck	2011	Personal communication. The 3.5% WPS is considered a historical data number, since no outbreaks have ever occurred in these products. Very few products are salted above this level. Data for growth between 3.5% - 5% WPS all show growth only after 30 days or more at 4-5°C. However, data show growth in less than 30 days at >5°C.				

Based on the above references the recommendation for growth limits from the committee should be ≤ 0.97 Aw and pH ≤ 5.0, WPS ≥ 5.0%. It is recognized that few products will have WPS of ≥ 5%. ***Products with 3.5% or more WPS would require additional scientific and mathmatical model evidence of safety at designated refrigeration temperatures for 30 days maximum storage.***

Appendix 3 - Table 3: References summarizing growth limitation of *Listeria monocytogenes.* 2 pages

CFP ROP Committee 2011 - Growth limitation of *Listeria monocytogenes*

Author	Year	Reference	Aw	pH	WPS	Comments
FDA	2008	Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance	≤ 0.92	≤ 4.4	-	Complete growth inhibition at any temperature. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProcessingHACCP/ucm073110.htm#formulate
USDA	2002	http://haccpalliance.org/sub/food-safety/fsisdirective102403.pdf	< 0.90 < 0.92 @ 5°C	< 4.5 < 5.5 @ Aw < 0.95 < 5.0 @ 5°C		These products are stable with respect to growth of L. monocytogenes by any of the following means. Also included is, "the presence of an antimicrobial agent (e.g., sodium or potassium lactate, sodium diacetate) that has been validated through scientific studies to inhibit growth of *L. monocytogenes* ".
FDA	2001	Fish and Fisheries Product Hazards and Controls Guidance Chap 13	≤ 0.92	≤ 4.4	≥ 10.0%	Complete growth inhibition at any temperature.
EC	2005	EC Regulation 2073/2005	≤ 0.92 ≤ 0.94 @ pH ≤ 5.0	≤ 4.4		Complete growth inhibition at any temperature. "At 4°C the pH and aw limits for growth predicted by all the models are considerably higher …"
Tienungoon, Ratkowsky, McMeekin, Ross	2000	Growth Limits of Listeria monocytogenes as a Function of Temperature, pH, NaCl, and Lactic Acid		≤ 5.0 @ 5°C		http://www.ncbi.nlm.nih.gov/pmc/articles/PMC92408/
Koutsoumanis	2004	http://www.sciencedirect.com/science?_ob=MImg&_imagekey=B6WFP-4BWVTF1-3-14&_cdi=6800&_user=464852&_pii=S0740002003001084&_origin=gateway&_coverDate=08%2F31%2F2004&_sk=999789995&view=c&wchp=dGLbVlW-zSkzV&md5=180ae8d3066f86b18807c1de05cccece&ie=/sdarticle.pdf		≤ 4.96 @ 4oC		The value obtained was only at Aw 0.99. This paper led to a growth/no growth model.
Farber et al	1989	The effect of various acidulants on the growth of Listeria monocytogenes		≤ 5.0 @ 5°C		http://onlinelibrary.wiley.com/doi/10.1111/j.1472-765X.1989.tb00319.x/pdf
Reyser and Marth	2007	Listeria, listeriosis, and food safety		≤ 5.0 @ 5°C	-	

McClure et al	1991	The effects of temperature, pH, sodium chloride and sodium nitrite on the growth of Listeria monocytogenes		≤ 5.0 @ 5°C		https://docs.google.com/viewer?a=v&pid=explorer&chrome=true&srcid=0Bx-qrmwZp8OaZDIyZTU1ZTYtMjhkZC00NDMyLTkxZTItNDg1MjdhMjFmNDU3&hl=en
Downes and Ito	2001	Compendium of methods for the microbiological examination of foods		≤ 5.23 @ 4°C		(p 524) ref - George et al 1988 Letters Applied Microbiol 6:153
Ingham, Buege, Dropp, and Losinski.	2004	Survival of Listeria monocytogenes during storage of ready-to-eat meat products processed by drying, fermentation, and/or smoking				Journal of Food Protection. 67: 2698-2702. Provides various parameters of inhibition of LM in meats at 41oF. pH values 4.8 - 5.6 with WPS 2.5-14.4. See http://www.meathaccp.wisc.edu/validation/assets/CL%20for%20LM.pdf
Health Canada	2004	Policy on Listeria monocytogenes in Ready-to-Eat Foods	≤0.92	≤ 5.0 @ 5°C	-	http://www.hc-sc.gc.ca/fn-an/legislation/pol/policy_listeria_monocytogenes_politique_toc-eng.php
Health Canada	2010	Policy on Listeria monocytogenes in Ready-to-Eat Foods	≤0.92	≤ 5.0 @ 5°C		http://members.wto.org/crnattachments/2010/sps/CAN/10_4322_00_e.pdf

http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProcessingHACCP/ucm073110.htm

Appendix 4- Committee summary of time to toxin formation of *C. botulinum* in foods with attached reference article (Skinner-Larkin paper reviews extensive research done by FDA scientists regarding time to toxin formation of *C. botulinum* in foods).

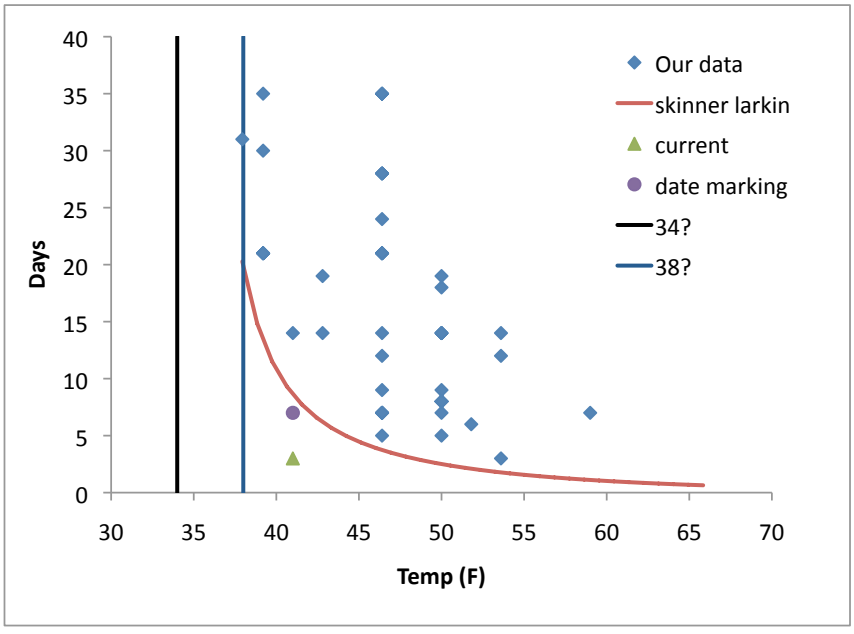
Status Report
Temperature Control Subcommittee
CFP ROP committee
January 19, 2011
Version 3

Three review articles were used to create a table summarizing the published literature on *Clostridium botulinum* time to growth or toxin production. Those three studies were: Lindstrom et al 2006, Graham et al, 1997 and Betts, 1995. A (mostly complete) excel spreadsheet containing the data from those studies is being shared with the committee.

A figure summarizing some of those data is show below, together with a line indicting the prediction from the most conservative Skinner-Larkin model (1998, JFP 61: 1154-1160). Note that the Skinner and Larkin paper is in the Google docs directory Brian set up, so you can download a copy if you are interested. You will note that the Figure from their manuscript contains many more points than our modest effort.

Also shown in the figure are key time temperature combinations, as well as key temperatures that Brian asked about in his January 18, 2011 email.

Jenny Scott has reached out to John Larkin and Guy Skinner. They have hundreds of articles included in their model and Guy continues to monitor the literature. So far he has not seen anything inconsistent with the model (although our committee needs to double-check the last 5 years). Guy can manipulate the database to give us data on food only, food other than seafood, media only. He can give us all the worst case data (e.g., for food at 3.3, it is the beef stew, with time to toxicity of 31 days). Guy will also join us on our call on Monday.



Journal of Food Protection. Vol. 61. No. 9. 1998. Pages 1154-1160

Conservative Prediction of Time to *Clostridium botulinum* Toxin Formation for Use with Time-Temperature Indicators To Ensure the Safety of Foods

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ABSTRACT

Integrating-type time-temperature indicators (TTIs) may be utilized to warn food processors and consumers about storage conditions that may have rendered a food potentially hazardous. As an example of how integrated TTIs could be manufactured to emulate an infinite set of time-temperature situations. a set of conditions which have supported C. *botulinum* growth and toxin production was compiled. The time-temperature curve representing conservative times required for toxin formation was constructed with data from literature relating to toxin formation as a function of temperature in any media or food product. This set of critical time-temperature data is fit by a conservative empirical relationship that can be used to predict combinations of incubation times and storage temperatures that represent a potential health risk from C. *botulinum* in foods. A TTI could be constructed to indicate deviation from such a given set of conditions to bring attention to foods that may have been exposed to potentially hazardous temperatures with respect to *C. botulinum* toxin formation.

Recent consumer attitudes have stimulated the development of new and innovative foods. Through renewed awareness, consumers are altering their eating habits and purchasing foods formulated to meet specific dietary needs or desires (i.e. light syrups and low-fat or low-salt processed meats). Changing lifestyles are resulting in consumer demand for refrigerated precooked foods and sour-vide processed products that require minimal preparation time in the home. By packaging these new foods under vacuum, modified. or controlled atmosphere, food processors have been able to significantly extend the shelf life of many foods. Concerns about the safety of some of these products exist, especially considering the potential for temperature abuse (37). The thermal treatment imposed on these products, often referred as pasteurization, may be insufficient to inactivate spores of *Clostridium botulinum. Focus* on these products exists because many of them rely on refrigeration temperatures as their only barrier against pathogenic microorganism growth and/or toxin production. In the United States, the food distribution chain is unable to ensure that foods will not be temperature abused at some time between processing and consumption. Use of time-temperature indicators (TTIs) can minimize potential public health risks associated with certain types of foods by monitoring product temperatures during distribution and on the retail shelf.

Temperature abuse. The importance of monitoring critical control point (CCP) temperatures during processing, distribution, retail display, and consumer storage of perishable foods is emphasized by the potential for temperature abuse reported by a number of researchers. Daniels (13) monitored refrigeration temperatures in retail operations and consumers' homes. Results showed that many refrigerated foods are exposed to temperatures above 10°C. The survey showed that in supermarkets tested, fresh meat cases were the area with the best temperature control; only 4% of the products were above 10°C. Delicatessen sections of supermarkets surveyed had the worst temperature control; 26% of foods were at temperatures above 10°C and 12.9170 were above 12.8°C. Davidson (14) showed that it was not uncommon for retail display temperatures to range from 7 to 10°C. Van Garde and Woodburn (44) discovered that up to 20% of the home refrigerators surveyed were set at temperatures in excess of 10°C. This indicated the potential for temperature abuse at the consumer level.

Psychrotrophic pathogens are receiving attention because of their ability to grow at or below 5°C (34). Such pathogens include *Yersinia enterocolitica,* enterotoxigenic *Escherichia coli*, *Listeria monocytogenes, Aeromonas hydrophila,* and nonproteolytic strains of *Clostridium botulinum.* Existence of documented temperature abuse throughout the food chain is important because nonproteolytic strains of C. *botulinum* have been found to produce toxin at temperatures as low as 3.3°C, and proteolytic strains have been shown to produce toxin at temperatures above 10°C (39, 40). Because of the potential for temperature abuse, it is necessary to devise a cost-effective means to monitor the temperature conditions of individually packaged foods during distribution and storage to ensure the safety of modified- or controlled-atmosphere-packaged (MAP) foods.

Risks from potential toxin production by Clostridium botulinum. Recent technologies such as controlledatmosphere packaging (CAP), modified-atmosphere packaging (MAP) and *sous-vide* processing have been shown to successfully extend the shelf life of many minimally processed new-generation refrigerated foods such as fish, meats, poultry, pasta. and salads. Some new-generation refrigerated foods rely on low temperatures as the primary or only barrier against potential growth and/or toxin production by pathogenic microorganisms (21). Some of these foods represent potential health hazards because they have been shown to support the growth of C. *botulinum.* Many have a pH and a water activity (aW) capable of supporting C. *botulinum* spore outgrowth and toxin production, and many have received a heat treatment intended to reduce or eliminate competitive vegetative cells but not sufficient to inactivate spores. Specific concerns regarding the safety of refrigerated foods of extended durability with specific reference to C. *botulinum* have been addressed (11, 12. 15, 19, 20, 23, 24. 27, 29, 33, 35) as have the safety issues of *sous-vide* processed products (3. 5, 31, 37).

Concerns regarding C. *botulinum* in refrigerated foods has led to the establishment of guidelines to help ensure their safe manufacture. In response to growing concerns about the relationship between storage temperatures and food safety, the *Fish and Fisheries Products Hazards & Controls Guide* (17) incorporated time-temperature guidance for maximum cumulative exposure time for seafoods, intended to prevent

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germination, growth and toxin production by the various types of C. *botulinum*. *A* discussion of guidelines and recommendations issued by other regulatory agencies and associations is presented by Lund and Notermans (27) and Peck (35).

Recent outbreaks of botulism were attributed to inadequate processing or temperature abuse of commercially available products. Foods implicated in such outbreaks include kapchunka (a commercially available ready-to-eat, air-dried, salt-cured, uneviscerated whole fish) (6) or similar products (7, 9, 10) and garlic in oil (7, 8). Accurate and reliable Ms represent potential devices for indicating temperature abuse of such products during their shelf life.

Essential performance criteria for a time-temperature indicator. Individual product TTIs have yet to become widely used for several reasons. Use of these TTIs could result in food processors losing money from the destruction of temperature-abused food. Processors would also lose economically if food considered a potential health hazard is destroyed because the TTIs incorrectly indicated temperature abuse. Presently, TTIs can be costly, have no reliability history, lack durability, and frequently lack the ability to measure the integrated effect of time and temperature (22, 45). However, because of their potential advantages, significant research is under way to make TTIs less expensive, more useful and reliable.

Time-temperature response must be reliable. Whether an indicator is a partial- or a full-history indicator, exposure of food products to a sudden increase in temperature should be registered within a reasonable amount of time. It is important that indicator response time at particular temperatures be verified (12). Malcata (28) noted that the TTIs in his study responded more quickly to temperature changes than did the foods and that the heat transfer limitations of a food can result in a 15% error in registered indicator temperature. an estimate most likely on the conservative side.

Most TTIs do not measure actual food product temperature, rather the temperature above the surface of a package (22). Taoukis et al. (41) discussed the importance of the position in which the time-temperature indicator is attached to a product and how this position may affect the indicator reading.

Safeguards must be engineered into TTIs to either prevent their removal after placement on a package or to indicate whether or not they have been removed from a package. Indicators should not be transferred from one package to another (22) and should be properly labeled so they are not affixed to the wrong product.

If TTIs utilize a color change to alert consumers to potential problems in safety or shelf life, it is imperative that any color change can be clearly interpreted by the untrained consumer with normal vision (41). Indiscrete or gradual changes in indicator color may increase the likelihood that consumers may misinterpret an indication of temperature abuse or expired shelf life. Certain colors may represent a problem for a percentage of the population that is color blind (41). Indicator response may be affected by light under certain circumstances (41). Lingle (26) and Blixt (-F) have also discussed these problems.

Certain pH-based colorimetric indicators may demonstrate accelerated time-temperature responses at low temperatures after extended exposure to elevated temperatures (41, 42). These authors also note that TTI accuracy must not change with indicator age, because the outward diffusion of the TTI reactant gases leaking through the containment film could influence the fundamental chemical reactions of some chemically based indicators and lead to erroneous readings (41).

Use of TTIs in an actual processing facility introduces additional nonfood materials into the processing operation. TTIs containing crystals polymers, enzymes and chemical compounds such as phthalates and dyes represent an additional potential public health hazard by their introduction into food-processing areas. As with broken mercury-in-glass thermometers, broken indicators could potentially lead to leakage of the chemicals into individual food products or into larger quantities of food. If TTIs are to be used directly in contact with foods, their composition and the chemical they contain must comply with pertinent government regulations. In addition, some small TTIs may represent a health hazard in the consumer's home because they could inadvertently be swallowed, particularly by children (22).

Types of time-temperature indicators. Numerous types of time-temperature indicators are presently available for monitoring food temperature. Wells and Singh (45) categorized TTIs into two classes, partial history or full history by their response. Partial-history TTIs can be referred to as temperature indicators (TIs), as they indicate that a specified temperature has been reached or exceeded (22, 45). Full-history indicators respond independently of threshold temperatures. Upon activation full-history TTIs monitor the continuous integrated time-temperature history to which the integrator is exposed. The integrated data can be used to obtain a product's relative time of exposure to particular storage temperatures. Fu et al. (18) established a term T_{eff} to describe data obtained from integrated TTIs. T_{eff} is used to quantify an exposure of an indicator or food to an unknown set of time-temperature conditions. Labuza and Fu (25) defined T_{eff} as the constant temperature resulting in the same quality change as the variable temperature distribution over the same time period. Fu et al. (18) further explained that if one assumes some rate constant versus temperature model, the calculated T_{eff} should represent some measurable amount of change, irrespective of the exact time-temperature conditions of exposure. In other words, two Ms could indicate the same T_{eff} after being exposed to two totally different combinations of time and temperature. The description of Tff assumes that there is no "history effect" (18). The term "history effect" is used to explain differences in microbiological growth or lag-phase behavior in terms of previous conditions of storage temperatures to which the microorganisms were exposed. Prior storage temperatures may lead to either positive or negative history effects on the lag phase (18). Ng et al. (32) reported that transferring microbial cells grown at near optimum temperatures to lower incubation temperatures may result in a positive history effect, or a shorter lag phase or growth rates greater than expected for those temperatures. On the contrary, introduction of cells grown at temperatures well below their optimum to higher temperatures may result in a negative history effect, or a lag-phase extension or lower growth rate due to phenomena such as sublethal injury (38). Fu et al. (18) and Labuza and Fu (25) note that predictive models could result in false estimations if such history effects are not accounted for.

From a safety perspective, the most conservative, yet effective, means for ensuring that a food product is not temperature-abused may be to set a fixed temperature (e.g. 3.3°C) that the product is not allowed to exceed. TTIs exist which indicate that a specific temperature endpoint has been reached or exceeded. Endpoint indicators may be designed to indicate temperature abuse of refrigerated foods or thawing of frozen food. One obvious drawback of this endpoint monitoring method is the ability of a food processor to maintain adequately low food storage temperatures. even if the target fixed temperature is set at 5°C. Another problem is that in numerous cases a food product may be held above the fixed temperature for a short time, but not long enough to adversely influence food safety at that time. Depending on the specific food product composition and the specific hazard of concern, such a product may be erroneously deemed a potential health hazard and discarded if a fixed temperature requirement is utilized and exceeded.

The alternative to adhering to a set fixed temperature is to establish a maximum integrated combination of time and temperature below which the food must be held. The integrated relationship results in an infinite number of combinations of potentially hazardous time-temperature growth conditions which must be understood in order to evaluate a product's safety. A standard curve of a pathogenic microorganism's generation

time or minimum time to toxin formation as a function of storage temperature (T_{eff}) would need to be established to resolve this issue. A TTI could be manufactured to comply with a scientifically selected set of conditions and indicate whether the integrated time-temperature boundary relationship has been violated.

Specific TTIs could be applied for a pathogen that may be present in a food, assuming the appropriate data is present for the TTI to model. For a microorganism such as *Staphylococcus aureus,* where proliferation to significant numbers is associated with production of enterotoxin, a TTI designed to model generation time as a function of temperature may be appropriate. For spore-forming pathogens such as Bacillus cereus and ***C. botulinum,*** a TTI modeling the relationship of time required for toxin production as a function of storage temperature would be used.

The objective of this project was to develop a conservative relationship between time to *C. botulinum* toxin formation and storage temperature that can be incorporated into a TTI. The impact of a positive growth history effect was tested against the conservative model using *C. botulinum* type E spores in vacuum-packaged fresh salmon fillets under conditions of fluctuating temperature.

MATERIALS AND METHODS

Clostridium botulinum type E spore preparations. *C. botulinum* type E strains (Birmingham. Minnesota. Beluga. G21-E. and 070) previously isolated from seafood products implicated in foodborne botulism were used in this study. Spore suspensions of individual strains were grown in trypticase-peptone-glucose-yeast extract (TPGY) medium at 28°C for 10 days (*Bacteriological Analytical Manual* [161]). Spores of each strain were harvested by centrifugation, washed three times with sterile distilled water and resuspended in sterile distilled water. Spore numbers per milliliter in each strain suspension were determined by the three-tube most probable number (MPN) method with TPGY broth as the culture medium. Equal numbers of the spores from each strain were mixed to form a spore mixture and diluted with sterile distilled water to contain 3.5 X 106 spores per ml. The spore mixture was stored at 4 - I °C until used.

Fish source, inoculation, packaging, and storage condi**tions.** To illustrate validation of the *C. botulinum* time-to-toxin curve from potential positive history growth effects. an inoculation study was performed to obtain *C. botulinum* toxin production data at fluctuating temperatures. Fresh salmon fillets were obtained immediately after processing, skinned and cut into appropriate portions, and packaged within 24 h. Fresh salmon portions. each weighing 90 to 120 g were cut from fillets, then surface inoculated on both sides with the non-heat-shocked spore mixture to obtain an inoculum level of 1 X 10= spores per g of fish. An aliquot from a known inoculum (i X 10° spores per ml) ranging from 0.90 to 1.2 ml was dispensed on both sides of the fillet on the basis of weight and spread with a sterile glass rod. Inoculated fillets were vacuum packaged in a high-barrier film bag (O, transmission rate of 3 to 6 cm3/m-'/24 h at 4.4°C, 1 arm (ca. 101 kPa) pressure, and Oslo humidity) with a Multivac Model A316 Vacuum Packaging Machine (Multivac, Inc., Kansas City, Mo.) equipped with a built-in vacuum pump. Vacuum-packaged fillets were stored under two temperature schemes. Treatment 1 involved an initial 24-h incubation at 16±°1°C, followed by incubation at 8 ± 1°C until toxin formation. Treatment 2 involved an initial 24-h incubation at 16 ±°C, followed by a 24-h incubation at 8 - 1 °C. and then incubation at 16 ± I °C until toxin presence was confirmed. Samples were taken daily to determine the presence of toxin.

Analysis for presence of C: botulinum toxin. Two vacuum-packaged fillets were removed from incubation each day for analysis for the presence of toxin. The whole fillet from each package was blended with 200 ml of cold gel-phosphate buffer (pH 6.2) for 2 min in a Stomacher 400 (Tekmar Co., Cincinnati, Ohio). The homogenate was centrifuged at 12,000 x *g* for 20 min at 4°C, and the supernatant was passed through a sterile 0.45µ-pore-size analytical filter. The clear filtrate was tested for the presence of C. *botulinum* toxin by the standard mouse bioassay (16). The filtrate was divided into three portions: the first was treated with trypsin (1:50: Difco Laboratories, Detroit. Mich.) for 1 h at 35°C (1.8 ml of filtrate. 0.2 ml of 5% trypsin solution) to activate type E toxin; the second was boiled for 10 min to serve as the negative control during confirmations; the third was neither trypsin-treated nor boiled. Each filtrate portion (trypsinized and nontrypsinized) was injected intraperitoneally into two mice (0.5 ml per mouse) and the mice were observed for 48 h for symptoms typical of botulism. All sample filtrates causing mouse deaths were confirmed by mouse protection tests using type E-specific antitoxin. Deaths due to toxin were confirmed by injecting boiled extracts as described (16).

RESULTS

Predictive curve for toxin formation by *Clostridium botulinum.* Data from the Food and Drug Administration and the literature were used to generate a plot of time to C. botulinum toxin formation as a function of incubation temperature under optimum growth conditions. Figure 1 shows a plot of the accumulated data, representing more than 1,800 data points. Data for all types of *C. botulinum* which have been implicated in causing human botulism were collected (type A. proteolytic types B and F, type E, and nonproteolytic types B and F). No attempt was made to distinguish between C. ***botulinum*** types for the purpose of this curve. It is well documented that different types of C. ***botulinum*** show great diversity with respect to their growth characteristics. However, because of the desire to be conservative, all data obtained for time to ***C. botulinum*** toxin formation as a function of incubation temperature were plotted on one graph, not separately by ***C. botulinum*** type. product, or growth medium. Experimental data obtained from the literature were generated under a variety of temperatures in growth systems ranging from jellied ox tongue to laboratory media.

Experimental validation of the conservative nature of the data in Figure 1 is not easily accomplished. When it is taken into consideration the infinite number of different time-temperature history paths to which a food product can be subjected, a validation protocol that would exercise all the areas of the time-to-toxin domain was considered impossible. Instead, the authors decided that as much of the available literature containing data for time to C ***botulinum*** toxin formation as possible needed to be accumulated and the data entered into Figure 1. This would help to ensure that all of the fastest time-to-toxin data existing in published research papers or reviews were included. It was decided that since the data in Figure 1 were not selectively added to the plot, the boundary curve exhibited in Figure 1 was in fact self-validating. After the initial recording of data into Figure 1, only one point during the 5 years of data collected was found to extend the conservative boundary. At 16°C the original curve established a minimum time to ***C. botulinum*** toxin formation of 1.5 days. A point published by Meng and Genigeorgis (30) showed that toxin was detected in a turkey roll after 1 day of incubation at 16°C. Because the literature is being continually reviewed and newly published data collected and used to challenge the existing curve, the authors believe that the boundary established in Figure 1 is self-validating.

Once a validated boundary for minimum time to C. botulinum toxin formation is established, an equation describing the boundary conditions is needed. This mathematical expression is integral to the development of a reliable TTI.

Baker and Genigeorgis (1) applied regression analysis to data accumulated for fish (rockfish, salmon. and sole) to generate an empirical. generalized conservative predictive polynomial equation for lag time (LT) of C. botulinum toxin formation as a function of incubation temperature, spore inoculum level. and initial aerobic plate count. Their generalized equation is shown as Equation 1.

$$\log LT = 0.974 - 0.042(T) + 2.74(1IT)$$

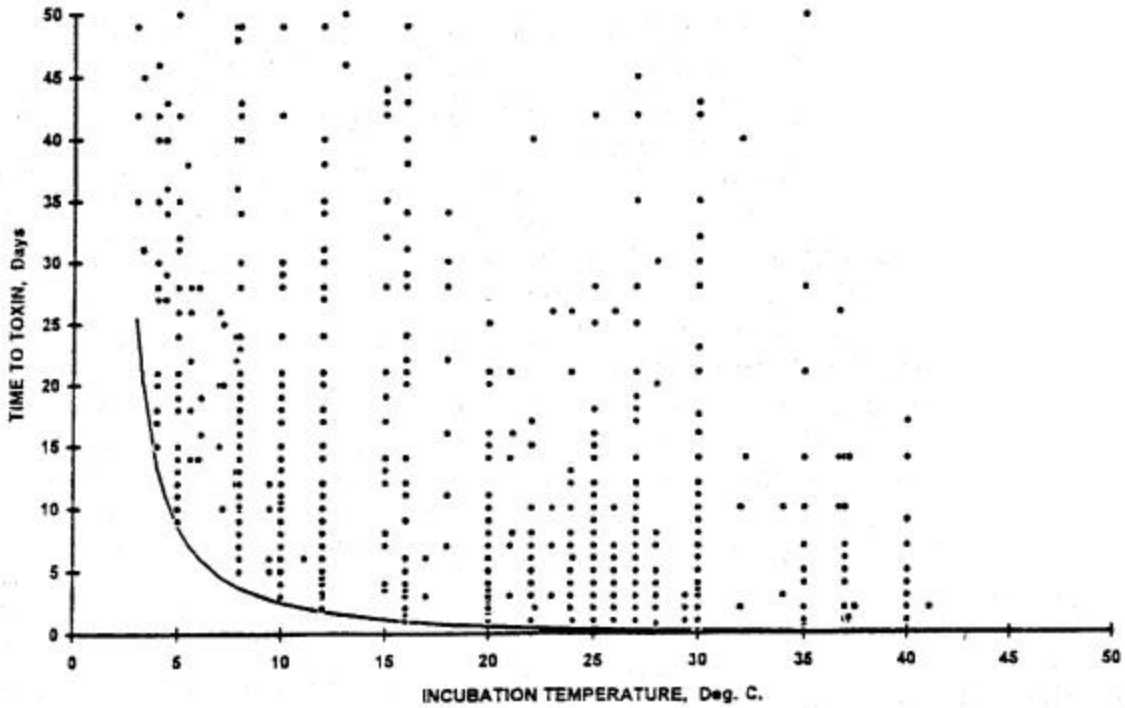
$$- 0.091 (\log \textit{spore inoculum}) \qquad [1]$$

$$+ 0.035(\log \textit{initial APC})$$

LT represents lag time for C. botulinum toxin formation, T represents temperature in degrees Celsius, spore inoculum represents the number of spores that are initially present in the sample (number of spores per gram) and initial APC (aerobic plate count) is the assumed initial number of bacteria that are present in the sample (CFU per gram).Equation 1 was derived for lag time data for C. botulinum toxin production in vacuum-packaged fish at refrigeration temperatures and is similar in shape to the one being sought to represent the lower boundaries of the data presented in Figure 1. Equation 1 is a simple polynomial equation having no real kinetic basis and it was felt that it could be modified to conservatively represent the boundary conditions for C. botulinum toxin production presented in Figure 1. A simplified, conservative version of Equation 1 is expressed by Equation 2. The lower and upper temperature limits of the curve are 3.3 and 40°C, respectively, because these are the minimum and maximum temperatures where toxin data were obtained.

$$\log LT - 0.65 - 0.0525(T) + 2.74(1/T) \qquad [2]$$

The curve generated by Equation 2 is plotted in Figure 1. It is understood that Equation 2 is strictly empirical: it has no actual kinetic basis. Equation 2 represents an example of a mathematical relationship for estimating the boundary conditions conservatively predicting *C. botulinum* toxin production at various temperatures under the most ideal conditions for which data could be obtained. As previously mentioned, the curve depicts boundary conditions for all *C. botulinum* types and therefore is extremely conservative. It could be argued that the curve is for nonproteolytic types exclusively, because it extends down to 3.3°C. Proteolytic types of *C. botulinum* do not grow and produce toxin between 3.3 and 10°C (35,-40). At temperatures just above the 10°C lower limit for proteolytic C. botulinum types, toxin production is very slow. If enough data could be generated or obtained for proteolytic types of C. botulinum at temperatures approaching the lower boundaries of growth, a separate model could be generated. In addition, numerous subsets of data could be made on the basis of particular food types such as fish, and these individual data sets could be modeled. The predictive value of these models would depend on the quantity and quality of data upon which thev are based, and may provide some information useful in planning challenge studies by providing estimates for time-to-toxin formation at a specific incubation temperature. The curve generated in the present work for C. botulinum is conservative, and therefore may not necessarily represent the most appropriate model for every food system or pathogen application. As conservative as the integrated time-temperature equation displayed in Figure 1 tray appear, it is in fair agreement with the guidelines provided in the Fish and Fisheries Products Hazards & Controls Guide (17) for germination, growth and toxin production by the various types of C. botulinum in seafood. In addition, the boundary conditions exhibited by Equation 2 are very similar to the predicted plot generated by the USDA/ARS Pathogen Modeling Program (PMP) version 5.0 (43) for nonproteolytic types of C. botulinum (types E, F, and B) in fish and media under ideal growth conditions. The PMP version 5.0 prediction for nonproteolytic C. botulinum toxin production in fish is based on data obtained by Baker and Geni2eorais (1) from vacuum packed fish meat (43). This same data was used by Baker and Genigeorgis (1) to derive Equation 1.Even though the boundary conditions established by Equation 2 are conservative, they still represent an advantage over a maximum-registering TI. For example, a hazard analysis critical control point (HACCP) plan for a refrigerated food may include distribution temperature as a critical control point (CCP) because of the potential for C. botulinum toxin



formation at abuse temperatures. Using TIs to monitor a CCP requires setting a fixed temperature such as 4°C as a critical limit, whereas, use of an integrated TTI allows a combination of time-temperature boundary conditions as described previously in Figure 1. A food product exposed to 5°C for a short time period would be in violation of the critical limit if TIs were used: however. a TTI manufactured to respond to the curve in Figure 1 would not indicate the product to be a potential hazard for approximately 9 days at the same temperature. The actual specific minimum time required for C. botulinum toxin production depends on the variables such as specific food product, number of competitive microflora, present spore load, inhibitors present, etc. Therefore, each food could have its own conservative curve of boundary conditions.

Validation by using fluctuating temperature data Although the 1,800 data points on which Equation 2 is based should make the equation self validating. an experiment was performed to determine if the model held for data obtained under conditions of fluctuating temperatures and would withstand any possible temperature effects. The realization that survival of Escherichia coli 0157:147 strains are apparently significantly affected by conditions of growth makes the subject of history effects very important and a phenomenon which must be considered in microbiological modeling. Vacuum-packaged salmon fillets from treatment 1 (24-h incubation at 16°C, then 8°C until toxin formation) and treatment 2 (24-hour incubation at 16°C, 24 h at 8°C. 16°C until toxin formation) of the validation storage study developed toxin after 6 and 5 days of incubation, respectively. Toxin results of Reddy et al. (j6) indicated that vacuum-packaged samples prepared identically to those in this research developed toxin in 13 and 3 days at 8 and 16°C, respective. These experimentally obtained times to toxin formation are greater than the values of 3.74 days at 8 and 0.96 days at 16 'C calculated by Equation 2, again demonstrating the conservative ability of the equation to predict potentially hazardous conditions of storage.

Modified-atmosphere-packaged fish were selected as a test matrix because they represent an actual food product which has been shown to rapidly support toxin formation by ***C. botulinum*** under certain conditions. Time-to-toxin data obtained by Reddy et al. (36) was used to convert the data obtained in the fluctuating-temperature experiments into equivalent days to toxin formation at a constant temperature. Equivalent days were calculated by using the ratio of time to ***C. botulinum*** toxin formation at 16 and at 8°C obtained by Reddy et al. (36) under the same experimental conditions, assuming a logarithmic relationship between time to toxin development and incubation temperature. Expressing the data as equivalent times allows comparison of lag-phase data obtained under fluctuating temperatures with results obtained under static temperature conditions (Figure 1).

Treatment 1 resulted in toxin formation in 6 days, which is equivalent to 8.4 and 2.5 days at 8 and 16°C, respectively. The equivalent time of 8.4 days at 8°C. obtained by moving the spores from a higher (16'C) to a lower (8°C) incubation temperature. is shorter than the 13 days required for toxin formation at a constant incubation temperature of 8°C. This represents a positive history effect by reducing the lag phase for toxin formation to a time less than that obtained at a constant temperature. Fu et al. (18) reported a significant positive history effect on lag phase of ***Pseudomonas fragi*** by using a single stepwise temperature distribution shift. Zwietering et al. (46) and Baranyi et al. (2) noted that once a cell population is -rowing exponentially, the growth rate instantaneously adapts to temperature changes. These researchers state, however, that temperature changes around the cell's lower growth limit may result in a lag resulting in predictive model deviations. This could explain the negative history effects observed by Fu et al. (18). Further research should be performed to study the history effects of microbiological growth.

Labuza and Fu (25) reported that negative history effects would lead to underprediction of growth rate or overestimation of lag phase. conditions which would not result in the potential health consequences which may be caused by a positive history effect. Treatment 2 resulted in toxin formation in 5 days, which would be equivalent to 14.4 and -1.3 days at 8 and 16°C, respectively.

Because of the possible existence of positive history effects that may affect the prediction of microbiological growth or lag phase, a model should be conservative enough to account for this phenomenon. For this reason, the equivalent times obtained for the fluctuating-temperature conditions were compared to the predicted time-to-toxin values given by Equation 2. All equivalent times presented in this manuscript calculated from data obtained under

fluctuating-temperature treatments are longer than the predicted time to *C. botulinum* toxin formation calculated by using Equation 2 (3.74 days at 8°C and 0.96 days at 16°C).

The one experiment presented in this manuscript is not enough to thoroughly challenge the present model for all possible history effects which may be generated. It is used as an illustrative example of how history effects should be considered in validating a predictive microbiological model. In the history effect validation study presented here, neither treatment supported toxin formation in less time than was predicted.

DISCUSSION

The use of time-temperature indicators designed to operate reliably and accurately appears to have potential for helping to increase the safety of certain food products. TTIs may be used to indicate temperature-abused foods or as part of a HACCP plan to monitor the various critical control points (CCPs) involved with the processing, distribution, and sale of a refrigerated food. The curve for *C. botulinum* toxin formation as a function of incubation temperature presented in this publication is based on a compilation of data and could be used to define the most conservative integrated boundary conditions that TTIs must predict to indicate potentially hazardous storage conditions. This curve represents C. botulinum toxin production in all growth matrices and is not specific to any one matrix. Data sets for particular applications such as individual food groups or specific pathogens can be compiled for numerous applications. Such relationships could be modeled using appropriate types of integrated TTIs. If found to be adequately conservative, an integrated relationship between time required for toxin formation and incubation temperature such as that shown in Equation 2 would: represent an improvement over a maximum registering type of TI which monitors a maximum allowable storage temperature (e.g., 3.33 or 10°C). Use of this integrated relationship of time and temperature would allow for a more accurate evaluation of the potential safety concerns regarding foods that are exposed to temperature abuse.

ACKNOWLEDGMENT

The authors thank Mr. Haim Solomon of the U.S. Food and Drug Administration for performing the mouse bioassay procedures on the toxin extracts to determine the presence of *C. botulinum* toxin.

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Appendix 5 – Email from FDA CFSAN clarifying when HACCP plans must be submitted.

Brian Nummer

From: Scott, Jenny <Jenny.Scott@fda.hhs.gov>
Sent: Thursday, March 10, 2011 10:59 AM
To: Brian Nummer; Charles McGuffey; Christopher Gordon; Dale Yamnik; Dale Grinstead; Don Schaffner; Goldberg, Dan; henry Blade; Ivory Cooper; Jessica Fletcher; Joe Graham; Joel Ortiz; Karen Reid; kevin Dreesman; Larry Payton; Linton, Richard H.; Moore, Veronica; osnyder@hi-tm.com; Richard Parker; 'Robert Jue'; stephen kenny; Thomas Schwartz
Cc: Smith, Kevin
Subject: RE: ROP HACCP Plan pre-approval or not??

Brian et al. -

Apologies from FDA for not weighing in earlier, but our retail experts on this have not been available.

I would interpret Food Code section 8-201.13 to say that a HACCP plan must be submitted for approval under A, which includes foods for which a variance is required. Packaging under ROP requires a variance, except when it doesn't - and this includes foods in which C bot and Lm are controlled as described in 3-502.12, which has criteria for ROP packaging without a variance. This section says you have to have a HACCP plan, but since no variance is involved, the HACCP plan does not need to be submitted for approval per 8-201.13 (A). (B) is silent on submission for approval, it just says you have to have a HACCP plan. (This interpretation appears to be what others have concluded as well.) Kevin Smith has indicated this is consistent with his interpretation and with what we have communicated in the past.

It seems to me that we would be better off titling 8-201.13 "Submission of HACCP plans." Then A can stay as is and B can say something like "A permit holder shall have a properly prepared HACCP plan as specified under 3-502.12 available for review during inspections but need not submit the plan to the regulatory authority for approval before engaging in the activity described in 3-502.12."

Kevin doesn't think this concept is as unclear as other parts of the Code, but he thinks something along the lines of my suggested edits to 8-201.13 may help with clarity. He thinks (B) could be placed in italics to indicate that it does not establish any additional requirement but is instead just reminding readers that ROPing in accordance with 3-502.12 does not require a variance and does not require submission of a HACCP plan to the RA. It may also be an option to build the exception language right into the introductory phrase of 8-201.13(A).

The one thing we need to consider is the provision in 8-201.13(A)(1) - that is, if the submission of a HACCP plan for a given process was required by LAW then it would need to be submitted even if it was for a process that is covered under 3-502.12 and that the Food Code indicated can be done without a variance.

Jenny

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Appendix 6 – Committee issue voting summary with individual members suggested edits.

Last Name	First Name			Issue 1	Issue 2 Revised definitions for Reduced Oxygen packaging	ROP Issue 3, sous vide issue, time and temp as controls	ROP Issue 4, sous vide, pH and temp as controls	ROP Issue 5, Requirement to submit HACCP plan to Regulatory Authority	ROP Issue 6, Changes to Public Health Annex and inclusion of additional references
Grinstead	Dale				As written	As written	As written	As written	As written
Nummer, Ph.D.	Brian A.				As written	As written	As written	As written	As written
McGuffey	Charles E.	Industry - Retail Food Stores	7-Eleven, Inc.		As written	As written	As written	As written	As written
Schwarz	Thomas L.	Industry - Food Service	International Flight Services Association		As written	As written	Does not aprove	Aprove with edits	As written
Blade	William Henry	Regulatory - State	Rhode Island Department of Health		As written	As written	Aprove with edits	As written	As written
Schaffner	Donald	Academia	Rutgers University		As written	As written	As written	As written	As written
Ortiz	Joel	Industry - Retail Food Stores	Whole Foods Market		As written	As written	As written	As written	As written
Payton	Larry	Industry - Food Service	Tokyo Gardens Sushi		As written	As written	As written	As written	As written
Gordon	Christopher	Regulatory - State	Virginia Department of Health		As written	As written	As written	Does not aprove	As written
Fletcher	Jessica	Industry - Food Service	Mohegan Tribe		As written	As written	As written	As written	As written
Dreesman	Kevin	Regulatory - State	Illinois Department of Health		As written	As written	As written	As written	As written
Kenney	Stephen	Industry - Food Service	Darden Restaurants		As written	As written	As written	As written	As written
Parker	Richard	Industry - Retail Food Stores	HEB			As written	As written	As written	As written
Snyder	Oscar Peter	Other - Consultant	Hospitality Institute of Tech and Mgmt		Aprove with edits	Aprove with edits	Aprove with edits	As written	Aprove with edits
Graham	Joe	Regulatory - State	Washington State Department of Health		As written	As written	As written	As written	As written
Yamnic	Dale	Industry	Yum Brands		As written	As written	As written	As written	As written
Goldberg	Dan	Industry - Food Service	Walt Disney Parks and Resorts US		no vote due to position change	no vote due to position change	no vote due to position change	no vote due to position change	no vote due to position change

ROP Committee Issue comments or reasons for opposition

These comments were provided with final issue voting by committee members. They are listed here to potentially assist the FDA in crafting language. All issues were approved by committee members. There were two individual opposition votes to the six issues, but neither specified a reason.

ROP Committee Issue 6

I approve Issue 6 with the following recommendations for changing the Annex 3. Below are my comments for consideration.

Regarding the FDA Food Code 2009: Annex 3 – Public Health Reasons / Administrative Guidelines – Chapter 3, Food, at the 4th paragraph, beginning, " Most foodborne pathogens are anaerobes or facultative anaerobes…," it says in the sentence, "For this reason, *C. botulinum* and *L. monocytogenes* become the pathogens of concern for ROP." This is partially true, but *Salmonella* and pathogenic *E. coli* are also organisms of concern, just like *Listeria*, if the ROP product is mishandled or somehow cross-contaminated. This should be included in the discussion.

On page 3, in the paragraph, "Time is also a factor that must be considered in ROP," we have this 48-hour time limit. There is no scientific basis for 48 hours or 72 hours. The scientific basis is 7 days. We should change this limitation to the 7-day rule.

At the end of this same paragraph, it says, "The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process…" This is not technically correct. It is reducing all pathogenic vegetative cells to an Appropriate Level of Protection; in other words, a 5-log reduction of pathogenic vegetative cells.

If you have any questions, please contact me.

--
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ROP Committee Issue 4

Sorry folks, I just am not comfortable with "pH" and "equilibrium pH" being used here without some further clarification. Extending the ROP shelf life based on pH level is dependent on initially achieving an equilibrium pH in the ROP product that will then continue to hold up during cold storage. If this limited application of food acidification is not clear or too complex for operators or regulators, there could be a problem. I worry that a few drops of vinegar in a bag of raw meat may show "pH" below 5, but after ROP cooking and storage and equilibrium, it won't suffice for extending ROP shelf life like we want it to. Or regulators may not understand that the pH needs to be measured at equilibrium for the shelf lif to be

safely extended. If we concretely state, or make reference to, what is meant by equilibrium pH and how it may be determined, I think it will help operators to properly acidify ROP foods they intend to store, and will help Inspectors/Officials to determine whether variances can be issued safely.

Maybe this could be handled in the Definititions section or an Annex of some sort, but here's some brief additions for Issue 4 that would address this concern, and I could go along with the following:

Line number:

Line 15 ... with an equilibrium pH lower than 5.0 and held at 41o F or below....

Line 20 & 21 ... how they will monitor measure equilibrium pH using calibrated instruments and maintain records of pH findings.
Further explanation and methods for determination of equilibrium pH are available at FDA's Draft Guidance for Industry: Acidified Foods, September 2010" (accessible at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/AcidifiedandLow-AcidCannedFoods/ucm222618.htm#ftn9). ...

Line 42 ... to add an acidifying agent to reduce equilibrium pH to below 5.0 so...

Does this make sense to everybody?
Henry

[Henry Blade]

ROP Committee Issue 5

Issue - line 2 - "their HACCP plan" to "its HACCP plan"
line 4 - add "approval" after "authority"; change "them" to "the appropriate authority"; change"they" to "it"

Significance - Delete both sentences and replace with "The ROP Committee does not recommend prior approval of the establishment's HACCP plan because the Food Code already includes quite specific requirements on how to conduct this operation safely."

[Tom Schwarz]

I approve Issue 4 with the following recommendations. Below are my comments for consideration.

On page 2, beginning line 81, 3-502.12(B)(5), if we are going to have *L. monocytogenes*, we need to include the possibility of cross-contamination of *Salmonella* or *E. coli*. In this case, the critical pH is not 4.4 for *L. monocytogenes*, but rather, 4.2 for *Salmonella* and *E. coli*. We need to modify the text in order to account for the possible contamination by *Salmonella* and *E. coli*.

--
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I approve Issue 3 with the following recommendations. Below are my comments for consideration.

On lines 18-19, it says, "Since paragraphs (C) and (D) in 3-401.11 refer to raw or undercooked products, these would not be acceptable cook temperatures." Raw and undercooked products are common with fish sous vide. In addition, the target pathogen for fish is *Vibrio parahaemolyticus* or *Vibro vulnificus*, and these are controlled with much lower pasteurization temperatures. This has not been covered here. When we specifically say sous vide, we need to allow for fish pasteurization temperatures. Also, I know of no undercooked product that is then cooked sous vide. I suggest we remove "undercooked product" from consideration.

On page 2, lines 80-81, (D)(2)(d), it says, " sealed immediately after cooking and before reaching a temperature below 57C (135F)". A better word than "reaching" would be "cooling to" a temperature before 57C.

Under (D)(2)(e), "Cooled to 5C (41F) in the sealed PACKAGE," at (i) (line 86), there is no reason for cooling to 34F (i). This is conservative regulatory writing. The critical temperature is 36F (3C). If it is a fish / seafood related item, it needs to be cooled to 36F (3C) in an appropriate period of time and held at that temperature. If it is meat, poultry, or mixed products, it is cooled to 41F and held for 7 days. We are not fudging the temperatures for type E *C. botulinum*; so, why should we fudge the temperatures for cooling of the product and cold holding at 34F, if we want 30 days? 36F is adequate.

--
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I approve Issue 2 with the following recommendations. Below are my comments for consideration.

In the submission, Revised definitions for Reduced Oxygen packaging, on line 50, it says, "vacuum packaged in an impermeable bag." It is not impermeable. It has a low oxygen transfer rate. "Impermeable" should be changed to "low oxygen transmission rate."

On line 51, we should add the word, "spore," between "psychrotrophic" and "pathogens," because the vegetative pathogenic cells have been reduced to an Appropriate Level of Protection, and all we need to worry about it is the non-proteolytic type E *C. botulinum* spore.

With both sous vide and cook-chill, since they are sealed, there is no chance of recontamination after the product is cooked. We need to write documents referring to cook-chill and sous vide excluding *Listeria monocytogenes*, since it will not be in the finished product.

The USDA makes no restrictions on storage times and temperatures for sous vide / cook-chill meat and poultry products. The USDA does not consider type E *C. botulinum* to be a significant risk in meat and poultry items. We are adding more control to the retail code that the USDA does not believe is necessary. This is not a level playing field. I believe we should write this for fish to have type E non-proteolytic *C. botulinum* control, but not meat and poultry, vegetables, etc.

On page 2, line 7, is says, "from which air has been expelled." Actually, the bag is twisted and clipped or sealed, but there is no special provision for expelling the air. On the same line, it also says, "closed with a plastic or metal crimp." There are a number of machines that bar-seal packages and are commonly used in retail commissaries. The sentence should be modified to include bar-sealed packages.

Also, a number of cook-chill facilities are producing cups of soup, pumping from the kettles into the cups, which are sealed and sold as cups of soup. A provision for other containers needs to be allowed for.

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Conference for Food Protection
2012 Issue Form

Internal Number: 077
Issue: 2012 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.

Title:
ROP 2: Definitions for Reduced Oxygen Packaging

Issue you would like the Conference to consider:
The 2010-2012 Reduced Oxygen Packaging (ROP) Committee examined the definitions of ROP provided in the Food Code (Chapter 1 - Purpose and Definitions) and concluded that the definitions of sous vide packaging needed to be harmonized with both the Food Code (Annex 6 - Food Processing Criteria) and with the accepted understanding of the ROP process. It was also felt by the Committee, that a statement of what is excluded from ROP could be useful for inspectors and operators. There is some confusion of what constitutes ROP and the exclusionary language proposed will address that confusion. Finally, the Committee thought that several changes to the definitions in Annex 6 - Food Processing Criteria also warranted some edits to improve the clarity of the definitions and make sure that the language of the annex was aligned with the Food Code itself.

Public Health Significance:
ROP offers unique advantages and opportunities for the food industry but also raises several microbiological and potential foodborne illness concerns. Products packaged using ROP may be produced safely if proper scientifically validated controls are in effect. Updates and clarifications of Food Code requirements and public health reasons are essential to ensure proper safeguards and to avoid unproductive confusion for inspectors and operators. Recommended changes are suggested to the most current Food Code 1-201.10. Iitems 1, 3 and 4 below are simply clarifications to exisiting defintions.
The Committee also recommended the addition of a new paragraph (item 2 below) to the most current Food Code section 1-201.12. This defintion was needed to define what is excluded from ROP. This includes short term storage of food products held in cold storage temperatures of 41°F or below in oxygen barrier bags for less than 48 hours as it does not allow sufficient time for the production of *Clostridium botulinum* toxin nor the rapid and progressive growth of *Listeria monocytogenes*. The current Food Code allows up to 48 hours to cool product from 41° F to 34° F for reduced oxygen packaging. As long as product is stored below 41° F no regulatory action would be taken on this product until the product reached the end of the 48 hour time period. The 48 hour time frame is validated by numerous studies reviewed by the CFP's ROP committee. The Skinner-Larkin model for pathogen growth (see Appendix 4 in the ROP issue report) shows that the 48 hour time

frame is a conservative estimate and *C. botulinum* and *L. monocytogenes* would take far longer to produce toxin or grow to dangerous levels.
Additional rationale for the recommended changes is included in the Table 1 Summary of Food Code and Annex changes proposed by the 2010-2012 ROP Committee. That table is included in the 2010-2012 Reduced Oxygen Packaging Committee Final Report as Appendix 1.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (using underlining for additions and strike through for language elimination):
1) Modify language in Section 1-201.10(B) Reduced Oxygen Packaging (2) (e) to read:
Sous vide PACKAGING, in which raw or partially cooked FOOD is ~~placed in a hermetically sealed impermeable bag~~ vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.
2) Add a new subparagraph (3) to Section 1-201.10(B) Reduced Oxygen Packaging with exclusionary language to read:
Section 1-201.10(B) (3) Reduced Oxygen Packaging does not include:
a) Placing product in a bag and sealing it immediately prior to or after, cooking, cooling or reheating the product as long as the product is:
i. Labeled with the time and date the product is placed in the bag; Pf
ii. Removed from the bag within 48 hours of the time product is placed in the bag; P
3) Modify language on page 572 in Annex 6 Food Processing Criteria, Section 2 Reduced Oxygen Packaging, paragraph (B) Definitions, subparagraph (1) to read:
Cook-chill is a process that uses a plastic bag filled with hot cooked food from which air has been expelled and which is sealed, or closed with a plastic or metal crimp.
4) Modify language on page 573 in Annex 6 Food Processing Criteria, Section 2 Reduced Oxygen Packaging, paragraph (B) Definitions, subparagraph (5) to read:
Vacuum Packaging reduces the amount of air from a package and hermetically seals the package so that a ~~near perfect~~ vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.

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2012 Issue Form

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Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
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Title:
ROP 3: Sous Vide - Cook Chill Time and Temperature Control

Issue you would like the Conference to consider:
The Reduced Oxygen Packaging (ROP) Committee reviewed the cook chill/sous vide time temperature parameters listed in Section 3-502.12 (D) of the 2009 Food Code relating to conducting ROP for these processes without a variance. The Committee recommends stating that Section 3-502.12 (D) pertains to only 'POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROLLED FOR SAFETY FOOD).' This would help align it with Sections 3-502.12 (A) and (B)

The Committee also recommends requiring that food be cooked to a temperature listed in Section 3-401.11 (A) and (B) of the 2009 Food Code. Right now Subparagraph 3-502.11 (D)(2)(b) references all four paragraphs of Section 3-401.11. Since paragraphs (C) and (D) in Section 3-401.11 refer to raw or undercooked products, these would not be acceptable cook temperatures.

The main changes the Committee recommends for Cook Chill and Sous Vide fall under Subparagraph 3-502.12(e) of the 2009 Food Code. There is no recommended change to Subparagraph (i) or the current (iv). We do recommend changing Subparagraph (ii). This paragraph currently requires that product be cooled to 34° F within 48 hours and then it can be held for up to 72 hours at 41° F. The Committee recommends allowing storage for up to 7 days at 41° F for product which has been properly cooled within the 6 hour timeframe as outlined in Section 3-501.14 of the 2009 Food Code. Research by Skinner and Larkin and listed in the *'Supplemental Information'* attachment to the 2012 CFP issue '*Report - ROP Committee'* shows that there is no significant change in pathogen growth between these two procedures.

Public Health Significance:
The objective of this issue is to clarify what controls are necessary to ensure the safety of food products packaged using Sous Vide or Cook Chill technologies.

Proposed ROP Committee changes to Section 3-502.12 (D) of the 2009 Food Code limits the following subparagraphs of this section to only potentially hazardous foods (PHF) (time / temperature controlled for safety (TCS) foods). Obviously, if a food is non-PHF (non-TCS), it will not support the growth of pathogens and therefore should not be subject to either variance or ROP provisions of the Food Code.

The change to the 2009 Food Code's Subparagraph 3-502.12 (D)(2)(b) limits items which can be packaged using Sous Vide or Cook Chill technologies to only those foods which are fully cooked. Undercooked, partially cooked or raw foods cannot be safely prepared using sous vide or cook chill technologies so these paragraphs are eliminated and only the paragraphs that provide appropriate thermal lethality are included in this reference, i.e., Sections 3-401.11 (A) and (B).

The change to Subparagraph 3-502.12 (D)(2)(e)(ii) of the 2009 Food Code is driven by conservative science which shows that there is no growth of Clostridium botulinum during the first seven days of storage at 41° F or less. This change is based upon research by Skinner and Larkin which can be found in the *'Supplemental Information'* attachment to the 2012 CFP issue entitled *Report - ROP Committee (ROP 1)*. Additionally, Listeria monocytogenes growth is prevented since this pathogen would have been eliminated through the cook step during the sous vide or cook chill process. All other pathogen growth is controlled by storage at temperatures at or below 41° F.

The change to Subparagraph 3-502.12 (D)(2)(e)(iii) of the 2009 Food Code is driven by the original wording now being obsolete and being covered by the change which was made to Subparagraph 3-502.12 (D)(2)(e)(ii) of the 2009 Food Code. The Skinner Larkin model clearly shows that there is no C. botulinum growth during the 7 days after product is cooked and cooled.

Additional changes are recommended in 2012 CFP issue entitled *ROP 6: Updates to Food Code Annexes 2 and 3,* as follows:

1. Changes to the Public Health Reasons, Annex 3 of the 2009 Food Code, which will explain the rationale for these changes; and
2. References included in the 'Supplemental Information' attached to the Committee's report also be included into Annex 2 of the 2009 Food Code.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (using underlining for additions and strike through for language elimination):

Cook-Chill or Sous Vide

Section 3-502.12 (D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT that PACKAGES <u>POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD)</u> FOOD using a cook-chill or sous vide process shall:

(1) Implement a HACCP PLAN that contains the information as specified under ¶ 8-201.14(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 <u>(A and B)</u>, 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 ~~subsequently~~: 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*;P

(ii) ~~*Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then*~~ *held at 5°C (41°F) or less for no more than ~~72 hours~~* 7 days*, at which time the FOOD must be consumed or discarded*; P

This issue recommends no additional changes to remainder of Section 3-502.12 (D).

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2012 Issue Form

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Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
ROP 4: Sous Vide and Cook Chill, pH and Temperature Control

Issue you would like the Conference to consider:
The Reduced Oxygen Packaging (ROP) Committee recommends changing the requirement to obtain a variance when an acidifying agent is used as a method of food preservation so long as the equilibrium pH of the final product is 5.0 or below which is checked using a pH meter and is held at 41° F or below for no more than 30 days.
The ROP Committee asks that the Council and CFP delegates recognize that products with a pH lower than 5.0 and held at 41° F or below controls pathogen growth and allows products to be held safely for up to 30 days.

Public Health Significance:
The change to Subparagraph 3-502.12 (D)(2)(e)(iii) of the 2009 Food Code is driven by 2 factors. First, the original wording is now obsolete and is covered by the recommended change to Subparagraph 3-502.12 (D)(2)(e)(ii) of the 2009 Food Code as requested in 2012 CFP Issue titled: *ROP 3: Sous Vide- Cook Chill Time and Temperature Control.*
The new wording is based upon research which shows that *C. botulinum* and *L. monocytogenes* cannot grow if a food has a pH below 5.0 and a temperature below 41° F. The growth of *L. monocytogenes* and other pathogens are also controlled by the same factors as listed for Subparagraph 3-502.12 (D)(2)(e)(ii) of the 2009 Food Code
Monitoring of pH as a control for pathogens *C. botulinum* and *L. monocytogenes* is important to the safety of the product to ensure that the proper food product pH is consistently maintained.
2012 CFP issue entitled *ROP 6: Updates to Food Code Annexes 2 and 3* is recommending:

1. Changes to the Public Health Reasons, Annex 3 of the 2009 Food Code, which will explain the rationale for these changes; and
2. References included in the '*Supplemental Information'* attached to the Committee's report also be included into Annex 2 of the 2009 Food Code.

Paragraph 3-502.11 (C) of the 2009 Food Code will now allow ROP processes to add an acidifying agent to reduce pH to below 5.0 so that product may be held at below 41° F for up to 30 days. Research has shown that this yields an acceptable method with a built in safety margin to allow ROP processes without the need for going through the variance process. Health Canada uses this pH and temperature combination to ensure safe

production of foods and control of *L. monocytogenes* and *C. botulinum.* Additionally, psychrophilic *C. botulinum* has a pH growth limit at 5.0 at ALL temperatures and *L. monocytogenes* has a pH growth limit of 4.4 at ALL temperatures and a pH growth limit at 5.0 at refrigeration temperatures (41F). The '*Supplemental Information'* attached to the 2012 CFP issue entitled *Report - ROP Committee* includes additional research to support the Committee's recommendation.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (using underlining for additions and strike through for language elimination):

1) The following exclusionary language be added to the end of Subparagraph 3-502.11 (C)

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

(A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement; Pf

(B) Curing FOOD; Pf

(C) Using FOOD ADDITIVES or adding components such as vinegar, except as specified in 3-502.12 (D)(2)(e)(iii): Pf

(1) As a method of FOOD preservation rather than as a method of flavor enhancement, Pf or

(2) To render a FOOD so that it is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL OF SAFETY FOOD); Pf

2) That a new paragraph (d) be added Section 3-502.12 (B)(5)

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

(B) A FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that: Pf ...(no changes to paragraphs 1-4)

(5) Includes operational procedures that:....(no changes to subparagraphs a-c)

(d) If pH is used as a barrier to growth of *Clostridium botulinum* and *Listeria monocytogenes* such as in 3-502.12 (D)(2)(e)(iii), delineate equilibrium pH measurement, instrument calibration, and pH recordkeeping procedures.

3) Replace existing Subpargraph (iii) of Section 3-502.12 (D)(2)(e) with new language

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

~~(iii) *Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from PACKAGING, at which time the food must be consumed or discarded*; P or~~

(iii) Has an equilibrium pH of 5.0 or less, verified by a properly calibrated digital pH meter, and held at 5°C (41°F) or less until consumed or discarded within 30 days after the date of PACKAGING; P or

This issue recommends no additional changes to remainder of Section 3-502.12 (D).

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2012 Issue Form

Internal Number: 089
Issue: 2012 III-013

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Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
ROP 5: Requirement to submit HACCP plan to regulatory authority

Issue you would like the Conference to consider:
The Reduced Oxygen Packaging (ROP) Committee is recommending that if a food establishment decides to conduct reduced oxygen packaging (ROP) without a variance as specified in Section 3-502.12 of the 2009 Food Code that the food establishment must first submit a copy of their HACCP plan to the regulatory authority. We do not recommend that the food establishment needs to await regulatory authority, but only to notify them through submission of the HACCP plan that they will be conducting ROP operations in conformance to the procedures enunciated in Section 3-502.12 of the 2009 Food Code.

Public Health Significance:
Since the consequences of an ill conceived plan to conduct ROP operations in a food establishment can be serious, and since many food establishments are only inspected by their regulatory authority once or twice a year, requiring notification of the regulatory authority by the food establishment of ROP processes being implemented is a prudent requirement. This will allow the regulatory authority to be made immediately aware of the food establishment's intention to conduct ROP operations and will also give the regulatory authority the option to review the plan to ensure that the requirements of Sections 3-502.12 of the most current Food Code are being followed.
Prior approval is not recommended to facilitate a food establishment initiating operations without a lengthy review process. Furthermore, the Food Code is quite specific in its requirements to conduct this operation safely.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (using underlining for additions):
1) Add a new Subparagraph (7) to Subparagraph 3-502.12 (B)
3-502.12 Reduced Oxygen Packaging without a Variance, Criteria.
(B) A FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that: [Pf]...(Subparagraphs 1-6 are unchanged)

(7) Is provided to the regulatory authority prior to implementation.

2) Modify Paragraph 8-201.13 (B)

8-201.13 When a HACCP Plan is Required.

(B) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN which is provided to the regulatory authority prior to implementation as specified under § 3-502.12.

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Conference for Food Protection
2012 Issue Form

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Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
ROP 6: Updates to 2009 Food Code Annexes 2 and 3

Issue you would like the Conference to consider:
The Reduced Oxygen Packaging (ROP) Committee recommends adopting the ROP Committee's changes to Annex 3, Public Health Reasons as listed in the 'Supplemental Information' attachment to the 2012 CFP issue titled *Report - ROP Committee (ROP 1).* The Committee further recommends inclusion of the references cited in the 'Supplemental Information' attachment to the 2012 CFP issue titled *Report - ROP Committee (ROP 1).*

Public Health Significance:
The changes to Public Health Annex 3 and references for Annex 2 as recommended in the *'Supplemental Information'* attachment to the 2012 CFP issue titled *Report - ROP Committee (ROP 1)* to help further clarify the ROP Committee's rationale in the proposed changes to the 2009 Food Code as they relate to ROP, and also provide guidance to the regulatory authority when evaluating a food establishment's reduced oxygen packaging procedures that are conducted without a variance or prior approval.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the Annex to the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:

1. include the references cited in the Committee's report into Food Code Annex 2; and
2. include the changes to the Food Code's Public Health Annex 3 as recommended by the ROP Committee and as listed below (using underlining for additions and strike through for language elimination):

FDA Food Code 2009: Annex 3 - Public Health Reasons / Administrative Guidelines - Chapter 3, Food

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). 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.

This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging material that readily allow the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 cc/m^2 ~~cm^2/m^3~~/24 hours or greater[i]. A reduced oxygen atmosphere will often result with an Oxygen Transmission rate of 10-100. The process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.

If packaging material OTR is to be used as a barrier to *C. botulinum* growth and an exemption from ROP HACCP requirements in sections 3-502.11 and 3-502.12 the operator must provide scientific evidence to the regulatory authority that the packaging, under it's intended use, maintains an oxygen atmosphere for the duration of the refrigerated shelf life. At the time of this writing, only one packaging product possesses an OTR greater than 10,000 cc/m2/24h with scientific evidence acceptable to the FDA that it maintains an aerobic atmosphere when shrink packaging raw seafood with no inclusions (marinades, oils, etc). The packaging allows oxygen to pass permitting resident bacteria to spoil the seafood before the toxin of *C. botulinum* could develop[ii].

Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic *C. botulinum* and *L. monocytogenes* are able to multiply slowly ~~well~~ below 5°C (41°F). For this reason, *C. botulinum* and *L. monocytogenes* become the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of *C. botulinum* and *L. monocytogenes* without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control *C. botulinum* and *L. monocytogenes* when used in conjunction with a food storage temperature of 5°C (41°F) or less. They include a_w of 0.91 or less; pH of 4.6 or less; cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or high levels of competing microorganisms. *C. botulinum* will not produce toxin below an a_w of 0.91. Nitrite, used in meat and poultry curing, inhibits the outgrowth of *C. botulinum* spores. Most foodborne pathogens do not compete well with other microorganisms, therefore foods that have a high level of spoilage organisms or lactic acid bacteria can safely be packaged using ROP. Other intrinsic or extrinsic factors can also control the growth and/or toxin production of *C. botulinum* and *L. monocytogenes.*

Non-potentially hazardous food (non-time/temperature control for safety food) as defined by interaction tables A and B (section 1-201.10) contain pH and Aw intrinsic factors that prevent the growth of both *C. botulinum* and *L. monocytogenes*. Therefore these foods are exempt from the reduced oxygen packaing HACCP requirements of 3-502.11 or 3-502.12 provided they are as received and not modified in the operation and labeled as non-potentially hazardous foods.[iii]

Naturally fermented cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all of the following: a lower pH, production of organic acids, and natural antibiotics or bacteriocins such as nisin by lactic acid bacteria, salt (NaCl) added during processing, low moisture content, added preservatives, and live competing cultures. Very few outbreaks have occurred that were associated with cheese. The few outbreaks of foodborne illness associated with cheeses or cheese products could be traced in large part to temperature abuse with storage at uncontrolled ambient air temperatures. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of *L. monocytogenes* under modified atmosphere conditions.

When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary barriers such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of *C. botulinum* and *L. monocytogenes.* Non-proteolytic *C. botulinum* spores are able to germinate and produce toxin at temperatures down to 3°C (38°F). Therefore, to control for toxin production by *C. botulinum*, an anaerobe, ROP foods must be held at 3°C (38°F) or less. *Listeria monocytogenes* is able to grow, although very slowly, at temperatures down to - 1°C (30°F). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential. Cooking at low temperatures below that stated in 3-401.11 (A-C) may not destroy vegetative cells and may in fact become an incubation temperature for some pathogens. Any use of these low cooking temperatures combined with ROP packaging must be approved via the variance process[iv].

Four separate options are provided in (D)(2)(e). These time-temperature combinations will provide equivalent food safety protection without need for a variance. The first is cooling the bagged product to 1°C (34°F) and holding for up to 30 days after the product is sealed in the bag. The second is cooling bagged product to 5°C (41°F), ~~1°C (34°F), removing product to a different refrigeration unit~~ and holding at any temperature up to 5°C (41°F) for up to 7 days ~~72 hours with the total storage time not to exceed 30 days~~[v]. ~~This situation is often encountered when a central kitchen prepares and stores the bagged product at 1°C (34°F) then transports it to a satellite kitchen under their control where it can be held at 5°C (41°F) or less~~.[vi] The third option relies on a secondary barrier, pH. When the pH is at or below 5.0 *C. botulinum* and *L. monocytogenes* cannot grow at 5ºC (41ºF). Therefore, 30

days storage is permitted. Note that when using pH as a barrier, a pH measurement, calibration and recordkeeping SOPs are required. ~~is cooling to 3°C (38°F) and holding for no more than 72 hours from packaging.~~[vii] The fourth option can be used without a restricted shelf life while the bagged product is held frozen until thawed to be consumed or used in another preparation.

Since there may not be ~~are no~~[viii] other controlling factors for *C. botulinum* and *L. monocytogenes* in a cook-chill or sous vide packaging system, temperature control must be continuously monitored electronically and visually examined twice daily to verify that refrigeration temperatures are adequate. New technology makes it relatively easy to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook chill and sous vide products at 1°C (34°F) or 5°C (41°F) ~~3°C (38°F)~~ or less[ix]. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures which can be displayed using computer software. Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.

Time is also a factor that must be considered in ROP. Processes that use ROP packaging for storage less than 48h do not pose a hazard for pathogen growth when refrigerated at 5°C (41°F) or less and are exempt from the HACCP requirement of sections 3-502.11 and 3-502.12. Examples are sous vide cooking provided a proper cooking temperature is used according to 3-401.11 (A-C) followed by immediate service and enhanced cooling of foods using ROP bags. The main factors in this exemption are that the food must be date marked and consumed or removed from packaging after 48h[x]. The 14 day "use by" date is required label information for VP, MAP, and CAP products and cannot exceed the manufacturer's "sell by" or "use by" date. This is considered a safe time period because two barriers to growth are required to be present. When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process or inhibiting their growth, preventing recontamination, and then refrigerating at 34°F or less ~~with an option of 3°C (38°F) for up to 72 hours after packaging with stringent temperature monitoring and recording requirements~~. The 7 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 5°C (41°F) or less[xi]. These criteria allow both institutional-sized cook chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook chill and sous vide processes.

The extended shelf life for vacuum packaged hard and semisoft cheeses is based on many intrinsic factors in these cheeses plus the normal refrigeration temperature of 41°F or less to maintain safety.

A Hazard Analysis Critical Control Point (HACCP) plan is essential when using ROP processing procedures. *C. botulinum* and *L. monocytogenes* are potential hazards which must be controlled in most foods unless the food is a low acid canned food produced under 21 CFR Part 108 or 113 or an acidified food produced under 21 CFR 114. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used.

When a food establishment intends to use ROP technology but does not use one of the secondary barriers defined in section 3-502.12 (a single barrier of 34°F combined with the criteria specified in paragraph 3-502.12(D), or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), the operator must submit an application for a variance under section 3-502.11 providing evidence that the ROP methodology intended for use is safe. It is highly recommended that the operator and/or the regulatory authority consult a process authority to validate the scientific evidence the ROP methodology intended for use is safe[xii].

Unfrozen raw fish and other seafood are specifically excluded from ROP without a variance[xiii] because of these products' natural association with *C. botulinum* type E which grows at or above 3°C (37-38°F). Fish and seafood that are frozen before, during and after the ROP packaging process are allowed.

[i] Corrects inaccurate description of OTR to that found in the US FDA Fisheries HACCP Guide.

[ii] Suggested text to clarify 10 K bag exclusion. Would require variance for all uses other than that approved by FDA Seafood HACCP Guidance for raw seafoods.

[iii] Adds text to clarify non-PHF exclusion from ROP HACCP 3-502.11 or 3-502.12.

[iv] Added text to clarify low temperature cooking processes, e.g. sous vide to obtain a variance.

[v] Changes this section to accommodate changes made to 3-502.12 (D)(2)(e).

[vi] Just deleting this text. It appears extraneous.

[vii] Corrects text to accommodate changes made to 3-502.12 (D)(2)(e)(iii).

[viii] Correct text to acknowledge that there may be other controlling factors.

[ix] The 38oF option has been deleted.

[x] This may need to be tweaked somewhat after the committee finalizes the definition change that establishes the 48 h storage point.

[xi] Clarifies this section to permit the 7 day at 41F code change.

[xii] This change was discussed by the committee and I am suggesting placing it here.

[xiii] Corrects text that implies ROP of non-frozen fish with a variance is not permitted.

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Conference for Food Protection
2012 Issue Form

Internal Number: 042
Issue: 2012 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.

Title:
Improving Ground Beef Food Safety in Restaurants and Food Service

Issue you would like the Conference to consider:
The Food and Drug Administration's (FDA) Food Code Consumer Advisory provision was implemented to assure that all consumers are informed about the increased risk to especially vulnerable populations of eating raw or undercooked animal foods. The Consumer Advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs, and sites where groceries are obtained that have operations such as deli's or seafood departments.
Although a variety of statements regarding this issue are currently standard on restaurant menus, the American Association of Meat Processors (AAMP) believes these statements do not provide a sufficient level of protection against foodborne pathogens at food service and restaurants. The meat industry, regardless of facility size (*e.g.,* very small, small, and large), has worked aggressively to do what they can to prevent this harmful *E. coli* O157:H7 pathogen from contaminating meat products. Meat processors rely on numerous interventions intended to specifically address *E. coli* O157:H7 and other harmful meat-related pathogens. Unfortunately, science and historical data indicates that the meat industry cannot guarantee that all ground beef produced is completely free of the *E. coli* O157:H7 pathogen and/or other non-*E. coli* O157 Shiga Toxin-producing *Escherichia coli* (commonly referred to as non-O157 STECs). See the attachment, *Background Information*, for more details.
Therefore, a risk still exists that consumer may get extremely ill by consuming under-cooked ground beef products. The consumer advisory statement may protect the food service or restaurant establishment from financial liability and/or lawsuits, but does very little to actually protect the consumer. The allowance of such dangerous food preparation practices is in complete opposition to U.S. Department of Agriculture (USDA) and FDA cooking recommendations.
AAMP is currently recommending that changes be made to the FDA Food Code for the Consumer Advisory statement on menus and that proper preparation of ground beef be mandated at the food service and restaurants. Specifically, AAMP recommends:

- Amend the FDA Food Code to add a statement that disallows food service/restaurants from serving undercooked ground beef products to consumers. This change would need to include a minimal cooking temperature for ground beef items (*e.g.*, ground beef, hamburgers, etc.) of 160°F to ensure that it has been properly cooked to eliminate the chances for the potential presence of *E. coli* O157:H7.
- Amend the FDA Food Code to allow ground beef or blade tenderized steaks to be cooked at a temperature lower than 160°F, if, and only if that ground beef or blade tenderized steaks has been irradiated.
- Amend the FDA Food Code to add a statement that disallows food service/restaurants from serving undercooked blade tenderized or moisture enhanced steaks. This change would need to include a minimal cooking temperature for blade tenderized or moisture enhanced steaks of 160°F to ensure that it has been properly cooked to eliminate the chances for the potential presence of *E. coli* O157:H7.

The importance of the change is to help alter the mindset of consumers to avoid consuming undercooked ground beef products, since these products carry increased risk of *E. coli* O157:H7 and other non-O157 STECs. When consumers begin to understand the reasons why they are not able to eat/order an undercooked ground beef patty at the food service and restaurant level, then ideally this understanding of food safety will likely transfer to at-home use of the product. The Consumer Advisory statement in its current form also is somewhat of a release of liability for restaurants, who have not in the past taken the responsibility for properly cooking products served to consumers. Instead, the blame is placed back onto the ground beef processor/supplier. With the current structure of the meat industry and the technology available, many of these ground beef processors/suppliers are simply receiving raw materials to produce ground beef and have very little control on potential *E. coli* O157:H7 contamination. Furthermore, the effectiveness of antimicrobial interventions against *E. coli* O157:H7 at the processors level have limitations.

Public Health Significance:

Escherichia coli O157:H7 (commonly referred to as *E. coli* O157:H7) has been a major concern in the meat industry for decades and has increasing concerns with the development of new processing techniques. *E. coli* O157:H7 has been associated with food since 1982, but *E. coli* O157 is naturally found in the intestinal tract of cattle and in cattle feces. A potential cascade effect of *E. coli* O157:H7 contamination can be seen during the slaughter and production process. *E. coli* O157:H7 in the feces of cattle can be transferred to the hide. The feces on the hide are transferred to the carcasses during the de-hiding process and from the carcass the knives and saws become a vector to transfer *E. coli* O157:H7 onto other cuts of meat. The contaminated cuts of meat are then ground and added to other animal's cuts of meat. This is a possible cascade of events that can lead to massive amounts of ground products contaminated with *E. coli* O157:H7.

E. coli is a common kind of bacteria that lives in the intestines of animals and people, and there are many strains of the pathogen. Most are relatively harmless, but *E. coli* O157:H7 is a strain that produces a powerful toxin that makes those affected very ill. *E. coli* can be found in meat, unpasteurized milk, raw fruits and vegetables, and contaminated water sources. Bloody diarrhea and stomach pain are the most common signs of *E. coli* O157:H7 sickness. Some of the population, especially children under 5 and the elderly, can become

very sick from *E. coli* O157:H7. The infection damages the body's red blood cells and kidneys, and can cause hemolytic uremic syndrome. The Centers for Disease Control and Prevention (CDC) estimates that every year at least 2000 Americans are hospitalized, and about 60 die as a direct result of *E. coli* O157:H7 infections and its complications. A study published in the Journal of Food Protection in 2005 by the Emerging Infections Program FoodNet Working Group, estimated the annual cost of *E. coli* O157:H7 illnesses to be $405 million (in 2003 dollars), which included $370 million for premature deaths, $30 million for medical care, and $5 million for lost productivity. Visit http://www.ncbi.nlm.nih.gov/pubmed/16355834# to view the abstract of the study, Economic Cost of Illness Due to *Escherichia* coli O157 Infections in the United States.

According to the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) data, in 2011 there were 11 *E. coli* recalls of beef products. In 2010, there were 9 *E. coli* O157:H7 recalls of beef products. According to CDC FoodNet data, the illness rate associated with *E. coli* O157:H7 was 0.9 in 2010. Although the incidence of STEC O157 infection has declined to reach the 2010 national health objective target of less than one case per 100,000, this still does not justify the undercooking of potentially harmful products.

USDA/FSIS and the meat industry instituted a testing program for the pathogen that focused on components used in the production of ground beef products as well as end-product sampling programs for ground beef. The goal is to keep contaminated product from reaching consumers and to spur industry focus towards pathogen reduction and HACCP-associated verification programs to reduce the risk of this pathogen in beef products. The USDA/FSIS policy is currently reflected in FSIS Directive 10,010.1. Visit http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10010.1Rev3.pdf to download a copy of the document. This testing is random and sporadic and still allows the potential for contaminated product to reach the consumer.

On September 13, 2011, USDA's Under Secretary for Food Safety, Dr. Elisabeth Hagen, announced that six additional serogroups of pathogenic *E. coli* were declared as adulterants in non-intact raw beef. As a result of this action, if the *E. coli* serogroups O26, O103, O45, O111, O121, and O145 (commonly referred to as non-O157 STECs) are found in raw ground beef or its precursors, those products will be prohibited from entering commerce. FSIS will begin testing for these six serogroups of STEC and enforcing the new policy on March 5, 2012.

Over the past two years, FSIS has announced several new measures to safeguard the food supply, prevent foodborne illness, and improve consumers' knowledge about the food they eat. These initiatives support the three core principles developed by the President's Food Safety Working Group (FSWG). When President Obama came into office, he said that "protecting the safety of our food and drugs is one of the most fundamental responsibilities government has." He pledged to strengthen our food safety laws and to enhance the government's food safety performance. As part of its multi-faceted approach to prevent foodborne illness, USDA also launched Food Safe Families, a consumer education campaign with the Ad Council, the FDA, and the CDC. Changing the Food Code to disallow food service/restaurants to serve undercooked ground beef products to consumers is consistent with the goals of the FSWG and would be another tool to protect public health from *E. coli*.

Ground beef makes up the largest market share of beef consumption in the U.S. Billions of hamburgers are consumed annually. Approximately 26.4 billion pounds of beef was

consumed in 2010, and approximately 50% of this amount was in the form of ground beef. Most Americans buy the product at least two times a week, and ground beef accounts for more than half of all beef sales, as well as a quarter of all the meat sold in North America. Consumers eat about 28 pounds of ground beef annually. Because of the amount of ground beef consumed, the concern over *E. coli* O157:H7 and other non-O157 STECs is taken very seriously by the beef industry, USDA/FSIS, and other stakeholders.

The language amendments recommended in this Issue would be more descriptive of products that are currently recognized by USDA/FSIS as foods that are regularly associated with potential *E. coli* O157:H7 contamination. The Food Code was previously amended to disallow the sale of under cooked ground beef (*i.e.*, comminuted meat) when it is selected from a children's menu. The *E. coli* O157:H7 pathogen is non-discriminatory and can potentially affect all people, regardless of age and immune system.

As the meat industry endeavors to prevent the occurrence of *E. coli* O157:H7 and other pathogen contamination, it is our hope that the food preparers and consumers will continue to practice proper food handling and cooking techniques in their kitchens in an effort to prevent food borne illnesses

AAMP doesn't believe that the recommended 160°F internal product temperature will create an unpalatable product for consumers. The National Cattlemen's Beef Association (NCBA), through funding from Beef Check-off dollars, has also developed an approach to teach the public that through proper cooking methods, beef is safe when cooked to 160°F and is also savory to eat when cooked to that temperature. The promotion attempts to educate the public to not ruin the hamburger by cutting into the hamburgers to check the color, but instead they are encouraged to use a meat thermometer to cook the hamburger to 160°F. NCBA has pointed out that the keys to a *Safe and Savory* hamburger are:

- Cook ground beef to an internal temperature of 160°F.
- Don't use visual appearance to determine doneness of the hamburger. An instant-read meat thermometer is the only way to ensure that the ground beef is cooked to the proper temperature of 160°F. Consumers cannot rely on color and juiciness.
- Check the internal temperature of the hamburger by inserting the meat thermometer into the center of the hamburger.

Because proper cooking is the most uniform method that can guarantee ground beef products are safe from *E. coli* O157:H7, AAMP believes that this change is very important to help improve food safety. It is our hope that this change would also improve consumer education on cooking ground beef, as well as the public's understanding of this pathogen. The change in the Food Code would ensure that all restaurants are required to cook their ground beef products to the proper temperature, and remove one more area of risk from the beef industry's concerns.

The American Association of Meat Processors is recommending that the members of the 2012 Conference for Food Protection support the identified changes of the FDA Food Code that will further help protect consumers from potential *E. coli* O157:H7 and/or non-O157 STEC illness.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline and deleted language shown with strike-through):

1. §3-401.11 (Raw Animal Foods) (D)

A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare; 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:

(1) *As specified under ¶¶ 3-801.11(C)(1) and (2), the food establishment serves a population that is not a highly susceptible population;*

(2) *The food, if served or offered for service by consumer selection from a children's menu, does not contain comminuted meat;* [Pf] *and*

(3) *The consumer is informed as specified under § 3-603.11 that to ensure its safety, the food should be cooked as specified under ¶ (A) or (B) of this section; or*

Revise subparagraph (D)(3) to read as follows:

~~*The* consumer is informed as specified under § 3-603.11 that to ensure its safety, the *food* should be cooked as specified under ¶ (A) or (B) of this section~~ The food, if is beef or contains beef which is comminuted beef meat (*e.g.*, ground beef), blade tenderized beef meat, or moisture-enhanced beef meat; it must be cooked to a minimal internal temperature of 160°F unless the food has been irradiated or guaranteed not to contain *E. coli* O157:H7 or other non-O157 STECs; or

2. §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

Revise subparagraph (B)(1) to read as follows:

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

These amendments would be more descriptive of products that are currently recognized by USDA/FSIS as foods that are regularly associated with potential *E. coli* O157:H7 contamination. The Food Code was previously amended to disallow the sale of under cooked ground beef (*i.e.*, comminuted meat) when it is selected from a children's menu. The *E. coli* O157:H7 pathogen is non-discriminatory and can potentially affect all people, regardless of age and immune system.

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Attachments:

- "Background Information"
- "Microbiological Results of Raw Ground Beef Products for E. coli O157:H7"

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BACKGROUND

A 1988 outbreak involving precooked patties lead to a rapid FSIS policy change on December 27, 1988. This increased the cooking temperature from 140 to 160°F (60 to 71.1°C). Opposition to the ruling was expressed as the high temperature often resulted in a very dry unpalatable hamburger.

In mid-1992, the USDA published a study and policy that required cooking temperature for hamburgers to 155°F (68.3°C). Although this is a "requirement," undercooked hamburgers can be ordered at food service establishments and restaurants if specifically requested. The FDA changed its policy in the Food Code during the 1993 outbreak to match the USDA recommended cooking temperature.

In 1993, Jack-In-The-Box, an American fast-food restaurant was the focal point of an *E. coli* O157:H7 epidemic in the Northwest of the United States. Hundreds of people were sickened in this outbreak, which resulted from the consumption of undercooked, contaminated ground beef, and four children died. It was the largest and deadliest *E. coli* O157:H7 outbreak in American history up to that time.

This epidemic sparked significant structural changes to how USDA/FSIS conducts inspection activities. FSIS developed the regulatory proposal that became the Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (HACCP) Rule (published as a final rule in 1996). In this rule, FSIS established that its food safety goal was to reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible measures are taken at each step in the food-production process where hazards can enter and where procedures and technologies exist or can be developed to prevent the hazard or reduce the likelihood it will occur. With respect to major enteric pathogens that contaminate meat and poultry products during the slaughter process, FSIS stated in this rulemaking that it believed that the risk of foodborne illness associated with these pathogens is largely avoidable and can be minimized by proper implementation of HACCP. The agency was clear that implementation of HACCP did not mean the absolute elimination of pathogens, but that it did mean preventing and reducing contamination with pathogenic microorganisms to a degree that very substantially reduces and minimizes the risk of foodborne illness.

HACCP is a system that enables the production of safe meat and poultry products through the thorough analysis of production processes, identification of all hazards that are likely to occur in the production establishment, the identification of critical points in the process at which these hazards may be introduced into product and therefore should be controlled, the establishment of critical limits for control at those points, the verification of these prescribed steps, and the methods by which the processing establishment and the regulatory authority can monitor how well process control through the HACCP plan is working.

Before the January 1993 Jack-In-The-Box outbreak in the Pacific Northwest, *E. coli* O157:H7 and related strains were considered by many to be relatively rare. During the outbreak the FDA increased its recommended cook temperature from 140°F to 155°F. Through the years, the federal government has recognized the danger of *E. coli* O157:H7, and has accordingly instituted specific policies regarding this pathogen. In 1993, USDA/FSIS implemented a "zero tolerance" policy for fecal contamination on beef carcass and it was strictly enforced. The USDA/FSIS declared *E. coli* O157:H7 an adulterant in ground beef under federal law in 1994. According to the International Commission on Microbiological Specification for Foods (Book 7 - 2002), no feasible sampling plan can ensure complete absence of a pathogen. It cannot be guaranteed that the lot is completely free of the organism, no matter how large the number of sample units.

The decision was then made in January, 1999 that the presence of *E. coli* O157:H7 would adulterate not just ground beef, but any non-intact product or intact product intended for use as a non-intact product. In February 1999, the USDA approved irradiation in red meats as a means of controlling *E. coli* O157:H7 and other pathogens. Currently, consumers are recommended to cook hamburgers to 160°F as measured by a thermometer.

Escherichia coli O157:H7 commonly referred to as *E. coli* O157:H7 has been a major concern in the meat industry for decades and has increasing concerns with the development of new processing techniques. *E. coli* O157:H7 has been associated with food since 1982, but *E. coli* O157 is naturally found in the intestinal tract of cattle and in cattle feces. A cascade effect of *E. coli* O157:H7 can be seen during the slaughter and production process. *E. coli* O157:H7 in the feces of cattle can be transferred to the hide. The feces on the hide are transferred to the carcasses during the de-hiding process and from the carcass the knives and saws become a vector to transfer *E. coli* O157:H7 onto other cuts of meat. The contaminated cuts of meat are then ground and added to other animal's cuts of meat. This is a possible cascade of events that can lead to massive amounts of ground products contaminated with *E. coli* O157:H7.

E. coli is a common kind of bacteria that lives in the intestines of animals and people, and there are many strains of the pathogen. Most are relatively harmless, but *E. coli* O157:H7 is a strain that produces a powerful toxin that makes those affected very ill. *E. coli* can be found in meat, unpasteurized milk, raw fruits and vegetables, and contaminated water sources. Bloody diarrhea and stomach pain are the most common signs of *E. coli* O157:H7 sickness. Some of the population, especially children under 5 and the elderly, can become very sick from *E. coli* O157:H7. The infection damages the body's red blood cells and kidneys, and can cause hemolytic uremic syndrome. The Centers for Disease Control and Prevention (CDC) estimates that every year at least 2000 Americans are hospitalized, and about 60 die as a direct result of *E. coli* O157:H7 infections and its complications. A study conducted in 2005 estimated the annual cost of *E. coli* O157:H7 illnesses to be $405 million (in 2003 dollars), which included $370 million for premature deaths, $30 million for medical care, and $5 million for lost productivity.

According to FSIS data, in 2007 there were 20 *E. coli* recalls, 10 of which were related to human illnesses. In 2008, however, there were 15 *E. coli* O157:H7 recalls, with five human illness related. Indeed, according to Centers for Disease Control's (CDC) FoodNet data, the illness rate associated with *E. coli* O157:H7 went from 1.2 in 2007 to 1.12 in 2008.

USDA/FSIS and the meat industry instituted a testing program for the pathogen that focused on components used in the production of ground beef products as well as end-product sampling programs for ground beef. The goal is to keep contaminated product from reaching consumers and to spur industry focus towards pathogen reduction and HACCP-associated verification programs to reduce the risk of this pathogen in beef products. The USDA/FSIS policy is currently reflected in FSIS Directive 10,010.1. This testing is random and sporadic and still allows the potential for contaminated product to reach the consumer.

On September 13, 2011, USDA's Under Secretary for Food Safety, Dr. Elisabeth Hagen, announced that six additional serogroups of pathogenic *E. coli* were declared as adulterants in non-intact raw beef. As a result of this action, if the *E. coli* serogroups O26, O103, O45, O111, O121, and O145 (commonly referred to as non-O157 STECs) are found in raw ground beef or its precursors, those products will be prohibited from entering commerce. FSIS will begin testing for these six serogroups of STEC and enforcing the new policy on March 5, 2012.

Ground beef makes up the largest market share of beef consumption in the U.S. Billions of hamburgers are consumed annually. Approximately 28.1 billion pounds of beef was consumed in 2007, and approximately 50% of this amount was in the form of ground beef. Most Americans buy the product at least two times a week, and ground beef accounts for more than half of all beef sales, as well as a quarter of all the meat sold in North America. Consumers eat about 28 pounds of ground beef annually. Because of the amount of ground beef consumed, the concern over *E. coli* O157:H7 is taken very seriously by the beef industry, USDA/FSIS, and other stakeholders.

Microbiological Results of Raw Ground Beef Products Analyzed for *Escherichia coli* O157:H7

The table below displays the microbiological results of raw ground beef products analyzed for *E. coli* O157:H7 since 1994. As the data represents, although the amount of positive samples compared to the amount of samples is relatively low, *E. coli* O157:H7 contamination of ground beef still occurs. Furthermore, not all contamination is discovered through USDA/FSIS and/or establishment product testing because it is not possible to test all ground beef products. Therefore, there still remains a level of risk that *E. coli* O157:H7 contamination may still reach the consumer, food service outlet, and/or restaurant.

Year		Federal Inspected Establishments	State Inspected Establishments	Retail Exempt Establishments
1994	Samples Analyzed	293	10	588
	Positive Samples	0	0	0
1995	Samples Analyzed	1,459	29	2,787
	Positive Samples	2	0	1
1996	Samples Analyzed	1,459	44	3,972
	Positive Samples	1	0	3
1997	Samples Analyzed	1,120	8	4,849
	Positive Samples	2	0	1
1998	Samples Analyzed	4,281	55	3,731
	Positive Samples	12	0	2
1999	Samples Analyzed	4,514	43	3,212
	Positive Samples	21	0	11
2000	Samples Analyzed	5,020	50	1,292
	Positive Samples	36	1	17
2001	Samples Analyzed	5,514	27	1,463
	Positive Samples	48	0	11
2002	Samples Analyzed	5,745	39	1,240
	Positive Samples	42	0	13
2003	Samples Analyzed	5,735	39	779
	Positive Samples	20	0	0

Year		Federal Inspected Establishments	State Inspected Establishments	Retail Exempt Establishments
2004	Samples Analyzed	7,683	0	311
	Positive Samples	14	0	0
2005	Samples Analyzed	10,866	0	95
	Positive Samples	18	0	0
2006	Samples Analyzed	11,626	0	133
	Positive Samples	20	0	0
2007	Samples Analyzed	12,046	0	184
	Positive Samples	29	0	0
2008	Samples Analyzed	11,230	0	362
	Positive Samples	53	0	0
2009	Samples Analyzed	12,070	0	631
	Positive Samples	36	0	2
2010*	Samples Analyzed	11,616	0	906
	Positive Samples	29	0	0

* In Quarter 3 (weeks of Aug 5 through Sep 2) approximately 1,100 fewer sample forms were sent out than were scheduled.

Note: No data is available on non-O157 STECs because it was only declared as an adulterant by USDA/FSIS on September 13, 2011, and microbiological testing at USDA/FSIS inspected establishments will not begin until March 5, 2012.

Conference for Food Protection
2012 Issue Form

Internal Number: 054
Issue: 2012 III-016

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

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Title:
Separation of Non-Intact Meats from Whole-Muscle Cuts of the Same Type

Issue you would like the Conference to consider:
Clarification on the storing and displaying of comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat unless they are packaged in a manner that precludes the potential for cross-contamination.
As amended by the 2011 FDA Food Code Supplement, subparagraphs 3-302.11(A)(2) and (3) of the FDA Food Code read:
3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.
(A) Food shall be protected from cross contamination by:
(1) [not relevant to Issue]
(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) Not storing and displaying comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat unless they are packaged in a manner that precludes the potential for cross-contamination
The requirements conflict, because (A)(2) specifies "types of raw animal foods" "such as beef" and "pork" while (A)(3) adds a distinction between comminuted meats and whole-muscle meats of the same type.
Based on the Public Health Reasons for 3-401.11 regarding comminuted meats, the difference in cooking temperatures between ground meats and pork and whole-muscle intact cuts is based on the lack of come-up/come-down time, not different pathogens or different microbial loads. "Come up time" is the time it takes the product to reach the specified temperature, "come down time" is the time it takes for the product to cool down.
The Public Health Reason for 3-401.11 reads, in pertinent part:
"When USDA established the time and temperature parameters for 9 CFR 318.23 Heat-Processing and Stabilization Requirements for Uncurred [sic] Meat Patties (known as the "patty rule"), the Agency based the 5D for *Salmonella* on extrapolations applied to the

research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of Shiga toxin-producing ***Escherichia coli***. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements."
Therefore, there is no reason to impose extra requirements on the storage or display of same types (beef, pork, poultry, fish, etc.) simply because they are ground or otherwise not intact.

Public Health Significance:
This requirement to store non-intact meats separately from whole-muscle cuts of the same type is unnecessary and leads to confusion among regulators and the regulated community.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended to delete Section 3-302.11(A)(3) and delete corresponding Public Health Reason language from the Model Food Code as follows (deleted language shown with strike-through):
Section 3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.
~~(3) Not storing and displaying comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat unless they are packaged in a manner that precludes the potential for cross-contamination;~~
(Public Health Reason) Section 3-302.11
Packaged and Unpackaged Food - Protection Separation, Packaging, and Segregation.
~~Storing or displaying comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat can also present a cross-contamination hazard unless they are packaged and displayed in a manner that creates a barrier to prevent leakage of contents from one package to the other. Cooking recommendations assume that lower levels of contamination will be present in whole muscle products than in non-intact meats. If the whole muscle product is subject to cross-contamination, the recommended cooking temperature may not be sufficient to ensure the safety of the product.~~

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Conference for Food Protection
2012 Issue Form

Internal Number: 002
Issue: 2012 III-017

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

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Title:
Thawing Vacuum Packaged Frozen Fish

Issue you would like the Conference to consider:
Some small, independent retail grocery stores and food service establishments have stored commercially processed and reduced oxygen packaged frozen fish in their refrigerated seafood service cases/ coolers in a thawed state despite warning labels to use immediately after thawing on boxes of frozen fishery products.
In addition, some retail food establishments may re-package bulk frozen fish in a reduced oxygen package for convenience and hold the fish frozen without use of a warning label for thawing, and not understand the food safety significance of the thawing step for vacuum packaged frozen fish.
Address the food safety concern regarding the thawing of frozen vacuum packaged fish in the Food and Drug Administrations' next edition of the Food Code.

Public Health Significance:
Section 3-502.12 (C) of the U.S. Food and Drug Administrations' 2009 Food Code offers an exception or allowance for the packaging of frozen fish using a reduced oxygen packaging method as long as the *fish was frozen before, during, and after packaging.*
The spores of *Clostridium botulinum* are very common in nature. They have been found in the gills and viscera of fin fish, crabs, and shellfish. *C. botulinum type E* is the most common form found in fresh water and marine environments. Types A and B are generally found on land, but may also be occasionally found in the water. It should be assumed that *C. botulinum* will be present in any raw fishery product, particularly in the viscera.
There are a number of strategies to prevent *C. botulinum* toxin formation during processing, storage and distribution of finished fishery products.
In Chapter 13, Clostridium botulinum Toxin Formation (A Biological Hazard) of the U.S. Food and Drug Administration's Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001, the requirement for the commercial seafood processor who manufactures frozen, reduced oxygen packaged fishery products states:

- Control in frozen, reduced oxygen packaged fishery products

If your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately

before use (e.g. " Important, keep frozen until used, thaw under refrigeration immediately before use"), then formation of ***C. botulinum*** toxin may not be a significant hazard.
.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended adding informational items (allowances) to Section 3-501.13, Thawing, and Section 3-502.12, Reduced Oxygen Packaging, Criteria as follows (new language in underline format):
1- Add the following language for thawing of reduced oxygen frozen fish after the exception sentence in Section 3-502.12(c):
To control C. botulinum toxin formation, reduced oxygen packaged fish must be held frozen until used or removed from ROP during the thawing process.
2- Add an informational only statement to section 3-501.13, Thawing:
(E) *Frozen, reduced oxygen packaged fishery products must be kept frozen until used, or removed from ROP during the thawing process.*

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Conference for Food Protection
2012 Issue Form

Internal Number: 120
Issue: 2012 III-018

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

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Title:
Harmonize Time/Temperature Charts in Food Code with FSIS Guidance

Issue you would like the Conference to consider:
The Food Safety Inspection Service (FSIS) is recommending that changes be made to FDA Food Code § 3-401.11 *Cooking* to:

- Resolve minor discrepancies between the time and temperature combinations specified in the Food Code for cooking of non-intact meat products at retail and what is specified in FSIS Guidance directed at meat and poultry processors;
- Revise the minimum time and temperature requirements for meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham to reflect updated FSIS Guidance for these products;
- Refer to appropriate FSIS Guidance documents for additional appropriate time and temperature combinations not currently specified in the Food Code for cooking of non-intact meat chops, roasts and steaks;
- Clarify what cooking criteria applies to intact meats and which applies to non-intact meats; and
- Establish minimum instantaneous cooking temperatures for products for ones which do not currently exist in the Food Code, including for poultry, baluts and wild game animals.

Public Health Significance:
The differences between specific criteria contained in the Food Code and in FSIS guidance documents are, for the most part, minimal and, therefore, would have negligible impact on food safety. For example, *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks* recommends that such products be cooked to 68°C (155°F) for 17 seconds while the Food Code recommends that such products be cooked to a minimum temperature of 68°C (155°F) for 15 seconds. These differences are likely a matter of rounding as all times in the FSIS guidance that were a fraction of a minute or second were rounded up to the next whole number (e.g., 16.2 seconds for 155 °F was rounded up to 17 seconds). Although small, such discrepancies lead to confusion. *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks* contains additional time-temperature combinations that are also appropriate for cooking the animal products

covered in 3-401.11(A)(2). FSIS recommends these additional time and temperature combinations be established in the Food Code by reference to the Guidance document.

The time and temperature combinations in § 3-401.11(A)(2) for mechanically tenderized and injected meats should also apply to meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham. The current Food Code time and temperature recommendations for meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham [see § 3-401.11(A)(3)] refer to time and temperature combinations that were derived from USDA/FSIS *Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products (*http://www.fsis.usda.gov/oa/fr/95033f-a.htm).

The time and temperature combinations in *Appendix A* achieve a 6.5 log reduction in *Salmonella*. More recently, FSIS has issued new guidelines specifying that a minimum of 5-log reduction in *Salmonella* is acceptable for lamb, pork, and cured pork roasts such as ham as well as for mechanically tenderized and injected meats. FSIS is considering extending the minimum 5 log reduction to meat roasts including beef and corned beef, prior to issuance of the 2013 Food Code. The time and temperature combinations in the *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks* will achieve a 5-log reduction in *Salmonella*. Therefore, in order to be consistent, retail and foodservice institutions producing meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham should have the option of meeting criteria that is based on the new guidance.

CFP Issue # 2002-I-33 from the 2002 Conference recommended that USDA and FDA work together to establish instantaneous cooking temperatures for animal products that to date had minimum cooking temperatures that included a minimum dwell time of 15 seconds. FSIS is recommending deleting the 15 second dwell time from the minimum criteria specified in Subparagraph 3-401.11(A)(3) for the products covered under that subparagraph. This recommended change is based on FSIS guidance in the *Time-Temperature Tables for Cooking RTE Poultry Products*. FSIS believes that if poultry products are cooked to the minimum temperatures specified, it is not necessary to specify a minimum 15 second dwell time.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:

1) Changes be made in strike through to remove language and underline to add language format to § 3-401.11 *Cooking* of the Food Code:

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 that is being cooked:

(1) 63°C (145°F) or above for 15 seconds for:

(a) Raw eggs that are broken and prepared in response to a CONSUMER's order and for immediate service, and

(b) Except as specified under Subparagraphs (A)(2) and (A)(3) and (B), and in (C) of this section, FISH and <u>INTACT</u> 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);
(A)(2) 68°C (155°F) for ~~15~~ 17 seconds or for the temperature specified in the following chart that corresponds to the holding time for RATITES, MECHANICALLY TENDERIZED, and INJECTED MEATS, MEAT roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham; 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 voluntary inspection program as specified under Subparagraph 30201.17(A)(2); and raw EGGS that are not prepared as specified under Subparagraph (A)(1)(a) of this section:
[See attachment (Table 1) for strike through changes to Table.]
(A)(3) 74°C (165°F) or above ~~for 15~~ for POULTRY, BALUTS, wild GAME ANIMALS 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 RATITES.
~~(A) Whole MEAT roasts including beef, corned beef, lamb, pork and cured pork roasts such as ham shall be cooked:~~
~~(1) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature:~~
[See attachment (Table 2) for strike through changes to Table.]
~~and~~
~~(2) 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:~~
[See attachment (Table 3) for strike through changes to Table.]
2) Food Code Annex 3 Public Health Reasons Section 3-401.11 related to Cooking (pages 396-398 of 2009 Food Code), that describe the background for the time temperature combinations, be updated to reflect these changes.
3) Food Code Annex 3 Public Health Reasons Section 3-401.11 related to Cooking (396-398 of 2009 Food Code), be updated to include further temperatures found in *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks*, available at: http://askfsis.custhelp.com/ci/fattach/get/4648/, and to include an additional recommendation that MEAT roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham may also be cooked using the time-temperature combinations in *Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products*, found at: http://www.fsis.usda.gov/oa/fr/95033f-a.htm.

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Attachments:

- "TIME-TEMPERATURE TABLES FOR COOKING READY-TO-EAT POULTRY PRODUCTS"
- "FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks"
- "Annex 3 Food Code"
- "Table 1"
- "Table 2"
- "Table 3"

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TIME-TEMPERATURE TABLES FOR COOKING READY-TO-EAT POULTRY PRODUCTS

The 1999 FSIS final rule, Performance Standards for the Production of Certain Meat and Poultry Products, requires a 6.5 $\log_{10}$ relative reduction (6.5 $\log_{10}$ lethality) of *Salmonella* for cooked beef, roast beef and corned beef (9 CFR318.17). Appendix A in the compliance guidelines for this 1999 final rule, included two time-temperature (TT) columns in a table for roast beef, cooked beef and corned beef products. One column was for 6.5 $\log_{10}$ and the other column was for a 7.0 $\log_{10}$ relative reduction of *Salmonella* **(Attachment 1)**. The TT column for a 7.0 $\log_{10}$ relative reduction in whole beef products was included as a guide for those establishments that wanted to process these beef products to exceed the required minimum 6.5 logs for an additional measure of safety.

The 1999 final rule also established a performance standard for poultry that requires a 7.0 $\log_{10}$ lethality of *Salmonella* in RTE poultry (9 CFR 381.150). The compliance guidelines for this rule provided one temperature each for cooking uncured poultry (160º F) and for cured poultry (155º F) to meet the performance standard. FSIS did not provide a time-temperature table for cooking poultry at temperatures lower than 160º F because there was inadequate research information at that time.

FSIS has been made aware that some users of the TT tables in Appendix A are under the impression that the TT column for a 7.0 $\log_{10}$ reduction of *Salmonella* for cooked beef can also be used for cooking poultry to achieve a 7.0 log reduction in poultry and meet the performance standard. As a result, some establishments use the 7.0 $\log_{10}$ meat TT column for cooking poultry. Establishments that have been applying the 7.0 $\log_{10}$ column in the meat tables for cooking poultry could be undercooking their products. There is relatively greater risk of undercooking if the initial level of *Salmonella* in their raw product is high. Furthermore, studies have shown that there is a difference in bacterial resistance due to the type of product species. This could result in Salmonella positive products and foodborne illness. Currently, there is no information as to how many establishments use the 7.0 log meat TT tables for cooking poultry, nor is there information on actual instances of poultry products cooked at a time and temperature combination from the these tables that were inadequately cooked, resulting in *Salmonella* positive products and foodborne illness.

The 1999 final rule provides for the use of an ‘alternative’ lethality to meet the performance standard (7.0 $\log_{10}$ required lethality) for *Salmonella* in poultry products. The alternative lethality achieves the same probability that no viable *Salmonella* organisms remain in any finished product as that achieved with 7.0-$\log_{10}$ lethality for the worst case default FSIS assumption. If an establishment is using a TT combination not included in the Compliance Guidelines for cooking poultry, then it can either: 1) validate that the TT combination it is using for its cooking process to establish that it achieves a 7.0 log lethality of *Salmonella*, or 2) demonstrate in some fashion that an equivalent probability of no remaining viable *Salmonella* organisms in the finished product is obtained. For the first case, validation can be done by conducting a challenge study or using studies or documentation showing that the establishment’s lethality process is

adequate to achieve 7.0 $\log_{10}$ lethality in its cooked poultry product. For the second case, for example, an establishment can provide documentation showing that its initial *Salmonella* levels in the raw material are low enough to assure that its lethality process eliminates the pathogen in any contiguous 100 grams of finished product, to the extent of providing the same probability that there are no viable *Salmonella* as that when a 7.0 $\log_{10}$ lethality is achieved, assuming the FSIS default worst case level. In both these cases, the validation and documentation must also demonstrate the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration of the finished product. The establishment should ensure that conditions of processing such as additives (e.g., salt) used in the product, and humidity applied during the lethality treatment, are reflected in the studies that determine lethalities and subsequent values of time and temperature parameters. A detailed explanation of validation or demonstration procedures for an alternative lethality can be found in Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper pp. 15-17 found on the FSIS website: www.fsis.usda.gov/OPPDE/rdad/FRPubs/Docs_95-033F.htm

In order to provide guidance to establishments on the processing of poultry products, FSIS requested ARS to conduct a study to determine the times and temperatures of cooking chicken and turkey to achieve a 7.0 $\log_{10}$ relative reduction of *Salmonella*. This study provided FSIS with new time/temperature tables for cooking poultry. The proposed performance standards for processed RTE meat and poultry products (issued 2/7/2001 in FR) included these new TT tables for cooking chicken and turkey of different fat contents to achieve a 7.0 $\log_{10}$ relative reduction of *Salmonella* **(Attachment 2)**. The proposed rule with the new poultry tables is posted on the FSIS website: www.fsis.usda.gov/OPPDE/rdad/FRPubs/Docs_97-013P.htm . The published study title and authors are as follows:

TITLE: Modeling non-linear survival curves to calculate thermal inactivation of *Salmonella* in poultry of different fat levels
AUTHORS: V. K. Juneja, B. S. Eblen, H. M. Marks
JOURNAL: International Journal of Food Microbiology 70 (2001) 37-51.

The holding times for cooking poultry at specific temperatures in these new tables for a 7.0 $\log_{10}$ relative reduction of *Salmonella* in poultry are longer than those listed in the column for the 7.0 $\log_{10}$ relative reduction of *Salmonella* in roast beef, cooked beef and corned beef. The 7.0 $\log_{10}$ meat TT table achieves lower lethality compared to the new TT tables for poultry. For example, the new tables specify that for a chicken product with 7% fat, 29 minutes at 140ºF is needed to obtain a 7-$\log_{10}$ lethality, whereas for this temperature, the TT tables for cooked beef specify 12 minutes is needed. The model in the above referred paper predicts that approximate 2.7-$\log_{10}$ lethality is obtained when poultry with 7% fat is cooked for 12 minutes; thus in this case the expected obtained lethality is about 4 $\log_{10}$ less than that required. For higher fat levels the difference would be greater. For cooking of poultry products other than chicken and turkey, use of the longer time at a certain temperature from the tables is recommended. Application of humidity such as those found in Appendix A should also be considered.

Establishments have been utilizing the cooking temperatures for poultry outlined in Appendix A for a number of years. However, the guidelines reflect new data on the temperatures needed to control *Salmonella* in poultry. The Agency is not rescinding the guidance for poultry in Appendix A, but an establishment needs to take this new data regarding increased time at a specific temperature to achieve a given level of reduction of *Salmonella* into consideration. An establishment can continue to utilize Appendix A within its process and should be conducting on-going verification to confirm that the process is being effectively controlled. The Agency will continue to collect verification samples for RTE products. If an establishment is using Appendix A, and the Agency collects an RTE sample that is positive for *Salmonella*, the establishment would be required under 417.3(b) to support its decision within its hazard analysis. Consequently, it is advisable that establishments using Appendix A verify its process on an on-going basis to ensure that *Salmonella* is being controlled effectively.

To summarize, in the absence of additional scientific rationale specific to the process within an establishment, in order to meet the objective of the performance standard, i.e., achieve a 7.0 $\log_{10}$ lethality of *Salmonella* in cooked poultry products, establishments could:
1) use the TT combinations in the new chicken and turkey tables (Attachment 2), and also found in the compliance guidelines for the proposed performance standards for processed meat and poultry products, with the application of adequate humidity, if deemed appropriate by the establishment; or
2) use any TT combinations provided they are validated for a process to achieve a 7.0 $\log_{10}$ lethality of *Salmonella;* or
3) apply a different (lower) minimum lethality, provided the same probability of no viable *Salmonella* in poultry as the probability obtained when there is a 7.0 $\log_{10}$ lethality assuming FSIS's default worst-case levels, while also assuring that other pathogens and their toxins or toxic metabolites are destroyed, so as not to adulterate the finished product. This provision can be used when *Salmonella* is not uniformly distributed in the product, or can be met by a plant when that plant establishes its worst-case level of *Salmonella* to be less than the FSIS assumed worst-case level.

ATTACHMENT 1

Cooked beef and roast beef, including sectioned and formed roasts, chunked and formed roasts, and cooked corned beef can be prepared using one of the following time and temperature combinations to meet either a 6.5-$\log_{10}$ or 7-$\log_{10}$ reduction of *Salmonella*. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for a least the stated time:

Minimum Internal Temperature		Minimum processing time in minutes or seconds after minimum temperature is reached	
Degrees Fahrenheit	Degrees Centigrade	6.5-$\log_{10}$ Lethality	7-$\log_{10}$ Lethality
130	54.4	112 min.	121 min.
131	55.0	89 min.	97 min.
132	55.6	71 min.	77 min.
133	56.1	56 min.	62 min.
134	56.7	45 min.	47 min.
135	57.2	36 min.	37 min.
136	57.8	28 min.	32 min.
137	58.4	23 min.	24 min.
138	58.9	18 min.	19 min.
139	59.5	15 min.	15 min.
140	60.0	12 min.	12 min.
141	60.6	9 min.	10 min.
142	61.1	8 min.	8 min.
143	61.7	6 min.	6 min.
144	62.2	5 min.	5 min.
145	62.8	4 min.	4 min.
146	63.3	169 sec.	182 sec.
147	63.9	134 sec.	144 sec.
148	64.4	107 sec.	115 sec.
149	65.0	85 sec.	91 sec.
150	65.6	67 sec.	72 sec.
151	66.1	54 sec.	58 sec.
152	66.7	43 sec.	46 sec.
153	67.2	34 sec.	37 sec.
154	67.8	27 sec.	29 sec.
155	68.3	22 sec.	23 sec.
156	68.9	17 sec.	19 sec.
157	69.4	14 sec.	15 sec.
158	70.0	0 sec.**	0 sec.**
159	70.6	0 sec.**	0 sec.**
160	71.1	0 sec **	0 sec.**

** The required lethalities are achieved instantly when the internal temperature of a cooked meat product reaches 158^{o} F or above.

ATTACHMENT 2

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

Temperature (^{o} F)	Time for Chicken (fat%=1)	Time for Turkey (fat%=1)
136	63.3 min	64 min
137	50.1 min	51.9 min
138	39.7 min	42.2 min
139	31.6 min	34.4 min
140	25.2 min	28.1 min
141	20.1 min	23 min
142	16.1 min	18.9 min
143	13 min	15.5 min
144	10.4 min	12.8 min
145	8.4 min	10.5 min
146	6.8 min	8.7 min
147	5.5 min	7.1 min
148	4.4 min	5.8 min
149	3.5 min	4.7 min
150	2.7 min	3.8 min
151	2.1 min	3 min
152	1.5 min	2.3 min
153	1.2 min	1.8 min
154	55.9 sec	1.5 min
155	44.2 sec	1.2 min
156	35 sec	59 sec
157	27.7 sec	47.9 sec
158	21.9 sec	38.8 sec
159	17.3 sec	31.5 sec
160	13.7 sec	25.6 sec
161	10.8 sec	20.8 sec
162	<10.0 sec	16.9 sec
163	<10.0 sec	13.7 sec
164	<10.0 sec	11.1 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=2 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	64.5 min	64.3 min
137	51 min	52.2 min
138	40.5 min	42.5 min
139	32.2 min	34.6 min
140	25.7 min	28.3 min
141	20.5 min	23.2 min
142	16.4 min	19 min
143	13.2 min	15.6 min
144	10.6 min	12.8 min
145	8.6 min	10.6 min
146	6.9 min	8.7 min
147	5.5 min	7.1 min
148	4.4 min	5.8 min
149	3.5 min	4.7 min
150	2.7 min	3.7 min
151	2 min	2.9 min
152	1.5 min	2.3 min
153	1.2 min	1.8 min
154	56.9 sec	1.5 min
155	45 sec	1.2 min
156	35.6 sec	59.3 sec
157	28.2 sec	48.1 sec
158	22.3 sec	39 sec
159	17.6 sec	31.7 sec
160	14 sec	25.7 sec
161	11 sec	20.9 sec
162	<10.0 sec	16.9 sec
163	<10.0 sec	13.7 sec
164	<10.0 sec	11.2 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=3 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	65.7 min	64.6 min
137	52.1 min	52.4 min
138	41.3 min	42.7 min
139	32.9 min	34.9 min
140	26.2 min	28.5 min
141	21 min	23.3 min
142	16.8 min	19.1 min
143	13.5 min	15.7 min
144	10.8 min	12.9 min
145	8.7 min	10.6 min
146	7 min	8.7 min
147	5.6 min	7.1 min
148	4.5 min	5.8 min
149	3.5 min	4.7 min
150	2.7 min	3.7 min
151	2 min	2.9 min
152	1.5 min	2.3 min
153	1.2 min	1.9 min
154	58 sec	1.5 min
155	45.9 sec	1.2 min
156	36.3 sec	59.5 sec
157	28.7 sec	48.3 sec
158	22.7 sec	39.2 sec
159	18 sec	31.8 sec
160	14.2 sec	25.8 sec
161	11.2 sec	21 sec
162	<10.0 sec	17 sec
163	<10.0 sec	13.8 sec
164	<10.0 sec	11.2 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=4 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	67 min	64.9 min
137	53.2 min	52.8 min
138	42.2 min	43 min
139	33.6 min	35.1 min
140	26.8 min	28.7 min
141	21.5 min	23.5 min
142	17.2 min	19.3 min
143	13.8 min	15.9 min
144	11.1 min	13 min
145	8.9 min	10.7 min
146	7.2 min	8.8 min
147	5.7 min	7.2 min
148	4.5 min	5.8 min
149	3.6 min	4.7 min
150	2.7 min	3.7 min
151	2.1 min	2.9 min
152	1.6 min	2.3 min
153	1.2 min	1.9 min
154	59.1 sec	1.5 min
155	46.8 sec	1.2 min
156	37 sec	59.8 sec
157	29.3 sec	48.5 sec
158	23.2 sec	39.4 sec
159	18.3 sec	32 sec
160	14.5 sec	26 sec
161	11.5 sec	21.1 sec
162	<10.0 sec	17.1 sec
163	<10.0 sec	13.9 sec
164	<10.0 sec	11.3 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=5 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	68.4 min	65.3 min
137	54.3 min	53.2 min
138	43.2 min	43.4 min
139	34.4 min	35.4 min
140	27.5 min	29 min
141	22 min	23.8 min
142	17.6 min	19.5 min
143	14.2 min	16.1 min
144	11.4 min	13.2 min
145	9.2 min	10.8 min
146	7.4 min	8.9 min
147	5.9 min	7.3 min
148	4.7 min	5.9 min
149	3.6 min	4.7 min
150	2.8 min	3.7 min
151	2.1 min	2.9 min
152	1.6 min	2.3 min
153	1.3 min	1.9 min
154	1 min	1.5 min
155	47.7 sec	1.2 min
156	37.7 sec	1 min
157	29.8 sec	48.8 sec
158	23.6 sec	39.6 sec
159	18.7 sec	32.1 sec
160	14.8 sec	26.1 sec
161	11.7 sec	21.2 sec
162	<10.0 sec	17.2 sec
163	<10.0 sec	13.9 sec
164	<10.0 sec	11.3 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=6 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	69.9 min	65.8 min
137	55.5 min	53.6 min
138	44.2 min	43.8 min
139	35.2 min	35.8 min
140	28.2 min	29.3 min
141	22.6 min	24.1 min
142	18.1 min	19.8 min
143	14.6 min	16.3 min
144	11.8 min	13.4 min
145	9.5 min	11 min
146	7.6 min	9 min
147	6.1 min	7.4 min
148	4.8 min	6 min
149	3.8 min	4.8 min
150	2.9 min	3.8 min
151	2.1 min	2.9 min
152	1.6 min	2.3 min
153	1.3 min	1.9 min
154	1 min	1.5 min
155	48.6 sec	1.2 min
156	38.4 sec	1 min
157	30.4 sec	49 sec
158	24 sec	39.8 sec
159	19 sec	32.3 sec
160	15 sec	26.2 sec
161	11.9 sec	21.3 sec
162	<10.0 sec	17.3 sec
163	<10.0 sec	14 sec
164	<10.0 sec	11.4 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=7 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	71.4 min	66.3 min
137	56.8 min	54.1 min
138	45.3 min	44.2 min
139	36.2 min	36.2 min
140	29 min	29.7 min
141	23.2 min	24.4 min
142	18.7 min	20.1 min
143	15.1 min	16.6 min
144	12.2 min	13.7 min
145	9.8 min	11.3 min
146	7.9 min	9.2 min
147	6.3 min	7.5 min
148	5 min	6.1 min
149	3.9 min	4.9 min
150	3 min	3.9 min
151	2.2 min	3 min
152	1.7 min	2.3 min
153	1.3 min	1.9 min
154	1 min	1.5 min
155	49.5 sec	1.2 min
156	39.2 sec	1 min
157	31 sec	49.2 sec
158	24.5 sec	40 sec
159	19.4 sec	32.4 sec
160	15.3 sec	26.3 sec
161	12.1 sec	21.4 sec
162	9.6 sec	17.3 sec
163	<10.0 sec	14.1 sec
164	<10.0 sec	11.4 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=8 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	73 min	66.9 min
137	58.2 min	54.7 min
138	46.4 min	44.8 min
139	37.2 min	36.7 min
140	29.8 min	30.2 min
141	24 min	24.9 min
142	19.4 min	20.5 min
143	15.6 min	17 min
144	12.6 min	14 min
145	10.2 min	11.5 min
146	8.2 min	9.5 min
147	6.6 min	7.7 min
148	5.2 min	6.3 min
149	4.1 min	5 min
150	3.1 min	4 min
151	2.3 min	3.1 min
152	1.7 min	2.3 min
153	1.3 min	1.9 min
154	1.1 min	1.5 min
155	50.4 sec	1.3 min
156	39.9 sec	1 min
157	31.6 sec	49.5 sec
158	25 sec	40.1 sec
159	19.8 sec	32.6 sec
160	15.6 sec	26.4 sec
161	12.4 sec	21.5 sec
162	9.8 sec	17.4 sec
163	<10.0 sec	14.1 sec
164	<10.0 sec	11.5 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=9 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	74.8 min	67.6 min
137	59.7 min	55.3 min
138	47.7 min	45.4 min
139	38.3 min	37.3 min
140	30.8 min	30.8 min
141	24.9 min	25.5 min
142	20.1 min	21.1 min
143	16.3 min	17.4 min
144	13.2 min	14.4 min
145	10.7 min	11.9 min
146	8.6 min	9.8 min
147	6.9 min	8 min
148	5.5 min	6.5 min
149	4.3 min	5.2 min
150	3.3 min	4.1 min
151	2.5 min	3.2 min
152	1.8 min	2.4 min
153	1.4 min	1.9 min
154	1.1 min	1.5 min
155	51.4 sec	1.3 min
156	40.7 sec	1 min
157	32.2 sec	49.7 sec
158	25.4 sec	40.3 sec
159	20.1 sec	32.7 sec
160	15.9 sec	26.6 sec
161	12.6 sec	21.6 sec
162	10 sec	17.5 sec
163	<10.0 sec	14.2 sec
164	<10.0 sec	11.5 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=10 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	76.7 min	68.4 min
137	61.4 min	56.2 min
138	49.2 min	46.2 min
139	39.6 min	38.1 min
140	32 min	31.5 min
141	25.9 min	26.2 min
142	21 min	21.7 min
143	17.1 min	18 min
144	13.9 min	15 min
145	11.3 min	12.4 min
146	9.1 min	10.2 min
147	7.4 min	8.4 min
148	5.8 min	6.8 min
149	4.6 min	5.4 min
150	3.5 min	4.3 min
151	2.6 min	3.3 min
152	1.9 min	2.5 min
153	1.4 min	1.9 min
154	1.1 min	1.6 min
155	52.4 sec	1.3 min
156	41.4 sec	1 min
157	32.8 sec	49.9 sec
158	25.9 sec	40.5 sec
159	20.5 sec	32.9 sec
160	16.2 sec	26.7 sec
161	12.8 sec	21.7 sec
162	10.2 sec	17.6 sec
163	<10.0 sec	14.3 sec
164	<10.0 sec	11.6 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=11 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	78.9 min	69.5 min
137	63.3 min	57.2 min
138	50.9 min	47.2 min
139	41.1 min	39.1 min
140	33.4 min	32.5 min
141	27.1 min	27.1 min
142	22.1 min	22.6 min
143	18.1 min	18.8 min
144	14.8 min	15.7 min
145	12.1 min	13 min
146	9.8 min	10.8 min
147	7.9 min	8.8 min
148	6.3 min	7.2 min
149	4.9 min	5.8 min
150	3.8 min	4.5 min
151	2.9 min	3.5 min
152	2.1 min	2.7 min
153	1.4 min	1.9 min
154	1.1 min	1.6 min
155	53.4 sec	1.3 min
156	42.2 sec	1 min
157	33.4 sec	50.2 sec
158	26.4 sec	40.7 sec
159	20.9 sec	33 sec
160	16.5 sec	26.8 sec
161	13.1 sec	21.8 sec
162	10.3 sec	17.7 sec
163	<10.0 sec	14.3 sec
164	<10.0 sec	11.6 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

Times for given temperature, fat level, and species needed to obtain 7-$\log_{10}$ lethality of *Salmonella**

---------- fat%=12 ----------

Temperature (^{o} F)	Time for Chicken	Time for Turkey
136	81.4 min	70.8 min
137	65.5 min	58.5 min
138	52.9 min	48.5 min
139	43 min	40.4 min
140	35 min	33.7 min
141	28.7 min	28.2 min
142	23.5 min	23.7 min
143	19.3 min	19.8 min
144	15.9 min	16.6 min
145	13 min	13.8 min
146	10.6 min	11.5 min
147	8.6 min	9.4 min
148	6.8 min	7.7 min
149	5.4 min	6.2 min
150	4.2 min	4.9 min
151	3.1 min	3.8 min
152	2.3 min	2.8 min
153	1.6 min	2.1 min
154	1.1 min	1.6 min
155	54.4 sec	1.3 min
156	43 sec	1 min
157	34 sec	50.4 sec
158	26.9 sec	40.9 sec
159	21.3 sec	33.2 sec
160	16.9 sec	26.9 sec
161	13.3 sec	21.9 sec
162	10.5 sec	17.7 sec
163	<10.0 sec	14.4 sec
164	<10.0 sec	11.7 sec
165	<10.0 sec	<10.0 sec

* The required lethalities are achieved instantly at the internal temperature in which the holding time is < 10 seconds.
Humidity is to be applied as necessary.

FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks
April 2009

Temp °F	Temp °C	Time for 5.0 log Reduction	Unit Time
130	54.4	86	min.
131	55.0	69	min.
132	55.6	55	min.
133	56.1	44	min.
134	56.7	35	min.
135	57.2	28	min.
136	57.8	22	min.
137	58.4	18	min.
138	58.9	14	min.
139	59.5	11	min.
140	60.0	9	min.
141	60.6	7	min.
142	61.1	6	min.
143	61.7	5	min.
144	62.2	4	min.
145	62.8	3	min.
146	63.3	130	sec.
147	63.9	103	sec.
148	64.4	82	sec.
149	65.0	65	sec.
150	65.6	52	sec.
151	66.1	41	sec.
152	66.7	33	sec.
153	67.2	26	sec.
154	67.8	21	sec.
155	68.3	17	sec.
156	68.9	14	sec.
157	69.4	11	sec.
158	70.0	0	sec.
159	70.6	0	sec.
160	71.1	0	sec.

The required lethalities are achieved instantly when the internal temperature of a cooked meat product reaches 158 °F or above. Humidity must be considered when using this Time/Temperature table.

This Time/Temperature table is based on Thermal Death Curve for *Salmonella* in Beef Emulsions in tubes (Derived from Goodfellow & Brown[1], 1978) Regulatory Curve obtained from Jerry Carosella, Deputy Director, Microbiology Division, Science and Technology. All times that were a fraction of a minute or second was rounded up to the next whole number (e.g., 16.2 seconds for 155 °F was round up to 17 seconds).

1. Goodfellow, S. J. and W. L. Brown. 1978. Fate of *Salmonella* Inoculated into Beef for Cooking. Journal of Food Protection. 41:598-605.

Annex

3 Public Health Reasons/ Administrative Guidelines

Chapter 1 Purpose and Definitions

Applicability and Terms Defined **1-201.10** **Statement of Application and Listing of Terms.**

(B) ***Terms Defined***

The individual definitions in Chapter 1 are not numbered, consistent with current conventions regarding the use of plain language in drafting rules, and with use in national and international standards and some Federal regulations. This facilitates making changes to the definitions as they become necessary in subsequent editions of the Food Code. The intent of the definitions to be binding in terms of the application and interpretation of the Code is clearly stated in Chapter 1.

Accredited Program.

Refer to the definition for Accredited Program in ¶1-201.10 (B)(3).

Food protection manager *certification* occurs when *individuals* demonstrate through a certification program that they have met specified food safety knowledge standards.

Food protection certification program *accreditation* occurs when *certification organizations* demonstrate through an accreditation program that they have met specified program standards.

Accreditation is a conformity assessment process through which organizations that certify individuals may voluntarily seek independent evaluation and listing by an accrediting agency based upon the certifying organization=s meeting program accreditation standards. Such accreditation standards typically relate to such factors as the certifying organization's structure, mission, policies, procedures, and the defensibility of its examination processes. These standards are intended to affirm or enhance the quality and credibility of the certification process, minimize the potential for conflicts of interest, ensure fairness to candidates for certification and others, and thereby increase public health protection.

Program accreditation standards known to be relevant to food protection manager certification programs include those contained in the *Standards for Accreditation of Food Protection Manager Certification Programs* available from the Conference for Food Protection, 2792 Miramar Lane, Lincoln, CA 95648 and found at http://www.foodprotect.org/managers-certification/

Allowing food protection managers to demonstrate their required food safety knowledge "through passing a test that is part of an accredited program" is predicated on the fact that their credentials have been issued by certifying organizations that have demonstrated conformance with rigorous and nationally recognized program standards.

Egg.

The definition of egg includes avian species' shell eggs known to be commercially marketed in the United States. Also included are the eggs of quail and ratites such as ostrich.

Not included are baluts. Baluts are considered a delicacy among Philippine and Vietnamese populations. They are derived from fertile eggs, typically duck eggs, subjected to incubation temperatures for a period of time less than necessary for the embryo to hatch resulting in a partially formed embryo within the shell. Under the Egg Products Inspection Act (EPIA), an egg is typically considered adulterated if it has been subjected to incubation. However, in 9 CFR 590.5, baluts are specifically exempted from inspection as eggs under the EPIA.

In producing baluts, fertile duck eggs are incubated for approximately 18 days at a temperature of 42.5°C (108.5°F) in incubators with a relatively high humidity. (Complete development and hatching would take place in 28 days.) Under these conditions, the potential for growth of transovarian *Salmonella* organisms such as *S.* Enteritidis within the shell, and the potential for an increase in pathogenic microflora on the shell itself, are increased. Where chicken eggs are used in preparing baluts, the incubation period may only be 14 days at an incubation temperature of 37°C (99°F). A balut is a potentially hazardous food (time/temperature control for safety food) subject to time/temperature management including proper cooking and hot and cold holding. Baluts are typically boiled and packed in salt before sale or service.

Also, not included in this definition are the eggs of reptile species such as alligators and turtles. Alligator eggs are available for sale in some parts of the southern United States. In restaurants, the menu item “Alligator Eggs” is sometimes made of alligator egg, but other times is simply a fanciful name for a menu item that may include seafood items such as shrimp, but contains no alligator egg.

Sea turtle eggs have been consumed in Asian and Latin American Countries. However, turtle eggs are not mentioned in the definitions section because sea turtles (Loggerhead, East Pacific Green, Leatherback, Hawksbill, Kemp’s Ridley, and Olive Ridley) are protected by The Endangered Species Act of 1973 and therefore may not be sold or consumed. This Act, with respect to turtle eggs, is enforced by the United States Department of Interior, U.S. Fish and Wildlife Service, Washington, DC.

Food establishment and food processing plant.

Food Establishment and a food processing plant located within the same premises of a food establishment

Some food businesses perform operations that provide food directly to consumers as a “Food Establishment,” and also supply food to other business entities as a “Food Processing Plant.” Within such a business, those operations that provide food directly to consumers only should be considered part of a “Food Establishment” for the purposes of applying the Food Code while those operations that supply food to other business entities may be subject to other rules and regulations that apply to “Food Processing Plants”. It is essential that the permit holder and persons in charge be aware that regulatory requirements and the appropriate operational practices for “Food Establishments” may differ from those for “Food Processing Plants.”

Some facilities and functions may be subject to different regulatory requirements depending on whether that facility or function is regulated as a “Food Establishment” or as a “Food Processing Plant”, or both. Those facilities and functions within a business that are shared by both the “Food Establishment” and “Food Processing Plant” operations, e.g., refrigeration units, dressing room and toilet facilities, food equipment, water and waste systems, pest control, might be subject to similar regulatory requirements. The Food Code is intended to apply to “food establishments”.

Potentially Hazardous Food (Time/Temperature Control for Safety Food)

Potentially hazardous food (PHF/TCS food) is defined in terms of whether or not it requires time/temperature control for safety to limit pathogen 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.

The definition of PHF/TCS food takes into consideration pH, a_w, pH and a_w interaction, heat treatment, and packaging for a relatively simple determination of whether the food requires time/temperature control for safety. If the food is heat-treated to eliminate vegetative cells, it needs to be addressed differently than a raw product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat treatment to destroy vegetative cells and subsequently packaged to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because remaining spore-forming bacteria are the only microbial hazards of concern. While foods will need to be cooled slightly to prevent condensation inside the package, they must be protected from contamination in an area with limited access and packaged before temperatures drop below 57°C (135°F). In some foods, it is possible that neither the pH value nor the a_w value is low enough by itself to control or eliminate pathogen growth; however, the interaction of pH and a_w may be able to accomplish it. This is an example of a hurdle technology. Hurdle technology involves several inhibitory factors being used together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone. When no other inhibitory factors are present and the pH and/or a_w values are unable to control or eliminate bacterial pathogens which may be present, growth may occur and foodborne outbreaks result. Cut melons, cut tomatoes, and cut leafy greens are examples where intrinsic factors are unable to control bacterial growth once pathogens are exposed to the cellular fluids and nutrients after cutting.

In determining if time/temperature control is required, combination products present their own challenge. A combination product is one in which there are two or more distinct food components and an interface between the two components may have a different property than either of the individual components. A determination must be made about whether the food has distinct components such as pie with meringue topping, focaccia bread, meat salads, or fettuccine alfredo with chicken or whether it has a uniform consistency such as gravies, puddings, or sauces. In these products, the pH at the interface is important in determining if the item is a PHF/TCS food.

A well designed inoculation study or other published scientific research should be used to determine whether a food can be held without time/temperature control when:

- process technologies other than heat are applied to destroy foodborne pathogens (e.g., irradiation, high pressure processing, pulsed light, ozonation);
- combination products are prepared; or
- other extrinsic factors (e.g., packaging/atmospheres) or intrinsic factors (e.g., redox potential, salt content, antimicrobials) are used to control or eliminate pathogen growth.

Before using Tables A and B in paragraph 1-201.10(B) of the definition for “potentially hazardous food (time/temperature control for safety food)” in determining whether a food requires time/temperature control for safety (TCS), answers to the following

questions should be considered:

- Is the intent to hold the food without using time or temperature control?
    - If the answer is No, no further action is required. The decision tree later in this Annex is not needed to determine if the item is a PHF/TCS food.
- Is the food raw, or is the food heat-treated?
- Does the food already require time/temperature control for safety by definition in paragraph 1-201.10(B)?
- Does a product history with sound scientific rationale exist indicating a safe history of use?
- Is the food processed and packaged so that it no longer requires TCS such as ultra high temperature (UHT) creamers or shelf-stable canned goods?
- What is the pH and a_w of the food in question using an independent laboratory and Association of Official Analytical Chemists (AOAC) methods of analysis?

A food designated as product assessment required (PA), in either table should be considered PHF/TCS Food until further study proves otherwise. The PA means that based on the food's pH and a_w and whether it was raw or heat-treated or packaged, it has to be considered PHF until inoculation studies or some other acceptable evidence shows that the food is a PHF/TCS food or not. The Food Code requires a variance request to the regulatory authority with the evidence that the food does not require time/temperature control for safety.

The Food Code definition designates certain raw plant foods as PHF/TCS food because they have been shown to support the growth of foodborne pathogens in the absence of temperature control and to lack intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these designations are supported by Tables A and B. For example:

For cut cantaloupe (pH 6.2-7.1, $a_w > 0.99$, not heat-treated),. fresh sprouts (pH > 6.5, $a_w > 0.99$, not heat-treated), and cut tomatoes (pH 4.23 – 5.04, $a_w > 0.99$, not heat-treated), Table B indicates that they are considered PHF/TCS Foods unless a product assessment shows otherwise. Maintaining these products under the temperature control requirements prescribed in this code for PHF/TCS food will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness.

If a facility adjusts the pH of a food using vinegar, lemon juice, or citric acid for purposes other than flavor enhancement, a variance is required under ¶ 3-502.11(C). A HACCP plan is required whether the food is a PHF/TCS food as in subparagraph 3-502.11 (C)(1) or not a PHF/TCS food, as in subparagraph 3-502.11(C)(2). A standardized recipe validated by lab testing for pH and a_w would be an appropriate part of the variance request with annual (or other frequency as specified by the regulatory authority) samples tested to verify compliance with the conditions of the variance.

More information can be found in the Institute of Food Technologists (IFT) Report, "Evaluation and Definition of Potentially Hazardous Foods" at http://www.fda.gov/Food/ScienceResearch/ResearchAreas/SafePracticesforFoodProcesses/ucm094141.htm .

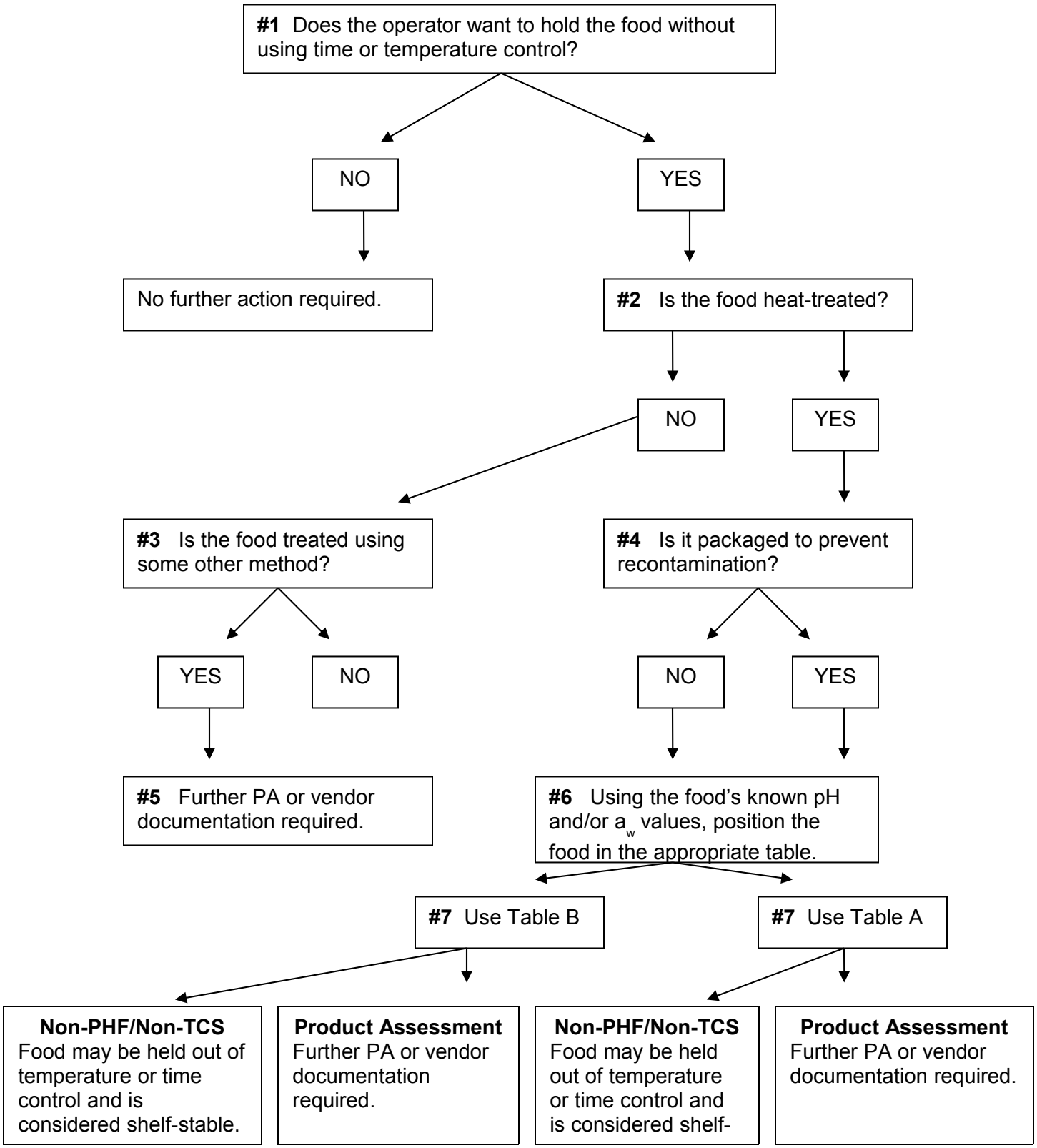
Instructions for using the following Decision Tree and Table A and Table B:

1. Does the operator want to hold the food without using time or temperature control?
    a. No – Continue holding the food at ≤5°C(41°F) or ≥57°C(135°F) for safety and/or quality.
    b. Yes – Continue using the decision tree to identify which table to use to determine whether time/temperature control for safety (TCS) is required.
2. Is the food heat-treated?
    a. No – The food is either raw, partially cooked (not cooked to the temperature specified in section 3-401.11 of the Food Code) or treated with some other method other than heat. Proceed to step #3.
    b. Yes – If the food is heat-treated to the required temperature for that food as specified under section 3-401.11 of the Food Code, vegetative cells will be destroyed although spores will survive. Proceed to step #4.
3. Is the food treated using some other method?
    a. No –The food is raw or has only received a partial cook allowing vegetative cells and spores to survive. Proceed to step #6.
    b. Yes – If a method other than heat is used to destroy pathogens such as irradiation, high pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the effectiveness of the process needs to be validated by inoculation studies or other means. Proceed to step #5.
4. Is it packaged to prevent re-contamination?
    a. No – Re-contamination of the product can occur after heat treatment because it is not packaged. Proceed to step #6.
    b. Yes – If the food is packaged immediately after heat treatment to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because spore-forming bacteria are the only microbial hazard. Proceed to step #7.
5. Further product assessment or vendor documentation required.
    a. The vendor of this product may be able to supply documentation that inoculation studies indicate the food can be safely held without time/temperature control for safety.
    b. Food prepared or processed using new technologies may be held without time/temperature control provided the effectiveness of the use of such technologies is based on a validated inoculation study.
6. Using the food's known pH and/or a_w values, position the food in the appropriate table.
    a. Choose the column under "pH values" that contains the pH value of the food in question.
    b. Choose the row under "a_w values" that contains the a_w value of the food in question.

c. Note where the row and column intersect to identify whether the food is “non-PHF/non-TCS food” and therefore does not require time/temperature control, or whether further product assessment (PA) is required. Other factors such as redox potential, competitive microorganisms, salt content, or processing methods may allow the product to be held without time/temperature control but an inoculation study is required.

7. Use **Table A** for foods that are heat-treated and packaged **OR** use **Table B** for foods that are not heat-treated or heat-treated but not packaged.
8. Determine if the item is non-PHF/non-TCS or needs further product assessment (PA).

1-201.10(B) Decision Tree #1 – Using pH, a_w, or the Interaction of pH and a_w to Determine if a Food Requires Time/Temperature Control for Safety



1-201.10(B) – Table A and Table B

Table A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged			
a_w values	pH values		
	4.6 or less	> 4.6 - 5.6	> 5.6
≤0.92	non-PHF*/non-TCS FOOD**	non-PHF/non-TCS FOOD	non-PHF/non-TCS FOOD
> 0.92 - .95	non-PHF/non-TCS FOOD	non-PHF/non-TCS FOOD	PA***
> 0.95	non-PHF/non-TCS FOOD	PA	PA
* PHF means Potentially Hazardous Food ** TCS food means Time/Temperature Control for Safety food *** PA means Product Assessment required			

Table B. Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged				
a_w values	pH values			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
< 0.88	non-PHF*/ non-TCS food**	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/non-TCS food
0.88 – 0.90	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA***
> 0.90 – 0.92	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA	PA
> 0.92	non-PHF/ non-TCS food	PA	PA	PA
* PHF means Potentially Hazardous Food ** TCS food means Time/Temperature Control for Safety food *** PA means Product Assessment required				

Chapter 2 Management and Personnel

Responsibility 2-101.11 Assignment.

Designation of a person in charge during all hours of operations ensures the continuous presence of someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Code's objectives are fulfilled. During the day-to-day operation of a food establishment, a person who is immediately available and knowledgeable in both operational and Code requirements is needed to respond to questions and concerns and to resolve problems.

In cases where a food establishment has several departments on the premises (e.g., a grocery store with deli, seafood, and produce departments) and the regulatory authority has permitted those departments individually as separate food establishments, it may be unnecessary from a food safety standpoint to staff each department with a separate Person in Charge during periods when food is not being prepared, packaged or served. While activities such as moving food products from a refrigerated display case to the walk-in refrigerator, cleaning the floors, or doing inventory when the department is not busy, do take place during these times, a designated Person in Charge for multiple departments or the entire facility can oversee these operations and be ready to take corrective actions if necessary.

Knowledge 2-102.11 Demonstration.

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.

There are many ways in which the person in charge can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. 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.

The Food Code does not require reporting of uninfected cuts or reporting of covered, protected infected cuts/lesions/boils since no bare hand contact with ready-to-eat (RTE) food is a Code requirement.

2-102.20 Food Protection Manager Certification.

Many food protection manager certification programs have shared a desire to have the food manager certificates they issue universally recognized and accepted by others – especially by the increasing number of regulatory authorities that require food manager certification.

Needed has been a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and administration.

After a multi-year effort involving a diversity of stakeholder groups, the Conference for Food Protection (CFP) completed work on its ***Standards for Accreditation of Food Protection Manager Certification Programs*** found at: http://www.foodprotect.org/managers-certification/. In 2002 the Conference entered into a cooperative agreement with the American National Standards Institute (ANSI) to provide independent third-party evaluation and accreditation of certification bodies determined to be in conformance with these Conference standards. ANSI published its first listing of accredited certifiers in 2003.

The Acting Commissioner of the Food and Drug Administration, in his address before the 2004 biennial meeting of the Conference for Food Protection, commended this Conference achievement and encouraged universal acceptance based on the CFP/ANSI accreditation program.

Distributed at this meeting was the following letter addressed to the Conference Chair and signed by the Director of FDA's Center for Food Safety and Applied Nutrition. The letter puts forth the Agency's basis for its support of universal acceptance of food protection manager certifications.

> "The 2004 biennial meeting of the **Conference for Food Protection** is a fitting occasion for FDA's Center for Food Safety and Applied Nutrition to commend the Conference for its significant achievements in support of State and local food safety programs.
>
> The FDA in a Memorandum of Understanding recognizes the Conference for Food Protection as a voluntary national organization qualified to develop standards to promote food protection. Conference recommendations contribute to improvements in the model FDA Food Code and help jurisdictions justify, adopt and implement its provisions.
>
> Conference mechanisms involving active participation by representatives of diverse stakeholder groups produce consensus standards of the highest quality. An excellent example is the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs***,

and its announcement of the new on-line listing of accredited certifiers of industry food protection managers. Many years in their development, these Conference standards identify the essential components necessary for a credible certification program. Components cover a wide range of requirements such as detailed criteria for exam development and administration, and responsibilities of the certification organization to candidates and the public.

FDA applauds the Conference for this significant achievement, and encourages agencies at all levels of government to accept certificates issued by listed certifiers as meeting their jurisdictions' food safety knowledge and certification requirements. The American National Standards Institute (ANSI) has independently evaluated these certification programs under an agreement with the Conference for Food Protection. Governments and industry widely recognize and respect ANSI as an accrediting organization. ANSI has found certifiers it lists as accredited (http://www.ansi.org/) under "conformity assessment" – "personnel certification accreditation" to conform to the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs***.*

The Food Code states the person in charge of a food establishment is accountable for developing, carrying out, and enforcing procedures aimed at preventing food-borne illness. Section 2-102.11 states that one means by which a person in charge may demonstrate required knowledge of food safety is through certification as a food protection manager by passing an examination that is part of an accredited program.** _

FDA encourages food regulatory authorities and others evaluating credentials for food protection managers to recognize the Conference for Food Protection/ANSI means of accrediting certification programs. This procedure provides a means for universal acceptance of individuals who successfully demonstrate knowledge of food safety. The procedure provides officials assurance that food safety certification is based on valid, reliable, and legally defensible criteria. In addition, universal acceptance eliminates the inconvenience and unnecessary expense of repeating training and testing when managers work across jurisdictional boundaries.

FDA, along with State, local, tribal, and other Federal agencies and the food industry, share the responsibility for ensuring that our food supply is safe. It is anticipated that this new Conference for Food Protection/ANSI program will lead to enhanced consumer protection, improve the overall

*The ANSI-CFP Accreditation Program list of accredited organizations utilizing the Conference for Food Protection (CFP) Standards may be viewed on-line by going to: https://www.ansica.org/wwwversion2/outside/ALLdirectoryListing.asp?menuID=8&prgID=8&status=4

** Accredited program does not refer to training functions or educational programs.

level of food safety, and be an important component of a seamless national food safety system."

Duties **2-103.11 Person in Charge.**

A primary responsibility of the person in charge is to ensure compliance with Code requirements. Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Code requirements, the person in charge establishes an important barrier to food contamination.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S. population, or twelve million Americans. Restaurant and retail food service managers need to be aware of the serious nature of food allergies, including allergic reactions, anaphylaxis, and death; to know the eight major food allergens; to understand food allergen ingredient identities and labeling; and to avoid cross-contact during food preparation and service. The 2008 Conference of Food Protection (CFP) passed Issue 2008-III-006 which provided that food allergy awareness should be a food safety training duty of the Person in Charge. Accordingly, the Person in Charge's Duties under paragraph (L) were amended to assure the food safety training of employees includes food allergy awareness in order for them to safely perform duties related to food allergies.

Paragraph (L) "EMPLOYEES are properly trained in FOOD safety, including food allergy awareness, as it relates to their assigned duties" allows industry to develop and implement operational-specific training programs for food employees. It is not intended to require that all food employees pass a test that is part of an accredited program.

2-2 Employee Health

Overall goals

The purpose of this section of the Food Code is to reduce the likelihood that certain viral and bacterial agents will be transmitted from infected food workers into food. The agents of concern are known to be readily transmissible via food that has been contaminated by ill food workers, and so for that reason, are the primary focus of the Employee Health section of the Food Code. However, there are different levels of risk associated with different levels of clinical illness. The structure of the restrictions and exclusions has, therefore, been designed in a tiered fashion depending on the clinical

situation to offer the maximum protection to public health with the minimal disruption to employees and employers.

Four levels of illness or potential illness have been identified with the first level being the highest potential risk to public health and the fourth level being the lowest. The first level relates to employees who have specific symptoms (e.g., vomiting, diarrhea, jaundice) while in the workplace. These symptoms are known to be associated commonly with the agents most likely to be transmitted from infected food workers through contamination of food. The first level also relates to employees who have been diagnosed with typhoid fever or an infection with hepatitis A virus (within 14 days of symptoms). The second level relates to employees who have been diagnosed with the specific agents that are of concern, but who are not exhibiting symptoms of disease because their symptoms have resolved. The third level relates to employees who are diagnosed with the specific agents, but never develop any gastrointestinal symptoms. The fourth level relates to those individuals who are clinically well but who may have been exposed to a listed pathogen and are within the normal incubation period of disease.

The most significant degree of restriction and exclusion applies to the first level of food employee illness. Infected food employees in the first level are likely to be excreting high levels of their infectious pathogen, increasing the chance of transmission to food products, and thus on to those consuming the food. The first level includes food employees who are:

- Experiencing active symptoms of diarrhea or vomiting – with no diagnosis,
- Experiencing jaundice within the last 7 days-- with no diagnosis,
- Diagnosed with typhoid fever,
- Diagnosed with hepatitis A within 7 days of jaundice or 14 days of any symptoms, or
- Experiencing active symptoms of diarrhea or vomiting, and diagnosed with Norovirus, ***E. coli*** O157:H7 or other Enterohemorrhagic ***Escherichia coli*** (EHEC) or Shiga toxin-producing ***Escherichia coli*** (STEC), or ***Shigella*** spp. infection.

Diagnosis with typhoid fever or hepatitis A virus is included in level 1 because employees diagnosed with these pathogens are likely to be shedding high levels of the pathogen in their stool without exhibiting gastrointestinal symptoms. Peak levels of hepatitis A viral shedding in the feces typically occurs before symptoms appear. Diarrhea and vomiting are reliable indicators of infection with Norovirus, ***E. coli*** O157:H7 or other EHEC, and ***Shigella*** spp., but are not typical symptoms of typhoid fever or hepatitis A. For example, employees diagnosed with typhoid fever are more likely to experience constipation, rather than diarrhea. Jaundice is also not always reliable as an indicator of a hepatitis A infection because employees can be infected with hepatitis A virus without experiencing jaundice (anicteric employees).

Maximum protection to public health requires excluding food employees suffering from typhoid fever, hepatitis A virus, or specific gastrointestinal symptoms associated with diseases identified as likely to be transmitted through contamination of food (See section 2-201.12, Tables 2-201.12 #1a and #1b in this Annex). This situation describes the highest level of risk in transmitting pathogens to food, or what we would find in the first level.

Food employees who have been diagnosed with one of the agents of concern, but are not symptomatic because their symptoms have resolved, are still likely to be carrying the infected agent in their intestinal tract. This makes such employees less likely to spread the agent into food than others who are actually symptomatic, but employees diagnosed with one of the agents of concern still pose an elevated threat to public health. For this reason, there are a series of exclusions (if the employees work in facilities serving highly susceptible populations (HSP)) and restrictions (for non-HSP facilities) depending on the agent involved (See section 2-201.12, Table #2). This situation describes the second level of risk in transmitting pathogens to food.

Diagnosed, asymptomatic food employees who never develop symptoms are typically identified during a foodborne illness outbreak investigation through microbiological testing. If infected and asymptomatic employees are not microbiologically tested, they will remain undetected and could therefore extend the duration of a foodborne illness outbreak through continued contamination of food. The Food Code provides restriction or exclusion guidelines for employees that are identified through microbiological testing with an infection from a listed foodborne pathogen, but are otherwise asymptomatic and clinically well (See section 2-201.12, Table #3). The exclusion or restriction guidelines are applied until the identified food employees no longer present a risk for foodborne pathogen transmission. This situation describes the third level of risk in transmitting pathogens to food.

Some food employees or conditional employees may report a possible exposure to an agent. For example, a food employee may have attended a function at which the food employee ate food that was associated with an outbreak of shigellosis, but the employee remains well. Such individuals fall into the category of having had a potential exposure and present a lower risk to public health than someone who is either symptomatic or who has a definitive diagnosis. They present a level of risk to public health that is greater than if they had not had the exposure. The approach taken in the Food Code to food employees who have had a potential exposure is based on the incubation times (time between exposure and the onset of symptoms) of the various agents. The times chosen for restriction are the upper end of the average incubation periods for the specific agents. The reasoning is that this will restrict food employees only up to the time when it is unlikely they will develop symptoms. As a further protection to public health, it is recommended that such exposed food employees pay particular attention to personal hygiene and report the onset of any symptoms (See section 2-201.12, Table #4). This situation describes the fourth level of risk in transmitting pathogens to food.

This structured approach has linked the degree of exclusion and restriction to the degree of risk that an infected food worker will transmit an agent of concern into food. The approach strikes a balance between protecting public health and the needs of the food employee and employer.

The Food Code provisions related to employee health are aimed at removing highly infectious food employees from the work place. They were developed with recognition of the characteristics of the five important pathogens, and of the risk of disease transmission associated with symptomatic and asymptomatic shedders. The provisions also account for the increased risk associated with serving food to HSP's and the need to provide extra protection to those populations.

The Employee Health section was developed and revised with assistance and input from the Centers for Disease Control and Prevention (CDC) and the U.S. Equal Employment Opportunity Commission (EEOC). The exclusion and restriction criteria are based on communicable disease information, as required by the Americans with Disabilities Act of 1990, in the "The List of Infectious and Communicable Diseases Which are Transmitted through the Food Supply" published in the Federal Register on November 23, 2009, (Volume 74, Number 224) by the CDC, and from the Control of Communicable Diseases Manual, 18th Ed., David L. Heymann, MD, Editor, by the American Public Health Association, Washington D.C., 2004.

2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201

The information provided in Subpart 2-201 is designed to assist food establishment managers and regulatory officials in removing infected food employees when they are at greatest risk of transmitting foodborne pathogens to food. Practical applications of the information in Subpart 2-201 by a food establishment manager may involve using Subpart 2-201 as a basis for obtaining information on the health status of food employees and can also be used as a basis in developing and implementing an effective Employee Health Policy. Regulatory officials can benefit by using the information provided below as a basis for determining compliance with Subpart 2-201 during a facility food safety inspection.

The development and effective implementation of an employee health policy based on the provisions in Subpart 2-201 may help to prevent foodborne illness associated with contamination of food by ill or infected food employees. The person in charge and food employees should be familiar with and able to provide the following information through direct dialogue or other means when interviewed by facility managers or regulatory officials. Compliance must be based, however, on first hand observations or information and cannot be based solely on responses from the person in charge to questions regarding hypothetical situations or knowledge of the Food Code. Also, when designing and implementing an employee health policy, the following information should be considered and addressed:

1. Does the establishment have an Employee Health Policy? If so, are the food employees aware of the employee health policy, and is it available in written format and readily available for food employees? (Note: A written Employee Health Policy is not a Food Code requirement unless the facility is operating under a pre-approved alternative procedure specified under ¶ 3-301.11(D)).
2. Does the establishment require conditional employees and food employees to report certain illnesses, conditions, symptoms, and exposures?
3. Are the reporting requirements explained to all employees?
4. What are the reporting requirements for conditional employees, food employees, and the food establishment manager?
5. Are conditional employees asked if they are experiencing certain symptoms or illnesses upon offer of employment? If so, which symptoms or illnesses?
6. If a food employee reports a diagnosis with one of the 5 listed pathogens in the Food Code, what questions are asked of the food employee? (The first question every food manager should ask a food employee who reports diagnosis with a listed pathogen is if the employee is currently having any symptoms.)
7. Who does the establishment notify when a food employee reports a diagnosis with one of the listed pathogens?
8. What gastrointestinal symptoms would require exclusion of a food employee from the food establishment?
9. What history of exposure is a conditional employee or food employee required to report?
10. If a food employee reports a gastrointestinal symptom, what criteria are used to allow the employee to return to work?

Responsibilities and Reporting Symptoms and Diagnosis	**2-201.11**	**Responsibility of the Person in Charge, Food Employees, and Conditional Employees.**

Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. The person in charge is responsible for ensuring all food employees and conditional employees are knowledgeable and understand their responsibility to report listed symptoms, diagnosis with an illness from a listed pathogen, or exposure to a listed pathogen to the person in charge. The person in charge is also responsible for reporting to the regulatory official if a food employee reports a diagnosis with a listed pathogen.

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or has a history of exposure to a listed pathogen in this Code may transmit disease through the food being prepared. The person in charge must first be aware that a food employee or conditional employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

The person in charge may observe some of the symptoms that must be reported. However, food employees and conditional employees share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the listed symptoms, have a history of exposure to one of the listed pathogens, or have been diagnosed with an illness caused by a listed pathogen. Food employees must comply with restrictions or exclusions imposed upon them.

A conditional employee is a potential food employee to whom a job offer has been made, conditional on responses to subsequent medical questions or examinations. A conditional employee becomes a food employee as soon as the employee begins working, even if only on a restricted basis. When a conditional employee reports a listed diagnosis or symptom, the person in charge is responsible for ensuring that the conditional employee is prohibited from becoming a food employee until the criteria for reinstatement of an exclusion are met (as specified under section 2-201.13 of the Food Code). When a symptomatic or diagnosed conditional employee has met the same criteria for reinstatement that apply to an excluded symptomatic or diagnosed food employee (as specified under section 2-201.13 of the Food Code), the conditional employee may then begin working as a food employee.

Reporting Symptoms:

In order to protect the health of consumers and employees, information concerning the health status of conditional employees and food employees must be disclosed to the person in charge. The symptoms listed in the Code cover the common symptoms experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected food employees. A food employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness. The symptoms of vomiting, diarrhea, or jaundice serve as an indication that an individual may be infected with a fecal-oral route pathogen, and is likely to be excreting high levels of the infectious agent. When a food employee is shedding extremely high numbers of a pathogen through the stool or vomitus, there is greater chance of transmitting the pathogen to food products.

Sore throat with fever serves as an indication that the individual may be infected with *Streptococcus pyogenes. Streptococcus pyogenes* causes a common infection otherwise known as “streptococcal sore throat” or “strep throat.” Streptococcal sore throat can spread from contaminated hands to food, which has been the source of explosive streptococcal sore throat outbreaks. Previous foodborne episodes with streptococcus sore throat have occurred in contaminated milk and egg products. Food products can be contaminated by infected food workers hands or from nasal discharges. Untreated individuals in uncomplicated cases can be communicable for 10-21 days, and untreated individuals with purulent discharges may be communicable for weeks or months.

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing ***Staphylococcus aureus*** into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but an impermeable bandage is not considered necessary for food safety purposes. Food employees should be aware that hands and fingers that contact pustular lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for introducing ***Staphylococcus aureus*** into food.

If a food employee has an infected cut and bandages it and puts on a glove, the employee does not have to report the infected cut to the person in charge. However, if the employee does not bandage it, reporting is required.

Title I of the Americans with Disabilities Act of 1990 (ADA)

Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of employment. In order for the permit holder and the person in charge to be in compliance with this particular aspect of the Code and the ADA, a conditional job offer must be made before making inquiries about the applicant's health status.

The ADA also requires that employers provide reasonable accommodation to qualified applicants and employees with disabilities. A reasonable accommodation is a change in the application process, in the way a job is done, or to other parts of the job that enables a person with a disability to have equal employment opportunities. ADA disabilities are serious, long-term conditions. Most people with diseases resulting from the pathogens listed in the Food Code do not have ADA disabilities because these diseases are usually short-term in duration. In addition, the gastrointestinal symptoms listed in the Food Code usually are not long-term and severe enough, in themselves, to be ADA disabilities. Of course, these symptoms may be linked to other conditions that may be serious enough to be ADA disabilities, like Crohn's disease or cancer.

A food employer may exclude any employee under the Food Code upon initially learning that the employee has *Salmonella* Typhi, or has a gastrointestinal symptom listed in the Food Code. The excluded employee may then ask for an ADA reasonable accommodation instead of the exclusion. In response, the employer's first step should be to ask the employee to establish that the employee is disabled by the disease or symptom (or that the symptom is caused by another ADA disability). If the employee successfully proves that the employee has an ADA disability, then the employer may continue to exclude the employee under the Food Code if:

- there is no reasonable accommodation at work that would eliminate the risk of transmitting the disease while also allowing the employee to work in a food handling position, or

- all reasonable accommodations would pose an undue hardship on the employer's business; and

- there is no vacant position **not involving food handling** for which the employee is qualified and to which the employee can be reassigned.

Example 1: A food employee working in the café of a department store informs the employer that the employee has been diagnosed with a disease caused by *Salmonella* Typhi. The employer immediately excludes the employee under the requirements of the Food Code. The employee then establishes that the disease is an ADA disability because it is severe and long-term and the employee requests reasonable accommodation instead of an exclusion. The employer determines that no reasonable accommodation would eliminate the risk of transmitting *Salmonella* Typhi through food and refuses to remove the exclusion. However, there is a vacant clerical position in another part of the store for which the employee is qualified. Unless the employer can establish that reassigning the employee to this position would be an undue hardship, the employer's failure to make the reassignment instead of continuing the exclusion would be a violation of the ADA.[1]

Example 2: A food employee has diarrhea and is excluded. The employee establishes that the diarrhea is caused by Crohn's disease. This employee also establishes a serious longstanding history of Crohn's disease and is an individual with an ADA disability. Crohn's disease is not a communicable disease and cannot be transmitted through food. No reasonable accommodation is needed to eliminate the risk of transmitting the disease through the food supply, so the Food Code exclusion should be removed. Of course, the Food Code's provisions on personal cleanliness for hands and arms apply as usual, requiring employees to clean hands and exposed portions of arms after using the toilet room and in other specified circumstances (Subpart 2-301).

Somewhat different rules apply to conditional employees. If a conditional employee reports a disease or symptom listed in the Food Code and shows that the disease or symptom makes the conditional employee an individual with an ADA disability, the employer may withdraw the job offer only if:

- The job involves food handling; and

- The employer determines that either there is no reasonable accommodation that would eliminate the risk of transmitting the disease

1 Whether or not the employee in question is an individual with an ADA disability, in those jurisdictions where the Code is adopted, Food Code exclusions or restrictions must be removed when requirements for removal under § 2-201.13 of the Code are met.

through food, or any such accommodation would be an undue hardship to the business.

- There is no need to offer the conditional employee a vacant position not involving food handling as a reasonable accommodation.

It should be noted that the information provided here about the ADA is intended to alert employers to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA and its implications, consult the references listed in Annex 2 that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission. See the Equal Employment Opportunity Commission's *How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers*, found at http://www.eeoc.gov/facts/restaurant_guide.html or http://www.eeoc.gov/facts/restaurant_guide_summary.html for detailed information about the interaction between the FDA Food Code and the ADA.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease that can be transmitted through food. It is the responsibility of the permit holder to convey to applicants and employees the importance of notifying the person in charge of changes in their health status. Once notified, the person in charge can take action to prevent the likelihood of the transmission of foodborne illness. Applicants, to whom a conditional offer of employment is extended, and food employees are required to report their specific history of exposure, medical symptoms, and previous illnesses. The symptoms listed may be indicative of a disease that is transmitted through the food supply by infected food employees.

As required by the ADA, the CDC published in the Federal Register November 23, 2009, (Volume 74, Number 224) a list of infectious and communicable diseases that are transmitted through food. The CDC updates the list annually.
See "List of Infectious and Communicable Diseases which are Transmitted through the Food Supply" at http://edocket.access.gpo.gov/2009/E9-28093.htm. The list is divided into two parts: pathogens often transmitted and pathogens occasionally transmitted by infected persons who handle food.

The following Lists summarize the CDC list by comparing the common symptoms of each pathogen. Symptoms may include diarrhea, fever, vomiting, jaundice, and sore throat with fever. The CDC has no evidence that the HIV virus is transmissible via food. Therefore, a food employee positive for the HIV virus is not of concern unless suffering secondary illness listed below. The following Lists include all enterohemorrhagic or Shiga toxin-producing ***E. coli*** likely to occur in foods in the United States.

LIST I. Pathogens Often Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens.

	D	F	V	J	S
1. Noroviruses	D	F	V		
2. Hepatitis A virus	-	F	-	J	-
3. ***Salmonella* Typhi**	-	F	-	-	-
4. Sapoviruses					
5. ***Shigella*** species	D	F	V	-	-
6. ***Staphylococcus aureus***	D	-	V	-	-
7. ***Streptococcus pyogenes***	-	F	-	-	S

LIST II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Persons Who Handle Food, But Usually Transmitted by Contamination at the Source or in Food Processing or by Non-foodborne Routes.

	D	F	V	J	S
1. ***Campylobacter jejuni***	D	F	V	-	-
2. ***Cryptosporidium species***	D	-	-	-	-
3. ***Entamoeba histolytica***	D	F	-	-	-
4. Enterohemorrhagic ***Escherichia coli***	D	-	-	-	-
5. Enterotoxigenic ***Escherichia coli***	D	-	V	-	-
6. ***Giardia intestinalis***	D	-	-	-	-
7. Non-typhoidal ***Salmonella***	D	F	V	-	-
8. ***Taenia solium***	-	-	-	-	-
9. ***Vibrio cholerae*** 01	D	-	V	-	-
10. ***Yersinia enterocolitica***	D	F	V	-	-

D = Diarrhea V = Vomiting S = Sore throat with fever
F = Fever J = Jaundice

The 5 Listed Pathogens:

The CDC has designated the 5 organisms listed in the Food Code as having high infectivity via contamination of food by infected food employees. This designation is based on the number of confirmed cases reported that involved food employees infected with one of these organisms and/ or the severity of the medical consequences to those who become ill.

The following is taken from information provided in the 18th Edition of Control of Communicable Diseases Manual, the CDC website, and the FDA Bad Bug Book, and is provided as background information on pathogen virulence, infectivity, and common symptoms exhibited with infection of each of the 5 listed pathogens.

NOROVIRUS

Noroviruses (genus Norovirus, family Caliciviridae) are a group of small (27-40nm), round structured, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans. Norovirus has also been commonly known as “Norwalk-like virus,” “Small Round-structured Virus,” and “Winter Vomiting Disease.”

The CDC estimates that Norovirus is the leading cause of foodborne illness in the United States. Transmission of Norovirus has been shown to occur most commonly through the fecal oral route, with contaminated food identified as a common vehicle of transmission. Exclusion of food employees exhibiting or reporting diarrhea symptoms is an essential intervention in controlling the transmission of Norovirus from infected food employees’ hands to RTE food items. Norovirus also has a high secondary attack rate (> 50%) via person-to-person contact.

Norovirus has also been reported to cause infection by airborne transmission when individuals are in close physical proximity to an infected individual vomiting in the facility. Therefore an infected individual vomiting in a food facility increases the risk of infecting employees and consumers. Foodborne illness outbreaks have occurred from consumers vomiting in the dining room, or employees vomiting on the premises. Removing food employees exhibiting or reporting vomiting symptoms from the food facility protects consumers and fellow workers from infection with Norovirus.

Incubation Period: Generally between 24 and 48 hours (median in outbreaks 33 to 36 hours), but cases can occur within 12 hours of exposure.

Symptoms and Complications: Acute-onset explosive (or projectile) vomiting, watery non-bloody diarrhea with abdominal cramps, nausea, and occasionally, a low grade fever. Symptoms usually last 24 to 60 hours. Vomiting is more common in children. Recovery is usually complete and there is no evidence of any serious long-term sequelae. Among the young and the elderly, dehydration is a common complication. There is no long-term immunity to Norovirus and individuals may be repeatedly infected throughout their lifetimes. There is no specific therapy for viral gastroenteritis. Symptomatic therapy consists of replacement of fluid loss by the administration of liquids orally, and in rare instances, through parenteral intravenous fluid therapy. Earlier feeding studies conducted on Norovirus have found that as many as 30% of individuals infected with Norovirus are asymptomatic.

Infectivity: Noroviruses are highly contagious, and it is thought that an inoculum of as few as 10 viral particles may be sufficient to infect an individual. Although pre-symptomatic shedding may occur, shedding usually begins with onset of symptoms and may continue for 2 weeks after recovery. However the degree of infectivity of prolonged shedding has not been determined. Norovirus is shed at high levels in the stool: 10^5 – 10^7/g or more.

SALMONELLA TYPHI

Salmonella enterica subspecies *enterica* serovar Typhi (commonly *S*. Typhi) causes a systemic bacterial disease, with humans as the only host. This disease is relatively rare in the United States, with fewer than 500 sporadic cases occurring annually in the U.S. Worldwide, the annual estimated incidence of Typhoid fever is about 17 million cases with approximately 600,000 deaths. Currently, most cases of ***S*. Typhi** in industrialized nations are imported into the country from developing countries. Antibiotic-resistant strains have become prevalent in several areas of the world.

Incubation period: Depends on inoculum size and on host factors: from 3 days to over 60 days, with a usual range of 8-14 days.

Symptoms: Insidious onset of sustained fever, marked headache, malaise, anorexia, relative bradycardia, splenomegaly, and nonproductive cough in the early stage of the illness, rose spots on the trunk in 25% of white skinned patients and constipation more often than diarrhea in adults. The illness varies from mild illness with low-grade fever to severe clinical disease with abdominal discomfort and multiple complications.

Infectivity: The minimal infectious dose is estimated to be less than 1000 bacterial cells. An individual infected with ***S*. Typhi** is infectious as long as the bacilli appear in the excreta, usually from the first week throughout the convalescence; variable thereafter. About 10% of untreated typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2%-5% become permanent carriers; fewer persons affected with paratyphoid organisms may become permanent gallbladder carriers.

ENTEROHEMORRHAGIC OR SHIGA TOXIN-PRODUCING ESCHERICHIA *COLI*

E. coli O157:H7 is the most commonly identified strain of Enterohemorrhagic ***Escherichia coli*** (EHEC) or Shiga toxin-producing ***Escherichia coli*** (STEC) as a cause of foodborne illness in the United States. ***E. coli*** O157:H7 is a zoonotic disease derived from cattle and other ruminants. However, ***E. coli*** O157:H7 also readily transmits from person-to-person, so contaminated raw ingredients and ill food employees both can be sources of foodborne disease. Other EHEC or STEC serotypes have been identified as a source of foodborne illness in the United States, however not as frequently as ***E. coli*** O157:H7. The other serogroups most commonly implicated as a cause of foodborne illness in the United States are 026, 0111, 0103, 045, and 0121.

The Food Code definition of STEC covers all ***E. coli*** identified in clinical laboratories that produce Shiga toxins. Nearly 200 O:H combinations of ***E. coli*** have been shown to produce Shiga toxins. The Food Code definition includes all STEC, including those that have not been specifically implicated in human disease such as hemorrhagic colitis (i.e., bloody diarrhea) or hemolytic uremic syndrome (HUS). A subset of STEC that has the capacity to both produce Shiga toxin and cause “attaching and effacing” lesions in

the intestine is classified as “enterohemorrhagic” (EHEC). EHEC ***E. coli*** cause hemorrhagic colitis, meaning bleeding enterically or bleeding from the intestine. Infections with EHEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Virtually all human isolates of ***E. coli*** O157:H7 seotypes are EHEC.

Incubation period: From 2-10 days, with a median of 3-4 days.

Symptoms: The illness is characterized by severe cramping (abdominal pain) and diarrhea with a range from mild and nonbloody to stools that are virtually all blood. Occasionally vomiting occurs. Some individuals exhibit watery diarrhea only. Lack of fever in most patients can help to differentiate this infection from other enteric pathogens. About 8% of individuals with ***E. coli*** O157:H7 diarrhea progress to HUS. This rate varies for other serotypes of Enterohemorrhagic ***E. coli***.

Infectivity: The infectious dose is for example ***E. coli*** O157:H7 can be as low as 10 bacterial cells. Children under 5 years old are most frequently diagnosed with infection and are at greatest risk of developing HUS. The elderly also experience a greater risk of complications. The duration of excretion of Enterohemorrhagic ***E. coli*** in the stool is typically 1 week or less in adults, but can be up to 3 weeks in one-third of infected children.

SHIGELLA SPP.

Causes an acute bacterial disease, known as shigellosis, and primarily occurs in humans, but also occurs in other primates such as monkeys and chimpanzees. An estimated 300,000 cases of shigellosis occur annually in the U.S. ***Shigella*** spp. consist of 4 species or serogroups, including ***S. flexneri***, ***S. boydii***, ***S. sonnei***, and ***S. dysenteriae***; which all differ in geographical distribution and pathogenicity. ***Shigella*** spp. are highly infectious and highly virulent. Outbreaks occur in overcrowding conditions, where personal hygiene is poor, including in institutions, such as prisons, mental hospitals, day care centers, and refugee camps, and also among men who have sex with men. Water and RTE foods contaminated by feces, frequently from food workers’ hands, are common causes of disease transmission. Multidrug-resistant ***Shigella*** (including ***S. dysenteriae*** 1) have appeared worldwide. Concern over increasing antimicrobial resistance has led to reduced use of antimicrobial therapy in treating shigellosis.

Incubation period: Usually 1-3 days, but ranges from 12 to 96 hours, and up to 1 week for ***S. dysenteriae*** 1.

Symptoms and Complications: Abdominal pain, diarrhea, fever, nausea, and sometimes vomiting, tenesmus, toxaemia, and cramps. The stools typically contain blood, pus, or mucus resulting from mucosal ulcerations. The illness is usually self-limited, with an average duration of 4-7 days. Infections are also associated with rectal

bleeding, drastic dehydration, and convulsions in young children. The fatality rate for ***Shigella dysenteriae*** 1 may be as high as 20% among hospitalized cases. Other complications can also occur, such as Reiter's disease, reactive arthritis, intestinal perforation, and hemolytic uremic syndrome.

Infectivity: The infectious dose for humans is low, with as few as 10 bacterial cells depending on age and condition of the host. Infectivity occurs during acute infection and until the infectious agent is no longer present in feces, usually within 4 weeks after illness. Asymptomatic carriers may transmit infection; rarely, the carrier state may persist for months or longer.

HEPATITIS A VIRUS

Hepatitis A virus (HAV) is a 27-nanometer picornavirus (positive strand RNA, non-enveloped virus). The hepatitis A virus has been classified as a member of the family *Picornaviridae*. The exact pathogenesis of HAV infection is not understood, but the virus appears to invade from the intestinal tract and is subsequently transported to the liver. The hepatocytes are the site of viral replication and the virus is thought to be shed via the bile.

HAV is most commonly spread by the fecal-oral route through person-to-person contact. Risk factors for reported cases of hepatitis A include personal or sexual contact with another case, illegal drug use, homosexual male sex contact, and travel to an endemic country. Common source outbreaks also can occur through ingestion of water or food that has fecal contamination. However, the source of infection is not identified for approximately 50% of reported cases.

HAV infection is endemic in developing countries, and less common in industrialized countries with good environmental sanitation and hygienic practices. In the developing world, nearly all HAV infections occur in childhood and are asymptomatic or cause a mild illness. As a result, hepatitis A (symptomatic infection with jaundice) is rarely seen in the developing world. More than 90% of adults born in many developing countries are seropositive.

Children play an important role in the transmission of HAV and serve as a source of infection for others, because most children have asymptomatic infections or mild, unrecognized HAV infections. In the United States, the disease is most common among school-aged children and young adults. After correction for under-reporting and undiagnosed infections, an estimated 61,000 HAV infections (includes cases of hepatitis A as well as asymptomatic infections) occurred in 2003.

HAV Immunization: Immune globulin can be used to provide passive pre-exposure immunoprophylaxis against hepatitis A. Protection is immediately conferred to an exposed individual following administration of IG, and immunity is provided for 3-5 months following inoculation. IG is effective in preventing HAV infection when given as post-exposure immunoprophylaxis, if given within 14 days of exposure. When a food

service worker with hepatitis A is identified, IG is often given to co-workers. Active immunoprophylaxis using hepatitis A vaccine (a formalin-inactivated, attenuated strain of HAV) has been shown to provide immunity in > 95% of those immunized, with minimal adverse reactions. Hepatitis A vaccination of food workers has been advocated, but has not been shown to be cost-effective and generally is not recommended in the United States, although it may be appropriate in some communities.

Incubation period: Average 28-30 days (range 15-50 days).

Symptoms and Complications: Illness usually begins with symptoms such as nausea/ vomiting, diarrhea, abdominal pain, fever, headache, and/or fatigue. Jaundice, dark urine or light colored stools might be present at onset, or follow illness symptoms within a few days. HAV infection of older children and adults is more likely to cause clinical illness with jaundice (i.e., hepatitis A); onset of illness is usually abrupt. In young adults, 76-97% have symptoms and 40-70% are jaundiced. Jaundice generally occurs 5-7 days after the onset of gastrointestinal symptoms. For asymptomatic infections, evidence of hepatitis may be detectable only through laboratory tests of liver infections such as alanine aminotransferase (ALT) tests. The disease varies in severity from a mild illness to a fulminant hepatitis, ranging from 1-2 weeks to several months in duration. In up to 10-15% of the reported cases, prolonged, relapsing hepatitis for up to 6 months occurs. The degree of severity often increases with age; however, most cases result in complete recovery, without sequelae or recurrence. The reported case fatality rate is 0.1% - 0.3% and can reach 1.8% for adults over 50 years old.

Diagnosis: Diagnosis of HAV infection requires specific serological testing for IgM anti-HAV. IgM anti-HAV becomes undetectectable within 6 months of illness onset for most persons; however, some persons can remain IgM anti-HAV positive for years after acute infection. Total anti-HAV (the only other licensed serologic test) can be detected during acute infection but remains positive after recovery and for the remainder of the person's life.

Infectivity: Evidence indicates maximum infectivity during the latter half of the incubation period, continuing for a few days after onset of jaundice. Most cases are probably noninfectious after the first week of jaundice. Chronic shedding of HAV in feces has not been reported. HAV is shed at peak levels in the feces, one to two weeks before onset of symptoms, and shedding diminishes rapidly after liver dysfunction or symptoms appear. Liver dysfunction or symptoms occur at the same time circulating antibodies to HAV first appear. Immunity after infection probably lasts for life; immunity after vaccination is estimated to last for at least 20 years.

Reporting History of Exposure:

The reporting requirements for history of exposure are designed to identify employees who may be incubating an infection due to Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC/STEC, typhoid fever, or HAV.

Which employees who report exposure are restricted?

- Employees who work in a food establishment serving a highly susceptible population (HSP) facility.

What constitutes exposure?

- Consuming a food that caused illness in another consumer due to infection with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC/STEC, typhoid fever, or HAV.
- Attending an event or working in a setting where there is a known disease outbreak.
- Close contact with a household member who is ill and is diagnosed with a listed pathogen.

Why are other guidelines provided, in addition to restriction for employees serving an HSP who report exposure to hepatitis A virus?

- Employees who have had a hepatitis A illness in the past are most likely protected from infection by life-time immunity to hepatitis A infection.
- Immunity developed through immunization or IgG inoculation prevents hepatitis A infection in exposed employees.
- Our standard definition of HSP doesn't apply very well to HAV. Children under 6 years old who become infected with HAV are generally asymptomatic, and while a higher proportion of susceptible elderly who become infected have serious illness, most institutionalized elderly are protected from HAV by prior infection.

What is the period of restriction?

- The period of restriction begins with the most recent time of foodborne or household member exposure and lasts for the usual incubation period of the pathogen as defined in the Control of Communicable Diseases Manual. This is the time that the employee is most likely to begin shedding the pathogen.
    - For Norovirus, 48 hours after the most recent exposure
    - For ***Shigella*** spp., 3 days after the most recent exposure
    - For ***E. coli*** O157:H7 or other EHEC/STEC, 3 days after the most recent exposure

- For typhoid fever (***S.* Typhi**), 14 days after the most recent exposure
- For HAV, 30 days after the most recent exposure

What is the period of restriction when exposed to a diagnosed, ill household member?

- While the household member is symptomatic with an infection due to Norovirus, ***Shigella*** spp., ***E coli*** O157:H7 or other EHEC/STEC, typhoid fever (***S.* Typhi**) or HAV;
- Plus during the usual incubation period of the pathogen of concern:
  - For Norovirus, symptomatic period plus 48 hours
  - For ***Shigella*** spp., symptomatic period plus 3 days
  - For ***E. coli*** O157:H7 or other EHEC/STEC, symptomatic period plus 3 days
  - For typhoid fever (***S.* Typhi**), symptomatic period plus 14 days
  - For HAV, onset of jaundice plus 30 days

What is the appropriate response to a report of exposure to other food employees?

- Employees who report a history of exposure but who do not work in a HSP facility should be reminded of the requirements for reporting illness, avoidance of bare hand contact with RTE foods, and proper hand washing and personal hygiene.

2-201.12 Exclusions and Restrictions.[2]

Refer to public health reasons for § 2-201.11 for actions to take with conditional employees.

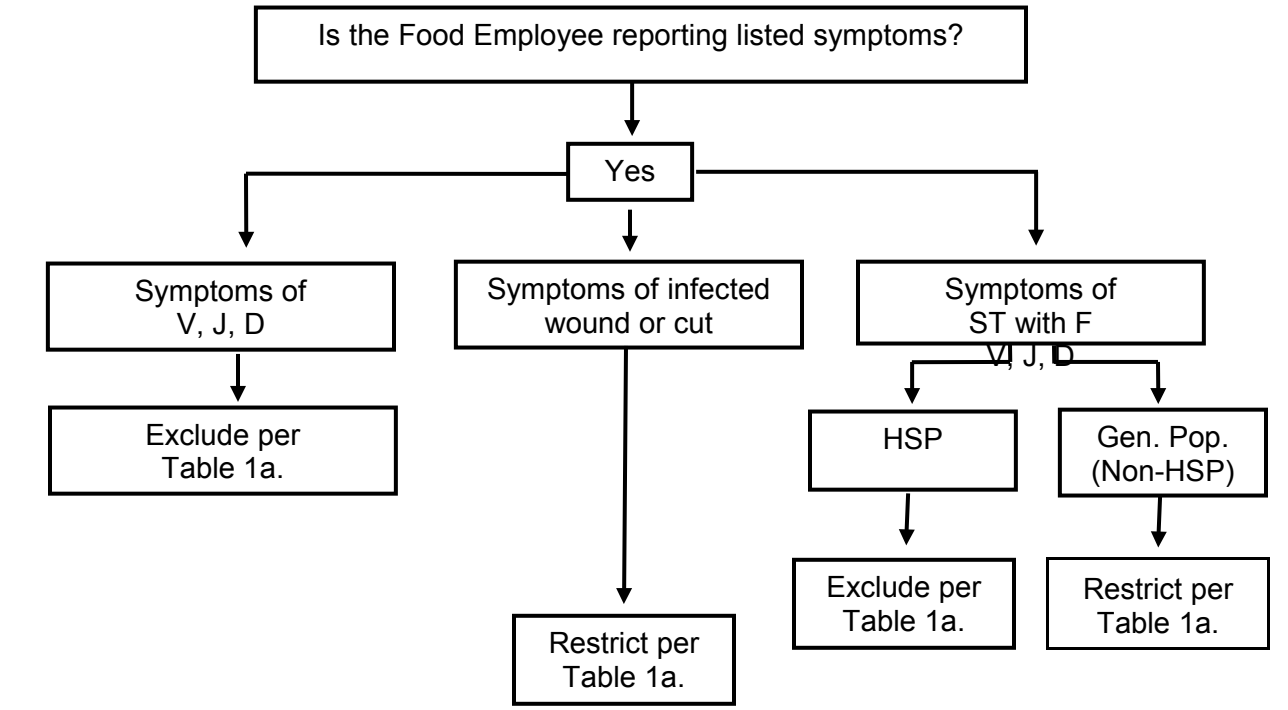
It is necessary to exclude food employees symptomatic with diarrhea, vomiting, or jaundice, or suffering from a disease likely to be transmitted through contamination of food, because of the increased risk that the food being prepared will be contaminated such as with a pathogenic microorganism. However, if the food employee is suffering from vomiting or diarrhea symptoms, and the condition is from a non-infectious condition, Crohn's disease or an illness during early stages of a pregnancy, the risk of transmitting a pathogenic microorganism is minimal. In this case, the food employee may remain working in a full capacity if they can substantiate that the symptom is from a noninfectious condition. The food employee can substantiate this through providing to the person in charge medical documentation or other documentation proving that the symptom is from a noninfectious condition.

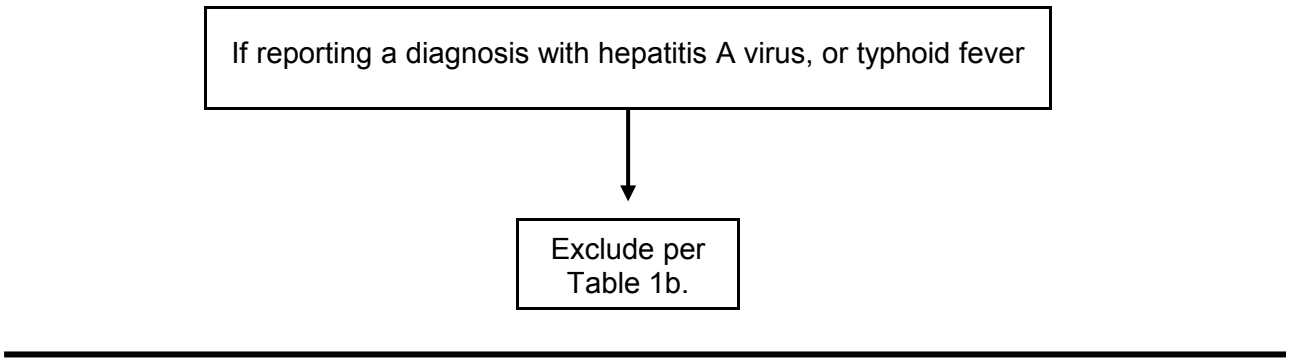
2In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

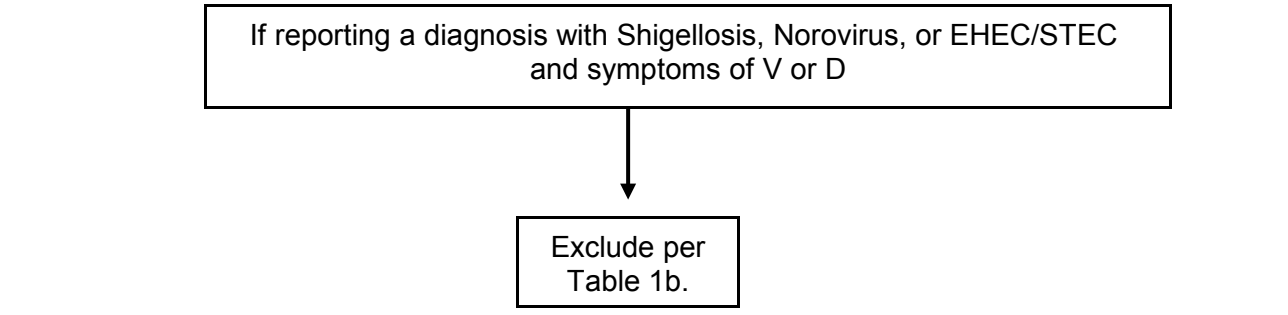
Because of the high infectivity (ability to invade and multiply) and/ or virulence (ability to produce severe disease), of typhoid fever (***Salmonella* Typhi**) and hepatitis A virus, a food employee diagnosed with an active case of illness caused by either of these two pathogens, whether asymptomatic or symptomatic, must be excluded from food establishments. The exclusion is based on the high infectivity, and/or the severe medical consequences to individuals infected with these organisms. A food employee diagnosed with an active case of illness caused by Norovirus, ***Shigella*** spp., or ***E. coli*** O157:H7 or other EHEC/STEC, is excluded if exhibiting symptoms of vomiting and diarrhea, and then allowed to work as the level of risk of pathogen transmission decreases (See section 2-201.12, Tables #1b, #2 and #3).

The degree of risk for a food employee or conditional employee who is diagnosed with an infection but asymptomatic with regard to symptoms, to transmit a foodborne pathogen decreases with the resolution of symptoms. This risk decreases even further for those employees that are diagnosed with a listed pathogen, but never developed symptoms. The decrease in risk is taken under consideration when excluding and restricting diagnosed food employees and results in a slight difference in the way food employees diagnosed with Norovirus, but asymptomatic with respect to gastrointestinal symptoms are handled (See section 2-201.12, Table #2).

2-201.11 / 2-201.12 Decision Tree 1. When to Exclude or Restrict a Food Employee Who Reports a Symptom and When to Exclude a Food Employee Who Reports a Diagnosis with Symptoms Under the Food Code



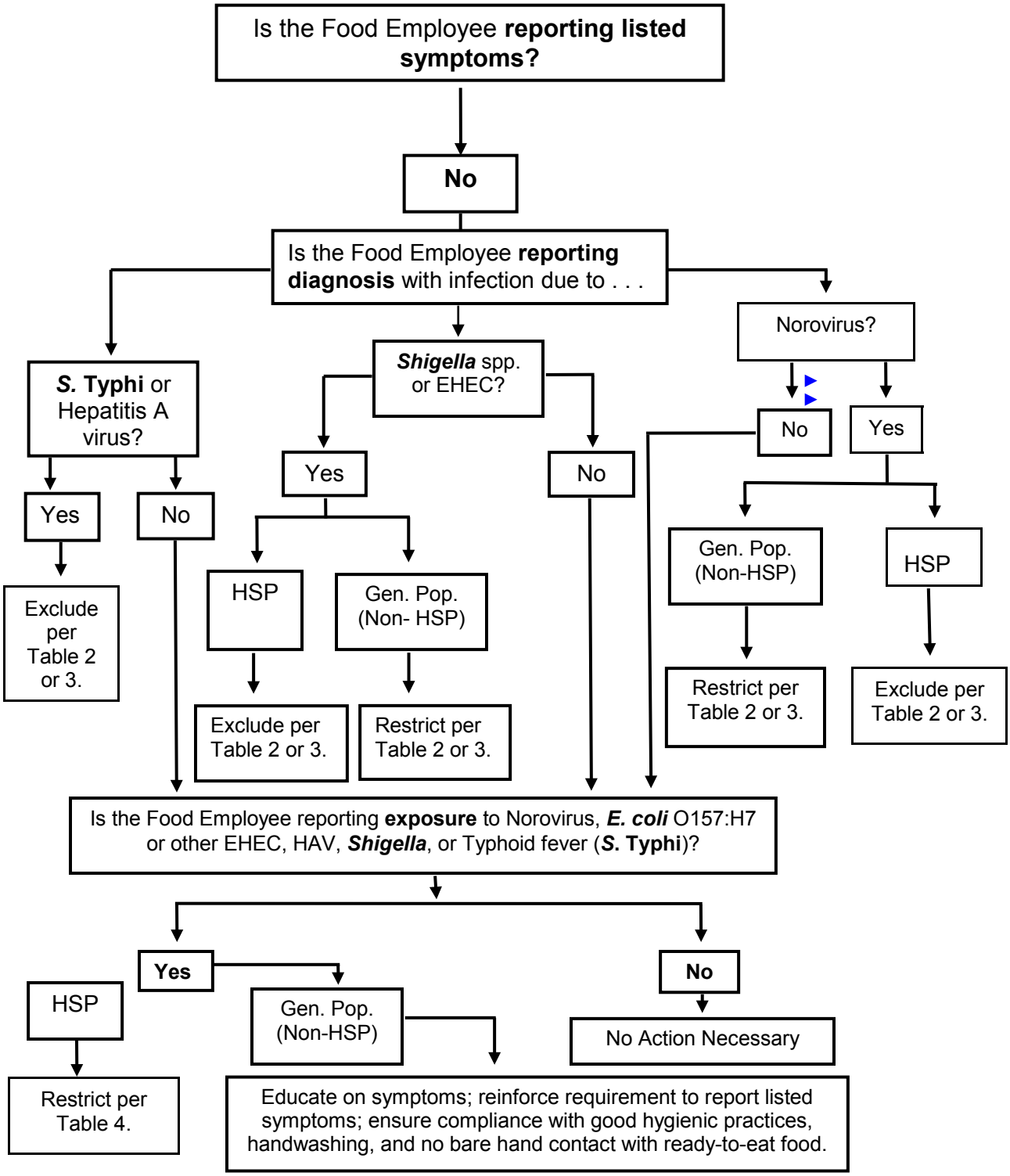




Key:
Listed Symptoms for Reporting: (V) Vomiting; (J) Jaundice; (D) Diarrhea; (ST with F) Sore Throat with

Fever; (HSP) Highly Susceptible Population; (Gen. Pop.) General Population

2-201.11 / 2-201.12 Decision Tree 2. When to Exclude or Restrict a Food Employee Who is Asymptomatic and Reports a Listed Diagnosis and When to Restrict a Food Employee Who Reports a Listed Exposure Under the Food Code



Key:

(HSP) Highly Susceptible Population; (Gen. Pop.) General Population

2-201.12 Table 1a: Summary of Requirements for Symptomatic Food Employees

Food employees and conditional employees shall report symptoms immediately to the person in charge				
The person in charge shall prohibit a conditional employee who reports a listed symptom from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a symptomatic food employee.				
Symptom	**EXCLUSION/ OR RESTRICTION**		**Removing Symptomatic Food Employees from Exclusion or Restriction**	**RA Approval Needed to Return to Work?**
	Facilities Serving an HSP	**Facilities Not serving an HSP**		
Vomiting	**EXCLUDE** 2-201.12(A)(1)	**EXCLUDE** 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A)(1). ***Exceptions:*** If diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC/STEC, HAV, or typhoid fever *(**S.* **Typhi***)* (see Tables 1b & 2).	No if not diagnosed
Diarrhea	**EXCLUDE** 2-201.12(A)(1)	**EXCLUDE** 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A). ***Exceptions:*** If Diagnosed with Norovirus, ***E. coli*** O157:H7 or other EHEC/STEC, HAV, or ***S.*** **Typhi** (see Tables 1b & 2).	No if not diagnosed
Jaundice	**EXCLUDE** 2-201.12(B)(1) if the onset occurred within the last 7 days	**EXCLUDE** 2-201.12(B)(1) if the onset occurred within the last 7 days	When approval is obtained from the RA 2-201.13 (B), and: • Food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • Food employee provides medical documentation 2-201.13(B)(3).	Yes
Sore Throat with Fever	**EXCLUDE** 2-201.12(G)(1)	**RESTRICT** 2-201.12(G)(2)	When food employee provides written medical documentation 201.13(G) (1)-(3).	No
Infected wound or pustular boil	**RESTRICT** 2-201.12(H)	**RESTRICT** 2-201.12(H)	When the infected wound or boil is properly covered 2-201.13(H)(1)-(3).	No

Key for Tables 1, 2, 3, and 4:
RA = Regulatory Authority
EHEC/STEC = Enterohemorrhagic, or Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population

2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees

Food employees and conditional employees shall report a listed Diagnosis with symptoms immediately to the person in charge			
The person in charge shall notify the RA when a food employee is jaundiced or reports a listed diagnosis			
The person in charge shall prohibit a conditional employee who reports a listed diagnosis with symptoms from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed, symptomatic food employee.			
Diagnosis	**EXCLUSION Facilities Serving an HSP or Not Serving an HSP**	**Removing Diagnosed, Symptomatic Food Employees from Exclusion**	**RA Approval Needed to Return to Work?**
Hepatitis A virus	**EXCLUDE** if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	When approval is obtained from the RA 2-201.13(B), and: • The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • The anicteric food employee has had symptoms or more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3) (also see Table 2).	Yes
Typhoid Fever (***S.* Typhi**)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: • Food employee provides medical documentation, that states the food employee is free of a ***S.* Typhi** infection 2-201.13(C)(2) (also see Table 2).	Yes
E. coli O157:H7 or other EHEC/ STEC	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving a non-HSP facility: 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from RA 2-201.13(F), and • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

(continued on next page)

2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees (continued)

Diagnosis	EXCLUSION Facilities Serving an HSP or Not Serving an HSP	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
Norovirus	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving a non-HSP facility: 2-201.13 (A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Shigella spp.	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving a non-HSP facility: 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(E), and • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(E)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge				
The person in charge shall notify the RA when a food employee reports a listed diagnosis				
The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee.				
Pathogen Diagnosis	**Facilities Serving an HSP**	**Facilities Not Serving an HSP**	**Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction**	**RA Approval Required to Return to Work?**
Typhoid fever (***S.* Typhi**) including previous illness with ***S.* Typhi** (see 2-201.11 (A)(3))	**EXCLUDE** 2-201.12(C)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: • Food employee provides medical documentation, that states the food employee is free of an ***S.* Typhi** infection 2-201.13)(C)(2) (also see Table 1b).	Yes
Shigella spp.	**EXCLUDE** 2-201.12(E)(1)	**RESTRICT** 2-201.12(E)(2)	1. Serving a non-HSP facility: 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(E), and: • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 201.13(E)(3)(a) (also see Table 1b).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

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2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms (continued)

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employee with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Norovirus	**EXCLUDE** 2-201.12(D)(1)	**RESTRICT** 2-201.12(D)(2)	1. Serving a non-HSP facility: 2-201.13(A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 1b).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
E. coli O157:H7 or other EHEC/ STEC	**EXCLUDE** 2-201.12(F)(1)	**RESTRICT** 2-201.12(F)(2)	1. Serving a non-HSP facility: 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(F), and • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

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2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms (continued)

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Hepatitis A virus	**EXCLUDE** if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	**EXCLUDE** if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	When approval is obtained from the RA 2-201.13(B), and: • The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3) (see also Table 1b).	Yes

2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge				
The person in charge shall notify the RA when a food employee reports a listed diagnosis				
The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee				
Pathogen Diagnosis	**Facilities Serving an HSP**	**Facilities Not Serving an HSP**	**Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction**	**RA Approval Required to Return to Work?**
Typhoid Fever (***S.* Typhi**) including previous illness with ***S.* Typhi** (see 2-201.11 (A)(3))	**EXCLUDE** 2-201.12(C)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: Food employee provides medical documentation, specifying that the food employee is free of a ***S.* Typhi** infection 2-201.13(C)(2).	Yes
Shigella spp.	**EXCLUDE** 2-201.12(E)(1)	**RESTRICT** 2-201.12(E)(2)	Remains excluded or restricted until approval is obtained from the RA, and: • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee was last diagnosed 2-201.13(E)(3).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Norovirus	**EXCLUDE** 2-201.12(D)(1)	**RESTRICT** 2-201.12(D)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee was diagnosed 2-201.13(D)(3).	Yes to return to an HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility

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2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms (continued)

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
E. coli O157:H7 or other EHEC/ STEC	**EXCLUDE** 2-201.12(F)(1)	**RESTRICT** 2-201.12(F)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(F), and: • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee was diagnosed 2-201.13(F)(3).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
Hepatitis A virus	**EXCLUDE** 2-201.12(B)(3)	**EXCLUDE** 2-201.12(B)(3)	When approval is obtained from the RA 2-201.13(B), and • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3).	Yes

Key for Tables 1, 2, 3, and 4:
RA = Regulatory Authority
EHEC/STEC = Enterohemorrhagic, or Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population

2-201.12 Table 4: History of Exposure, and Absent Symptoms or Diagnosis

Food employees and conditional employees shall report a listed exposure to the person in charge				
The person in charge shall prohibit a conditional employee who reports a listed exposure from becoming a food employee in a facility serving an HSP until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of an exposed food employee				
The person in charge shall reinforce and ensure compliance with good hygienic practices, symptom reporting requirements, proper handwashing and no BHC with RTE foods for all food employees that report a listed exposure				
Pathogen Diagnosis	**Facilities Serving an HSP**	**Facilities Not Serving an HSP**	**When Can the Restricted Food Employee Return to Work?**	**RA Approval Needed?**
Typhoid Fever (***S.* Typhi**)	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(3) When 14 calendar days have passed since the last exposure, or more than 14 days has passed since the food employee's household contact became asymptomatic.	No
Shigella spp.	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 days have passed since the food employee's household contact became asymptomatic.	No
Norovirus	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(1) When more than 48 hours have passed since the last exposure, or more than 48 hours has passed since the food employee's household contact became asymptomatic.	No
E. coli O157:H7 or other EHEC/ STEC	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 calendar days has passed since the food employee's household contact became asymptomatic.	No
Hepatitis A virus	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(4) When any of the following conditions is met: • The food employee is immune to HAV infection because of a prior illness from HAV, vaccination against HAV, or IgG administration; or • More than 30 calendar days have passed since the last exposure, or since the food employee's household contact became jaundiced; or • The food employee does not use an alternative procedure that allows BHC with RTE food until at least 30 days after the potential exposure, and the employee receives additional training.	No

Key for Table 4: GHP = Good Hygienic Practices; RTE = Ready-to-Eat foods; BHC = Bare Hand Contact

2-201.12 Exclusion and Restrictions (continued)[3]

Restrictions and exclusions vary according to the population served because highly susceptible populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious medical consequences in immunocompromised individuals. This point is reinforced by statistics pertaining to deaths associated with foodborne illness caused by ***Salmonella* Enteritidis**. Over 70% of the deaths in outbreaks attributed to this organism occurred among individuals who for one reason or another were immunocompromised. This is why the restrictions and exclusions listed in the Code are especially stringent for food employees serving highly susceptible populations.

Periodic testing of food employees for the presence of diseases transmissible through food is not cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active gastrointestinal symptoms, followed by diagnosis and history of exposure.

The history of exposure that must be reported applies only to the 5 organisms listed.

Upon being notified of the history of exposure, the person in charge should immediately:

1. Discuss the traditional modes of transmission of fecal-oral route pathogens.

2. Advise the food employee to observe good hygienic practices both at home and at work. This includes a discussion of proper handwashing, as described in the Code, after going to the bathroom, changing diapers, or handling stool-soiled material.

3. Review the symptoms listed in the Code that require immediate exclusion from the food establishment.

4. Remind food employees of their responsibility as specified in the Code to inform the person in charge immediately upon the onset of any of the symptoms listed in the Code.

5. Ensure that the food employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.

3In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

A restricted food employee may work in an area of the food establishment that houses packaged food, wrapped single-service or single-use articles, or soiled food equipment or utensils. Examples of activities that a restricted person might do include working at the cash register, seating patrons, bussing tables, stocking canned or other packaged foods, or working in a non-food cleaning or maintenance capacity consistent with the criteria in the definition of the term "restricted." A food employee who is restricted from working in one food establishment may not work in an unrestricted capacity in another food establishment, but could work unrestricted in another retail store that is not a food establishment. A restricted food employee may enter a food establishment as a consumer.

An excluded individual may not work as a food employee on the premises of any food establishment.

2-201.13 Removal of Exclusions and Restrictions.[4]

Food employees diagnosed with Norovirus, hepatitis A virus**, *Shigella*** spp., ***E. coli*** O157:H7 or other EHEC, and symptomatic with diarrhea, vomiting, or jaundice, are excluded under subparagraph 2-201.12 (A)(2) or 2-201.12(B)(2). However these symptomatic, diagnosed food employees differ from symptomatic, undiagnosed food employees in the requirements that must be met before returning to work in a full capacity after symptoms resolve.

The person in charge may allow undiagnosed food employees who are initially symptomatic and whose symptoms have resolved to return to work in a full capacity 24 hours after symptoms resolve.

However, diagnosis with a listed pathogen invokes additional requirements before the person in charge may allow diagnosed food employees to return to work in full capacity.

Asymptomatic food employees diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC may not return to work in a full capacity for at least 24 hours after symptoms resolve. The person in charge shall only allow these food employees to work on a restricted basis 24 hours after symptoms resolve and they shall only allow this if not in a food establishment that serves a highly susceptible population. These restricted food employees remain restricted until they are medically cleared or otherwise meet the criteria for removal from restriction as specified under subparagraphs 2-201.13(D) (1)-(2); 2-201.13(E)(1)-(2); or 2-201.13(F)(1)-(2).

4In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

In a food establishment that serves a highly susceptible population, food employees who are diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC and initially symptomatic with vomiting or diarrhea, shall not work on a restricted basis after being asymptomatic for at least 24 hours. These food employees must remain excluded until they are medically cleared or otherwise meet the criteria for removal from exclusion from a highly susceptible population under subparagraph 2-201.13(D)(1)-(2), 2-201.13(E)(1)-(2), or 2-201.13 (F)(1)-(2).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B) (1)-(4).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B) (1)-(3). A food employee with an anicteric infection with the hepatitis A virus has a mild form of hepatitis A without jaundice. Food employees diagnosed with an anicteric infection with the hepatitis A virus are excluded if they are within 14 days of any symptoms. Anicteric, diagnosed food employees shall be removed from exclusion if more than 14 days have passed since they became symptomatic, or if medically cleared. Asymptomatic food employees diagnosed with an active infection with the hepatitis A virus are also excluded until medically cleared.

Food employees diagnosed with typhoid fever (caused by a ***Salmonella*** **Typhi** infection) are always excluded, even without expressing gastrointestinal symptoms, since these symptoms are not typically exhibited with typhoid fever. Outbreaks of foodborne illness involving typhoid fever (***Salmonella*** **Typhi**) have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness. The high virulence combined with the extremely high infectivity of ***S.*** **Typhi** warrant exclusion from the food establishment until the food employee has been cleared by a physician or has completed antibiotic therapy.

Despite lacking specific epidemiological evidence of transmission through food contaminated by food employees infected with ***E. coli*** O157:H7 or other EHEC/STEC bacteria are included with the 5 listed pathogens in the Food Code. This is because of the documented ease of transmission from person-to-person in a day care setting and because characteristics of foodborne outbreaks suggest a low infectious dose and the potential for the organism to be transmitted through food contaminated by soiled hands. The severity and consequences of infection, including hemolytic uremic syndrome (HUS), associated with Shiga toxin-producing ***E. coli*** warrant the institution of disease interventions.

Asymptomatic shedders are food employees who do not exhibit the symptoms of foodborne illness but who are identified through diagnosis, or laboratory confirmation of

their stools to have Norovirus, or any one of the three bacterial pathogens identified in Chapter 2 in their gastrointestinal system.

The risk that food employees who are asymptomatic shedders will transmit a communicable disease varies depending upon the hygienic habits of the worker, the food itself and how it is prepared, the susceptibility of the population served, and the infectivity of the organism. Exclusion in a food establishment that serves a highly susceptible population affords protection to people who are immune-suppressed. Restriction in a food establishment that does not serve a highly susceptible population affords protection for the general population and the immune-suppressed subset of the general population provided there is adequate attention to personal hygiene and avoidance of bare-hand contact with RTE foods.

To minimize the risk in all food establishments of the transmission of foodborne disease by an asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the three bacterial pathogens are either restricted or excluded, depending on the population served. Requiring restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion and is consistent with APHA-published recommendations in the "Control of Communicable Diseases Manual."

Hands and Arms **2-301.11 Clean Condition.**

The hands are particularly important in transmitting foodborne pathogens. Food employees with dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity which may contaminate the hands must be followed by thorough handwashing in accordance with the procedures outlined in the Code.

Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth, throat, and nose of many employees. The hands of employees can be contaminated by touching their nose or other body parts.

2-301.12 Cleaning Procedure.

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. Many employees fail to wash their hands as often as necessary and even those who do may use flawed techniques.

In the case of a food worker with one hand or a hand-like prosthesis, the Equal Employment Opportunity Commission has agreed that this requirement for thorough handwashing can be met through reasonable accommodation in accordance with the Americans with Disabilities Act. Devices are available which can be attached to a lavatory to enable the food worker with one hand to adequately generate the necessary friction to achieve the intent of this requirement.

The greatest concentration of microbes exists around and under the fingernails of the hands. The area under the fingernails, known as the “subungal space”, has by far the largest concentration of microbes on the hand and this is also the most difficult area of the hand to decontaminate. Fingernail brushes, if used properly, have been found to be effective tools in decontaminating this area of the hand. Proper use of single-use fingernail brushes, or designated individual fingernail brushes for each employee, during the handwashing procedure can achieve up to a 5-log reduction in microorganisms on the hands.

There are two different types of microbes on the hands, transient and resident microbes. Transient microbes consist of contaminating pathogens which are loosely attached to the skin surface and do not survive or multiply. A moderate number of these organisms can be removed with adequate handwashing. Resident microbes consist of a relatively stable population that survive and multiply on the skin and they are not easily washed off the hands. Resident microbes on the hands are usually not a concern for potential contamination in food service.

All aspects of proper handwashing are important in reducing microbial transients on the hands. However, friction and water have been found to play the most important role. This is why the amount of time spent scrubbing the hands is critical in proper handwashing. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

Research has shown a minimum 10-15 second scrub is necessary to remove transient pathogens from the hands and when an antimicrobial soap is used, a minimum of 15 seconds is required. Soap is important for the surfactant effect in removing soil from the hands and a warm water temperature is important in achieving the maximum surfactant effect of the soap.

Every stage in handwashing is equally important and has an additive effect in transient microbial reduction. Therefore, effective handwashing must include scrubbing, rinsing, and drying the hands. When done properly, each stage of handwashing further decreases the transient microbial load on the hands. It is equally important to avoid recontaminating hands by avoiding direct hand contact with heavily contaminated environmental sources, such as manually operated handwashing sink faucets, paper towel dispensers, and rest room door handles after the handwashing procedure. This can be accomplished by obtaining a paper towel from its dispenser before the handwashing procedure, then, after handwashing, using the paper towel to operate the hand sink faucet handles and restroom door handles.

Handwashing done properly can result in a 2-3 log reduction in transient bacteria and a 2-log reduction in transient viruses and protozoa. With heavy contamination of transient microbial pathogens, (i.e., > 10^4 microbes, as found on hands contaminated

with bodily wastes and infected bodily fluids) handwashing may be ineffective in completely decontaminating the hands. Therefore, a further intervention such as a barrier between hands and ready-to-eat food is necessary.

2-301.13 Special Handwash Procedures.

This section is reserved.

In earlier editions of the Code, FDA's model contained a provision for a Special Procedure in certain situations. Pursuant to a 1996 Conference for Food Protection (CFP) Recommendation, the text of this Code provision is removed and the section is reserved. It is FDA's intent to further research the matter and to submit the findings to the CFP for reconsideration of the matter.

2-301.14 When to Wash.

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately after the activities listed. The specific examples listed in this Code section are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.

2-301.15 Where to Wash.

Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing facility in order to help ensure that food employees effectively clean their hands. Handwashing sinks are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may not be used for food employee handwashing since this practice may introduce additional hand contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

2-301.16 Hand Antiseptics.

In the 2005 Food Code, the use of the term “hand sanitizer” was replaced by the term “hand antiseptic” to eliminate confusion with the term “sanitizer,” a defined term in the Food Code, and to more closely reflect the terminology used in the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994.

The term “sanitizer” is typically used to describe control of bacterial contamination of inert objects or articles, or equipment and utensils, and other cleaned food-contact surfaces. The Food Code definition of “sanitizer” requires a minimum microbial reduction of 5 logs, which is equal to a 99.999% reduction. The FDA bases the 5-log reduction on the AOAC International’s “Official Methods of Analysis 2003,” which requires a minimum 5-log reduction in microorganisms to achieve “sanitization.”

Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement. However, removing microorganisms from human skin is a totally different process and sterilization of human skin is nearly impossible to achieve without damaging the skin. Many antimicrobial hand agents typically achieve a much smaller reduction in microorganisms than the 5-log reduction required for “sanitization.” Therefore, the effect achieved from using antimicrobial hand agents is not consistent with the definition of “sanitization” in the Food Code.

The word “antiseptic” is a Greek term, meaning “against putrefaction”, and eventually evolved into a second definition, meaning, “a substance used to destroy pathogenic microorganisms.” The term “antiseptic” is often used to describe agents used on skin to prevent infection of the skin.

“Antiseptic” is defined under section 201 (o) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 (o)), as: “The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation of a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.”

Section 333.403 of the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994, defines a “health-care antiseptic” as an antiseptic-containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination. An “antiseptic handwash” or “health-care personnel handwash drug product” is defined in Section 333.403 of the Monograph as an antiseptic containing preparation designed for frequent use; it reduces the number of transient microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is a broad spectrum, and persistent antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin.

Replacing the term “hand sanitizer” with the term “hand antiseptic” allows the use of a more scientifically appropriate term that is used to describe reduction of microorganisms on the skin and will improve clarification and regulation of these products.

The provisions of § 2-301.16 are intended to ensure that an antimicrobial product applied to the hands is 1) safe and effective when applied to human skin, and 2) a safe

food additive when applied to bare hands that will come into direct contact with food. Because of the need to protect workers and to ensure safe food, hand antiseptics must comply with both the human drug and the food safety provisions of the law. The prohibition against bare hand contact contained in ¶ 3-301.11(B) applies only to an exposed ready-to-eat food.

As a Drug Product

There are two means by which a hand antiseptic is considered to be safe and effective when applied to human skin:

1. A hand antiseptic may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*. This document is maintained by the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs. Also known as the "Orange Book," this document provides "product-specific" listings rather than listings by compound. It is published annually with monthly supplements and is available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm . However, as of the end of 1998, no hand antiseptics are listed in this publication since no new drug applications have been submitted and approved for these products.

2. A hand antiseptic active ingredient may be identified by FDA in the monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products under the antiseptic handwash category. Since hand antiseptic products are intended and labeled for topical antimicrobial use by food employees in the prevention of disease in humans, these products are "drugs" under the Federal Food, Drug, and Cosmetic Act § 201(g). As drugs, hand antiseptics and dips must be manufactured by an establishment that is duly registered with the FDA as a drug manufacturer; their manufacturing, processing, packaging, and labeling must be performed in conformance with drug Good Manufacturing Practices (GMP's); and the product must be listed with FDA as a drug product.

Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975, for hand antiseptic use by food handlers, are being evaluated under the Over-the-Counter (OTC) Drug Review by FDA's Center for Drug Evaluation and Research. However, as of May 2005, a final OTC drug monograph for these products has not been finalized. Therefore, FDA has not made a final determination that any of these products are generally recognized as safe and effective (GRAS/E).

GRAS/E antimicrobial ingredients for hand sanitizer use by food handlers will be identified in a future final monograph issued under the OTC Drug Review. Information about whether a specific product is covered by the proposed monograph may be obtained from the tentative final monograph (TFM) for "Health Care Antiseptic Drug

Products for OTC Human Use; Proposed Rule." This TFM, which was published in the ***Federal Register*** of June 17, 1994 (59 FR 31402), describes the inclusion of hand sanitizers in this Review on page 31440 under Comment 28 of Part II. Information about whether a specific product is included in this proposed monograph may also be available from the manufacturer.

Questions regarding acceptability of a hand antiseptic with respect to OTC compliance may be directed to the Division of New Drugs and Labeling Compliance (HFD-310), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852. Specific product label/promotional information and the formulation are required for determining a product's regulatory status.

<u>As a Food Additive</u>

To be subject to regulation under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the substances in a hand antiseptic must *reasonably* be expected to become a component of food based upon the product's intended use.

Where the substances in a hand antiseptic are reasonably expected to become a component of food based upon the product's intended use, circumstances under which those substances may be legally used include the following:

1. The intended use of a substance may be exempted from regulation as a food additive under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*. A review by FDA's Center for Food Safety and Applied Nutrition is required in order to determine whether such an exemption can be granted.

.2 A substance may be regulated for the intended use as a food additive under 21 CFR 174 – *Indirect Food Additives – General*, and be listed along with conditions of safe use in 21 CFR 178 - *Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers*.

.3 The intended use of a substance, including substances that contact food such as those in hand antiseptics, may be "generally recognized as safe (GRAS)" within the meaning of the FFDCA. A partial listing of substances with food uses that are generally recognized as safe may be found in CFR Parts 182, 184, and 186. These lists are not exhaustive because the FFDCA allows for independent GRAS determinations.

For the use of a substance to be GRAS within the meaning of the FFDCA, there must be publicly available data that demonstrate that the substance is safe for its intended use. There also must be a basis to conclude that there is a consensus among qualified experts that these publicly available data establish safety. If the use of a substance in food is GRAS, it is not subject to premarket review by FDA.

While there is no legal requirement to notify FDA of an independent GRAS determination, a number of firms have chosen to do so with the expectation of receiving a response letter from FDA (see FDA's Inventory of GRAS Notices at http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm . Although such a letter does not affirm the independent GRAS determination, it is an opportunity for the firm to receive comment from FDA regarding the materials supporting its determination.

.4 A substance may be the subject of a Food Contact Substance Notification that became effective in accordance with the FFDCA Section 409 (h). Substances that are the subject of an effective food-contact substance notification are listed, along with conditions of safe use, in the FDA Inventory of Effective Food Contact Substance (FCS) Notifications. This list is available on-line at: http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm or http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=fcsListing A food-contact substance that is the subject of an effective notification submitted under FFDCA 409(h) does not include similar or identical substances manufactured or prepared by any person other than the manufacturer identified in that notification.

The Division of Food Contact Substance Notifications does not certify or provide approvals for specific products. However, if the intended use of a substance in contact with food meets the requirements of 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*, FDA may provide a letter to a firm stating that the intended use of this product is exempt from regulation as a food additive. However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

Questions regarding the regulatory status of substances in hand antiseptics as food additives may be directed to the Division of Food Contact Substance Notifications, HFS-275, 5100 Paint Branch Parkway, College Park, MD 20740. It may be helpful or necessary to provide label/promotional information when inquiring about a specific substance.

Fingernails **2-302.11 Maintenance.**

The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms.

Jewelry **2-303.11 Prohibition.**

Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

The term "jewelry" generally refers to the ornaments worn for personal adornment and medical alert bracelets do not fit this definition. However, the wearing of such bracelets carries the same potential for transmitting disease-causing organisms to food. If a food worker wears a medical alert or medical information bracelet, the conflict between this need and the Food Code's requirements can be resolved through reasonable accommodation in accordance with the Americans with Disabilities Act. The person in charge should discuss the Food Code requirement with the employee and together they can work out an acceptable alternative to a bracelet. For example, the medical alert information could be worn in the form of a necklace or anklet to provide the necessary medical information without posing a risk to food. Alternatives to medical alert bracelets are available through a number of different companies (*e.g.,* an internet search using the term "medical alert jewelry" leads to numerous suppliers).

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

Outer Clothing **2-304.11 Clean Condition.**

Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

Food Contamination Prevention **2-401.11 Eating, Drinking, or Using Tobacco.**

Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Insanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also adversely affect consumer confidence in the establishment.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

2-401.12 Discharges from the Eyes, Nose, and Mouth.

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food, equipment, utensils, linens, and single-service and single-use articles. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize the potential for contaminating food and surrounding surfaces and objects.

Hair Restraints **2-402.11 Effectiveness.**

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

Animals **2-403.11 Handling Prohibition.**

Dogs and other animals, like humans, may harbor pathogens that are transmissible through food. Handling or caring for animals that may be legally present is prohibited because of the risk of contamination of food employee hands and clothing.

Chapter 3 Food

Condition **3-101.11 Safe, Unadulterated, and Honestly Presented.**
Sources **3-201.11 Compliance with Food Law.**

Refer to the public health reason for § 3-401.11.

Source

A primary line of defense in ensuring that food meets the requirements of § 3-101.11 is to obtain food from approved sources, the implications of which are discussed below. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consumers should exercise vigilance in controlling the conditions to which foods are subjected and be alert to signs of abuse. FDA considers food in hermetically sealed containers that are swelled or leaking to be adulterated and actionable under the

Federal Food, Drug, and Cosmetic Act. Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential hazard.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of farm animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals.

Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or in an undercooked state and thus receive neither heat treatment nor any other process that would destroy or inactivate microbial pathogens. For safety, these foods must be accompanied by cer`tification that documents that they have been harvested from waters that meet the water quality standards contained in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also provides confidence that processing, packaging, and shipping have been conducted under sanitary conditions.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

Labeling - General

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In addition, consumers have a basic right to be protected from misbranding and fraud.

Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. Labeling should accompany the product to advise as to whether the product was frozen properly. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Fish

Except for raw molluscan shellfish, certain species of large tuna, certain aquacultured fish, and fish eggs that have been removed from the skein and rinsed, if fish are intended for raw or undercooked consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. Labeling or other information should accompany the product to advise as to whether the product was frozen properly. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Juice

On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products. FDA expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume such juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these juices.

On July 18, 2001 FDA announced a final rule designed to improve the safety of fruit and vegetable juice and juice products. Under the rule, juice processors must use Hazard Analysis and Critical Control Point (HACCP) principles for juice processing. Processors making shelf-stable juices or concentrates that use a single thermal processing step are exempt from the microbial hazard requirements of the HACCP regulation. Retail establishments where packaged juice is made and only sold directly to consumers (such as juice bars) ae not required to comply with this regulation.

Rather, the Food Code requires fresh fruit or vegetable juices that are packaged at retail (untreated juices or beverages containing untreated juices that are offered to consumers as prepackaged foods) to be processed under HACCP with a 5 log reduction in pathogens of concern OR bear the warning statement as specified in 21 CFR Section 101.17(g). That statement is: “WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the eldersly, and persons with weakened immune systems.” Refer to Chapter 1 for the definition of juice. It is important to note that the definition of "juice" includes puréed fruits and vegetables, which are commonly prepared for service to highly susceptible populations.

Food establishments that serve a highly susceptible population (HSP) cannot serve prepackaged juice that bears the warning label and they must serve only pasteurized juice. For juice only, this population includes children who are age 9 or less and receive food in a school, day care setting, or similar facility that provides custodial care.

Unpackaged juice (glasses of juice prepared at a juice bar, for example) does not require the 5 log reduction nor a warning statement or other consumer advisory (juice is not an animal food and therefore not covered by section 3-603.11) when prepared and served at retail. Usually the juice is served by the glass or in small batches compared to a commercial juice processor. The risk of using "drops" and damaged fruits or vegetables is much less at retail because of buyer specs that provide higher quality produce, meaning that fruits for juicing are less likely to be of a lower quality or damaged.

Additional information is available in the document, "Guidance for Industry: Exemptions from the Warning Label Requirement for Juice - Recommendations for Effectively Achieving a 5-Log Pathogen Reduction; Final Guidance", October 7, 2002 which can be found at: ***http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm058962.htm*** or obtained from the FDA Office of Nutritional Products Labeling and Dietary Supplements.

Labeling for Meat and Poultry

Retail food establishments that process and package meat or poultry in a form that is not ready-to-eat, are obligated by Federal regulation to label the product with safe food handling instructions. The intent of this requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that handles only prepackaged and prelabeled products or if they obtain their meat or poultry at an operation such as a supermarket with a meat processing operation or from a small neighborhood butcher.

Labeling Guidance for Irradiated Raw Meat and Meat Products

In December 1999, the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) issued a final regulation to permit the use of ionizing radiation to reduce foodborne pathogens, including *Escherichia coli O*157:H7, and extend the shelf life of raw refrigerated and frozen meat and meat products (Irradiation of Meat Food Products 64 *Federal Register* 72150, December 23, 1999).

The final regulations are published in Title 9 of the Code of Federal Regulations (9 CFR 424.21 Use of food ingredients and sources of radiation and provide that raw refrigerated products may receive a maximum absorbed dose of no more than 4.5 kGy,

and that frozen product receive no more than 7.0 kGy, in accordance with the FDA restrictions provided for in Title 21 of the Code of Federal Regulations (21 CFR 179.26(a) Ionizing radiation for the treatment of food, (a) Energy sources). The regulations further require that all irradiated meat and meat products bear labeling that reflects that the product was irradiated, or that the product contains an irradiated meat or poultry product. This labeling requirement is applicable even at retail facilities where irradiated coarse ground beef might be finely ground for retail sale, or in cases where irradiated product is combined with other non-irradiated meat or poultry product for retail sale.

In cases where the entire package of product is irradiated, the labeling must include both a statement and the international symbol, called the radura. Additionally, the product name must include the word “irradiated,” or the labeling must bear a disclosure statement such as, “treated with radiation” or “treated by irradiation.” If either statement is used, the logo must be placed in conjunction with the statement. If an irradiated meat or meat product is used to formulate a multi-ingredient product with other non-irradiated components, the irradiated meat ingredient must be identified as such in the ingredients statement, but the logo is not required. For example, the ingredients statement for a Chicken and Beef Sausage product that contains irradiated beef would be, Ingredients: chicken, irradiated beef, seasonings (salt, pepper, spice), and the logo would not be required to be present.

All labels for products produced at federally inspected establishments bearing statements about irradiation must be submitted to USDA/FSIS for evaluation and approval prior to use.

Optional labeling statements about the purpose of the irradiation process may be included on the labeling of irradiated products provided they are not false or misleading and have been evaluated first by USDA/FSIS. If such statements indicate a specific benefit from irradiation, such as a reduction of microbial pathogens, such statements must be substantiated by processing documentation and validated through the processing and Hazard Analysis and Critical Control Point (HACCP) system. Such validation and documentation of the HACCP system would only be applicable in federally inspected establishments.

Because irradiation can substantially reduce and, in some situations, eliminate any detectable level of pathogenic bacteria, it is important that the meat products be held at the proper refrigerated temperatures to prevent growth of any pathogens present, and that the packaging is not compromised. Although co-mingling irradiated beef with non-irradiated meat or poultry is not prohibited under the current regulations, USDA/FSIS believes that such a process would decrease the benefit of irradiation by potentially exposing the irradiated product to pathogenic bacteria. While FSIS considers such comingling to be highly unlikely, if it did occur, a statement advising the consumer that the product contains both irradiated and non-irradiated components would be required.

The Radura, International Symbol:

Further information about labeling irradiated raw meat is available through Directive 7700.1, Irradiation of Meat and Poultry Products, on the USDA/FSIS website at http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/7700-1.htm. Irradiation Questions & Answers can be found at http://www.fsis.usda.gov/oppde/larc/policies/iradqa.pdf.

Labeling for Raw Shell Eggs

The Code of Federal Regulations 21 CFR 101.17 **Food Labeling warning, notice, and safe handling statements**, paragraph (h) *Shell* eggs state in subparagraph (1), "The label of all shell eggs, whether in intrastate or interstate commerce, shall bear the following statement: 'SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria; keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.'" Further, in subparagraph (4) it states, "Shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (h) of this section."

Labeling for Whole-muscle, Intact Beef Steaks

In order for a food establishment operator to know that a steak is a whole-muscle, intact cut of beef that can therefore be undercooked and served without a consumer advisory, the incoming product must be labeled. Processors can accommodate this need at the retail level by developing proposed labels, obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately affixing the labels to their products.

Refer also to public health reason for § 3-602.11.

3-201.12 Food in a Hermetically Sealed Container.

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of ***Clostridium botulinum***, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is

canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.13 Fluid Milk and Milk Products.

Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as Shiga toxin-producing ***Escherichia coli***, ***Salmonella*** spp., and ***Listeria monocytogenes***, and provides a rich medium for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. Dairy products are normally perishable and must be received under proper refrigeration conditions.

3-201.14 Fish.

After December 18, 1997, all processors of fish are required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.

The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family **Scombridae**, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow the growth of mesophilic bacteria.

Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large predatory fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

RECREATIONALLY CAUGHT FISH

Recreationally caught fish received for sale or service may be approved by the regulatory authority. The EPA recognizes that fish are a healthy part of our diet and recognizes fishing as an all-American recreational pastime, however, they add the cautionary note that some individuals, such as pregnant women and small children, may need to limit their intake of certain noncommercial fish. Recreationally caught fish may contain possible contaminants that may pose health risks. Fish advisories can be found in EPA Listing of Fish Advisories the EPA website at: http://www.epa.gov/waterscience/fish/.

States issue fish consumption advisories if elevated concentrations of chemicals such as mercury or dioxin are found in local fish. For most people, the risk from mercury by eating fish is not a health concern. Yet, some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system. Therefore, the FDA and the EPA recently advised women who may become pregnant, pregnant women, nursing mothers, and young children to avoid some types of fish and eat fish and shellfish that are lower in mercury. (http://www.epa.gov/waterscience/fishadvice/advice.html).

State-issued advisories apply primarily to non-commercial fish obtained through sport, recreation, and subsistence activities. Each advisory is different; it may recommend unrestricted, limited, or totally restricted consumption; may be targeted to everyone or limited to women, children, or other people at risk; and may apply to certain species or sizes of fish or a specific waterbody.

States may issue safe-eating guidelines in addition to issuing fish advisories. A fish advisory is issued to warn the public of the potential human health risks from chemical contamination of certain species from particular types of waterbodies such as lakes, rivers, and/ or coastal waters within the State. In contrast, a safe-eating guideline is issued to inform the public that fish from specific waterbodies have been tested for chemical contaminants and the fish from these waters are safe to eat without consumption restrictions.

Regulatory authorities are encouraged to monitor and review the National Listing of Fish Advisories (See August 2004 EPA Fact Sheet at http://www.epa.gov/waterscience/fish/advisories/factsheet.pdf as well as the local listings, as part of the decision-making process regarding the approval of recreationally caught fish being used in food establishments.

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.

3-201.16 Wild Mushrooms.

Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous, whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper cooking.

Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. In most parts of the country there is at least one organization that include individuals who can provide assistance with both identification and program design. Governmental agencies, universities, and mycological societies are examples of such groups. If a food establishment chooses to sell wild mushrooms, management must recognize and address the need for a sound identification program for providing safe wild mushrooms.

Regulatory authorities have expressed their difficulty in determining what constitutes a "wild mushroom identification expert" and enforcing the Food Code provisions associated with it. In 1998, the Conference for Food Protection (CFP) attempted to alleviate this problem through the formation of a committee that was charged with determining what constitutes a wild mushroom expert. However, the committee was unable to provide this information in a practical, useful manner for State and local regulators within the constraints of the Food Code. The 2000 CFP recommended and FDA accepted the committee's alternative solution that a brochure be developed that will provide information on what constitutes a wild mushroom expert, and to replace "identification by a wild mushroom expert" with "written buyer specifications."

The CFP's recommendation attempts to provide the necessary information in a practical, useful manner for all stakeholders, and yet still convey the highest level of public health protection. The CFP committee suggested that written buyer specifications place more responsibility on the food establishment to ensure that wild mushrooms are obtained from a safe source, and also provides State and local regulators a template to use in ensuring wild mushrooms sold at retail are obtained from a safe source.

However, the recommendation for written buyer specifications will not replace Food Code paragraph 3-201.16(A) until the brochure is developed and accepted by the CFP and FDA. In the interim, the following guidance is provided regarding the identification of wild mushrooms:

A food establishment that sells or serves mushroom species picked in the wild shall have a written buyer specification that requires identification of:

(1) The Latin binomial name, the author of the name, and the common name of the mushroom species,
(2) That the mushroom was identified while in the fresh state,
(3) The name of the person who identified the mushroom,
(4) A statement as to the qualifications and training of the identifier, specifically related to mushroom identification.

Additional information can be found on the California Poison Control web site: http://www.calpoison.org/

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.17 Game Animals.

The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the

human host. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

Specifications for Receiving **3-202.11 Temperature.**

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. USDA published a final rule (63 FR 45663, August 27, 1998 Shell Eggs; Refrigeration and Labeling Requirements) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2ºC (45ºF).

High temperatures for a long enough time, such as those associated with thorough cooking, kill or inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced in foods by certain bacteria (such as the enterotoxins of ***Staphylococcus aureus***). Cooking or hot holding that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the Code prevents significant regrowth of heat-injured microorganisms and prevents recontamination with bacteria that are newly introduced.

3-202.12 Additives.

It is imperative for safety that food supplies come from sources that are in compliance with laws regarding chemical additives and contaminants.

Food additives are substances which, by their intended use, become components of food, either directly or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved application, additives may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for these chemicals are determined by risk assessment evaluations based on toxicity studies and consumption estimates.

Food and Color additives must be used in compliance with a federal food, or color additive regulation, an effective food-contact notification, or a threshold of regulation exemption. Such regulations, notifications, and exemptions are generally composed of three parts: the *identity* of the substance, *specifications* including purity or physical properties, and *limitations* on the conditions of use. In order for a food, or color additive use to be in compliance, the use must comply with all three criteria.

Federal Food Additive regulations are found in Title 21 CFR, Parts 172-180. Color additive regulations are found in Title 21 CFR Parts 73-Subpart A, 74-Subpart A, 81 and 82. Effective food-contact notifications are listed at http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm

116567.htm, and threshold of regulation exemptions are listed at http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm093685.htm.

Other substances that are added to food include those prior sanctioned for use in food by either the FDA or USDA, or those generally recognized as safe for their intended use in food. Some of these are listed in Title 21 CFR Parts 181-186, Title 9 CFR Section 424.21(b) and at http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm. Tolerances and exemptions from tolerance for pesticide chemical residues in or on food are found in Title 40 CFR Part 180. Substances that are prohibited form use in human food are listed in Title 21 CFR Part 189.

3-202.13 Eggs.

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

The Definition of "Restricted Egg" contains several terms that are explained in this paragraph. An egg may be restricted because it is a/an:

(i) "Check" meaning an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

(ii) "Dirty egg or Dirties" meaning an egg that has a shell that is unbroken and has adhering dirt, foreign material, or prominent stains.

(iii) "Incubator reject" meaning an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.

(iv) "Inedible" meaning eggs of the following descriptions: Black rots, yellow rots, white rots, mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

(v) "Leaker" meaning an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.

(vi) "Loss" meaning an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

On December 5, 2000 Federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inappplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs…
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

The labeling rule became effective September 4, 2001, and the refrigeration rule became effective June 4, 2001. These rules are one part of a larger farm-to-table approach for ensuring the safety of our nation's egg supply. The public health goal is a 50 percent reduction in all salmonellosis and a 50 percent reduction in ***Salmonellae* Enteritidis** illnesses by 2010.

3-202.14 Eggs and Milk Products, Pasteurized.

Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in these potentially hazardous foods (time/temperature control for safety foods). Freezing and drying of unpasteurized products will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.

3-202.15 Package Integrity.

Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the contained food. If the integrity of the packaging has been compromised, contaminants such as ***Clostridium botulinum*** may find their way into the food. In anaerobic conditions (lack of oxygen), botulism toxin may be formed.

Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods. Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many cases, suspect packaging may have to be inspected by trained persons using magnifying equipment. Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate

that not enough heat was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

3-202.16 Ice.

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that comes into contact with food to cool it or that is used directly for consumption must be as safe as drinking water that is periodically tested and approved for consumption.

3-202.17 Shucked Shellfish, Packaging and Identification.

Plastic containers commonly used throughout the shellfish industry for shucked product bear specific information regarding the source of the shellfish as required by the NSSP Guide for the Control of Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their subsequent reuse by shellfish packers which could result in shucked product that is inaccurately identified by the label. The reuse of these containers within the food establishment must be assessed on the basis of the Food Code's criteria for multi-use containers and the likelihood that they will be properly relabeled to reflect their new contents.

3-202.18 Shellstock Identification.

Accurate source identification of the harvesting area, harvester, and dealers must be contained on molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the information is available to expedite the epidemiological investigation and regulatory action.

3-202.19 Shellstock, Condition.

Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility continues throughout the distribution chain.

3-202.110 Juice Treated.

Refer to public health reason for § 3-801.11.

Original Containers and Records

3-203.11 Molluscan Shellfish, Original Container.

Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. Proper identification is needed for tracing the origin and determining conditions of shellfish processing and shipment. If the lots are commingled

at retail, traceability is undermined and the root of the problem may remain undetected. If no causative factors are identified in the food establishment, tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that may need to be closed to harvesting.

When shucked shellfish are prepackaged in consumer self service containers, the labeling information as specified under section 3-202.17 must be recorded on a log sheet to correlate with the date of sale of the consumer sized containers.

3-203.12 Shellstock, Maintaining Identification.

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light. The 90 day requirement is based on the following considerations:

Shelf-life of the product	14 days
Incubation period	56 days
Medical diagnosis and confirmation	5 days
Reporting	5 days
Epidemiological investigation	10 days
Total	90 days

In reality and as stated in the provision, the 90-day “clock” starts at the time the container of shellstock is emptied. Starting from the date of harvest is not correct because the shellstock may be sold/consumed in less than the 14 days of shelf life cited in the chart above. Therefore, the 90 days may expire and the tag discarded before an illness is reported and investigated.

Shellstock could be frozen in the food establishment during the 14-day estimated shelf life period, which would effectively stop the clock on the shelf life. The shellstock could be thawed and consumed past the 14-day shelf life. In this case, the 90 days would expire before consumption if the clock started 90 days from the harvest date.

Freezing shellstock in the food establishment is not usually done because, although oysters-in-the-shell can be frozen with fair results, they do not have the same texture and appearance of a fresh oyster when thawed. Commercially frozen oysters are frozen rapidly to retain product quality.

Preventing Contamination by Employees **3-301.11 Preventing Contamination from Hands.**

In November 1999, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) concluded that bare hand contact with ready-to-eat foods can contribute to the transmission of foodborne illness and agreed that the transmission could be interrupted. The NACMCF recommended exclusion/restriction of ill food workers as the first preventative strategy and recognized that this intervention has limitations, such as trying to identify and manage asymptomatic food workers.

The three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral route, identified by the NACMCF, include exclusion/restriction of ill food workers; proper handwashing; and no bare hand contact with ready-to-eat foods. Each of these factors is inadequate when utilized independently and may not be effective. However, when all three factors are combined and utilized properly, the transmission of fecal-oral pathogens can be controlled. Depending on the microbial contamination level on the hands, handwashing with plain soap and water, as specified in the Food Code, may not be an adequate intervention to prevent the transmission of pathogenic microbes to ready-to-eat foods via hand contact with ready-to-eat foods. Handwashing as specified in the Food Code will reduce microbial contamination of the hands by 2-3 logs.

Food employees and conditional employees infected with fecal-oral pathogens can shed viral and protozoan pathogens in the feces at levels up to 10^8 viral particles or oocysts per gram of feces. Having a high potential contamination level on the hands combined with a very low infectious dose necessary to cause infection are the reasons that FDA believes that handwashing alone is not an effective single barrier in the transmission of these fecal-oral pathogens. The infective dose for ***Giardia*** and ***Cryptosporidium*** is believed to be as low as 1-10 oocysts, and as few as 10 virus particles can infect an individual with Norovirus or hepatitis A.

The CDC now estimates that Norovirus is the leading cause of foodborne illness in the United States. Contaminated hands are a significant factor in the transmission of enteric viruses, including Norovirus and hepatitis A virus. Further, contamination of food by an infected food worker is the most common mode of transmission of hepatitis A in foodborne disease outbreaks. Research has shown the viral transfer rate from contaminated hands to ready-to-eat food to be about 10% and that proper handwashing will significantly reduce the chance of transmitting pathogenic viruses. However, with heavy initial contamination of the hands, especially in the subungal space of the fingers, a basic 2-3 log reduction handwash procedure may not be adequate to prevent the transmission of viral foodborne illness.

Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

Refer to the public health reasons for §§ 2-301.11, 2-301.12, and 2-301.14.

3-301.11(D) Prior Approval for Food Employees to Touch Ready-to-Eat Food with Bare Hands

Infected food employees are the source of contamination in approximately one in five foodborne disease outbreaks reported in the United States with a bacterial or viral cause.[1] Most of these outbreaks involve enteric, i.e., fecal-oral agents. These are organisms that employees were shedding in their stools at the time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in contamination of food. Viral, bacterial, and parasitic agents can be involved.

Traditionally, food regulations have required two methods of preventing the spread of foodborne disease by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral transmission interventions, the Food Code provides focused and specific guidance about ill workers and when handwashing must occur. As a final barrier, bare-hand contact with ready-to-eat food (i.e., food that is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be used. Any alternative to this requirement must convincingly address how food employees will be managed to preclude food contamination and how management will ensure that thorough handwashing occurs after employees use the toilet.

Because highly susceptible populations include persons who are immunocompromised, the very young and elderly, establishments serving these populations may not use alternatives to the no bare hand contact with ready-to-eat food requirement.

Acceptability of an alternative procedure to no bare hand contact requires prior approval from the regulatory authority based on the food establishment having a written employee health policy that details how the establishment complies with management of ill employees as specified under sections 2-201.11 - .13 and management of handwashing practices as specified under Part 2-3 of the Code. The approval should also be based on evidence provided through written procedures and documentation that at least all of the following are addressed:

1 Based on CDC Summary Surveillance for Foodborne-Disease Outbreaks – United States, 1988-1992 and New York State Department of Health data 1980-1991 published: Weingold, Guzewich, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

(A) **Personal Cleanliness, i.e., handwashing** procedures, including frequency and methodology of handwashing that ensure food employees keep their hands and fingertips clean and handwashing occurs at the times specified in section 2-301.14, including after using the toilet and between tasks that may recontaminate the hands.

(B) **Hygienic Practices** as specified in Part 2-4.

(C) **Employee Health** regarding:

(1) **Reporting of diseases and medical conditions,** and

(2) **Exclusions and restrictions,** i.e., that food employees and conditional employees report their health status as specified in section 2-201.11; ill food employees are restricted or excluded as specified in section 2-201.12; and the exclusions and restrictions are removed as specified in section 2-201.13;

(D) **How the alternative practices and procedures will control the hazard through an active managerial control program.** Such a program includes monitoring and verifying the institution of the provisions described in paragraphs A-C above and satisfies the following:

(1) The public health hazard associated with bare hand contact specific to the food establishment operation is identified and understood. The regulatory authority needs assurance that the permit holder recognizes that the hazard being addressed is the possible contamination of ready-to-eat food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.

(2) The ready-to-eat foods that will be contacted with bare hands are identified and both procedures and practices are in place so that food employees wash their hands before returning to their work station and cross-contamination from touching raw and ready-to-eat food is precluded.

For example, identifying the specific type of food to be prepared, such as tacos, and the specific location, such as a situation where a food employee is assigned solely to the designated taco work station. The work station is located immediately adjacent to the taco assembly unit and the employee will be preparing only the specified ready-to-eat food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of ready-to-eat foods.

(3) Institution of an effective training program for food employees that emphasizes not working when ill with any of the gastrointestinal symptoms listed in the Code, and explains good hygienic practices, proper handwashing

procedures, and safe food preparation procedures. This should include a documented training plan that specifies how management responsibility for training has been designated, training program content, and the frequency of administration including periodic refresher sessions.

(E) The alternative procedure should clearly describe monitoring, documentation, and verification actions to ensure that the practices and procedures are followed. Corrective actions need to be predetermined for situations where the practices and procedures are not followed, e.g., an ill employee is found preparing foods.

(F) Documentation of the practices, procedures, and corrective actions related to an alternative to no bare hand contact with ready-to-eat food must be maintained and readily available at the food establishment at all times for use by the person in charge and for review by the regulatory authority.

Preventing Food and Ingredient Contamination

3-302.11 Packaged and Unpackaged Food – Protection Separation, Packaging, and Segregation.

With regard to the storage of raw animal foods as specified under subparagraph 3-302.11(A)(2), it is the intent of this Code to require separation based on anticipated microbial load and raw animal food type (species). Raw animal foods shall be separated based on a succession of cooking temperatures since cooking temperatures as specified under § 3-401.11 are based on thermal destruction data and anticipated microbial load. For example, to prevent cross-contamination, fish and pork, which are required to be cooked to an internal temperature of 145°F for 15 seconds, shall be stored above or away from raw poultry, which is required to be cooked to an internal temperature of 165°F for 15 seconds due to its considerably higher anticipated microbial load. In addition, raw animal foods having the same cooking temperature, such as pork and fish, shall be separated from one another during storage and preparation by maintaining adequate spacing or by placing the food in separate containers because of the potential for allergen cross-contamination or economic adulteration via inadvertent species substitution. An exception is permitted for frozen, commercially packaged raw animal food to be stored or displayed adjacent to or above frozen, commercially packaged ready-to-eat food. The freezer equipment should be designed and maintained to keep foods in the frozen state. Corrective action should be taken if the storage or display unit loses power or otherwise fails. Raw or ready-to-eat foods or commercially processed bulk-pack food that is packaged on-site presents a greater risk of cross-contamination. Additional product handling, drippage during the freezing process, partial thawing or incomplete seals on the package increase the risk of cross-contamination from these products packaged in-house.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment

stored in close proximity or by persons delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.

Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because the virulent organism ***Salmonella*** **Enteritidis** may be present in raw shell eggs. Pasteurized eggs provide an egg product that is free of pathogens and is a ready-to-eat food. The pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

3-302.14 Protection from Unapproved Additives.

Refer to the public health reason for § 3-202.12.

Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a variance and to Annex 6 Food Processing Criteria which addresses the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

3-302.15 Washing Fruits and Vegetables.

Pathogenic microorganisms, such as *Salmonella* spp., and chemicals such as pesticides, may be present on the exterior surfaces of raw fruits and vegetables. It has been assumed that washing removes the majority of organisms and/or chemicals present, however, more recent studies have demonstrated washing to fall short of their complete removal. Biofilm development by *Salmonella* allows bacterial cells to survive under adverse environmental conditions and also reduces the ability to remove pathogens by washing, even with antimicrobial agents. All fresh produce, except commercially washed, pre-cut, and bagged produce, must be thoroughly washed under running, potable water 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.

Infiltration of microorganisms can occur through stem scars, cracks, cuts or bruises in certain fruits and vegetables during washing. Once internalized, bacterial pathogens cannot be removed by further washing or the use of sanitizing solutions. To reduce the likelihood of infiltration, wash water temperature should be maintained at 10°F warmer than the pulp temperature of any produce being washed. Because certain fruits and vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is recommended that soaking or submerging produce during cleaning be avoided. It is important that proper handwashing procedures are followed, in accordance with Section 2-301.12 (F) Cleaning Procedure, before and after handling fresh produce.

Scrubbing with a clean brush is only recommended for produce with a tough rind or peel, such as carrots, cucumbers or citrus fruits, that will not be bruised easily or penetrated by brush bristles. Scrubbing firm produce with a clean produce brush and drying with a clean cloth towel or fresh disposable towel can further reduce bacteria that may be present. Washing fresh fruits and vegetables with soap, detergent or other surfactants should be avoided as they facilitate infiltration and may not be approved for use on food. Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations. Unless otherwise stipulated in 21 CFR 173.315, chemicals used to wash or peel fruits and vegetables should not exceed the minimum amount required to accomplish the intended effect, need to be accurately tested for proper concentration, and must adhere to any indications as dictated on the product label.

Many pre-cut, bagged produce items are pre-washed. If so, these products will be identified as such on the package label, and can be used as ready-to-eat without further washing. The label should also state if further washing is recommended or necessary. Precut or prewashed produce in open bags should be washed before use. After being cut, certain produce such as melons, leafy greens and tomatoes are considered potentially hazardous food (PHF) requiring time/temperature control for safety (TCS) and should be refrigerated at 41°F or lower to prevent any pathogens that may be

present from multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and other produce, you may consult the FDA Program Information Manual, Retail Food Protection Storage and Handling of Tomatoes, dated October 5, 2007, available at http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm and Recommendations to Food Establishments for Serving or Selling Cut Leafy Greens, available at http://www.fda.gov/RetailFoodProtection.

On October 26, 1998 a voluntary guidance document for the produce industry which addresses microbial hazards and good agricultural and management practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents and was updated on August 19, 2003. This "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables", October 26, 1998, is available from FDA's Food Safety Initiative staff and also on the Internet at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm.

Additionally, in February 2008, the FDA Center for Food Safety and Applied Nutrition (CFSAN) issued "Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables," which covers fresh-cut fruits and vegetables that have been minimally processed (e.g. no kill step) and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. This guide is available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm.

On January 11, 2006 FDA/CFSAN published additional safe handling advice on the purchase, storage, and preparation of fresh produce, as well as Q & A's for consumers on their website at: http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm114299.htm. This document is available in PDF (3.5 MB) format (also available in Spanish) and provides additional information on the cleaning of fresh produce.

Preventing Contamination from Ice Used as a Coolant

3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

3-303.12 Storage or Display of Food in Contact with Ice and Water.

Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

Preventing Contamination From Equipment, Utensils, and Linens

3-304.11 Food Contact with Equipment and Utensils.

Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

Probe-type price or identification tags are defined as a utensil. This means that if such tags are for multiuse, they must meet the criteria listed in Parts 4-1 Materials for Construction and Repair, and 4-2 Design and Construction. Probe-type price or product identification tags can cause microbial, chemical, or physical contamination if not properly designed, constructed, and maintained.

The Food Code defines gloves as a "utensil" and therefore gloves must meet the applicable requirements related to utensil construction, cleaning, and storage.

3-304.12 In-Use Utensils, Between-Use Storage.

Refer to the public health reason for § 3-304.11.

Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils may be safely stored in hot water maintained at 135°F or above during intermittent use because microbial growth is controlled at such temperatures.

A food utensil should be designed and used to prevent bare hand contact with ready-to-eat food or to minimize contact with food that is not in a ready-to-eat form. On-site evaluations can be made to determine if a utensil is improperly designed for the task or whether a food employee is misusing an appropriately designed utensil.

3-304.13 Linens and Napkins, Use Limitation.

Because of their absorbency, linens and napkins used as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

3-304.14 Wiping Cloths, Use Limitation.

Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution at all times, with the proper sanitizer concentration in the solution. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with an appropriate chemical test kit.

3-304.15 Gloves, Use Limitation.

Refer to the public health reason for § 3-304.11.

Gloves used in touching ready-to-eat food are defined as a "utensil" and must meet the applicable requirements related to utensil construction, good repair, cleaning, and storage.

Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat food or may indirectly contaminate food if stored with articles that will be used in contact with food. Multiuse gloves must be washed, rinsed, and sanitized between activities that contaminate the gloves. Hands must be washed before donning gloves. Gloves must be discarded when soil or other contaminants enter the inside of the glove.

Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could contaminate the food.

Natural Rubber Latex (NRL) Gloves

Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves (refer to Annex 2, 3-304.15). This information should be taken into consideration when deciding whether single-use gloves made of latex will be used during food preparation.

Although many allergic reactions occur as a result of occupational exposure, CFSAN is actively reviewing its current policy on the use of disposable NRL gloves in food operations in light of the possible transmission of the latex protein via food. To gain additional information regarding allergic reactions allegedly due to the ingestion of food contaminated by NRL in retail settings, CFSAN has been collecting reports of such reactions from consumers who have contacted the Agency. Several offices within CFSAN will continue to collaborate in reviewing incoming data. The results of these activities and other related efforts will be used to determine if policy changes regarding the use of latex in food operations, based on food safety considerations, are warranted. The FDA, Office of Food Additive Safety, Division of Food Contact Notification, reviews gloves submitted for food-contact use in the food industry on the basis of the glove's formulation or components. FDA regulates NRL gloves used for medical purposes only. FDA is aware of the following information related to occupational hazards (not food safety hazards) associated with the use of NRL gloves:

- The National Institute for Occupational Safety and Health (NIOSH) published a 1997 Alert titled "Preventing Allergic Reactions to Natural Rubber Latex in the Workplace" (NIOSH publication number 97-135) which is found at http://www.cdc.gov/niosh/latexalt.html.

- The American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy Asthma and Immunology (AAAAI) issued a joint statement discouraging the routine use of NRL gloves by food handlers. (1997) http://www.acaai.org/public/physicians/joint.htm.

  The AAAAI provides information on latex allergies on the web at http://www.aaaai.org/patients/allergic_conditions/latex_allergy.stm.

The ACAAI provides information on latex allergies on the web at http://www.acaai.org/public/facts/latex.htm.

- An OSHA Technical Information Bulletin recommends reducing allergy potential by reducing unnecessary exposure to NRL. Stating "Food service workers ... do not need to use NRL gloves for food handling..." (1999) http://www.latexallergylinks.org/LA-TIB.html.

OSHA addresses gloves in the following Federal regulation, which can be found at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9788.

OSHA Regulations (Standards - 29 CFR)
Standard Number: 1910.138
Standard Title: Hand Protection.
SubPart Number: I
SubPart Title: Personal Protective Equipment

(a) General requirements. Employers shall select and require employees to use appropriate hand protection when employees' hands are exposed to hazards such as those from skin absorption of harmful substances; severe cuts or lacerations; severe abrasions; punctures; chemical burns; thermal burns; and harmful temperature extremes.

(b) Selection. Employers shall base the selection of the appropriate hand protection on an evaluation of the performance characteristics of the hand protection relative to the task(s) to be performed, conditions present, duration of use, and the hazards and potential hazards identified.

3-304.16 Using Clean Tableware for Second Portions and Refills.

Refer to the public health reason for § 3-304.11.

3-304.17 Refilling Returnables.

Refer to the public health reason for § 3-304.11.

Preventing Contamination from the Premises

3-305.11 Food Storage.

3-305.12 Food Storage, Prohibited Areas.

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

3-305.13 Vended Potentially Hazardous Food (Time/Temperature Control for Safety Food), Original Container.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended potentially hazardous food (time/temperature control for safety food) allows microbes that may be present an opportunity to contaminate the food. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, many potentially hazardous foods (time/temperature control for safety foods) are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

3-305.14 Food Preparation.

Food preparation activities may expose food to an environment that may lead to the food's contamination. Just as food must be protected during storage, it must also be protected during preparation. Sources of environmental contamination may include splash from cleaning operations, drips form overhead air conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Food Code requirements.

Preventing Contamination by Consumers

3-306.11 Food Display.

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

3-306.12 Condiments, Protection.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On- or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

3-306.13 Consumer Self-Service Operations.

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

Bean sprouts that are displayed in produce areas for consumer self-service are potentially hazardous foods (time/temperature control for safety foods) and appropriate refrigeration must be maintained. However, they are not considered ready-to-eat since they are intended to be washed by the consumer before consumption.

3-306.14 Returned Food and Re-Service or Sale.

Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. Any unpackaged foods, even bakery goods in a bread basket that are not potentially hazardous (time/temperature control safety foods) and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

Preventing Contamination from Other Sources

3-307.11 Miscellaneous Sources of Contamination.

This Code section provides a category in which to capture sources of contamination not specifically delineated in Subparts 3-301 through 306. Codes prior to 1993 had such a provision for addressing food contamination for reasons other than those elsewhere

specified. Regardless of its specificity, a Code can not anticipate all the diverse means by which food can become contaminated after receipt.

Cooking	**3-401.11**	**Raw Animal Foods.**
	3-401.12	**Microwave Cooking.**
	3-401.13	**Plant Food Cooking for Hot Holding.**

Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the food's bulk which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise and the time the food must be held at a specified internal temperature.

Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these products.

To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 112 minutes after it has reached 54.4°C (130°F) is the same lethality attained as if it were cooked for 4 minutes after it has reached 62.8°C (145°F). Cooked beef and roast beef, including sectioned and formed roasts, chunked and formed roasts, lamb roasts and cooked corned beef can be prepared using one of the time and temperature combinations listed in the chart in § 3-401.11 to meet a 6.5-$\log_{10}$ reduction of Salmonella. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for a least the stated time. The source of the time and temperature parameters is from the USDA/FSIS Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at http://www.fsis.usda.gov/oa/fr/95033F-a.htm.

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of food aid thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

The temperature and time combination criteria specified in Part 3-4 of this Code are based on the destruction of *Salmonellae*. This organism, if present in raw shell eggs, is generally found in relatively low numbers. Other foods, uncomminuted fish and meats including commercially raised game animal meat, specified as acceptable for cooking at this temperature and time parameter are expected to have a low level of internal contamination. The parameters are expected to provide destruction of the surface contaminants on these foods. Part 3-4 includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at 63°C(145°F), a time span of 15 seconds will provide a 3D reduction of ***Salmonella*** **Enteritidis** in eggs.

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.

In consumer self-service operations, such as buffets, salad bars, sushi bars, or display cases, the consumer advisory as specified under section 3-603.11 must be posted or available at the self-service unit where the raw or partially cooked food is held for service and readily accessible to consumers prior to making their food selections. In a catered situation, such as a wedding reception, guests are responsible for making their own requests or selections.

Slow-cooked roasts - Heating Deviations and Slow Come Up Time

(Source: USDA/FSIS Appendix A Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at http://www.fsis.usda.gov/oa/fr/95033F-a.htm.

Heating deviations, which most often involve slow come-up time or an inordinate dwell time within the optimum temperature range for microorganism growth can foster the multiplication of many pathogens. This multiplication sometimes can be so prodigious that even recooking may be ineffective in rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of these toxins, such as those of ***Staphylococcus aureus***, are extremely heat stable and are not inactivated by normal recooking temperatures.

Further, the sampling of product following a heating deviation may not yield sufficient information to determine the safety of the product in question. Heating deviations can favor the multiplication of many types of bacteria. It would be difficult and expensive to sample for all of them. Depending on the circumstances, establishments may want to use computer modeling to estimate the relative multiplication of bacteria. For example,

in a past incident involving an extreme heating deviation, product was put in an oven in which the temperature was inadvertently set to 95°F for about 12 hours. Computer modeling was easily applied in this case because much of the dwell time was at one temperature. The USDA/FSIS determined that within a 6-hour time frame (with other growth conditions assumed to be favorable), the relative multiplication of many pathogens of concern could have exceeded 5-logs. Clearly the product could not be salvaged by reprocessing and was therefore destroyed. Under changing conditions of temperature, however, computer modeling becomes more difficult. One approach is to average lag/log times over small increments such as 5° and add these times to get an approximation of possible total relative growth over a larger increment of time. Establishments must keep in mind that the population of bacteria before processing is generally unknown and that assumptions in the high range often are used as input parameters in the modeling.

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and USDA. Paragraph 3-401.11(C) includes their recommendations.

USDA comments included, “For the purposes of this discussion, steak is a whole beef muscle. It does not include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or Chateaubriand. Other species, such as poultry, pork, and lamb are not included.”

NACMCF comments included, “Due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 145°F to achieve a cooked color change on all external surfaces. The searing of all surfaces should be continuous until the desired degree of doneness and appearance are attained. This is considered a ready-to-eat food.”

As reflected in the definition of “whole-muscle, intact beef steak,” marination is a food safety concern when the fascia (exterior surface) of the steak is broken by scoring or other means which allows the marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Code allowance for undercooking without a consumer advisory is negated.

Pork

In pork, ***Trichinella spiralis***, ***Toxoplasma gondii***, and ***Taenia solium***, parasites causing foodborne illness, are inactivated at temperatures below 145°F. Therefore, pork roasts can be cooked like beef roasts (e.g., 145°F for 3 minutes) and pork chops cooked like steaks to achieve an internal temperature of 145°F for 15 seconds.

Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68°C (155°F) for 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program. Ratites such as ostrich, emu, and rhea are included in this list of raw animals foods because when cooked to a temperature greater than 68°C (155°F), ratites exhibit a (metallic) "off" taste.

When USDA established the time and temperature parameters for 9 CFR 318.23 Heat-Processing and Stabilization Requirements for Uncurred Meat Patties (known as the "patty rule"), the Agency based the 5D for Salmonella on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of Shiga toxin-producing ***Escherichia coli***. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

Temperature for Comminuted Meat at Less Than 1 Second

In the "Report of the Task Force on Technical Issues Arising from the National Advisory Committee on Microbiological Criteria for Foods" (NACMCF) Review of the Meat Patty Proposal" (undated), it is stated on page 7, in Option (A), that:

> "Based on the 1998 research data ... and an assumption that instantaneous is defined as eight seconds, manufacturers would be required to process fully-cooked meat patties at a temperature of 157°F. Given the lack of any significant margin of safety in this process, there should be no deviation below the 158°F requirement."

In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures for cooking hamburger and advised FDA that cooking hamburger to 158°F for less than one second is an adequate cook based on the following:

> 1. The cooking recommendations contained in the Food Code and in USDA guidance provide a large margin of safety for killing vegetative enteric pathogens;

2. The concept of integrated lethality (the kill imparted during the entire heating and cooling process) adds to the margin of safety; and

3. The time component of the time and temperature requirement will be exceeded before the temperature can be determined.

The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74°C (165°F) or above for 15 seconds yield greater than a 7D reduction.

Children's Menu

The 2005 FDA Food Code Section 3-401.11 (D) "Raw Animal Foods" allows operators to serve raw or partially cooked animal food items on their customer's request, as long as the establishment does not serve a "Highly Susceptible Population" and the customer is informed of the risks associated with consuming undercooked items.

The definition of "Highly Susceptible Population" however, only includes young children who are of pre-school age and who obtain food under custodial care (as from a child daycare center). This definition does not address pre-school and older children eating in retail food establishments (such as restaurants), where it is common practice to offer menu items intended for children (e.g. "Kids Menu").

The Food Code seeks to increase current protection of children beyond custodial care facilities and establish needed safeguards in all retail food establishments. The importance of this issue can be demonstrated for numerous combinations of raw animal foods and associated pathogens. The greatest impact on children however, is undercooked ground beef, where the specific organism of concern is *Escherichia coli* O157:H7.

Children are at relatively high risk for infection with *E.coli* O157:H7. It is possibly the leading cause of acute kidney failure and Hemolytic Uremic Syndrome (HUS) in children [10]. Infection with *E. coli* O157:H7 can result with mild to severe symptoms such as: non-bloody or bloody diarrhea to HUS, which is a condition that includes destruction of red blood cells, problems with blood clotting and kidney failure. About 2% to 20% of patients that are infected with *E. coli* O157:H7 develop HUS [6]. The risk of illness from *E. coli* O157:H7 in ground beef has been shown to be about 2.5 times higher for preschool children and infants than for the rest of the population [6]. The CDC has reported the following *E. coli* 0157:H7 infection rates per 100,000 by age range: 8.2 for young children 1-9 years old and 3.0 for older children 10-20 years of age [4].

Precluding undercooked foods from being offered on a children's menu may result in increased protection to children from foodborne illness, particularly *E. coli* O157:H7, which can result in severe consequences in children.

3-401.12 Microwave Cooking.

The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction of microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 74°C (165°F) in all parts of the food. Since cold spots may exist in food cooking in a microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed from the oven and then allow the food to stand covered for two minutes post microwave heating to allow thermal equalization and exposure. Although some microwave ovens are designed and engineered to deliver energy more evenly to the food than others, the important factor is to measure and ensure that the final temperature reaches 74°C (165°F) throughout the food.

"The factors that influence microwave thermal processes include many of the same factors that are important in conventional processes (mass of objects, shape of objects, specific heat and thermal conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of the electric field involved in causing molecular friction. These factors are exemplified by moisture and salt contents of foods, which play a far more important role in microwave than conventional heating." (Reference: Heddelson and Doores, see Annex 2)

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 57°C (135°F) prevents the growth of pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced over time at the specified hot holding temperature.

3-401.14 Non-Continuous Cooking of Raw Animal Foods.

Close attention must be paid to control of biological hazards when a food establishment cooks raw animal foods using a process in which the food is partially cooked then cooled with the expectation of fully cooking the food at a later date or time. Section 3-401.14 requires that establishments wishing to use a non-continuous process for the cooking of raw animal foods establish and follow a written plan that ensures each stage of the process is completed within time and temperature parameters that adequately prevent pathogen survival and growth. Section 3-401.14 also requires that establishments take special precautions to ensure that raw animal foods that have only been initially heated to temperatures that are not lethal to the pathogens of concern are clearly identified so that they will not be inadvertently sold or served to the consumer in a partially cooked state.

To ensure the food does not dwell for extended periods within temperature ranges that favor pathogen growth, § 3-401.14 establishes limits on the time permitted to initially heat the food (initial "come-up" time) and the time permitted to cool the product to temperatures that are safe for refrigerated storage. Together, these limits should prevent food from remaining at temperatures at which pathogen growth to harmful levels may occur.

The criteria in § 3-401.14 were developed with consideration of the United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) *Performance Standards for Partially Cooked and Char-Marked Meat Patties and Partially Cooked Poultry Breakfast Strips* found in 9 CFR 318.23 and 9 CFR 381.150. (http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr318.23.pdf, http://www.access.gpo.gov/nara/cfr/waisidx_08/9cfr381_08.html)

The maximum one hour time limit for the initial heating stage was established based on estimates from predictive microbial modeling. It is intended to limit the cumulative growth of *Clostridium perfringens* that may occur during the come-up time and the subsequent cooling of the product in accordance with the requirements in ¶ 3-501.14(A). Unless properly controlled, processes in which animal foods are heated to sub-lethal temperatures and times and then cooled may create an environment for the growth of ***Clostridium perfringens, Clostridium botulinum*** and other spore forming, toxigenic bacteria.

The product temperature achieved during the initial heating process may not be sufficient to destroy vegetative cells of ***Clostridium botulinum***, ***Clostridium perfringens***, and ***Bacillus cereus,*** if present. The concern is the generation of a large number of vegetative cells of ***Clostridium perfringens*** and/or ***Clostridium botulinum*** before the final cooking stage. For ***Clostridium botulinum***, if enough vegetative cells are produced, toxigenesis can occur in the product before the product is fully cooked. The toxin is not destroyed at the minimum required cooking temperatures. For ***Clostridium perfringens***, if a large number of vegetative cells are consumed, illness can result. In either case a high number of vegetative cells may challenge the lethality step of the ultimate cooking process to the extent that it will be unable to completely eliminate all of these vegetative cells. The cumulative growth of these bacterial pathogens must be taken into account during both the initial heating and cooling steps. The hazard may be compounded with an extended initial "come-up" time and/or a prolonged cooling stage. Hence the degree of hazard may be dependent upon the ultimate effect of the initial heating and cooling, as well as the final cooking step.

A full and adequate cook during the final cooking step is of critical importance to ensure destruction of any pathogens that may have survived and proliferated during any initial heating and cooling stages of the non-continuous cooking process. Section 3-401.14 requires that animal foods cooked by a non-continuous cooking process achieve a minimum final cook temperature that heats all parts of the food to a temperature of at least 74°C (165°F) for 15 seconds to ensure the destruction of vegetative microbial pathogens, no matter the size of the product. This provides for an additional safeguard

beyond the minimum cooking temperature required for many types of animal foods that are cooked using a continuous, uninterrupted process. This requirement also precludes serving animal foods that have undergone non-continuous cooking in an undercooked or raw state. In other words, animal foods cooked using a non-continuous process are not covered in the exceptions provided for in ¶ 3-401.11(D) that allow for serving undercooked animal foods upon consumer request and with an adequate consumer advisory.

Section 3-401.14 requires that an establishment using non-continuous cooking processes also establish procedures for identifying foods that have only been partially cooked and cooled. This is necessary to ensure these foods are not mistaken by food workers for foods that have been fully cooked and therefore ready-to-eat without a full cook. Partially cooked foods may appear to be fully cooked.

Requiring that food establishments obtain prior approval by the regulatory authority before employing non-continuous cooking processes will help to ensure that the establishment has the proper procedures in place, as well as the necessary facilities and capacity to monitor the appropriate cooling, cooking, separation and product identification of the foods. in accordance with the requirements

Freezing **3-402.11 Parasite Destruction.**

Refer to the public health reason for § 3-201.11.

Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

The recommended control strategies refer to the ambient air temperature during freezing and to the length of time that the fish is held at the appropriate freezer temperature, or the length of time that the fish is held after it is solid frozen, whichever it appropriate. The parasite hazard is not considered to be reasonably likely to occur if the finished product is fish eggs that have been removed from the skein (the tissue that contains the egg mass) and rinsed.

In response to information provided to the FDA Office of Seafood, the Fish and Fisheries Products Hazards and Controls Guidance lists certain species of tuna as not being susceptible to parasites of concern and therefore exempted from the freezing requirements that apply to other fish species that are consumed raw.

The Fish and Fisheries Products Hazards and Controls Guidance states that species that normally have parasites as a result of consuming infected prey, apparently do not have the same parasite hazard when raised on pelleted food in an aquaculture

operation. On the other hand, aquacultured fish that are fed processing waste and by-catch fish may have a parasite hazard, even when wild caught fish of that species do not normally have a parasite hazard. Feed must not contain any live parasites. For example, the use of fresh fish meat in feed could transmit such parasites. Only heat treated feed or feed otherwise produced in a manner that would kill parasite intermediate stages infective to the aquacultured fish, such as most pelleted feeds, should be used.

Additionally, it should be noted that the Fish and Fisheries Products Hazards and Controls Guidance, Edition 3, Table 3.1 only lists fish with well documented parasite hazards. Fish species in Table 3.1 that do not have specific parasite hazards listed are not necessarily safe when consumed raw or undercooked. This is because fish species in Table 3.1 were not listed with a parasite hazard if the species were generally cooked before consumption. In addition, in some cases, there is insufficient information or data to be able to denote a specific parasite hazard or deem the species as naturally parasite-free. The exemptions to freezing as specified in ¶ 3-402.11(B) of the *Food Code* are inclusive of and in harmony with the information and recommendations provided in the Fish and Fisheries Products Hazards and Controls Guidance.

3-402.12 Records, Creation and Retention.

Records must be maintained to verify that the critical limits required for food safety are being met. Records provide a check for both the operator and the regulator in determining that monitoring and corrective actions have taken place.

While the Country of Origin Labeling requirements, http://www.ams.usda.gov/COOL/ effective Sept. 30, 2004, mandate identification of wild and farm-raised fish and shellfish, the requirements do not address contents of pelleted feed used in the aquaculture operation. Documentation must be available in the food establishment from the source-through-purchase specifications or labeling that pelleted feed used did not contain fresh fish or plankton. Follow the guidance provided in the Fish and Fisheries Products Hazards and Controls Guidance, Table #3-1 – Potential Vertebrate Species Related Hazards and Table #3-2 – Potential Invertebrate Species Related Hazards.

Reheating **3-403.11 Reheating for Hot Holding.**

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of ***Clostridium perfringens*** that may grow in meat, poultry, or gravy if these products were improperly cooled. Vegetative cells of ***C. perfringens*** can cause foodborne illness when they grow to high numbers. Highly resistant ***C. perfringens*** spores will survive cooking and hot holding. If food is abused by being

held at improper holding temperatures or improperly cooled, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by ***Staphylococcus aureus***, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

Refer also to the public health reason for § 3-401.12.

3-404.11 Treating Juice.

Refer to the public health reason for § 3-801.11.

Temperature and	**3-501.11**	**Frozen Food.**
Time Control	**3-501.12**	**Potentially Hazardous Food (Time/Tempurture Control for Safety Food), Slacking.**
	3-501.13	**Thawing.**

Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved.

3-501.14 Cooling.

Safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of potentially hazardous foods (time/temperature control for safety foods) has been consistently identified as one of the leading contributing factors to foodborne illness. During slow cooling, potentially hazardous foods (time/temperature control for safety foods) are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 21ºC - 52ºC (70ºF - 125ºF), is to be avoided. If the food is not cooled in accordance with this Code requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

The Food Code provision for cooling provides for cooling from 135ºF to 41°F or 45°F in 6 hours, with cooling from 135ºF to 70°F in 2 hours. The 6-hour cooling parameter, with an initial 2-hour rapid cool, allows for greater flexibility in meeting the Code. The initial 2-hour cool is a critical element of this cooling process. An example of proper cooling might involve cooling from 135ºF to 70ºF in 1 hour, in which case 5 hours remain for

cooling from 70ºF to 41ºF or 45ºF. Conversely, if cooling from 135ºF to 41°F or 45°F is achieved in 6 hours, but the initial cooling to 70ºF took 3 hours, the food safety hazards may not be adequately controlled.

If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming organisms such as ***Clostridium perfringens*** or ***Bacillus cereus*** should be killed or inactivated. However, under substandard sanitary conditions, other pathogens such as ***Salmonella*** or ***Listeria monocytogenes*** may be reintroduced. Thus, cooling requirements are based on growth characteristics of organisms that may survive or be a post-cook contaminate and grow rapidly under temperature abuse conditions.

Shell Eggs

FDA has approved the use of ionizing radiation for shell eggs. This approval means that FDA has not found the ionizing radiation process to be unsafe for shell eggs. However, shell eggs that have been subjected to the approved ionizing radiation process are not considered to have been pasteurized. Shell egg pasteurization requires the egg to have been subjected to a 5-log kill process for ***Salmonella*** **Enteritidis**, while the approved ionizing radiation process may deliver only 2 or 3 logs reduction. Therefore, eggs treated by ionizing radiation process alone must be held under refrigeration, as it cannot be guaranteed that ***Salmonella*** **Enteritidis** will be eliminated in all treated eggs. Further, irradiated eggs must be labeled in accordance with 21 CFR 179.26 *Ionizing radiation for the treatment of food*.

Hard-boiled eggs with shell intact may be cooled in ambient air and are not considered to be a potentially hazardous food (time/temperature control for safety food) after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be a potentially hazardous food (time/temperature control for safety food) after cooling because pathogens, which may be present in the water, may pass through the egg shell during cooling.

Salmonella **Enteritidis** has been shown to have an extended lag phase in shell eggs due to inhibitory characteristics of the albumen. Research indicates that the organisms are physically located near the exterior of the yolk membrane, in contact with the bacteriostatic components. Growth does not appear until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron, become available to the organisms.

Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under refrigeration at an ambient temperature not to exceed 45°F. Packed shell eggs must be labeled indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45°F.

On December 5, 2000 federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inappplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs…
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

Shell eggs must be placed immediately after receipt in refrigerated equipment that is capable of maintaining an ambient air temperature of 45°F. With the newly established Federal requirement for eggs to be in an ambient storage and transportation temperature of 45°F, and with refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that allow the growth of ***Salmonella*** spp. should be shortened. Additionally, this requirement negates the need to "cool" shell eggs upon receipt, although food establishment operators should maximize the circulation of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

CFSAN/FSIS Joint Position Paper on Cooling

The processing of most ready-to-eat products includes a heat treatment or cooking step to eliminate pathogenic and spoilage microorganisms. However, this heat treatment does not eliminate spores of ***Clostridium botulinum*** and ***Clostridium perfringens*** and other spore-forming bacteria. Furthermore, these organisms can thrive in the warm product since other competing organisms have been eliminated. Non-refrigerated, anaerobic conditions are conducive to their growth and multiplication.

To prevent the growth and multiplication of spore-forming organisms, product should be cooled rapidly after cooking. When there is inadequate cooling, spores can germinate and the resulting vegetative cells can multiply to hazardous levels. The presence of sufficient numbers of ***C. botulinum*** or other spore-forming organisms may lead to production of harmful toxins. Therefore, ensuring no growth of these organisms will provide the greatest amount of safety.

The USDA/FSIS Performance Standards for the Production of Certain Meat and Poultry Products require a stabilization step (cooling) after the lethality step. The stabilization requirements allow for no growth of ***C. botulinum*** and no more than 1 log growth of ***C. perfringens***. The performance standard of no more than 1 log growth of ***C. perfringens*** was based on the following reasons:

1. The Centers for Disease Control and Prevention (CDC) suggested viable counts of 10^5 or greater of ***C. perfringens*** per gram as one of the criteria for incriminating ***C. perfringens*** as a causative agent of foodborne illness in finished product. However, foods responsible for ***C. perfringens*** outbreaks were found usually to contain 10^6 vegetative ***C. perfringens*** cells per gram. In FSIS microbiological raw product surveys, samples were found to contain more than 1000 ***C. perfringens*** per gram. There is some probability that greater than 10^4 ***C. perfringens*** per gram can occur in the raw product on rare occasions. It is a conservative assumption that the great majority of ***C. perfringens*** in the raw product are spores.

2. Heating activates spores that, during cooling, become vegetative cells that can multiply to hazardous levels. If there are more than 10^4 ***C. perfringens*** (spores) per gram on raw product, it is possible that there may be more than 10^4 vegetative ***C. perfringens*** per gram in the product if it is improperly cooled after cooking.

3. Based on the CDC recommended upper limit of 10^5 which should not be exceeded, it was determined that a limit of no more than 1 $\log_{10}$ growth of ***C. perfringens*** would be appropriate to ensure that there would be no more than 10^5 ***C. perfringens*** per gram on the finished product after cooling.

4. The performance standard was discussed with experts on clostridia research. The experts agreed that limiting the relative growth of ***C. perfringens*** to no more than 1 $\log_{10}$ would be reasonable and somewhat conservative with respect to product safety. (64 FR 732, January 6, 1999, Performance Standards for the Production of Certain Meat and Meat Products).

The FSIS compliance guideline for the cooling performance standards, which can be found at http://www.fsis.usda.gov/oa/fr/95033F-b.htm Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization), is that product must be cooled from 130ºF to 80°F in 1.5 hours and from 80ºF to 40°F in 5 hours. This cooling rate can be applied universally to cooked products like partially cooked or fully cooked, intact or non-intact meat and poultry products. The guideline results in continuous and rapid cooling of the product in the temperature range where the spore-forming organisms can grow rapidly.

The former USDA guideline of cooling from 120ºF to 55°F in no more than 6 hours is also included in the new compliance guidelines. In using this guideline, chilling should begin within 90 minutes after the cooking cycle is completed, and cooling should continue until product reaches 40°F. The 6-hour rule begins when the product reaches 120ºF, and product should not be shipped until the product reaches 40°F. This older cooling guideline results in a significantly smaller margin of safety, especially if the product is non-intact. In using this older guideline, the establishment has to ensure that cooling is as rapid as possible, especially between 120ºF and 80°F, and should monitor the cooling closely to prevent any deviation. If product remains between these temperatures for more than an hour, compliance with the performance standard is less certain.

The FSIS cooling guideline **for meat and poultry products containing 100 ppm added nitrite** is 130ºF to 80°F in 5 hours and from 80ºF to 45°F in 10 hours, a total of 15 hours cooling time. This cooling process provides a narrow margin of safety. In case of cooling deviations, the establishment should assume that their process has exceeded the performance standard for controlling the growth of ***C. perfringens***, and should take corrective action. However, the **presence of nitrite** should ensure compliance with the performance standard for ***C. botulinum***.

The Food Code provision for cooling is similar, though not identical to the FSIS cooling compliance guidelines. It provides for cooling from 135ºF to 70°F in 2 hours and from 135ºF to 41°F or 45°F in 6 hours and is based on the same food safety concerns as FSIS' guidance. The Food Code provides prescriptive cooling time/temperature combinations without a HACCP plan in place. Federally inspected meat and poultry establishments are required to implement a HACCP plan for their operations.

The Conference for Food Protection (CFP) at its 2000 meeting recommended that FSIS and FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the data on safe cooling times for cooked, potentially hazardous foods (time/temperature control for safety foods). The review would include data from a study, submitted to the CFP, showing that cooling of a meat product from 130ºF to 45°F can safely take place in 15 hours based on a study by V.K. Juneja, et al., 1994. According to the authors of the study, continuous cooling of a meat product from 130ºF to 45°F in 15 hours permitted about 1 log growth of ***C. perfringens***.

In response to the CFP recommendation, the FSIS Administrator and CFSAN agreed that the data referenced in the CFP recommendation do not support a change in the FSIS guidance or the Food Code § 3-501.14 and considered it inadvisable to ask the NACMCF to undertake the task requested for several reasons:

1. The study did not address growth of ***C. botulinum***.

2. The results are from a carefully controlled laboratory study in which cooling of the product was steady and continuous, conditions difficult to maintain in most commercial processing or retail environments even with data loggers and other control mechanisms in place.

3. The study was done only on ground beef and may not be applicable to other meat and poultry or to other potentially hazardous foods (time/temperature control for safety foods).

As an alternative response, CFSAN and FSIS advised CFP that they would provide this written position paper to clarify their joint position on the cooling issues.

3-501.15 Cooling Methods.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased.

Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

3-501.16 Potentially Hazardous Food (Time/Temperature Control for Safety Food), Hot and Cold Holding.

Bacterial growth and/or toxin production can occur if potentially hazardous food (time/temperature control for safety food) remains in the temperature "Danger Zone" of 5°C to 57°C (41°F to 135°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

Cold Holding

Maintaining PHF (TCS) foods under the cold temperature control requirements prescribed in this code will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness. All microorganisms have a defined temperature range in which they grow, with a minimum, maximum, and optimum. An understanding of the interplay between time, temperature, and other intrinsic and extrinsic factors is crucial to selecting the proper storage conditions for a food product. Temperature has dramatic impact on both the generation time of an organism and its lag period.

When considering growth rate of microbial pathogens, time and temperature are integral and must be considered together. Increases in storage and/or display temperature will decrease the shelf life of refrigerated foods since the higher the temperature, the more permissive conditions are for growth.

The exception for holding potentially hazardous food (time/temperature control for safety food) in specially designed dispensing equipment recognizes technology designs that maintain the safety of aseptically-packaged fluid foods when the equipment is

manufactured and operated in conformance with the NSF/ANSI Standard No. 18. NSF/ANSI 18 was revised in 2006, with FDA input, to address the storage of certain types of potentially hazardous food or beverages in dispensing equipment without temperature control. The key condition for FDA allowing this exemption from 3-501.16 is that the equipment conforms to the requirements as specified in NSF/ANSI 18.

Except for raw shell eggs, control of the growth of ***Listeria monocytogenes*** (*Lm*) is the basis for the list of cold holding temperature and time combinations in paragraph 3-501.17(A). The list addresses time, in addition to temperature, as a control for the growth of *Lm* in refrigerated, ready-to-eat, potentially hazardous food (time/temperature control for safety food). The Code provisions for cold holding focus on environmental conditions that allow 1 log of growth of *Lm*, and do not set an acceptable number of *Lm* in food. Neither do they imply that *Lm* is in the product.

The times and temperatures in the 1999 Food Code were based on the USDA Pathogen Modeling Program (PMP), which is conservative in estimating how soon *Lm* begins to grow and how fast. The PMP was based largely on observations of microbial growth in broth cultures, but some observations in specific foods were also included. The PMP allows for some variation in temperature, pH, and water activity, and gives a conservative estimate of safe times and temperatures for holding foods. The 1999 Food Code estimated safe times and temperatures that would allow 3 logs of growth, based on the PMP.

During 2000, CFSAN researched published literature and compiled a listing of the growth potential of *Lm* in various food commodities using real food data. Based on this information, the 1999 Food Code times and temperatures of 41ºF for 7 days and 45ºF for 4 days were validated, but the underlying performance standard changed for the commodities studied. The research-based, food-specific times and temperatures allow no more than 1 log of growth instead of the 3 log growth predicted in the PMP. This more stringent performance standard of 1 log is consistent with the USDA/FSIS performance standard and the fact that the infectious dose of *Lm* remains unknown.

FDA concluded that the 1999 Code time/temperature criteria hold true and provide both a greater level of safety and a more realistic basis for regulatory requirements without compromising public health protection.

In October 2003, FDA, in cooperation with the USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods (risk assessment). This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

The risk assessment identified several broad factors that affect consumer exposure to *Lm* at the time of food consumption. Two of these factors, refrigerated storage

temperature and duration of refrigerated storage before consumption, have a direct bearing on cold holding time/temperature combinations used in food establishments.

FDA continues to have concerns about the potential for growth of *Lm* in refrigerated, ready-to-eat, potentially hazardous food (time/temperature control for safety food), prepared and packaged in a food processing plant and held in a food establishment. Data from the risk assessment (see the following Annex 3, 3-501.16, Table 1) show a significant reduction in the projected cases of listeriosis when refrigerated storage is limited to 41ºF. Based on these data and conclusions from the risk assessment, FDA continues to recommend that food establishments limit the cold storage of potentially hazardous (time/temperature control for safety), ready-to-eat foods to a maximum temperature of 41ºF.

3-501.16 – Table 1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures*

Maximum Refrigerator Temperature	Cases of Listeriosis[a]		
	Median	5th Percentile	95th Percentile
Baseline[b]	2105	3/4[c]	3/4[c]
7 ˚C (45 ˚F) maximum	656	331	761
5 ˚C (41 ˚F) maximum	28	1	126

[a]Values for the median, upper and lower uncertainty levels.
[b]The baseline uses the full empirical distribution of refrigerator temperatures from the Audits International (1999) survey.
[c]The baseline number of cases of listeriosis is fixed based on CDC surveillance data.
*The scenario assumed the distribution of storage times is the same for all three temperature sets.
Source: Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003. Table VI-1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures.

Regarding shell eggs, USDA published a final rule (63 FR 45663, August 27, 1998 Refrigeration and Labeling Requirements for Shell Eggs) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7ºC (45ºF). This regulation, however, does not apply to eggs while held at all retail establishments. FDA is concerned that without continued refrigeration up until the time that the eggs are cooked, there would be an opportunity for the egg's defenses to degrade and growth of ***Salmonella* Enteritidis** to occur. The agency reviewed research indicating that ***Salmonella Enteritidis*** multiplies at temperatures of 10ºC (50ºF) and above but can be inhibited at lower temperatures, e.g., 8ºC (46ºF), 7ºC (45ºF), and 4ºC (39ºF). Based on this research and USDA's temperature requirement during transport, FDA implemented regulations that establish a maximum ambient air

temperature of 7ºC (45ºF) for eggs stored and displayed at retail establishments. Amended Federal regulations 21 CFR Part 115.50 issued on December 5, 2000 and became effective on June 4, 2001.

Although Congress did not expressly preempt State law in this area, FDA found preemption is needed because State and local laws that are less stringent than the Federal requirements will not support the important public health goals of these regulations. FDA does not believe that preemption of State and local refrigeration and labeling requirements that are the same as or more stringent than the requirements of these regulations is necessary, as enforcement of such State and local requirements will support the food safety goals of these regulations. Accordingly, the preemptive effect of this rule is limited to State or local requirements that are not as stringent as the requirements of these regulations; requirements that are the same as or more stringent than FDA's requirements remain in effect.

Historical Record of Cold Holding Temperature Provisions

The 1976 Food Service Sanitation Manual recommended 45°F as the cold holding temperature. Based on the available science at the time, the 1993 Food Code lowered the cold holding temperature to 41°F.

However, stakeholders raised concerns that many of the refrigerators currently in place in food establishments would not be capable of maintaining food at that temperature. There was also concern that most of the open-top buffet and food prep table-type units being built at the time could not reliably maintain food at 41°F or less. Industry pointed out that operators needed to recover investments in new refrigeration equipment purchased just before or after a state adopted the 41°F provision.

Consequently, the Conference of Food Protection (CFP) recommended the 1997 Food Code incorporate the option of having a 5-year phase-in period for the 41°F requirement to allow for upgrading of existing equipment, and the FDA agreed.

By 2006, many states adopted and implemented the phase-in period, the 5 years had expired and they were requiring cold holding at 41°F or less. In addition, NSF/ANSI Standard 7 was revised in 1997 and again in 1999 to ensure that equipment conforming to the Standard, including open-top and display units, could achieve the desired performance under conditions typically found in the food service and retail environments. Thus, there are mechanisms in place to allow industry flexibility in holding foods out of temperature control and the exemption for holding at 45°F was no longer necessary, given equipment capabilities, existing provisions of the Food Code that could be utilized (e.g., variances, time as a public health control), and the impact on public health. Additionally, the FDA believed this exemption was no longer necessary and perhaps was detrimental to public health protection in light of what had been learned about the growth and survival of *Listeria monocytogenes* (LM) in refrigerated foods.

In 2006, the CFP recommended (CFP Issue 2006-I-033) and FDA agreed that the option of maintaining 45°F as a cold holding temperature be deleted from § 3-501.16. In the Supplement to the 2005 Food Code, the option to maintain 45°F as the cold holding temperature was deleted from the Food Code and 41°F became the standard for cold holding.

Hot Holding

In a January 2001 report, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommended that the minimum hot holding temperature specified in the Food Code:

- Be greater than the upper limit of the range of temperatures at which ***Clostridium perfringens*** and ***Bacillus cereus*** may grow; and
- Provide a margin of safety that accounts for variations in food matrices, variations in temperature throughout a food product, and the capability of hot holding equipment to consistently maintain product at a desired target temperature.

C. perfringens has been reported to grow at temperatures up to 52°C (126°F). Growth at this upper limit requires anaerobic conditions and follows a lag phase of at least several hours. The literature shows that lag phase duration and generation times are shorter at incubation temperatures below 49°C (120°F) than at 52°C (125°F). Studies also suggest that temperatures that preclude the growth of ***C. perfringens*** also preclude the growth of ***B. cereus***.

CDC estimates that approximately 250,000 foodborne illness cases can be attributed to ***C. perfringens*** and ***B. cereus*** each year in the United States. These spore-forming pathogens have been implicated in foodborne illness outbreaks associated with foods held at improper temperatures. This suggests that preventing the growth of these organisms in food by maintaining adequate hot holding temperatures is an important public health intervention.

Taking into consideration the recommendations of NACMCF and the 2002 Conference for Food Protection meeting, FDA believes that maintaining food at a temperature of 57°C (135°F) or greater during hot holding is sufficient to prevent the growth of pathogens and is therefore an effective measure in the prevention of foodborne illness.

3-501.17	**Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking.**
3-501.18	**Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Disposition.**

Refer to Annex 7, Chart 4-C.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as ***Listeria monocytogenes***, is significantly slowed but not stopped by refrigeration. Over a period of time, this and similar organisms may increase their risk to public health in ready-to-eat foods.

Based on a predictive growth curve modeling program for ***Listeria monocytogenes***, ready-to-eat, potentially hazardous food (time/temperature control for safety food) may be kept at 5°C (41°F) a total of 7 days. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for ***Listeria monocytogenes*** to multiply, before freezing and after thawing. Potentially hazardous (time/temperature control for safety) refrigerated foods must be consumed, sold or discarded by the expiration date.

Date marking is the mechanism by which the Food Code requires active managerial control of the temperature and time combinations for cold holding. Industry must implement a system of identifying the date or day by which the food must be consumed, sold, or discarded. Date marking requirements apply to containers of processed food that have been opened and to food prepared by a food establishment, in both cases if held for more than 24 hours, and while the food is under the control of the food establishment. This provision applies to both bulk and display containers. It is not the intent of the Food Code to require date marking on the labels of consumer size packages.

A date marking system may be used which places information on the food, such as on an overwrap or on the food container, which identifies the first day of preparation, or alternatively, may identify the last day that the food may be sold or consumed on the premises. A date marking system may use calendar dates, days of the week, color-coded marks, or other effective means, provided the system is disclosed to the Regulatory Authority upon request, during inspections.

FDA/USDA/CDC *Listeria monocytogenes* Risk Assessment

In September, 2003, FDA, in cooperation with USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

In examining these closely, FDA showed that 5 factors are important in measuring the public health impact to consumers from foodborne listeriosis. These factors are: (1) amounts and frequency of consumption of a ready-to-eat food; (2) frequency and levels of ***L. monocytogenes*** in a ready-to-eat food; (3) potential of the food to support

growth of the bacterium during refrigeration; (4) refrigerated storage temperature; and (5) duration of refrigerated storage before consumption.

Based on these 5 factors, the 23 categories of ready-to-eat foods were ranked according to their relative risk of contamination and growth of ***Listeria monocytogenes***. The risk categories used were: very high risk; high risk; moderate risk; low risk; and very low risk.

Impact of the Listeria monocytogenes Risk Assessment on Date Marking

Based on the results of the risk assessment and the recommendations from the 2004 Conference for Food Protection meeting, it was necessary to re-evaluate date marking in an effort to focus the provision on very high and high risk foods, while at the same time, exempting foods that present a very low, or low risk of contamination and growth of ***Listeria monocytogenes***. Based on this evaluation, date marking provisions of the Food Code do not apply to the following foods:

Deli Salads Prepared and Packaged in a Food Processing Plant

Examples of deli salads include ham salad, chicken salad, egg salad, seafood salad, pasta salad, potato salad, and macaroni salad, manufactured according to 21 CFR 110. According to data from the risk assessment, deli salads prepared and packaged by a food processing plant contain sufficient acidity, along with the addition of preservatives (e.g., sorbate, benzoates), to prevent the growth of ***Listeria monocytogenes***. There are estimates that 85% of all deli salads are prepared and packaged in a food processing plant and do not support growth. Based on discussions with deli salad manufacturers and trade associations, it is a nearly universal practice for food processing plants preparing and packaging deli salads to add one or more preservatives that inhibit the growth of ***Listeria monocytogenes***. Based on their wide use within this segment of the industry and their effectiveness at inhibiting the growth of ***Listeria monocytogenes***, all deli salads prepared and packaged in a food processing plant are exempt from date marking. However, all deli salads prepared in a food establishment require date marking.

Hard and Semi-Soft Cheeses

In December, 1999, FDA issued an exemption from date marking for certain types of hard and semi-soft cheeses (http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113942.htm), based on the presence of several factors that may control the growth of ***Listeria monocytogenes***. These factors may include organic acids, preservatives, competing microorganisms, pH, water activity, or salt concentration. The results of the risk assessment support this interpretation and therefore, hard and semi-soft cheeses each manufactured according to 21 CFR 133 are exempt from date marking.

List of Some Hard and Semi-Soft Cheeses Exempt from Datemarking	
Asadero	Asiago soft
Abertam	Battelmatt
Appenzeller	Bellelay (blue veined)
Asiago medium or old	Blue
Bra	Brick
Cheddar	Camosum
Christalinna	Chantelle
Colby	Edam
Cotija Anejo	Fontina
Cotija	Gorgonzola (blue veined)
Coon	Gouda
Derby	Havarti
Emmentaler	Konigskase
English Dairy	Limburger
Gex (blue veined)	Milano
Gloucester	Manchego
Gjetost	Monterey
Gruyere	Muenster
Herve	Oka
Lapland	Port du Salut
Lorraine	Provolone
Oaxaca	Queso de Bola
Parmesan	Queso de la Tierra
Pecorino	Robbiole
Queso Anejo	Roquefort (blue veined)
Queso Chihuahua	Samsoe
Queso de Prensa	Tilsiter
Romanello	Trappist
Romano	
Reggiano	
Sapsago	
Sassenage (blue veined)	
Stilton (blue veined)	
Swiss	
Tignard (blue veined)	
Vize	
Wensleydale (blue veined)	

Cultured Dairy Products

Cultured dairy products include yogurt, sour cream, and buttermilk, each manufactured according to 21 CFR 131. Many of these products often are low pH foods manufactured with lactic acid fermentation. Data from the risk assessment show that ***Listeria monocytogenes*** does not grow in these foods and therefore, these products are exempt from date marking.

Preserved Fish Products

Preserved fish products include pickled herring and dried, or salted cod, and other acidified fish products, manufactured according to 21 CFR 114. Data from the risk assessment show that the high salt and/or acidity of these products does not allow for the growth of ***Listeria monocytogenes*** and therefore, these products are exempt from date marking. This exemption does not apply to hot or cold smoked fish products, nor does it apply to fish products that are dried, marinated, or otherwise preserved on-site, in a food establishment, such as ceviche.

USDA-regulated products

Date marking provisions of the Food Code do not apply to shelf stable ready-to-eat meat and poultry products. Shelf stable ready-to-eat meat and poultry products are not required by USDA to be labeled “Keep Refrigerated.” For these products, the nitrite and salt in the cure and the lower pH resulting from fermentation give additional protection against microbial growth. Some fermented sausages and salt-cured products are shelf stable, do not require refrigeration, and do not bear the label “Keep Refrigerated.” To be shelf stable, a product manufactured under USDA inspection must have a process that results in a product that meets one of the recognized objective criteria for shelf stability, such as water activity, moisture-protein ratio (MPR), or combination of MPR and pH (acidity). Therefore they are exempt from the Food Code date marking requirements.

Shelf stable fermented sausages such as pepperoni and dry salami do not have to be refrigerated or date marked. Shelf stable salt-cured products such as prosciutto, country cured ham, or Parma ham do not require refrigeration or Food Code date marking. Other salt-cured products include basturma, breasaola, coppa, and capocolla.

Some ready-to-eat fermented sausages and salt-cured products must be refrigerated and therefore bear the USDA-required label “Keep Refrigerated.” Examples of these products are cooked bologna, cooked salami, and sliced country ham which are ready-to-eat fermented products that need refrigeration. Bologna is a cooked, perishable sausage and there are other salamis, e.g., cotto that are perishable.

Regarding the exemption from date marking for shelf-stable sausages in a casing, the exemption does not apply if the casing is removed. The intact casing on shelf-stable sausages may be overwrapped to protect the cut face of the sausage. With shelf stable (not potentially hazardous (time/temperature control safety)) sausages, the intact

casing provides a barrier to contamination (although not an absolute one), the exposed face is likely to be sliced again within 4 or 7 days, and contamination is minimized because only the face is exposed. The coagulated protein that occurs on the surface of some nonshelf stable cooked sausages is not a casing.

Slices of cured and fermented sausages that require refrigeration and are kept for 24 hours or longer do need to be date marked.

If open dating information is applied to lunchmeats at a federally inspected meat or poultry establishment, the information must comply with the requirements in 9 CFR 317.8 and 381.129. However, such dating is not required by USDA/FSIS and if applied, would not supercede or replace date marking requirements established by the Food Code or by State/local authorities that apply after the food is opened in a retail establishment.

Manufacturer's use-by dates

It is not the intent of this provision to give a product an extended shelf life beyond that intended by the manufacturer. Manufacturers assign a date to products for various reasons, and spoilage may or may not occur before pathogen growth renders the product unsafe. Most, but not all, sell-by or use-by dates are voluntarily placed on food packages.

Although most use-by and sell-by dates are not enforceable by regulators, the manufacturer's use-by date is its recommendation for using the product while its quality is at its best. Although it is a guide for quality, it could be based on food safety reasons. It is recommended that food establishments consider the manufacturer's information as good guidance to follow to maintain the quality (taste, smell, and appearance) and salability of the product. If the product becomes inferior quality-wise due to time in storage, it is possible that safety concerns are not far behind.

It is not the intention of this provision that either the manufacturer's date or the date marked by the food establishment be placed on consumer packages.

3-501.19 Using Time as a Public Health Control.

The 2000 Conference for Food Protection (CFP) meeting recommended that FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the Food Code provision that addresses using time alone as a public health control, section 3-501.19. In response to the CFP recommendation, FDA in consultation with USDA/FSIS, determined that there is sufficient scientific information available to support the current provision in the Food Code without requesting consideration by the NACMCF. As an alternative response, FDA informed the CFP that it would provide the following position paper on using time alone as a public health control.

Position Paper

Food Code section 3-501.19 allows potentially hazardous food (time/temperature control for safety) food that is ready-to-eat (RTE) to be stored without temperature control for up to 4 hours, after which it must be discarded or consumed or for up to 6 hours for refrigerated food, if the food is 5°C (41°F) when initially removed from temperature control, and as long as the food temperature does not exceed 21°C (70°F). The following information is provided to explain the reasoning in allowing time alone to be used as a public health control for food safety.

Background Information

Food kept without temperature control allows product to warm or cool as it equilibrates with the environment. Each temperature scenario incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range during its equilibration with its surroundings. Several factors influence the rate of temperature change in a food, such as the type of food, thickness of the food, and temperature differential between the food and its surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected to create a worst-case scenario for pathogens growth and possible toxin production.

Holding Cold Food Without Temperature Control

When a food is removed from refrigerated storage and begins to warm to room temperature, ***Listeria monocytogenes*** is a primary organism of concern. Even while food is held at refrigeration temperatures, the growth potential of ***L. monocytogenes*** warrants concern for potentially hazardous (time/temperature control for safety foods) RTE foods. Although the FDA and USDA have a zero tolerance for ***L. monocytogenes*** in RTE food, conditions are permitted in the Food Code that would allow ***L. monocytogenes*** cells 1 log of growth (3.3 generations). ***Salmonella*** is also a concern especially with products containing eggs. However ***L. monocytogenes*** grows more rapidly than ***Salmonella*** at refrigeration and room temperatures. By ensuring minimal ***Listeria*** growth in food, the threat from ***Salmonella*** would be negligible. Warming conditions will allow food to remain exposed to temperatures that allow ***B. cereus*** to produce emetic toxin. However the 4-hour time constraint in the Food Code is sufficient to prevent any toxin formation.

For food refrigerated at 41ºF or 45°F then transferred to an ambient temperature of 75°F for 4 hours, the growth rate of ***L. monocytogenes*** remains slow enough to ensure that the critical limit of 1 log growth is not reached. Published generation times at 75°F for ***L. monocytogenes*** in food were not found, however published values at 68ºF and 70°F in egg and milk products confirmed slow ***L. monocytogenes*** growth at room temperatures.

Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum

conditions of pH 6.8, 0.5% NaCl, 0.0% nitrite, ***L. monocytogenes*** would require more than 4 hours to grow 1 log at 75°F. The PMP is based on broth studies and not on food products. Therefore, the growth rates reported at various temperatures by the PMP are faster than growth rates in most food products. Another factor exaggerating the growth rate in this warming scenario as predicted by the PMP is the assumption that the food product spent all 4 hours at 75°F. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly.

Unfortunately there are no models that take changing temperatures into consideration when predicting growth. Likewise there are very few published papers dealing with the growth of organisms in food during warming. The conservative nature of the 4-hour limit for keeping foods without temperature control allows for a needed margin of safety if the temperature of the environment is higher than 75°F.

It is important to note that potentially hazardous (time/temperature control for safety) foods held without cold holding temperature control for a period of 4 hours do not have any temperature control or monitoring. These foods can reach any temperature when held at ambient air temperatures as long as they are discarded or consumed within the four hours.

Holding Hot Food without Temperature Control

The second scenario for food without temperature control exists when food is cooked according to Food Code recommendations, then kept at room temperature for 4 hours before discarding. Foodborne pathogens of concern for an uncontrolled temperature scenario are sporeformers including ***Clostridium perfringens*** and ***Bacillus cereus***. Food cooked according to Food Code guidelines should be free of vegetative cells. However, the heat requirements are not sufficient to kill spores of ***C. perfringens*** or ***B. cereus*** and may actually serve as a heat shock that activates the spores. ***B. cereus*** is found commonly in outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a multitude of food products. ***C. perfringens*** is found commonly in outbreaks attributed to inadequate hot holding of beef and poultry. Despite the prevalence of both spores in nature, ***C. perfringens*** cases are estimated to be more numerous than ***B. cereus*** cases by a factor of 10.

B. cereus can produce emetic toxin in food, and the optimum temperature for the production of toxin is between 77°F and 86°F. However, the time needed to produce the toxin is longer than the time the food will be exposed to any temperature range with a 4-hour holding limit. Both ***C. perfringens*** and ***B. cereus*** produce enterotoxin inside the intestine of the infected host if substantial numbers of vegetative cells are present in the food (10^{5-7} CFU/g). Although the reported levels of both spores in raw foods vary in the literature, generally the level expected in food can be assumed to be low (around 10-1000 CFU/g). This implies that conditions allowing 1 log growth of either spore could be tolerated in food.

During the time without temperature control, the temperature of the food could

decrease slowly enough to expose spores of both organisms to optimal growth conditions for a significant length of time. Like warming, several variables exist that determine the rate of heat transfer. Because of the wide variety of foods prepared it would be impossible to generalize how fast a typical product loses temperature after cooking. As with warming, it is prudent to imagine a worst-case scenario where heat loss is slowed. A beef roast slow cooked to 130°F for the appropriate time according to the Food Code was used as consideration for possible spore growth. Cooking roast beef to 130°F can create an anaerobic environment in both the meat and gravy. The low internal temperature creates a small temperature differential with the environment (assumed at 75°F), allowing for a slower decrease in the food's temperature.

After evaluating published studies as well as data collected at the FDA, the surface of a roast beef or rolled meat product would lose heat quickly enough to discourage significant growth of either ***C. perfringens*** or ***B. cereus***. If all spores were distributed on the surface of the product by either pre- or post-cooking contamination, storing this product for 4 hours at room conditions would be considered safe. Likewise, products that are stirred or products that lose heat faster than a roast would also be considered safe.

---------- End of position paper ---------

At the 2004 meeting of the CFP, a committee submitted and the Conference accepted a document that examined scientific research related to the growth of ***Listeria monocytogenes****,* and the influence of time and temperature on its growth.

The 2004 CFP report stated that the USDA-PMP program can be used as a tool to estimate time periods for a 1-log increase in growth for ***Listeria monocytogenes*** in ideal (laboratory media) growth conditions. Using this modeling approach, at 41°F, 45°F, and 50°F, the time for a 1-log increase was, 87.8, 53.9, and 34.7 hours, respectively. At room temperature (70°F) a 1-log increase was noted at 5.2 hours and at ideal growth temperatures (95°F), the reported time for a 1-log increase was 3.0 hours. In general, the data from the USDA-PMP program provides very conservative growth data and, in most cases, growth would be expected to be less rapid in a food system. This table does provide comparative information relative to growth rates at different holding temperatures in the event that time was used as a factor in managing food safely.

The report further recommended that food could safely be held for up to 6 hours without external temperature control as long as the food temperature did not exceed 70°F. Based on that report and data from the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003, the Food Code allows potentially hazardous food (time/temperature control for safety) food to be stored up to 6 hours without external temperature control provided that the food temperature does not exceed 70°F and the food is discarded or consumed at the end of the 6 hours.

The Safety of the Time as a Public Health Control Provision from Cooking Temperatures (135°F or above) to Ambient

FDA conducted in-house laboratory experiments to test the safety of the existing TPHC provisions of 4 hours without temperature control starting with an initial temperature of 135°F or above. *Clostridium perfringens* was chosen to represent a worst case scenario pathogen for foods allowed to cool from cooking temperatures to ambient without temperature control,because its spores can survive normal cooking procedures, it can grow at relatively high temperatures (>120°F) and it has a short lag period. *C. perfringens* spores were inoculated into foods that were cooked and then cooled to yield a cooling curve that would promote outgrowth as quickly as possible. The growth data suggest that the existing 4-hour TPHC provision will be safe for 6 hours after cooking, with the additional 2-hour margin of safety built-in for consumer handling.

Consumer Handling Practices

An Audits International study was funded in 1999 by FDA to determine the food handling practices of consumers purchasing food at retail and returning home to refrigerate their items. Forty-six (46) states are represented, and the data comprises several food groups purchased from different grocery-store types. The food groups represented were: pre-packaged lunch meat, deli-counter products, seafood, fresh meat, pre-packaged deli product, liquid dairy, semi-solid dairy product, ice cream, frozen entrées, frozen novelties and whipped topping.

The study evaluated information regarding time and food temperature at retail food stores, time to reach home refrigeration, temperature after transport home, location and type of retail establishment where purchase was made and type of product purchased.

For product temperature at retail and after transportation, 5 product categories were used: pre packaged lunch meat, pre packaged deli product, deli counter products, seafood and fresh meat. These categories were considered most applicable to the TPHC recommendations. The temperature ranges for these products at retail and after transport to the home are summarized in Figures 1 and 2 respectively. The data suggest that with current retail refrigeration practices, 25% of items are held above 45°F (Figure 1). The data also show that by the time the product arrives at the home, 98% of products were at 65°F or less (Figure 2).

The time of transport for all food categories from the retail establishment to home refrigeration was also recorded. The data summarized in Figure 3 shows that over 97% of the foods purchased were ready to be placed in refrigeration within 2 hours of purchase. For this histogram, all food categories except for frozen entrées were included. Because all foods end up bagged and transported together, the time each product was transported to the home was considered a valid data point and therefore used. Based on the data, a benchmark was established that PHF/TCS foods purchased in a food establishment would be either consumed, or placed under temperature control, within 2 hours.

Figure 1. Temperatures of refrigerated products at retail (Audits International).

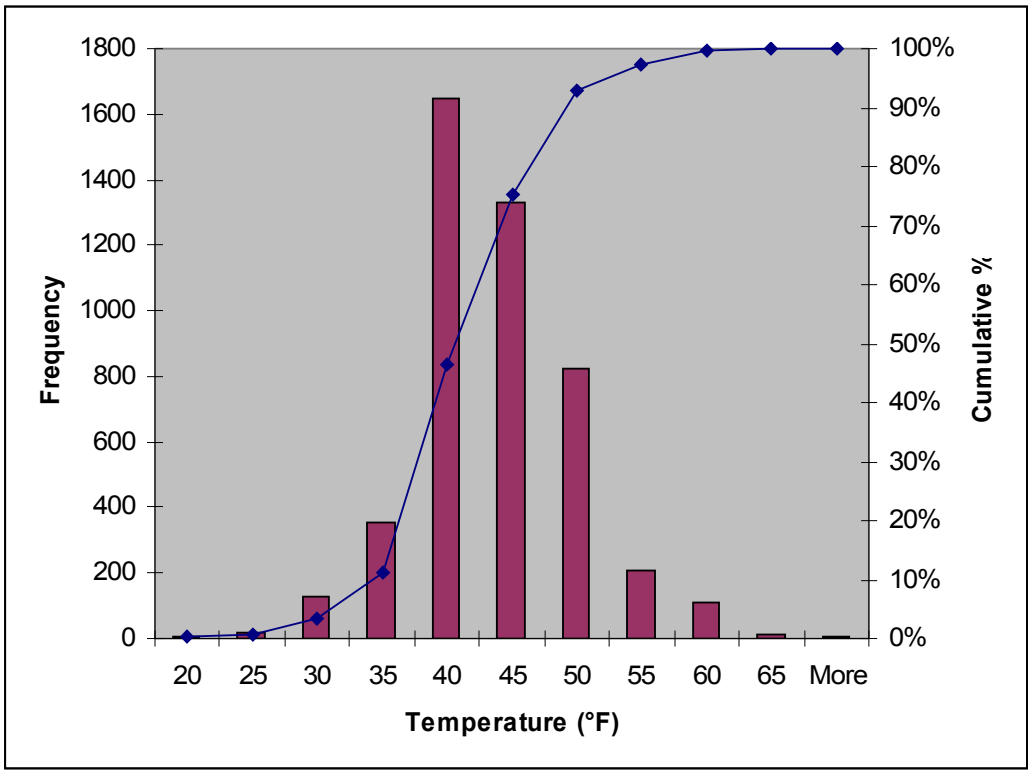


Figure 2. Product temperatures after transport to the home (Audits International).

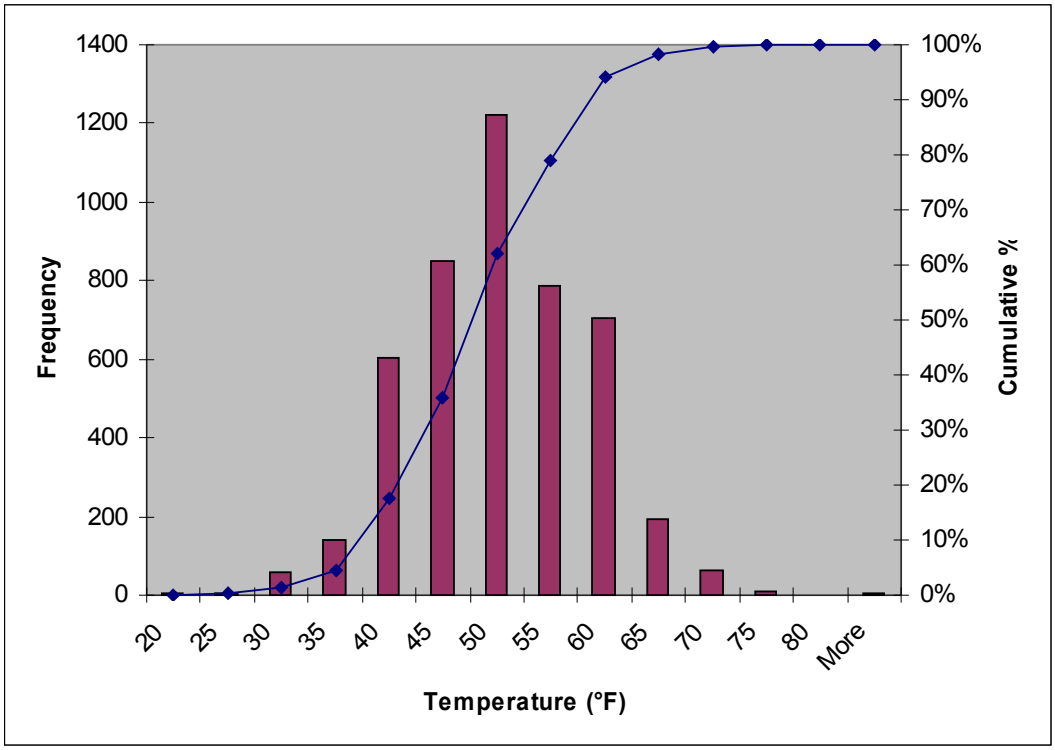
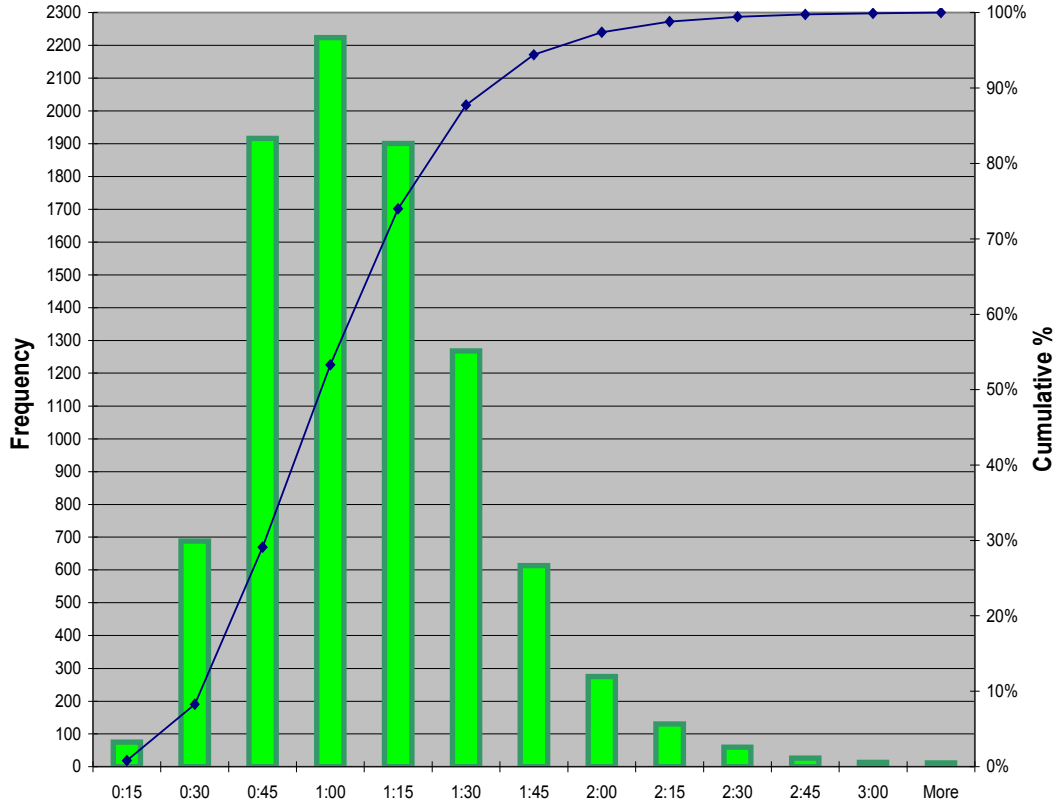


Figure 3. Times reported for transport of grocery items from the retail outlet to the home (Audits International).



The Safety of the Time as a Public Health Control Provision from Refrigeration Temperatures (41°F or less) to Ambient

As noted above, the current TPHC provision has two time provisions. Food can be kept with no temperature stipulations for 4 hours in a food establishment, at which time the food must be cooked and served, served if RTE, or discarded within the four hours. However, if food does not exceed 70°F, it may be held for 6 hours and cooked and served, served if RTE or discarded within the six hours. For foods warming from refrigeration to ambient temperatures, the data from the Audits International study outlined above, along with simulations from the USDA Pathogen Modeling Program (PMP), were used to determine the safety of the existing TPHC recommendations.

Assuming pathogen growth in foods going from refrigeration (41°F or less) to ambient temperature, the following parameters were used for the PMP simulation:

- 65°F was used as the temperature for the entire simulation;
- 2 hours were added to all times (4h or 6h) allowed in the current TPHC recommendation, to factor in transportation time (per the Audits International study outlined above);

- The data were generated from PMP broth models (pH 6.8), with the minimal NaCl and no sodium nitrite.

Table 1 summarizes the predicted growth of *Bacillus cereus* (vegetative), *Escherichia coli*, *Listeria monocytogenes*, Salmonella spp., *Shigella flexneri*, and *Staphylococcus aureus*, using the PMP and based on the assumptions discussed above. The data predicted that less than 1-log growth would be seen for each organism, during the 8 hour time period. Thus, the data show that the current 4 and 6 hour TPHC provisions from 41°F or less to ambient, allow minimal growth of a number of pathogens of concern.

Table 1. The USDA Pathogen Modeling Program estimation of growth (Log CFU/g) of several pathogens for 6 hours or 8 hours, at 65°F.

Pathogens	6 Hours	8 hours
B. cereus (vegetative cells)	0.62	0.87
E. coli	0.35	0.52
L. monocytogenes	0.47	0.71
Salmonella Spp.	0.25	0.41
S. flexneri	0.26*	0.34*
S. aureus	0.38*	0.51*

* Model predictions were in 5 hour increments, the 6 and 8 hour data was extrapolated between 5 hour and 10 hour predictions.

References

U.S. Department of Agriculture. 1997. *Pathogen Modeling Program.* USDA Agricultural Research Service, Wyndmoor, PA.

Food and Drug Administration. 2006. Growth of *Clostridium perfringens* inoculated into beef roasts and meatloaf (unpublished data).

---------- End of Summary of Consumer Handling Practices study ----------

Raw eggs

Recipes in which more than one egg is combined carry an increased risk of illness and possible serious consequences for certain people. It is due to this increased risk, and documented occurrences of foodborne illness and death among highly susceptible populations from temperature-abused raw shell eggs contaminated with ***Salmonella* Enteritidis**, that the use of time as a public health control in institutional settings is not allowed.

Specialized Processing Methods **3-502.11 Variance Requirement.**

Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

The concept of variances may be new to some regulatory authorities. Some jurisdictions may not have a formal process to respond to industry requests for variances, although informal allowances may have been allowed in specific situations. Recognizing the opportunity to use the variance process may require additional rulemaking, or at least policy development, at the jurisdictional level. Rulemaking can be used to outline the procedures for a variance request, including the information required in section 8-103.11. In addition, the rulemaking process can address the regulatory authority's responsibility to consider an industry's variance application and an appeals process in case a variance is not given due consideration or is denied. The Conference for Food Protection Variance Committee recommended that regulatory agencies adopt a variance review process. General guidance regarding administrative procedures is given below.

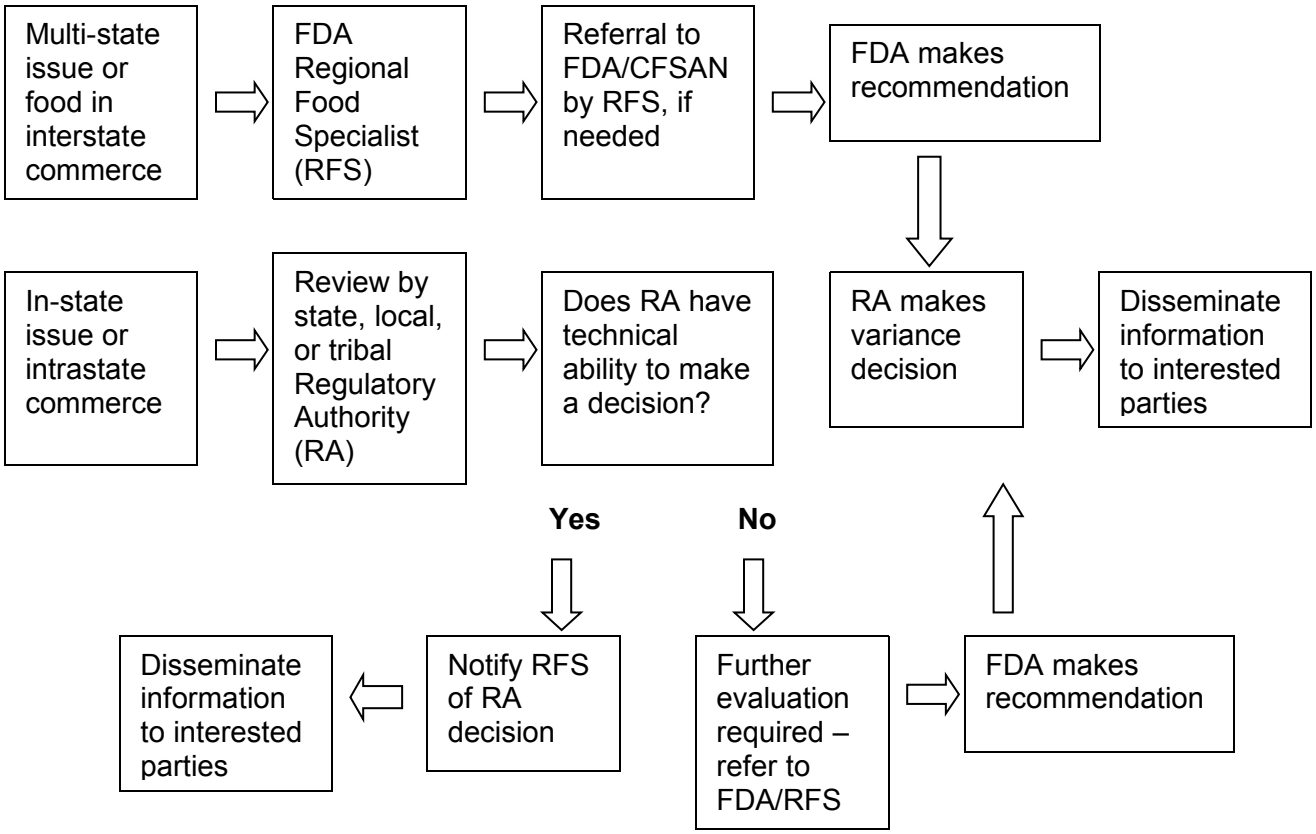
Regulatory authorities considering implementing variances have encountered issues relating to their authority or technical, scientific ability to evaluate or validate a variance request. From any variance request there may emerge a set of complex issues and scientific competencies beyond the ability of the regulatory authority to validate. The Conference for Food Protection Variance Committee recommended that rulemaking should reflect a multi-level matrix of regulatory agencies ranging from local regulatory authorities through FDA and reflected that recommendation in the following flow chart. The regulatory authority is encouraged to seek input and guidance from authoritative sources such as processing authorities, professional associations, or academia. Within the Variance Committee's model, the process for seeking FDA advice begins with the Regional Food Specialists.

Except for the Interstate Travel Program, FDA generally does not directly regulate retail and food service establishments, including entertaining variances for that segment of the industry. FDA is still exploring processes for handling variances on a national basis such as those received from national chain businesses. In conjunction with the 2000 CFP Variance Committee, FDA will continue to explore ways to provide assistance and guidance to regulators regarding access to scientific and technical resources in order to make science-based decisions regarding variances.

FDA recommends that regulatory authorities develop a written administrative process that is consistent with, and addresses the information contained in, Food Code sections 8-103.10, 8-103.11, and 8-103.12, and follow a process consistent with the recommendations of the CFP Variance Committee as shown in its flow chart.

3-502.11 Chart 1 – A Model Flow Process for State Regulators to Address Variances

Developed by the CFP Variance Committee



Model Administrative Procedures for Regulators to Address Variances

1) Designate an agency team and assign a leader to address variance requests.

2) Establish an agency review process leading to approval or denial of variance applications. For food safety issues, include recommendations for consulting with food processing authorities, food scientists, academia, professional organizations, other government agencies including the FDA Regional Food Specialist, or other experts external to the agency.

3) Set reasonable timelines for decision making. Determine if the variance application addresses an intrastate or interstate issue.

   a) For variances that have interstate or national implications, especially those that address food safety, regulators are urged to contact and work closely with their FDA Regional Food Specialist to determine if a national policy related to the issue exists. Regulators are encouraged to be consistent with national policies, guidelines, or opinions.

b) For variances that address intrastate issues, regulators are also encouraged to determine if other State or national guidance exists, and to stay consistent with it.

4) Make the agency's decision. Inform the applicant.

a) If the variance request is approved, determine the starting date and document all special provisions with which the applicant must comply.

b) If the variance request is denied, inform the applicant as to the reasons for the denial, the applicant's right to appeal, and the appeal process.

5) Inform other interested parties, including the FDA Regional Food Specialist.

a) For variances having interstate or national implications, especially those that address food safety, regulators are urged to inform their FDA Regional Food Specialist so that FDA is aware of, and can appropriately disseminate the information regarding food safety variances that may affect food establishments in other jurisdictions, such as national chains.

b) For variances that address intrastate issues, regulators are encouraged to share the information as if it were an interstate issue.

6) Document all agency actions and decisions in the facility's file. Consider including documentation of special variance provisions on the establishment's permit to operate.

7) If the variance is approved, inform the inspector assigned to that facility and train the inspector on the variance provisions, including the implementation of the industry's HACCP plan, if required.

8) Establish procedures to periodically review the status of the variance, determine if it successfully accomplishes its public health objective, and ensure that a health hazard or nuisance does not result from its implementation.

9) Establish written procedures for withdrawing approval of the variance if it is not successful.

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). 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.

This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging material that readily allow the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 cm^2/m^3/24 hours or greater. A reduced oxygen atmosphere will result with an Oxygen Transmission rate of 10-100. The process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.

Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic ***C. botulinum*** and ***L. monocytogenes*** are able to multiply well below 5°C (41°F). For this reason, ***C. botulinum*** and ***L. monocytogenes*** become the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of ***C. botulinum*** and ***L. monocytogenes*** without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control ***C. botulinum*** and ***L. monocytogenes*** when used in conjunction with a food storage temperature of 5°C (41°F) or less. They include a_w of 0.91 or less; pH of 4.6 or less; cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or high levels of competing microorganisms. ***C. botulinum*** will not produce toxin below an a_w of 0.91. Nitrite, used in meat and poultry curing, inhibits the outgrowth of ***C. botulinum*** spores. Most foodborne pathogens do not compete well with other microorganisms, therefore foods that have a high level of spoilage organisms or lactic acid bacteria can safely be packaged using ROP. Other intrinsic or extrinsic factors can also control the growth and/or toxin production of ***C. botulinum*** and ***L. monocytogenes***.

Naturally fermented cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all of the following: a lower pH, production of organic acids, and natural antibiotics or bacteriocins such as nisin by lactic acid bacteria, salt (NaCl) added during processing, low moisture content, added preservatives, and live competing cultures. Very few outbreaks have occurred that were associated with cheese. The few outbreaks of foodborne illness associated with cheeses or cheese products could be traced in large part to temperature abuse with storage at uncontrolled ambient air temperatures. Examples of cheeses that may be packaged under ROP include Asiago

medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of ***L. monocytogenes*** under modified atmosphere conditions.

When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary barriers such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of ***C. botulinum*** and ***L. monocytogenes***. Non-proteolytic *C. botulinum* spores are able to germinate and produce toxin at temperatures down to 3ºC (38ºF). Therefore, to control for toxin production by *C. botulinum*, an anaerobe, ROP foods must be held at 3ºC (38ºF) or less. *Listeria monocytogenes* is able to grow, although very slowly, at temperatures down to - 1ºC (30ºF). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential. Four separate options are provided in (D)(2)(e). These time-temperature combinations will provide equivalent food safety protection without need for a variance. The first is cooling the bagged product to 1ºC (34ºF) and holding for up to 30 days after the product is sealed in the bag. The second is cooling bagged product to 1ºC (34ºF), removing product to a different refrigeration unit and holding at any temperature up to 5ºC (41ºF) for up to 72 hours with the total storage time not to exceed 30 days. This situation is often encountered when a central kitchen prepares and stores the bagged product at 1ºC (34ºF) then transports it to a satellite kitchen under their control where it can be held at 5ºC (41ºF) or less. The third option is cooling to 3ºC (38ºF) and holding for no more than 72 hours from packaging. The fourth option can be used without a restricted shelf life while the bagged product is held frozen until thawed to be consumed or used in another preparation

Since there are no other controlling factors for ***C. botulinum*** and ***L. monocytogenes*** in a cook-chill or sous vide packaging system, temperature control must be continuously monitored electronically and visually examined twice daily to verify that refrigeration temperatures are adequate. New technology makes it relatively easy to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook chill and sous vide products at 1°C (34°F) or 3ºC (38ºF) or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures which can be displayed using computer software.

Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.

Time is also a factor that must be considered in ROP. The 14 day "use by" date is required label information for VP, MAP, and CAP products and cannot exceed the manufacturer's "sell by" or "use by" date. This is considered a safe time period because two barriers to growth are required to be present. When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 34°F or less with an option of 3ºC (38ºF) for up to 72 hours after packaging with stringent temperature monitoring and recording requirements. These criteria allow both institutional-sized cook chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook chill and sous vide processes.

The extended shelf life for vacuum packaged hard and semisoft cheeses is based on many intrinsic factors in these cheeses plus the normal refrigeration temperature of 41°F or less to maintain safety.

A Hazard Analysis Critical Control Point (HACCP) plan is essential when using ROP processing procedures. ***C. botulinum*** and ***L. monocytogenes*** are potential hazards which must be controlled in most foods unless the food is a low acid canned food produced under 21 CFR Part 108 or 113 or an acidified food produced under 21 CFR 114. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used.

When a food establishment intends to use ROP technology but does not use one of the secondary barriers defined in section 3-502.12 (a single barrier of 34°F combined with the criteria specified in paragraph 3-502.12(D), or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), the operator must submit an application for a variance under section 3-502.11 providing evidence that the ROP methodology intended for use is safe.

Unfrozen raw fish and other seafood are specifically excluded from ROP because of these products' natural association with ***C. botulinum*** type E which grows at or above 3ºC (37-38ºF). Fish and seafood that are frozen before, during and after the ROP packaging process are allowed.

Accurate	**3-601.11**	**Standards of Identity.**
Representation	**3-601.12**	**Honestly Presented.**
Labeling	**3-602.11**	**Food Labels.**
	3-602.12	**Other Forms of Information.**

The identity of a food in terms of origin and composition is important for instances when a food may be implicated in a foodborne illness and for nutritional information requirements. Ingredient information is needed by consumers who have allergies to certain food or ingredients. The appearance of a food should not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

Recent illnesses and deaths from Shiga toxin-producing ***Escherichia coli*** have occurred across the United States as a result of people eating hamburgers that were contaminated and then undercooked. USDA issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe-handling label or sticker or be accompanied by a leaflet that contains information on proper handling and cooking procedures.

Certain requirements in the CFR relating to aspects of nutrition labeling became effective in May, 1997. The following attempts to provide guidance regarding those requirements and exemptions as they relate to the retail environment and to alert regulators to authority that has been given to them by the Nutrition Labeling and Education Act (NLEA) of 1990. The statute and the CFR should be reviewed to ensure a comprehensive understanding of the labeling requirements.

I. The following foods need not comply with nutrition labeling in the CFR referenced in subparagraph 3-602.11(B)(5) if they do not bear a nutrient claim, health claim, or other nutrition information:

(A) Foods packaged in a food establishment if:

(1) The food establishment has total annual sales to consumers of no more than $500,000 (or no more than $50,000 in food sales alone), and

(2) The label of the food does not bear a reference to the manufacturer or processor other than the food establishment;

(B) Low-volume food products if:

(1) The annual sales are less than 100,000 units for which a notification claiming exemption has been filed with FDA's Office of Nutritional Products Labeling and Dietary Supplements Food Labeling by a small business with less than 100 full-time equivalent employees, or

(2) The annual sales are less than 10,000 units by a small business with less than 10 full-time equivalent employees;

(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;

(F) Bulk food for further manufacturing or repacking; and

(G) Raw fruits, vegetables, and fish.

II. Game animal meats shall provide nutrition information which may be provided by labeling displayed at the point of purchase such as on a counter card, sign, tag affixed to the food, or some other appropriate device.

III. Food packaged in a food processing plant or another food establishment, shall meet the requirements specified in § 3-602.11 and enforcement by the regulatory authority is authorized in the NLEA, Section 4. State Enforcement.

In 1998, 21 CFR Part 73, Section 73.75 was amended to address canthaxanthin as a color additive for salmonid fish. According to the FDA Regulatory Fish Encyclopedia, the family Salmonidae includes pink salmon, coho salmon, sockeye salmon, chinook salmon, Atlantic salmon, chum salmon, rainbow trout, cutthroat trout, and brown trout. This color additive may be in the feed that is fed to aquacultured fish, and when those fish are placed into a bulk container for shipment, the bulk container must bear a label declaring the presence of canthaxanthin. That same label information must be displayed at retail when those fish are offered for sale.

The 21 CFR Section 73.75(d)(4) requires that the presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2) and 101.100(a)(2). For additional information, see the Federal Register announcement 63 FR 14814, March 27, 1998, Listing of Color Additives Exempt from Certification; Canthaxanthin.

On August 2, 2004, President Bush signed into law the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282). This new law amended Sections 201 and 403 of the Federal Food, Drug, and Cosmetic Act to establish food allergen labeling requirements for all packaged foods regulated by FDA. The new provisions require that all affected packages of food labeled on or after January 1, 2006 must identify on the label the names of the food sources of any major food allergens (i.e., the following eight foods and any protein derived from them: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans) used as ingredients in the food. The names of the food sources are the same as the names of the eight foods that are major food allergens, with the exception that for fish, crustacean shellfish, and tree nuts, their respective food source names are the specific species of fish (e.g., bass, flounder, or cod), the specific species of crustacean shellfish (e.g., crab, lobster, or shrimp), and the specific types of tree nuts (e.g., almonds, pecans, or walnuts).

Consumer Advisory	**3-603.11**	**Consumption of Raw or Undercooked Animal Foods.**

Refer to the public health reason for § 3-401.11.

Purpose:

At issue is the role of government agencies, the regulated industry, and others in providing notice to consumers that animal-derived foods that are not subjected to adequate heat treatment pose a risk because they may contain biological agents that cause foodborne disease. The deliverance of a balanced message that communicates fairly to all consumers and, where epidemiologically supported, attempts to place risk in perspective based on the consumer's health status and the food being consumed is part of the challenge. Notification of risk must be achieved via a meaningful message and in a manner that is likely to affect behavior. The following information is to alert the reader to the options available to food establishments in advising consumers of the increased possibility of foodborne illness when animal-derived foods are eaten raw or undercooked.

Background:

Although no specific advisory language was recommended, beginning with the 1993 Food Code, FDA included a codified provision for a point-of-purchase consumer advisory and stated in Annex 3:

> "FDA has requested comments and will consider the responses as well as other information that is available related to the risks involved and methods of risk communication to determine what action may be necessary by FDA to effectively inform consumers."

Consumer Focus Groups:

During 1996 - 1998, FDA conducted two different consumer focus group studies. Because the first set of focus groups (conducted before the 1997 Code) were not receptive to the language recommended at the 1996 Conference for Food Protection (CFP) meeting, that language was not included in the 1997 Code. Before the 1998 CFP meeting, the Agency convened a second set of focus groups with a modified approach. The latter set expressed similar thoughts as those in the earlier set and a pattern for consumer acceptance and receptiveness to menu-based advisories emerged.

It became apparent that there is a general appreciation for "**disclosure**" of what consumers view as "hidden ingredients, " for example, whether a particular menu item contains raw egg. In addition to disclosure being viewed as helpful, consumers are accepting, if not appreciative, of a "**reminder**" that consuming raw or undercooked animal-derived foods carries an increased risk of foodborne illness. In the food establishment venue, consumers are less willing to accept a message that extends beyond a reminder and becomes a lesson or an educational message.

Satisfactory Compliance:

FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that **satisfactory compliance with the Code's consumer advisory provision is fulfilled when both a disclosure and reminder are provided**, as described in § 3-603.11 of the Code. **Disclosure is** achieved when there is clear identification of animal-derived foods that are sold or served raw or undercooked, and of items that either contain or may contain (to allow for ingredient substitution) such raw or undercooked ingredients. A third option for the consumer "reminder" was added later. The **reminder is** a notice about the relationship between thorough cooking and food safety.

Two options were endorsed for disclosure and two for the reminder. One of the reminder options is a menu statement that advises consumers that food safety information about the disclosed items is available upon request. Essential criteria for such written information are available from FDA through the Retail Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College Park, Maryland 20740. All brochures must meet these essential criteria. The other option is a short notice alerting consumers to the increased risk of consuming the disclosed menu items.

In response to concerns raised by the Interstate Shellfish Sanitation Conference (ISSC) in an October 8, 1998 letter to FDA, a third option has been added to allow for a statement that links an increased risk of illness to consumption of raw or undercooked animal foods by persons with certain medical conditions.

The information contained in both the disclosure and reminder should be publicly available and readable so that consumers have benefit of the total message (disclosure and reminder) before making their order selections.

It is not possible to anticipate all conceivable situations. Therefore, there will always be need for discussion between the food establishment and the Regulatory Authority as to the most effective way to meet the objectives of satisfactory compliance.

The *Implementation Guidance for the Consumer Advisory Provision of the FDA Food Code* (section 3-603.11 in the FDA Model Food Code), is a resource intended to assist regulators and industry in the implementation of the Consumer Advisory provision. It is recommended that it be used in conjunction with the FDA Food Code. It is available from FDA through the Retail Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College Park, Maryland 20740.

Locating the Advisory:

Disclosure of raw or undercooked animal-derived foods or ingredients and reminders about the risk of consuming such foods belong at the point where the food is selected by the consumer. Both the disclosure and the reminder need to accompany the information from which the consumer makes a selection. That information could appear in many forms such as a menu, a placarded listing of available choices, or a table tent.

Educational Messages:

Educational messages are usually longer, more didactic in nature, and targeted to consumers who have been alerted to the food safety concern and take the initiative to obtain more detailed information. It is expected that, in most cases, educational messages that are provided pursuant to § 3-603.11 (i.e., in situations where the option for referring the consumer to additional information is chosen), will be embodied in brochures that will not be read at the site where the immediate food choice is being made. Nonetheless, such messages are viewed as an important facet of arming consumers with the information needed to make informed decisions and, because the information is being requested by the consumer, it would be expected to play a role in subsequent choices.

Applicability:

Food Establishments:

The consumer advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs,

and sites where groceries are obtained that have operations such as delicatessens or seafood departments.

"*... Otherwise Processed to Eliminate Pathogens... ":*

This phrase is included in § 3-603.11 to encompass new technologies and pathogen control/reduction regimens as they are developed and validated as fulfilling a specific performance standard for pathogens of concern. Pasteurization of milk is an example of a long-standing validated process. For purposes of the Food Code, the level of pathogen reduction that is required before a raw or undercooked animal food is allowed to be offered without a consumer advisory must be equivalent to the levels provided by § 3-401.11 for the type of food being prepared.

The absorbed dose levels of radiation approved by FDA on December 3, 1997 for red meat are insufficient to reduce the level of most vegetative pathogens to a point that is equivalent to the reductions achieved in ¶¶ 3-401.11(A) and (B). Irradiated poultry provides a 3D kill which does not provide the level of protection of the 7D kill that results from the cooking regimen in the Food Code. Therefore, irradiated meat and poultry are not allowed to be offered in a ready-to-eat form without a consumer advisory. It is intended that future Food Code revisions will address time/temperature requirements that take into consideration the pathogen reduction that occurs with irradiated foods.

Recognition of Other Processes:

Animal-derived foods may undergo validated processes that target a specific pathogen. In such instances, along with the required consumer advisory may appear additional language that accurately describes the process and what it achieves. For example, a technology for reducing ***Vibrio vulnificus*** in oysters to nondetectable levels has been validated. FDA concurs that shellfish subjected to that process can be labeled with a truthful claim that appropriately describes the product. That is, a statement could be made such as, "pasteurized to reduce ***Vibrio vulnificus***" or "temperature treated to reduce ***Vibrio vulnificus***. " Such a claim must be in accordance with labeling laws and regulations, accurate, and not misleading. The claim would not, however, negate the need for a consumer advisory because the treatment only reduces the level of one pathogenic organism.

Product-specific Advisories:

Consumer advisories may be tailored to be product-specific if a food establishment either has a limited menu or offers only certain animal-derived foods in a raw or undercooked ready-to-eat form. For example, a raw bar serving molluscan shellfish on the half shell, but no other raw or undercooked animal food, could elect to confine its consumer advisory to shellfish. The raw bar could also choose reminder, option #3, which would highlight the increased risk incurred when persons with certain medical conditions ingest shellfish that has not been adequately heat treated.

Terminology:

It should be noted that the actual on-site (e.g., on-the-menu) advisory language differs from the language in the codified provision, § 3-603.11. In the insert page for § 3-603.11, the **Reminder** options 2 and 3 use terms for foods that are less specific than the terms used in the actual code section. That is, the words "meat" rather than "beef, lamb, and pork" and "seafood" rather than "fish" are used. Categorical terms like "meat" are simpler and may be more likely used in conversation, making them suitable for purposes of a menu notice.

Milk:

In addition, "milk" is not mentioned in the actual on-site advisory language. The sale or transportation of final packaged form of unpasteurized milk into interstate commerce is specifically prohibited by 21 CFR 1240.61. Also the consumption of raw milk is not recommended by FDA (this statement is in the form of an official FDA position statement found at http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/CodedMemoranda/MemorandaofInformation/ucm079103.htm . Nonetheless, approximately 25 states allow unpasteurized milk in intrastate commerce which usually involves direct dairy farm-to-consumer procurement.

In the event that a food establishment governed by § 3-603.11 of this Code operates in conjunction with a dairy farm in a State that allows the in-State sale or service of unpasteurized milk, or in the case where a State allows unpasteurized milk to be marketed via retail-level food establishments, consumers need to be advised of the risk associated with drinking unpasteurized milk. In these situations, the actual advisory language needs to be amended to include milk (refer to Consumer Advisory Reminder, paragraph 3-603.11(C), options 2 or 3).

Molluscan Shellstock:

In addition to areas of retail food stores such as delis in supermarkets, the consumer advisory is to be provided when a seafood department or seafood market offers raw molluscan shellstock for sale or service. There is a risk of death from ***Vibrio*** infections from consuming raw molluscan shellstock for persons who have certain medical conditions.

Disposition 3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.

Pathogens may be transmitted from person to person through contaminated food. The potential spread of illness is limited when food is discarded if it may have been contaminated by employees who are infected, or are suspected of being infected, or by any person who otherwise contaminates it.

Additional Safeguards **3-801.11 Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.**

Refer to the public health reason for § 3-201.11.

The Code provisions that relate to highly susceptible populations are combined in this section for ease of reference and to add emphasis to special food safety precautions that are necessary to protect those who are particularly vulnerable to foodborne illness and for whom the implications of such illness can be dire.

As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of a “juice” means it is served as such or used as an ingredient in beverages. Puréed fruits and vegetables, which are commonly prepared as food for service to highly susceptible populations, are not juices and do not require HACCP plans or compliance with 21 CFR Part 120. 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***. As new information becomes available, the Food Code will be modified or interim interpretive guidance will be issued regarding foodborne illness interventions for on-site juicing and puréeing.

The 21 CFR 120 regulation applies to products sold as juice or used as an ingredient in beverages. This includes fruit and vegetable purees that are used in juices and beverages, but is not intended to include freshly prepared fruit or vegetable purees that are prepared on-site in a facility for service to a highly susceptible population.

In lieu of meeting the requirements of 21 CFR 120, juices that are produced as commercially sterile products (canned juices) are acceptable for service to a highly susceptible population. Persons providing pureed meals to highly susceptible populations may also wish to use fruit and vegetables that are produced as commercially sterile products (canned fruit or vegetables) as a means of enhancing food safety.

Salmonella often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of ***Salmonella*** **Enteritidis** traced to stuffed pasta made with raw eggs and labeled "fully cooked." Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked as was the case in the 1986 outbreak linked to stuffed pasta. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Operators of food establishments serving highly susceptible populations may wish to discuss buyer specifications with their suppliers. Such specifications could stipulate

eggs that are produced only by flocks managed under a ***Salmonella* Enteritidis** control program that is recognized by a regulatory agency that has animal health jurisdiction. Such programs are designed to reduce the presence of ***Salmonella* Enteritidis** in raw shell eggs. In any case, the food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to ***Salmonella* Enteritidis**.

Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in place to improve the safety of these products. Further information is available at the FDA website, http://www.fda.gov, by entering "sprouts" in the search window.

Although the Code's allowance for the Regulatory Authority to grant a variance (refer to §§ 8-103.10 - .12, 8-201.14, and 8-304.11) is applicable to all Code provisions, variance requests related to the preparation of food for highly susceptible populations must be considered with particular caution and scrutiny. With all variances, the hazard(s) must be clearly identified and controlled by a HACCP plan that is instituted in conjunction with a standard operating plan that implements good retail practices. Variances that will impact a highly susceptible population must be considered in light of the fact that such a population is at a significantly higher risk of contracting foodborne illnesses and suffering serious consequences including death from those illnesses, than is the general population.

Subparagraph 3-801.11(F)(3) requires a HACCP plan for the use of raw shell eggs when eggs are combined in food establishments serving highly susceptible populations. A variance is not required since the HACCP plan criteria are specific, prescriptive, and conservative and require a cooking temperature and time to ensure destruction of ***Salmonella* Enteritidis**.

3-801.11(G) and (H) Re-service of food

The Food Code addresses two issues concerning persons in isolation:

1. Contamination from an isolated patient to others outside.

The re-service of any food including unopened, original, intact packages in sound condition, of non-potentially hazardous food (temperature controlled for safety) from a person in isolation or quarantine for use by anyone else (other patients, clients, or consumers) is not permitted. The "isolation or quarantine" terminology in the Code text refers to a patient-care setting that isolates the patient, thereby preventing spread of key pathogens to other patients and healthcare workers. Once food packages come to a contact isolation room, they stay there until the patient uses or discards them. If packages of food are still in the room when the patient is discharged or moved from isolation, they must be discarded.

2. Contamination from the outside into a room with a patient in a “protective environment” isolation setting which protects the patient from contacting pathogens from other patients, healthcare workers, or other persons.

Packages of food from any patients, clients or other consumers should not be re-served to persons in protective environment isolation. Precautions similar to the isolation setting apply to this setting, i.e., once an unopened, original, intact package of condiment is delivered to this patient, the package stays there until used or discarded. New (not re-served) packages of food should be delivered to this patient each time.

To summarize the key difference between the two scenarios:

- Food packages served to patients in contact isolation may not be re-served to other patients because of the potential for disease transmission to other patients.

- Patients in protective environments should not be re-served with food packages from other patients because of the potential for disease transmission to the protective environment patient.

Chapter 4 Equipment, Utensils, and Linens

Multiuse **4-101.11 Characteristics.**

Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared which could lead to foodborne illness. In addition, some materials can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

4-101.12 Cast Iron, Use Limitation.

Equipment and utensils constructed of cast iron meet the requirement of durability as intended in section 4-101.11. However, the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean. On the other hand,

when cast iron use is limited to cooking surfaces the residues in the porous surface are not of significant concern as heat destroys potential pathogens that may be present.

4-101.13 Lead, Use Limitation.

Historically, lead has been used in the formulation or decoration of these types of utensils. Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused high concentrations of lead to leach into the food they contain.

Lead poisoning continues to be an important public health concern due to the seriousness of associated medical problems. Lead poisoning is particularly harmful to the young and has caused learning disabilities and medical problems among individuals who have consumed high levels. The allowable levels of lead are specific to the type of utensil, based on the average contact time and properties of the foods routinely stored in each item listed.

FDA has established maximum levels (see FDA Compliance Policy Guide Section 545.450 Pottery (Ceramics); Imported and Domestic – Lead Contamination (CPG 7117.07) for leachable lead in ceramicware, and pieces that exceed these levels are subject to recall or other agency enforcement action. The levels are based on how frequently a piece of ceramicware is used, the type and temperature of the food it holds, and how long the food stays in contact with the piece. For example, cups, mugs, and pitchers have the most stringent action level, 0.5 parts per million, because they can be expected to hold food longer, allowing more time for lead to leach. Also, a pitcher may be used to hold fruit juice. And a coffee mug is generally used every day to hold a hot acidic beverage, often several times a day.

The FDA allows use of lead glazes because they're the most durable, but regulates them tightly to ensure their safety. Commercial manufacturers employ extremely strict and effective manufacturing controls that keep the lead from leaching during use. Small potters often can't control the firing of lead glazes as well so their ceramics are more likely to leach illegal lead levels, although many do use lead-free glazes.

In 21 CFR 109.16, FDA requires high-lead-leaching decorative ceramicware to be permanently labeled that it's not for food use and may poison food. Such items bought outside the United States may not be so labeled, potentially posing serious risk if used for food.

Pewter refers to a number of silver-gray alloys of tin containing various amounts of antimony, copper, and lead. The same concerns about the leaching of heavy metals and lead that apply to brass, galvanized metals, copper, cast iron, ceramics, and crystal also apply to pewter. As previously stated, the storage of acidic moist foods in pewter containers could result in food poisoning (heavy metal poisoning).

Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals. Solder may be composed of tin and lead alloys.

4-101.14 Copper, Use Limitation.

High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released into a water supply because of an ineffective or nonexistent backflow prevention device between a carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide leaches copper from the plumbing components and the leachate is then transferred to beverages, causing copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and have resulted in, the leaching of both copper and lead into carbonated beverages.

Brass is an alloy of copper and zinc and contains lead which is used to combine the two elements. Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.

The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in order to optimize enzymatic activity. The pH is commonly lowered to 5.1-5.2, but may be adjusted to as low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to 22 hours or more. After boiling, the wort is cooled, inoculated with brewers yeast, and fermented. The use of copper equipment during the prefermentation and fermentation steps typically result in some leaching of copper.

Because copper is an essential nutrient for yeast growth, low levels of copper are metabolized by the yeast during fermentation. However, studies have shown that copper levels above 0.2 mg/L are toxic or lethal to the yeast. In addition, copper levels as low as 3.5 mg/L have been reported to cause symptoms of copper poisoning in humans. Therefore, the levels of copper necessary for successful beer fermentation (i.e., below 0.2 mg/L) do not reach a level that would be toxic to humans.

Today, domestic beer brewers typically endeavor to use only stainless steel or stainless steel-lined copper equipment (piping, fermenters, filters, holding tanks, bottling machines, keys, etc.) in contact with beer following the hot brewing steps in the beer making process. Some also use pitch-coated oak vats or glass-lined steel vats following the hot brewing steps. Where copper equipment is not used in beer brewing, it is common practice to add copper (along with zinc) to provide the nutrients essential to the yeast for successful fermentation.

4-101.15 Galvanized Metal, Use Limitation.

Galvanized means iron or steel coated with zinc, a heavy metal that may be leached from galvanized containers into foods that are high in water content. The risk of leaching increases with increased acidity of foods contacting the galvanized container.

4-101.16 Sponges, Use Limitation.

Sponges are difficult, if not impossible, to clean once they have been in contact with food particles and contaminants that are found in the use environment. Because of their construction, sponges provide harborage for any number and variety of microbiological organisms, many of which may be pathogenic. Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use, food-contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.

4-101.17 Wood, Use Limitation.

The limited acceptance of the use of wood as a food-contact surface is determined by the nature of the food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface may become difficult to clean. In addition, wood that is treated with preservatives may result in illness due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are allowed.

4-101.18 Nonstick Coatings, Use Limitation.

Perfluorocarbon resin is a tough, nonporous and stable plastic material that gives cookware and bakeware a surface to which foods will not stick and that cleans easily and quickly. FDA has approved the use of this material as safe for food-contact surfaces. The Agency has determined that neither the particles that may chip off nor the fumes given off at high temperatures pose a health hazard. However, because this nonstick finish may be scratched by sharp or rough-edged kitchen tools, the manufacturer's recommendations should be consulted and the use of utensils that may scratch, abrasive scouring pads, or cleaners avoided.

4-101.19 Nonfood-Contact Surfaces.

Nonfood-contact surfaces of equipment routinely exposed to splash or food debris are required to be constructed of nonabsorbent materials to facilitate cleaning. Equipment that is easily cleaned minimizes the presence of pathogenic organisms, moisture, and debris and deters the attraction of rodents and insects.

Single-Service and Single-Use **4-102.11 Characteristics.**

The safety and quality of food can be adversely affected through single service and single use articles that are not constructed of acceptable materials. The migration of components of those materials to food they contact could result in chemical contamination and illness to the consumer. In addition, the use of unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors transferred to the food.

Durability and Strength **4-201.11 Equipment and Utensils.**

Equipment and utensils must be designed and constructed to be durable and capable of retaining their original characteristics so that such items can continue to fulfill their intended purpose for the duration of their life expectancy and to maintain their easy cleanability. If they can not maintain their original characteristics, they may become difficult to clean, allowing for the harborage of pathogenic microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that parts do not break and end up in food as foreign objects or present injury hazards to consumers. A common example of presenting an injury hazard is the tendency for tines of poorly designed single service forks to break during use.

4-201.12 Food Temperature Measuring Devices.

Food temperature measuring devices that have glass sensors or stems present a likelihood that glass will end up in food as a foreign object and create an injury hazard to the consumer. In addition, the contents of the temperature measuring device, e.g., mercury, may contaminate food or utensils.

Cleanability **4-202.11 Food-Contact Surfaces.**

The purpose of the requirements for multiuse food-contact surfaces is to ensure that such surfaces are capable of being easily cleaned and accessible for cleaning. Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have imperfections such as cracks, chips, or pits allow microorganisms to attach and form biofilms. Once established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

4-202.12 CIP Equipment.

Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be monitored via access points to ensure that cleaning has been effective throughout the system.

The CIP design must ensure that all food-contact surfaces of the equipment are contacted by the circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas which are not contacted by the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-draining.

4-202.13 "V" Threads, Use Limitation.

V-type threads present a surface which is difficult to clean routinely; therefore, they are not allowed on food-contact surfaces. The exception provided for hot oil cooking fryers and filtering systems is based on the high temperatures that are used in this equipment. The high temperature in effect sterilizes the equipment, including debris in the "V" threads.

4-202.14 Hot Oil Filtering Equipment.

To facilitate and ensure effective cleaning of this equipment, Code requirements, §§ 4-202.11 and 4-202.12 must be followed. The filter is designed to keep the oil free of undesired materials and therefore must be readily accessible for replacement. Filtering the oil reduces the likelihood that off-odors, tastes, and possibly toxic compounds may be imparted to food as a result of debris buildup. To ensure that filtering occurs, it is necessary for the filter to be accessible for replacement.

4-202.15 Can Openers.

Once can openers become pitted or the surface in any way becomes uncleanable, they must be replaced because they can no longer be adequately cleaned and sanitized. Can openers must be designed to facilitate replacement.

4-202.16 Nonfood-Contact Surfaces.

Hard-to-clean areas could result in the attraction and harborage of insects and rodents and allow the growth of foodborne pathogenic microorganisms. Well-designed equipment enhances the ability to keep nonfood-contact surfaces clean.

4-202.17 Kick Plates, Removable.

The use of kick plates is required to allow access for proper cleaning. If kick plate design and installation does not meet Code requirements, debris could accumulate and create a situation that may attract insects and rodents.

Accuracy 4-203.11 Temperature Measuring Devices, Food.

The Metric Conversion Act of 1975 (amended 1988, 1996, and 2004, 15 USC 205a et seq) requires that all Federal government regulations use the Celsius scale for temperature measurement. The Fahrenheit scale is included in the Code for those jurisdictions using the Fahrenheit scale for temperature measurement.

The small margin of error specified for thermometer accuracy is due to the lack of a large safety margin in the temperature requirements themselves. The accuracy specified for a particular food temperature measuring device is applicable to its entire range of use, that is, from refrigeration through cooking temperatures if the device is intended for such use.

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

A temperature measuring device used to measure the air temperature in a refrigeration unit is not required to be as accurate as a food thermometer because the unit's temperature fluctuates with repeated opening and closing of the door and because accuracy in measuring internal food temperatures is of more significance.

The Celsius scale is the federally recognized scale based on The Metric Conversion Act of 1975 (amended 1988, 1996, and 2004, 15 USC 205a et seq) which requires the use of metric values. The ±1.5°C requirement is more stringent than the 3°F previously required since ±1.5°C is equivalent to ±2.7°F. The more rigid accuracy results from the practical application of metric equivalents to the temperature gradations of Celsius thermometers.

If Fahrenheit thermometers are used, the 3°F requirement applies because of the calibrated intervals of Fahrenheit thermometers.

The accuracy specified for a particular air or water temperature measuring device is applicable to its intended range of use. For example, a cold holding unit may have a temperature measuring device that measures from a specified frozen temperature to 20°C (68°F). The device must be accurate to specifications within that use range.

4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.

Flow pressure is a very important factor with respect to the efficacy of sanitization. A pressure below the design pressure results in inadequate spray patterns and incomplete coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water droplets needed to convey heat into a vapor mist that cools before reaching the surfaces to be sanitized.

Functionality **4-204.11 Ventilation Hood Systems, Drip Prevention.**

The dripping of grease or condensation onto food constitutes adulteration and may involve contamination of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use articles that are subjected to such drippage are no longer clean.

4-204.12 Equipment Openings, Closures and Deflectors.

Equipment openings and covers must be designed to protect stored or prepared food from contaminants and foreign matter that may fall into the food. The requirement for an opening to be flanged upward and for the cover to overlap the opening and be sloped to drain prevents contaminants, especially liquids, from entering the food-contact area.

Some equipment may have parts that extend into the food-contact areas. If these parts are not provided with a watertight joint at the point of entry into the food-contact area, liquids may contaminate the food by adhering to shafts or other parts and running or dripping into the food.

An apron on parts extending into the food-contact area is an acceptable alternative to the watertight seal. If the apron is not properly designed and installed, condensation, drips, and dust may gain access to the food.

4-204.13 Dispensing Equipment, Protection of Equipment and Food.

This requirement is intended to protect both the machine-dispensed, unpackaged, liquid foods and the machine components from contamination. Barriers need to be provided so that the only liquid entering the food container is the liquid intended to be dispensed when the machine's mechanism is activated. Recessing of the machine's components and self-closing doors prevent contamination of machine ports by people, dust, insects, or rodents. If the equipment components become contaminated, the product itself will be exposed to possible contamination.

A direct opening into the food being dispensed allows dust, vermin, and other contaminants access to the food.

NSF/ANSI 18-*Manual Food and Beverage Dispensing Equipment* is the standard for manual food and beverage dispensing equipment which has been designed to maintain the safety of aseptically packaged fluid foods without refrigeration even after the hermetic seal is broken.

NSF/ANSI 18 was revised in 2006 to specifically address dispensing equipment designed to hold potentially hazardous food or beverages in a homogeneous liquid form without temperature control. NSF/ANSI 18 requires that such equipment designs include a number of safeguards that prevent the contamination of specially packaged food stored within the dispensing equipment. The Standard also requires that the dispensing equipment have lockout mechanisms that preclude the dispensing of the product if such safeguards fail or if a prescribed duration of storage is exceeded. The American National Standards Institute (ANSI) recognizes NSF/ANSI 18 as the sole American National Standard for the sanitary design of manual food and beverage dispensers.

4-204.14 Vending Machine, Vending Stage Closure.

Since packaged foods dispensed from vending machines could attract insects and rodents, a self-closing door is required as a barrier to their entrance.

4-204.15 Bearings and Gear Boxes, Leakproof.

It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation of these types of equipment could contaminate food or food-contact surfaces if the equipment is not properly designed and constructed.

4-204.16 Beverage Tubing, Separation.

Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment, mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice through condensate migrating along the exterior of the lines.

Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in the bin.

4-204.18 Condenser Unit, Separation.

A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-contact areas from contamination by dust that is accumulated and blown about as a result of the condenser's operation.

4-204.19 Can Openers on Vending Machines.

Since the cutting or piercing surfaces of a can opener directly contact food in the container being opened, these surfaces must be protected from contamination.

4-204.110 Molluscan Shellfish Tanks.

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern. If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

4-204.111 Vending Machines, Automatic Shutoff.

Failure to store potentially hazardous (time/temperature control for safety) food at safe temperatures in a vending machine could result in the growth of pathogenic microorganisms that may result in foodborne illness. The presence of an automatic control that prevents the vending of food if the temperature of the unit exceeds Code requirements precludes the vending of foods that may not be safe.

It is possible and indeed very likely that the temperature of the storage area of a vending machine may exceed Code requirements during the stocking and servicing of the machine. The automatic shut off, commonly referred to as the "public health control," provides a limited amount of time that the ambient temperature of a machine may exceed Code requirements. Strict adherence to the time requirements can limit the growth of pathogenic microorganisms.

4-204.112 Temperature Measuring Devices.

The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Code requirements. Therefore, the temperature measuring device must be placed in a location that is representative of the actual storage temperature of the unit to ensure that all potentially hazardous (time/temperature control for safety) foods are stored at least at the minimum temperature required in Chapter 3.

Installing an air thermometer in some open display refrigerators can be difficult without physically impairing the usability of the case and interfering with cleaning and sanitation. Use of a temperature monitoring system that uses probe-like sensors that are placed in material resembling the density of food is an acceptable alternative. Thus, the direct temperature of the substitute product is measured by use of this product mimicking method.

A permanent temperature measuring device is required in any unit storing potentially hazardous (time/temperature control for safety) food because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed Code requirements. In order to facilitate routine monitoring of the unit, the device must be clearly visible.

The exception to requiring a temperature measuring device for the types of equipment listed is primarily due to equipment design and function. It would be difficult and impractical to permanently mount a temperature measuring device on the equipment listed. The futility of attempting to measure the temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point. In such cases, it would be more practical and accurate to measure the internal temperature of the food.

The importance of maintaining potentially hazardous (time/temperature control for safety) foods at the specified temperatures requires that temperature measuring devices be easily readable. The inability to accurately read a thermometer could result in food being held at unsafe temperatures.

Temperature measuring devices must be appropriately scaled per Code requirements to ensure accurate readings.

The required incremental gradations are more precise for food measuring devices than for those used to measure ambient temperature because of the significance at a given point in time, i.e., the potential for pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the ambient temperature of the storage unit; it will depend on many variables including the temperature of the food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time the food is stored in the unit.

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

The data plate provides the operator with the fundamental information needed to ensure that the machine is effectively washing, rinsing, and sanitizing equipment and utensils. The warewashing machine has been tested, and the information on the data plate represents the parameters that ensure effective operation and sanitization and that need to be monitored.

4-204.114 Warewashing Machines, Internal Baffles.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

4-204.116 Manual Warewashing Equipment, Heaters and Baskets.

Hot water sanitization is accomplished in water of not less than 77°C (170°F) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.

The presence of adequate detergents and sanitizers is necessary to effect clean and sanitized utensils and equipment. The automatic dispensing of these chemical agents, plus a method such as a flow indicator, flashing light, buzzer, or visible open air delivery system that alerts the operator that the chemicals are no longer being dispensed, ensures that utensils are subjected to an efficacious cleaning and sanitizing regimen.

4-204.118 Warewashing Machines, Flow Pressure Device.

Flow pressure is a very important factor impacting the efficacy of sanitization in machines that use fresh hot water at line-pressure as a final sanitization rinse. (See discussion in Public Health Reason for section 4-203.13.) It is important that the operator be able to monitor, and the food inspector be able to check, final sanitization rinse pressure as well as machine water temperatures. ANSI/NSF Standard #3, a national voluntary consensus standard for Commercial Spray-Type Dishwashing Machines, specifies that a pressure gauge or similar device be provided on this type machine and such devices are shipped with machines by the manufacturer. Flow pressure devices installed on the upstream side of the control (solenoid) valve are subject to damage and failure due to the water hammer effect caused throughout the dishwashing period each time the control valve closes. The IPS valve provides a ready means for checking line-pressure with an alternative pressure measuring device. A flow pressure device is not required on machines that use only a pumped or recirculated sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-pressure.

4-204.121 Vending Machines, Liquid Waste Products.

The presence of internal waste containers allows for the collection of liquids that spill within the vending machine. Absence of a waste container or, where required, a shutoff valve which controls the incoming liquids could result in wastes spilling within the machine, causing a condition that attracts insects and rodents and compounds cleaning and maintenance problems.

4-204.122 Case Lot Handling Equipment, Moveability.

Proper design of case lot handling equipment facilitates moving case lots for cleaning and for surveillance of insect or rodent activity.

4-204.123 Vending Machine Doors and Openings.

The objective of this requirement is to provide a barrier against the entrance into vending machines of insects, rodents, and dust. The maximum size of the openings deters the entrance of common pests.

Acceptability **4-205.10 Food Equipment, Certification and Classification.**

Under ANSI document CA-1 ANSI Policy and Criteria for Accreditation of Certification Programs, it has been stipulated that:

"For food equipment programs, standards that establish sanitation requirements shall be specified government standards or standards that have been ratified by a public health approval step. ANSI shall verify that this requirement has been met by communicating with appropriate standards developing organizations and governmental public health bodies."

The term certified is used when an item of food equipment has been evaluated against an organization's own standard. The term classified is used when one organization evaluates an item of food equipment against a standard developed by another organization.

Equipment **4-301.11 Cooling, Heating, and Holding Capacities.**

The ability of equipment to cool, heat, and maintain potentially hazardous (time/temperature control for safety) foods at Code-required temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold holding equipment with enough capacity to meet the heating and cooling demands of the operation.

4-301.12 Manual Warewashing, Sink Compartment Requirements.

The 3 compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

1. Application of cleaners and the removal of soil;

2. Removal of any abrasive and removal or dilution of cleaning chemicals; and

3. Sanitization.

Refer also to the public health reason for § 4-603.16.

4-301.13 Drainboards.

Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

4-301.14 Ventilation Hood Systems, Adequacy.

If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings of the food establishment, causing an insanitary condition and possible deterioration of the surfaces of walls and ceilings. The accumulation of grease and condensate may contaminate food and food-contact surfaces as well as present a possible fire hazard.

Refer also to the public health reason for § 4-204.11.

4-301.15 Clothes Washers and Dryers.

To protect food, soiled work clothes or linens must be efficiently laundered. The only practical way of efficiently laundering work clothes on the premises is with the use of a mechanical washer and dryer.

Refer also to the public health reason for § 4-401.11.

Utensils, Temperature Measuring Devices, and Testing Devices

4-302.11 Utensils, Consumer Self-Service.

Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil so that it may be used for another, use of soiled tableware to transfer food, and cross contamination between foods, including a raw food to a cooked potentially hazardous (time/temperature control for safety) food.

4-302.12 Food Temperature Measuring Devices.

The presence and accessibility of food temperature measuring devices is critical to the effective monitoring of food temperatures. Proper use of such devices provides the operator or person in charge with important information with which to determine if temperatures should be adjusted or if foods should be discarded.

When determining the temperature of thin foods, those having a thickness less than 13 mm (1/2 inch), it is particularly important to use a temperature sensing probe designed for that purpose. Bimetal, bayonet style thermometers are not suitable for accurately measuring the temperature of thin foods such as hamburger patties because of the large diameter of the probe and the inability to accurately sense the temperature at the tip of the probe. However, temperature measurements in thin foods can be accurately determined using a small-diameter probe 1.5 mm (0.059 inch), or less, connected to a device such as thermocouple thermometer.

4-302.13 Temperature Measuring Devices, Manual Warewashing.

Water temperature is critical to sanitization in warewashing operations. This is particularly true if the sanitizer being used is hot water. The effectiveness of cleaners and chemical sanitizers is also determined by the temperature of the water used. A temperature measuring device is essential to monitor manual warewashing and ensure sanitization.

4-302.14 Sanitizing Solutions, Testing Devices.

Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:

1. The use of chemical sanitizers requires minimum concentrations of the sanitizer during the final rinse step to ensure sanitization; and

2. Too much sanitizer in the final rinse water could be toxic.

Location **4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.**

Food equipment and the food that contacts the equipment must be protected from sources of overhead contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects. When equipment is installed, it must be situated with consideration of the potential for contamination from such overhead sources.

If a clothes washer and dryer are installed adjacent to exposed food, clean equipment, utensils, linens, and unwrapped single-service and single-use articles, it could result in those items becoming contaminated from soiled laundry. The reverse is also true, i.e., items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located.

Installation **4-402.11 Fixed Equipment, Spacing or Sealing.**

This section is designed to ensure that fixed equipment is installed in a way that:

1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes the need for cleaning due to closely abutted surfaces;

2. Ensures that equipment that is subject to moisture is sealed;

3. Prevents the harborage of insects and rodents; and

4. Provides accessibility for the monitoring of pests.

4-402.12 Fixed Equipment, Elevation or Sealing.

The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

The economic impact of the requirement to elevate display units in retail food stores, coupled with the fact that the design, weight, and size of such units are not conducive to casters or legs, led to the exception for certain units located in consumer shopping areas, provided the floor under the units is kept clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer units in the consumer shopping areas requires a rigorous cleaning schedule.

Equipment **4-501.11 Good Repair and Proper Adjustment.**

Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to operate as designed. Failure to properly maintain equipment could lead to violations of the associated requirements of the Code that place the health of the consumer at risk. For example, refrigeration units in disrepair may no longer be capable of properly cooling or holding potentially hazardous (time/temperature control for safety) foods at safe temperatures.

The cutting or piercing parts of can openers may accumulate metal fragments that could lead to food containing foreign objects and, possibly, result in consumer injury.

Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Code requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Contact time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

4-501.12 Cutting Surfaces.

Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

4-501.13 Microwave Ovens.

Failure of microwave ovens to meet the CFR standards could result in human exposure to radiation leakage, resulting in possible medical problems to consumers and employees using the machines.

4-501.14 Warewashing Equipment, Cleaning Frequency.

During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

To ensure properly cleaned and sanitized equipment and utensils, warewashing machines must be operated properly. The manufacturer affixes a data plate to the machine providing vital, detailed instructions about the proper operation of the machine including wash, rinse, and sanitizing cycle times and temperatures which must be achieved.

4-501.16 Warewashing Sinks, Use Limitation.

If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing and thawing foods, contamination of equipment and utensils could occur.

4-501.17 Warewashing Equipment, Cleaning Agents.

Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create safety concerns for the employee and consumer. For example, employees could suffer chemical burns, and chemical residues could find their way into food if detergents or cleaners are used carelessly.

Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or detergents are used.

4-501.18 Warewashing Equipment, Clean Solutions.

Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature required in the Code is essential for removing organic matter. If the temperature is below 110°F, the performance of the detergent may be adversely affected, e.g., animal fats that may be present on the dirty dishes would not be dissolved.

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.

If the temperature during the hot water sanitizing step is less than 77°C (171°F), sanitization will not be achieved. As a result, pathogenic organisms may survive and be subsequently transferred from utensils to food.

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

The temperature of hot water delivered from a warewasher sanitizing rinse manifold must be maintained according to the equipment manufacturer’s specifications and temperature limits specified in this section to ensure surfaces of multiuse utensils such as kitchenware and tableware accumulate enough heat to destroy pathogens that may remain on such surfaces after cleaning.

The surface temperature must reach at least 71ºC (160ºF) as measured by an irreversible registering temperature measuring device to affect sanitization. When the sanitizing rinse temperature exceeds 90ºC (194ºF) at the manifold, the water becomes volatile and begins to vaporize reducing its ability to convey sufficient heat to utensil surfaces. The lower temperature limits of 74ºC (165ºF) for a stationary rack, single temperature machine, and 82ºC (180ºF) for other machines are based on the sanitizing rinse contact time required to achieve the 71ºC (160ºF) utensil surface temperature.

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.

If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing solution may be inadequate to reach all surfaces of equipment or utensils.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Correction Act of 1998, Federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940. The Food Code contains provisions that were not captured in either 21 CFR 178.1010 or 40 CFR 180.940, such as pH, temperature, and water hardness. There is need to retain these provisions in the Code.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. Provisions for pH, temperature, and water hardness in section 4-501.114 have been validated to achieve sanitization; however, these parameters are not always included on EPA-registered labels. Therefore, it is critical to sanitization that the sanitizers are used consistently with the EPA-registered label, and if pH, temperature, and water hardness (for quat) are not included on the label, that the solutions meet the standards required in the Code.

With respect to chemical sanitization, section 4-501.114 addresses the proper use conditions for the sanitizing solution, i.e., chemical concentration range, pH, and temperature minimum levels and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these parameters are not as specified in the Code or on the EPA-registered label, then this provision is violated.

By contrast, paragraph 4-703.11(C) addresses contact time in seconds. For chemical sanitization, this paragraph is only violated when the specified contact time is not met.

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940.

EPA sanitizer registration assesses compliance with 40 CFR 180.940, therefore if the product is used at the appropriate concentration for the application on the EPA-registered label, it is not necessary to consult 40 CFR 180.940 for futher compliance verification. If a sanitarian determined that a solution exceeded the concentration for the application on the EPA-registered label or is used for an application that is not on the EPA-registered label, section 7-204.11 would be violated.

To summarize, a sanitizing solution that is too weak would be a violation of section 4-501.114. A solution that is too strong would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use chemical sanitizers.

4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

Some chemical sanitizers are not compatible with detergents when a 2 compartment operation is used. When using a sanitizer that is different from the detergent-sanitizer of the wash compartment, the sanitizer may be inhibited by carry-over, resulting in inadequate sanitization.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

Utensils and Temperature and Pressure Measuring Devices

4-502.11 Good Repair and Calibration.

A utensil or food temperature measuring device can act as a source of contamination to the food it contacts if it is not maintained in good repair. Also, if temperature or pressure measuring devices are not maintained in good repair, the accuracy of the readings is questionable. Consequently, a temperature problem may not be detected, or conversely, a corrective action may be needlessly taken.

4-502.12 Single-Service and Single-Use Articles, Required Use.

In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-service and single-use articles must be used to ensure safety.

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

Articles that are not constructed of multiuse materials may not be reused as they are unable to withstand the rigors of multiple uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

4-502.14 Shells, Use Limitation.

The reuse of mollusk and crustacean shells as multiuse utensils is not allowed in food establishments. This prohibition does not apply to the removal of the oyster or other species from the shell for preparation, then returning the same animal to the same shell for service.

The shell itself may be potentially unsafe for use as a food utensil because of residues from natural and environmental contamination occurring after the mollusk or crustacean is removed. In addition, natural shells are not durable or easily cleanable as specified under section 4-502.13. When mollusk or crustacean shells (from commercial sources) are re-used by filling them with shucked shellfish, the food is considered misleading and not honestly presented.

Objective **4-601.11 Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.**

The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

Frequency **4-602.11 Equipment Food-Contact Surfaces and Utensils.**

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for potentially hazardous (time/temperature control for safety) foods should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent the growth of microorganisms on those surfaces.

Refrigeration temperatures slow down the generation time of bacterial pathogens, making it unnecessary to clean every four hours. However, the time period between cleaning equipment and utensils may not exceed 24 hours. A time-temperature chart is provided in subparagraph 4-602.11(D)(2) to accommodate operations that use equipment and utensils in a refrigerated room or area that maintains a temperature between 41^{o}F or less and 55^{o}F.

Surfaces of utensils and equipment contacting food that is not potentially hazardous (time/temperature control for safety food) such as iced tea dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent the development of slime, mold, or soil residues that may contribute to an accumulation of microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry, develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide cleaning specifications for food-contact surfaces of equipment that are not readily visible, the person in charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular items of equipment.

Regarding the possible adulteration from one species of meat to another between cleaning of food-contact surfaces, USDA/FSIS does not automatically consider species

adulteration as a health hazard. FSIS stated in an Advance Notice of Proposed Rulemaking that species adulteration falls into a gray area between safety and economic adulteration (65 FR 14486, March 17, 2000, Other Consumer Protection Activities). FSIS will review public comments received on the species adulteration issue and further review the scientific literature and risk assessment mechanisms before declaring species adulteration a health hazard. Meanwhile, species adulteration is generally considered by FSIS as an economic issue. However, investigations by FSIS of species adulteration incidents may include a determination regarding the impact of species adulteration as a health hazard on a case-by-case basis.

4-602.12 Cooking and Baking Equipment.

Food-contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect attractant when not in use. Because of the nature of the equipment, it may not be necessary to clean cooking equipment as frequently as the equipment specified in § 4-602.11.

4-602.13 Nonfood-Contact Surfaces.

The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

Methods **4-603.11 Dry Cleaning.**

Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not potentially hazardous (time/temperature control for safety foods). Under some circumstances, attempts at wet cleaning may create microbiological concerns.

4-603.12 Precleaning.

Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

4-603.13 Loading of Soiled Items, Warewashing Machines.

Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure adequate cleaning. Items which are stacked or trays which are heavily loaded with silverware cannot receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

4-603.14 Wet Cleaning.

Because of the variety of cleaning agents available and the many different types of soil to be removed it is not possible to recommend one cleaning agent to fit all situations. Each of the different types of cleaners works best under different conditions (i.e., some work best on grease, some work best in warm water, others work best in hot water). The specific chemical selected should be compatible with any other chemicals to be used in the operation such as a sanitizer or drying agent.

4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.

Some pieces of equipment are fixed or too large to be cleaned in a sink. Nonetheless, cleaning of such equipment requires the application of cleaners for the removal of soil and rinsing for the removal of abrasive and cleaning chemicals, followed by sanitization.

4-603.16 Rinsing Procedures.

It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or inactivating the sanitizer.

4-603.17 Returnables, Cleaning for Refilling.

The refilling of consumer-owned beverage containers introduces the possibility of contamination of the filling equipment or product by improperly cleaned containers or the improper operation of the equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of consumer-owned containers is limited to beverages that are not potentially hazardous (time/temperature control for safety) foods. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

Objective **4-701.10 Food-Contact Surfaces and Utensils.**

Effective sanitization procedures destroy organisms of public health importance that may be present on wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its maximum benefit.

Frequency **4-702.11 Before Use After Cleaning.**

Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-contact surfaces are sanitized before coming in contact with food and before use.

Methods **4-703.11 Hot Water and Chemical.**

Efficacious sanitization depends on warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as rinse pressure, temperature, and chemical concentration are used in combination with time to achieve sanitization.

When surface temperatures of utensils passing through warewashing machines using hot water for sanitizing do not reach the required 71ºC (160ºF), it is important to understand the factors affecting the decreased surface temperature. A comparison should be made between the machine manufacturer's operating instructions and the machine's actual wash and rinse temperatures and final rinse pressure. The actual temperatures and rinse pressure should be consistent with the machine manufacturer's operating instructions and within limits specified in §§ 4-501.112 and 4-501.113.

If either the temperature or pressure of the final rinse spray is higher than the specified upper limit, spray droplets may disperse and begin to vaporize resulting in less heat delivery to utensil surfaces. Temperatures below the specified limit will not convey the needed heat to surfaces. Pressures below the specified limit will result in incomplete coverage of the heat-conveying sanitizing rinse across utensil surfaces.

Objective **4-801.11 Clean Linens.**

Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.

Frequency **4-802.11 Specifications.**

Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food-contact surfaces. The laundering of wet wiping cloths before being used with a fresh solution of cleanser or sanitizer is designed to reduce the microbiological load in the cleanser and sanitizer and thereby reduce the possible transfer of microorganisms to food and nonfood-contact surfaces.

Methods **4-803.11 Storage of Soiled Linens**.

Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single-service and single-use articles.

4-803.12 Mechanical Washing.

Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.

4-803.13 Use of Laundry Facilities.

Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.

Drying **4-901.11 Equipment and Utensils, Air-Drying Required.**

Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

4-901.12 Wiping Cloths, Air-Drying Locations.

Cloths that are air-dried must be dried so that they do not drip on food or utensils and so that the cloths are not contaminated while air-drying.

Lubricating and Reassembling **4-902.11 Food-Contact Surfaces.**

Food-contact surfaces must be lubricated in a manner that does not introduce contaminants to those surfaces.

4-902.12 Equipment.

Equipment must be reassembled in a way that food-contact surfaces are not contaminated.

Storing **4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.**

Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and single-service and single-use articles can become contaminated

before their intended use in a variety of ways such as through water leakage, pest infestation, or other insanitary condition.

4-903.12 Prohibitions.

The improper storage of clean and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

Preventing Contamination

4-904.11 Kitchenware and Tableware.
4-904.12 Soiled and Clean Tableware.
4.904.13 Preset Tableware.

The presentation or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food- and lip-contact surfaces.

4-904.14 Rinsing Equipment and Utensils after Cleaning and Sanitizing.

The rinsing of cleaned and sanitized utensils and equipment in a manner that may contaminate the surfaces before they are used, such as running them under a faucet or by dipping them in a vessel of water, is prohibited. The application of a post-sanitizing rinse is restricted to warewashing machines because there will be little opportunity for contamination of the potable water rinse if applied within the confines of a compliant warewashing machine. Provided the sanitization is achieved before the rinse is applied and as long as any chemical sanitizers are used in accordance with an EPA-registered label, the sanitary state of utensils and equipment should not be altered by applying a potable water rinse after the required final sanitizing rinse within a warewashing machine.

Chapter 5 Water, Plumbing, and Waste

Source

5-101.11 Approved System.

Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmission of disease organisms. Water can also become contaminated with natural or man-made chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

5-101.12 System Flushing and Disinfection.

During construction, repair, or modification, water systems may become contaminated with microbes from soil because pipes are installed underground or by chemicals resulting from soldering and welding. Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as oils may also be present on or in the components of the system. To render the water safe, the system must be properly flushed and disinfected before being placed into service.

5-101.13 Bottled Drinking Water.

Bottled water is obtained from a public water system or from a private source such as a spring or well. Either means of production must be controlled by public health law to protect the consumer from contaminated water.

Quality **5-102.11 Standards.**

Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

5-102.12 Nondrinking Water.

Food establishments may use nondrinking water for purposes such as air-conditioning or fire protection. Nondrinking water is not monitored for bacteriological and chemical quality or safety as is drinking water. Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking water, or food-contact surfaces by nondrinking water. Identifying the piping designated as nondrinking waterlines and inspection for cross connections are examples of safety precautions.

Irrigation water used in the cultivation of fresh produce, e.g. herb gardens or other onsite gardens, is another example of nondrinking water. Whenever water comes into contact with fresh produce, its quality dictates the potential for pathogen contamination. Water has the potential to be a direct source of contamination and vehicle for spreading contamination. Research has shown that irrigation water can increase the frequency of pathogen contamination of harvested produce, and may contain or convey pathogens, such as *Salmonella* spp. Where used, irrigation water should be adequate and approved for its intended use in accordance with Good Agricultural Practices (GAPs) that minimize the potential for contaminated water to contact the edible portion of the crop. FDA's "*Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruit and Vegetables*" provides useful information about GAPs and safely growing, harvesting, washing, sorting, packing and distributing produce. It is available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm

5-102.13 Sampling.

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary to ensure the safety of drinking water used in the establishment.

5-102.14 Sample Report.

The most recent water sampling report must be kept on file to document a safe water supply.

Quantity and Availability

5-103.11 Capacity.

Availability of sufficient water is a basic requirement for proper sanitation within a food establishment. An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and utensils and of food employees' hands.

Hot water required for washing items such as equipment and utensils and employees' hands, must be available in sufficient quantities to meet demand during peak water usage periods. Booster heaters for warewashers that use hot water for sanitizing are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization can not be reached. Manual washing of food equipment and utensils is most effective when hot water is used. Unless utensils are clean to sight and touch, they cannot be effectively sanitized.

5-103.12 Pressure.

Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashers operate according to manufacturer's specifications.

Distribution, Delivery, and Retention **5-104.11 System.**

Inadequate water systems may serve as vehicles for contamination of food or food-contact surfaces. This requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be safe, through a distribution system which is protected.

5-104.12 Alternative Water Supply.

Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in contamination of safe water and render it hazardous to human health.

Materials **5-201.11 Approved.**

Plumbing systems and hoses conveying water must be made of approved materials and be smooth, durable, nonabsorbent, and corrosion-resistant. If not, the system may constitute a health hazard because unsuitable surfaces may harbor disease organisms or it may be constructed of materials that may, themselves, contaminate the water supply.

Design, Construction, and Installation **5-202.11 Approved System and Cleanable Fixtures.**

Water within a system will leach minute quantities of materials out of the components of the system. To make sure none of the leached matter is toxic or in a form that may produce detrimental effects, even through long-term use, all materials and components used in water systems must be of an approved type. New or replacement items must be tested and approved based on current standards.

Improperly designed, installed, or repaired water systems can have inherent deficiencies such as improper access openings, dead spaces, and areas difficult or impossible to clean and disinfect. Dead spaces allow water quality to degrade since they are out of the constant circulation of the system. Fixtures such as warewashing sinks that are not easily cleanable may lead to the contamination of food products.

5-202.12 Handwashing Facility, Installation.

Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. ASTM Standards for testing the efficacy of handwashing formulations specify a water temperature of 40°C ± 2°C (100 to 108°F).

An inadequate flow or temperature of water may lead to poor handwashing practices by food employees. A mixing valve or combination faucet is needed to provide properly tempered water for handwashing. Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding is a possible hazard.

5-202.13 Backflow Prevention, Air Gap.

During periods of extraordinary demand, drinking water systems may develop negative pressure in portions of the system. If a connection exists between the system and a source of contaminated water during times of negative pressure, contaminated water may be drawn into and foul the entire system. Standing water in sinks, dipper wells, steam kettles, and other equipment may become contaminated with cleaning chemicals or food residue. To prevent the introduction of this liquid into the water supply through back siphonage, various means may be used.

The water outlet of a drinking water system must not be installed so that it contacts water in sinks, equipment, or other fixtures that use water. Providing an air gap between the water supply outlet and the flood level rim of a plumbing fixture or equipment prevents contamination that may be caused by backflow.

5-202.14 Backflow Prevention Device, Design Standard.

In some instances an air gap is not practical such as is the case on the lower rinse arm for the final rinse of warewashers. This arm may become submerged if the machine drain becomes clogged. If this failure occurs, the machine tank would fill to the flood level rim, which is above the rinse arm. A backflow prevention device is used to avoid potential backflow of contaminated water when an air gap is not practical. The device provides a break to the atmosphere in the event of a negative pressure within the system. Minerals contained in water and solid particulate matter carried in water may coat moving parts of the device or become lodged between them over time. This may render the device inoperative. To minimize such an occurrence, only devices meeting certain standards of construction, installation, maintenance, inspection, and testing for that application may be used. The necessary maintenance can be facilitated by installing these devices in accessible locations.

5-202.15 Conditioning Device, Design.

Water conditioning devices must be designed for easy disassembly for servicing so that they can be maintained in a condition that allows them to perform the function for which they were designed.

Numbers and Capacities **5-203.11 Handwashing Sinks.**

Because handwashing is such an important intervention in the control of foodborne illness, sufficient handwashing sinks must be available to make handwashing not only possible, but likely to occur at all appropriate times and places as outlined in Sections 2-301.14 and 2-301.15.

According to Greig et el. (July 2007) an analysis of 816 reported outbreaks of infected worker-associated outbreaks from 1927-2006 found that over 61% of these outbreaks came from food service facilities and catered events, and another 11% of them are attributed to schools, day care centers and health care institutions. The two most frequently reported risk factors associated with these implicated food workers was bare hand contact with food, and failure to properly wash hands.

Green et al (JFP, March 2007) found that handwashing was more likely to occur in restaurants whose food workers received food safety training, had more than one handwashing sink, and had a handwashing sink in the observed worker's sight. This suggests that improving food worker hand hygiene requires more than food safety education.

5-203.12 Toilets and Urinals.

Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.

5-203.13 Service Sink.

Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Waste water must be disposed of in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal.

5-203.14 Backflow Prevention Device, When Required.

The delivery end of hoses attached to hose bibbs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bibb to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

5-203.15 Backflow Prevention Device, Carbonator.

When carbon dioxide is mixed with water, carbonic acid, a weak acid, is formed. Carbonators on soft drink dispensers form such acids as they carbonate the water to be mixed with the syrups to produce the soft drinks. If carbon dioxide backs up into a copper water line, carbonic acid will dissolve some of the copper. The water containing the dissolved copper will subsequently be used in dispensing soft drinks and the first few customers receiving the drinks are likely to suffer with the symptoms of copper poisoning.

An air gap or a vented backflow prevention device meeting ASSE Standard No. 1022 will prevent this occurrence, thereby reducing incidences of copper poisoning.

Location and Placement

5-204.11 Handwashing Sinks.

Hands are a common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. The transfer of contaminants can be limited by providing food employees with handwashing sinks that are properly equipped and conveniently located.

A handwashing sink that is properly located is one that is available to food employees who are working in food preparation, food dispensing, and warewashing areas. Handwashing sinks that are blocked by portable equipment or stacked full of soiled utensils and other items, are rendered unavailable for employee use. Nothing must block the approach to a handwashing sink thereby discouraging its use, plus it must be kept clean and well stocked with soap and sanitary towels to facilitate frequent use. Therefore, a handwashing sink that is located in the immediate work area, or between work areas that the Code states must be equipped with handwashing sinks, depending upon the size and function of the facility, would be considered properly located. Such placement of handwashing sinks facilitates frequent handwashing by food employees in all work areas.

5-204.12 Backflow Prevention Device, Location.

Backflow prevention devices are meant to protect the drinking water system from contamination caused by backflow. If improperly placed, backflow prevention devices will not work. If inconveniently located, these devices may not be accessed when systems are extended, altered, serviced, or replaced. Over a period of time, unserviced devices may fail and system contamination may occur.

5-204.13 Conditioning Device, Location.

When not located for easy maintenance, conditioning devices will be inconvenient to access and devices such as filters, screens, and water softeners will become clogged because they are not properly serviced.

Operation and Maintenance **5-205.11 Using a Handwashing Sink.**

Facilities must be maintained in a condition that promotes handwashing and restricted for that use. Convenient accessibility of a handwashing facility encourages timely handwashing which provides a break in the chain of contamination from the hands of food employees to food or food-contact surfaces. Sinks used for food preparation and warewashing can become sources of contamination if used as handwashing facilities by employees returning from the toilet or from duties which have contaminated their hands.

5-205.12 Prohibiting a Cross Connection.

Nondrinking water may be of unknown or questionable origin. Waste water is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

5-205.13 Scheduling Inspection and Service for a Water System Device.

Water system devices, such as filters and backflow preventers, are affected by the water in the system. How devices are affected depends on water quality, especially pH, hardness, and suspended particulate matter in the water. Complexity of the device is also a factor. Manufacturer recommendations, as well as inspection and maintenance schedules for these devices, must be strictly followed to prevent failure during operation.

Cleaning **5-205.14 Water Reservoir of Fogging Devices, Cleaning.**

Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with respiratory pathogens such as ***Legionella pneumophila***. This organism is extremely infectious and can be transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by this bacterium.

5-205.15 System Maintained in Good Repair.

Improper repair or maintenance of any portion of the plumbing system may result in potential health hazards such as cross connections, backflow, or leakage. These conditions may result in the contamination of food, equipment, utensils, linens, or single-service or single-use articles. Improper repair or maintenance may result in the creation of obnoxious odors or nuisances, and may also adversely affect the operation

of warewashing equipment or other equipment which depends on sufficient volume and pressure to perform its intended functions.

Materials **5-301.11 Approved.**

Materials used in the construction of a mobile water tank are affected by the water they contact. Tank liners may deteriorate and flake. Metals or platings can be toxic. To prevent the degradation of the quality of the water, it is important that the materials used in the construction of the tank are suitable for such use.

Design and Construction **5-302.11 Enclosed System, Sloped to Drain.**
5-302.12 Inspection and Cleaning Port, Protected and Secured.

The tank must be a closed system from the filling inlet to the outlet to prevent contamination of water. It is important that the bottom of the tank be sloped to the outlet to allow the tank to drain completely, to facilitate the proper cleaning and disinfection of the tank, and to prevent the retention of water or solutions after cleaning.

Some tanks are designed with an access opening to facilitate the cleaning and servicing of the water tank. The access must be constructed to prevent the opening from becoming a source of contamination of the water.

5-302.13 "V" Type Threads, Use Limitation.

V-type threads are difficult to clean if contaminated with food or waste. To prevent the contamination of the drinking water, this type of thread should only be used on water tank inlets and outlets if the connection is permanent which eliminates exposed, difficult-to-clean threads.

5-302.14 Tank Vent, Protected.

Water tanks are equipped with a vent to preclude distortion during filling or draining. The vent should be equipped with a suitable screen or filter to protect the tank against the entry of insects or other vermin that may contaminate the water supply.

5-302.15 Inlet and Outlet, Sloped to Drain.

Both the inlet and outlet must be sloped to drain to prevent the pooling of possibly contaminated water or sanitizing solution.

5-302.16 Hose, Construction and Identification.

Hoses used to fill potable water tanks should be dedicated for that one task and should be identified for that use only to prevent contaminating the water. Hoses must be made of a material that will not leach detrimental substances into the water.

Numbers and Capacities

5-303.11 Filter, Compressed Air.

Compressor pistons are lubricated with oil to minimize wear. Some of the oil is carried into the air lines and if not intercepted may contaminate the tank and water lines.

5-303.12 Protective Cover or Device.

Protective equipment provided for openings of the water supply must be in use to prevent contamination which may be present where the supply is exposed to the environment, i.e., at water inlets or outlets or the ends of transfer hoses.

5-303.13 Mobile Food Establishment Tank Inlet.

Mobile units may be particularly vulnerable to environmental contamination if soiled hose connections are coupled to the tank inlet.

Operation and Maintenance

5-304.11 System Flushing and Disinfection.

Contaminants of various types may be introduced into a water system during construction or repair or other incidents. The system must be flushed and sanitized after maintenance and before it is placed into service to prevent contamination of the water introduced into the tank.

5-304.12 Using a Pump and Hoses, Backflow Prevention.

When a water system includes a pump, or a pump is used in filling a water tank, care must be taken during hookup to prevent negative pressure on the supplying water system. Backflow prevention to protect the water supply is especially necessary during cleaning and sanitizing operations on a mobile system.

5-304.13 Protecting Inlet, Outlet, and Hose Fitting.

When not connected for use, water inlets, outlets, and hose fittings should be closed to the environment. Unless capped or otherwise protected, filling inlets, outlets, and hoses may become contaminated by dust or vermin.

5-304.14 Tank, Pump, and Hoses, Dedication.

Hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. If a hose, tank, or pump has been used to transfer liquid food, the equipment must be cleaned and sanitized before using it for water delivery. Failure to properly clean and sanitize the equipment would introduce nutrients, and possibly bacteria, into the water as well as inactivate residual chlorine from public water supplies.

Mobile Holding Tank

5-401.11 Capacity and Drainage.

Liquid waste from a mobile or temporary food establishment must be stored in a properly constructed waste tank to discourage the attraction of flies and other vermin. The waste tank must be 15% larger than the water storage tank to allow for storage of wastes and used water from the drinking water supply tank. The drain from the waste tank must be larger than the filling hose to prevent the use of the drinking water filling hose to drain the waste tank.

Retention, Drainage, and Delivery

5-402.10 Establishment Drainage System.

The drainage system must be designed and installed properly to prevent the backup of sewage and the possible contamination of foods or food-contact surfaces in the establishment.

5-402.11 Backflow Prevention.

Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food-contact surfaces. It may also adversely affect the operation of equipment such as warewashing machines.

The exception in paragraph 5-402.11(B) allows for a direct connection to the sanitary sewer system for floor drains originating in refrigerated spaces that are constructed as an integral part of the building structure. Examples of refrigerated spaces that are considered an integral part of the building include refrigerated prep rooms, meat cutting rooms, and refrigerated storage rooms. The exception specifically targets refrigerated

spaces that are considered an integral part of the building. It does not apply to prefabricated walk-in refrigerators and freezers with prefabricated floors. It is not intended to apply to pieces of equipment, including those which may be located in a refrigerated room and which indirectly drain to a floor drain within the room. Drainage from equipment is addressed under paragraph 5-402.11(A).

5-402.12 Grease Trap.

Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the harborage of vermin and/or the failure of the sewage system.

5-402.13 Conveying Sewage.
5-402.14 Removing Mobile Food Establishment Waste.

Improper disposal of waste provides a potential for contamination of food, utensils, and equipment and, therefore, may cause serious illness or disease outbreaks. Proper removal is required to prevent contamination of ground surfaces and water supplies, or creation of other insanitary conditions that may attract insects and other vermin.

5-402.15 Flushing a Waste Retention Tank.

Thoroughly flushing the liquid waste retention tank will prevent the buildup of deposits within the tank which could affect the proper operation of the tank.

Disposal Facility

5-403.11 Approved Sewage Disposal System.

Many diseases can be transmitted from one person to another through fecal contamination of food and water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal contamination. This Code provision is intended to ensure that wastes will not contaminate ground surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or insects to serve as vectors of disease from this source.

5-403.12 Other Liquid Waste and Rainwater.

Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

Facilities	**5-501.10**	**Indoor Storage Area.**
on	**5-501.11**	**Outdoor Storage Surface.**
the Premises	**5-501.12**	**Outdoor Enclosure.**
	5-501.13	**Receptacles.**
	5-501.14	**Receptacles in Vending Machines.**
	5-501.15	**Outside Receptacles.**
	5-501.16	**Storage Areas, Rooms, and Receptacles, Capacity and Availability.**
	5-501.17	**Toilet Room Receptacle, Covered.**
	5-501.18	**Cleaning Implements and Supplies.**
	5-501.19	**Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.**
	5-501.110	**Storage Refuse, Recyclables, and Returnables.**
	5-501.111	**Areas, Enclosures, and Receptacles, Good Repair.**
	5-501.112	**Outside Storage Prohibitions.**
	5-501.113	**Covering Receptacles.**
	5-501.114	**Using Drain Plugs.**
	5-501.115	**Maintaining Refuse Areas and Enclosures.**
	5-501.116	**Cleaning Receptacles.**

Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors, prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents, and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of food, equipment, and utensils.

Storage areas for garbage and refuse containers must be constructed so that they can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In addition, such storage areas must be large enough to accommodate all the containers necessitated by the operation in order to prevent scattering of the garbage and refuse.

All containers must be maintained in good repair and cleaned as necessary in order to store garbage and refuse under sanitary conditions as well as to prevent the breeding of flies.

Garbage containers should be available wherever garbage is generated to aid in the proper disposal of refuse.

Outside receptacles must be constructed with tight-fitting lids or covers to prevent the scattering of the garbage or refuse by birds, the breeding of flies, or the entry of rodents. 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.

Removal	**5-502.11**	**Frequency.**
	5-502.12	**Receptacles or Vehicles.**

Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of the original contents. Spillage from these containers soils receptacles and storage areas and becomes an attractant for insects, rodents, and other pests. The handling of these materials entails some of the same problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these materials are removed from the premises at a reasonable frequency.

Facilities for Disposal and Recycling	**5-503.11**	**Community or Individual Facility.**

Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

Chapter 6 Physical Facilities

Indoor Areas	**6-101.11**	**Surface Characteristics.**

Floors, walls, and ceilings that are constructed of smooth and durable surface materials are more easily cleaned.

Floor surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of foods from dust and organisms from pooled moisture.

The special requirements for carpeting materials and nonabsorbent materials in areas subject to moisture are intended to ensure that the cleanability of these surfaces is retained.

Although food served from temporary food establishments is subject to the same potential for contamination as food served in permanent establishments, the limited capabilities and short duration of operation are recognized by less stringent requirements for surface characteristics.

Outdoor Areas	**6-102.11**	**Surface Characteristics.**

The requirements concerning surface characteristics of outdoor areas are intended to facilitate maintenance and minimize the accumulation of dust and mud on walking and driving areas, provide durable exterior building surfaces, and prevent the attracting,

harboring, or breeding of insects, rodents, and other pests where refuse, recyclables, or returnables are stored.

Cleanability	**6-201.11**	**Floors, Walls, and Ceilings.**
	6-201.12	**Floors, Walls, and Ceilings, Utility Lines.**

Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed.

When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing. Grading of the floor to drain allows liquid wastes to be quickly carried away, therebypreventing pooling which could attract pests such as insects and rodents or contribute to problems with certain pathogens such as ***Listeria monocytogenes***.

6-201.14 Floor Carpeting, Restrictions and Installation.

Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or waste is likely.

6-201.15 Floor Covering, Mats and Duckboards.

Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is possible and that accumulation of dirt and waste is prevented.

6-201.16 Wall and Ceiling Coverings and Coatings.
6-201.17 Walls and Ceilings, Attachments.
6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned. Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joists, and rafters are intended to ensure the cleanability of these surfaces.

Functionality **6-202.11 Light Bulbs, Protective Shielding.**

Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter-resistant are necessary to protect exposed food, clean equipment, utensils and linens, and unwrapped single-service and single-use articles from glass fragments should the bulb break.

6-202.12 Heating, Ventilating, Air Conditioning System Vents.

Heating and air conditioning system vents that are not properly designed and located may be difficult to clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or other accumulated soil from the exhaust vents.

6-202.13 Insect Control Devices, Design and Installation.

Insect electrocution devices are considered supplemental to good sanitation practices in meeting the Code requirement for controlling the presence of flies and other insects in a food establishment.

Improper design of the device and dead insect collection tray could allow dead insect parts and injured insects to escape, rendering the device itself a source of contamination.

Exposed food and food-contact surfaces must be protected from contamination by insects or insect parts. Installation of the device over food preparation areas or in close proximity to exposed food and/or food-contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or be blown from the device onto food or food-contact surfaces.

6-202.14 Toilet Rooms, Enclosed.

Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of flies and other insects between the toilet facility and food preparation areas.

6-202.15 Outer Openings, Protected.

Insects and rodents are vectors of disease-causing microorganisms which may be transmitted to humans by contamination of food and food-contact surfaces. The presence of insects and rodents is minimized by protecting outer openings to the food establishment.

In the National Fire Protection Association's NFPA 101, Life Safety Code, 2009 Edition, doors to exit enclosures such as stairs, horizontal exits, or exit passageways are required to be self closing. The Life Safety Code does not require exterior doors used as exits to be self closing, but they can be.

The intent of subparagraph 6-202.15(A)(3) is to protect food establishments from the entry of insects and rodents by keeping doors closed when not in use. Self-closing devices allow a door to return to its closed position after use. If an exterior door is not routinely used for entry or exit because its use is restricted by the fire protection authority for emergency use only, it is not a portal for the entry of pests and does not need a self-closing device. Doors not requiring a self-closing device include exterior emergency exit doors that open into a public way from a fire and that meet the criteria in ¶ 6-202.15(C).

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

The potential for contamination from airborne dust and particulates or inclement weather is present in outside areas. Overhead protection minimizes the potential for contamination of food under such conditions.

6-202.18 Outdoor Servicing Areas, Overhead Protection.

Pooled water, which may result if overhead protection is not provided for outdoor servicing areas, attracts wild animals and birds and creates a condition suitable for the breeding of insects.

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and driving surfaces may also attract rodents and breed insects.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

If refuse areas are not graded properly, waste water will pool and attract insects and rodents.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibited.

6-202.112 Living or Sleeping Quarters, Separation.

Areas or facilities that are not compatible with sanitary food establishment operations must be located or separated from other areas of the establishment to preclude potential contamination of food and food-contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure in their homes against unreasonable search and seizure. This provision could hinder the regulatory authority's access to conduct routine inspections of a food establishment operated in the living area of a private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be difficult to obtain and might not authorize the necessary inspectional activities.

Handwashing Sinks **6-301.10 Minimum Number.**

Refer to the public health reason for § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on hands.

6-301.12 Hand Drying Provision.

Provisions must be provided for hand drying so that employees will not dry their hands on their clothing or other unclean materials.

It is known that wet hands transfer bacteria more readily than dry hands. The residual moisture found on the hands after washing allows for bacterial and viral transfer to food or solid surfaces by touch. The method in which hands are dried is a critical factor in reducing chances of cross-contamination by hands to food and environmental surfaces (Patrick et al., (1997)).

With regard to the addition of air knife technology for hand drying, data reviewed by FDA scientists at the FDA's National Center for Food Safety Technology (Moffitt Center) demonstrates that the use of this technology in hand dryers has been found to be equivalent to the hand drying treatment in existing heated-air devices.

While the Food Code does not specifically address the configuration or ergonomic design of hand drying devices, technologies employing air knife systems do not appear to accommodate the drying of one's arms and may not be large enough to

accommodate surrogate prosthetic devices for hands and arms to fit within the hand-dryer. In the case where food employees are expected to wash their forearms or are fitted with a surrogate prosthetic device, the food establishment would need to provide an alternate means for drying of the arms and certain prosthetic devices.

6-301.14 Handwashing Signage.

A sign or poster is required to remind food employees to wash their hands.

6-301.20 Disposable Towels, Waste Receptacle.

Waste receptacles at handwashing sinks are required for the collection of disposable towels so that the paper waste will be contained, will not contact food directly or indirectly, and will not become an attractant for insects or rodents.

Toilets and Urinals **6-302.10 Minimum Number.**

Refer to the public health reason for § 5-203.12.

6-302.11 Toilet Tissue, Availability.

To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use of toilet facilities. Toilet tissue must be supplied to meet the demand.

Lighting **6-303.11 Intensity.**

Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up. Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

Ventilation **6-304.11 Mechanical.**

When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

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

Dressing Areas and Lockers **6-305.11 Designation.**

Street clothing and personal belongings can contaminate food, food equipment, and food-contact surfaces. Proper storage facilities are required for articles such as purses, coats, shoes, and personal medications.

Service Sinks **6-306.10 Availability.**

A service sink or curbed facility is required so that the cleanliness of the food establishment can be maintained, attractants for insects and rodents minimized, and contamination of food and equipment by accumulated soil prevented. Liquid wastes generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks such as food preparation and handwashing sinks.

Handwashing Sinks **6-401.10 Conveniently Located.**

Facilities must be located in or adjacent to toilet rooms and convenient to the different work stations of the food employee for proper and routine handwashing to prevent contamination of the food and food-contact surfaces.

Toilet Rooms **6-402.11 Convenience and Accessibility.**

Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.

Employee Accommodations **6-403.11 Designated Areas**.

Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because street clothing and personal belongings carry contaminants, areas designated to accommodate employees' personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-service and single-use articles must not be in jeopardy of contamination from these areas.

Distressed Merchandise **6-404.11 Segregation and Location.**

Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment, utensils, linens, or single-service or single-use

articles. To preclude this, separate and segregated areas must be designated for storing unsalable goods.

Refuse, Recyclables, and Returnables **6-405.10 Receptacles, Waste Handling Units, and Designated Storage Areas.**

Waste materials and empty product containers are unclean and can be an attractant to insects and rodents. Food, equipment, utensils, linens, and single-service and single-use articles must be protected from exposure to filth and unclean conditions and other contaminants. This Code provision addresses these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas, and to preclude creation of a nuisance.

Premises, Structures, Attachments,* and *Fixtures, - Methods **6-501.11 Repairing.**

Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is intended to ensure that the physical facilities are properly maintained in order to serve their intended purpose.

6-501.12 Cleaning, Frequency and Restrictions.

Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

6-501.13 Cleaning Floors, Dustless Methods.

Dustless floor cleaning methods must be used so that food; equipment, utensils, and linens; and single-service and single-use articles are not contaminated.

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and food preparation and warewashing areas.

6-501.16 Drying Mops.

Mops can contaminate food and food preparation areas if not properly cleaned and stored after use. Mops should be cleaned and dried in a sanitary manner away from food flow areas.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Cleanliness of the food establishment is important to minimize attractants for insects and rodents, aid in preventing the contamination of food and equipment, and prevent nuisance conditions. A clean and orderly food establishment is also conducive to positive employee attitudes which can lead to increased attention to personal hygiene and improved food preparation practices. Use of specified cleaning procedures is important in precluding avoidable contamination of food and equipment and nuisance conditions.

Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become a nuisance to the food operation.

6-501.18 Cleaning of Plumbing Fixtures.

Handwashing facilities are critical to food protection and must be maintained in operating order at all times so they will be used.

Refer also to the public health reason for § 5-205.11.

Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food contamination and to motivate employees to use sanitary practices in the establishment.

Hand contact with contaminated surfaces can result in self-inoculation by touching of the nose and mouth. The spread of *Shigella sonnei* in a nursery school has been traced to contaminated toilets. Experiments by Gerba, et al and Barker and Bloomfield have shown that when bacteria and viruses were seeded into a household toilet, the detection of bacteria and viruses in the fallout droplets from the aerosols produced when flushing remain airborne long enough to settle on surfaces throughout the bathroom. Barker and Bloomfield also demonstrated that *Salmonella* Enteritidis could be isolated from the air surrounding a household toilet after flushing the toilet.

Noroviruses which are a major cause of gastroenteritis can be transmitted by fecal-oral, airborne inhalation, person-to-person and environmental-to-person routes. Norovirus, which is highly infectious, is shed in vomitus and stool in high numbers. A study was conducted by J. Barker et al to look at the transmission of norovirus via fingers, cloths and contact surfaces. The results indicated that where fingers come into contact with virus-contaminated toilet tissue, norovirus is consistently transferred via the fingers to a melamine surface and from there to other typical hand-contact surfaces such as taps, door handles and telephone receivers. In this study epidemiological evidence suggests that environmental spread from an infective person occurs by settling of aerosol particles on to contact surfaces. Hands can then spread the virus when they touch toilet seats or flush handles contaminated by splash from vomit or aerosol particles generated during toilet flushing.

6-501.19 Closing Toilet Room Doors.

Toilet room doors must remain closed except during cleaning operations to prevent insect and rodent entrance and the associated potential for the spread of disease.

6-501.110 Using Dressing Rooms and Lockers.

Street clothing and personal belongings can contaminate food, food equipment, and food preparation surfaces and consequently must be stored in properly designated areas or rooms.

6-501.111 Controlling Pests.

Insects and other pests are capable of transmitting disease to humans by contaminating food and food-contact surfaces. Effective measures must be taken to eliminate their presence in food establishments.

6-501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

6-501.113 Storing Maintenance Tools.

Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food-contact surfaces. These items must be stored in a manner that precludes such contamination.

To prevent harborage and breeding conditions for rodents and insects, maintenance equipment must be stored in an orderly fashion to permit cleaning of the area.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The presence of unnecessary articles, including equipment which is no longer used, makes regular and effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.

Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and insects.

6-501.115 Prohibiting Animals.

Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with service animals are required under § 2-301.14 to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

The definition for "service animal" is adapted from 28 CFR 36.104 adopted pursuant to the Americans with Disabilities Act (ADA) of 1990 (42 U.S.C. 12101 et seq.). A service animal performs some of the functions that persons with a disability cannot perform for themselves, such as those provided by "seeing eye dogs"; alerting persons with hearing impairments to sounds; pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.

Under Title III of the ADA, privately owned businesses that serve the public are prohibited from discriminating against individuals with disabilities. The ADA requires these businesses to allow people with disabilities to bring their service animals onto business premises in whatever areas customers are generally allowed. Some, but not all, service animals wear special collars or harnesses. Some, but not all, are licensed or certified and have identification papers.

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S. Equal Employment Opportunity Commission, the Federal agency which has the lead in these matters, in documents such as, “Commonly Asked Questions About Service Animals in Places of Business”; “The Americans with Disabilities Act Questions and Answers”; “A

Guide to Disability Rights Laws"; and "Americans with Disabilities Act Title III Technical Assistance Manual, 1994 Supplement." The ADA Information Line is 800-514-0301 (voice) or 800-514-0383 (TDD) and the Internet Home Page address is http://www.usdoj.gov/crt/ada/adahom1.htm.

Chapter 7 Poisonous or Toxic Materials

Original Containers **7-101.11 Identifying Information, Prominence.**

The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

Working Containers **7-102.11 Common Name.**

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

Storage **7-201.11 Separation.**

Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

Presence and Use **7-202.11 Restriction.**

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are

present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

7-202.12 Conditions of Use.

Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

Because of the toxicity of restricted use pesticides, they can only be applied by certified operators. A certified operator would be aware of the dangers involved in the contamination of food and food-contact surfaces during the application of these materials. Improperly applied pesticides present health risks to employees as well as consumers and special precautions must be taken when restricted use pesticides are applied.

Container Prohibitions **7-203.11 Poisonous or Toxic Material Containers.**

Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of the potential for contamination of the food. The risk of serious medical consequences to anyone consuming food stored in these containers coupled with the lack of confidence that all of the material could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

Chemicals **7-204.11 Sanitizers, Criteria.**

See explanation in § 4-501.114.

Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

7-204.12 Chemicals for Washing Fruits and Vegetables, Criteria.

Criteria.*

7-204.13 Boiler Water Additives, Criteria.
7-204.14 Drying Agents, Criteria.

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 could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are listed in the CFR can be used.

Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive Petition. Wash chemicals, boiler water additives, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR.

21 CFR Section 173.315 specifically identifies chemicals that may be used in washing fruits and vegetables, but it **does not specify any maximum level** (2000 ppm or otherwise) of chemical usage for sodium hypochlorite. FDA acknowledges the use of sodium hypochlorite on fruits and vegetables and also allows calcium hypochlorite to be used interchangeably with sodium hypochlorite under 21 CFR 173.315.

Boiler water additives that may be safely used in the preparation of steam that may contact food, and their condition of use, are identified in 21 CFR 173.310 Boiler Water Additives.

Lubricants **7-205.11 Incidental Food Contact, Criteria.**

Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants used must be approved as food additives or generally recognized as safe and listed in the CFR. Lubricants that are not safe present the possibility of foodborne illness if they find their way into the food.

Pesticides **7-206.11 Restricted Use Pesticides, Criteria.**
7-206.12 Rodent Bait Stations.

Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

7-206.13 Tracking Powders, Pest Control and Monitoring.

The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

Medicines **7-207.11 Restriction and Storage.**

Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage.

There are circumstances that require employees or children in a day care center to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials. Proper labeling and storage of medicines to ensure that they are not accidentally misused or otherwise contaminate food or food-contact surfaces.

7-207.12 Refrigerated Medicines, Storage.

Some employee medications may require refrigerated storage. If employee medications are stored in a food refrigerator, precautions must be taken to prevent the contamination of other items stored in the same refrigerator.

First Aid Supplies **7-208.11 Storage.**

First aid supplies for employee use must be identified and stored in accordance with the requirements of this Code in order to preclude the accidental contamination of food, food equipment, and other food-contact surfaces.

Other Personal Care Items **7-209.11** **Storage.**

Employee personal care items may serve as a source of contamination and may contaminate food, food equipment, and food-contact surfaces if they are not properly labeled and stored.

Storage and Display **7-301.11** **Separation.**

Poisonous or toxic materials held for sale on store shelves or stored in stock rooms present a risk of contamination of food, equipment, utensils, linens, and single-service and single-use articles if not stored properly.

Chapter 8 Compliance and Enforcement

Construction **8-201.12** **Contents of the Plans and Specifications.**
Inspection and Approval **8-203.10** **Preoperational Inspections.**

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this FDA/CFP Food Establishment Plan Review Guide – 2000 has been used in the FDA State Training Team Plan Review courses. It can be accessed through http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ComplianceEnforcement/ucm101639.htm.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Standard operating procedures (SOPs) are a part of that foundation and ideally are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about such procedures and their scope.

SOPs need to be developed by the time of the preoperational inspection and put into effect when the food operation begins. It is recommended that such procedures be written, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections.

Operating procedures should include definitive practices and expectations that ensure that:

(1) The transmission of foodborne disease is prevented by managing job applicants and food employees as specified under Subpart 2-201,

(2) Food is received from approved sources as specified under § 3-201.11,

(3) Food is managed so that the safety and integrity of the food from the time of delivery to the establishment throughout its storage, preparation, and transportation to the point of sale or service to the consumer is protected,

(4) Potentially hazardous (time/temperature control for safety) food is maintained, including freezing, cold holding, cooking, hot holding, cooling, reheating, and serving in conformance with the temperature and time requirements specified under Parts 3-4 and 3-5,

(5) Warewashing is effective, including assurance that the chemical solutions and exposure times necessary for cleaning and sanitizing utensils and food-contact surfaces of equipment are provided as specified under Parts 4-6 and 4-7, and

(6) Records that are specified under §§ 3-203.11, 3-203.12, and 5-205.13 are retained for inspection.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with ¶ 2-103.11(L) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

8-402.10 Competency of Inspectors.

Regulatory agencies are encouraged to use Standard #2 of the draft *FDA's Recommended National Retail Food Regulatory Program Standards* (http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/default.htm) to ensure employees who inspect food establishments are properly trained. Regulatory inspectors are also encouraged to seek food safety certification through a nationally recognized and accredited program.

8-501.20 Restriction or Exclusion of Food Employee, or Summary Suspension of Permit.

See discussion in Annex 3, § 2-201.12.

Minimum	
Temperature °C (°F)	Time
63 (145)	3 minutes
66 (150)	~~1 minute~~ **52 seconds**
70 (158)	< 1 second (instantaneous)

~~Oven Type~~	~~Oven Temperature Based on Roast Weight~~	
	~~Less than 4.5 kg (10 lbs)~~	~~4.5 kg (10 lbs) or More~~
~~Still Dry~~	~~177oC (350oF) or more~~	~~121oC (250oF) or more~~
~~Convection~~	~~163oC (325oF) or more~~	~~121oC (250oF) or more~~
~~High Humidity1~~	~~121oC (250oF) or less~~	~~121oC (250oF) or less~~
~~1Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.~~		

Temperature °C (°F)	Time1 in Minutes	Temperature °C (°F)	Time1 in Seconds
54.4 (130)	112	63.9 (147)	134
55.0 (131)	89	65.0 (149)	85
56.1 (133)	56	66.1 (151)	54
57.2 (135)	36	67.2 (153)	34
57.8 (136)	28	68.3 (155)	22
58.9 (138)	18	69.4 (157)	14
60.0 (140)	12	70.0 (158)	0
61.1 (142)	8		
62.2 (144)	5		
62.8 (145)	4		
1*Holding time may include postoven heat rise*.			

Conference for Food Protection
2012 Issue Form

Internal Number: 010
Issue: 2012 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.

Title:
Final cooking temperature requirement for non-continuous cooking

Issue you would like the Conference to consider:
Amend 2009 FDA Food Food Code Section 3-401.14, (D) which currently requires a final temperature of 165°F before service to allow an exception for the use of the cooking temperature of 145°F for 15 seconds for intact whole-muscle beef.

Public Health Significance:
The 2009 FDA Food Code requires a final cook for non-continuously cooked raw animal foods of 165 °F based on the USDA/FSIS *Performance Standards for Partially Cooked and Char-Marked Meat Patties and Partially Cooked Poultry Breakfast Strips* found in 9 CFR 318.23[31] and 9 CFR 381.150. Since the initial partial heat treatment may not eliminate the vegetative organisms of concern or spores, the second and final heating process is necessary to eliminate the hazards associated with these products before service. However, the cooking temperatures in FDA Food Code Section 3-401.11 likewise based on USDA/FSIS data are adequate and vary based on scientifically based anticipated load and thermal destruction needed for different types of raw animal products and organisms of concern.

The current requirement for non-continuous cooking limits the time for the initial partial cook and the cooling time/temperatures such that, if done as per the current Code requirements, it will limit the growth of both possible vegetative and spore-forming organisms of concern. Non-continuous cooking is typically done for small mass products such as grill marking of steaks and burgers and poultry, or diced raw animal products for Asian style cooking with brief initial heating and rapid cooling.

Assuming these steps (initial heating and cooling) follow the current Code requirements, the expected load would not have increased significantly relative to a completely raw animal food or a fully cooked animal food that has been properly cooled and can be eaten without reheating as long as it is not going to be held hot. In the case of non-continuous cooked animal foods, these products are going to receive a second heat treatment before service; the final cooking temperatures in Section 3-401.11 will eliminate possible pathogens present, which the initial partial cook did not control.

The cooking requirements used to control both the vegetative and spore forming pathogens such as *C. perfringens*, *B. cereus*, and *C. botulinum* in 3-502.12 (D) (2) (b) for cook-chill or

sous vide products likewise uses the same time/temperature parameters in 3-401.11, not 165°F.

According to the 2009 Food Code Annex 3 Section 3-401.14, the cumulative growth of *C. perfringens*, *B. cereus*, and *C. botulinum* must be taken into account during both the initial heating and cooling steps. The hazard may be compounded with an extended initial "come up" time and /or a prolonged stage. Hence the degree of hazard may be dependent upon the ultimate effect of the initial heating and cooling, as well as the final cooking step.

The hazard of vegetative cell growth and spores of *C. perfringens*, *B. cereus*, and *C. botulinum* can be controlled if the initial cook was within 1 hour and the fast cooling process to less than 70 °F is achieved in less than 2 hours.

Section 3-401.11 (C) also allows for the service of raw or undercooked whole-muscle intact beef steak if the surface temperature reaches 145℉ for 15 seconds based on National Advisory Council on Microbiological Criteria for Foods (NACMCF) and USDA recommendations due to the low probability of pathogenic organisms being present in or migrating from the surface to the interior. This would likewise apply to non-continuously cooked whole-muscle, intact beef steaks. As long as the outside is seared to at least 145°F for 15 seconds during the final heat treatment before service, any pathogens will be controlled as long as Section 3-401.14 (A), (B), and (C) has been met.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 3-401.14, (D), be amended as follows (new language shown with underline):

3-401.14 *(D) Prior to sale or service, cooked using a process that heats all parts of the food to a temperature of at least 165°F for 15 seconds: except to allow for the use of the cooking temperature of 145°F for 15 seconds found in 3-401.11 for raw intact whole-muscle beef.*

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Conference for Food Protection
2012 Issue Form

Internal Number: 013
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Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Reduced Minimum Temperature for Microwave Steam Cooking of Seafood

Issue you would like the Conference to consider:
Section 3-401.12 of the 2009 edition of the FDA Food Code requires that raw animal foods, including seafood, heated via microwave energy must attain an internal temperature of at least 165°F. However, traditional steam heating of seafood products need only attain an internal temperature of 145°F. The recently published paper, "Utilization of Steam Heat Generated via Microwave Energy" (attached) summarized the results of a study that was conducted to evaluate the effectiveness of steam heat processing of seafood within a covered pan containing water with the energy generated via microwaves [1]. The study demonstrated that when water was added in a ratio of 30ml per pound of seafood product and placed within a covered container in a microwave oven, microwave energy effectively converted the water to steam and thoroughly cooked the product within 4 minutes (2 minutes cooking time plus 2 minutes holding time). Internal product temperatures in excess of 145°F were consistently recorded at each of seven sites along the products. The study showed that there was no appreciable difference between the cooking of seafood in a conventional steam oven and that of cooking seafood in a covered pan containing a measured quantity of water with microwaves used as the steam generating energy source.

[1] Specchio, J., Schrade,J., & Unanski, M., 2011, Food Safety Magazine, Utilization of Steam Heat Generated via Microwave Energy

Public Health Significance:
The FDA Food Code permits seafood products to be safely cooked in a conventional steamer to an internal temperature of 145°F. The study referenced above demonstrated that heat transfer within seafood products via microwave generated steam in a covered pan with water added was comparable to the heat transfer within a convention steamer.

There are several advantages to using microwave energy to generate steam to cook seafood in covered pans. First, the microwave units are portable and don't require expensive and complicated steam and waste water plumbing hookups. Second, there are many microwavable-safe containers available in different sizes to economically accommodate the volume of food items being prepared. Third, the stainless steel microwave units as well as the containers are easily cleaned and sanitized. Fourth, cooking time is reduced in comparison to conventional steam units yet safe internal product

temperatures are attained. Fifth, there is a large savings in energy costs using microwaves to generate steam as opposed to using convention gas or electric steaming units.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
3-401.15 Microwave Cooking of Seafood
Raw seafood cooked in a microwave oven shall be:
(A) Placed within a covered container with the addition of a sufficient amount of water to cover the bottom of the pan;
(B) Steam heated to a temperature of at least 62.8°C (145°F) in all parts of the food; and
(C) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

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Attachments:

- "Utilization of Steam Heat Generated via Microwave Energy"

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.

Utilization of Steam Heat Generated via Microwave Energy

John J. Specchio, Ph.D., John P. Schrade and Mandy Unanski

Purpose:

The purpose of this study was to evaluate the effectiveness of steam heat processing of food within a covered Cambro pan containing water with energy generated via microwaves. Specifically, the study was designed to determine adequate heat transfer and time/temperature cooking parameters for seafood products.

Background and Introduction:

Most restaurants and retail food stores rely upon traditional steamers to cook seafood products to the required temperature of 145°F as specified within the FDA Food Code (USFDA Food Code, 2009, U.S. Department of Health and Human Services, Public Health Service). The problems associated with conventional steamers include the high costs of the units, energy expenses and the complicated plumbing hookups. The difficulty of cleaning and sanitizing the interior area of conventional steamers is of particular concern. A solution to these issues is the use of microwave generated energy to steam cook seafood products within covered Cambro pans containing water (Panasonic Sonic Steamer, (2011). http://www.panasonic.com/business/commercial-food-services/includes/pdf/2010-Sonic-Steamer-Ad-insert.pdf), (Jean, B.R., (2007),"A Microwave Sensor for Steam Quality," IEEE Transactions on Instrumentation and Measurement,Vol. 5 V, Issue i, pages 113-125.), (Pingkuan Di, et. Al., (2000), Heat and Mass Transfer during Microwave Steam Treatment of Contaminated Soils, Journal of Environmental Engineering, Vol. 126, No. 12, pp. 1108-1115.). First, the microwave units are portable and don't require expensive and complicated steam and waste water plumbing hookups. Second, the Cambro pans are available in different sizes to economically accommodate the volume of food items being prepared. Third, the stainless steel microwave units as well as the Cambro pans are easily cleaned and sanitized. Fourth, cooking time is reduced significantly in that a traditional 1 ½ pound lobster can be steamed to a minimal internal temperature of 145°F in a total of 4 minutes (two minutes cooking and 2 minutes holding). Fifth, there is a large savings in energy costs using microwaves to generate steam as opposed to using conventional steamers.

Section 3-401.12 of the 2009 edition of the FDA Food Code requires that raw animal foods, including seafood, heated via microwave energy must attain an internal temperature of at least 165°F (USFDA Food Code, 2009, U.S. Department of Health and Human Services, Public Health Service). However, traditional steam heating of seafood products need only attain an internal temperature of 145°F. This study was designed to determine if cooking seafood in covered Cambro pans with added water and using microwaves as the energy source to produce steam was equivalent to cooking seafood in traditional style steamers. If this premise is proven to be true, then it could be suggested that the FDA Food Code be amended to allow for the steam heating of seafood products to a minimum internal temperature of 145°F using microwave energy as the source.

Objectives:

The four major objectives of this research were: (a) compare the cooking of seafood using traditional microwave energy for heat transfer versus using microwave generated steam within covered Cambro pans; (b) determine time/temperature cooking parameters for heat transfer using microwave generated steam within a covered Cambro pan; (c) determine variations of temperature within various seafood products processed using microwave generated steam within a covered Cambro pan, and (d) ultimately, determine the equivalency of heat transfer within seafood utilizing steam generated via microwave energy within a covered Cambro pan as compared to traditional seafood steamers.

Materials

A Panasonic 3200 watt, 4 magnetron microwave "sonic steamer" was used as the energy source for creating microwave generated steam (2). The 12" x 20" x 4" pans used were Cambro microwave steaming trays with covers, composed of high density PE (polyethylene). Lobsters weighing 1 ½ pounds each and 23.2 oz. jumbo shrimp (12/25) were used as the examples of shellfish typically steamed by traditional methods. Water was added as a catalyst to create steam. A Fluke model 189 True RMS Multimeter thermocouple using an 80B-A Integrated DMN temperature probe was used to monitor internal food product and steam temperatures.

Procedures

Both lobster and shrimp were processed within the microwave oven in a covered Cambro pan at high power and allowed to stand for 2 minutes after cooking to obtain temperature equilibrium. When water was added, a ratio of 30ml per pound of lobster or shrimp was utilize. Internal temperatures of the lobsters were taken at 5 locations at approximate 1 inch intervals from the head to the tail; the temperatures of each claw were also taken. The internal temperatures of the shrimp were taken at the large headless end only. The five experiments conducted were: (1) 45 ml of H20 only in a covered Cambro pan; (2) one 1 ½ pound lobster in a covered Cambro pan with 45 ml of H20 added; (3) one 1 ½ pound lobster in an uncovered Cambro pan with 45 ml H20 added; (4) one 1 ½ pound lobster in an uncovered Cambro pan with no H20 added and, (5) 23.2 oz. large shrimp in a covered Cambro pan with 45 ml H20 added.

Results

The results of the five experiments were as follows:

1 - The temperature of the steam environment in the covered Cambro pan which contained H20 only, was 191°F after 2 minutes at high power;

2 - The 1 ½ pound lobster in a covered Cambro pan with 45 ml of H20 added, after 2 minutes at high power followed by 2 minutes of stand time, exhibited internal temperature readings at the 5 locations from head to tail and left and right claws of the lobster are shown in Table 1 . *The Standard Deviation was calculated as 1.799.* The temperatures of both the right and left claws were 170.0°F and 149.3°F respectively.

3 - In a comparison of a covered Cambro pan with an uncovered Cambro pan, a 1 ½ pound lobster was placed in an uncovered Cambro pan with 45 ml of H20 added. After 2 minutes at high power followed by 2 minutes of standing time, the internal temperature readings at 5 locations from head to tail and left and right claws of the lobster are shown in Table 2. *The standard deviation was calculated as 4.347.* Also the temperatures of both the right and left claws were 138.8F and 149.9F respectively.

4 - In an effort to show that the steam was being generated from the water, a 1 ½ pound lobster was placed in an uncovered Cambro pan with no H2O added. After 2 minutes at high power followed by 2 minutes of standing time, the internal temperatures were taken at 5 locations from head to tail and left and right claws of the lobster. The results are presented in Table 3. *The standard deviation was 5.413*. The temperature of the right and left claws were 176.1°F and 194.7°F respectively.

5 - In the last experiment, 23.2 oz. of shrimp were placed in a covered Cambro pan with 45 ml H20 added. After 2 minutes at high power followed by 2 minutes of standing time, the internal temperatures were taken on 12 shrimp at the largest headless end. The results are presented in Table 4. *The standard deviation was 4.371.*

Discussion

This study was conducted to compare heat transfer within seafood products via microwave generated steam in covered Cambro pans with added water placed within a Panasonic "Sonic Steamer" 3200 watt 4 magnetron microwave unit to the heat transfer within a conventional steamer (Panasonic Sonic Steamer, (2011). http://www.panasonic.com/business/commercial-food-services/includes/pdf/2010-Sonic-Steamer-Ad-insert.pdf), (Jean, B.R., (2007),"A Microwave Sensor for Steam Quality," IEEE Transactions on Instrumentation and Measurement,Vol. 5 V, Issue i, pages 113-125.).

The first part of the study was to determine the temperature of the steam environment within the covered Cambro pan with the addition of 45 ml of H20 only. The results indicate that the

temperature within the steam filled pan was 191°F after two minutes at high power and 2 minutes of holding time. This showed that microwave energy can effectively and consistently be utilized to generate steam within the covered Cambro pan.

The second part of the study showed that lobsters placed in the covered Cambro pans with 45 ml of H20, steamed for two minutes and held for two minutes reached above the required internal temperatures of 145° F. Additionally, the temperatures taken from various parts of the lobster were very close within a standard deviation of 1.799 (Table 1) indicating an evenness of heating via steam energy. Also, the combination of the covered Cambro pan with the added water along with the microwave energy generated a "steam environment" similar to conventional steamers.

In an attempt to demonstrate that the evenness of heating was related to the steam generated heat transfer within the covered Cambro pan with H20, the experiment was repeated under the same conditions EXCEPT the Cambro pan was left uncovered (Jean, B.R., (2007),"A Microwave Sensor for Steam Quality," IEEE Transactions on Instrumentation and Measurement,Vol. 5 V, Issue i, pages 113-125.), (Pingkuan Di, et. Al., (2000), Heat and Mass Transfer during Microwave Steam Treatment of Contaminated Soils, Journal of Environmental Engineering, Vol. 126, No. 12, pp. 1108-1115.). The results indicated an expected unevenness of heating from the traditional microwave energy. Steam was not able to be generated as in the covered Cambro pan. The temperatures were below the required 145° F for steam heating and the standard deviation was 4.347 (Table 2) indicating unevenness of heat transfer in the lobster. This proves that the heat energy was being provided by the microwaves not the steam.

The fourth part of the study was similar to the previous two except the lobster was placed in an uncovered Cambro pan with NO added water. This experiment would prove or not that the covered Cambro pan along with the H20 is required for even steam heat generation. The temperatures did reach the required 145°F for cooking but were not consistent throughout the lobster. The standard deviation was 5.413 (Table 3). This indicated that the water is necessary for the development of steam and the heat was generated unevenly via traditional microwave energy (Pingkuan Di, et. Al., (2000), Heat and Mass Transfer during Microwave Steam Treatment of Contaminated Soils, Journal of Environmental Engineering, Vol. 126, No. 12, pp. 1108-1115.).

The final experiment included the use of large shrimp cooked in a covered Cambro pan with H20 added using microwave energy. Again, the product was steamed for two minutes and held for two minutes. Temperatures ranged from 176°F - 193°F, well above the required 145°F internal product temperature. The standard deviation was 4.371 (Table 4) or well within the average variation of traditional steamed cooked shrimp. Also, the evenness of heating was quite evident.

In all experiments, the sensory quality of the seafood in the covered Cambro pan with H20 and microwave generated energy was excellent. The appearance, texture, color, flavor and overall eating quality were equivalent or better than traditional steam cooking.

There are many advantages to using microwave energy to generate steam to cook seafood in covered Cambro pans (Jean, B.R., (2007),"A Microwave Sensor for Steam Quality," IEEE Transactions on Instrumentation and Measurement,Vol. 5 V, Issue i, pages 113-125.), (Pingkuan Di, et. Al., (2000), Heat and Mass Transfer during Microwave Steam Treatment of Contaminated

Soils, Journal of Environmental Engineering, Vol. 126, No. 12, pp. 1108-1115.). First, the microwave units are portable and don't require expensive and complicated steam and waste water plumbing hookups. Second, the Cambro pans are available in different sizes to economically accommodate the volume of food items being prepared. Third, the stainless steel microwave units as well as the Cambro pans are easily cleaned and sanitized. Fourth, cooking time is reduced significantly in that a traditional 1 ½ pound lobster can be steamed to a minimal internal temperature of 145°F in a total of 4 minutes (two minutes cooking and 2 minutes holding). Fifth, there is a large savings in energy costs using microwaves to generate steam as opposed to using conventional steamers.

Section 3-401.12 of the 2009 edition of the FDA Food Code requires that raw animal foods, including seafood, heated via microwave energy must attain an internal temperature of at least 165°F (USFDA Food Code, 2009, U.S. Department of Health and Human Services, Public Health Service). However, traditional steam heating of seafood products need only attain an internal temperature of 145°F. This study has shown that cooking seafood in covered Cambro pans with added water and using microwaves as the energy source to produce steam was equivalent to cooking seafood in conventional style steamers. In keeping with the scientific evidence, the next logical step is to petition the FDA for an amendment within the FDA Food Code allowing for the steam heating of seafood products to a minimum internal temperature of 145°F using microwave energy as the source.

References

1. USFDA Food Code, 2009, U.S. Department of Health and Human Services, Public Health Service

2. Panasonic Sonic Steamer, (2011). http://www.panasonic.com/business/commercial-food-services/includes/pdf/2010-Sonic-Steamer-Ad-insert.pdf

3. Jean, B.R., (2007),"A **Microwave** Sensor for **Steam** Quality," IEEE Transactions on Instrumentation and Measurement,Vol. 5 V, Issue i, pages 113-125.

4. **Pingkuan Di, et. Al., (2000),** Heat and Mass Transfer during **Microwave Steam** Treatment of Contaminated Soils, **Journal** of Environmental Engineering, Vol. 126, No. 12, pp. 1108-1115.

About the authors:

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Conference for Food Protection
2012 Issue Form

Internal Number: 074
Issue: 2012 III-021

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

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Title:
Determining the Disposition of Refrigerated PHF (TCS food) above 5°C (41°F)

Issue you would like the Conference to consider:
Food establishments and regulators often have to make decisions about the safety of refrigerated PHF (TCS food) when product temperature has increased above 5°C (41°F). For example, during emergency power outages, refrigerated food may have a slight increase in temperature until actions can be taken to maintain the food at 5°C (41°F). During these times, it is equally important that food establishments be able to safely sell food to consumers, donate food to the community and prevent the needless destruction of safe food.

Food establishments and regulators need science-based procedures for determining when refrigerated PHF (TCS) food can be safely sold and when it should be destroyed or re-conditioned in the event there is an increase in the food temperature above 5°C (41°F). Such a provision in the FDA Food Code would be most useful in emergency situations such as during a power outage.

This provision would provide disposition recommendations such that refrigerated PHF (TCS) food that exceeds 5°C (41°F) for a specified time and temperature combination can be safely sold, and establish the limits of time and temperature when such food must be destroyed or reconditioned. Based on science, such provisions would offer a sound basis for making disposition decisions of refrigerated PHF (TCS) food, especially during emergency situations.

Food Code Part 3-7, *Contaminated Foods*, should be renamed *Disposition of Food.* This Part of the Food Code should also be revised to include science-based recommendations for the disposition options for refrigerated PHF (TCS) food that is above 5°C (41°F) but which can still be safely sold.

During times of emergencies and follow-up recovery, food establishments and regulators often consult the *CFP Emergency Action Plan for Retail Food Establishments*[1] (See Reference #1 on the list of Attachments) including the section titled *Interruption of Electrical Service, Part III, Recovery*, on page 10. This guide includes a table labeled "Cold Foods Internal Temperature Guidance" which offers guidance for handling refrigerated PHF (TCS) food when the product temperature has increased above 5°C (41°F). The guidance provided is not based on science nor is it reflective of recommendations in the Food Code. The Food Code is of little use in such situations since it does not provide specific

recommendations on the disposition options for such food. Having consistent, science-based recommendations in both the Food Code and the *CFP Emergency Action Plan for Retail Food Establishments* for disposition of refrigerated PHF (TCS) food when the product temperature has increased above 5°C (41°F) would benefit regulators and food establishments, while protecting and serving the public.

Public Health Significance:

The time and temperature parameters for this recommendation were based on the considerable body of science available regarding growth of pathogens at various time/temperature combinations and the current recommendations in the Food Code. It also includes a variety of conservative (fail-safe) assumptions.

The decision was made to review two different data sets regarding pathogen growth, and to use the more conservative numbers when developing disposition recommendations. The first body of science referenced was the 2004 CFP report from the "Time Only as a Public Health Control Committee - Council III[2] (See reference #2 on the list of Attachments) which used the USDA-Pathogen Modeling Program (PMP) to predict the time for a 1-log increase in *Listeria monocytogenes (Lm)* concentration. The second set of scientific data includes model predictions from the ComBase predictor model, found at:

- The results from both the PMP and ComBase models are included in the *Predicted Time for the Increase in Growth of Listeria monocytogenes (Lm) at Various Temperatures* tables.[3] (See reference #3 on the list of Attachments) The 2004 Committee Report using the USDA PMP shows the time needed for a 1-log growth increase in *Lm* at 45°F (7.2°C) and 50°F (10.0°C) is 53.9 hours and 34.7 hours, respectively. (Table 4, located at Reference #3 on the list of Attachments) The results from the ComBase predictor model shows the time needed for a 1-log growth increase in *Lm* at 45°F (7.2°C) and 50°F (10.0°C) is 30 hours and 18 hours, respectively. (Table 1, located at Reference #3 on the list of Attachments)

The predicted times using the ComBase model are less than those shown for the PMP, primarily due to the assumption that no lag time occurs. The ComBase predictor model also has the added benefit of being extensively validated with published data for actual pathogen growth in foods. For example, the ComBase database contains 20 growth rates for *Lm* growth in foods, between 8°C and 12°C, pH 6.5 to 7 and water activity between 0.99 and 1.00. In almost every case the ComBase growth rate prediction was equal to or faster than the actual measured growth rate in the food product. In a related analysis, *Lm* is known to be a risk in processed meats. The ComBase database contains 153 potential data sets on *Lm* in processed meats. From those 153 data sets (growth curves), 68 showed growth or were in the range encompassed by the model, further demonstrating good validation of the ComBase model.

Additionally, when making the calculations below, four safety factors were built in:

- The scenario assumes the food is held at 45°F or 50°F for the complete time. It does not take into account the time at which the food is less than 45°F or 50°F as it equilibrates with the ambient or surrounding temperature.
- The model assumes ideal growth conditions in the food.
- The model assumes no lag time, even though most scientific literature does show a lag time for Lm growth in foods.

- The model assumes all food, both raw and RTE, contain Lm at the onset even though RTE foods should not contain pathogens.

The FDA Position Paper in support of using time and temperature for public health control of PHF (TCS) food can be found in the Food Code *Annex 3 - Public Health Reasons/Administrative Guidelines, 3-501.19, Using Time as a Public Health Control (419-422).* The same assumptions used to support *Time as a Public Health Control* in the current Food Code were considered in developing this proposal. Some relevant points from the position paper that provided assumptions for the proposal are cited below:

- Food held without temperature control equilibrates with the environment. Most models are based on the assumption that the food product spent all of the time at the highest temperature. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly. This assumption adds an extra margin of safety into the predictive models.
- When evaluating the safety of time and temperature control, parameters must be selected to create a conservative (fail-safe) scenario for the potential for pathogen growth.
- When evaluating pathogen growth in refrigerated PHF (TCS) food, it is recommended to use *Listeria monocytogenes (Lm)* is the primary organism of concern due to its psychotropic properties.
- A 1-log growth increase in *Lm* should be used as the critical limit.

To establish the most fail-safe approach to disposition, it was decided to use the data from the ComBase predictor (with no lag time) because it resulted in more conservative estimates and because the model is extensively validated. The conservative time/temperature parameters discussed above should provide a fail-safe system for determining the safe disposition of refrigerated PHF (TCS food) that exceeds 41°F.

However, because this recommendation is intended to provide procedures whereby food can be restored to 41°F and safely sold, the authors opted to use an even more conservative margin of safety. Therefore, the decision was made to use the ComBase predictor for time/temperature combinations that would result in a 0.5-log increase in *Lm*. These results show the time needed for a 0.5-log growth increase in *Lm* at 45°F (7.2°C) and 50°F (10.0°C) is 15 hours and 9 hours, respectively (Table 1, located at Reference #3 on the list of Attachments).

A half-log is generally accepted as the resolution limit of microbial testing, resolution being the capability of making distinguishable two sets of results. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 2010, JFP 73:140-202) has, in general, used <1 log as the criteria for determining the absence of measurable growth of pathogens of concern[4] (See Reference #4 on the list of Attachments) Furthermore, in the same publication, NACMCF has stated that the growth of pathogens at less than a 1-log increase "reflects the inherent variation that exists with enumeration of microorganisms." [4] (See Reference #4 on the list of Attachments)

Using a half-log increase as the critical limit means that the disposition criteria are based on the assumption that food which is allowed to exceed 41°F for a specified time and returned back to 41°F within a specified time will have the same microbiological profile as that which was maintained at 41°F for the same period of time. In other words, there is essentially no microbiological difference, and no increased risk, in the food continually held at 41°F and that which is handled according to the recommended disposition criteria. The ComBase predictor model was again used to verify these time/temperature combinations,

only using a 0.5-log Lm growth increase (Table 1, located at Reference #3 on the list of Attachments.) All other assumptions remained the same.
The new provision would allow refrigerated PHF (TCS food) that has been held up to 45°F and brought back to 41°F in a total of 15 hours or, held up to 50°F and brought back to 41°F in a total of 9 hours, to be sold. At these times and temperatures, there is a significant safety margin, especially when using a half-log *Lm* increase as the critical limit.

Recommended Solution: The Conference recommends...:
1. that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended using strike through to remove language and underline for new language as follows:
Food Code Part 3-7 *Contaminated Food* be renamed *Disposition of Food* as follows:
3-7 ~~Contaminated Food~~ Disposition of Food
AND:
Subpart 3-701 be renamed *Disposition of contaminated food;* the Sections and Paragraphs A-D under 3-701 remain the same; and a new Subpart 3-702 be added named *Disposition of Refrigerated PHF (TCS food)* as follows:
Subparts

- 3-701 Disposition of Contaminated Food
- 3-702 Disposition of Refrigerated PHF (TCS food)

AND:
The new Subpart 3-702 will include a Section and Paragraphs explaining the time/temperature parameters that can be used when determining the disposition of refrigerated PHF (TCS food) held at temperatures above 41°F but still eligible for sale as indicated below:
3-702 Disposition of Refrigerated PHF (TCS food)
3-702.11 Determining when Refrigerated PHF (TCS food) can be Safely Sold Following an Increase in Cold Holding Temperature
(A) Refrigerated PHF (TCS Food) can be safely held and sold at temperatures above 5°C (41°F) provided:
(1) Written procedures are in place to specify the methods used to demonstrate compliance with Subparagraphs B and C of this section
(B) Refrigerated PHF (TCS food) can be held and sold at a temperature up to 7.2°C (45ºF) provided:
(1) The total time during which the food is above 5°C (41°F) but not over 7.2°C (45ºF) is 15 hours or less
(2) By the end of 15 hours the food has returned to 5°C (41°F) or lower
(3) The food shall be monitored to ensure the warmest portion of the food does not exceed 7.2ºC (45ºF) during the 15-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 7.2ºC (45ºF) during the 15-hour period;
(4) The food shall be destroyed if at the end of 15 hours the food is not at 5°C (41°F) or lower as described in subparagraph 1-3 above, unless using Section 3-501.19 *Time as a Public Health Control* to determine the disposition of the food.
(C) Refrigerated PHF (TCS food) may be held and sold at a temperature up to 10°C (50ºF) provided:

(1) The total time during which the food is above 5°C (41°F) but not over 10.0°C (50°F) is 9 hours or less
(2) By the end of 9 hours the food has returned to 5°C (41°F) or lower
(3) The food shall be monitored to ensure the warmest portion of the food does not exceed 10.0°C (50°F) during the 9-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 10.0°C (50°F) during the 9-hour period*;*
(4) The food shall be destroyed if at the end of 9 hours the food is not at 5°C (41°F) or lower as described in subparagraph 1-3 above, unless using Section 3-501.19 *Time as a Public Health Control* to determine the disposition of the food.
AND:
2. The Conference further recommends revising the *CFP Emergency Action Plan for Retail Food Establishments, Interruption of Electrical Service, Part III. Recovery*, on page 10, by removing the table labeled "Cold Foods Internal Temperature Guidance" and replacing it with the same language as above in the new Food Code Subpart 3-702 *Disposition of Refrigerated PHF (TCS food)*.

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Attachments:

- "References cited in Attachment: "Disposition of Refrigerated TCS Food""

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Issue Title: Determining the Disposition of Refrigerated PHF (TCS food) above 5°C (41°F)

Issue Submitter: Jill Hollingsworth, DVM

The following references are cited in the Issue. The superscript numbers used in the Issue (1 through 4) correspond to the references below.

Attachments:

1. Emergency Preparedness Committee of Council II, 2004-2006, Emergency Action Plan for Retail Food Establishments, Conference for Food Protection. Available at: http://www.foodprotect.org/media/guide/EmergencyActionPlanforRetailFoodEstablishments2008.pdf (Jan 6, 2012)

2. Conference for Food Protection Council III Committee Report, Time as a Public Health Control. January 27, 2004. Richard H. Linton, Committee Chair. Available at: http://www.fmi.org/docs/foodsafety/time_as_a_public_health_control.pdf (Jan 6, 2012)

3. Tables: Predicted Time for the Increase in Growth of *Listeria monocytogenes (Lm*) at Various Temperatures. Available at: http://www.fmi.org/docs/foodsafety/Predicted_Lm_Growth_Tables_2.pdf (Jan 6, 2012)

4. National Advisory Committee on Microbiological Criteria for Foods, 2010, Parameters for Determining Inoculated Pack/Challenge Study Protocols, *Journal of Food Protection*, Vol. 73:140–202. Available at: http://www.fsis.usda.gov/PDF/NACMCF_JFP_Inoculated_Pack.pdf (Jan 6, 2012)

Conference for Food Protection
2012 Issue Form

Internal Number: 115
Issue: 2012 III-022

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

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Title:
Revision of the 2006 CFP Listeria Retail Guidelines

Issue you would like the Conference to consider:
With FDA's support, the Food Safety and Inspection Service is recommending the formation of a CFP Committee to revise the 2006 CFP "Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes.*" The guidelines should be revised to reflect new information on sanitation of slicers, harborage points for *Lm* at retail, and specific *Listeria* sampling protocols for retail facilities. In addition, the 2009 FDA Food Code Annex 2 (References, Part 3-Supporting Documents) should be amended to include a reference and summary of the revised guidelines.

Public Health Significance:
Listeria contamination at retail continues to be a significant public health issue.
Since the CFP *Listeria* retail guidelines were issued in 2006, new information has been published regarding risk from listeriosis from retail products. In 2010, FSIS published a risk assessment[1] that found that of the listeriosis cases attributed to deli meat, most (approximately 83%) were associated with deli meats sliced at retail. In addition, FDA has issued sanitation guidance for slicers, stating that recent foodborne illness outbreaks have been associated with commercial deli slicers that are difficult to clean and sanitize. Also, new information has been published identifying sources of *Lm* harborage and cross contamination, and demonstrating that *Lm* can survive in the environment of retail delis for more than a year.[2] This information indicates that sampling for *Lm* at retail can be an important tool for retailers to identify and address *Lm* contamination in retail delis and develop focused approaches to prevent deli products from becoming contaminated.
Although the 2006 CFP *Listeria* retail guidelines provided general information about cleaning and sanitizing and sampling in the retail environment, it did not provide steps for cleaning and sanitizing slicers, specific sites of harborage or cross contamination for *Listeria*, or sampling protocols for *Lm* in the retail environment. Therefore, FSIS and FDA jointly recommend that the CFP retail guidelines be revised to better address this new information. By forming a committee to revise the guidelines, CFP can ensure that view-points from a wide variety of backgrounds are considered and that the guidelines provide the best possible information to help retailers protect public health.

[1] FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-eat Meat and Poultry Deli Meats, 2010, found at: http://www.fsis.usda.gov/PDF/Comparative_RA_Lm_Report_May2010.pdf.
[2] Sauders, B.D. et al. Prevalence and Molecular Diversity of *Listeria monocytogenes* in Retail Establishments. Journal of Food Protection, Vol. 72, No. 11, 2009, Pages 2337-2349. Found at: http://www.ingentaconnect.com/content/iafp/jfp/2009/00000072/00000011/art00015.

Recommended Solution: The Conference recommends...:
that a CFP Committee be created to revise the 2006 CFP "Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes*" to incorporate the following:
1. Sanitation guidance for slicers,
2. Information on cross contamination and harborage points for *Lm,*
3. More detailed information about how sampling for *Lm* can be conducted as part of a strategy for preventing *Lm* contamination at retail,
4. Updating outdated links to other documents, and
5. Other relevant information identified by the Committee.
The Conference also recommends that the Committee report recommendations back to the 2014 Biennial Meeting with Issues to address the charges and include 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.

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Conference for Food Protection
2012 Issue Form

Internal Number: 107
Issue: 2012 III-023

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

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Title:
Amend FDA Food Code Section 3-403-11(C)

Issue you would like the Conference to consider:
The 2009 FDA Food Code Section 3-403.11(C) addresses the reheating for hot holding of product that was received already fully cooked and packaged to prevent contamination during distribution. Product users may remove less than full case quantity out of the package to prepare at a single time. This leaves identical product in the freezer/cooler in a non-intact package. Manufacturers of this type of product and national and regional chain foodservice outlets have expressed concern that the code as stated can and is interpreted that the 135°F reheating temperature is no longer adequate once that package is opened and the provision of Section 3-403.11(C) no longer applies. Since remaining product must then be cooked to 165°F, some chains have taken the position to only have one cook procedure and then cook all products to 165°F for hot holding and therefore dramatically change the quality of the products.

Public Health Significance:
These products were processed under food processing regulations covering the lethality for vegetative pathogens as well as the cooling and/or stabilization of the product after cooking to control C. botulinum and C. perfringens germination and outgrowth. This same product from a previously opened package can also be heated to any temperature for immediate service in response to an individual consumer order per Section 3-403.10.
The following was supplied by FDA Food Specialist John Marcello in response to my enquiry on interpretation of Section 3-403.11(C).
"The cooked meat products and chicken patties have received a thermal process that reduces or eliminates all bacterial pathogens to an acceptable level. The commercially processed, ready-to-eat, packaged cooked meat and chicken patties have received a controlled cooking process that destroys vegetative bacterial cells and a controlled cooling process that prevents the germination of any spores present. Packaging prevents recontamination and refrigeration (freezing in the scenario you submitted) prevents spore germination. Because of the low levels of contaminations in both types of products, a reheating temperature of 135°F is considered safe and adequate prior to hot holding.
Any remaining portions of cooked meat or chicken patties that were not removed from the original package of commercially processed food, may still be reheated to 135°F. for hot

holding provided it has been held under refrigeration at 41°F or below (or as in the scenario you provided - frozen) at all times; had no bare hand contact; clean and sanitized utensils were used to dispense and process the products; and the packaging was covered/closed to prevent re-contamination. This seems to me something that can be accomplished with reasonable care.

If any remaining portions of the cooked meat products or chicken patties are held above 41°F, such as a "working supply;" cross contaminated; reheated then cooled; or in some other way had the potential for bacterial levels to increase from recontamination and/or proliferation; the reheating temperature should be 165°F for 15 seconds or the product should be discarded depending on the situation.

While there may be some limited potential for recontamination of the cooked meats or chicken patties during opening and removal of the first portion, reclosing/recovering the package/container and holding the product under refrigeration (frozen) prevents any increase in bacterial numbers (proliferation)."

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting Section 3-403.11(C) of the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language is underlined):

(C) Ready-to-eat food taken from a commercially processed, hermetically sealed container, or from an intact package from a food processing plant that is inspected by the food regulatory authority that has jurisdiction over the plant, shall be heated to a temperature of at least 57°C (135°F) for hot holding. [P] Product, cooked chicken tenders as an example, that remains after the original package is opened may still be heated to 57°C (135°F) for hot holding provided the product continues to be held under refrigeration at 5°C (41°F) or below at all times; had no bare hand contact; clean and sanitized utensils were used to dispense and process the products; and the packaging was covered/closed to prevent re-contamination.

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Conference for Food Protection
2012 Issue Form

Internal Number: 055
Issue: 2012 III-024

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

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Title:
Cleaning of Food Contact Surfaces between Raw Animal Foods

Issue you would like the Conference to consider:
Deleting the allowance to use food contact surfaces with different types of raw animal foods without intermediate cleaning and sanitizing.
Annex 3, Public Health Reason, for the 2009 FDA Food Code Section 4-602.11 reads, in pertinent part:
"Regarding the possible adulteration from one species of meat to another between cleaning of food-contact surfaces, USDA/FSIS (Food Safety and Inspection Service) does not automatically consider species adulteration as a health hazard. FSIS stated in an Advance Notice of Proposed Rulemaking that species adulteration falls into a gray area between safety and economic adulteration (65 FR 14486, March 17, 2000, Other Consumer Protection Activities). FSIS will review public comments received on the species adulteration issue and further review the scientific literature and risk assessment mechanisms before declaring species adulteration a health hazard. Meanwhile, species adulteration is generally considered by FSIS as an economic issue. However, investigations by FSIS of species adulteration incidents may include a determination regarding the impact of species adulteration as a health hazard on a case-by-case basis."
Annex 3, Public Health Reason, for the 2009 FDA Food Code Section 3-302.11 reads, in pertinent part:
"In addition, raw animal foods having the same cooking temperature, such as pork and fish, shall be separated from one another during storage and preparation by maintaining adequate spacing or by placing the food in separate containers because of the potential for allergen cross-contamination or economic adulteration via inadvertent species substitution."

Public Health Significance:
The provisions described above may result in cross contamination of foods with allergens as well as possible economic adulteration.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (deleted language shown with strike-through):

Section 4-602.11(B)

~~(B) *Subparagraph (A)(1) of this section does not apply if the food-contact surface or utensil is in contact with a succession of different raw animal foods each requiring a higher cooking temperature as specified under § 3-401.11 than the previous food, such as preparing raw fish followed by cutting raw poultry on the same cutting board*.~~

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Conference for Food Protection
2012 Issue Form

Internal Number: 047
Issue: 2012 III-025

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

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Title:
Dual-step hand cleanse-sanitize protocol without water

Issue you would like the Conference to consider:
Safe and proper changing of single-use gloves at catered events where potable running water is unavailable, is a current danger to public health. Hands must be washed before donning gloves per 2009 FDA *Food Code*, Section 2-301.14(H).
An effective hand cleansing, "equivalent or superior to hand washing with soap and water" (per *Journal of Food Protection*, Vol. 73, No. 12, 2010, Pages 2296-2300, attached) as specified in Section 2-301.12 of the *FDA Food Code*, can be achieved by using alcohol-based hand antiseptic first as a soap substitute to loosen contaminants with a 15 second scrub cycle, followed by their removal onto a single-use paper towel. This cleaning step is followed by a high impact kill step, applying the hand sanitizer to the pre-cleaned hand and allowing it to air dry per label instructions.
The latest testing of this hand cleansing/degerming technique shows it to be effective in the presence of organic food soils and if norovirus is the target pathogen, norovirus-effective sanitizers are available.(See attachment titled *Comparison of the Activity of Alcohol-Based Handrubs Against Human Noroviruses Using the Fingerpad Method and Quantitative Real-Time PCR*)
This adds an additional safety factor to support incorporation of the method into food safety practices. It gives operators a choice and its simplicity and portability adds to compliance. This protocol is not a substitute for handwashing in stationary facilities where cleaning can be accomplished per Section 2-301.12. The economics keep this innovation reserved for special situations.
[Note: After the near unanimous vote for adoption by Council III , a similar issue, III-027, was extracted during the Assembly of Delegates, citing the need for additional testing which has now been concluded along with an additional four years of field testing under the guidance of the Southern Nevada Health District (SNHD). SNHD also cleared this intervention for school foodservice use during water outages, and it has been in use for the past two years.]

Public Health Significance:
Potential contamination of ready-to-eat foods is increased in situations where access to soap and potable running water is limited or simply unavailable. The new proposed option

increases the likelihood of effective hand degerming in those situations, including its use between single-use glove changes.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline and deleted language shown with strike-through):
5-203.11 Handwashing Sinks (A)(B)
(C) If approved, when food exposure is limited and handwashing sinks are not conveniently available, such as in some mobile or temporary food establishments or at some vending machine locations, employees may use chemically treated towelettes for handwashing or a regimen of sequential application of hand antiseptic wherein the first application 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 instructions. (i) Said hand antiseptic shall meet requirements of 2-301.16. Said hand antiseptic shall have supporting test data indicating statistical equivalence to a standard handwash in hand degerming.

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Attachments:

- "Comparison of the Activity...Handrubs Against Human Noroviruses"
- "SaniTwice: A Novel Approach to Hand Hygiene ..."
- "Comparative Efficacy of Alcohol Hand Sanitizers...against Noroviruses..."

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Food Environ Virol (2011) 3:35–42
DOI 10.1007/s12560-011-9053-x

ORIGINAL PAPER

Comparison of the Activity of Alcohol-Based Handrubs Against Human Noroviruses Using the Fingerpad Method and Quantitative Real-Time PCR

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Abstract Noroviruses (NoV) are the most common cause of acute nonbacterial gastroenteritis in the United States, and human hands play an important role in their transmission. Little is known about the efficacy of hand hygiene agents against these highly infectious pathogens. We investigated the activity of seven commercially available hand hygiene products against human noroviruses by in vivo fingerpad tests. The in vivo activity of alcohol-based handrubs ranged from 0.10 to 3.74 log reduction and was not solely dependent on alcohol concentration. A handrub (VF481) based on 70% ethanol and a blend of other skin care ingredients reduced Norwalk virus (NV) by 3.74 log in 15 s and provided significantly greater NV reduction than all the other products tested ($P < 0.001$). Furthermore, VF481 was the most effective product tested against the NoV genogroup II strains Snow Mountain virus (GII.2) and a GII.4 strain. These results demonstrate that alcohol by itself is not effective against NoV, but effective formulation of alcohol-based handrubs can achieve significant reduction of norovirus RNA on fingers.

Keywords Norovirus · Quantitative RT-PCR · Handrub · Fingerpad · ASTM

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Introduction

Noroviruses (NoV) are the major cause of acute nonbacterial gastroenteritis in humans worldwide (Widdowson et al. 2005; Blanton et al. 2006; Lopman et al. 2002). In the United States, NoV account for 59% of the estimated 76 million food-related infections (Mead et al. 1999) and have also been implicated in outbreaks in both long-term care and acute care facilities (Wu et al. 2005; Hansen et al. 2007). Human NoV are classified into three genogroups, designated GI, GII, and GIV, and multiple clusters (genotypes) within each genogroup. Norwalk virus (NV) and Snow Mountain virus (SMV) are prototype GI.1 and GII.2 genotypes, respectively. GII.4 is the most commonly detected NoV genotype throughout the world and accounted for 62% of all reported NoV outbreaks from 2001 to 2007 (Siebenga et al. 2009).

Hands are known to be an important vehicle for the transmission of NoV (Bidawid et al. 2004; Todd et al. 2008; Moe et al. 2001), and the use of hand hygiene products that are effective at removing or inactivating NoV is likely to be a critical part of an effective NoV infection control strategy (Bidawid et al. 2004; Lages et al. 2008; Kampf et al. 2005). Despite the important role of hands in

the transmission of NoV, little is known about the efficacy of hand hygiene practices in reducing the spread of NoV.

Alcohol-based handrubs have some advantages over traditional hand washes, particularly when running water is not accessible. The effectiveness of handrubs against bacteria (Davis et al. 2006; Kampf et al. 2003; Weber et al. 2003), and viruses, including influenza (Kramer et al. 2006), rotavirus (Sattar et al. 2000; Sattar and Ansari 2002), hepatitis A virus (Mbithi et al. 1993), poliovirus (Mbithi et al. 1993), adenovirus (Sattar et al. 2000), and rhinovirus (Sattar et al. 2000) has been widely studied. The efficacy of handrubs against human NoV has been rarely reported primarily due to the lack of an available animal model or routine culture system for studying human NoV infectivity.

Although preliminary results from Straub et al. (2007) demonstrate that it may be possible to culture NoV, routine and replicable culture-based methods to quantify infectious human NoV are not yet available. Most studies on the efficacy of disinfectants and antiseptics against NoV have employed surrogate animal caliciviruses, including feline calicivirus (FCV) (Gehrke et al. 2004; Kampf et al. 2005) and more recently murine norovirus (MNV) (Cannon et al. 2006; Macinga et al. 2008; Park et al. 2010; Okunishi et al. 2010; Magulski et al. 2009), to predict the behavior of human norovirus. These viruses are useful because they can be measured via cell culture assays and possibly by animal challenge studies. However, the appropriateness of FCV and MNV as surrogates for human NoV has been debated because they do not always behave in the same manner in environmental persistence or inactivation studies (Park et al. 2010). Specifically, FCV is quite pH sensitive under acidic conditions, while MNV is sensitive to desiccation (Cannon et al. 2006) and is likely much more susceptible to ethanol inactivation (Belliot et al. 2008; Magulski et al. 2009; Park et al. 2010). These observations are inconsistent with current knowledge of the behavior of the human NoV. Synergistically formulated ethanol-based handrubs have recently been reported to have significantly enhanced antiviral efficacy against several non-enveloped viruses, including FCV and MNV (Macinga et al. 2008; Belliot et al. 2008). Moreover, the results obtained using surrogate viruses may not be a good indication of the actual efficacy of these products against human NoV strains. It is therefore important to evaluate hand hygiene products against human NoV to determine the ability of antisepsis to reduce transmission of NoV by hands.

Quantitative real-time PCR (RT-qPCR) is currently the best available method for the enumeration of human NoV genomic copies in food, clinical, and environmental samples (Topping et al. 2008; Duizer et al. 2004; Rodriguez-Lazaro et al. 2007). Recently, we combined RT-qPCR and the ASTM fingerpad methodology (Sattar and Ansari 2002; E-1838-02, ASTM International 2002) to test hand hygiene products against Norwalk Virus (NV). Our results indicated that the performance of an antimicrobial handwash was similar to that of a water rinse, and that a handrub based on 62% ethanol was not effective at reducing NV on fingerpads (Liu et al. 2010). The aim of this study was to examine the efficacy of several commercial alcohol-based handrubs against three human NoV strains, NV (GI.1), SMV (GII.2) and a recent GII.4 isolate, using the fingerpad method and RT-qPCR assays for virus quantification. This study expands our previous work with NV by including additional human NoV strains and evaluating the efficacy of additional hand hygiene agents—including those previously shown to be effective against surrogate animal caliciviruses (Macinga et al. 2008).

Materials and Methods

Antimicrobial Test Products

A total of seven commercially available hand hygiene products were evaluated (Table 1): seven products against NV (Table 2 and Fig. 1), three against SMV (Table 3), and two against GII.4 (Table 4). The benchmark handrub (PURELL Original Instant Hand Sanitizer, subsequently referred to as "Benchmark"), PURELL Instant Hand Sanitizer VF447 (subsequently referred to as "VF447"), and PURELL Instant Hand Sanitizer VF481 (subsequently referred to as "VF481") are commercially available products from GOJO Industries Inc., Akron, OH). Other products that are commercially available handrubs were purchased through standard market distributors and were all tested before their expiration dates on the label.

Virus Inoculum

Norwalk virus and Snow Mountain virus were obtained from the stool samples of previously healthy adult volunteers who became infected with norovirus in previous human challenge studies (Lindesmith et al. 2003, 2005). GII.4 norovirus was kindly provided by Dr. Lee-Ann Jaykus (North Carolina State University), and was confirmed by RT-PCR and sequencing a 172 bp fragment of the capsid region that showed 100% homology with 2006-USA GII.4 Minerva strain. The stool samples were diluted to 20% suspensions with RNAse-free water, vortexed briefly, and centrifuged at $550\times g$ for 30 s. To ensure the safety of the study participants, careful screening and strict exclusion criteria for volunteer enrollment and post decontamination procedures were performed as described below.

Table 1 Test products and ingredients

Test product	Product format	Active ingredient[a]	Other ingredients[a]
Benchmark PURELL Instant Hand Sanitizer (GOJO Industries)	Gel Sanitizer	62% (v/v) ethanol	Water, glycerin, propylene glycol, sodium hydroxide, tocopheryl acetate, carbomer, fragrance
PURELLVF447 (GOJO Industries)	Gel Sanitizer	70% (v/v) ethanol	Water, isopropyl alcohol, isopropyl myristate, glycerin, diisopropyl sebacate, citric acid, PEG/PPG-20/6 dimethicone, pentaerythrityl tetra-di-*t*-butyl hydroxyhydro-cinnamate, hydroxypropylcellulose, polyquaternium-37, methylchloroisothiazolinone, methylisothiazolinone
PURRELLVF481 (GOJO Industries)	Gel Sanitizer	70% (v/v) ethanol	Water, isopropyl alcohol, copper gluconate, diisopropyl sebacate, PEG/PPG-20/6 dimethicone, pentaerythrityl tetra-di-*t*-butyl hydroxyhydrocinnamate, polyquaternium-37
Endure 300 (Ecolab. Inc.)	Gel Sanitizer	70% (v/v) ethanol	Water, isopropyl alcohol, carbomer, propylene glycol, aminomethyl propanol, fragrance
Sterillium Virugard (Bode Chemie)	Sanitizer Rub	95% (w/w) ethanol	Alkane/cyclo alkane mixture, glycerin, myristyl, alcohol, hexane
Germstar Noro (Soaptronic LLC)	Sanitizer Rub	63% (w/w) ethanol	Water, isopropanol, emollient complex, fragrance
Anios Gel 85 NPC (Laboratoires ANIOS)	Gel Sanitizer	85% (v/v) ethanol	Aqua, glycerin, acrylates/C10-30 alkyl acrylate crosspolymer, bisabolol, caprylic/capric triglycerides PEG-4 esthers, PEG-8 caprylic/capric glycerides, aminomethylpropanol, ethylpropanediol

[a] As represented on the product labels

Table 2 Efficacy of handrubs against Norwalk virus after a 15 s exposure

Treatment	*N*	Mean log reduction (SD)
VF481	12	3.74 (0.85)[a]
VF447	12	2.04 (0.78)[b]
Endure 300	12	1.49 (0.62)[b]
Sterillium Virugard	12	0.10 (0.17)
Germstar Noro	12	0.11 (0.22)
Anios Gel 85 NPC	6	1.27 (0.22)[b]

[a] Significantly greater reduction compared to all other test products ($P < 0.001$)

[b] Significantly greater reduction compared to Sterillium Virugard and Germstar Noro ($P < 0.01$)

Human Test Subjects

Study protocols involving human volunteers were reviewed and approved by the Institutional Review Board of Emory University. A total of 30 adult volunteers, between 18 and 50 years of age, were enrolled in the study. After providing informed consent, both hands of each volunteer were carefully inspected prior to each experiment to ensure that they were free of any cuts, abrasions or rashes.

Fingerpad Method

A modification of the ASTM (American Society for Testing and Materials) standard E-1838-02 fingerpad method,

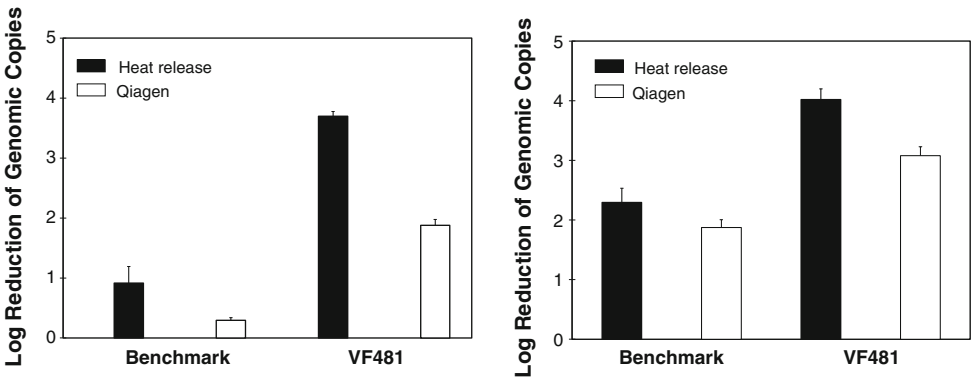

Fig. 1 Efficacy of benchmark and VF481 against Norwalk virus (*left*) and GII.4 (*right*) at 15 s exposure time using heat release (HR) and Qiagen (QI) RNA extraction methods ($N = 11$ for Norwalk trials and $N = 12$ for GII.4 trials)

Table 3 Comparison of in vivo efficacy of handrubs against Snow Mountain virus (GII.2) after 15 s exposure

Hand hygiene treatment	*N*	Log reduction (mean ± SD)
Benchmark sanitizer	12	1.22 (0.31)
VF447	12	0.30 (0.24)[b]
VF481	12	2.27 (1.70)[a]

[a] Significantly greater log RNA reduction compared to VF447 and benchmark sanitizer ($P < 0.001$)

[b] Significantly lower log RNA reduction compared to benchmark sanitizer ($P < 0.001$)

Table 4 Comparison of in vivo efficacy of handrubs against NoV GII.4 strain after 15 s exposure

Hand hygiene treatment	*N*	Log reduction (mean ± SD)
Benchmark sanitizer	12	2.30 (0.82)
VF481	12	4.02 (0.61)[a]

[a] Significantly greater log RNA reduction compared to benchmark sanitizer using heat release RNA extraction ($P < 0.0001$)

which has been described in detail previously, was used in this study (Sattar and Ansari 2002; Macinga et al. 2008; E-1838-02, ASTM International 2002). The modification involved not scraping the fingers after the handrub use in order to avoid physical removal of the virus and to more accurately model actual use of a handrub by a consumer. Prior to inoculation of the fingerpads, the volunteers were asked to clean their hands completely by washing with a mild soap followed by sanitizing with a solution of 70% ethanol.

Inoculation of Fingerpads

Ten microliters of a 20% suspension of NV (approximately 6.3×10^6 genome copies), SMV (approximately 2.0×10^8 genome copies), or GII.4 NoV (approximately 6.4×10^6 genome copies) were placed on the center of each fingerpad of volunteers' hands. For determination of input virus (time 0 control), the seeded inoculum was eluted immediately from the thumbs after fingerpad inoculation (without drying) with 990 µl of Hanks Balanced Salt Solution (HBSS). The thumbs were decontaminated as described below, and the virus inocula on other digits were air dried for 20 min.

Test Method for Handrub Test Products

For all handrub test products, the fingerpads were exposed to 1 ml of the test substance in an open vial after virus inoculation and drying, respectively, for a contact time of 15 s without inversion. Upon completion of product testing, the volunteers were instructed to wash their hands with antibacterial liquid soap, and their fingerpads were then decontaminated by pressing onto a paper towel soaked with 10% bleach for 2–3 min.

Virus Elution from Fingerpads

To elute the virus remaining on a control fingerpad after drying or on fingerpads after treatment with test products, the volunteers were asked to place the contaminated area of the fingerpad over the mouth of a 1.7 ml plastic vial containing 1 ml of HBSS. The vial was inverted and the eluent in the vial was allowed to remain in contact with the inoculated area for 10 s. The vial was next inverted 20 times with the fingerpad still in place. The soak and inversion steps were repeated once. The vial was then turned upright, and the eluate remaining in contact with the fingerpad was scraped against the inside rim of the vial to recover as much of the fluid as possible.

Virological Analysis

Recovery of Viruses from Eluates

The viruses in the eluates were precipitated by adding 12 mg polyethylene glycol (PEG) 8000 (Sigma, St. Louis, MO), incubated at 4°C for 1 h, and centrifuged at $12{,}000 \times g$ for 15 min. The virus-containing pellets were reconstituted in 50 µl of RNAse-free water prior to freezing at −80°C.

RNA Extraction and Real-time RT-PCR

For release of RNA, a heat release RNA extraction was used as described previously (Schwab et al. 1997) for all experiments except for those presented in Fig. 1. An alternative RNA extraction method, the QIAamp Viral RNA kit (QIAGEN, Valencia, Calif.), was used in accordance with the manufacturer's instructions for the experiments in Fig. 1. NV specific RT-qPCR (genogroup I) that targets the RNA-dependent RNA polymerase region of the NV was carried out following methods described previously (Teunis et al. 2008). SMV and GII.4 RNA were quantified using a norovirus GII broadly reactive RT-qPCR assay that the primers and probe span the open reading frame 1 (ORF1) and ORF2 junction region (Kageyama et al. 2003). To generate a standard curve for NV RNA quantification, a full-length NV RNA standard was in vitro transcribed from NV plasmid cDNA with T7 RNA polymerase (Ambion Inc.), serially diluted and quantified by UV absorbance at 260 nm. Similarly, a SMV RNA standard was generated from SMV plasmid with a 2179-bp insert (nt 3,000–5,178) spanning the entire RNA-dependent

RNA polymerase region) and used for the quantification of SMV and GII.4 samples in this study. NoV genome copies in the test samples were estimated by comparing the cycle threshold (Ct) number to that of the RNA standards. All test samples were assayed in duplicate, and the estimated number of genome copies for each sample was an average of replicate test wells.

The log reduction in NoV genome copies associated with exposure to each hand hygiene product was calculated by subtracting the log-transformed NoV titer for each product from the log-transformed baseline control (virus genome copies remaining after 20 min drying). The NoV log reduction for each hand wash product was calculated by averaging the log reductions from all the replicate fingerpads (both hands of all subjects in the experiment). If no viral RNA was detected in a sample, we assumed that the sample had $\leq$5 genomic copies (half of the limit detection of the NV specific RT-qPCR assay) and used 5 to calculate log reduction from the baseline control.

To test for PCR inhibition, 10 µl of the test product was mixed with 980 µl of HBSS and 10 µl of 20% NV stool suspension, and then 10- and 100-fold dilutions were amplified by TaqMan real-time RT-PCR. The Ct values from these serially diluted samples were compared with those from serially diluted baseline samples that only contained NV mixed with HBSS. We considered a difference of 1.5 or more between the Ct values of the solutions with and without test product (comparing the same dilutions) as an indication of PCR inhibition in the solution with test product.

Statistical Analyses

To examine the differences in virus reduction between each hand hygiene product, a one-way analysis of variance (ANOVA) test with Tukey's post hoc analysis was performed at an alpha level of 0.05 using the SAS 9.2 (Statistical Analysis Software) PROC GLM. Paired *t* tests were used to examine the differences between Qiagen vs. heat release RNA extraction and Norwalk virus vs. GII.4 strain. Only data from side-by-side conditions in a single trial were compared in each analysis.

Results

NV RNA Reduction by Multiple Hand Hygiene Products

Previous experiments in our lab demonstrated that a handrub based on 62% ethanol (Liu et al. 2010) and a 70% ethanol in water (control test article) were ineffective (Data not shown, mean log reductions = 0.03) at reducing NV RNA. In this study, we examined the efficacy of six additional hand hygiene products against Norwalk virus (Table 2). There were considerable differences in the viral RNA reductions by the different hand hygiene products, with mean log reductions from 12 replicate fingerpads (6 fingerpads for Anios Gel 85 NPC) ranging from 0.10 to 3.74. Exposure to VF481 gave the greatest mean reduction of NV RNA (3.74 log) that was significantly higher than any other product tested ($P < 0.001$). Sanitizers VF447, Endure 300 and Anios Gel 85 NPC, provided moderate NV RNA reduction (1.27–2.04 log) and were significantly different than the baseline controls ($P < 0.001$). The lowest NV RNA reductions were by Sterillium Virugard and Germstar Noro and were not significantly different from the baseline control ($P > 0.05$).

NoV Strains Exhibit Unique Sensitivities to Alcohol-Based Handrubs

To investigate potential strain-to-strain differences in NoV reduction by handrubs, we evaluated the efficacy of the two most effective hand hygiene products in our first experiments (VF481 and VF447) and the benchmark handrub product against SMV in a trial with six subjects. VF481 was again the most effective product, reducing SMV RNA by a mean 2.27 log reduction using heat release RNA extraction method (Table 3). However, SMV RNA reduction was less than that observed for VF481 against NV RNA (3.74 log reduction) in the previous trial in Table 2. The SMV RNA reduction by VF481 was significantly different from the baseline control samples ($P < 0.0001$) and also from the RNA reductions associated with the benchmark sanitizer ($P = 0.0055$) and VF447 ($P < 0.0001$).

The performance of the benchmark sanitizer and VF481 were also compared against NoV GII.4 using heat release RNA extraction method (Table 4). VF481 reduced the GII.4 RNA by a mean of 4.02 log in a 15-s exposure in comparison to 2.30 log for the benchmark sanitizer at the same exposure time ($P < 0.0001$).

Impact of RNA Extraction Methods on Estimates of NoV Reduction

Two RNA extraction methods, heat release and Qiagen, were compared for NV and GII.4 NoV to determine if the RNA reductions we observed were due to PCR inhibition rather than virus inactivation. Two products were examined in this experiment—the 62% ethanol "benchmark" handrub (Liu et al. 2010) and VF481. For both test products, the mean NoV RNA reductions were lower in samples processed by the Qiagen method (1.88 log for VF481 and 0.29 log for benchmark against NV) compared to the reductions measured in aliquots of the same samples processed by the heat release method (3.70 log for VF481 and

0.92 log for the benchmark sanitizer against NV) (Fig. 1, left). This difference was significant ($P < 0.0001$) for VF481 but not significant ($P = 0.09$) for the benchmark sanitizer. Similar trends were observed for the GII.4 virus (Fig. 1, right) when comparing the Qiagen and heat release results ($P = 0.01$ for VF481, and $P = 0.25$ for the benchmark). These findings suggest that the NoV RNA reductions observed for some test products (VF481 and possibly others) using the heat release method may be overestimated due to PCR inhibitors even though the samples were tested at a 1:100 dilution. Despite these differences, both extraction methods indicated similar trends in terms of the relative magnitude of RNA reduction by each product for the two different NoV strains. For both extraction methods and for both virus strains, VF481 produced significantly greater mean NoV RNA reductions than the benchmark sanitizer ($P < 0.0001$).

Discussion

In this study, we examined the efficacy of seven commercial hand hygiene products against multiple NoV strains using the fingerpad method and RT-qPCR. A wide range of efficacy (between 0.10 and 3.74 log reduction) was observed. The most effective product tested, VF481, is a 70% ethanol gel containing additional ingredients that appear to potentiate the virucidal activity of the product. The mean NoV RNA log reductions produced by VF481 ranged from 2.27 for SMV (Table 3) to 3.74 for NV (Table 2) and 4.02 for GII.4 (Table 4) using the heat release method. The efficacy of the other five commercial products (with ethanol concentrations from 62% to 95% [see Table 1]) against NV ranged from 0.10 to 2.04 log reduction (Table 2). These results indicate that formulation plays an important role in product efficacy and that alcohol alone does not dictate NoV reduction. In products like VF447 and VF481, additional ingredients, such as citric acid, polyquaternium-37 or copper gluconate (Table 1), may work with the ethanol to help denature the viral capsid protein. Further studies are needed to specifically examine the effect of these additives on viral RNA and clarify our understanding of the mechanism of action. However, the increased magnitude or broader spectrum of virucidal activity from these synergistic blends has been reported in two previous studies using norovirus animal surrogates as well as poliovirus, rotavirus, adenovirus, hepatitis A virus, and bacteriophage MS2 (Kramer et al. 2006; Macinga et al. 2008). Mean MNV log reduction (measured by plaque assay) was 1.16 for the benchmark sanitizer vs. $\geq$3.68 for VF447 in in vitro studies and 0.91 for 75% ethanol vs. 2.48 for VF447 in fingerpad studies (Macinga et al. 2008).

Because NoV strains are highly diverse, handrubs need to be effective against a range of NoV strains including the predominant circulating epidemiological NoV strains. Our results indicate differences in NoV reduction depending on the virus strain and demonstrate the importance of testing more than one strain. The GII.4 NoV was more readily reduced from fingerpads than NV by both VF481 and the benchmark sanitizer (Fig. 1). This finding is consistent with previous research (Butot et al. 2008, 2009) but is somewhat surprising because GII.4 NoV strains have been the predominant NoV outbreaks strains for years (Siebenga et al. 2009), therefore we expected they might be more resistant to inactivation on hands. In contrast, the SMV strain appeared to be more resistant than NV to the handrubs tested but was still significantly reduced by VF481 (Table 3). These findings suggest that VF481 could be helpful in controlling outbreaks due to various NoV strains. Further evaluation of other strains would be of value.

This study extends our previous work and knowledge (Liu et al. 2010) in two ways. First, it demonstrates that some alcohol-based handrubs can be effective against human NoV as measured by RNA reduction using RT-qPCR, and that there are significant differences in the ability of various hand hygiene products to reduce these viruses on fingerpads. These findings highlight the need for evidence-based decision-making about hand hygiene products in settings where NoV transmission and outbreaks can occur. Second, different human NoV strains display different susceptibilities to hand hygiene agents, so it is important to evaluate these products against several NoV strains.

Several questions arise because the methodology in this study uses the presence of RNA genome copies as an indicator of infectious virions. However, it is possible that naked RNA from inactivated virus may be detected by RT-PCR in the fingerpad eluates—thus resulting in an underestimate of the efficacy of the hand hygiene agent. We addressed this concern in our previous study where we compared samples pre-treated with RNAse H to duplicate untreated samples and found no significant difference between the results (Liu et al. 2010). However, some investigators have reported differences in the log reductions of surrogate animal caliciviruses measured by RT-PCR and by plaque assay (Belliot et al. 2008; Park et al. 2010). Therefore, reduction in measurable viral RNA should be considered a conservative measure of the efficacy of a hand hygiene product, and side-by-side comparisons with culture methods have confirmed that significant reductions in RNA titer consistently reflect significant reductions in infectivity of MNV (Park et al. 2010).

Another potential concern is that the observed virus reduction may have been overestimated due to PCR inhibitors in the test products. A side-by-side comparison of the RNA heat release method and the Qiagen RNA extraction method, which is designed to remove PCR inhibitors, showed less NoV RNA reduction in samples processed by the Qiagen method than the same samples processed by the heat release method. For the benchmark sanitizer, there was not a significant difference between the measured reductions from the two RNA extraction methods. However, for VF481, the PCR titer of NoV RNA was significantly lower in the samples tested by the heat release method and may be due in part to residual PCR inhibitors in these samples even though they were tested at a 1:100 dilution. These results suggest that the heat release results for all the test products in this study may represent the upper bound of NoV reduction by these products. Future method developments, such as using immunomagnetic separation (IMS) assay to detect RNA from virions with intact capsids and developing an internal RNA control to directly control for the presence of PCR inhibitors is under investigation.

The true measure of efficacy of a hand hygiene product is the impact on NoV outbreak control or prevention in high-risk settings where NoV outbreaks commonly occur, such as food service and food processing, healthcare (acute care hospitals and long-term elder care facilities), cruise ships and military vessels. Is the 2–4 log NoV reduction associated with VF481 sufficient to significantly reduce or prevent NoV transmission via hands? One recent report indicates that a NoV outbreak in an infirmary in Hong Kong was successfully contained by directly observed hand hygiene with WHO formulation of a handrub with 80% vol/vol ethanol (Cheng et al. 2009). Further field studies are needed with products that have demonstrated efficacy against human noroviruses.

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Research Note

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

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ABSTRACT

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

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

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

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

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

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

MATERIALS AND METHODS

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

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

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

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

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

Hand contamination procedures. For the moderate soil study, a 24-h culture of *E. coli* was suspended in beef broth (Swanson low sodium beef broth, Campbell Soup Company, Camden, NJ) at 1×10^9 CFU/ml. Three aliquots of 1.5 ml were transferred into each participant's cupped hands. Each aliquot was distributed over the entire front and back surfaces of the hands up to the wrists during a 20-s period and allowed to air dry for 30 s after the first and second aliquots and for 90 s after the third aliquot. After samples were collected for baseline bacterial counts and hands were decontaminated with a 30-s wash with nonmedicated soap, a second cycle of contamination was initiated. After the 90-s final drying step, participants applied the randomly assigned test product.

For the heavy soil study, 5.0-ml aliquots of the challenge suspension of *E. coli* were transferred to 4-oz (113-g) portions of sterile 90% lean ground beef and distributed evenly with gloved hands to achieve contamination levels of approximately 5.0×10^8 CFU per portion. Each participant then kneaded the inoculated raw hamburger for 2 min. Hands were air dried for 90 s and then sampled for baseline counts. After a 30-s decontamination with nonmedicated soap, the cycle was repeated, and the test product was applied.

Test article or product application and SaniTwice procedure. The hand washing procedure used for the nonantimicrobial and antimicrobial hand washing products was consistent with Food Code specifications. Table 1 shows the stepwise product application procedures for all test configurations.

Bacterial recovery and microbial enumeration. Within 1 min after contamination for baseline evaluation or after product application, powder-free sterile latex gloves were placed on each participant's hands and secured above the wrist, and 75 ml of sterile stripping fluid (0.4 g of KH_2PO_4, 10.1 g of Na_2HPO_4, and 1.0 g of isooctylphenoxypolyethoxyethanol in 1 liter of distilled water, pH adjusted to 7.8) was transferred into each glove. Following a 60-s massage of the hands through the gloves, a 5.0-ml aliquot of the glove rinsate sample was removed and diluted in 5.0 ml of Butterfield's phosphate buffer solution with product neutralizers. Each aliquot was serially diluted in neutralizing solution, and appropriate dilutions were plated in duplicate onto MacConkey agar plates (BD; 50.0 g of dehydrated medium added to 1 liter of deionized water, heated, and sterilized; final pH, 7.1 ± 0.2) and incubated for 24 to 48 h at 30°C. Colonies were counted and data were recorded using the computerized Q-COUNT plate-counting systems (Advanced Instruments, Inc., Norwood, MA).

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

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

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

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

[a] All application procedures were initiated within 10 s of completing the 90-s drying step.
[b] SaniTwice is a registered trademark with James Mann (Handwashing for Life, Libertyville, IL).

generated for the log recovery data from baseline samples, postproduct application samples, and the log differences between baseline and postapplication samples. Product comparisons were made using a one-way analysis of variance with post hoc analysis (Bonferroni's multiple comparison test) using the 0.05 level of significance for alpha error.

RESULTS

Reduction in microbial contamination of moderately soiled hands. Two studies were conducted to evaluate microbial count reductions on hands that had been contaminated by handling beef broth containing *E. coli*. Reductions from baseline produced by the five test product configurations in these two studies are shown in Figure 1.

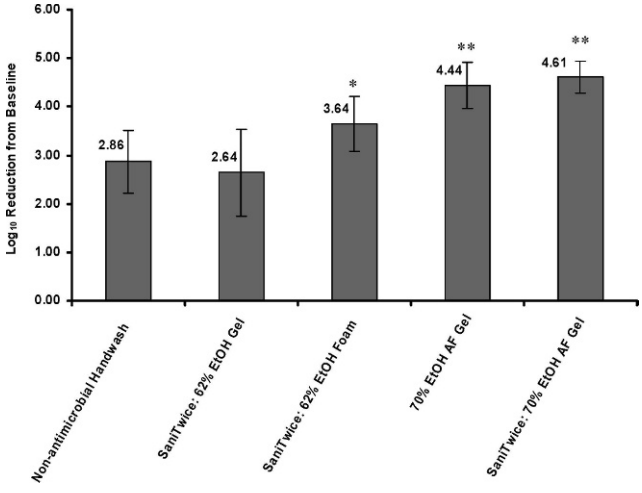

FIGURE 1. *Log reduction from baseline for microbial contamination of hands moderately soiled with contaminated beef broth after application of test products. Error bars represent standard deviation. Data are from two separate studies. In study 1 (*n = *11), nonantimicrobial hand washing product and SaniTwice with 62% EtOH gel were compared. In study 2 (*n = *12), the conditions evaluated were nonantimicrobial hand washing product, SaniTwice with 62% EtOH foam, 70% EtOH AF gel without SaniTwice, and SaniTwice with 70% EtOH AF gel. Results for nonantimicrobial hand washing product represent pooled data from both studies.* * P < *0.05 for SaniTwice with 62% EtOH foam versus nonantimicrobial hand washing product or SaniTwice with 62% EtOH gel.* ** P < *0.05 for 70% EtOH AF gel or for SaniTwice with 70% AF gel versus nonantimicrobial hand washing product, SaniTwice with 62% EtOH gel, or SaniTwice with 62% EtOH foam.*

All SaniTwice regimens were equivalent to or better than the Food Code hand washing protocol. Reductions from baseline ranged from 2.64 ± 0.89 log CFU/ml for SaniTwice with the 62% EtOH gel to 4.61 ± 0.33 log CFU/ml for SaniTwice with the 70% EtOH AF gel.

SaniTwice using the 62% EtOH gel was equivalent to the nonantimicrobial Food Code hand washing protocol. However, SaniTwice using the 62% EtOH foam (3.64 ± 0.57-log reduction) was more effective than SaniTwice with the 62% EtOH gel and the Food Code hand washing protocol ($P < 0.05$).

The 70% EtOH AF gel was the most effective sanitizing product. When used independently, it was significantly more effective (4.44 ± 0.47-log reduction) than SaniTwice with 62% EtOH foam or 62% EtOH gel or the nonantimicrobial hand washing product ($P < 0.05$ for all comparisons). Although the log reduction data suggest that SaniTwice with 70% EtOH AF gel (4.61 ± 0.33-log reduction) was equivalent to the 70% EtOH AF gel used independently, this lack of differentiation was most likely due to the limitations of the assay. The 4.61-log reduction was at the limit of detection for all participants using 70% EtOH AF gel with SaniTwice but for only half the participants using 70% EtOH AF gel alone. Therefore, the log reductions produced by the 70% EtOH AF gel after either a single sanitization or the SaniTwice regimen are likely underestimated, and the log reductions in both cases would likely be higher if the limits of detection were lower.

Reduction in microbial contamination of heavily soiled hands. Figure 2 shows microbial count reductions produced by test product configurations on hands that had been contaminated by handling ground beef containing *E. coli*. All SaniTwice regimens tested were equivalent to or better than the Food Code hand washing protocol, indicating that under conditions of heavy soil, the SaniTwice procedure is as effective as hand washing. The performance of the antimicrobial hand washing product was equivalent to that of the nonantimicrobial hand washing product in this heavy soil challenge, with log reductions of 2.69 ± 0.32 and 2.65 ± 0.33, respectively. SaniTwice with the 70% EtOH AF gel outperformed all other sanitizer configurations tested and was superior to hand washing for reduction of organisms on heavily soiled hands ($P < 0.05$ for comparisons of SaniTwice with 70% EtOH AF gel versus each of the other procedures).

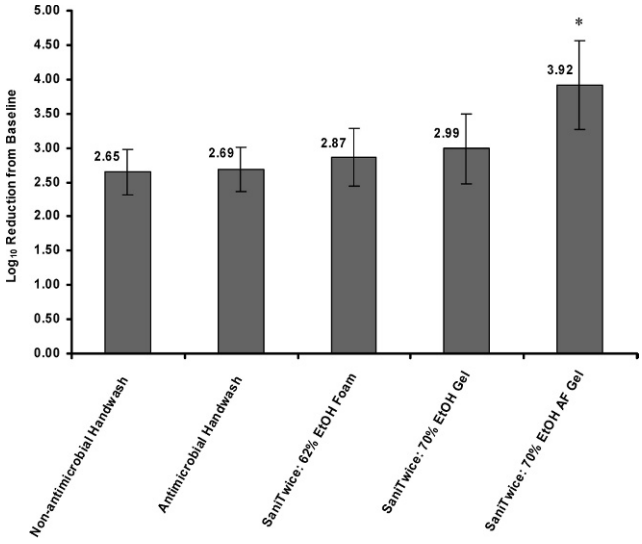

FIGURE 2. *Log reduction from baseline for microbial contamination of hands heavily soiled with contaminated uncooked hamburger after application of test products and protocols. Error bars represent standard deviation. Data are from study 3 (*n = *15), in which five test configurations were evaluated.*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

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

DISCUSSION

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

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

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

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

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

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

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

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P4-10

Comparative Efficacy of Alcohol-based Hand Sanitizers and Antibacterial Foam Handwash against Noroviruses Using The Fingerpad Method

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ABSTRACT

Background: Noroviruses are commonly associated with outbreaks of acute non-bacterial gastroenteritis in food service establishments, and hands are a principal vehicle of this transmission. Alcohol-based hand sanitizers and antibacterial foam handwashes are popular hand hygiene products, but little is known about their effectiveness against noroviruses on contaminated hands.

Methods: We examined the efficacy of two commercial alcohol-based hand sanitizers (one based on 62% ethyl alcohol, and one based on 70% isopropyl alcohol), a new formulation (based on 70% ethanol and a synergistic blend of polyquaternium-37 and citric acid), one commercially available antibacterial foam handwash (0.5% chloroxylenol active ingredient), and a hard water rinse control against Norovirus using the ASTM (American Society of Testing and Materials) E1838-02 standard method. Approximately 6.3 X 10^6 Norwalk Virus (NV) or 8.9 X 10^6 Snow Mountain Virus (SMV) particles were inoculated on each fingerpad. NV and SMV RNAs were extracted by a heat-release method and RNA titers were assayed by a one-step TaqMan real-time quantitative RT-PCR.

Results: The 70% ethanol-based hand sanitizer, antibacterial foam handwash and water rinse resulted in average of 1.36 ($\pm$0.49), 1.53 ($\pm$0.82) and 1.40 ($\pm$0.34) $\log_{10}$ NV RNA reductions, respectively. All three hygiene methods provided a significant reduction of NV compared to a dried virus control (P<0.001), but were not significantly different from each other (P>0.05). The 62% ethanol-based hand sanitizer reduced the NV titers by an average of 0.57 ($\pm$0.31) $\log_{10}$ and was significantly different from the control (P<0.001). The 70% isopropanol-based hand sanitizer reduced the NV titers by an average of 0.00 $\log_{10}$ ($\pm$0.31) and was not significantly different from the control (P>0.05). A "regimen" of the antibacterial foam handwash followed by the 70% ethanol hand sanitizer produced the best reduction of NV [3.81 $\log_{10}$ ($\pm$0.35)]. The activity of all products was lower against SMV with the antibacterial foam handwash alone achieving an average $\log_{10}$ reduction (0.94 $\pm$0.51) that was significant compared to the dried virus control (P<0.001).

Significance: These results demonstrate that handwashing with water and antibacterial foam are effective methods to remove NV from fingers. The results also show it is feasible for an alcohol-based hand sanitizer to give significant NV removal on contaminated fingers. This new synergistically formulated hand sanitizer is therefore a viable option to reduce the spread and risk of NV in food service or other settings. Because SMV is more difficult to remove than NV on human fingerpads, a regimen of handwashing followed by sanitizing may be the most appropriate hand hygiene strategy.

INTRODUCTION

Outbreaks of human norovirus (NoV) often originate in food service establishments and the hands of food handlers are thought to be a principal vehicle for NoV transmission. Hand washing is therefore considered to be an important method to control NoV transmission. Previous studies indicated that alcohol-based hand sanitizers had a significant effect against feline calicivirus (FCV, a surrogate for human NoV) on human hands (1). Recently, mouse norovirus (MNV) has been considered as a more appropriate surrogate for human NoV, but questions continue as to the relevance of these viruses because both FCV and MNV belong to different calicivirus genera than the human viruses. A previous study by our group demonstrated that hand wash with water alone or an antibacterial soap effectively reduced Norwalk virus (NV) from contaminated fingerpads but a 62% ethanol-based hand sanitizer was not effective for NV removal on human hands (2). In this study, we tested the efficacy of three marketed alcohol-based hand sanitizers (PURELL Food Code Compliant [62% Ethanol], Product 1 [60% Ethanol], and Product 2 [70% Isopropanol]), a marketed antimicrobial handwash (MICRELL Antibacterial Foam Handwash [0.5% Chloroxylenol] and a new synergistically formulated hand sanitizer (PURELL VF447 [70% Ethanol]) foam hand wash against Norwalk virus and/or Snow Mountain Virus using a standard ASTM fingerpad method.

METHODS

Virus inocula: Norwalk Virus and Snow Mountain Virus were obtained from the stool samples of two experimentally infected volunteers in our previous studies. The stool was diluted 20% in RNAse free water prior to seeding on volunteers' fingerpads.

ASTM Standard Method for Testing Handwash Agents using fingerpads: We collected samples from volunteers following the standard methods (3) of the American Society of Testing and Materials (ASTM E 1838-02) for handwash agents using fingerpads. Figure 1 shows the sample collection procedures. The foam handwash product was exposed to virus for 15 seconds followed by a 10 second hard water rinse. All other test products were exposed to virus for 30 seconds and were not followed by a rinse.

Hand hygiene products: Products used in this study were PURELL Food Code Compliant Instant Hand Sanitizer, Product 1, Product 2, PURELL VF447, and MICRELL Antibacterial Foam Handwash. Table 1 shows the active ingredient and concentration of the handwash products that were tested.

Virus concentration: The Norwalk virus eluates were precipitated by the addition of 12% polyethylene glycol (PEG) 8000, incubated for 2 h at 4ºC and centrifuged at 12,000 × g for 10 min. The supernatant was discarded and the precipitate was suspended in sterile DNase-RNase free water and stored at -80ºC until molecular amplification.

RNA extraction and real-time RT-PCR: Norovirus RNA was extracted by a heat-released RNA extraction method (4). NV real-time RT-PCR method has been described before (2). SMV real-time RT-PCR was followed by Kageyama's method (5).

Statistical analysis: The viral genomic copies for each sample were $\log_{10}$ transformed. The $\log_{10}$ reduction for each handwash agent was calculated by subtracting the $\log_{10}$-transformed virus for each agent from the $\log_{10}$-transformed baseline control. We performed a paired t-test to examine the difference in $\log_{10}$ reduction between the dry control and each individual handwash product.

Table 1. Tested Products Used in This Study

Product Name	Active Ingredient	Concentration
PURELL VF447	Ethanol	70%
PURELL Food Code Compliant	Ethanol	62%
MICRELL Antibacterial Foam Handwash	Chloroxylenol	0.5%
Product 1	Ethanol	60%
Product 2	Isopropanol	70%

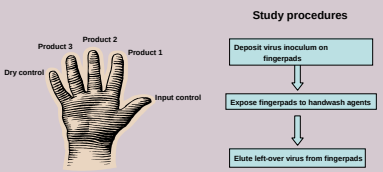

Figure 1. Diagram of American Standard Test Method for *in vivo* evaluation of the activity of handwash agents using the fingerpad method (ASTM E 1838-02).

RESULTS

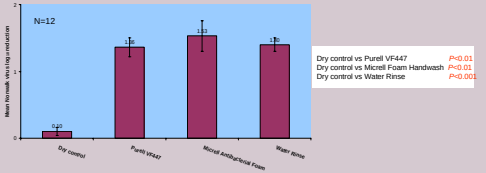

Figure 2 depicts the efficacy of PURELL VF447, MICRELL Antibacterial Foam Handwash, and a hard water rinse alone against NV compared to a dried virus control on two hands of 6 subjects. The graph illustrates the mean $\log_{10}$ NV reduction compared to the baseline virus levels eluted from fingerpads.

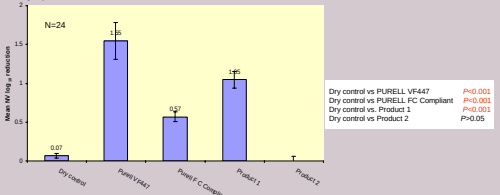

Figure 3 demonstrates the efficacy of PURELL VF447, PURELL Food Code Compliant, Product 1 and Product 2 against NV compared to a dried virus control for 24 subjects. The graph depicts the mean $\log_{10}$ NV reduction by each product compared to the baseline virus levels.

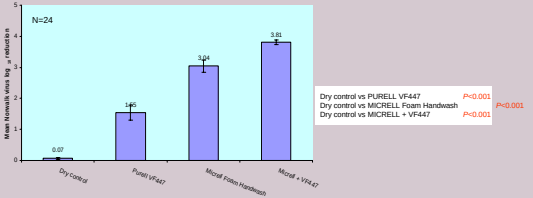

Figure 4 illustrates the efficacy of PURELL VF447, MICRELL Antibacterial Foam Handwash and a regimen of MICRELL **followed by** VF447 against NV for 24 subjects. The graph shows the mean $\log_{10}$ NV reduction compared to the baseline virus levels. Note: a "blot dry" step using a KimWipe was used after all MICRELL washes.

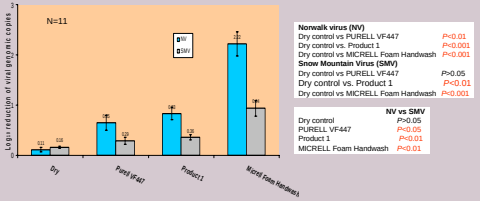

Figure 5. The mean $\log_{10}$ NV and SMV reduction of PURELL VF447, Product 1 and MICRELL Antibacterial Foam Handwash compared to the baseline virus levels for 11 subjects using the ASTM fingerpad method.

SUMMARY AND CONCLUSIONS

- PURELL VF447, MICRELL Antibacterial Foam Handwash and a hard water rinse were effective at reducing Norwalk Virus on human hands. MICRELL Foam was also effective for SMV removal.
- PURELL Food Code Compliant had a relatively weak activity against NV compared to PURELL VF447, MICRELL Antibacterial Foam Handwash and a hard water rinse. The effectiveness of all these products was statistically better than the dried virus control.
- Product 2 was not effective for NV removal on human hands in this study. This result is not surprising in that a previous study demonstrated isopropanol to be inferior to ethanol against calicivirus (6).
- The regimen of MICRELL Antibacterial Foam Handwash followed by PURELL VF447 was significantly better than MICRELL or PURELL VF447 foam alone for removing NV on human hands.
- Comparison of test products side-by-side against NV and SMV demonstrated that SMV is significantly harder to remove / kill than NV.
- The reduction of NoV RNA measured in this study may be due to physical removal and/or chemical inactivation. Some products appeared to give better physical removal of the stool suspension inocula as assessed by the color of the eluate. Further studies are needed to elucidate the mechanism of NoV reduction by different handwash agents.

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2. Liu, P., L-A Jaykus, CL Moe. Efficacy of Handwash Agents against Norwalk Virus Using the Fingerpad Method. Poster P-018. 106th General Meeting for the American Society for Microbiology, May 2006, Orlando, FL.
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Conference for Food Protection
2012 Issue Form

Internal Number: 045
Issue: 2012 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.

Title:
Expanded Use of Time Only as a Public Health Control

Issue you would like the Conference to consider:
The provision in Section 3-501.19 for use of Time as a Public Health Control (TPHC) requires potentially hazardous food time/temperature control for safety (PHFTCS) food be taken from temperature control (have an initial temperature of 5ºC (41ºF) or 57ºC (135ºF). This requires ambient temperature FOODS that become PHFTCS during preparation (such as opening a hermetically sealed container, cutting PHFTCS produce or mixing garlic and oil, etc) to undergo cooling before TPHC is allowed. Expanding the provision, would allow for use of TPHC immediately after preparation (when foods are at ambient temperatures).

Public Health Significance:
The relationship between Time AND temperatures has long been recognized as boundaries of retail food safety because they effectively prevent the growth of foodborne pathogens ((below 41ºF (5ºC) and above 135ºF (57ºC)) or lead to microbial inactivation (above 135ºF). Food Code provides science based guidance for steps in the flow of food (preparation, cooking, cooling, reheating, TPHC where PHFTCS will be exposed to temperatures above 41ºF and below 135ºF.

Proper Cooling requirements (Paragraph 3-501.14(B)) allow for food taken from ambient temperatures (such as hermetically sealed containers, or ambient temperature whole uncut PHFTCS produce) to be cooled to 41ºF within 4 hours. These products are considered Ready-to-Eat and safe for consumption as long as they comply with date marking provisions §3-501.17).

There is currently no provision in Section 3-501.19 to allow for ambient temperature foods that become PHFTCS during preparation to be held under TPHC. There are situations (e.g. opening a hermetically sealed container, cutting PHFTCS produce or mixing garlic and oil) in the flow of food where foods may be taken from ambient temperatures and served to the public within the time frame allowed for proper cooling.

The position paper included in the TPHC Section (3-501.19) of the Public Health Annex (3) supports the allowance of this process (use of TPHC as specified in the Food Code) stating that current time frames (for using TPHC) were "selected to create a worst-case scenario for pathogens growth and possible toxin production." The paper further states that "the 4-hour limit for keeping foods without temperature control allows for a needed margin of

safety if the temperature of the environment is higher than 75ºF" with the assumption that "these foods can reach any temperature as long as they are discarded or consumed within the four hours."

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended to include new language to Section 3-501.19 as indicated below in underlined format:

(B) If time temperature control is used as the public health control up to a maximum of 4 hours:

(1) Except as specified in Subparagraph (a), the food shall have an initial temperature of 5ºC (41ºF) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control; P

(a) FOOD may be at ambient temperatures if it becomes POTENTIALLY HAZARDOUS during preparation, such as opening a hermetically sealed container or cutting POTENTIALLY HAZARDOUS plan foods.

(3) The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control or becomes POTENTIALLY HAZARDOUS; P and

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Conference for Food Protection
2012 Issue Form

Internal Number: 108
Issue: 2012 III-027

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

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Title:
Food Guards

Issue you would like the Conference to consider:
The 2009 FDA Food Code Section 1-103.1 states that THE CODE sets standards for FOOD EQUIPMENT, among other things. Section 3-306.11 provides criteria for the protection of ready to eat (RTE) food from the consumer, and this is shown to be a "Priority item"(^{P}). Sections 4-1 and 4-2 of Chapter 4 are intended to provide minimum reasonable safety criteria for foodservice EQUIPMENT. Therefore, the CODE should establish the minimum safety criteria for FOOD GUARDS and the criteria should be based on the science of preventing disease transmission. Currently, the CODE only refers in section 4-205.10 to an ANSI-accredited program for acceptability, stating that ANSI sanitation certified equipment is "deemed to comply" with the code. Recent changes to ANSI standards are not based on the science of preventing disease transmission and should be subject to criteria established by the conference and documented in the CODE.

Public Health Significance:
Because FOOD guards ^{P} comprise a Priority item in the 2009 FDA FOOD CODE, reasonable minimum safety criteria should be developed by the Conference. These new criteria will provide direction for ANSI's sanitation standards development organizations (SDO's) regarding the FOOD CODE's organisms of concern and guide all revisions to the standard criteria accordingly. Establishing reasonable minimum safety criteria is rightly the scope of the FDA FOOD CODE, whereas ANSI and/or ISO equipment standards are intended to establish best practice criteria for equipment cleanability and durability.
The 2008 ANSI NSF Std 2 section 5.35 "FOOD Shields" standard criteria currently in use is complex and confusing for all stakeholders. The results are very expensive food guard structures that burden the food service operators with unnecessary costs and equipment that often interferes with food service. As a result many operators struggle to purchase equipment that can be adjusted into compliance for inspections and adjusted out of compliance for daily use. There are additional costs to all local jurisdictions as their agents attempt to enforce compliance with the standards and the required measurement calculations. This creates a distraction from risk-based inspection and presents an undue burden to the entire industry. Much if not all of the overly burdensome minutia of the current ANSI NSF Std 2 for food shields lacks validated scientific review or data, and though

current food shield standard criteria may be perceived to theoretically reduce the risk associated with transmission of virus particles from a cough or sneeze, these do not comprise food borne disease organisms of concern and there is no data to suggest the current ANSI NSF Std 2 criteria reduces the risk of disease transmission. It is interesting to note that the food shield is only required on the guest's side of the buffet and not on the server's side, yet the risk of disease transmission from an ill worker is well established by scientific data.

Recommended Solution: The Conference recommends...:

that a Committee be created to:

1. evaluate CDC statistical data relating to risk factors for consumer cross-contamination and disease transmission associated with buffet service,
2. report Committee findings back to the 2014 Biennial Meeting, and
3. recommend revisions to FDA Food Code Chapter 4 by submitting the proposed language in Issues to the Conference.

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Conference for Food Protection
2012 Issue Form

Internal Number: 096
Issue: 2012 III-028

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

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Title:
Acrylamide Management in Retail Preparation of Processed Potato Products

Issue you would like the Conference to consider:
Since acrylamide's discovery in heated food products in 2002, Frozen Potato Products Institute (FPPI) members have invested significant resources in the exploration of acrylamide in processed potato products, as well as methods to reduce or mitigate the accumulation of acrylamide in finished products. This investigation has been and continues to be among the highest priorities for FPPI members.

As the majority of acrylamide is formed during preparation of processed potato products, most of the variability in the recorded levels of acrylamide is a result of differences in cooking method, time and temperature. Variability in cooking apparatuses (e.g., oven and fryer calibration, temperature cycling in ovens, variability in microwave oven wattage) can contribute to variability in the recorded levels of acrylamide in finished products. Similarly, variability in the incoming electrical power to the cooking equipment can contribute to inconsistencies in recorded levels of acrylamide. Slight differences in cooking conditions or product composition (even slight differences in the heat distribution during cooking or raw product from different parts of the process year) can also lead to major differences in acrylamide levels-as much as several multiples between different samples of the same product that have been prepared under the same conditions.

Customer and consumer expectations of color, texture and flavor (hereinafter referred to as "sensory" properties) of processed potato products, particularly French fries, are specific and distinct, and manufacturers implement precise processing techniques to produce products consistent with the taste, color and texture specifications of their customers and consumers. An effective and successful acrylamide mitigation technique must result in meaningful reductions in acrylamide levels; adhere to food safety requirements; contain only ingredients that are permitted for use; be able to implement at the factory level; be cost effective; and deliver a product that consistently meets the specific sensory requirements of customers and consumers.

Since 2002, to the extent that they can be applied safely and without undesired side effects, frozen potato processors presently employ several mitigation techniques, and have, as a result, achieved reductions in acrylamide levels in their products. In 2005 and 2006, members of the U.S. frozen potato product processing industry cooperated in the development of the Confédération des Industries Agro-Alimentaires de l'UE/Confederation

of the Food and Drink Industries of the EU (CIAA) Acrylamide "Toolbox," which continues to serve as a guiding instrument in U.S. efforts to identify effective techniques for the mitigation of acrylamide in foods. CIAA "Toolbox" recommendations for the reduction of acrylamide in processed potato products include measures performed at the agronomical, processing and final preparation stages of processing and as described below.

As mentioned previously the majority of acrylamide is formed during preparation of processed potato products, FPPI would recommend the Conference consider CIAA "Toolbox" recommendations for the retail-foodservice preparation of processed potato products, particularly French fries, to assist with the reduction of acrylamide in processed potato products. In addition, FPPI has created materials in the forms of training videos and a poster that could further aid in helping educate the retail-foodservice industry about measures that can be employed in the storage, preparation, and cooking to assist with acrylamide reduction.

Public Health Significance:

Background

Although some of this research has resulted in successful mitigation methods that have been implemented in the processing of potatoes, the research is incomplete and ongoing. Acrylamide is naturally occurring in many cooked, high-carbohydrate, plant-based foods. It is not a food additive, nor does it come from packaging. Though only recently discovered, it is not a new substance and has been present since humans began cooking foods. Acrylamide forms as food "browns" during high-heat cooking methods, such as frying, grilling, roasting, baking and toasting. Acrylamide has been shown to cause cancer in lab animals when exposed for their lifetimes at very high levels - 1,000 to 10,000 times the acrylamide found in foods; its effect on human health is being investigated, though there is not yet sufficient data to make an official determination. No health authority has recommended any changes in the diet because of acrylamide. Because it can be present in such a wide variety of foods, from coffee, bread, cereal, nuts, potato chips, and French fries to even some cooked fruits and vegetables, it is important to maintain a healthy, balanced diet. There is greater formation of acrylamide in food products that are heavily browned or crisped as a result of cooking. Consumers should fry, grill, bake, roast and toast foods to the lightest acceptable color to reduce the formation of acrylamide at home.

Agronomical Control

Manufacturers have sought to reduce acrylamide levels first by controlling the levels of reducing sugars in raw potatoes. Reducing sugars are among the key reactants in the formation of acrylamide, so controlling sugar content is one of the primary means by which the industry has achieved a reduction in acrylamide levels in processed potato products. All process varieties of potatoes are selected for their low reducing sugar content with a goal of lowering sugars through raw material sourcing, and several additional varieties are under consideration for use. Each is currently being evaluated for its acrylamide formation tendencies. Assessing the quality of a new potato variety for processing and its acrylamide-forming tendencies, however, requires significant time and resources; it can take up to 10 years or longer to develop and evaluate new varieties. Generally, only mature potatoes are considered for processing, as they contain fewer reducing sugars than do young potatoes.

Manufacturers also seek to reduce the formation of acrylamide in frozen potato products by storing and transporting raw potatoes at the "Toolbox" recommended temperature of >6°C or >43°F to suppress build-up of reducing sugars. Continually circulated, tempered air

throughout the storage facility helps ensure the potatoes remain dry and the gas mixtures appropriate. Consistent with Good Agricultural Practices (GAP), sprout suppressant is applied when evidence of sprouting is observed, as sprouting causes potatoes to convert starch to sugar.

Processing

Acrylamide is formed during the Maillard reaction, which is the predominant chemical process determining color, flavor and texture in many cooked foods. Specifically, acrylamide is formed by the reaction of two main components, each occurring naturally in potatoes: free asparagine and reducing sugars. Asparagine is the main free amino acid found in potatoes, and can account for 20 percent to 60 percent of the total free amino acids found in potatoes. Flavor evaluations also show that asparagine has a significant impact on French fry flavor.

Manufacturers have explored many techniques for reducing acrylamide during the processing of potato products, including frying conditions, blanching, acidification and the use of other additives. Par-frying has been shown to have little or no effect on the level of acrylamide found in finished potato products. Blanching, however, can be effective in removing excess reducing sugars and thus lowering acrylamide formation in finished products.

The use of sodium acid pyrophosphate (SAPP) is standard industry practice for reducing after-cooking darkening. The application of SAPP has also demonstrated some ability to reduce acrylamide in finished products. Its efficacy as an acrylamide mitigating agent, however, is limited by the development of bitter "off" flavors that increase as the concentration of SAPP increases. Accordingly, use of SAPP above current industry standards is not a viable mitigation strategy.

Asparaginase, an enzyme that converts asparagine to aspartic acid, thereby reducing asparagine and thus potential for the formation of acrylamide in foods, has been tested with limited success on some products in a laboratory setting. Asparaginase has also been tested at factory scale on a limited basis; however, additional testing is required to determine its efficacy as an effective acrylamide mitigant.

Preparation

As the majority of acrylamide is formed during final preparation of frozen potato products, the industry has taken steps to reduce acrylamide by lowering the recommended preparation temperature on on-pack cooking instructions, and eliminating certain methods of preparation from use. For foodservice, the cooking instructions on par-cooked frozen potato products have been changed to reflect a reduced recommended frying temperature from 360°F to 345°-350°F.

The primary methods of preparing retail frozen potato products are oven baking and stovetop skillet frying. On-pack baking instructions on retail products are being optimized to reduce acrylamide formation and maintain product quality. Still other preparation methods, such as toaster oven cooking, have been eliminated for some retail products, as these methods can produce acrylamide levels in finished products at significantly higher levels than do other cooking methods.

Intensity of browning during cooking is a significant variable determining the level of acrylamide present in a finished product. The frozen potato products industry, therefore, has attempted to encourage over time a change in customer and consumer perceptions and expectations of the color of prepared French fries from "golden brown" to a "golden

yellow" or "light golden" color. FPPI expects this action to help reduce acrylamide exposure over time.

To that end, cooking instructions for retail products prepared in the oven now include cautionary statements such as the following:

- Do not overcook.
- Cook to a golden yellow or light golden color.
- When cooking small amounts, reduce the cooking time.

Conclusion

The food industry, the scientific community and many global government entities are all investigating the prevalence of acrylamide in the human diet, the possible effects of acrylamide on human health and ways to reduce the formation of acrylamide during the cooking process.

Potato growers are growing potato varieties that contain lower levels of sugars, which lead to lower levels of acrylamide during cooking. Growers are also adjusting potato storage temperatures to keep sugar levels low.

Food manufacturers, including potato processors, are incorporating best manufacturing practices to reduce acrylamide formation in food, including reformulating products; increasing moisture levels during processing (blanching); lowering cooking times and temperature levels during processing (par-frying); and providing specific instructions to consumers on packaging, like "cook to a light golden color."

FPPI member companies continue to research strategies and techniques to reduce the formation of acrylamide in its products. The frozen potato products industry is also undertaking efforts to educate consumers and restaurant operators about ways to reduce acrylamide in French fries during the cooking process.

Food producers continue to innovate and find new ways to improve the health and safety of their products. The frozen potato industry is committed to working with the scientific community and government agencies around the world to address the presence and reduction of acrylamide in food.

Recommended Solution: The Conference recommends...:

The frozen potato products industry would support efforts to provide guidance to retail-foodservice operators and consumers on proper preparation (e.g., temperature and time) to aid in the reduction of acrylamide based on easily recognized product characteristics, such as color.

- that the Conference review all relevant documents contained in the CIAA "Toolbox" recommendations for the retail-foodservice preparation of processed potato products, particularly French fries, to determine if the materials can be added to the CFP web site to provide assistance to this sector with the reduction of acrylamide in processed potato products.

In addition, FPPI has created materials in the forms of training videos and a poster that could further assist in education efforts for the retail-foodservice industry about measures that can be employed further in the storage, preparation, and cooking to assist with acrylamide reduction. We recommend the Conference review these materials to determine if there is value in adding these resource tools as links or attachments on the CFP web site."

- that the Conference posts on the CFP web site the links to acrylamide resources that could aide in educating the retail-foodservice industry about measures that can be employed in the storage, preparation, and cooking to assist with acrylamide reduction in processed potato products. These links would include:

European Commission Directorate - General for Health and Consumers
http://ec.europa.eu/food/food/chemicalsafety/contaminants/ciaa_acrylamide_toolbox09.pdf
U.S. Food and Drug Administration
http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/ChemicalContaminants/Acrylamide/UCM053569
Codex CODE OF PRACTICE FOR THE REDUCTION OF ACRYLAMIDE IN FOODS, (CAC/RCP 67-2009).
www.codexalimentarius.net/download/standards/11258/CXP_067e.pdf
Joint FAO/WHO Expert Committee on Food Additives (JECFA): Seventy-second meeting, Rome, 16-25 February 2010.
http://www.who.int/foodsafety/chem/summary72_rev.pdf.
Frozen Potato Products Institute's "Know Your Fries" poster and educational videos about Fryer Management for Acrylamide Reduction available in both English and Spanish (see https://www.yousendit.com/dl?phi_action=app/orchestrateDownload&rurl=https%253A%252F%252Fwww.yousendit.com%252Ftransfer.php%253Faction%253Dbatch_download%2526batch_id%253DT2djclVBMm1Fd2ZtcXNUQw).

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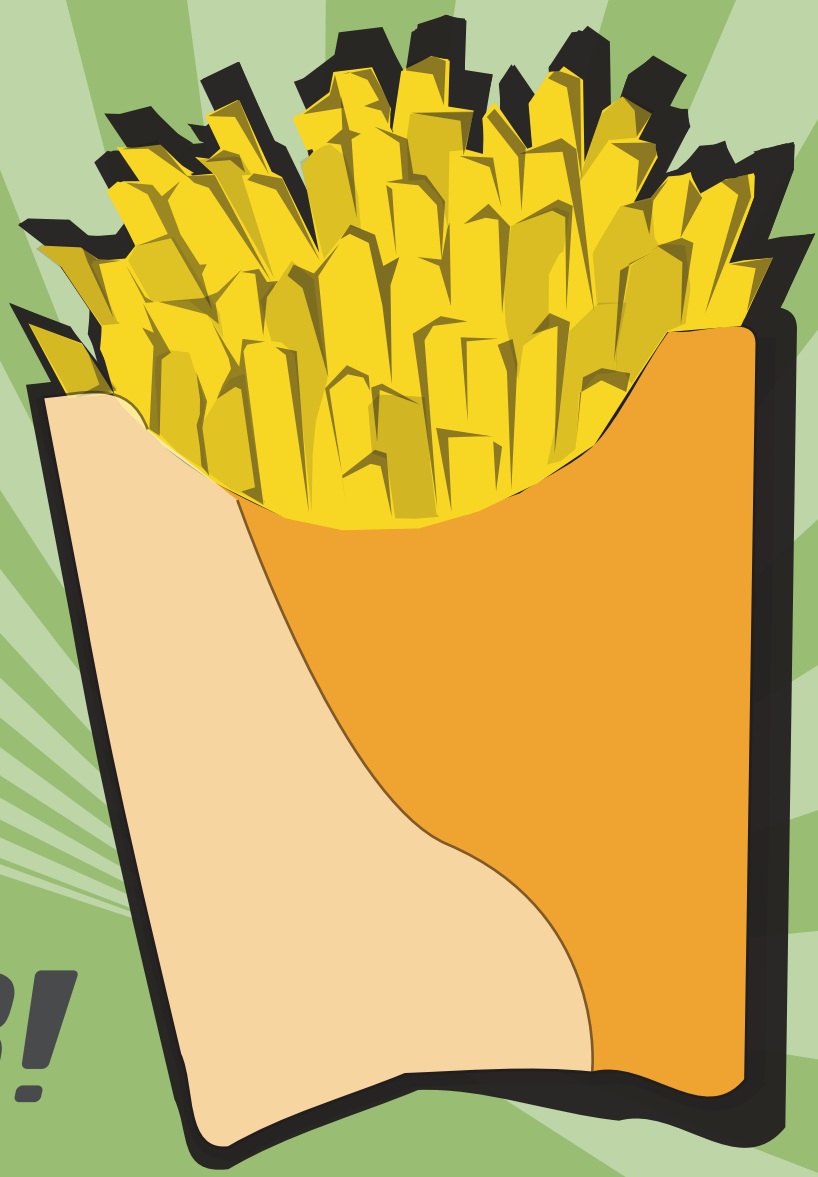
Attachments:

- "Know Your Fries Poster, English"

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.

Know Your FRIES

Reduce Acrylamide!



REMEMBER!

- Keep fries frozen
- Cook at 350°F/175°C or below
- Use a timer
- Check for color
- Follow the directions

FPPI
FROZEN POTATO PRODUCTS INSTITUTE

For more information, please contact the Frozen Potato Products Institute at (703) 821-0770.

Conference for Food Protection
2012 Issue Form

Internal Number: 118
Issue: 2012 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.

Title:
Public Release of Food Allergy Resource Document

Issue you would like the Conference to consider:
Public release in 2012 of the eagerly anticipated food allergen management guidelines, being reviewed by the CFP Food Allergen Committee as directed in Issue 2010 III-001, and in accordance with the Food Allergen Labeling Consumer Protection Act (FALCPA) "Section 209. Food Allergens in the Food Code" which states: *the Secretary of Health and Human Services shall, in the Conference for Food Protection, as part of its efforts to encourage cooperative activities between the States under section 311 of the Public Health Service Act (42 U.S.C. 243), pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries, and elementary and secondary school cafeterias. The Secretary shall consider guidelines and recommendations developed by public and private entities for public and private food establishments for preparing allergen-free foods in pursuing this revision.*

Public Health Significance:
A significant number of food allergy reactions occur in restaurants/food service establishments.[i] [ii] [iii] In fact, in two published studies on *fatal* food allergy reactions, *almost half* were triggered by food served in or provided by restaurants / food service. Studies also show significant gaps in restaurants' understanding of food allergies. [iv] Restaurant employees generally receive little or no training on the serious nature of food allergy; reading ingredient labels; the importance of strict allergen avoidance; and avoiding cross-contact during food preparation.[v]
The intent of any guidelines should be allergen management.

i Vierk KA, Koehler KM, Fein SB, Street DA. *Prevalence of self-reported food allergy in American adults and the use of food labels.* J Allergy Clin Immunology 2007;119:1504-10.
ii Furlong TJ, DeSimone J, Sicherer SH. *Peanut and tree nut allergic reactions in restaurants and other food establishments.* J Allergy Clin Immunol 2001;108(5):867-70.
iii Greenhawt MJ, McMorris MS, Furlong TJ. *Self-Reported Allergic Reactions to Peanuts and Tree Nuts Occurring at Restaurants and Food Service Establishments*. Poster presented at the 2008 annual meeting of the American Academy of Allergy, Asthma & Immunology, March 14-18, 2008, Philadelphia, PA.

iv Aline R. Ajalaa, Adriano G. Cruza, Jose A.F. Fariaa, Eduardo H.M. Waltera, Daniel Granatob and Anderson S. Sant? Anab. *Food allergens: Knowledge and practices of food handlers in restaurants.* Food Control, Volume 21, Issue 10, October 2010, Pages 1318-1321.

v Ahuja R, Sicherer SH. *Food-allergy management from the perspective of restaurant and food establishment personnel.* Ann Allergy Asthma Immunol 2007;98:344-48.

Recommended Solution: The Conference recommends...:

public release in 2012 of the food allergen guidelines and recommendations developed by the 2010-12 CFP Food Allergen Committee for use by the CFP membership, and the food preparation and inspection communities.

The Conference further recommends that these documents:

- be posted to the CFP web site, and
- that a letter be sent to the FDA requesting dissemination on the FDA website.

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Conference for Food Protection
2012 Issue Form

Internal Number: 025
Issue: 2012 III-030

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

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Title:
Allergen Committee - Importance of Allergen Guidance to CFP Members

Issue you would like the Conference to consider:
The Allergen Committee has not progressed on any of its charges since the 2010 Biennial Meeting in Providence, Rhode Island. The committee chair did not submit a report for council at the 2012 Biennial Meeting. This Issue is submitted by the Executive Director on behalf of the Conference.

Public Health Significance:
The risk of allergic reactons to foods sold at retail food establishemts is of great concern to consumers and the retail food industry. Many avoidable injuries occur annually in the United States simply because retailers do not have sufficient information and guidance in the proper labeling and handling of potential allergens. Allergic reactions sometimes occur in pesons who consume ordinary foods sold legally throughout the United States. With proper labeling and handling practices retail food facility operators can minimize the potential for injuries and their liability resulting from unitended consumption of food allergens.

Recommended Solution: The Conference recommends...:
1. The disbanding of the CFP Allergen Committee in its current form. This Committee was not active, did not submit a final report for this Biennial Meeting, and the Committee charges assigned at the 2010 Biennial Meeting were not addresed.
2. The issue of prevention of allergic reactions in customers of retail food facilities continues to be a concern of the Conference; therefore, the Conference for Food Protection Executive Board is directed to reach out to interested groups to be better informed about food allergens and preventive measures for allergic reactions to food legally sold in retail food facilities.

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